American Hospital Association™
Advancing Health in America

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Don Rucker, M.D.
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St SW, 7033A
Washington, DC 20201

RE: RIN 0955-AA02, Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID-19 Public Health Emergency

Dear Dr. Rucker:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the interim final rule titled, "Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID-19 Public Health Emergency."

The AHA appreciates the Office of the National Coordinator (ONC) for Health Information Technology's (IT) recognition of the significant challenges facing health care providers as they continue to battle on the front lines of the surging COVID-19 pandemic. While the ongoing public health emergency (PHE) certainly highlights the critical importance of ensuring health information is available where and when it is needed to inform both patients and care decisions, hospitals and health systems have spent years implementing technology to enable information access and exchange. Today, nearly every hospital in the U.S. provides patients with the ability to view their information online, as well as communicate electronically with their clinicians, highlighting the field's commitment to empowering patients to be active partners in their health and health care through access to information.

At the same time, it is important to recognize that throughout the PHE hospitals' IT and compliance resources have largely been redirected to critical priorities, including implementation and scaling of telehealth, hospital COVID-19 data reporting and, most critically, support for direct patient care. Simultaneously, hospitals and health systems are now taking on a central role in vaccine planning and distribution and use of

therapeutics aimed at preventing the need for hospitalization, and those require significant IT support. Hospitals are, without question, the epicenter of the pandemic response. And hospitals' ability to meet this unprecedented challenge relies heavily on supporting IT.

With these considerations in mind, the AHA offers the following comments on the interim final rule.

Applicability Dates. The Cures Act final rule was released just as COVID-19 began to spread across our nation. Health care providers need a true runway to come into compliance with the complex information blocking regulations. Hospitals need to be given sufficient time to achieve compliance, considering that they must weather the continuous strain on resources from the ongoing PHE, the lack of availability of enabling technologies and guidance to support common understanding of real-world application of the rule's information blocking requirements, and the absence of a complete picture of the enforcement approach for health care providers.

While we appreciate the steps taken in the interim final rule to provide additional time, current circumstances make clear that this extension does not adequately consider these factors or reflect the reality of what health care providers are and will be facing in 2021. **We urge ONC to further extend the applicability date for the information blocking provisions from April 5, 2021 to Jan. 1, 2022 or six months after the end of the PHE, whichever is later.**

There is a clear disconnect between the information blocking applicability date and deadlines by which IT developers are required to make new certified health IT available, including those related to the US Core Data for Interoperability (USCDI), standardized application programing interfaces (APIs) and Electronic Health Information (EHI) export. These functionalities are key enablers of interoperability and critical tools for health care providers as they work to mitigate the risk of information blocking within their organizations.

Health care providers should not be required to comply with requirements prior to the technology being made available. The meaningful use program was successful in driving adoption of certified electronic health record (EHR) technology. Ingrained in the program was a careful staging of the availability of standardized technology followed by use of regulatory levers. Information blocking should follow a similar approach of first ensuring the availability of enabling technology and subsequently requiring its use.

We encourage ONC to address this disconnect, in part, by extending until Dec. 31, 2023 the period during which the definition of EHI for the purposes of information blocking applies to the data elements in the USCDI. As health care providers gain experience with the regulations and implement new technical capabilities to provide seamless access to information, they need a clear understanding of the data elements they are required to share in order to be in compliance with the information

blocking rules. Before requiring the full definition of EHI, ONC also should clearly define the types of standards and data elements that comprise electronic protected health information (ePHI).

Implementation Challenges. Building a compliance program for a regulation of this magnitude is an enterprise effort. It requires significant work to analyze and update internal processes and procedures, implement necessary changes to technology platforms, train staff across multiple departments and address related operational issues at a time when resources must continue to be prioritized for patient care.

While we appreciate that ONC has published an initial set of information blocking FAQs, there remains confusion in the field regarding key provisions of the Cures Act final rule, including release of clinical notes, documentation requirements, and the intersection of the rule with HIPAA, among other issues. **We urge ONC to disseminate additional FAQs as soon as possible to assist health care providers as they continue to develop organizational approaches to preventing information blocking.**

In addition, the AHA is concerned that certain requirements in the Cures Act final rule could inadvertently undermine the patient-clinician relationship. For example, under the Cures Act final rule a provider must release confirmed lab results once they become available unless the patient's clinician makes an individualized determination that delaying the results will prevent harm – specifically, an endangerment to the life or physical safety of an individual (or another person). While we agree that information should not be unnecessarily withheld, it is common practice for clinicians to engage with patients in a timely review of sensitive lab results prior to their release in order to help them interpret what the results mean and discuss appropriate next steps.

We continue to hear significant concerns from the field, particularly our behavioral health providers, regarding this decision by ONC to omit psychological, emotional and other types of non-physical harm from the scope of the patient harm exception. We urge ONC to work with stakeholders to ensure the continued prioritization of the patient-clinician relationship and mitigate unintended consequences through establishment of an appropriate standard for non-physical harm.

Enforcement. Congress created a clear distinction in the 21st Century Cures Act between health care providers and health information exchanges (HIEs), health information networks (HINs) and IT developers by establishing different sanctions for each group of actors – including "appropriate disincentives" for providers and civil monetary penalties (CMPs) for HIEs, HINs and IT developers. Per the Cures Act, any health care provider determined by the Office of Inspector General (OIG) to have committed information blocking will be referred to the "appropriate agency to be subject to appropriate disincentives" determined by the Health and Human Services (HHS) Secretary through notice and comment rulemaking. Congress additionally included language stating that penalties imposed related to information blocking should not be

duplicative with penalties imposed under other parts of the law, as well as under OIG's authority to impose CMPs.

OIG acknowledged in its proposed rule on information blocking enforcement for IT developers and HIEs/HINs that "information blocking is newly regulated conduct." **As HHS considers the establishment of "appropriate disincentives" for health care providers found to have engaged in information blocking, we urge an initial focus on education and corrective action rather than financial penalties.** ONC and OIG also should work with CMS to closely coordinate their respective roles in regulating and enforcing information blocking to ensure consistency for health care providers and other actors.

We appreciate the opportunity to comment. Please contact me if you have questions or feel free to have a member of your team contact Samantha Burch, director of health information technology policy, at sburch@aha.org or 202-626-2313.

Sincerely,

/s/

Ashley B. Thompson
Senior Vice President
Public Policy Analysis and Development