



Charles N. Kahn III
President and CEO

December 18, 2020

Don Rucker, MD
National Coordinator
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
330 C Street SW, Floor 7
Washington, DC 20201

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

Dear Dr. Rucker:

The Federation of American Hospitals (FAH) appreciates the opportunity to provide comments to the Office of the National Coordinator for Health Information Technology (ONC) on the *Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID-19 Public Health Emergency* interim final rule with comment period (IFC), published in the Federal Register on November 4, 2020. The FAH is the national representative of more than 1,000 leading, tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural America. Our members include teaching and non-teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services.

The FAH continues to believe in the potential of health information technology (health IT) to improve the quality and efficiency of care provided to patients, reduce provider burden, and advance population health management and breakthroughs in health care research. As we have noted in previous comment letters, FAH members are committed to ensuring electronic health records (EHRs) and other health IT achieves the quality and efficiency goals desired by stakeholders across the health care sector and appreciate the goals of the policies in the *21st Century Cures Act* (Cures Act) and implementing regulations.

Information Blocking Applicability Date

The regulations implementing the 21st Century Cares Act were released in the midst of the COVID-19 public health emergency (PHE), and the time hospitals and other providers set aside to prepare for and implement these significant changes has been overtaken by the all-hands-on-deck effort to address the ongoing pandemic. While the FAH appreciates the ONC amending the effective date of the “information blocking” requirements until April 5, 2021, the additional five months is unfortunately not enough time for hospitals and other providers to come into compliance while also continuing to battle COVID-19. ***As such, the FAH urges ONC to amend the compliance date to the later of January 1, 2022 or at least six months after the end of the PHE, recognizing that it is unknown how the pandemic will unfold over the coming months.***

In addition, the FAH urges the agency to ensure alignment across other dates in the ONC regulation and corresponding policies in the Centers for Medicare & Medicaid Services (CMS) regulations. For example, per the IFC, the date after which information blocking rules will apply with respect to all electronic health information (EHI) (rather than elements represented in the USCDI) is now October 6, 2022, but vendors do not have to deliver on the technology necessary for hospitals and other providers to comply with the regulations until well after this date. Under the IFC, vendors have until December 31, 2022 to deliver the upgrades to USCDI and have until December 31, 2023 to deliver EHI export capability. Again, while the FAH appreciates the flexibility ONC has provided in the IFC, these dates simply do not align in a way that allows for successful implementation.

Exchanging all EHI is a significant undertaking that should be given the appropriate time for innovative, thoughtful effort. The FAH is concerned that vendors will be rushed in meeting their deadlines, particularly in building export capability for EHI, which currently lacks defined data elements and standards. The FAH is also concerned that these dates do not give hospitals and other providers the necessary time to implement the new technology. ***As vendors are not required to deliver the USCDI capability until December 31, 2022, and EHI export capability until December 31, 2023, the FAH strongly recommends that the information blocking rules continue to apply only to the elements represented in the USCDI until at least December 31, 2023.*** This date aligns with a more appropriate technology development and implementation cycle and would reduce the burden of compliance on health care providers who would otherwise need to develop and implement short-term workarounds.

In addition, it is vital that in the interim between the effective date of the information blocking provisions and the delivery of both the USCDI capability and the EHI export capability, ONC clarify that lack of technological capability meets the information blocking infeasibility exception.

Ongoing Guidance and Information Blocking Enforcement

The FAH notes that the Department of Health and Human Services (HHS) Office of Inspector General (OIG) has not completed its rulemaking related to information

blocking enforcement for actors (other than health care providers), and that HHS has not yet undertaken rulemaking related to information blocking enforcement for providers.

Given the significant penalties for information blocking of up to \$1 million per violation, there is an urgent need for clear regulatory requirements and ongoing guidance to hospitals and other providers regarding what is considered compliant behavior and how they should document their compliance with any requirements and information blocking exceptions. While the FAH appreciates the FAQs released by ONC so far, there remain significant technical, operational, compliance, and documentation questions that must be answered to ensure the information blocking regulations achieve their desired goals while providing certainty to regulated actors.

The FAH strongly urges ONC to work with the Secretary of HHS and OIG to ensure the use of enforcement discretion such that any enforcement against health care providers related to information blocking not begin until six months after the OIG and HHS regulations are finalized. In addition, ONC should coordinate with HHS and OIG to ensure that any action against health care providers focuses on information blocking behavior that results in harm to patients and health care providers, as opposed to technical violations of the law that do not have a similar impact. As such, any future enforcement action should first focus on education and outreach and then transition to a gradual application of enforcement actions, such as a corrective action plan, before assessing monetary penalties.

In particular, ONC and OIG should notify a provider that may become the subject of an information blocking investigation and/or enforcement action. Such notification would allow the provider an opportunity to conduct a self-assessment and, if the practice in question requires modification, alter its practice to come into compliance with the regulation. Alternatively, the provider may be able to provide up-front information to ONC and the OIG that favorably resolves the investigation and/or enforcement action. Either scenario preserves ONC and OIG resources while achieving the desired outcome.

If actors fail to implement the corrective action plan satisfactorily or are repeat offenders, penalties would be appropriate, but they should first be given the opportunity to demonstrate that they have learned from their mistake and that they have a process in place so as not to repeat it.

Appropriate Adoption / Deployment Timelines

While ONC establishes timelines under which vendors must develop certified electronic health record technology (CEHRT), CMS establishes timelines under which health care providers must adopt and deploy this technology. It is vital that vendor development deadlines be at least one year earlier than the CMS adoption/deployment timelines to provide sufficient time for hospitals to receive, evaluate, and implement the updated technology, including staff and clinician training. Unfortunately, the ONC compliance deadlines for vendors are often the same as the CMS compliance deadlines for health care providers, which, as noted above, significantly hampers providers' implementation.

We look forward to continued collaboration to advance health information exchange. If you have any questions, please contact me at 202-624-1534, or Erin Richardson, Senior Vice President at erichardson@fah.org or 202-624-1516.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrew M. K. Smith". The signature is fluid and cursive, with a large initial "A" and a stylized "S" at the end.