

ConnectedHealthInitiative

June 9, 2025

Robert F. Kennedy, Jr.
U.S. Secretary of Health and Human Services
200 Independence Ave. Southwest
Washington, DC 20201

RE: *Preventing Illegal Information Blocking to Support the Seamless Exchange of Health Information*

The Connected Health Initiative,¹ representing stakeholders from across the healthcare community, shares your goals of driving the development and adoption of digital health management and care navigation applications and strengthening interoperability and secure access to health data through open, standards-based technologies. In response to the Administration's request for suggestions to improve the healthcare regulatory system and promote innovation and competition, many of our members are providing separate, detailed input. While those suggestions are provided separately, we are committed to achieving patient-centered care, reducing administrative burdens, and overcoming barriers to the seamless exchange of health information.²

The free flow of information and interoperability are therefore important and life-saving for patients. A truly interoperable healthcare system facilitates patient engagement across a range of modalities with open application programming interfaces (APIs) that allow the safe and secure introduction of patient-generated health data (PGHD) into electronic health records (EHRs). Data stored in standardized and structured formats with interoperability facilitated by APIs provides analytics as well as near real-time alerting capabilities. The efficacy of precision medicine, population health, and clinical decision support – all critical means for combatting chronic diseases – is dependent in large part on the availability of data.

We emphasize the linkage of ensuring interoperability to the Administration's priority for leveraging the tremendous potential of artificial intelligence (AI). Many AI use cases, ranging from solving administrative/backend efficiencies to supportive clinical decisions, have already begun to emerge as necessary to advancing the Quadruple Aim. Data exchange, use of standardized terminologies, and the normalization of data flows across the care continuum, are a must if AI is to positively transform the American healthcare system.

The 21st Century Cures Act prohibits providers, developers, health information exchanges (HIEs), and health information networks (HINs) from practices that are likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information (EHI) so that health information may be accessed, exchanged, and used without special effort through the use of application programming interfaces, including providing access to all data elements of a patient's

¹ www.connectedhi.com.

² E.g., <https://www.cms.gov/medicare-regulatory-relief-rfi>.

EHR. Yet, Congress' goals in this law, passed in 2016, are far from realized. Although federal regulations have been fully in effect since 2022, patients and providers still face major barriers to interoperability and access to health information, often stemming from a subset of developers that elect to use tactics amounting to information blocking (e.g., vendors who prohibit access to their FHIR API). These practices delay care coordination, undermine clinical decision-making, and stall innovation.

In the most immediate, the Administration should take steps to end information blocking practices that are actively harming patients, with a focus on health IT developers who view information blocking as a competitive advantage. While we appreciate the resources created thus far by HHS, it is critical that the Administration acknowledge that existing rules addressing information blocking are not consistently being followed due in large part to a lack of enforcement. While some are implicitly violating the rules (e.g., offering "compliant" information exchange mechanisms that do not work in practice while offering functional solutions in parallel for a fee), others are unapologetically ignoring the rules. We emphasize that enforcement should be meaningful so as not to be viewed as a mere cost of doing business.

If the Administration is going to accomplish its goal of overcoming barriers to the seamless exchange of health information across systems, it should first make immediate efforts to resolve information blocking complaints, publish its findings, and take action on them to ensure that a baseline of data exchange is occurring. Enforcement should contribute to a predictable environment while taking into consideration the severity of the alleged misconduct so as to avoid disproportionate impacts.

In parallel, we encourage HHS to provide regulated entities and other affected stakeholders with rule clarifications and practical guidance for the information blocking rules. For instance, OIG should specify that denying access to regulated FHIR APIs for payers, providers, or patients constitutes information blocking. Additionally, all fees associated with TEFCAs-related data exchange should be removed for every TEFCA participant. While we support preserving existing information blocking exceptions, HHS must provide clearer guidance on how each exception should be applied in practice, including specific examples to help actors understand what constitutes compliance.

We also emphasize that it is crucial for coordination across HHS in achieving health data interoperability. ASTP/ONC and CMS should ensure that their rules and approaches are aligned to advance interoperability in a coordinated way and to avoid putting stakeholders into a position where they are forced to violate one rule (e.g., meet the requirements of the CMS interoperability rule but face ambiguities as to whether the requirements of an exception to ONC information blocking is being satisfied).

We again express our support for the Administration's launching of multiple efforts to identify ways to advance interoperability and competition in and across the American healthcare system. While many of the organizations that have signed this letter will be submitting detailed input to the Administration in the coming months with further and more detailed recommendations, we agreed that swift action to address known information blocking practices will support countless American patients, and will also support the Administration's wider aim of enhancing competition.

Our community appreciates your focus on modernizing the American healthcare system and welcomes the opportunity to meet with you to discuss our shared views.

Sincerely,



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