January 2, 2024

Micky Tripathi, PhD
Office of the National Coordinator for Health IT
Department of Health and Human Services
330 C Street, SW
Washington, DC 20201

Chiquita Brooks-LaSure, MPP, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Baltimore, MD 21244-8016

Re: 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking (RIN 0955–AA05)

Dear Dr. Tripathi and Administrator Brooks-LaSure:

The Sequoia Project is pleased to submit comments to the Department of Health and Human Services (HHS) on the Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking Proposed Rule. We appreciate HHS's demonstrated record of responding thoughtfully to the comments that it receives on such proposed rules from its many stakeholders.

The Sequoia Project is a non-profit, 501(c)(3) public-private collaborative that advances the interoperability of electronic health information for the public good. The Sequoia Project previously served as a corporate home for several independently governed health IT interoperability initiatives. Today, The Sequoia Project convenes industry and government to identify, prioritize, and overcome discrete barriers to interoperability through our rapidly expanding Interoperability Matters cooperative. We are also honored to serve as the Office of the National Coordinator for Health IT (ONC) Recognized Coordinating Entity™ (RCE™) for the Trusted Exchange Framework and Common Agreement℠ (TEFCA℠).

These comments reflect our experience supporting large-scale, nationwide health information sharing initiatives, including active work with several federal government agencies. Through these efforts, we serve as an experienced, transparent, and neutral convener of public and

private sector stakeholders to address and resolve practical challenges to interoperability. This work includes our Interoperability Matters Information Sharing Workgroup, which has convened providers, developers, health information networks (HINs) and data requestors since 2019, to discuss real-world solutions and challenges to compliance with the information blocking rules. The workgroup has proactively created a set of good practices and other resources to educate the community on how best to share information and be in compliance with the information blocking rules. The group has also identified remaining policy issues that would support compliance, including the need for additional educational efforts by federal agencies.

Our decade of experience building public-private collaborations and launching highly successful nationwide health IT initiatives provide us with a unique perspective on the proposed rule. The comments and recommendations in this letter reflect this expertise independent of our role as the TEFCA RCE.

The Sequoia Project appreciates HHS's forward thinking and thoughtful approach to this proposed rule, which establishes the framework to implement the 21st Century Cures Act provider disincentive provisions. Establishing penalties underscores the importance of the information blocking prohibitions, further encouraging a culture of information sharing. We share the following perspectives for your consideration as the rule is finalized.

Enforcement Priorities and Investigations

The proposed rule includes a listing of the priorities that will be used to determine which complaints will be investigated. The Office of the Inspector General (OIG) stated that its information blocking CMP enforcement priorities will include practices that: (i) resulted in, are causing, or have the potential to cause patient harm; (ii) significantly impacted a provider's ability to care for patients; (iii) were of long duration; (iv) caused financial loss to Federal healthcare programs, or other government or private entities; or (v) were performed with actual knowledge[1]. We agree with the proposed enforcement priorities outlined by the Office of the Inspector General (OIG). **We recommend that investigations be limited to egregious acts and persistent, bad behavior. And we believe that, as a matter of due process, providers should always have the right to an appeal of the decision that information blocking occurred.**

We also recommend that OIG provide additional detail on how an investigation will work and how the knowledge standard will be assessed either through guidance or additional rulemaking. Specifically, provider organizations have the following questions:

[1] Federal Register :: 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking

- How will OIG identify who to investigate? How will OIG decide whether to investigate an individual provider or a hospital s/he practices at? What if a provider has multiple practice locations?
- How will the entity under investigation be informed of the investigation?
- How will OIG determine what a provider "knew"?
- What opportunity will providers have to defend against an allegation?
- How will OIG proceed if the complaint is filed against an entity, but the liability really falls somewhere else, such as in the following scenarios?
    - Complaint is made against a provider, but the information blocking is a result of the health IT developer technology.
    - Complaint is made against a business associate (BA) as a result of a provision of their contract with a covered entity under HIPAA.
    - Complaint is made against a hospital/practice stemming from the actions of a provider that has since left the hospital/practice.
- Will those found to have engaged in information blocking be provided with an opportunity to engage in corrective action rather than be subject to a penalty? Will they be followed over time to assess whether behavior has changed?

Transparency for Information Blocking Determinations, Disincentives, and Penalties. We agree with the need to promote transparency about how and where information blocking is impacting the nationwide information sharing infrastructure through the proposed establishment of a website by ONC. However, we recommend that ONC establish guardrails to ensure accuracy and fairness for the public facing website, such as clearly identifying when information blocking occurred and limiting the amount of time that a provider is listed. We are concerned that the finding of information blocking could be made public long after the violation occurred, leading to reputational harm when a provider is currently in compliance. We are also concerned that providers sharing a tax identification number (TIN) will suffer reputational harm based on the actions of a single provider given that a single TIN can include hundreds of providers.

We believe that, in the early stages of enforcement, it is **better to take an educational approach over a "shaming" approach and to provide entities an opportunity to demonstrate corrective actions**. ONC and OIG should engage with the provider community and offer detailed examples and guidance on the information blocking complaints that have been received as well as best practices for information sharing.

To date, ONC has only published the number of complaints received, without much additional context. We believe it is important for providers and other actors to understand what types of practices have led to complaints, and the extent to which they are related to violations of the HIPAA right of access or other provisions of HIPAA versus Information Blocking.

Given the complexity of the information blocking rules and the significance of the penalties, HHS should conduct significantly more education for actors. This is particularly important for smaller provider organizations. In addition, education for individuals on how to access their records and their rights under HIPAA could enhance their ability to access information and subsequently reduce the number of information blocking complaints.

Appropriate Disincentives for Health Care Providers

Impacted Providers. We understand why HHS chose to focus initially on providers that are also eligible to participate in certain Federal Programs under Medicare. We note, however, that establishing penalties for only a subset of the provider community creates an imbalance in enforcement. We recommend rapidly expanding enforcement to additional types of providers with a priority on laboratories and post-acute care facilities.

Comments on specific penalties. The proposed rule establishes both an overall framework for provider disincentives as well as specific disincentives tied to Medicare programs. We share the following perspectives on those specific proposals.

- **Medicare Promoting Interoperability Program (PIP):** The proposed penalties for hospitals are very large and could be particularly devastating for critical access hospitals. We recommend that special consideration be provided to these essential providers. We also question whether CMS could scale the penalty, rather than equating it to failure to meet the PIP. We also note that there will be a significant time lag between when the action occurred and the implementation of penalties due to the payment mechanism being used, weakening the link between the action and the consequence. In addition, if a determination of information blocking is made at the beginning of the reporting PIP period, but the penalty is imposed at the end, there is little motivation to correct the violation. This weakens the disincentive.
- **Quality Payment Program (QPP):** The proposed penalties for eligible clinicians are linked to the reporting entity for the QPP. Penalizing an entire TIN for the action of one member will be significant when a TIN is composed of many clinicians. While CMS notes that a TIN could be dissolved to avoid this situation, the use of a TIN serves many purposes and cannot be easily undone to avoid a penalty.
- **Medicare Shared Savings Program (MSSP):** The disincentives under this program are more significant because they would impact a wider set of providers, including SNFs, ACOs, etc. This will provide a broader disincentive than the PIP or QPP. To create additional disincentives, CMS could consider expanding penalties to other innovation models beyond the MSSP.
- For both eligible hospitals and clinicians, the link to a hardship exception is unclear and warrants clarification.

In conclusion, we strongly support ONC's commitment to advancing nationwide interoperability and are dedicated to working together to achieve this important goal. We look forward to continued collaboration and will continue to support real-world efforts to create a culture of information sharing through our convening of The Sequoia Project's Interoperability Matters Information Sharing Workgroup.

Sincerely,

Mariann Yeager

CEO, The Sequoia Project