



October 4, 2024

Micky Tripathi, PhD

Assistant Secretary for Technology Policy/Office of the National Coordinator for Health IT
330 C Street, SW
Washington, DC 20201

Re: Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability Proposed Rule (RIN 0955-AA06)

Dear Dr. Tripathi:

The Sequoia Project is pleased to submit comments to the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC) on select proposals in the HTI-2 proposed rule. We appreciate ASTP/ONC'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. We previously served as a corporate home for several independently governed health IT interoperability initiatives. The Sequoia Project currently supports the Interoperability Matters cooperative and was selected by ASTP/ONC to be the Recognized Coordinating Entity (RCETM) for the Trusted Exchange Framework and Common Agreement (TEFCATM).

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. Our over a decade of experience building public-private collaborations and launching highly successful nationwide health IT initiatives provides 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.



Part 171—Information Blocking

§171.104 Interferences

ASTP/ONC proposes to codify certain practices that constitute interferences for purposes of the information blocking definition. We understand that the codified practices are not an exhaustive list and that a determination of information blocking is subject to the facts and circumstances of the situation. However, we still have concerns with this proposal.

We believe that finalizing this proposal would create additional confusion without providing enough clarification for regulated entities on whether a given practice is an interference. The examples provided are extremely broad and, in some cases, represent scenarios that occur regularly. For example, Actors are commonly faced with requests for information in volumes or at times that are inappropriate. Therefore, data holders will often limit the scope and timing of Electronic Health Information (EHI) requested for access, exchange, or use for a variety of reasons. Whether or not this is done “improperly” is extremely subjective.

By codifying such a broad example as an interference, this proposal presupposes that the practice is an interference and removes the Actor’s ability to claim that the practice is not an interference. While we understand that in a hypothetical investigation, the Actor in question could avail themselves of any number of exceptions in the regulation, the resources and additional burden required to prove that the action or omission falls into a regulatory exception could be damaging to the organization.

Further, this approach is inconsistent with ASTP/ONC’s authority under the Cures Act to identify the reasonable and necessary activities that *do not* constitute information blocking, rather than to identify the interferences. ***We recommend that ASTP/ONC retain the examples without codifying them in regulation.***

§171.204 Infeasibility Exception

We applaud ASTP/ONC for including a proposed modification to provide Actors with clarity on the 10-day period to respond to requests stating the reason the request is infeasible. The Sequoia Project and its Information Sharing Workgroup have advocated for such clarity in our previous comments. ***We agree with the proposal to retain the 10-day time period for the manner exception exhausted condition and infeasible under the circumstances condition and to give the Actor time to determine, without unreasonable delay, and based on a reasonable assessment of the facts that the requested access, exchange, or use cannot be provided due to infeasibility. We suggest further clarity to specify that the 10-day time period begins on the***



business day in which the Actor has determined that the request is infeasible. This will provide stronger assurance that an Actor is acting upon their determination as soon as it is made.

§171.304 Requestor Preferences Exception

We support this proposed exception and believe it provides an important mechanism to reduce ambiguity regarding when it is permissible to withhold data. Additionally, it encourages providers to initiate critical conversations with patients in sensitive circumstances, such as when delivering a potentially life-changing diagnosis. By actively engaging requestors in discussions about their data preferences, this proposal helps ensure that patients are informed and empowered to control access to their personal health information in ways that align with their unique needs and circumstances.

§171.206 Protecting Care Access Exception

We support this proposed exception and believe it is a crucial addition to the regulation, as it offers healthcare providers a clear pathway to protect themselves and their patients from potential legal risks related to reproductive health care. By allowing actors to restrict the exchange of specific EHI when they believe it could expose individuals to legal action, this proposal ensures that providers can continue offering critical care without fear of legal repercussions.

§171.403 TEFCA Manner Exception Request for Information

We support the inclusion of an information blocking exception or condition that encourages participation in TEFCA. We emphasize the need for such a proposal to be crafted in a way that will grow and evolve with TEFCA. *We offer our support and collaboration to ensure that the inclusion of TEFCA in the information blocking exceptions aligns with the constructs of the Common Agreement and Qualified Health Information Network (QHIN) Technical Framework.*

Fees Exception and Licensing Exception

ASTP/ONC requests feedback on whether there are drawbacks to applying the Fees and Licensing Exceptions, and if regulation should continue to apply the exceptions to the TEFCA Manner Exception, as currently required in 171.403(d).

In our comment letter on HTI-1, The Sequoia Project strongly urged ASTP/ONC to apply the Fees and Licensing Exceptions to the TEFCA Manner Exception. In the HTI-2 preamble,



ASTP/ONC thoughtfully summarized feedback from various commenters, including our own. It noted that the Common Agreement prohibits fees between QHINs but allows for fees between Participants and Subparticipants. This could inadvertently allow entities to charge fees for accessing, exchanging, or using EHI in ways that do not align with the Fees Exception or the Licensing Exception. Commenters expressed concerns that this situation could disincentivize participation in TEFCA, prompting stakeholders to seek alternative electronic exchange options outside of TEFCA, where they believe the Fees and Licensing Exceptions would be applicable.

We stand by our original feedback and strongly urge ASTP/ONC to retain the current language in 171.403(d).

FHIR API Standards

ASTP/ONC is seeking feedback on the current limitations regarding requests for access, exchange, or use of EHI via FHIR API standards. This includes various options for modifying the existing exception.

The Common Agreement and TEFCA Standard Operating Procedures (SOPs) do not specify a timeline for when organizations will be required to support Facilitated FHIR. Additionally, there is no established date for when all Qualified Health Information Networks (QHINs) will adopt Brokered FHIR, nor are there defined specifications for its implementation. Given this context, we believe it is premature to consider lifting the current limitation.

Should ASTP/ONC decide to modify the exception in the future, we recommend that any changes stipulate that both parties involved must participate in TEFCA and that both the requestor and the responder support the requested standard, as outlined in TEFCA. This approach ensures that both parties have the capability to successfully exchange requests and responses.

Part 172 – Trusted Exchange Framework and Common Agreement (TEFCA)

Overall, we have concerns with this Part due to the potential for inconsistency with the Common Agreement and TEFCA Onboarding and Designation Standard Operating Procedure (SOP). While we understand that certain elements of this section stem from statutory requirements directed to ASTP/ONC; ***we strongly suggest that ASTP/ONC fulfill these requirements by incorporating the Common Agreement and applicable SOPs into the regulation by reference, rather than including extensive language from those documents into the regulation itself.***

We are concerned that restating or duplicating entire sections of the SOPs and the Common Agreement within regulatory text may jeopardize the program's ongoing operations and ability to evolve. Any discrepancies between the regulatory text and the Common Agreement or SOPs will lead to confusion or misinterpretation. We note that the regulation will always take



precedence over the Common Agreement due to its status as applicable law; therefore, to the extent there are differences, the Common Agreement and SOPs will have to be reinterpreted in light of the regulatory text. In addition, such reinterpretation could ultimately result in unintentional amendments to the Common Agreement and SOPs, which were painstakingly developed through a consensus process under ASTP/ONC's leadership.

To the extent that sections of the Common Agreement or SOPs are adopted in regulations, any updates to the Common Agreement or SOP would simultaneously need to be updated in the regulation, which could trigger substantial clearance processes, potentially disrupting TEFCA Exchange. Maintaining the Common Agreement and SOPs as the single authoritative source for these requirements would reduce the risk of conflict, misinterpretation, and disruption to ongoing exchange activities.

We urge ASTP/ONC to coordinate closely with the TEFCA RCE to ensure alignment of all requirements and to develop a strategy to meet the agency's regulatory and statutory objectives without compromising the purpose or integrity of the Common Agreement and SOPs.

Below are several key areas of concern that illustrate the potential challenges we foresee. We would welcome the opportunity for a more thorough discussion and review.

- **§172.102 Definitions**— We have concerns about codifying definitions from the Common Agreement. Differing definitions between the Common Agreement and the regulation will lead to confusion and misinterpretation, or potential amendments to the Common Agreement. Below are some examples of inconsistencies that are concerning:
 - Some definitions do not fully align with the Common Agreement v2 (e.g., Threat Condition and Recognized Coordinating Entity).
 - Some of the definitions (e.g., XP Code) are included in the regulation but not used in the regulatory text.
 - Certain definitions refer to applicable Standard Operating Procedures (SOPs) (e.g., the definition for Participant/Subparticipant Terms of Participation), while others do not, even when the Common Agreement does (e.g., Exchange Purposes in the proposed regulatory text omits reference to SOPs, though the Common Agreement includes such reference). Leaving out references to SOPs could change the meaning of the Common Agreement and render the SOPs inapplicable.
 - The term Responding Node is used in the definition of Required Information but not defined in the regulation.
 - Some definitions refer to “ONC (or an RCE)” (e.g., threat condition), other times there is no mention of an RCE, even though the Common Agreement includes such a reference (e.g., Qualified Health Information Network).



- **§172.300 Applicability** — This subpart proposes to establish, among other things, a redetermination process for QHINs. However, the remainder of 172.300 does not reference a redetermination. The Onboarding & Designation SOP on the RCE website also does not include a redetermination process, but rather states that “the RCE is not in a position to review an application once the RCE has determined that the application should be denied.”
- **§172.304 QHIN Designation**— This section references provisional Designation. However, the RCE, under ASTP/ONC guidance, is currently revising the Onboarding and Designation SOP to remove references to Provisional Status.
- **§172.606 Adjudication** — The proposed language sets a de novo standard for the hearing officer when deciding appeals. We believe that there should be a higher bar for overturning decisions related to suspensions and terminations requiring clear and convincing evidence to support the appellant's claim.
- **§172.701 Attestation submission and acceptance** —
 - The proposed language requires QHINs to attest to (1) agreement with and adherence to the Trusted Exchange Framework (TEF) and (2) adoption of the Common Agreement. We note that the TEF is intentionally broad and cannot be practically “adhered to”. We suggest striking the “adherence to” language and simply say “agreement with” the TEF.
 - We understand the proposed attestation process to be procedural and intended to occur after the QHIN has already received its written Designation determination from the RCE. At this point in the process, both the QHIN and the RCE will have signed the Common Agreement.
 - To streamline workflows, reduce burden, and minimize redundancy, we suggest incorporating the required attestation into the RCE’s current Onboarding and Designation process so that once Designation is granted and the QHIN has countersigned the agreement they do not need to re-attest.
 - If integrating this procedure into the current RCE Onboarding & Designation process is not possible, we recommend adding language to clarify that submission of the attestation— and any potential rejection from ASTP/ONC—will not affect the QHIN’s Designation status or its ability to participate in TEFCA Exchange.
- **§172.702 QHIN Directory** —
 - We are concerned that the term “QHIN Directory” will confuse stakeholders, as the Common Agreement refers to an “RCE Directory Service” and the QHIN Technical Framework (QTF) refers to a “QHIN Directory”. To avoid confusion, we suggest replacing the term “Directory” with “list”, which aligns with the Cures



Act language describing a “list of the health information networks that have adopted the common agreement...”.

- Additionally, since the RCE already maintains a list of Designated QHINs on its website, we recommend that ASTP/ONC link directly to the current RCE website. This will avoid the potential for conflicting information and redundant processes.

The above list is not exhaustive, and we anticipate other inconsistencies will arise, especially as the RCE is currently making updates to the Onboarding and Designation SOP and QHIN Application. We offer our support and collaboration to make sure these updates are in alignment with the final rule.

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.

Mariann Yeager

A handwritten signature in cursive script that reads 'Mariann Yeager'.

CEO, The Sequoia Project