



February 27, 2026

Thomas Keane, MD

Assistant Secretary for Technology Policy/National Coordinator for Health Information
Technology (ASTP/ONC)

Department of Health and Human Services

200 Independence Ave, SW

Washington, DC 20201

Re: RIN 0055-AA09; Health Data, Technology, and Interoperability: ASTP/ONC
Deregulatory Actions to Unleash Prosperity (HTI-5)

Submitted electronically to www.regulations.gov

Dear Dr. Keane,

The Sequoia Project is pleased to submit comments to the Assistant Secretary of Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC), on the *Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions to Unleash Prosperity (HTI-5) proposed rule*.

The Sequoia Project is a non-profit, 501(c)(3) public-private collaborative dedicated to advancing nationwide interoperability of electronic health information for the public good. For more than a decade, we have worked to enable sustainable, scalable health information exchange by bringing together stakeholders from across healthcare and health IT to identify, prioritize, and collaboratively address the most pressing challenges to nationwide health information sharing.

Through our Interoperability Matters initiative, we convene providers, consumers, caregivers, payers, health IT companies, health information networks, federal agencies, and other stakeholders to develop practical, consensus-driven solutions that drive meaningful progress in interoperability. Our Interoperability Matters workgroups provide a forum for engagement on key topics, including Consumer Engagement, Privacy and Consent, Payer-to-Payer API Implementation (CMS-0057), Data Usability, Public Health, Pharmacy Interoperability, and Information Blocking Compliance.

We are also honored to serve as the Recognized Coordinating Entity (RCE) for the Trusted Exchange Framework and Common Agreement (TEFCA), as designated by ASTP/ONC. Our decade of experience building public-private collaborations and launching successful, sustainable nationwide health IT initiatives provides us with a unique and practical perspective on the proposed rule. TEFCA exchange has reached nearly 500 million health records exchanged and continues to accelerate, providing a real-world lens on how the



industry currently uses document-based exchange, suggesting that it will be important to affect the smooth adoption of a FHIR-first strategy. We thank ASTP/ONC for the opportunity to provide feedback.

Health Information Technology Standards, Implementation Specifications, and Certification Criteria and Certification Programs for Health Information Technology (Part 170)

The Sequoia Project appreciates ASTP/ONC's efforts to reduce regulatory burden and modernize longstanding components of the Health IT Certification Program. We support the goal of creating a more flexible, innovation-friendly framework and generally support ASTP/ONC's proposals to revise and remove the certification criteria, as proposed.

We encourage ASTP/ONC to carefully consider the timing of these changes and, where appropriate, delay certain removals or revisions until a clearer end state is defined. Implementing significant changes without a well-articulated path forward could create uncertainty and disrupt alignment across industry and federal initiatives.

Below, we offer additional comments on specific criteria that intersect with the interoperability programs and initiatives driven by The Sequoia Project.

Care Coordination Certification Criteria (Sections III.A.2.a-d, III.A.5.a, III.A.7.f)

The Sequoia Project supports the long-term direction toward API-based exchange. C-CDA document exchange, however, remains foundational at national scale today. For example, Carequality supports over 1.2 billion clinical documents exchanged each month, and TEFCA has surpassed 600 million health records exchanged since going live in December 2023.

As ASTP/ONC advances HTI-5, we encourage careful consideration to ensure that high-value, high-volume workflows remain stable until clear, implementation-ready guidance and tooling are available to support equivalent FHIR-based document semantics, validation, and privacy controls.

The Sequoia Project understands ASTP/ONC's rationale that without federal requirements to support C-CDA capabilities within EHR products, developers will likely keep the capabilities within their systems. In practice, capabilities that are not required for certification and procurement are often deprioritized or subject to increased variability.

Through its [Interoperability Matters](#) program, the [Sequoia Project's Data Usability Workgroup](#) is focused on practical, implementable approaches to improving data quality, consistency, and safe clinical use across exchange modalities. This work reflects ongoing industry recognition that, while the ecosystem advances toward FHIR-based exchange,



significant volumes of document-based exchange will persist for the foreseeable future and will require continued attention to quality, validation, and usability.

The Sequoia Project also maintains and supports widely used interoperability testing tools that help implementers validate transport, security, and data content conformance, promoting consistent, high-quality exchange across networks. As policy and certification requirements evolve, these types of community-supported resources can help provide continuity for implementers and reduce disruption as focus shifts to more API and FHIR-centric approaches.

Recommendation: If ASTP/ONC finalizes the proposal to sunset the C-CDA-centered criteria and/or capabilities, we suggest that ASTP/ONC support industry efforts to 1) define C-CDA and FHIR equivalence expectations for USCDI data, and 2) ensure continued availability of C-CDA validation capabilities that are currently supported in ONC SITE test tools to support implementers. Community-supported testing resources, including those maintained by The Sequoia Project, can help promote consistent, high quality document exchange, provide continuity for implementers, and reduce disruption while the ecosystem evolves.

§ 170.315(d) Privacy and Security Criteria (Section III.A.4)

The Sequoia Project appreciates ASTP/ONC's efforts to modernize the Health IT Certification Program and reduce burden around privacy and security criteria. We understand the interest in streamlining requirements and creating space for innovation. A common baseline of privacy and security tooling is essential to maintaining stakeholder trust when engaging in the interoperable exchange of health information. As these changes are considered, careful attention to potential impacts will help ensure continued progress while minimizing unintended consequences.

- **Evolving and Fragmented Security Landscape.** States are currently advancing varying approaches to cybersecurity oversight, while the industry continues to await revisions to the HIPAA Security Rule, which may present opportunities for stronger alignment with Certification Program objectives. At the same time, cybersecurity threats remain persistent across the healthcare ecosystem. Removing certification criteria in advance of a coordinated national approach to health IT security, particularly alignment with any HIPAA security rule updates, may inadvertently signal reduced prioritization of security capabilities within certified health IT.
- **Timing and Transitions Considerations.** Given the evolving regulatory environment, we encourage ASTP/ONC to carefully consider the timing of the proposed removals. Eliminating privacy and security certification criteria prematurely could increase



regulatory fragmentation and uncertainty. While we recognize the rule’s broader deregulatory goals and ASTP/ONC’s stated intent to address privacy and security in future updates, a phased or delayed approach may better support thoughtful alignment with forthcoming federal requirements. Maintaining an optional pathway could help reduce burden while preserving transparency and market flexibility.

- **Importance of Maintaining Multi-Factor Authentication.** The Sequoia Project wishes to highlight the value of § 170.315(d)(13): Multi-factor authentication (MFA). MFA is already required across multiple federal and industry security requirements (e.g., DEA EPCS, IRS Pub 1075 for FTI, NIST 800-171 for covered contractors, PCI DSS for cardholder environments). By contrast, HIPAA does not explicitly require MFA, making Health IT certification one of the only consistent levers promoting MFA in healthcare.

As an alternative to removing these criteria, ASTP/ONC could consider removing the required dependencies that are currently outlined in the privacy and security framework, making the certification to such privacy and security criteria purely at a developer’s discretion. This would eliminate the burden on those that do not wish to certify to or maintain certification to the privacy and security criteria but allow others to demonstrate their capabilities for their product offerings. An optional pathway can also preserve transparency and support market differentiation for developers that choose to invest in advanced security capabilities. Maintaining voluntary criteria would also preserve a consistent reference point that states and other regulatory programs can leverage when establishing or aligning their own requirements for regulated entities.

Removing certification-driven security capabilities shifts the burden (and liability) to providers and networks who may reasonably assume certified products include baseline controls, thus creating a mismatch between perceived and actual security posture.

Recommendation: The Sequoia Project recommends that ASTP/ONC carefully evaluate the timing of any removal of privacy and security certification criteria, and consider a phased transition aligned with any forthcoming federal security requirements. To reduce burden while preserving transparency and market flexibility, ASTP/ONC could maintain these capabilities as voluntary certification criteria and remove associated required dependencies in the Privacy and Security Framework.

Security Tags Criteria (§ 170.315(b)(7) and (b)(8))

In addition to our comments regarding the general privacy and security criteria, The Sequoia Project also recommends ASTP/ONC retain the voluntary criteria at 170.315(b)(7) “Security tags – summary of care – send” and 170.315(b)(8) “Security tags - summary of care –



receive.” Maintaining these voluntary criteria would not add burden but continue to signal the importance of a standards-based approach to computable consent.

As discussed in The Sequoia Project’s Interoperability Matters Privacy and Consent workgroup white paper, “[Guidance to States: Legislating Technical Standard Definitions for Existing State Sensitive Health Data Laws](#)” we believe that the national use of technical standards around data segmentation for privacy (DS4P) is a critical step to creating a unified approach “for understanding how to identify information that falls under each sensitive category, and how to record and communicate this identification in the form of security labels in different data structures and protocols.” The Sequoia Project is also working on guidance to health care organizations on how to adopt computable consent to allow for greater ability to both share data and protect sensitive information. Furthermore, removing these criteria could result in impeding the ability to test conformance to these standards. Rather than fully removing these criteria, we encourage ASTP/ONC to establish a clear timeline to adopt widespread use of FHIR-based functionality for DS4P.

Patients with sensitive conditions will disengage from exchange, or be harmed, if computable privacy controls are unavailable. Maintaining DS4P signals commitment to trust and equitable participation. It will also support additional efforts to support health information exchange in the context of behavioral health.

Recommendation: The Sequoia Project recommends that ASTP/ONC retain the security tag-related criteria until an approach for FHIR-based functionality is provided as an option within the Certification Program.

Information Blocking (Part 171)

The Sequoia Project supports ASTP/ONC’s efforts to strengthen the Information Blocking rule and ensure it keeps pace with evolving exchange practices. We appreciate the agency’s focus on reducing unnecessary burden and addressing potential misuse of existing exceptions through our Interoperability Matters program, The Sequoia Project convenes an [Information Sharing Workgroup](#) (formerly the Information Blocking Workgroup) focused on the practical implications of implementing the Information Blocking rules, as well as on the ground approaches to facilitate information sharing. Established in 2019, this group includes participants from across the health IT ecosystem and continues to provide diverse, cross-sector input on emerging policy and operational considerations. Our comments are informed, in part, by input from this workgroup but should not be attributed to any individual workgroup members.

We understand ASTP/ONC’s objectives in proposing these revisions and appreciate the intent to promote clarity and appropriate use of the exceptions. Across these proposals, we



encourage ASTP/ONC to prioritize clear, workable standards, provide greater transparency and implementation guidance, and avoid unintended operational burden or compliance uncertainty for actors working in good faith to comply with the Information Blocking requirements. We further recommend increased transparency regarding enforcement expectations and continued coordination with the Office of the Inspector General (OIG) to promote consistent and predictable application of the Information Blocking regulations.

Infeasibility Exception Revisions (45 CFR 171.204).

Third Party Seeking Modification Use Condition (§ 171.204(a)(3))

The Sequoia Project appreciates ASTP/ONC's continued efforts to refine the Information Blocking rules and to reduce opportunities for misuse of exceptions in ways that unnecessarily inhibit access, exchange, or use of EHI. We understand and generally support the agency's rationale for proposing to remove the Third Party Seeking Modification Use Condition from the Infeasibility Exception, particularly given concerns that this provision may be invoked inappropriately to withhold EHI from third parties that patients and health care providers wish to engage.

As ASTP/ONC finalizes this proposal, we recommend accompanying it with an FAQ describing how actors should address legitimate concerns related to confidentiality, integrity, or availability of the EHI through other existing exceptions, including by engaging in information gathering and analysis to work through the available alternative exceptions. Given the frequency of recent Information Blocking policy changes and limited transparency into enforcement expectations, additional clarity will be important to support consistent implementation, compliance investment, and long-term program stability.

Recommendation: The Sequoia Project supports finalizing the removal of the Third Party Seeking Modification Use Condition, provided that ASTP/ONC issue accompanying FAQs describing how actors should address legitimate concerns related to confidentiality, integrity, or availability of the EHI through other existing exceptions, including by engaging in information gathering and analysis to work through the available alternatives.



Manner Exception Exhausted Condition (§ 171.204(a)(4))

The Sequoia Project appreciates ASTP/ONC's continued focus on ensuring that the Infeasibility Exception is not used inappropriately to limit access, exchange, or use of EHI. We understand the concern that the Manner Exception Exhausted Condition (Exhausted Condition) may be susceptible to misuse in certain circumstances. We encourage careful consideration, however, of whether the proposed revisions, or the alternative proposal to remove § 171.204(a)(4) entirely, could introduce additional uncertainty or operational complexity without fully resolving the underlying concerns identified.

- **Potential Impact of Proposed Terminology Changes.** Several of the proposed changes may warrant careful consideration to ensure they enhance clarity rather than reduce it. Replacing “same” with “analogous” may introduce subjectivity and raise questions about how actors and requestors will determine what qualifies as sufficiently comparable access in practice. Similarly, revising the “substantial number” element to “any” individual or entity may allow isolated or edge-case situations to drive broader compliance obligations in ways that may not reflect typical operational realities.
- **Operational Implications of Exhaustion Requirements and Timing.** We also encourage consideration of the operational implications of requiring actors to offer “all” alternative manners within the existing 10-business-day timeframe. In practice, organizations often present multiple options at once and work collaboratively with requestors, particularly those with less technical sophistication to identify a workable path forward. A more rigid exhaustion process could increase documentation burden and potentially slow negotiations without materially improving access outcomes. As noted in our HTI-2 comment letter, we continue to ask for clarification of the 10-business day timeframe and suggest specifying that the 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.
- **Value of a Clear Compliance Endpoint.** More broadly, the current Exhausted Condition provides organizations with a clear way to demonstrate good-faith efforts to meet a request under the Manner Exception. Revising or removing this endpoint could make it less clear when an actor has satisfied its obligations, particularly where requestors are not required to respond within the same timeframe. Additional clarity regarding the specific misuse ASTP/ONC is seeking to address would help ensure that any revisions do not inadvertently burden actors making good-faith compliance efforts.



Recommendation: The Sequoia Project recommends that ASTP/ONC further clarify the specific misuse motivating these revisions and ensure that any modifications remain practical and workable to implement. We also encourage consideration for retaining the current Exception Exhausted condition so that actors have a clear and consistent endpoint for demonstrating compliance.

Manner Exception Revisions (§ 171.301)

The Sequoia Project supports ASTP/ONC’s goal of ensuring that agreements reached under the Manner Exception are fair and do not impose coercive or abusive terms on requestors. We agree that this exception should not be used to pressure requesters into accepting unreasonable conditions. Standardized agreements can be important tools for enabling exchange at scale, particularly when they are supported by transparent governance and meaningful opportunities for stakeholder input. Any additional policy to promote fair contracting needs to balance operational realities. For example, there are important questions about how the definitions of “market rate”, “contracts of adhesion”, and “unconscionable terms” would be defined and applied across organizations with very different sizes, cost structures, and business models.

We encourage ASTP/ONC to clarify how the concept of a “contract of adhesion” applies in participatory governance and change management structures by distinguishing unreasonably coercive contracting practices from trust agreements that support broad participation.

Recommendation: We encourage ASTP/ONC to carefully weigh operational realities as it seeks to ensure fair terms. In addition, we ask ASTP/ONC to clarify how the concept of a “contract of adhesion” applies in participatory governance and change management structures by distinguishing unreasonably coercive contracting practices from trust agreements that support broad participation.

TEFCA Manner Exception (§171.403)

The Sequoia Project does not object to ASTP/ONC’s proposal to remove subpart D of 45 CFR part 171, including the TEFCA Manner Exception and associated definitions. Removing the TEFCA-specific exception does not diminish the importance of clear, consistent treatment of standardized agreements under the broader Manner Exception framework. TEFCA participation remains voluntary, and its value derives from operational efficiency and trusted exchange.

Recommendation: The Sequoia Project does not object to the removal of the TEFCA Manner Exception and recommends that ASTP/ONC provide clear communication to ensure stakeholders understand that TEFCA remains a viable path for meeting information sharing obligations.



Conclusion

The Sequoia Project appreciates ASTP/ONC's leadership in advancing interoperability and modernizing both the Health IT Certification Program and Information Blocking framework. We support ASTP/ONC's goals of reducing unnecessary burden and strengthening exchange, while encouraging careful calibration of proposed changes to avoid unintended ambiguity, disruption of widely relied-upon capabilities, or operational and security risks.

We respectfully urge ASTP/ONC to prioritize clear pathways, practical implementation guidance, and alignment with broader federal and industry efforts. Thoughtful pacing and targeted refinements will help sustain stakeholder confidence, support consistent compliance, and continue progress toward a trusted and scalable nationwide health information exchange ecosystem.

Most respectfully,

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

Mariann Yeager
CEO, The Sequoia Project