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February 26, 2026

Dr. Thomas Keane

Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology

Attention: Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions to Unleash Prosperity Proposed Rule

Mary E. Switzer Building

Mail Stop:7033A

330 C Street, S.W., Washington, D.C. 20201.

RE: Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions to Unleash Prosperity Proposed Rule (RIN 0955-AA09)

Dear Assistant Secretary Keane:

The Healthcare Trust Institute (HTI) appreciates the opportunity to comment on the Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions To Unleash Prosperity (HTI-5) proposed rule (proposed rule) published by the Department of Health and Human Services (HHS) Assistant Secretary for Technology Policy/Office of the National Coordinator of Health Information Technology (ASTP/ONC) in the Federal Register on December 29, 2025.¹

HTI is an alliance of healthcare organizations committed to promoting and implementing effective protections for health information that engender trust in the healthcare system and allow for the necessary exchange of health data to advance treatments, cures and improved healthcare quality for individuals and populations. HTI members, which include companies and organizations from across the U.S. healthcare economy, agree that strong national standards for the protection of health information are critical to engender trust in information sharing and spur medical innovation.

We appreciate ASTP/ONC's continued leadership in advancing interoperability through HTI-5. We support the agency's focus on Fast Healthcare Interoperability Resources (FHIR)-based APIs, modernization of the ONC Health IT Certification Program, and efforts to reduce unnecessary burden on the healthcare ecosystem. We especially

¹ 90 Fed. Reg. at 60970 (December 29, 2025).

support ASTP/ONC's deregulatory efforts with the goal of making it easier for health care providers to focus on preventing and treating chronic disease and to spend more time on caring for their patients. Removing duplicate and/or onerous requirements that provide little direct clinical benefit and prioritizing interoperability standards that promote innovative and more efficient ways for patients to view and use their health information will lead to improved care and better health outcomes. We also welcome the efforts to clarify and rationalize the information blocking regulation by removing duplicate, unnecessary and/or overlapping conditions and exceptions, and to ensure that patients do not face barriers in accessing their health information. Simpler, clearer, and more stable exceptions will allow the workforce of actors to better understand the operation of the exceptions, resulting in better compliance and fewer unintended violations.

At the same time, we believe it is critical that deregulatory changes be evaluated not only in terms of developer burden, but also in terms of their downstream impact on healthcare providers. We are concerned that several of the proposed changes—particularly those related to app-level API FHIR implementation, privacy and security certification, and AI transparency—may unintentionally shift compliance risk and operational burden to healthcare providers. Providers remain accountable for patient safety, regulatory compliance, and care delivery outcomes as interoperability, API access, and AI-enabled tools expand. Federal certification and transparency requirements have historically provided important baseline assurances that support HIPAA compliance, CMS program participation, information blocking obligations, and emerging state AI requirements.

We encourage ASTP/ONC to ensure that HTI-5 advances interoperability in a manner that is operationally meaningful for providers, preserves trust and safety, and avoids replacing standardized federal guardrails with fragmented, provider-by-provider risk management obligations.

We discuss the above issues in greater detail below.

A. Certification Program Proposals

1. FHIR-Based Interoperability Should Enable Real-World Clinical Use

We strongly support ASTP/ONC's increasing emphasis on FHIR-based interoperability under 45 CFR §170.315(g)(10) and related API certification criteria. FHIR represents a scalable and standards-based foundation for nationwide interoperability. We support prioritizing FHIR-based APIs that move beyond mandatory "read-only" data access to enabling "write" capabilities to support automated, bidirectional data exchange, clinical efficiency, and patient-centered care. FHIR APIs that primarily support data retrieval, without allowing healthcare providers to enable controlled and appropriate data contribution, often fail to reduce clinician burden or replace legacy exchange mechanisms. Providers must still manually re-enter externally sourced data into EHRs, increasing documentation burden and risk of error.

While we support ASTP's deregulatory efforts, there is also a need to engender trust in

information exchange in a deregulated environment. A common approach or set of rules is needed to advance the FHIR environment and bolster partnerships. In a FHIR-based ecosystem that depends on distributed development and delegated functionality, participants must be able to rely on consistent technical, governance, and accountability norms. Without a shared framework—such as minimum expectations for FHIR implementation consistency, write-access governance, auditability, data provenance, and model or decision-support transparency—healthcare providers face increased legal, operational, and patient safety risk. This uncertainty can discourage participation, slow adoption, and undermine the very interoperability goals HTI-5 seeks to advance. A common set of rules, even if largely voluntary or implementation-guided rather than prescriptive, would help align incentives, reduce transaction costs, and provide clarity to all participants. Such a common set of rules would support trust, scalability, and sustainable partnerships in a FHIR-enabled environment while preserving flexibility for innovation.

We encourage ASTP/ONC to continue evolving FHIR policy toward:

- Practical workflow integration, not just technical access.
- Use-case-specific, safeguarded data contribution where clinically appropriate.
- Preservation of clinician oversight and accountability.
- A common set of rules for consistent technical, governance, and accountability norms.

2. Privacy and Security Certification Requirements

ASTP/ONC proposes to remove all the 14 privacy and security criteria, including authentication, audit logs, encryption, and multi-factor authentication. ASTP/ONC explains that certification is likely no longer a primary factor driving improvements or compliance in these areas, and that by removing these requirements, it will provide health IT developers with the flexibility to provide more innovative solutions, spur competition and give healthcare providers the opportunity to choose the best privacy and security technologies that fit their needs at the best price versus being forced to accept those capabilities included in certified health IT.

We appreciate ASTP/ONC's intent to provide health IT developers with greater flexibility to innovate, spur competition, and enable healthcare providers to select privacy and security technologies that best meet their needs and budgets. We agree that reducing overly prescriptive certification requirements potentially allows for more tailored and advanced solutions, particularly for organizations with mature security programs. However, we are concerned that the removal of all privacy and security certification requirements may have unintended negative consequences for health care providers that outweigh the potential benefits of the proposal. Many healthcare providers rely on certified health IT to help them meet their HIPAA and other privacy and security law compliance obligations and may struggle to meet these on their own or to find cost-effective alternatives. This is especially the case for smaller or rural health care providers that have more limited resources.

For similar reasons we support ASTP/ONC’s decision to retain certain audit-related requirements as a safeguard to help identify fraud and abuse. This approach appropriately recognizes that, even in a more flexible and competitive market, baseline technical and documentation requirements play an important role in enabling oversight, accountability, and trust in the health IT ecosystem.

Without clear alternative mechanisms, the absence of common expectations for privacy and security capabilities may increase costs, contribute to fragmentation, and introduce new risks to trusted exchange and patient access, potentially undermining broader interoperability goals.

We encourage ASTP/ONC to consider whether the same principles that justify retaining audit-related requirements—namely, supporting accountability, oversight, and system integrity—could also support maintaining or offering voluntary, modular, or standardized approaches to other core privacy and security capabilities. Such an approach would preserve flexibility and innovation for developers while ensuring that providers retain the baseline assurances necessary to responsibly adopt new technologies and safeguard patient data.

3. AI Transparency Requirements

While HTI-5 preserves the fundamental requirement for Certified Health IT to support evidence-based and predictive decision support interventions (DSIs), it proposes to significantly streamline the associated transparency and administrative obligations to align with broader deregulatory goals. Specifically, ASTP/ONC proposes to reduce the scope of the DSI certification criterion to fully remove the artificial intelligence (AI) “model card” requirements, including source attribute information transparency and intervention risk management for predictive DSIs. ASTP/ONC states that healthcare delivery organizations and health care professionals have not used this information, and that the developers have reported that the requirements are burdensome and detrimental to innovation, which is contrary to ASTP/ONC’s stated policy intent to optimize the ubiquitous use of high-quality AI in health care.

We appreciate ASTP/ONC’s acknowledgment that AI governance is evolving, and that overly prescriptive federal requirements may inadvertently constrain innovation. At the same time, we encourage ASTP/ONC to incorporate practical, real-world measures that meaningfully enhance AI tool transparency. We respectfully recommend that ASTP/ONC take the following considerations into account:

- Clinical oversight of AI-enabled tools,
- Patient safety and appropriate use, and
- Compliance with emerging state AI and automated decision-making laws.

Standardized transparency artifacts—such as AI model cards—have provided practical tools to understand intended use, limitations, and risks, and to support internal governance and procurement decisions. Without continued attention to strengthening

these mechanisms, users of certified health IT may be left without the technical and functional detail necessary to meet increasing due diligence and disclosure obligations related to the use of AI in the healthcare sector.

We encourage ASTP/ONC to consider retaining a voluntary or recommended transparency framework to support responsible AI adoption without imposing undue regulatory burden.

4. Permanent Enforcement Discretion for HTI-1 Requirements

ASTP/ONC proposes to make permanent several enforcement discretion policies previously announced in 2025, including limiting Insights reporting requirements to FHIR usage only, descoping real-world testing obligations, allowing developers to adopt newer standards without waiting for regulatory updates and declining direct review authority over noncompliance tied solely to the January 1, 2026, HTI-1 compliance date.

We appreciate ASTP/ONC's decision in HTI-5 to codify certain enforcement discretions. Formalizing these policies provides welcome clarity to regulated entities and meaningfully reduces compliance uncertainty and administrative burden, particularly during periods of regulatory transition and technical maturation. At the same time, we urge ASTP/ONC to ensure that any enforcement actions taken under these provisions are applied consistently and transparently across regulated actors. Clear, predictable, and uniform application of enforcement discretion is essential to maintaining stakeholder confidence, supporting good-faith compliance efforts, and avoiding unintended disparities among similarly situated entities.

We encourage ASTP/ONC to continue communicating how enforcement discretion will be operationalized, including through guidance, examples, or FAQs, and to reaffirm that good-faith efforts to comply with evolving requirements will remain a central consideration in enforcement decisions.

B. Information Blocking

While we support ASTP/ONC's goal in HTI-5 to streamline the Information Blocking framework and add clarity by revising provisions that are duplicative, confusing, or susceptible to misuse, we are concerned that there are several ambiguities in the proposed information blocking changes that work against these goals.

In addition, as the agency simplifies and potentially narrows exceptions, it is important to ensure that actors are not exposed to increased compliance risk when they refuse or limit access in good faith based on legitimate technical, security, operational, or governance constraints. Clear standards and explicit enforcement discretion are essential to preserving trust in the regulatory framework and encouraging continued participation in national interoperability efforts. We discuss the proposed changes to the information blocking exceptions below.

1. Infeasibility Exception

a. Third Party Seeking Modification Condition

We understand ASTP/ONC's concern that the "third party seeking modification" conditions in the infeasibility exception may be interpreted more broadly than intended, and that this could result in inhibiting appropriate access to electronic health information. However, rather than remove the condition entirely, we support the less drastic step of clarifying the condition to foreclose the overly broad interpretations leading to misuse and confusion.

ASTP/ONC notes that it had previously proposed limiting this condition, and that this proposal received general support. It also states that most commentators did not support sunseting or eliminating the condition, and that ASTP/ONC agreed that this should not be done until "health IT is capable of supporting third-party modification use of EHI by any party with a legal right to do so (or no legal prohibition against it), with no or minimal infeasibility or other concerns." ASTP/ONC does not claim in HTI-5 that health IT has reached this point today but appears to base its proposal for eliminating the condition on the fact that there has been "substantial growth in technical approaches that enable efficient, appropriately secure modification" and that elimination of the condition is the simplest, most efficient, approach. Since ASTP/ONC's rationale for creating the condition still holds, we recommend that ASTP/ONC instead finalize its earlier proposal to narrow the condition and provide additional guidance on its application to avoid misunderstanding or misuse.

b. Manner Exception Exhausted Condition

ASTP/ONC raises similar concerns about the potential misuse of the "manner exception exhausted" condition to deny access to EHI and proposes to either narrow its application or eliminate it entirely. As with the "third party seeking modification" condition, we understand that eliminating the condition may be the easiest and simplest approach for ASTP/ONC, but do not believe this is the optimal way to address ASTP/ONC's concerns. The rationale for the creation of this condition, namely, to avoid the diversion of substantial technical, human or financial resources to "new, unique or unusual manners of supporting access, exchange or use of EHI" and away from scalable, consensus standards-based solutions, is still valid, and perhaps even more so today as scarce resources in the health sector need to be spread across not only for interoperability, but also priority areas such as cybersecurity and innovative AI solutions. We therefore recommend that ASTP/ONC retain this condition and make changes to it as necessary to address concerns about its potential misuse.

It is important though that in revising this condition, ASTP/ONC not switch out certain vague or unclear terms such as "substantial number" and "similarly situated" with equally subjective or undefined terms such as "analogous," or unintentionally create new uncertainties, such as by the use of the term "all alternative manners" without clarifying what it considers to be the universe of "all alternative manners," particularly for actors that do not use certified health IT.

We encourage ASTP/ONC to combine these steps with explicit enforcement discretion, including clear recognition that reasonable, contemporaneous good-faith determinations of infeasibility—supported by proportionate documentation—will be afforded deference in enforcement decisions for at least a year after the required compliance. This is critical to allow ASTP/ONC to work out any kinks i.e., to gauge whether its new requirements are clear and operating as intended and, if not, to issue modifications or clarifying guidance.

2. Manner Exception

We support ASTP/ONC's proposal to clarify the "manner requested" condition in the manner exception to address concerns that the existing formulation has been overly broad and subject to inconsistent interpretation, creating uncertainty and compliance risk for actors and, in some cases, allowing actors to abuse the exception.

As with the manner exception exhausted condition in the infeasibility exception, we caution against introducing new terms and concepts that are also unclear, require subjective judgments or are susceptible of different meanings. This would result simply in replacing one set of unclear requirements susceptible to misinterpretation with another set, creating further confusion and not advancing ASTP/ONC's goal to increase access to EHI.

For example, while ASTP/ONC introduces and defines the terms "contract of adhesion" and "unconscionable terms," these definitions in turn use unclear and subjective terms such as "realistic opportunity," "excessive" and "unreasonable," without providing any further clarification, such as specifying the scenarios that ASTP/ONC would consider as falling within these terms and those it would not, based on actual situations that have been brought to its attention.

As with the changes to the infeasibility exception, we encourage ASTP/ONC to clearly articulate how enforcement discretion will apply where actors make good-faith efforts to comply with the revised conditions, particularly in complex technical environments.

3. TEFCA Manner Exception

ASTP/ONC proposes to remove the TEFCA manner exception on the basis that it is unnecessary considering the robust participation in TEFCA and the availability of the manner and infeasibility exceptions. ASTP/ONC also notes that it may be negatively impacting participants in the health information ecosystem due to some entities' potential misunderstanding regarding its purpose and applicability.

We caution against assuming that TEFCA participation is so robust that it can safely remove existing incentives to participate without a detrimental impact on TEFCA participation. Participation in TEFCA involves significant technical, operational, and contractual commitments, and actors have relied on a clear understanding of how information blocking obligations would be evaluated within that framework. Without

additional clarity, the removal of the TEFCA manner exception could introduce uncertainty regarding how TEFCA-related technical, security, or governance constraints will be assessed under remaining exceptions.

To address this concern, we encourage ASTP/ONC to explicitly describe how enforcement discretion will be applied to actors participating in TEFCA who, in good faith, refuse or limit access based on TEFCA-specific requirements. Guidance, examples, or FAQs illustrating appropriate reliance on the infeasibility, privacy, or security exceptions in TEFCA contexts would help preserve confidence in TEFCA participation while maintaining the benefits of regulatory streamlining.

All stakeholders will benefit from simpler and clearer rules, and from rules that are not constantly being adjusted, but this clarity and simplicity should not come at the expense of legitimate concerns about privacy, security, or the diversion of health IT resources from other areas of priority. Instead, we encourage ASTP/ONC to take a measured and balanced approach that pairs targeted regulatory simplification with explicit enforcement discretion and clear expectations for good-faith compliance across all actors. In this way ASTP/ONC can reduce unnecessary burden, discourage misuse, and support trusted, scalable health information exchange nationwide.

Conclusion

We appreciate ASTP/ONC's efforts in HTI-5 to modernize the interoperability framework by reducing unnecessary burden, increasing flexibility, and focusing regulation on practical, outcomes-based exchange. We support this direction, including the emphasis on a FHIR-based foundation, streamlined certification requirements, codified enforcement discretion, and clearer information blocking provisions. As these reforms shift away from prescriptive requirements, it is essential that flexibility be paired with clarity, consistency, and appropriate safeguards, including explicit recognition of good-faith compliance. Applying this balanced approach consistently across HTI-5 will support broad adoption of interoperable exchange, sustain trust in national efforts such as TEFCA, and advance a health information ecosystem that is both flexible and reliable.

Thank you for your consideration of our comments. Please do not hesitate to contact me at tina@hctrustinst.com or 202-750-1989 if you have any questions.

Sincerely,

A handwritten signature in black ink that reads "Tina O. Grande". The signature is written in a cursive, flowing style.

Tina O. Grande
President, Healthcare Trust Institute