



February 27, 2026

Assistant Secretary for Technology Policy
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C Street SW
Washington, D.C. 20201

Re: Health Data, Technology, and Interoperability (HTI-5): Deregulatory Actions to Unleash Prosperity

Submitted electronically via regulations.gov

Dear Assistant Secretary Keane:

The Health Innovation Alliance (HIA) appreciates the opportunity to comment on the Assistant Secretary for Technology Policy (ASTP) *Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions to Unleash Prosperity* proposed rule, known as HTI-5. We support ASTP's effort to streamline certification requirements and remove regulatory barriers that have unnecessarily burdened health IT developers and providers. Implemented thoughtfully, this deregulatory effort can free the private sector to innovate while preserving appropriate guardrails to protect patients and promote interoperability.

HIA is a diverse coalition of patient advocates, health care providers, consumer organizations, employers, technology companies, and payers who support the commonsense use of data and technology to improve health outcomes and lower costs. Founded in 2007, HIA has shaped major health IT legislation, including HITECH Act and 21st Century Cures Act. We consistently advocate for a risk-based, innovation-forward approach to health technology oversight.

We believe HTI-5 appropriately recognizes several realities: not every health IT function requires federal certification; certification criteria should not be used as a substitute for broader policy goals unrelated to interoperability; and innovation cycles in software and AI move far more quickly than traditional rulemaking.

However, as we noted in prior comments and detailed below, more needs to be done to ensure that oversight is risk-based, aligned across agencies, grounded in existing statutory authority, and enables multi-way participation in the care ecosystem.

Reform Information Blocking to Enable “Right to Integrate”

Interoperability cannot occur without meaningful compliance with information blocking requirements. While the regulatory framework is in place, implementation lags, headwinds are strong, and loopholes abound. HIA is concerned that privacy and security are increasingly used as a ploy to delay and distract from achieving interoperability necessary for patient-centric innovation.

The benefits of AI-enabled tools, predictive analytics, value-based care models, and patient-facing care management solutions are being blocked by continued information blocking practices that choke access to complete, timely data. The entire healthcare ecosystem, including patients, suffers from information silos and the inability to do “two-way” data exchange. We support the proposed rule and encourage additional steps to enable a “right to integrate” by:

- Refining the Manner Exception. Prevent abuse of the "third-party seeking modification" conditions, including contract terms that functionally withhold data based on vague IP or safety claims, where standards are being followed.
- Narrowing Infeasibility Claims. Prevent exceptions from being used as blanket refusals when standards-based integration is technically feasible.
- Advance automation. Clarify that "access" and "use" include the automated exchange of information, ensuring that low-risk AI and administrative processes aren't blocked simply because a human isn't manually triggering the data flow.
- Enable write-back. Ensure the "Right to Integrate" includes the ability for authorized outputs to be written back into the clinical workflow in a trusted, standards-compliant manner.
- Close any loophole that allows actors to technically comply while functionally restricting data flow. When integration is secure and patient-authorized, it should not be blocked for competitive reasons.

Finalize Image Sharing Requirements

HIA is disappointed to see the withdrawal of the HTI1-2 imaging proposal, which we had called for in our Interoperability Workgroup Report¹. Diagnostic imaging is currently a

¹ <https://health-innovation.org/wp-content/uploads/2023/06/HIAInteroperabilityReport.pdf>

siloed "read-only" asset. To improve patient experience and reduce the clinician's administrative burden, it should be a computable data class. We recommend:

- Finalize certification criteria. Require the ability to share images via DICOMweb and FHIR ImagingStudy resources. A "link" is a starting point for humans, but an API is required for third-party AI tools to integrate and process imaging data.
- Bridge the PACS-EHR divide. Require that Picture Archiving and Communication Systems support standards-based connections to both EHRs and cloud-based storage to ensure imaging is available to the entire care team.
- Prevent "Imaging Fees." Clarify that charging prohibitive fees for third-party apps to access imaging metadata or studies via APIs constitutes information blocking.

Strengthen Enforcement to Provide Market Certainty that Enables Innovation

Innovation thrives when rules are predictable and fairly enforced. HIA believes enforcement has been insufficient to deter functional blocking. Without meaningful and visible enforcement, even well-designed interoperability policies fail to achieve their intended outcomes. Selective or sporadic enforcement also undermines market certainty and trust.

At the ASTP Annual Meeting on February 11 and 12, representatives from the Department of Justice Anti-trust Division, the Federal Trade Commission, and the HHS OIG signaled positively on this topic. While encouraging to see the wider government using tools at their disposal, we encourage HHS OIG to:

- Use its existing authority. Signal loudly by using OIG's Civil Monetary Penalty authority, focusing on functional blocking, not just technical noncompliance.
- Increase transparency. Publish reports and information around enforcement activity, including the status and disposition of complaints, which can improve compliance without new regulations.
- Continue coordination. Accelerate collaboration between ASTP, FTC, and DOJ to clamp down on behaviors that ultimately harms patients and providers and drives up overall health system costs. This signals seriousness.

Deregulate Disconnected Certification Criteria to Foster Innovation

HIA strongly supports ASTP's efforts to pare back certification criteria that have become overly prescriptive, duplicative, or disconnected from patient benefit. While technically voluntary, the Certification Program functions as a de facto requirement. When it expands beyond core interoperability, it can inadvertently stifle the broader commercial health IT market. We recommend:

- Align with AI innovation cycles. Modify Decision Support Intervention (DSI) criteria to move away from a one-size-fits-all approach and limit DSI scope by removing burdensome source attribution requirements that add cost without improving provider understanding.
- Replace function-based regulation of AI with a risk-based approach that considers the specific use case and deployment environment.
- Eliminate privacy and security redundancy by removing certification criteria that simply restate existing HIPAA or 42 C.F.R. Part 2 obligations. We support strong, consistent privacy and security protection.
- Align any future requirements with existing federal standards. Patient trust is foundational, but redundant regulation creates shifting goalposts that hinder responsible innovation.
- Apply the disciplined test. Reconsider any requirement that does not materially advance interoperability or patient safety through existing authorities.

Conclusion

HIA commends ASTP for taking meaningful steps to streamline certification and reduce regulatory overreach through the HTI-5 proposed rule. We appreciate the opportunity to comment and look forward to working with ASTP to deliver on an interoperable system and build an innovation-forward regulatory framework.

Sincerely,

Roslyn Docktor
Executive Director
Health Innovation Alliance