



October 10, 2024

Assistant Secretary for Technology Policy
U.S. Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Mary E. Switzer Building, Mail Stop: 7033A
330 C Street, S.W., Washington, D.C. 20201

Attn: Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability Proposed Rule

Submitted electronically at: <http://www.regulations.gov>

Dear Dr. Tripathi:

As nursing stakeholders, the Alliance for Nursing Informatics (ANI) is pleased to offer comments on the ***Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability Proposed Rule***, (hereinafter the “HTI-2”).

[The Alliance for Nursing Informatics](#) (ANI), co-sponsored by AMIA and HIMSS, advances nursing informatics leadership, practice, education, policy, and research through a unified voice of nursing informatics organizations. We transform health and healthcare through nursing informatics and innovation. ANI is a collaboration of organizations representing more than 25,000 nurse informaticists and bringing together 28 distinct nursing informatics groups globally. ANI crosses academia, practice, industry, and nursing specialty boundaries and collaborates with the more than 4 million nurses in practice today.

ANI has previously commented on ONC efforts related to interoperability standards and implementation specifications, including the USCDI v1, v2, v3, v4, and the Trusted Exchange Framework and Common Agreement (TEFCA).¹ We appreciate the opportunity to advance health IT standards that support high-priority target areas, including workforce burden, health equity, and underserved communities. In addition, we applaud the prioritization of the interoperability standards focused on areas referenced by the 21st Century Cures Act and in The Future of Nursing 2020-2030 report.²

¹ Alliance for Nursing Informatics Statements and Positions. (2023). <https://www.allianceni.org/statements-positions>

² Wakefield, M., Williams, D. R., & Le Menestrel, S. (2021). *The future of nursing 2020-2030: Charting a path to achieve health equity*. National Academy of Sciences. https://nap.nationalacademies.org/resource/25982/Highlights_Future%20of%20Nursing_4.30.21_final.pdf

General Comments

We support continued health data, technology, and interoperability standardization efforts from ASTP, and the majority of the changes in this proposed rule. We applaud the following provisions:

- The HL7® FHIR Bulk Data Access implementation specification to better support interoperability and provide meaningful improvements in the performance of Bulk APIs.
- Accelerated adoption of USCDI v4 and the alignment of current and future USCDI versions with FHIR standards, including the mandate that Health IT Modules certified under criteria referencing the USCDI must be updated and made available by January 1, 2028. These efforts reduce the burden of versioning mismatch, providing certified health IT customers with more timely technology updates, including the expansion of data elements and one new class for data exchange.
- Incorporation of the National Council of Prescription Drug Programs (NCPDP) SCRIPT standard version 2023011 as the updated version of electronic prescribing certification.
- An option for either manual or automated processes in reconciling and incorporating C-CDA documents and constituent data.
- Updating multi-factor authentication certification criteria to align with industry best practices for securing health IT systems.
- Renaming the encryption of authentication credentials certification criterion to "Protect stored authentication credentials" to improve and include advanced methods for the security of certified health IT while acknowledging healthcare data continues to be breached.

Information Blocking and Protection of Access to Care

We support ASTP's efforts to add more detail to information blocking exceptions in recognition of the individual's nuanced personal preferences express for data sharing.^{3,4} This detail is particularly critical to reproductive health, as stated in the "Protecting Care Access Exception". Regarding the "Privacy Exception" relating to "an actor's respecting an individual's request for restriction on access, exchange, or use of their EHI," it would be helpful to clarify whether the individual requesting restrictions would include minors and if so, how will this exception honor each state's determination of the age of majority. This exception is an ongoing point of confusion, leading different states and health systems to adopt different practices based on privacy laws.⁵ We also support exclusions for patient safety reasons. However, we believe that more details are needed to standardize exclusions

³ Cascini F, Pantovic A, Al-Ajlouni YA, Puleo V, De Maio L, Ricciardi W. Health data sharing attitudes towards primary and secondary use of data: a systematic review. *EClinicalMedicine*. 2024 Mar 18;71:102551.

⁴ Mangal S, Niño de Rivera S, Choi J, Reading Turchioe M, Benda N, Sharko M, Myers A, Goyal P, Dugdale L, Masterson Creber R. Returning study results to research participants: Data access, format, and sharing preferences. *Int J Med Inform*. 2023 Feb;170:104955.

⁵ Sharko M., Jameson R., Ancker J.S., Krams L., Webber E.C., Rosenbloom, S.T.; State-by-State Variability in Adolescent Privacy Laws. *Pediatrics* June 2022; 149 (6): e2021053458.

so that there are fewer broad strokes of exclusions from organizations wanting to protect themselves.

We would like to highlight the pivotal role of the nurse as a patient advocate for educating patients on information blocking rules and the impact on patient experience and continuity of care. We believe patient education efforts on information blocking should consider nursing workflows and workload by leveraging nursing input in creating processes and educational products. While nursing burnout is rampant and healthcare worker burnout is a national concern,⁶ there is an interdependency to improving access to health information and reducing the information-blocking burden for clinicians and patients. Outreach efforts to the public on data-sharing options should be coordinated and prioritized.

Insight Conditions/Maintenance

We support the additional clarity and detailed measure specifications for the noted measures. However, for the measures Spec_Use_FHIR_508 and Spec_Individual_Access_508, we recommend an extension of the timeline to allow organizations to prepare for the reporting requirements.

Patient Access APIs

ANI encourages broadening the intent of “enabling patients to access health and administrative information using a health application of their choice.” While choice is important, available applications are emerging on the open market at an unprecedented rate⁷. ASTP should anticipate that it may be difficult for patients to discern whether the application of choice can serve patient goals. We recommend ASTP consider compiling a catalog of applications meeting the Patient Access API requirements that patients can access.

CPOE Laboratory

We support this provision. It contributes to a more complete patient record, decreases the likelihood of transcription errors, and scanning of lab results into the electronic health record. However, we would like to raise a concern connected to the cost of interfaces and the resources needed to configure and maintain the interfaces in low-resourced settings such as rural and community hospitals. We encourage outreach to these communities to understand the barriers to full implementation.

In conclusion, we fully support a robust data infrastructure that supports transparency and standardization of data elements, putting data in the hands of patients and caregivers to enable better and more equitable patient care through systemic improvements in the access,

⁶ Office of the Surgeon General. (2022). Addressing Health Worker Burnout: The US Surgeon General’s Advisory on Building a Thriving Health Workforce. <https://www.hhs.gov/sites/default/files/health-worker-wellbeing-advisory.pdf>

⁷ McKinsey & Company. (2024). *Technology trends outlook 2024*. <https://www.mckinsey.com/capabilities/mckinsey-digital/our-insights/the-top-trends-in-tech#/>

exchange, and use of data. We welcome the opportunity to contribute nursing input to any related HTI-2 efforts supporting ASTP ongoing efforts.

Thank you for the opportunity to comment.

Sincerely,



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ANI Co-chair

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