OCHIN

A driving force for health equity

Submitted via regulations.gov

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Micky Tripathi, PhD, MPP
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, 7th Floor
Washington, DC 20201

Re: *Proposed Rule on Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2)*

Dear National Coordinator Tripathi,

On behalf of OCHIN, I appreciate the opportunity to comment on the Proposed Rule on *Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2)*. OCHIN is a **national nonprofit health information technology innovation and research network** comprised of over 2,000 community health care sites with more than 34,500 providers serving 6.3 million patients and includes Critical Access Hospitals (CAHs), rural and frontier health clinics as well as federally qualified health centers (FQHCs) and local public health agencies in 40 states. **OCHIN applauds the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC) advancement of major initiatives to strive toward health care data interoperability.** OCHIN welcomes the opportunity to partner with ASTP to support providers in underserved and rural communities to ensure they are neither left behind nor face undue increased staff and clinician pressure due to health IT upgrades that impact workflow and impose other implementation burdens associated with the proposed rule.

OCHIN: DRIVING INNOVATION, ACCESS, AND SELF-SUFFICIENCY

Since its inception in 2000, the OCHIN collaborative of community providers has focused on expanding access and public health readiness in underserved and rural communities to quality health care services through technology solutions, technical assistance, operational support, informatics, evidence-based research, workforce development and training, and policy. In the OCHIN network, 53.8 percent of our members' patients are covered under Medicaid, 17.8 percent are uninsured, 54.3 percent live at or below the federal poverty level, and one in three prefer a language other than English.

OCHIN has also partnered with OSIS, another non-profit technology services organization that is a network of health centers. Together, OCHIN and OSIS collectively support over 39,000 providers serving more than 9.3 million patients. By collaborating to develop affordable and tailored health information technology and services for providers in systemically underserved communities, our partnership with OSIS builds the resilience of both networks and will help transform care for roughly 30% of the estimated 31.5 million health center patients nationwide. Our partnership will also bring greater community healthcare center (CHC) representation to national health equity research and advocacy by augmenting the OCHIN-led **ADVANCE Clinical Research Network** and voluntarily contributing to

practice-based research and innovation powered by the largest collection of de-identified community health data in the country.

RECOMMENDATIONS

In order to drive interoperability, as a threshold matter, we urge ASTP to coordinate and regularly communicate with sister federal agencies and state policymakers. There are a growing number of states introducing and passing laws related to digital data and technical standards for health IT that are undermining interoperability, increasing cost, and complexity. It is urgent that ASTP provide a dynamic and detailed roadmap that all stakeholders can easily query and consult when developing state policies and planning stakeholder education and implementation. Conflicting standards drive complexity and cost which disparately burdens the least resourced providers. ASTP should dedicate resources to ensure there is clarity for state policymakers and stakeholders responsible for implementing change management on a rolling basis for a wide number of federal and state regulations. We also urge ASTP to create clear timelines and deadlines for rules impacting health technology digital data and technical standards as well as required functionalities and reporting requirements.

Specific to the proposed rule, we offer key recommendations below along with additional comments in the Appendix. OCHIN urges ASTP to:

- **Maintain existing successful interoperable public health capabilities.** We urge ASTP to continue authorized use of the existing HL7 standards for electronic case reporting (eCR) as well as FHIR-based exchanges. We do not support mandating use of the latter only. Without the recommended flexibility, significant progress toward public health modernization and interoperability will be reversed. Health care providers and public health agencies have spent considerable time and effort to implement the existing HL7 version standards related to eCR. OCHIN partnered with the Centers for Disease Control and Prevention (CDC) along with other national public health partners to develop, test, and scale a dynamic sentinel reporting capability. OCHIN members alone have delivered more than 4.62 million eCR messages triggered by COVID, Mpox, and Orthopoxvirus events since April 2020. ASTP's proposal to require FHIR standards for existing criteria (e.g., Electronic Lab Reporting, eCR) will impose substantial cost and time and degrade public health capabilities. Stakeholders would need to replace their existing public health exchange interfaces. We recommend ASTP and ONC explore ways to provide incentives to providers and public health agencies that adopt and use hosted, maintained, and certified health IT.
- **Level the playing field between providers and payers and health plans by ensuring the latter have the same timelines, technical standard requirements, and certified health IT requirements as providers.** Having both parties use conformant, certified technology and standards is essential to achieving interoperability, care coordination and innovation as well as transitions to new payment and delivery models. The resources of payers to implement and maintain such systems and standards is vastly disproportionate to the capacity that providers in underserved and rural communities have. Based on the existing proposed rule, the responsibility of ensuring interoperability rests primarily on community health clinics and rural providers, who must ensure their systems can interface with multiple payers. Providers in underserved and rural communities must invest in additional technology and staff training to manage the various workflows as there are different processes for each payer. These additional burdens, coupled with the complexities of integrating with non-certified systems, will not drive administrative simplification, lower costs, and will undermine the ability to move to new payment and delivery models.
- **Finalize the proposed updates and new additions to the exceptions to the No Information Blocking requirements with some clarification and modification.** State-level regulation around

health data privacy continues to proliferate following the US Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*. The proposed updates to existing exceptions and new exceptions provide patients, healthcare providers, and other regulated actors with certainty and allow for continued sharing of EHI. They also promote better healthcare while protecting patients' rights and respecting their privacy preferences. While we appreciate ASPT's efforts, we do ask ASTP to clarify certain language and consider modifications related to the updates and additions to the Privacy, Infeasibility, Protecting Care Access, and Requestor Preferences as outlined in the Appendix.

Finally, our members will need adequate time, resources, and technical assistance to integrate changes as well as prepare for the adjacent programmatic obligations likely to accompany new health IT functionality capabilities. Please contact me at **stollj@ochin.org** if we can provide any additional information to support your efforts.

Sincerely,

Jennifer Stoll
Chief External Affairs Officer

APPENDIX

NO INFORMATION BLOCKING

Definitions – Health Care Provider, Health IT, Business Day

OCHIN supports the updates for the definitions of "health care provider" and "business day," and seeks clarification on the definition for "health IT" as well as how definitions apply to covered versus non-covered entities. We appreciate the clarifications made to the "health care provider" definition and for updating "business day" to reflect a more realistic application allowing for more time. While we appreciate ASTP's codification of "health information technology" (and its short form "health IT") to align with the same meaning as they do in ONC's authorizing statute, we ask the Agency to clarify the definition of "offer health IT", which explicitly references the definition of "health IT". Specifically, **we ask ASTP to adopt and further clarify the definition of "offer health IT" to narrow the applicability of the definition to exclude activities of safety net health IT collaboratives with a single, shared instance of an electronic health record system (EHR)** when the collaborative/network implement features and functionalities in their instance of the EHR system. We also request ASTP share further guidance (e.g., providing examples/scenarios for each definition) and clarify how the proposed rule treats an actor who is a covered entity different than an actor that is not a covered entity.

Privacy Exception (Updates)

OCHIN asks ASTP to provide additional resources and education if it finalizes its proposal to broaden the applicability of the sub-exception for denying individuals access on "unreviewable grounds." As written, it is unclear the changes this proposal may introduce in practice. Actors will need additional information on these potential changes in policies and workflows that they may need to comply with the proposal. If finalized, we encourage ASTP to provide additional resources and education for healthcare organizations, non-HIPAA-covered entities, and end-users on implementing this regulation.

OCHIN recommends ASTP provide education on the ability (or lack thereof) of actors to fulfill requests for restrictions and risks for doing so if finalized. ASTP proposed to revise the privacy sub-exception by removing the existing limitation that applies the exception only to individual requested restrictions on EHI sharing that are permitted by other applicable law. We appreciate the intent of ASTP to broaden this sub-exception to help actors in honoring individual requested restriction while maintaining compliance with information blocking requirements. However, OCHIN has concerns about the implementation and effect of this update. There may unintended legal consequences for actors who restrict the sharing of EHI under the information blocking rule that may be contradict existing law. Patients who request such restrictions may not be aware of the potential safety impacts of choosing to restrict information sharing, especially with other clinicians in their care team. They may also be under-informed of the feasibility of requests to restrict data since the scope and speed of EHI is often far-reaching that commonly understood. As such, we urge ASTP to provide education to patients on the ability (or lack there) of actors to fulfil requests for restrictions and the risks of doing so.

Infeasibility Exception (Updates)

OCHIN agrees with ASTP's updates to the Infeasibility Exception which clarifies which situations can be deemed infeasible as well as the proposed timeframe. OCHIN agrees with the

overall purpose of the language, which clarifies which situations can be considered infeasible and agrees that 10 business days are appropriate timeframe for responding.

Protecting Care Access Exception (Newly Proposed)

OCHIN supports the proposed Protecting Care Access Exception. This exception would allow actors who meet certain conditions to limit EHI sharing to reduce the risk of exposing patients, providers, or persons who facilitate reproductive health care to legal action based on the mere fact they sought, obtained, provided, or facilitated lawful reproductive healthcare. However, we request that ASTP apply this exception when an individual is acting in good faith without applying additional conditions. As currently constructed, actors must act in good faith and satisfy the of two additional requirements, creating uncertainty and documentation burden.

Requestor Preferences Exception (Newly Proposed)

OCHIN supports the proposed addition of a Requestor Preferences Exception. This exception is appropriate for circumstances when a patient or other requestor asks for only certain information or asks for a delay in receiving information. However, we strongly urge ASTP to modify the proposed requirement that the preferences of a patient or other requestor be provided in writing as this creates impediments for patients in underserved communities in particular. Instead, we urge that this can be done verbally and documented in the medical record.

CERTIFIED HEALTH IT: STANDARDS AND FUNCTIONALITY UPDATES

United States Core Data for Interoperability (USCDI) Version 4

OCHIN supports ASTP's iterative adoption of USCDI v4 by January 1, 2028. We appreciate the Agency's approach for updating USCDI in a transparent, collaborative, and incremental way that allows for manageable periodic adoption of new versions. USCDI v4 includes 20 new data elements, including Care Experience Preferences, which will help improve the exchange of data to support patients and help clinicians better serve their patients. We also recommend ASTP emulate this helpful and iterative process for other proposals related to new, untested standards. Given the timing between the proposed rule and the previously finalized HTI-1, we ask ASTP to allow for time in between implementation of new requirements to allow for proper and timely assessment of requirements to see if they are successful or not.

Diagnostic Imaging Hyperlink

OCHIN recommends ASTP not finalize its proposal to have software support the capability to exchange links to diagnostic and other images by Jan. 1, 2028. While we understand that intent of ASTP's in making this proposal is to improve access to imaging, **we are concerned about the potential security risks of generating hyperlinks to images that could potentially expose patients' information if there are no sufficient cyber protections.** Healthcare organizations would have to anticipate all potential external users and provide credentials creating an infeasible administrative burden. Organizations may also be hesitant to provide unaffiliated clinicians access to their systems.

Furthermore, only links to view the images are transmitted, not the actual images, they cannot be entered into the patient's legal medical record. This contradicts the purposes of exchanging imaging links to support patient care as access imaging via the link could disrupt clinicians' workflows. Exchanging images via links also creates compliance challenges as a doctor viewing

these images will be making decisions on an image that is not housed in their respective organization's legal medical record of the patient creating potential difficulties in defending their decision-making should a legal challenge arise. Currently, medical images are not stored in the EHR most of the time and instead stored in picture archiving and communication systems (PACs), vendor neutral archives (VNAs), or other systems. **Instead, we recommend ASTP work to develop standards for the exchange of actual images rather than links to images.** Enabling the exchange of native EHR images with patient portal authentication allows for better security especially as external systems are not covered by Certification.

Public Health Data Exchange Proposals

OCHIN strongly urges ASTP to continue to allow use of the HL7 existing standards for electronic case reporting in lieu of requiring the use of FHIR-based exchanges. Further, we urge HHS to explore ways to invest in the capabilities of the Centers for Disease Control and Prevention (CDC) and public health agencies to parse and use the data they collect by developing and aligning public health infrastructure through inter-Departmental collaboration. We do appreciate ASTP's efforts to create a multi-prong approach to nationwide public health infrastructure and data exchange including:

- updating existing certification criteria,
- adding new requirements for receipt, updating standards, and
- including a glidepath for transitioning to FHIR-based exchange in the future.

However, without the recommended flexibility significant progress toward public health modernization and interoperability will be reversed. In the past couple of years, health care providers and public health agencies have spent considerable time and effort in implementing the existing HL7 version standards related to electronic case reporting (eCR). While there is a lot of momentum behind FHIR in the industry, ASTP's proposal to require FHIR standards for existing criteria (e.g., Electronic Lab Reporting, eCR) will create additional cost and burden for healthcare providers as well as public health agencies. They would need to overhaul their existing public health exchange interfaces, which they have already spent considerable time and resources on, to comply—to great success. Since April 2020, OCHIN members have delivered more than 4.62 million eCR messages triggered by COVID, Mpox, and Orthopoxvirus events. We recommend ASTP explore alternative ways to improve data access for public health through FHIR without asking providers and public health agencies to reinvent their systems once again.

Revised End-User Device Encryption Criterion

OCHIN recommends ASTP not finalize the proposal to require Certified Health IT support encryption of all personally identifiable information (PII) at the server level by January 1, 2026. This is instead of just the electronic health information (EHI) previously required at just the end-user device level. While we appreciate ASTP's efforts to protect PII and EHI, encryption at the server-side level could strain and reduce server performance. Furthermore, the timeline proposed is unrealistic and concerning since organizations will likely need to procure costly new hardware and services to maintain the current server performance standards to meet the timeline proposed.

Revised Clinical Information Reconciliation and Incorporation Criterion

Require automatic reconciliation for a subset of USCDI data elements rather than all the elements. While we appreciate ASTP's intent to increase data reconciliation capabilities as well as streamline and ease provider workflows, we have reservations with the proposed automated reconciliation. For many practices, automatic reconciliation has not yet been optimized and could result in additional burden rather than reducing administrative work by creating an unwieldy "summary." In addition, certain data elements require clinicians to assess the source of the information. In order to create summaries, software would have to render medical decisions. This could undermine patient safety, undermine clinician judgement, and create legal complexities. Instead, we recommend ASTP pursue its alternative proposal to focus on a subset of USCDI data element for certification, ideally one or two, and eventually adding additional USCDI data elements.