October 4, 2024

Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology
ATTN: Health Data, Technology, and Interoperability-Patient Engagement, Information Sharing, and Public Health Interoperability
Mary E. Switzer Building
Mail Stop: 7033A
330 C Street, SW
Washington, DC 20201

RE: Health Data, Technology, and Interoperability-Patient Engagement, Information Sharing, and Public Health Interoperability (RIN 0955-AA06)

Dear Assistant Secretary Tripathi:

Civitas Networks for Health ("Civitas") appreciates the opportunity to provide input on RIN 0955-AA06, Health Data, Technology, and Interoperability-Patient Engagement, Information Sharing, and Public Health Interoperability ("HTI-2 Proposed Rule"). Civitas is a national nonprofit collaborative comprised of more than 175 member organizations—health information exchanges (HIEs), regional health improvement collaboratives (RHICs), quality improvement organizations (QIOs), All-Payer Claims Databases (APCDs), and providers of services to meet their needs—working to use data frameworks, information infrastructure, and multi-stakeholder, cross-sector approaches to improve health for individuals and communities. We educate, promote, and guide the private sector and policymakers on matters of interoperability, quality, coordination, and cost-effectiveness within the health system.

In recent years, ASTP/ONC's leadership in implementing key provisions of the Health Information Technology for Economic and Clinical Health Act (HITECH Act) and the 21st Century Cures Act (Cures Act) has been a focal point of our public policy engagement at the federal level. Civitas members are largely not "developers" of health IT in the context of these efforts. However, as "health information networks" and "health information exchanges" under the relevant statutes and accompanying rulemaking, we are deeply invested in the ongoing evolution of the ONC Health IT Certification Program and its portfolio of baseline technical criteria for developers' products. Our member organizations have been built by and for health data as a vehicle to advance better public health outcomes and systematic efficiencies, which makes the standards used to collect, process, and exchange the data through their digital infrastructure and wider networks integral to their operations. ASTP/ONC's regulation of information blocking under the Cures Act, intended to break down the artificial (and largely intentional) barriers created by various health system actors to impede the free and secure flow of information for their own benefit at the expense of HIEs, is critically important for our members' day-to-day operations and long-term objectives.

The previous iteration of the Health Data, Technology, and Interoperability Rule (RIN 0955-AA03, "HTI-1") was finalized early this year and went into effect in March 2024. Included in the Final Rule were several helpful provisions revising and expanding core data elements, API and eCR standards, and EHR reporting requirements that Civitas supported alongside changes to the information blocking rules that sharpened key definitions (notably the meaning of "offer health IT," which Civitas also supported); added to the conditions of the infeasibility and manner exceptions

(which Civitas largely supported); and created a new exception that applies to actors and requestors transacting information exclusively through TEFCA's QHIN exchange (which Civitas did not support, given that QHIN exchange was then inactive).

The HTI-2 Proposed Rule seeks to further develop the certification standards, information blocking exceptions, and TEFCA components under ASTP/ONC jurisdiction through a series of updates that reflect continued stakeholder feedback and Administration priorities.
Civitas offers the following responses on behalf of our members:

New and Revised Standards and Certification Criteria

- ***Civitas supports the proposed adoption of USCDI v4, SMART v2.2 Guide functionality, and the updated vendor consolidated "FHIR Bundle" requirement by January 1, 2028.*** Nearly all Civitas member systems are already capable of FHIR®-based API (FHIR) functionality and have implemented USCDI v4 and SMART v2.2, even while many partner organizations (especially state, local, and tribal public health authorities, or PHAs) remain in the early stages of adoption. The updated requirements for developers will help raise the federal certification baseline to the industry standard, facilitating our members' efforts to help their partners modernize and enabling more efficient and accurate data exchange between all participants in the health data pipeline—up to and including federal agencies, such as the Centers for Disease Control & Prevention (CDC) and the Centers for Medicare and Medicaid Services (CMS).

- The Proposed Rule includes new certification criterion for a standardized FHIR API for public health data exchange and requests comments on whether, and for how long, to employ a "functional approach" to public health exchange or a "standards-based approach." Civitas members exchange data with state PHAs through a variety of measures. Some are advanced and realizing interoperability through data exchange via HIE and Health Data Utility (HDU) intermediaries. Other state PHAs continue to send flat files over secure messaging or transfer services or employ fax machines. ***To ensure PHAs have the flexibility and access the data they need as quickly and as close to real time as possible, Civitas recommends a functional approach to data exchange in the short term.*** This will allow various incentive programs ONC mentions in the Proposed Rule to build an infrastructure capable of using standards-based exchange. Once a certain FHIR API utilization threshold is reached (for instance, more than 70 percent of Public Health Authorities equipped with the capability), we recommend that ONC move to a standards-based approach, while providing lead-time for those Public Health Authorities that may need more time to transition or build trust in these systems.

- ***Civitas also applauds the newer versions of minimum standard code sets, with the older code sets expiring between 2026 and 2028, to maintain certification.*** Updating these code sets (for problems, lab tests, medications, immunizations, race & ethnicity, sex, sexual orientation/gender & social, psychological & behavioral data) is vital to improve the utility and accuracy of HIE systems. The updates mirror the work that Civitas and nonprofit partners have done on the Gravity Project, a national public collaborative that develops

consensus-based data standards to improve how we use and share information on social determinants of health (SDOH).

- The Proposed Rule includes requirements for certified health technology to make diagnostic image links available to patients, providers, and other organizations. Certified health technology must be capable of supporting access, exchange, and use of diagnostic images via imaging links across three certification (transitions of care, application access – all data request, and standardized API for patient and population services) criteria by January 1, 2028. ***Civitas appreciates that ONC is allowing flexibility for different standards, given the diversity in the marketplace (especially since DICOM is not universal) and the importance of raising this functionality baseline, particularly for smaller providers to which Civitas members provide connectivity and technical assistance.***

- The Proposed Rule also proposes to incorporate the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard for "electronic prescribing" certification, which includes electronic prior authorization transactions. ***Civitas agrees that this is important for Medicare Part D consistency and implements HITAC's e-prescribing recommendations to improve interoperability.***

- Finally, the Proposed Rule includes updated developer requirements related to public health functionality, transmission, and exchange with PHAs. The revisions are proposed for the immunization, syndromic surveillance, electronic lab reporting, cancer registry reporting, and electronic case reporting standards (the most important changes are related to FHIR conformance), plus new functionality requirements for lab order transmission, cancer pathology data sharing (as part of cancer registry reporting), birth reporting, and bi-directional PDMP exchange. ***Civitas supports these functionality requirements. The new module functionality requirements related to birth reporting and PDMP exchange are particularly important for Civitas because they align with many of our members' priority public health activities.*** Civitas HIEs and HDUs in multiple states are in the process of fully digitizing birth screening records at the state and local levels to improve vital records reporting, while PDMP exchange is becoming a standard HIE/HDU activity in a growing number of states (due in part to recent Medicaid 1115 demonstrations). Making these functions part of ASTP/ONC certification helps advance these initiatives around the country.

Information Blocking Exceptions and Definitions

- ASTP/ONC is proposing new "requestor preferences exception" to clarify the conditions under which an actor tailoring the access, exchange, or use of electronic health record information to a requestor's preferences is *not* information blocking. There are three such conditions: (1) limitations on the scope of EHI made available to the requestor; (2) the conditions under which EHI is made available to the requestor; and (3) the timing of when EHI is made available to the requestor for access, exchange, or use. ***Civitas supports this new requestor preference exception because it is responsive to the operational flexibility that HIEs/HDUs need to exercise in the course of managing different types of health data a***

wide range of clinical and non-clinical stakeholders with different technical capabilities. This is particularly important for sensitive health information, such as Part 2 records and psychiatric data from behavioral health providers.

- ASTP/ONC is also proposing to establish different timeframes for sending written responses to the requestor based on the condition under which fulfilling the requested access, exchange, or use of EHI is infeasible. ***Civitas recommends that ONC does not adopt a specific timeframe.*** Although our members have experienced indefinite delays in some instances, we also appreciate that requests may require multiple conversations and fact findings. Often, complicated requests could last many weeks, if not months. Therefore, the parties should be allowed the flexibility to discuss, evaluate, and meaningfully engage. If ONC must adopt a timeframe, Civitas suggests a minimum period of thirty business days to respond to requests.

- The Proposed Rule recommends a new "protecting care access exception" designed for circumstances in which actors subject to the information blocking regulations are protected from blocking charges if they decline to share health data with an entity not required to comply with the HIPAA Privacy Rule, because they are concerned that the entity in question does not adhere to a HIPAA standard of privacy and security protection (which as of June includes the HIPAA Privacy Rule to Support Reproductive Health Care Privacy). ***Civitas supports the overarching aim of protecting patient privacy and sensitive health data while giving HIPAA covered entities and business associates (including HIEs/HDUs) the legal flexibility they need to make decisions about information sharing with entities outside of HIPAA's jurisdiction in different circumstances.*** However, ASTP/ONC should also underscore that much of the practical responsibility for honoring patient preferences and effectively managing consent rests with EHR vendors, whose activities at the point of care are a far more efficient filter for sensitive data control and promoting interoperability.

- The Proposed Rule clarifies and expands on the definition of "health care provider" for information blocking purposes by bringing the regulatory (Cures Act Final Rule) and statutory (PHSA) definitions into alignment. This explicitly makes clear that pharmacists and labs are "health care providers" and are subject to information blocking regulations. ***Civitas supports this clarification as it is important to Civitas members because pharmacies and commercial labs are among the most significant information blockers that HIEs/HDUs encounter daily.*** Changing the definition is only the first step; we encourage ASTP/ONC to update its disincentives rule to provide for targeted enforcement in subsequent rulemaking.

- Additionally, ASTP/ONC is proposing modifications to its segmentation exception intended to clarify that it would apply in circumstances where an individual requests that some data not be shared which cannot be segmented, rather than limiting this exception only to where the segmented data cannot be shared according to law. Civitas strongly supports measures to ensure that individuals retain a meaningful degree of control over their data, including the ability to opt-out of data sharing. However, we note that ***ONC could affect the same change, without worrying about the inability to segment, by finalizing a version of the patient requirement similar to HTI-1's directive that certified health IT developers "enable a***

user to implement a process to restrict uses or disclosures of data in response to a patient request when such restriction is necessary."

- Finally, the Proposed Rule expands the regulatory definition of "interfere with" or "interference" for information blocking purposes to include (but not be limited to) certain practices. These practices are delaying actions, non-standard HIT implementation intended to reduce interoperability, contract provisions which are discriminatory or offer "improper inducements," and intentional omissions of information (which includes failure to fulfill requests). ASTP/ONC also reiterates that compliance with TEFCA (the Common Agreement, TEFCA TOPs, SOPs) "requirements, in the context of TEFCA participation by a QHIN, participant, or subparticipant, is unlikely to constitute an interference under the information blocking definition." While we appreciate ASTP/ONC's intent, ***Civitas does not support this proposal because it would narrow the necessary room for factual analysis based on widely varying circumstances.*** In our members' legal analysis, explicitly defining "interference" as certain relatively broad acts and omissions threatens to replace the current interpretations and operational understanding of information blocking regulations—as a series of limitations on organizations and practices in context, intended to require conversations and negotiation between parties—with *per se* categories of activity. By defining certain acts and omissions that constitute Interferences, ONC is effectively eliminating a large part of factual analysis beyond whether the practice is expressly required by law, while also providing some actors with a perverse incentive to toe the line of "interference" as closely as possible rather than creating practices and policies through multi-stakeholder collaboration that encourage the exchange of data

<u>TEFCA Regulatory Codification</u>

- ASTP/ONC is requesting comments on the TEFCA Manner Exception, which notes that "eventually all TEFCA QHINs will be required to support exchange via FHIR API standards." While we agree that the proliferation of FHIR capabilities is an important long-term objective for QHIN exchange and the health data ecosystem at large, we would caution that as of now and for the immediate future it is far from universal. ***Civitas suggests that for the time being, ONC make the exception such that if the Actor supports the "more advanced FHIR standard," then the Actor must respond to a request via that standard.*** However, if the Actor does not support the more advanced FHIR standard at the time of the request, then the TEFCA manner exception should be applicable. This middle ground will allow those still migrating to these standards time to do so, while holding those that support the advanced standard to that level of exchange. Eventually, Civitas supports the sunsetting of the exception once the more advanced FHIR API standard is mandatory.

- Finally, the Proposed Rule would codify provisions of the TEFCA Common Agreement (CA) into federal regulations (as a new "part 172 of Subchapter D of Title 45 of the CFR") to further "support reliability, privacy, security, and trust within TEFCA" and thereby reinforce its adoption. The CA provisions to be codified are those related to QHIN qualifications, designation, onboarding, suspension, and termination of QHINs by the RCE, RCE/ONC

appeal procedures for QHINs, and QHIN public attestation. ***Civitas' perspective is that the proposed codifications are unnecessarily duplicative of the CA.*** More significantly, putting these provisions in the CFA seems to place them beyond the jurisdiction of the CA's own "change management framework" and the CA/QTF amendment process that are intended to guide all major alterations to the agreement and related TEFCA material (not to mention the TEFCA Governing Council and Participant/Subparticipant Caucus, which have yet to be constituted).

On behalf of Civitas and our members, thank you again for the chance to comment on RIN 0955-AA06 and for considering our recommendations. We would also like to draw your attention to comments from Civitas members CRISP and DirectTrust, which have been submitted separately in response to this Proposed Rule, and which further articulate unique perspectives and priorities based on their extensive experience. The Civitas community is deeply engaged in multiple corners of the health data policy and regulation space, and we stand ready to collaborate to achieve our shared goal of creating a higher-value health system.

Please do not hesitate to reach out if you have any questions or comments for us.

Sincerely,

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