

June 20, 2023

Office of the National Coordinator for Health Information Technology
ATTN: Health Data, Technology, and Interoperability:
Certification Program Updates, Algorithm Transparency, and Information Sharing Proposed Rule
Mary E. Switzer Building
Mail Stop: 7033A
330 C Street, SW
Washington, DC 20201

Re: Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Proposed Rule (RIN 0955-AA03)

Dear Dr. Tripathi:

[Civitas Networks for Health \(“Civitas”\)](#), appreciates the opportunity to provide input on the Office of the National Coordinator for Health Information Technology (“IT”) (“ONC”) Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Proposed Rule (RIN 0955-AA03) (the “Proposed Rule”). Civitas is a national collaborative of regional and statewide Health Information Exchanges (“HIEs”) and Regional Healthcare Improvement Collaboratives (“RHICs”). We are significant stakeholders in the health data interoperability landscape, helping providers, facilities, and other key stakeholders achieve many of the policy goals presented in this Proposed Rule. Civitas Networks for Health is a national nonprofit collaborative comprised of more than 165 member organizations working to use health information exchange, health data, and multi-stakeholder, cross-sector approaches to improve health. We educate, promote, and influence both the private sector and policy makers on matters of interoperability, quality, coordination, health equity and cost-effectiveness of health care, and as a 501(c)(3) nonprofit organization we lead multi-site grant-funded programs and projects. While there are many areas of this rule on which Civitas’ work and stakeholders’ expertise is applicable, we would specifically like to provide comment on the sections discussed below:

1. Proposed Patient Requested Restrictions Criterion

To support a patient’s “right to request a restriction” on uses and disclosures as required by the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) (45 CFR 164.522(a)), ONC is proposing to require certified health IT developers to “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.” (88 FR 23822). This proposal would allow a “standards-agnostic” approach to the development of this functionality but must allow a patient (or their authorized representatives) to use an internet-based method to request such a restriction. If adopted, the functionality must “prevent any data flagged . . . from being included in a subsequent use or disclosure . . .” (88 FR 23822).

Although most Civitas members are not certified health IT developers that would be regulated by this proposal, our members acutely feel the demand from consumers to segment sensitive data without blocking a whole record. Currently, if a patient believes his/her/their data should not be shared, to prevent the exchange or disclosure of this data, absent a law defining such data as otherwise sensitive, that patient must *entirely* opt-out of the exchange. Patients, then, have an “all or nothing” approach, which could be defined as a “choice” only in the most meager sense. Most electronic health records (EHRs) currently do have a confidentiality tag, and they are often used in a manner that perpetuates the all or nothing approach. **To truly give patients meaningful agency over their information, we support this proposal. However, to support patient choice downstream, we suggest that ONC require that developers ensure their “standards-agnostic solution” is interoperable when data is exchanged with other actors, like community HIEs and health information networks (HINs) and carried across exchanges over time.** Many of our members have successfully created and implemented such solutions, and we encourage certified health IT vendors to work with these members to ensure interoperability.

Importantly, community HIEs typically agree in their HIPAA business associate agreements to respect patient privacy restrictions granted by covered entities. However, without a direct requirement for certified health IT vendors to transmit that flag to third parties, most HIEs will be unable to enforce these restrictions, which could limit the utility of this function for patients and providers alike.

In addition, we note that, even if data is considered sensitive under federal or state law, there is a lack of developed technology to allow the parsing and filtering of this data, often leading to the *entire* record being blocked, in this case, without the patient even being aware. For example, records at facilities regulated by 42 CFR Part 2 are typically *entirely* blocked from exchange because the industry does not possess common codes and standards for what could be segmented from these records so that they are no longer considered sensitive under 42 CFR Part 2. Similarly, some states¹ are implementing regulations requiring that “sensitive reproductive data” be segmented from records before they are shared, with the result that *entire* records are blocked for individuals with uterus. In both these cases, the unintended consequences of the current state of technology further limits the health resources of the very individuals the laws intend to protect. Furthermore, with the implementation of the Trusted Exchange Framework and Common Agreement (“TEFCA”), National Networks and inter-state data exchange will be more pervasive than it already is, bringing to light differences in state security and privacy laws.

Without common codes and standards of what could be considered sensitive data under these laws, querying under TEFCA may result in “null” responses. If the promise of interoperability under TEFCA is to be realized, ONC must partner with states to create nationally recognized standards and code sets for various categories of sensitive data that could then be parsed and filtered based on state and local law, without blocking an entire record.

2. Proposed Definition of “Offer Health Information Technology”

In response to questions from the health IT community, ONC is proposing to explicitly codify the definition of “offer health IT” to clarify that individuals or other entities do *not* offer health IT when they engage in activities such as certain donation and subsidized supply arrangements, specific implementation and use activities, and certain legal services arrangements. These entities may otherwise be “actors” apart from “offering health IT,” but, absent some other qualifier, would not be considered an “actor” for purposes of Information Blocking. (88 FR 23862). **We support ONC’s clarification and the resulting proposal.**

3. Proposed “Third Party Seeking Modification Use” Infeasibility Exception

ONC is proposing to add a new condition as an infeasibility exception where a “third party [is seeking] modification use.” Specifically, if this proposal is finalized, a request to enable one or more third parties to modify electronic health information (“EHI”) (including but not limited to creation and deletion functionality) could be considered infeasible **unless** the request is from a health care provider requesting such use from an actor that is its business associate. (88 FR 23865). **We support this proposal** and thank ONC for the clarification that it would not apply when the modification is being requested by a health care provider or a business associate on behalf of a health care provider. **As business associates of many healthcare providers, it is not only vital that our members are able to access records on behalf of covered entities with whom they contract, but is also critical for patient care that providers have access to the most up-to-date, accurate information.**

4. Proposed “Manner Exception Exhausted” Infeasibility Exception

ONC is also proposing a new condition to the Infeasibility Exception where “an actor is unable to fulfill a request for access, exchange, or use of EHI despite having exhausted the Content and Manner exception.” (88 FR 23867) Specifically, a request could fall under this new condition under the Infeasibility Exception if: (1) the actor could not reach agreement with a requestor in accordance with, or was technically unable to fulfill a request for EHI in the manner requested condition; (2) the actor offered all alternative manners required by the regulation, but could not reach agreement with the requestor; and (3) the actor does not provide the same access, exchange, or use of EHI in the manner requested to a substantial number of individuals or entities that are similarly situated to the requestor.

¹ See, e.g., [2023 Regular Session - Senate Bill 786 Third Reader \(maryland.gov\)](#).

(88 FR 23869). **We support this proposal and thank ONC for the clarification.** Without this newly proposed infeasibility exception, entities could have claimed “Information Blocking” if an actor did not try every means possible to exchange data. **By finalizing this proposal, Civitas member HIEs and other data exchanging entities will be protected from anticompetitive behaviors that would have required them to make any number of time-intensive and costly technical changes or solutions for fear of Information Blocking.**

5. Proposed Additional Manner Exception

ONC is proposing to add an exception to the newly renamed “Manner Exception.” Specifically, if an actor who participates in TEFCA offers to fulfill a request for EHI access, exchange, or use for any permitted purpose under the Common Agreement and Framework Agreement(s) through their TEFCA connectivity services to another TEFCA participant or sub-participant, then: (1) the actor is not required to offer the EHI in any alternative manner; (2) any fees charged by the actor in relation to fulfilling the request are not required to satisfy the fees exception; and (3) any license of interoperability elements granted by the actor in relation to fulfilling the request is not required to satisfy the licensing exception. (88 FR 23872). This exception would, ostensibly, incentivize participation in TEFCA, which is otherwise voluntary.

Although we support a contractual framework, such as TEFCA, that would encourage more data sharing and interoperability, we continue to caution ONC and CMS in incentivizing a framework that is neither tested nor currently available. While ONC does have an aggressive timeline for the implementation of TEFCA, many of the Standard Operating Procedures (SOPs) are still under development. **Without these SOPs, even if an exchange function is *permitted* under TEFCA, it may not be *required*, ultimately leading to a decrease in interoperability if entities utilize this exception.** Once TEFCA has been operationalized and tested, we strongly encourage such an exception, which will incentivize actors to exchange data via a federally endorsed national system for advancing health data interoperability.

6. Request for Information – Possible Additional TEFCA Reasonable and Necessary Activities

Within the Proposed Rule, ONC also asks for comment on whether “practices not otherwise required by law but are required of an individual person or entity by virtue of their status as a QHIN, Participant, or Subparticipant pursuant to the Common Agreement pose a substantial concern or uncertainty regarding whether such practices could constitute information blocking.” **Our members have expressed concern that many of the flow down terms, specifically the privacy and security terms for Individual Access Service providers, could be viewed as so burdensome that they fall within information blocking.** We ask that ONC specifically clarify that compliance with the flow down terms, or any other terms and conditions related to TEFCA, or requiring the flow down terms is not considered information blocking.

7. Supporting Comment Letters

Several of our members, listed below, wish to add their individual support for the items raised in this comment letter. As you will see, the Civitas community is deeply engaged in health information exchange and interoperability across the country, and we stand ready to collaborate to achieve the goals of this proposed rule.

Thank you for the opportunity to comment. Please do not hesitate to reach out to Civitas if we can be a resource as we work together to make a more interoperable health care system.

Sincerely,



Lisa Bari
CEO, Civitas Networks for Health
lbari@civitasforhealth.org
(415) 680-6921

Sign-on Organizations

Chesapeake Regional Information System for our Patients (“CRISP”)
CRISP DC
CRISP Shared Services, Inc.
Contexture
Delaware Health Information Network
MyHealth Access Network
New York eHealth Collaborative
Reliance eHealth Collaborative
SYNCRONYS
VITL
Ohio Health Information Partnership (“CliniSync”)