



EHNAC
25 Brookshire Lane
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June 17, 2019

Office of the National Coordinator for Health Information Technology
Attention: 21st Century Cures Act: Interoperability, Information Blocking and the ONC Health IT
Certification Program Proposed Rule - RIN 0955-AA01
Mary E. Switzer Building
Mail Stop: 7033A
330 C Street SW
Washington, DC 20201

RE: 21st Century Cures Act: Trusted Exchange Framework and Common Agreement
TEFCA DRAFT 2

Dear Dr. Rucker:

The Electronic Healthcare Network Accreditation Commission (EHNAC) appreciates the opportunity to comment on this second draft of the Trusted Exchange Framework.

Founded in 1993, the Electronic Healthcare Network Accreditation Commission (EHNAC) is an independent, federally recognized, standards development organization and tax-exempt 501(c) (6) non-profit accrediting body designed to improve transactional quality, operational efficiency and data security in healthcare. EHNAC's accreditation programs are specifically designed to support the protection of electronic health information with a focus on Protected Health Information (PHI) and Personally Identifiable Information (PII) as well as support for industry-adopted standards allowing for a more seamless information exchange between participants in health information networks. EHNAC has over 18 stakeholder-specific programs available across the industry including but not limited to Health Information Exchanges (HIEs), Health Information Service Providers (HISPs), Electronic Healthcare Networks (EHNs), and Electronic Prescription of Controlled Substances (EPCS). New programs are under development such as one in alignment with Trusted Exchange components as set forth within the 21st Century Cures proposed Trusted Exchange Framework.

In general, EHNAC is fully supportive of the Department's aim to promote the interoperable exchange of healthcare data in a secure and efficient manner. This rule sets forth many requirements that will facilitate reaching this overall goal.

More specific comments are provided as follows:

EHNAC appreciates that ONC released the TEFCA2 Draft document prior to receiving comment on the Blocking rule. The User- Guide with practical examples and pictures of expected data handling provides much greater clarity to the overall concept and is greatly appreciated. Some of the new definitions and expectations have been further clarified.

Still, to the degree that this proposed framework includes topical areas and definitions from HIPAA and at the same time new definitions, duplicate requirements and conflicting definitions and

subsequent interpretations by multiple agencies have proven challenging and will be difficult to understand and implement.

EHNAC supports HIPAA Privacy and Security provisions and believes our industry has become accustomed to most of the protections built within. The implementation of HIPAA has taken decades to implement and has proven to be complex, but also seems to generally provide the balance between safeguarding health data and making it available for individuals. However, the use of “Meaningful Choice” and variations of individual rights is problematic in the current draft. Additionally, the proposed “disclosures” to Individuals appears to be beyond HIPAA’s Accounting of Disclosures. Lastly it is not uncommon for US based companies to utilize resources or data support outside the US. As long as policy and technical controls are validated as implemented, this is an area that with certain limitations should be reconsidered. Based on all of the above, *EHNAC supports Interoperability definitions, concepts and principles in alignment with HIPAA Privacy and Security, including Individual Rights.*

Consistency across rules when citing definitions is necessary. EHNAC recommends that all definitions, principles across all rules and to the extent that they match current HIPAA requirements be clarified.

The Draft TEFCA2 document implies a number of key documents will need to be modified including the Notice of Privacy Practices, Business Associate Agreements and Data Use Agreements. Revisions of these may cause burden to the industry and concerns about state preemption may pose further confusion. *EHNAC suggests ONC utilize assistance from the Workgroup for Electronic Data Exchange WEDI to facilitate industry implementation assistance once rules are finalized.*

EHNAC also supports the Office of Civil Rights as the primary agency for issuing and interpreting Privacy regulations and to that degree recommends that future rules be co-issued with OCR.

There are significant penalties for HIPAA violations. If an entity acts in good faith to comply with these provisions, *it is suggested that a safe harbor be considered* to insulate HIPAA subject organizations from penalties/OCR enforcement.

Further information should be provided to clarify how enforcement will occur and by whom, both for those not subject to HIPAA, such as actors who participate in the HIN, how enforcement will be carried out and by whom. While the TEFCA2 Draft adds further information, it now appears that any one QHIN might be subject to enforcement by the RCE, ONC, OCR, CMS, the OIG and the FTC. Having so many potential “enforcers” may create confusion and it is suggested that ideally, one agency should have operational authority; otherwise, further informational clarification of which authority has the ultimate decision-making is required. Additionally, because this document was not formally released via the Federal Register, the delegation of authority to the RCE could be questioned.

The definition of EHI is more expansive than PHI. As such, organizations that don’t maintain HIPAA defined “designated record sets” may have challenges parsing out data into smaller subgroups for export. *EHNAC suggests that consideration be given to limiting the information to be exported perhaps to a subset of the DRS (rather than all EHI).*

EHNAC, as a federally recognized Standards Development Organization (SDO), has spent the last year developing a program to allow for accreditation to be used to promote privacy and security best practices in this new interoperable world. Our Trusted Network Accreditation Program (TNAP), contains industry standard best practice requirements in privacy and security

and further expands into new stakeholder criteria addressing data exchange needs. Organizations are currently using this program in beta mode. EHNAC recommends, as has been suggested throughout the 21st Century Cures rules that certain organizations (like payers and Health IT Developers/Suppliers, whether functioning as the QHIN, Participant or Participant Member) be required to prove privacy and security via accreditation/certification to assure stakeholder trust across participants.

The concept of Security Labeling may cause confusion on multiple fronts. EHNAC questions why some forms of sensitive categories have been included, like mental health and drug and alcohol, but not genetic information or family planning. Additionally, more information from organizations with experience using security labeling could prove helpful as some question if the use of it could potentially interfere with treatment. Lastly, it is unclear who's responsible to apply security labels as it appears under the responsibility of the QHIN in the MTRC, but the User's Guide states that it is the responsibility of the "data holder" to appropriately supply labels to the EHI. Further clarity on the concept, use and requirement would be helpful.

Finally, this rule is very complex. Therefore, adequate time and support should be afforded to the industry to assure compliance can be attained. The concept of "phased approach" tackling the exchange of data for patient treatment and access first; then following with other requests for operations and payment seems reasonable.

EHNAC appreciates the opportunity to provide feedback on this draft framework and stands available to assist with any specific questions and to participate in future endeavors.

Sincerely,

A handwritten signature in blue ink that reads "Lee B. Barrett". The signature is written in a cursive, flowing style.

Lee Barrett,
Executive Director EHNAC

Cc: EHNAC Commission