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President & CEO

February 18, 2018

Electronically Submitted at exchangeframework@hhs.gov

Donald Rucker, MD
National Coordinator for Health Information Technology
Department of Health and Human Services
330 C Street, SW, Floor 7
Washington, DC 20201

Re: Draft Trusted Exchange Framework and Common Agreement

Dear Dr. Rucker:

The Federation of American Hospitals (FAH) appreciates the opportunity to comment on the Office of the National Coordinator for Health Information Technology's (ONC) Draft Trusted Exchange Framework and Common Agreement (Draft TEFCA). The FAH is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching, short-stay, rehabilitation, long-term acute care, psychiatric, and cancer hospitals in urban and rural America, and they provide a wide range of acute, post-acute, and ambulatory services.

Health information technology (HIT) holds enormous potential to improve the quality and efficiency of care provided to patients, reduce provider burden, and advance population health management and breakthroughs in health care research. While the *Health Information Technology for Economic and Clinical Health (HITECH) Act* catalyzed broad adoption of electronic health records (EHRs), the use of such technology has not yet achieved the quality and efficiency goals desired by stakeholders across the health care sector. The inability of various forms of HIT – from EHRs to devices – to both exchange and use information is a significant barrier to achieving these goals. Congress recognized this barrier at it relates to EHRs in directing ONC to develop a Trusted Exchange Framework in the *21st Century Cures Act*. The FAH appreciates ONC's efforts to further the exchange and use of information and offers the below comments in response to the Draft Framework.

Scope of the Draft TEFCA

In the *21st Century Cures Act*, Congress directed ONC to focus on exchange and use of information between health information networks (HINs), which, if implemented appropriately, can advance the exchange of meaningful health information. However, while network-to-network exchange is an important piece of the interoperability puzzle, it is not sufficient to achieve comprehensive interoperability, which involves HIT beyond EHRs and HINs. The FAH appreciates ONC's recognition of this in the Draft TEFCA, which notes that "an individual's health information is not limited to what is stored in electronic health records (EHRs), but includes information from many different sources."¹ This vision – that there should be information exchange throughout the health care system, including during an episode of care to care transitions to an applications-based marketplace – is shared by the health care community. Private-sector led efforts are underway to advance other components of the interoperability puzzle, such as plug-and-play interoperability among devices and systems.² **The FAH supports these private-sector-led endeavors and urges ONC to look beyond the Draft TEFCA to align the with those efforts.** Only when all stakeholders in the health care system focus on comprehensive interoperability will we achieve the progress to which we have long aspired.

TEFCA Timeline

The Draft TEFCA is meant to support four important outcomes, including patient and provider access to information, availability of population level data, and support of user-focused innovation.³ The FAH believes the likelihood of achieving these goals would be improved by revising the timeline for the TEFCA. As discussed in more detail below, the Draft TEFCA raises several questions that should be answered – and on which stakeholders should have the opportunity to comment – before being finalized. **Specifically, the FAH recommends that ONC use the feedback on this version of the Draft TEFCA to release a second version of the Draft TEFCA (Draft TEFCA 2.0) on which stakeholders would again be invited to comment. In addition, the Draft TEFCA 2.0 should be released *before* ONC issues a Funding Opportunity Announcement (FOA) for the Recognized Coordinating Entity (RCE).** Lastly, the statute requires ONC to consult "with the National Institute of Standards and Technology [NIST]...for the pilot testing of the trusted exchange framework and common agreement."⁴ ONC should build this pilot testing into the revised timeline for finalizing the TEFCA.

Additionally, the FAH believes the likelihood of success would improve by phasing in the supported purposes and use cases over time. The permitted purposes outlined in the Draft TEFCA will require considerable time and resources to implement and may initially be out of reach for some HINs and Participants. Prioritization coupled with a manageable timeline for implementation will best serve the stakeholders participating under the TEFCA.

¹ Office of the National Coordinator for Health Information Technology, *Draft Trusted Exchange Framework*, p. 3 (January 5, 2018).

² Center for Medical Interoperability, *Fact Sheet*, available at: <http://medicalinteroperability.org/wp-content/uploads/2017/01/CMI-Overview-Jan2017.pdf>.

³ Office of the National Coordinator for Health Information Technology, *Draft Trusted Exchange Framework*, p. 7 (January 5, 2018).

⁴ P.L. 114-255, Section 4003 (December 13, 2016).

Recognized Coordinating Entity (RCE)

As described by ONC, the RCE will be the linchpin for the success or failure of implementation of the TEFCA. The FAH agrees with ONC's assessment "that a private-sector organization would be best positioned to serve as the RCE" and that the RCE "will need to have experience with building multi-stakeholder collaborations and implementing governance principles."⁵ **The FAH further believes that the RCE should be a sector-neutral group that is able to represent the end-users of health information – first and foremost providers and patients – to ensure that all viewpoints are included in the Common Agreement and implementation of the Framework. Specifically, the RCE should *not* be an HIT developer or developer-affiliated entity.** In order to achieve the necessary balance of viewpoints among the health care sector, ONC may need to consider a conglomerate RCE model, such as one organization to serve as the multi-stakeholder arm that further fleshes out and updates the TEFCA and another organization to ensure compliance with the TEFCA. Another factor for consideration in selecting the RCE is whether the entity can also participate as a Qualified HIN. The FAH urges ONC to clarify that the RCE (or RCEs) *cannot* also be a Qualified HIN.

Additionally, the FAH questions whether a cooperative agreement is the most appropriate structure for the relationship between the RCE and ONC. The ideal structure should maximize transparency in the process and place stakeholders on at least equal footing as compared to ONC. Lastly, the FAH has concerns about the sustainability of the model laid out in the TEFCA, including the availability of adequate funding for the RCE over time. This concern is heightened by the recently released President's FY19 Budget in which the Administration lays out plans for further reductions to ONC's budget. As noted above, the FAH strongly recommends that ONC address these concerns in a Draft TEFCA 2.0 and prior to releasing the FOA for the RCE.

Questions Raised by the TEFCA

The Draft TEFCA raises several important questions that should be addressed prior to finalization. **The FAH again strongly recommends the release of a Draft TEFCA 2.0 with comment period, as well as ample time for pilot testing in collaboration with NIST.** Some specific questions that the FAH encourages ONC to address in the Draft TEFCA 2.0 involve the voluntary nature of the agreement and associated enforcement, the sustainability of the model and fees, patient access to data, and provider burden.

Voluntary Participation

The Draft TEFCA lays out some of the requirements by which Qualified HINs and Participants must abide, while also noting that participation is voluntary. This presents a unique challenge for the RCE when implementing and enforcing the TEFCA. The FAH's members currently participate in regional health information exchanges (HIEs) across the country and have found various levels of sophistication regarding the ability to quickly update standards or accurately perform patient matching. How will the RCE ensure Qualified HINs are complying with the TEFCA, including staying current with standards, performing updates within a

⁵ Office of the National Coordinator for Health Information Technology, *Draft Trusted Exchange Framework*, p. 9 (January 5, 2018).

reasonable timeframe, or accurate patient matching? Should the RCE find a deficiency, what are the mechanisms by which the RCE can enforce the terms of the TEFCA?

Another question that arises when evaluating the Draft TEFCA is whether ONC is planning for overlap between the TEFCA and the information blocking rulemaking the agency expects to release in the spring. **The FAH urges ONC to maintain the voluntary nature of the TEFCA, specifically that hospitals and other health care providers cannot be deemed “information blockers” if they determine that participation under the TEFCA is not optimally serving their patients or that such participation is not possible due to EHR limitations.** Such a requirement – de facto mandatory participation by health care providers – would place providers at a distinct disadvantage relative to Qualified HINs should they determine, for example, that there are deficiencies with the Qualified HIN network, including information security or even fees for membership or queries. A de facto mandatory requirement also would be counter to the Administration’s intent to simplify the current burdensome regulatory structure by unnecessarily applying a regulatory standard that could unintentionally thwart the end goals of TEFCA.

Sustainability of the TEFCA Model / Fees

A network of Qualified HINs naturally raises questions about the sustainability of the TEFCA model, including the fees associated with participating in or making queries via a Qualified HIN and the viability of Qualified HINs over time. The Draft TEFCA states that Qualified HINs must make their fees⁶ public within 15 days of signing the Common Agreement.⁷ **The FAH appreciates and supports this requirement and also believes that the fees – and any fee increases – should be reasonable and relatively consistent across Qualified HINs.** If a Qualified HIN uses a transaction fee or similar model, the entity should be required to provide the associated fee after the End User inputs the query and before the Qualified HIN completes the query. This will ensure Participants and/or End Users are not hit with surprise fees. Additionally, should a Qualified HIN’s fees grow rapidly or the quality of the Qualified HIN’s product decreases, it is unclear what sort of authority either ONC or the RCE would have to ameliorate such concerns. At the very least, health care providers should have the ability to: 1) quickly and easily switch to another Qualified HIN; and 2) stop participation without penalty if there are no suitable Qualified HINs available.

As health care providers switch Qualified HINs based on fees or performance, it seems there is a risk that some Qualified HINs could exit the marketplace over time, resulting in gaps in available information and/or consolidation in the market. A diminishing number of Qualified HINs could lead to higher prices for Participants, even as their access to patient information dwindles. This is especially problematic if health care providers find that belonging to a Qualified HIN advances better patient care, yet participation is not feasible, or, alternatively, providers feel they may risk regulatory consequences for lack of participation. **The FAH**

⁶ *Id.* at p. 25. “Fees: all fees and other amounts charged by a person or entity with respect to the services provided by the person or entity in connection with the Common Agreement. Fees may include but not limited to, one-time membership fees, ongoing membership fees, testing fees, ongoing usage fees, transaction fees, data analytics fees, and any other present or future obligation to pay money or provide any other thing of value.”

⁷ *Id.* p. 34.

recommends that ONC thoroughly and fairly address these concerns by requiring and policing reasonable and consistent fees across Qualified HINs and by reassuring health care providers that participation under the TEFCA is not a requirement to avoid potential penalties associated with information blocking.

Patient Access to Data / HIPAA Protections

The FAH has long supported patients' rights to access their health care information under HIPAA. The Draft TEFCA notes that the "terms and conditions for trusted exchange [of electronic health information (EHI)] align with all of the requirements of and sit on the foundation of the HIPAA Rules."⁸ Health care providers are familiar with the HIPAA Rules and believe they provide important protections for both patients and providers regarding the exchange of protected health information (PHI). However, the requirements in the Draft TEFCA for information sharing and privacy (e.g., breach notification requirements) differ from those with which covered entities much comply under HIPAA, which could lead to confusion and increased burden. **Additionally, ONC should further clarify that Participants and End Users are not responsible for data breaches either by a Qualified HIN or an application (app) or other third-party product to which a patient has directed their EHI. A certification process should be used to determine that apps or third-party products are appropriately requesting EHI and meet the necessary security standards.** The FAH also urges ONC to clarify the parameters of access to information shared via the Common Agreement by Qualified HIN Participants that are not themselves Covered Entities or Business Associates.

An important part of using patient information is ensuring the patient has provided his or her consent. The "Consent" requirements in the Draft TEFCA state that "Each Qualified HIN shall require its Participants to provide the Qualified HIN with a copy of each consent of a Qualified HIN's consenting individual."⁹ **While health care providers currently routinely obtain consent from individuals in the course of providing services, the FAH is concerned about the burden associated with providing the Qualified HIN with a copy of each consent – or withdrawal of consent – signed by a patient during the course of business.** It also remains unclear what mechanism would be available to allow providers to electronically track consent (and changes in consent) and enable this information to move swiftly and efficiently from the Participant to the Qualified HIN.

The FAH also encourages ONC to clarify that providing a patient with access to EHI that is not directly maintained by the Participant entity is the responsibility of the Qualified HIN. To do otherwise would place an extraordinary burden – of both time and associated fees – on health care providers to query and provide access to multiple records that do not exist in their systems. In providing this clarification, ONC should permit health care providers to direct patients to the Qualified HIN for access to their EHI and ensure HINs are appropriately situated to respond to and fulfill these patient inquiries as a condition of becoming a Qualified HIN.

⁸ *Id.* at p. 22.

⁹ *Id.* at p. 37.

Lastly, the FAH recommends that ONC work closely with the Centers for Medicare & Medicaid Services (CMS) to ensure any requirements for patient access to data are in synch with requirements for eligible hospitals under the EHR Meaningful Use Program.

Participant Requirements

The FAH has concerns about Participant responsibilities related to housing EHI and updating clinical records. The Draft TEFCA is currently unclear as to whether the Qualified HIN (either itself or through a connectivity broker) or the Participant will be responsible for storing the EHI and maintaining the infrastructure necessary to facilitate information exchange. In one scenario, Participants respond to requests for EHI from the Qualified HIN and supplies only the information requested; in another scenario, Participants are continually sending EHI to the Qualified HIN, which is responsible for storing the information and fulfilling any queries. **The FAH urges clarification regarding whether the TEFCA will prescribe a required model or whether each Qualified HIN will choose based on its preferences, recognizing that the burden of operating under the different scenarios will vary among health care providers.** The latter model may be too burdensome for some Participants, while the first model may also impose unnecessary burdens depending on the resources (e.g., time, staff, costs) required to reply to queries.

Additionally, the discussion surrounding Principle 4A in the document notes that, as part of ensuring information integrity, “Qualified HIN participants need to update individuals’ clinical records to ensure that medications, allergies, and problems are up to date prior to exchanging such data with another healthcare organization.”¹⁰ **This requirement is not only over-burdensome for health care providers but also potentially dangerous, as the clinician may not have seen the patient in months or even years and has no way of knowing the patient’s status or medications. The FAH strongly recommends that ONC remove this requirement.**

The FAH appreciates the opportunity to comment on the Draft TEFCA. We look forward to continued partnership with ONC as we strive to advance the use of HIT to improve our nation’s health care system. If you have any questions regarding our comments, please do not hesitate to contact me or a member of my staff at (202) 624-1500.

Sincerely,



¹⁰ *Id.* at p. 19.