



Charles N. Kahn III
President and CEO

June 17, 2019

Electronically Submitted

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: Trusted Exchange Framework and Common Agreement – Draft 2

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) Trusted Exchange Framework and Common Agreement Draft 2 (Draft TEFCA 2.0). 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.

The FAH continues to believe that 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. The FAH appreciates ONC's efforts to further the exchange and use of information and offers the below comments in response to the Draft TEFCA 2.0.

General Comments

Need for Notice and Comment Rulemaking

The FAH appreciates that ONC listened to the feedback on the Draft TEFCA, particularly the need for a Draft TEFCA 2.0 on which stakeholders could comment. The FAH also appreciates ONC's careful attention to the previous round of comments and corresponding modifications. However, in reviewing the scope of the Draft TEFCA 2.0, and taken in concert with the proposals and request for comment in the recent ONC and Centers for Medicare & Medicaid Services (CMS) Proposed Rules related to interoperability and patient access, the FAH believes the TEFCA necessitates a formal rulemaking process. The FAH believes the TEFCA meets the threshold for an economically significant rule (i.e., \$100 million or more in economic impact) given its nationwide scope and anticipated participating entities. Additionally, while ONC has stated that participation in the TEFCA is voluntary, both the ONC and CMS Proposed Rules related to interoperability and patient access sought comment on mandating stakeholder participation (e.g., HIT vendors, health insurance plans). These requests for comment signal the Agencies' intention that all stakeholders participate in the TEFCA, including participation mandated (or de facto mandated) through other government regulations. As such, the TEFCA itself necessitates the formal rulemaking process to ensure appropriate stakeholder participation and federal government impact analysis and review.

Scope of the Draft TEFCA

In the *21st Century Cures Act*, Congress directed ONC to focus on the exchange and use of information between health information networks (HINs), which, if implemented appropriately, can advance the exchange of meaningful health information. As the FAH noted in previous comments, 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 electronic health records (EHRs) and HINs. The FAH appreciates ONC's recognition in the Draft TEFCA and in this Draft TEFCA 2.0 that individual health information involves data from many different sources – many of which are outside of that which is contained in EHRs. This vision of information exchange throughout the health care system, from episodes of care to care transitions to an applications-based marketplace, is shared by the health care community. As noted in the FAH's comments in response to the Draft TEFCA, private-sector led efforts are underway to advance other components of the interoperability puzzle, such as plug-and-play interoperability among devices and systems.¹ The FAH continues to encourage ONC to align with these private-sector-led efforts.

Timeline and the Need for a Phased Implementation

The Draft TEFCA 2.0 focuses on three high-level goals: provide a single on-ramp to nationwide connectivity; enable the flow of electronic health information (EHI) to securely

¹ Center for Medical Interoperability, *Fact Sheet*, available at: <http://medicalinteroperability.org/wp-content/uploads/2017/01/CMI-Overview-Jan2017.pdf>.

follow the patient when and where it is needed; and support nationwide scalability.² The FAH previously commented in response to the Draft TEFCA on the need to prioritize and phase in the use cases over time, and supports the narrowing of various exchange purposes and exchange mechanisms in the Draft TEFCA 2.0, as well as the intention to phase in updates over time.³ The FAH particularly supports providing TEFCA entities 18 months to update their agreements and practices to comply with new versions of the Common Agreement (rather than the 12 months proposed in the Draft TEFCA). The FAH believes these changes will help stakeholders achieve the TEFCA’s high-level goals.

The FAH also appreciates the opportunity for stakeholders to comment on the Draft Common Agreement, expected sometime in 2020. However, other milestones for TEFCA’s implementation, such as the final TEFCA, the Qualified HIN (QHIN) Technical Framework Draft 2 and final version 1, and the Common Agreement final version remain unclear.⁴ The FAH understands that the timeline for these documents is dependent on factors that may be out of ONC’s control, but notes that the TEFCA is closely intertwined with the ONC and CMS interoperability and patient access Proposed Rules, as well as the CMS Promoting Interoperability Programs (PIPs) for eligible hospitals, critical access hospitals (CAHs), and practitioners. Taken together, these programs and Proposed Rules seek to implement significant changes to the collection, sharing, and use of health information that will require significant resources – in both time and money – from stakeholders across the care continuum. Without an understanding of the other significant milestones required for successful implementation of the TEFCA, the FAH and other stakeholders are not able to adequately comment on the feasibility of the TEFCA milestones, and particularly as they relate to the other ONC and CMS programs.

To help address these concerns, the FAH recommends a phased approach to TEFCA implementation with clearly delineated milestones and pilot testing, as mandated by the statute. 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. Specifically, the FAH recommends that phase one focus on the exchange of information for treatment and patient access to information, with a corresponding pilot test in certain geographic areas. The pilot testing is mandated by the statute, which 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.”⁵ This should be followed by phase two focused on expanding these sharing and patient access functions nationally. Phase two or three could also focus on implementing the sharing of information for health care operations and payment purposes.

Similar to the FAH’s comments in response to the recent ONC Proposed Rule on interoperability and information blocking, the FAH also recommends narrowing the scope of the EHI exchanged under the TEFCA to focus on the data classes and elements established under the

² Office of the National Coordinator for Health Information Technology, *Trusted Exchange Framework Draft 2*, p. 4 (April 19, 2019).

³ *Id.* at p. 16.

⁴ *Id.* at p. 23.

⁵ P.L. 114-255, Section 4003 (December 13, 2016).

United States Core Data for Interoperability (USCDI) standard. Focusing on the USCDI – along with ONC’s proposed process for future expansion of the USCDI in the recent ONC Proposed Rule – would enable ONC to scale up the information shared through the TEFCA over time while providing stakeholders with the opportunity to comment on the USCDI’s expansion, increasing transparency and ensuring a wider range of stakeholder input.

The FAH believes that prioritization coupled with a manageable timeline for implementation will best serve the stakeholders participating under the TEFCA and that ONC should determine and publish a timeline that accounts for other related ONC and CMS initiatives and incorporates the required pilot testing.

Recognized Coordinating Entity (RCE)

As previously commented in response to the Draft TEFCA, the FAH believes that the RCE should be a sector-neutral group that is free from conflicts and 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 Trusted Exchange Framework. As such, the FAH appreciates ONC’s clarifications that the RCE “should be a not-for-profit, neutral entity that is broadly trusted, transparent, free of conflicts of interest, and can ensure a level playing field for all stakeholders.”⁶ The FAH also appreciates the ONC’s clarification that the RCE cannot also be a QHIN. The FAH also urges ONC to ensure that the RCE is *not* a HIT developer or developer-affiliated entity.

Additionally, the FAH continues to question 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.

Questions Raised by the TEFCA

While the Draft TEFCA 2.0 answers some questions raised in the Draft TEFCA, the FAH believes the scope and impact of the TEFCA necessitates notice and comment rulemaking and ample time for pilot testing in collaboration with NIST. Some specific questions that the FAH encourages ONC to address through notice and comment rulemaking remain from the Draft TEFCA, including the voluntary nature of the agreement; the sustainability of the model and fees; and the privacy, security, and safety of the information being exchanged.

Privacy, Security, and Safety

The FAH has long supported patients’ rights to access their health care information under HIPAA and believes the HIPAA Privacy and Security Rules provide important protections for patients and their providers regarding the exchange of protected health information (PHI). As such, the FAH appreciates ONC’s recognition of comments received in response to the Draft TEFCA and the subsequent changes in the Draft TEFCA 2.0, including that “the Common Agreement requires non-HIPAA entities, who elect to participate in exchange, to be bound by

⁶ *Trusted Exchange Framework Draft 2*, p. 11 (April 19, 2019).

certain provisions that align with safeguards of the HIPAA Rules.”⁷ The FAH also supports requiring QHINs, Participants, and Participant Members to comply with the HIPAA Breach notification requirements “regardless of whether or not they are a Covered Entity or Business Associate,” as well as requiring QHINs to “notify the RCE, as well as other QHINs, Participants, Participant Members, and Individual Users who may have been affected by the Breach without unreasonable delay.”⁸ The FAH also appreciates the recent clarification from the Office for Civil Rights (OCR) regarding Covered Entities’ responsibilities for data breaches by an application (app) or other third-party product to which a patient has directed their EHI.⁹

Vetting for Third-Party Applications

Concerns related to privacy, security, and safety remain, however. For example, the FAH continues to call for a vetting / certification process for non-HIPAA covered third-party applications and other products. The FAH submitted similar comments in response to the CMS and ONC patient access and interoperability Proposed Rules and cautions ONC and CMS against allowing these unvetted, non-HIPAA-covered, third-party applications fairly open access to patient digital health data without patients fully understanding how those applications might use that data and the implications of that usage. The FAH agrees that it is an individual’s prerogative to specify where and to whom to send their information. The FAH does not agree, however, that individuals understand how the information they are sharing will be used and monetized.

While the FAH supports requiring entities that sign the Comment Agreement to follow certain HIPAA requirements, the FAH also believes these applications can easily get access to patient information outside of the TEFCA structure, necessitating both increased patient education and an industry-backed vetting process. The FAH has previously called for ONC, CMS, OCR, and the Federal Trade Commission (FTC) to undertake a joint campaign to educate patients about the differences between HIPAA and non-HIPAA-covered entities and how those differences may affect the ways in which their data is used, stored, and shared with others. In addition, an industry-backed process to independently vet third-party applications is needed to ensure they are: a) meeting all relevant security standards; b) using data appropriately and in line with consumer expectations; and c) clinically sound (for those applications that offer medical advice). The vetting process results should be made public in the form of an application “safe list.” More detail regarding the vetting process can be found in the FAH comment letter in response to the recent ONC Proposed Rule.¹⁰

Meaningful Choice

The FAH also questions how the “meaningful choice” requirements align with HIPAA and various state laws, which could lead to confusion and increased burden. ONC states that

⁷ *Id.* at p. 17.

⁸ *Id.* at p. 19.

⁹ Office for Civil Rights, *The HIPAA access right, health apps & APIs* (last accessed June 12, 2019), available at: <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access-right-health-apps-apis/index.html>.

¹⁰ Federation of American Hospitals comment letter Re: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule (June 3, 2019), available at: https://www.fah.org/fah-ee2-uploads/website/documents/060319_ONC_Proposed_Rule_-_FAH_LETTER_-_FINAL.pdf.

individuals must be presented “with the opportunity to exercise Meaningful Choice to request that their EHI not be Used or Disclosed via the Common Agreement, except as required by Applicable Law...” and that the “choice must be respected on a prospective basis.”¹¹ The FAH supports that the exercising of “meaningful choice” would be prospective only, as a retrospective requirement would be unduly burdensome and impracticable. The FAH is concerned, however, as to how QHINs, Participants, and Participant Members respect an individual’s exercise of “meaningful choice” while ensuring compliance with HIPAA and state laws. For example, under HIPAA, Covered Entities do not need patient consent to share information for certain purposes, such as treatment, payment, and health care operations. Is it ONC’s intention that individuals can opt-out of sharing their information for these vital purposes – including payment of their medical claims by their insurance plan? In addition to alignment with HIPAA, the FAH requests clarification regarding how the “meaningful choice” requirements under the TEFCA interact with state information sharing requirements, which can vary from “opt-in” (e.g., the individual must give affirmative consent to share) to “opt-out” (e.g., the information is shared unless the individual opts-out). Is it the ONC’s intention that the policy established for purposes of the TEFCA preempts state law in this regard? Given these questions, at a minimum, the FAH urges ONC to ensure that any “meaningful choice” requirements exclude information exchanged for treatment, payment, and health care operations purposes.

Capturing and Communicating Patient Consent

A question remains from the Draft TEFCA regarding the requirements on the Participant or Participant Members in obtaining and communicating consent when such consent is required to use or disclose certain types of information. The Draft TEFCA 2.0 says that the Participant or Participant member will obtain and maintain copies of that consent and make it available to other Participants and QHINs as needed. Health care providers currently routinely obtain consent from individuals in the course of providing services, but it is 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 (or Participant Member) to the QHIN. The FAH encourages ONC to clarify such processes, including the technical standards for consistently capturing and communicating such consent.

Patient Access to Data

The FAH reiterates previous comments urging ONC to clarify that providing a patient with access to EHI that is not directly maintained by the Participant or Participant Member is the responsibility of the QHIN. To do otherwise places an extraordinary burden – of both time and potentially 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 QHIN 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 QHIN.

¹¹ *Trusted Exchange Framework Draft 2*, p. 19 (April 19, 2019).

Identity Proofing and User Authentication

The FAH supports the identity proofing requirements contained in the Draft TEFCA 2.0, including requiring proof of all QHINs, Participants, Participant Members, and Individual Users at a minimum of IAL2 prior to issuance of credentials.

The FAH also supports the user authentication requirements contained in the Draft TEFCA 2.0, including requiring all QHINs, Participants, Participant Members, and Individual Users at a minimum of AAL2 and support for at least FAL2 prior to the issuance of a credential. Two-factor authentication with a token that expires after a period of inactivity is the industry standard for actions involving other sensitive data (e.g., financial data), and the FAH supports the application of this standard to the TEFCA.

Security Labeling

ONC seeks feedback in the Draft TEFCA 2.0 regarding the possible inclusion of a new security labeling requirement for sensitive protected data (e.g., HIV/AIDs status, substance abuse data, mental health data). While the FAH appreciates ONC's attention to security labeling, the standards for such labeling are not currently mature enough to implement such requirements. The FAH instead recommends including security labeling over time as the standards mature.

Updating EHI Prior to Exchange

Similar to the Draft TEFCA, the Draft TEFCA 2.0 states that, as part of ensuring EHI integrity, "clinicians should update individuals' EHI in their EHR to ensure that medications, allergies, and problems are up to date prior to exchanging such data with another organization."¹² 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 continues to urge ONC to remove this requirement. At a minimum, the FAH urges ONC to amend this requirement such that the information is updated with each visit or encounter and that the information shared is the most up-to-date information the entity has at the time it is requested.

Exchange Purposes

The Draft TEFCA 2.0 narrows the purposes for exchanging information as compared to the Draft TEFCA. Specifically, the payment purpose has been narrowed to a subset – quality assessment and improvement; and the health care operations purpose has been narrowed to a subset – business planning and development, and utilization review. The FAH believes the payment purpose and health care operations purpose were too broad under the Draft TEFCA and supports the narrowing to a subset of each in the Draft TEFCA 2.0. The FAH also supports ONC's intention to phase in additional subsets under the payment purpose and health care operations purpose over time as the TEFCA matures. As discussed above, the FAH believes that the TEFCA would be more successful if the broad categories of exchange purposes were phased in over time as well. As such, the FAH recommends that ONC focus first on prominent

¹² *Id.* at p. 29.

foundational use cases, such as treatment and patient access to information, and then move on to others once these initial use cases are successfully implemented.

Summary of Disclosures

Under the Individual Rights and Obligations listed in Appendix 2, individuals would have “the right to receive a summary of Disclosures of EHI for applicable Exchange Purposes in the context of the Framework Agreements for up to a period of six (6) years immediately prior to the date on which the summary of Disclosures is requested.”¹³ An individual could request such a summary from any QHIN, Participant, or Participant Member with which the individual has a direct relationship, and the information must be provided within 60 days. Taking into account the listed exceptions, which the FAH supports, under the current exchange purposes in the Draft TEFCA 2.0, this summary of disclosures would be required for the public health and benefits determinations purposes only. The FAH urges ONC to confirm this understanding of the application of this requirement. In addition, the FAH believes that such a summary of disclosures would only be feasible if the information was electronically tracked and maintained in structured format by the QHINs. A Participant or Participant Member would not have access to the information on the various disclosures from the QHIN or other Participants or Participant Members. As such, the FAH urges ONC to clarify that responding to such requests, including compiling and maintaining the information necessary for such responses, rests solely with the QHINs.

Exchange Modalities

The Draft TEFCA 2.0 contains changes to the exchange modalities as compared to the Draft TEFCA. Specifically, the Draft TEFCA 2.0 removes the population level data exchange and adds the QHIN message delivery (“push”). The FAH agrees that the population level data exchange is not yet mature enough for inclusion as an exchange purpose under the TEFCA and supports its removal.

Regarding the “push” modality, the FAH notes that it not yet mature and instead urges ONC to phase this in over time as the workflow, standards, and fee issues are resolved. There are still workflow concerns with incorporating Direct messages in terms of how the messages are received and flow through to the correct department and clinician. Implementing a “push” via TEFCA will exacerbate these concerns. Regarding standards, the FAH notes that the standards proposed in the TEFCA Draft 2.0 are not common or well-known standards. Lastly, the FAH questions how the fee structure would work for “push” messages. In a query-type model, the requesting QHIN pays the responding QHIN. But who would be responsible for any fees associated with a “push,” which is sent, possibly unsolicited, from one entity to another?

When this modality is implemented over time, the FAH also urges ONC to ensure that: a) there is a clear directory of TEFCA Participants / Participant Members so entities know who is or is not participating in the TEFCA before attempting a “push”; and b) there is a clear acknowledgement returned to the “pushing” entity signaling receipt of the notification to confirm operational accuracy and ensure quality. The FAH also recommends that these

¹³ *Id.* at p. 69.

acknowledgements be designed such that they can be used for meeting the Health Information Exchange objective under the Medicare PIP.

Voluntary Participation

With the release of the Draft TEFCA 2.0 and the ONC interoperability and information blocking Proposed Rule, it is apparent that ONC anticipates significant overlap between them but is unclear precisely how they will interact over time. For example, while ONC has previously stated that participation in the TEFCA is voluntary, both the ONC and CMS Proposed Rules related to interoperability and patient access sought comment on mandating stakeholder participation (e.g., HIT vendors, health insurance plans, etc.). These requests for comment signal the Agencies' intention that all stakeholders participate in the TEFCA, including participation mandated (or de facto mandated) through other government regulations.

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 or burden, including associated costs. Such a requirement – de facto mandatory participation by health care providers – would place providers at a distinct disadvantage relative to QHINs should they determine, for example, that there are deficiencies with the QHIN network, including information security or fees for membership or queries.

Sustainability of the TEFCA Model / Fees

As the FAH commented in response to the Draft TEFCA, we are concerned about the sustainability of the TEFCA model, including the fees associated with participating in or making queries via the QHINs and the viability of QHINs over time. The Draft TEFCA required QHINs to make their fees public within 15 days of signing the Common Agreement.¹⁴ The Draft TEFCA 2.0, however, appears to remove this public reporting requirement and replace it with a requirement to "file with the RCE a schedule of Fees used by the QHIN relating to the use of the QHIN's services provided pursuant to the Common Agreement that are charged to other QHINs and Participants."¹⁵ It is unclear whether the RCE would then make this information public and/or available to Participants and Participant Members.

The FAH supported the requirement in the Draft TEFCA to ensure that fees are reasonable and relatively consistent across QHINs. Given the changes to the fee language in the Draft TEFCA 2.0, the FAH urges ONC to clarify what the RCE will do with the schedule of fees used by a QHIN. Will the RCE make this information public? And, if so, would it be made public on an individual QHIN level or in the aggregate (i.e., combined for all QHINs)? If the intention is for the RCE *not* to make the information public, then what actions is the RCE empowered to take to ensure fees remain reasonable and relatively consistent?

¹⁴ Office of the National Coordinator for Health Information Technology, *Draft Trusted Exchange Framework*, p. 34 (January 5, 2018).

¹⁵ *Trusted Exchange Framework Draft 2*, p. 47 (April 19, 2019).

The FAH also urges ONC to ensure that QHINs using a transaction fee or similar model are required to provide the associated fee after the Participant inputs the query and before the QHIN completes the query. This will ensure Participants and/or other users are not hit with surprise fees. Lastly, the FAH is concerned that a diminishing number of QHINs over time could lead to higher prices for Participants. This is especially problematic if health care providers find that belonging to a QHIN advances better patient care, yet participation is not feasible, or, alternatively, providers feel they may risk regulatory consequences for lack of participation. To address these concerns, the FAH recommends that ONC and the RCE ensure reasonable and consistent fees across QHINs and reassure health care providers that participation under the TEFCA is not a requirement and will not incur penalties associated with information blocking.

The FAH appreciates the opportunity to comment on the Draft TEFCA 2.0. 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,

A handwritten signature in black ink, appearing to read "Andrew M. Kohn". The signature is fluid and cursive, with a large initial "A" and "M".