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Don Rucker, M.D.
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St SW, Floor 7
Washington, DC 20201

RE: Trusted Exchange Framework and Common Agreement Draft 2

Dear Dr. Rucker,

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to respond to the Office of the National Coordinator for Health Information Technology's (ONC) Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2.

The AHA is generally supportive of the overall concept of the TEFCA and ONC's goal to create a voluntary network-of-networks that would enable hospitals to join one network and access all of their trading partners. ONC's responsiveness to comments on the agency's first draft of the TEFCA, including the addition of this second round of comments and a "walk before we run" approach, is beneficial to help ensure that this goal can be met in a manner that is workable and useful for all parties involved.

More specifically, we support ONC's removal of the population-level data requests until such time as the standards and deeper levels of trust exist, and the selection of a non-profit organization to serve as the Recognized Coordinating Entity (RCE). We also appreciate ONC's clarification that HIPAA takes precedence over TEFCA. We are, however, concerned that ONC's approach to the TEFCA has the potential to disrupt efforts already underway, which have grown since the first iteration of the TEFCA was released, and we are concerned that ONC may stifle progress. In addition, we are concerned with the removal of Fast Healthcare Interoperability Resource (FHIR) from the standards stack that Qualified Health Information Networks (QHINs) would be required to support.

Our detailed comments on ONC's proposals follow.

TEFCA STRUCTURE

ONC has proposed a modified TEFCA structure in its second draft that ultimately results in two discreet elements: 1) the Trusted Exchange Framework, which is set of general, core principles Health Information Networks (HINs) should abide by; and 2) the Common Agreement, which is composed of the Minimum Required Terms and Conditions (MRTCs), Additional Required Terms and Conditions (ARTCs), and the QHIN Technical Framework.

The AHA supports this modified structure and agrees with the removal of the technical requirements from the legal terms and conditions. Given ONC will need to pursue rulemaking to establish the process by which HINs are identified as following the TEFCA, we believe that ONC should include the Trusted Exchange Framework as part of this rulemaking process. However, the Common Agreement should not be included in a regulation, since this would inhibit the ability of the industry to update legal terms and conditions on a timely basis, as well as respond to field needs and privacy/security requirements. Additionally, we agree that the RCE, working closely with field stakeholders, should develop the ARTCs for a full set of legal terms and conditions as well as the QHIN Technical Framework. We urge ONC to give the RCE, working with industry stakeholders, significant authority to develop these documents, rather than dictating to the industry what should be done.

In addition, we appreciate that ONC has reduced the number of terms and conditions in the MRTCs, and we urge the agency not to expand those terms in the next iteration. Rather, ONC should allow the RCE to develop the bulk of the terms and conditions. The field is making good progress with frameworks like Carequality and DirectTrust, and we are concerned that, if ONC dictates too many of the terms and conditions or the technical framework, it will derail the pace of innovation we are currently seeing. The field is in the best position to push forward on interoperability and, as such, we strongly encourage ONC to limit its involvement.

RECOGNIZED COORDINATING ENTITY

The AHA agrees with ONC's intention to select an RCE from the field to finish and operationalize the Common Agreement. We strongly encourage the agency to build on the work already being done by the field and choose an RCE that has experience developing data use and participation agreements, as well as one that has a strong record of accomplishment of building consensus. Further, we encourage ONC to provide the RCE with a significant level of autonomy to create the ARTCs and build the QHIN Technical Framework. The RCE will work with the field to develop these items, and, again, we urge ONC to limit its involvement and refrain from unilaterally overruling consensus on technical standards and legal terms and conditions with which it does not agree.

HIPAA, PRIVACY AND SECURITY

ORDER OF PRECEDENCE

In the definition for the Common Agreement, ONC clarified that HIPAA and other applicable laws (which we infer to mean state and other federal laws) take precedence over the Common Agreement. We appreciate this clarification and urge ONC to maintain it in the next iteration. Organizations should not have to choose between meeting the requirements of the law or the requirements of the Common Agreement. We also appreciate ONC's clarifications in the terms and conditions that HIPAA's minimum necessary requirements must be met when exchanging data.

As we stated in our comments on ONC's proposed rule on information blocking, our members are deeply concerned about third parties that are not governed by HIPAA accessing patient data and reusing it in ways of which patients are unaware. We urged ONC to consider how it could help patients access their data while not sacrificing their privacy. **Therefore, we are very supportive of ONC's proposal in the MRTCs that any organization participating in the Common Agreement would be required to abide by HIPAA privacy and security requirements.** We urge ONC to maintain this requirement in the next draft so that patient data has reasonable protections when it leaves a HIPAA-governed organization's boundaries. ONC also proposed in the MRTCs that, when the original exchange purpose for which data was requested is individual access, data can be reused only for that purpose – if an organization wishes to use the data for another purpose it would have to receive explicit consent from the patient. We strongly support this secondary data use limitation and urge ONC to finalize this limitation in the MRTCs.

EXCHANGE PURPOSES

The first draft of the TEFCA included a broad set of permitted Exchange Purposes, including: treatment, payment, operations, individual access, public health and benefits determination. It also required QHINs and their participants to support and participate in all of the permitted purposes. In its second draft, ONC has narrowed the Exchange Purposes to treatment, individual access, public health, benefits determination, utilization review, quality assessment and improvement, and business planning and development, but has maintained its requirement that QHINs and their participants support all of these exchange purposes. **We recommend that ONC broaden the exchange purposes to include all of the payment and operations purposes allowed under HIPAA, so that health systems can fully realize the single "on-ramp" concept ONC has proposed.**

We do however reiterate our concern that updating participant and business associate agreements will take a significant amount of time, which ONC does not seem to be accounting for in its timelines. As such, we urge ONC to modify the MRTCs to allow

organizations to participate in the exchange purposes they already support while phasing in additional purposes over time. For example, a QHIN may currently only support treatment purposes. ONC could allow the QHIN to join the TEFCA and set a timeline for when the organization would have to expand its exchange purposes. Likewise, participants in a QHIN may only support a small set of exchange purposes in their current policies. Since it will take time to modify these policies, participants should be able to participate in a QHIN and respond to a more limited set of purposes until such time as its internal policies are updated. This type of flexibility would enable participation from a larger number of stakeholders in the near-term while building greater exchange capabilities over time.

APPROPRIATE ACCESS

We appreciate ONC's clarification in the MRTCs that requests for data must sit within the bounds of when and how covered entities are allowed to request health information. This addresses concerns we raised in our last letter about organizations accessing data for patients with whom they do not have a relationship. However, we remain concerned about how a hospital or health system who is the data holder would know that the requesting organization has an applicable relationship with the patient prior to releasing data. ONC does not address how such a verification would be performed or even if it is allowed. Specifically, the MRTCs require that data be shared when requested, so it is unclear if it would be considered a breach of the Common Agreement if an organization does not share data because they cannot verify the requestor has the appropriate relationship. We do not believe that a hospital or health system should be considered an information blocker if they are taking steps of due diligence before sharing data.

Related to appropriate access is the issue of consent. We appreciate ONC's clarifications that meaningful consent should be collected from the organization with whom the patient has a relationship. However, it is not clear from the MRTCs or the QHIN Technical Framework whether the data requestor or the data holder is required to collect such consent, and the concept of meaningful consent is generally unclear. In ONC's proposed rule on information blocking, the agency indicated that the data *holder* is responsible for collecting consent. However, we urged ONC to make the data *requestor* responsible. Similarly, we ask ONC to clarify in the MRTCs and QHIN Technical Framework that the data requestor is responsible. Further, we urge ONC to work with the RCE and the field to specify how QHINs would communicate consent prior to sharing data (when such consent is required). Currently, there is no standard being used in the field to communicate consent. While ONC has proposed that certified health IT developers would need to implement the Consent2Share FHIR specifications, it is unclear whether these could be used by QHINs to communicate consent. Finally, we suggest that, rather than creating a new concept of meaningful choice, ONC create a global opt-out policy for the Common Agreement and remove the meaningful choice provisions.

EXCHANGE MODALITIES

Additionally, ONC removed the requirement for QHINs to support FHIR APIs as an exchange modality. While we understand that most potential QHINs currently use the Integrating the Healthcare Enterprise (IHE) standards to support data exchange, it is unclear to us why ONC would not require them to use the emerging FHIR standard, which it is requiring certified health IT products to implement. We recommend that ONC or the RCE include FHIR APIs in the QHIN Technical Framework as a minimum requirement.

FLOW DOWN CLAUSES

TIMELINES

The MRTCs include nearly 30 terms and conditions that would need to be incorporated into existing business associate and participation agreements, and it is likely that the ARTCs will add even more. We are concerned that ONC is underestimating the amount of time it will take to incorporate these clauses into existing agreements. Many of our hospitals and health systems will participate in the TEFCA via their electronic health record (EHR) vendors, which will necessitate updating their contracts with these vendors to incorporate the flow down terms. ONC also has proposed, under its information blocking regulation, that EHR vendors (who are certified) would have to update their contracts as a condition of certification. These requirements will compound on each other, and we believe organizations will need significant time to modify their agreements. Yet, ONC has proposed that the first cohort of QHINs would be up and running by August 2020. We do not believe this is enough time for QHINs to update their participation agreements and for their participants to update their member agreements. **We encourage ONC to consider taking a phased approach that will allow QHINs and their participants and members to participate in the TEFCA while their agreements are being updated.**

ELECTRONIC HEALTH INFORMATION (EHI) AND US CORE DATA FOR INTEROPERABILITY (USCDI)

Throughout the MRTCs, ONC refers to both EHI and USCDI. Sections 7.1 and 8.1, which describe the data reciprocity requirements for participants, state that all EHI must be provided but in the USCDI format. The language used is confusing, and it is unclear what the expectation would be for hospitals and health systems. Would they need to provide all EHI they have, simply what they are asked for, or the USCDI? We ask ONC to clarify the data requirements for participants and members. This could be accomplished by modifying clause 7.1(ii)(b) to the following: If the Participant stores or maintains EHI, the Participant shall also respond by providing all of the then applicable USCDI to the extent that all of the following conditions are satisfied. ONC could modify clause 8.1(ii) in the same manner. Further, we submitted substantial comments in our letter to ONC on its proposed information blocking rule about the data included in EHI.

We ask ONC to carefully consider our comments on excluding price information and non-observational health data from the definition of EHI and to modify the Common Agreement definition appropriately.

ITEMS PERTAINING TO INDIVIDUALS

ONC has specified that participants and members who have a direct relationship with patients should obtain consent from individuals when necessary and electronically share that consent with their QHIN. As we noted earlier, standards for electronically sharing consent are still emerging and have not been widely adopted. If ONC requires participants and members to share consent electronically, the methods for sharing such consent also must be specified either by ONC or the RCE. Further, we believe that a global opt-out policy is more appropriate and implementable than a meaningful choice policy and recommend that ONC replace the meaningful choice policies with a global opt out.

Sections 7 and 8 include the following flow down clause:

> *Written Privacy Summary. Each Participant agrees to publish and make publicly available a written notice in plain language that describes each Participant's privacy practices regarding the access, exchange, Use and Disclosure of EHI with substantially the same content as described in ONC's Model Privacy Notice. The written privacy summary shall include the following additional information: (a) a description, including at least one (1) example, of each type of Exchange Purpose; (ii) a description that provides an Individual with a reasonable understanding of how to exercise Meaningful Choice; and (iii) whom Individuals can contact for further information about the Participant's privacy policies. This written privacy summary requirement does not supplant the HIPAA Privacy Rule obligations of a Participant that is a Covered Entity to post and distribute a Notice of Privacy Practices that meets the requirements of 45 CFR § 164.520.*

While we are very supportive of providing patients with plain language notices on privacy practices, we disagree with the requirement that such notices mirror ONC's Model Notice of Privacy Practices. Because the clause indicates that this summary does not supplant the HIPAA requirements to provide the Notice of Privacy Practices, we are concerned that the net effect of this clause will be to require that hospitals and health systems maintain multiple Notice of Privacy Practices. This may confuse patients and add significant burden. As such, the HIPAA required Notice of Privacy Practices should be sufficient for the Common Agreement and we recommend that ONC modify these clauses accordingly.

IDENTITY PROOFING AND AUTHENTICATION

Health systems already identity proof to NIST Identity Assurance Level (IAL) 2 requirements for their clinicians and employees. However, we are concerned that IAL 2, even with modifications, is too high of a bar for identity proofing *patients*, especially in the near term. Consequently, we recommend that ONC take a phased approach to raising the identity proofing bar for individuals. ONC should start by requiring NIST Level of Assurance 2 for individuals and allow several years to phase in the higher IAL 2 requirements for individuals. This will ensure that health systems have appropriate time to implement new processes and that patients will be able to access their health information while they do so.

We appreciate your consideration of these issues. Please contact me if you have questions or feel free to have a member of your team contact Joanna Hiatt Kim, vice president of payment policy, at (202) 626-2340 or jkim@aha.org.

Sincerely,

/s/

Ashley Thompson
Senior Vice President
Public Policy Analysis and Development