June 17, 2019

The Honorable Donald Rucker, MD,
National Coordinator for Health Information Technology,
US Department of Health and Human Services
200 Independence Ave. SW
Washington, DC, 20201

Comments submitted at: https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement

Re: Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2

Dr. Rucker:

AMIA appreciates the opportunity to comment on ONC's Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2.

AMIA is the professional home for more than 5,500 informatics professionals, representing frontline clinicians, researchers, public health experts, and educators who bring meaning to data, manage information, and generate new knowledge across the research and healthcare enterprise. As the voice of the nation's biomedical and health informatics professionals, AMIA plays a leading role in advancing health and wellness by moving basic research findings from bench to bedside, and evaluating interventions, innovations and public policy across settings and patient populations.

In comments submitted to ONC in 2018,[1] AMIA recommended ONC:
- Develop a roadmap that details an implementation plan at least three years into the future;
- Establish pilot tests to inform TEFCA implementation that are relevant clinically, geographically, and that reflect real-world care patterns; and
- Develop mechanisms to garner stakeholder feedback and public input, including formal opportunities convened by the RCE to hold open comment periods, listening sessions, and other accountability mechanisms.

In reviewing Draft 2 of the TEFCA, we note several deliberate steps were taken to make participation more achievable without compromising the policy's stated goals. With slight modifications, AMIA supports Draft 2 Exchange Purposes, Exchange Modalities, and acknowledgement that a phased approach will be necessary to TEFCA's success. However, we

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[1] AMIA Comments to ONC re: Draft Trusted Exchange Framework and Common Agreement (TEFCA), February 20, 2018. Available at: https://www.amia.org/sites/default/files/AMIA-Comments-on-Draft-TEFCA.pdf

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reiterate our initial call for a detailed implementation plan and we strongly recommend that ONC develops such a roadmap with substantial input by the eventual Recognized Coordinated Entity (RCE) and other TEFCA stakeholders. This roadmap should include specific milestones and points of engagement, as well as describe (1) what will be required of TEFCA stakeholders for the initial phase; (2) generally, what is being considered for inclusion in a subsequent phase; and (3) what accountability mechanisms will be in place to garner feedback and input. It will only be through engagement, accountability, and transparency that this "network of networks," will successfully emerge and evolve.

In addition, AMIA offers the following high-level recommendations, with detailed comments in the attachment to this transmittal letter.

- **AMIA is concerned that the Exchange Purposes, while improved, may be still too broad for the initial phase of the TEF, especially the purpose of "Business Planning and Development."** The TEF Exchange Purposes were redefined to narrow the permitted purposes for exchange to specific subset activities of HIPAA Payment, Treatment, and Operations (TPO). These limitations on HIPAA TPO to include "Quality Assessment and Improvement," "Business Planning and Development," and "Utilization Review." AMIA is concerned that there is too much ambiguity in "Business Planning and Development" to have that be a permitted purpose at this phase of the TEF. It may be prudent for ONC and the RCE to consider permitted purposes beyond treatment and individual access in a subsequent phase of the TEF.

- **AMIA supports the Draft 2 Exchange Modalities, but caution that various technical specifications to support those modalities are immature.** The Exchange Modalities included a new "message delivery" modality and dropped a proposed "population-level data exchange." These changes are appropriate for the initial phases of the TEF and will help onboard stakeholders with valuable functionality. However, we caution that various technical specifications meant to support these modalities are either under-developed or in a state of flux. Specifically, AMIA notes that standards for patient matching, "Meaningful Choice" (consent), and security labels are especially problematic and warrant immediate attention. While we support the establishment of a QHIN Technical Framework (QTF) and support the policy decision to make the QTF adjunct to the TEFCA itself, we anticipate that the draft QTF will need significant rework, based on expected industry adoption of FHIR and anticipated timelines for TEFCA operationalization.

- **AMIA strongly supports ONC's embrace of a "phased approach" to adopt new TEF functions (Purposes and Modalities) and we strongly recommend ONC and the RCE develop a detailed implementation plan before the TEFCA and QTF are finalized.** The ONC intends to phase in new Purposes and Modalities in the Common Agreement to support additional use cases over time. ONC envisions that TEF actors would have 18 months to incorporate necessary standards into their architectures, as well as resolve any variation in
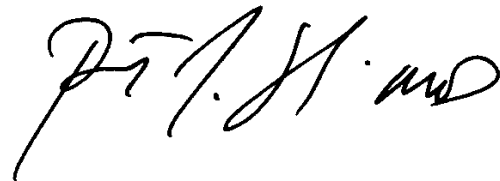
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> standards and policies that exist. AMIA recommends this phased approach to development of new functions should establish public, transparent processes to evolve and adapt the TEF over time. This should be initiated through development of a detailed roadmap and implementation plan for public input before the TEFCA and QTF are finalized.

We continue to appreciate ONC's work in this important area, and we are eager to bring the expertise of health informatics professionals to further refining the TEFCA's mechanics and operative concepts. Thank you for considering our comments. Should you have questions about these comments or require additional information, please contact Jeffery Smith, Vice President of Public Policy at jsmith@amia.org or (301) 657-1291. We look forward to continued partnership and dialogue.

Sincerely,

Douglas B. Fridsma, MD, PhD, FACP,
FACMI
President and CEO
AMIA

Peter J. Embi MD, MS, FACP, FACMI
AMIA Board Chair
President & CEO
Regenstrief Institute

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Recognized Coordinating Entity (RCE)

Through a Cooperative Agreement, ONC is seeking eligible applicants to become the RCE and receive funding from ONC to 1) Develop a Common Agreement that includes the MRTCs and ARTCs, for ONC approval and publication to HealthIT.gov and in the Federal Register; 2) Virtually convene public listening sessions that will allow industry stakeholders to provide objective and transparent feedback to the RCE; 3) Identify and monitor QHINs that voluntarily agree to sign and adopt the Common Agreement; 4) Implement an ONC-approved process to adjudicate QHIN noncompliance with the Common Agreement, up to and including removal from ONC's public directory on HealthIT.gov; 5) Implement a process to update the Common Agreement, as needed, for ONC final approval and publication to HealthIT.gov and in the Federal Register; 6) Modify and update the QHIN Technical Framework Draft 1, for ONC approval, to detail proposed technical components for exchange among QHINs as required by the latest version of the MRTCs; and 7) Propose strategies that an RCE could employ to sustain the Common Agreement at a national level after the expiration of the term of the Cooperative Agreement.

AMIA Comments: We applaud the increased level of transparency that ONC is proposing with regards to the RCE, especially the new public listening sessions. We reiterate our recommendations from Draft 1 that ONC release a more detailed roadmap and implementation plan to help stakeholders better understand how the TEFCA and USCDI are meant to be operationalized. Additionally, we reiterate that the Cooperative Agreement should stipulate that the RCE have a governance structure that includes a broad array of stakeholders, including representatives from the informatics community, standards developers, IT professionals, clinicians, public health, payers, HIEs, and individual / patient advocates. Finally, we remind ONC that the RCE, and thus TEFCA, can only be successful with adequate funding and personnel.

Timelines

QHINs were originally to have 12 months to update agreements and technical requirements. ONC has extended that timeframe to 18 months.

AMIA Comments: We support the extended timeframe for QHINs to update contractual agreements and technical requirements to 18 months. The added visibility provided by our proposed implementation roadmap would provide adequate time for QHIN updates.

QHIN Prerequisites

In order to apply for QHIN Designation, a HIN must meet certain prerequisites, including already operating a network that provides the ability to locate and transmit EHI between multiple persons or entities electronically, with existing persons or entities exchanging EHI in a live clinical environment; and providing the RCE with a written plan of how it will achieve all of the requirements of the Common Agreement within a specified time period. A HIN must submit a QHIN Application to the RCE that documents that it meets these prerequisites, and the RCE must

certify in writing that the HIN in question has satisfied these requirements. Once the RCE has approved a QHIN Application, the HIN becomes a Provisional QHIN and is assigned to a Cohort to complete the remainder of the requirements in the Common Agreement and QTF. A Provisional QHIN is only Designated a QHIN once the RCE has confirmed and documented that the Provisional QHIN in question has satisfied the requirements of the Common Agreement and the QTF. The RCE will also be responsible for monitoring QHINs on an ongoing basis and adjudicating noncompliance with the Common Agreement up to and including removal of the QHIN from ONC's public directory on HealthIT.gov, when necessary.

AMIA Comments: We support the added prerequisites for QHIN application, as these will ensure that QHINs are better able to manage this new and important effort. We also appreciate the added process that a Provision and Designated QHIN provided. Members note that it would be helpful to understand how many QHIN's ONC expects to seek Designated status. This rationale will help stakeholders better understand the scope of ONC's intentions.

Participants, Participant Members, and Individual Users

Draft 2 expands who can qualify as a QHIN in order to provide them flexibility in their services and support of various stakeholders:

- Participants: Participants may include persons or entities that have entered into a contract to participate in a QHIN. Some examples of Participants could include, but are not limited to, a HIN, a health system, a health IT developer, a payer, or a federal agency.
- Participant Members: Participant Members may include persons or entities that use the services of a Participant to send and receive EHI. For example, if a QHIN is composed of health information exchanges, the health information exchange would be the Participant, and those who use the health information exchange services, (such as health systems, ambulatory providers, health IT developers, payers, and others) are the Participant Members. Alternatively, a health IT developer could be a direct Participant of a QHIN, in which case, the Participant Members may be the provider practice that uses the health IT developer's software or services.
- Individual Users: An Individual User represents an actual person who is the subject of the EHI, such as a patient, health plan member, or a patient representative. Individual Users may have a Direct Relationship with the QHIN, Participant, or Participant Member, depending on the structure of the QHIN to which they belong, but they are not themselves considered Participants or Participant Members.

AMIA Comments: AMIA appreciates the clarification of these roles from Draft 1 and we appreciate how similar organizations and entities (e.g. health systems) may be designated as different stakeholder types, depending on their relationship to the QHIN. We anticipate that confusion will remain high among some stakeholder groups, and we encourage ONC to develop additional examples and education materials. We also note that that the TEFCA relies heavily on the as-yet-

defined concept of Electronic Health Information (EHI). The TEFCA will not succeed without a definition of EHI that is widely understood and consistently implemented across actors. As defined in ONC's recently proposed rule and in the TEFCA, we note that actors requesting EHI through the TEFCA will likely obtain vastly different payloads based on three factors: (1) the health IT developers' native configuration; (2) the implementation decisions and customizations at each implementation; and (3) the institution's interpretation of what constitutes EHI. This challenge is compounded when additional actors, e.g. HINs and QHINs, are introduced into the data query supply chain. It is critical that this key definition and its relationship to TEFCA be examined closely.

Exchange Modalities

In the list of exchange modalities, Draft 1 of the TEFCA had suggested that in addition to Targeted Query and Broadcast Query, QHINs should support Population-Level Data Exchange. However, ONC removed this use case in Draft 2. Additionally, push message delivery has been added to query.

AMIA Comments: In our Draft 1 comments, we acknowledged the complexity of the numerous legal and technical aspects of population level data exchange. We support the removal of this modality to allow for more refinement, and we encourage ONC to continue its work with stakeholders so it may be included in a future phase of the TEF. We additionally support the inclusion of the QHIN (push) Message Delivery modality.

Exchange Purposes

Draft 2 requires exchange for only a subset of activities in Payment (Utilization Review) and Health Care Operations (Quality Assessment and Improvement, and Business Planning and Development) as defined in the HIPAA Privacy Rule. In addition, Individual Access as defined in Draft 1 has been modified to Individual Access Services, which includes the HIPAA Privacy Rule right for an individual to view or obtain a copy of his or her Protected Health Information from Covered Entities. The Individual Access Services Exchange Purpose also now includes a corresponding requirement for non-HIPAA entities that elect to participate in the Common Agreement.

AMIA Comments: AMIA appreciates ONC's recognition that non-HIPAA entities are growing in significance to individuals' health and are fast becoming important parts of the care continuum. We fully support ONC's policy that "requires non-HIPAA entities, who elect to participate in exchange, to be bound by certain provisions that align with safeguards of the HIPAA Rules," as part of the Common Agreement. For non-HIPAA entities who produce and/or manage EHI, such requirements are appropriate.

AMIA also supports the narrowing of permitted purposes for Health Care Operations and Payment. However, we remain concerned that the category of "Business Planning and Development" is insufficiently specified. While Quality Assessment and Improvement may take various forms, it is a

well-understood endeavor that could underscore the benefits of the TEFCA. Meanwhile, Utilization Review is a constrained use case that could also deliver value at scale.

Finally, there is some ambiguity regarding the provisions for Individual Access Services and whether a public health registry is required to respond to such a request if it is unable or unwilling to do so. TEFCA clearly states that a response is not necessary if such a response would be against the law (as it is in some jurisdictions). Normally, response to Individual Access Services requests is based on the requirement under HIPAA for covered entities (CE) and their business associates (BA) to provide a patient with his/her EHI on request. However, the TEFCA draft (in section 7.14(ii)) makes this requirement to respond incumbent on all participants whether they are CEs/BAs or not. Upon careful read of this section, it requires a "direct relationship" between the patient and the registry, which does not exist without an explicit offering of this service by the registry. Therefore, it appears that public health registries who do not explicitly offer patient access services are not required to do so. We recommend that ONC issue a clarification on this issue.

Phased Approach

ONC intends to phase in new exchange modalities and Exchange Purposes in the Common Agreement to support additional use cases. ONC intends to work with the National Institute of Standards and Technology (NIST) and the industry on pilots focusing on use cases of the TEF and the Common Agreement. As ONC phases in new requirements, QHINs, Participants, and Participant Members are in no way limited from voluntarily offering additional exchange modalities and services or from entering into point-to-point or one-off agreements between organizations that are different from the Common Agreement's MRTCs, provided that such agreements do not conflict with the policies of the Common Agreement.

AMIA Comments: AMIA supports the phased approach, but we reiterate that ONC should work with the RCE to publish an implementation roadmap to help all stakeholders prepare for each phase.

Meaningful Choice and Written Privacy Summary

The MRTCs Draft 2 requires that QHINs, Participants, and Participant Members provide Individuals 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. Participants and Participant Members are responsible for communicating this Meaningful Choice up to the QHIN who must then communicate the choice to all other QHINs. This choice must be respected on a prospective basis. Additionally, all QHINs, Participants, and Participant Members who provide Individual Access Services must publish and make publicly available a written notice describing their privacy practices regarding the access, exchange, Use, and Disclosure of EHI. This notice should mirror ONC's Model Privacy Notice and include an explanation of how an Individual can exercise

their Meaningful Choice and who they may contact for more information about the entity's privacy practices.

AMIA Comments: We strongly support the concept of "Meaningful Choice." Across numerous venues and policy engagements, AMIA has fiercely advocated for patients to have complete access to and control over their health data.[2, 3, 4] We also acknowledge that patients express a scale of sensitivity across various data types, not simply those considered substance use disorder, reproductive, and mental health.[5] Thus, we advocate for development of granular data specifications – including metadata – that will enable granular control of all data, not simply a class of data considered "sensitive" by policymakers. We view the work that has been done as part of Data Segmentation for Privacy (DS4P) and Consent2Share as positive steps towards providing such control. However, these standards (in addition to Security Labeling capabilities) are far from mature.

Unfortunately, "Meaningful Choice" is unimplementable without mature standards to represent the policy. This is true at every level of the TEF, from Participant Members to QHINs, and the millions of patients with whom they will interact. ONC acknowledges this lack of standards on page 84 of Draft 2 noting, "…the healthcare industry has not established a common approach for electronically managing patient privacy preferences."

Further, the inclusion of "Meaningful Choice" as part of the TEFCA will create yet another distinct and separate privacy regime without getting us closer to the goal of enabling patients to be in full control of all their health data. Experience with an existing distinct and separate privacy regime in health care, 42 CFR Part 2, should give ONC pause regarding "Meaningful Choice." Part 2 regulations have had the effect of erecting a "brick wall" that blocks information exchange between Part 2 programs and other health system elements. Technically, Part 2 programs can share information with appropriate patient consent or under narrowly defined circumstances (e.g., life threatening medical emergencies) but on a practical level, information exchange is incomplete and infrequent. Logistical barriers and widespread confusion about the regulatory requirements often

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[2] In comments to SAMHSA (2016), AMIA urged the Department of Health and Human Services (HHS) to lead a national effort to develop technical standards that would enable patients to have total control of their health data and enable providers to have a more complete picture of their SUDs patients. Available at: https://www.amia.org/public-policy/amia-response-samhsa-proposed-rule-regarding-confidentiality-substance-use-disorder
[3] In comments to OCR RFI (2019), AMIA recommended that the Office ensure that HIPAA both requires and permits information-sharing upon patient and clinician request, as well as robust penalties for failing to deliver data pursuant to the patient "right of access." Available at: https://www.amia.org/public-policy/hipaa-must-better-promote-information-sharing-urges-amia
[4] In comments to ONC (2019), AMIA recommended ways to improve data access for patients, clinicians, and researchers, as well as several measures ONC could take to protect the privacy of patient data. Available at: https://www.amia.org/public-policy/amia-supports-onc-cures-rule-recommends-ways-improve-data-access-patients-clinicians-and
[5] Caine K., Hanania R. "Patients want granular privacy control over health information in electronic medical records." Journal of the American Medical Informatics Association. 2013;20:7–15.

paralyze organizations from exchanging data or coordinating care with Part 2 programs. We fear the same outcome will be true of "Meaningful Choice" unless or until standards

Given that TEF actors simply cannot deliver on "Meaningful Choice," due to the current state of technological capability, we recommend that ONC proceed with new privacy notice requirements for access, exchange, use, and disclosure of EHI, and rely on existing HIPAA Privacy Rule, 42 CFR Part 2, and other Applicable Laws for consent/authorization, tabling "Meaningful Choice" requirements to a subsequent phase. In specific, AMIA recommends: (1) Early TEF phase requirements for use and disclosure mirror those defined in the HIPAA Privacy Rule and other Applicable Law; (2) ONC pilot standards development to enable "Meaningful Choice;" and (3) ONC/RCE leverage the QTF to promulgate standards as part of the next TEF phase following standards development.

1. **Initial TEF phase should proceed with privacy notice requirements, but avoid creating new requirements regarding use and disclosure.** AMIA supports Draft 2 proposals to require all QHINs, Participants, and Participant Members who provide Individual Access Services to publish and make publicly available a written notice describing their privacy practices regarding the access, exchange, use, and disclosure of EHI. We also support use of ONC's Model Privacy Notice in the MRTCs to encourage consistency across how actors present this information. However, AMIA is concerned with the "Meaningful Choice" construct described in Draft 2 because (1) it would hold the same patient data to distinct and separate use and disclosure requirements depending on whether those uses and disclosures occur within or outside of the TEF (2) it positions QHINs to manage "Meaningful Choice" notices when QHIN Participants and Participant Members are unable to communicate / manage such notices to the QHIN.

    The policy established for "Meaningful Choice" would create a new use and disclosure environment at the federal level, creating a need to have multiple policies for the same patient data. For example a hospital who is a Participant Member in the TEF would need to have different policies for the same patient data, depending on if the disclosure was to an in-TEF or out-of-TEF actor, given that the out-of-TEF actor could plausibly still have a right to such data under HIPAA. The TEF is meant to be voluntary, so it is likely that such a scenario would be common. In addition, Draft 2 requires QHINs to "electronically communicate," "electronically maintain" and "use electronically maintained Meaningful Choice notices to determine whether to initiate QHIN Queries or QHIN Message Deliveries." Were standards developed and widely adopted to represent this policy, we would support these functions. However, it is currently technically infeasible for Participants and Participant Members to effectively manage Meaningful Choice notices electronically, making it equally infeasible for QHIN's fulfil this aspect of the TEFCA.

    Rather than proceed with "Meaningful Choice" at this time, we recommend ONC require TEFCA actors to follow HIPAA Privacy Rule, 42 CFR Part 2, and other Applicable Laws

for use and disclosure of patient data.

2. **ONC should pilot standards development to enable Meaningful Choice.** We applaud ONC for issuing a Special Emphasis Notice (SEN) earlier this year to encourage rapid advancement of standards development for the FHIR Consent Resource and its associated "Directives," or use cases.[6] This work must be fast-tracked through the standards development process before "Meaningful Choice," will be technically feasible. Given the current state of standards, and the focus of this SEN on development of FHIR, not IHE profiles, we view this as another reason to proceed with "Meaningful Choice" in a subsequent phase of the TEF.

3. **Leverage QTF updates to propagate standards as part of a subsequent TEF phase.** ONC rightly proposed a different approach for the technical aspects of the TEF by creating the QTF and positioning it to be referenced in the Common Agreement. Following the pilots articulated in the SEN and refinement/development of standards mentioned above, ONC can update the QTF section on "Individual Privacy Preferences" with the specific standards necessary to provide and abide "Meaningful Choice." It is likely that results of the SEN work will be available for incorporation in a second phase, based on our understanding of the timeline, and ONC should use its certification program to ensure that certified health IT can manage future "Meaningful Choice" requirements.

Breach Notification Requirements
The MRTCs Draft 2 requires that QHINs, Participants, and Participant Members comply with the Breach notification requirements pursuant to the HIPAA Breach Notification Rule at 45 CFR §164.400-414, regardless of whether or not they are a Covered Entity or Business Associate. Further, each QHIN shall 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 and in accordance with Applicable Law. Where applicable, actors in the Common Agreement may be subject to the Federal Trade Commission Health Breach Notification Rule, which applies to a vendor of personal health records (PHRs), a PHR-related entity, or a third-party service provider for a vendor of PHRs or a PHR-related entity. The Breach notification requirements of the Common Agreement do not supplant any HIPAA or FTC breach reporting requirements or responsibilities.

AMIA Comments: AMIA supports these requirements. We note that strong Participant-level and Member Participant-level controls will be needed to ensure that malicious actors who use the TEF to successfully access, exchange, and use unauthorized data are quickly identified and removed.

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[6] ONC Announces Interest in Applications to Address Standardization of Patient Information for Seamless Access, Exchange, and Use, March 11, 2019. Available at: https://www.healthit.gov/sites/default/files/page/2019-03/LeadingEdgeAccelerationProjectSpecialEmphasisNotice.pdf

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Minimum Security Requirements

The MRTCs Draft 2 requires that QHINs comply with the HIPAA Privacy and Security Rules as it pertains to EHI. Also, QHINs must evaluate their security program for the protection of Controlled Unclassified Information (CUI), and develop and implement an action plan to comply with the security requirements of the most recently published version of the NIST Special Publication 800-171 (Protecting Controlled Unclassified Information in Non-federal Information Systems and Organizations). A CUI category includes EHI. This Publication provides principle guidelines to federal government-wide requirements for CUI, and entities which handle EHI are required to demonstrate the security controls and be compliant with the NIST 800-171 requirements of the most recent publication. In addition, as part of its ongoing security risk analysis and risk management program, QHINs shall review the most recently published version of the HIPAA Security Rule Crosswalk to the NIST Cybersecurity Framework.

AMIA Comments: AMIA supports these requirements.

EHI Used or Disclosed Outside the United States

ONC seeks public comment on how the Common Agreement should handle potential requirements for EHI that may be used or disclosed outside the United States. For example, there are federal agencies and other multinational entities that have employees receiving care outside the United States, and their health care providers may want to request the patients' health care records that are located within the United States. Currently, the MRTCs Draft 2 does not permit QHINs to Use or Disclose EHI outside the United States, except to the extent that an Individual User requests his or her EHI to be Used or Disclosed outside of the United States.

AMIA Comments: AMIA believes that the Common Agreement should abide by a general principle of patient centeredness so as long as an Individual User requests his or her EHI to be Used or Disclosed outside of the United States, we have little concern with this policy. However, we do believe it is appropriate to inform patients about potential risks prior to being permitted to make an authorization to send their data out of the country.

Security Labeling – this should be part of QTF work

Currently, security labels can be placed on data to enable an entity to perform access control decisions on EHI such that only those persons appropriately authorized to access the EHI are able to do so. ONC is considering the inclusion of a new requirement regarding security labeling that states the following:

- Any EHI containing codes from one of the SAMHSA Consent2Share sensitivity value sets for mental health, HIV, or substance use in Value Set Authority Center (VSAC) shall be electronically labeled;
- Any EHI of patients considered to be minors shall be electronically labeled;

- The data holder responding to a request for EHI is obligated to appropriately apply electronic security labels to the EHI;
- At a minimum, such EHI shall be electronically labeled using the confidentiality code set as referenced in the HL7 Version 3 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1 (DS4P IG), Part 1: CDA R2 and Privacy Metadata; and
- Labeling shall occur at the highest (document or security header) level.

While the DS4P Implementation Guide was included as an optional criterion in the 2015 Edition of certification criteria, ONC recognizes that the use of the DS4P IG has yet to reach wide adoption. Therefore, we have limited the proposed requirement to four (4) of the most commonly requested sensitive data categories.

AMIA Comments: Please see our comments on "Meaningful Choice." AMIA strongly cautions ONC that security labeling is still immature. Before ONC finalizes any new requirements, we recommend it conduct pilots and seek industry guidance.

QHIN Technical Framework (QTF)

The QTF Draft 1 seeks to facilitate the immediate availability of QHIN services. As such, the QTF Draft 1 enables organizations seeking to become QHINs to leverage their existing, deployed technical infrastructure (i.e., services based on IHE profiles) to support network-to-network exchange. The QTF Draft 1 includes requests for comment to highlight where the industry can leverage the QTF development process to recommend appropriate standards or suggest alternatives to today's commonly used technology.

AMIA Comments: The initial implementation of TEFCA, as guided by the QTF, is expected to rely almost exclusively on Integrating the Healthcare Enterprise (IHE) standards and transactions, which we note are largely document-centered (as opposed to message-centered). Further, they do not represent most health information exchange implementations today. The QTF has nominal recognition of HL7's Fast Health Interoperability Resources (FHIR) standard as an alternative or emerging standard, but QHINs would still be required to support IHE standards. Given the push for FHIR in the February 2019 ONC Interoperability NPRM with its ambitious proposed timelines, we recommend that ONC advocate for FHIR more strongly. At a minimum, we recommend the RCE and ONC seek expert input and develop version 2 of the QTF as an immediate deliverable after the RCE is established.

We also are concerned that the QTF minimizes the difficulty TEF actors will have in identifying the right patient with the right data. The issue of patient matching across the healthcare ecosystem continues to be a serious obstacle to interoperability. The description of patient matching for query purposes within the MRTC presents a rather simplistic view of patient matching, with no

recognition of the complexity of uncertain matches, multiple matches, and similar issues. The Patient Identity Resolution section of the QTF does detail more expectations of a QHIN in this area but offers no real solutions to the difficulties we will experience. And the same requests for comment about recommended data elements for matching (RFC #7), standardization of patient identity resolution (RFC #8), and matching algorithm performance metrics (RFC #9) continue to be made. Patient data should not be considered a match until or unless there is a high probability of accuracy. As such, clinicians should be presented with an estimate of that accuracy for each record shared so they can make a clinical determination about whether to use the data in treatment of the patient.