TENNESSEE DEPARTMENT OF HEALTH (TDH)
Office of Informatics Analytics (OIA)
For more information contact the *Tennessee Partner Engagement Coordinator*

June 14th, 2019

Donald W. Rucker, MD
National Coordinator for Health Information Technology
U.S. Department of Health and Human Service
330 C Street SW, 7th Floor
Washington, DC 20201

RE: Public Comment on Trusted Exchange Framework and Common Agreement Draft 2

Dear Dr. Rucker,

The Tennessee Department of Health (TDH) Office of Informatics and Analytics (OIA) appreciates the opportunity to share our comments and concerns on the Office of the National Coordinator's (ONC's) Trusted Exchange Framework and Common Agreement Draft 2, developed in response to the 21st Century Cures Act. TDH is the primary public health agency responsible for public health in Tennessee. The department oversees eighty nine rural county health departments and works closely with six metropolitan health departments under local governance to Protect, Promote, and Improve the Health and Prosperity off People in Tennessee. Each county in Tennessee has a county health department providing direct and indirect services to Tennessee residents and visitors. TDH staff participates in many health care and health IT industry associations, workgroups and task forces to ensure the needs of public health programs that conduct surveillance, outbreak investigations, laboratory testing, and prevention of communicable and non-communicable diseases and conditions in Tennessee are heard.

TDH's vision is to be a recognized and trusted leader, partnering and engaging to accelerate Tennessee to one of the nation's ten healthiest states. TDH has a great deal of interest in the wide spread adoption and use of nationally accepted standards and requirements that increase data sharing, improves timely reporting and accuracy, that enforces information sharing between the clinical sector and public health. TDH recognizes that the deregulation or removal of certification criteria will ease the burden of developers of health IT and the cost inherited by TDH trading partners. The primary goals behind certification was not only to ensure that electronic health record technology being implemented met certain functional interoperability requirements to enhance patient care, but also, and more importantly, to protect patients. The certification requirements and the EHR Incentive programs of the past has helped TDH staff to onboard providers reporting to Tennessee Cancer Registry (TCR), Tennessee Immunization Information System (TennIIS), Syndromic Surveillance messaging, and Electronic lab Reporting (ELR) since 2011. As we move forward we hope to include an Electronic Case Reporting (eCR) option in 2020 for hospitals.

TDH appreciates that ONC proposes the HL7 Fast Healthcare Interoperability Resources (FHIR) RESTful API in the Qualified Health Information Network (QHIN) Technical Framework (QTF) Draft 1 as an Alternative/Emerging Standard or Profile in several critical areas. We strongly emphasize the need for implementation guides regarding the potential use of the HL7 FHIR RESTful API referenced in the Qualified Health Information Network (QHIN) Technical Framework (QTF). The **Recognized**

Coordinating Entity (RCE) should be a guiding principal in the updating and finalizing of the **Minimum Required Terms and Conditions (MRTC) as well as development of the** Additional Required Terms and Conditions (ARTCs); however public health should be a part of larger collaborative effort to modify the MRTCs draft.

Push based exchange modality is greatly appreciated and is strongly supported by TDH and others in the public health community. This inclusion recognizes public health a crucial participant/stakeholder and a critical component for interoperability as well as data sharing. We are somewhat concerned with the complex Meaningful Choice concept as it does not address consent complexities of opt-in/opt-out provisions, age-based reporting requirements, automated vs. manual reporting, and modified or rescinded consent over time all add complexity to a nation-wide approach to interoperability. QHIN-to-QHIN data exchange is addressed in the draft; however public health will likely be participating member and it is not clear as to how the exchange of public health data will be standardized and continued over time to support nation-wide exchange.

We offer for your consideration, the following comments which are consistent with those submitted by the Council of State and Territorial Epidemiologists (CSTE), the American Immunization Registry Association (AIRA), the Promoting Interoperability Taskforce, and Health Level Seven International (HL7).

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Page 9	ONC will develop the MRTCs, which will consist of mandatory minimum required terms and conditions with which Qualified Health Information Networks (QHINs) may voluntarily agree to comply.	This wording seems ambiguous. Is adherence to the MRTCs really voluntary for QHINs? Clarification would be helpful.
Page 10	The TEF and the Common Agreement follow a "network of networks" structure, which allows for multiple points of entry and is inclusive of many different types of health care stakeholders. Such stakeholders include, but are not limited to: • …Public Health Agencies…	ONC's unequivocal inclusion of the public health community as a stakeholder and contributor to the TEFCA concept is greatly appreciated.
Page 14	Additionally, ONC received a number of requests from commenters to include a "push-based" exchange modality in the TEF and the Common Agreement. Commenters noted that push transactions play a vital role in supporting transitions of care and public health use cases and would be necessary to fully support required Public Health reporting. Therefore, ONC has included QHIN Message Delivery, which supports instances where a QHIN sends EHI to	TDH supports the inclusion of QHIN Message Delivery (push modality) as a core component of TEFCA. This modality is a key part of public health interoperability today and will be crucial to Public Health's success in TEFCA.

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	one or more QHINs for delivery. We request comment on the inclusion of QHIN Message Delivery and its definition.	
Page 14	As such, the TEF, MRTCs, and QTF do not dictate the internal requirements or business structures of QHINs, but rather provide QHINs flexibility to provide different services and support different stakeholders.	While it is important to not micro-manage the activities of QHINs, there may be reason for concern if each QHIN requires adherence to different standards and processes. Some stakeholders, most notably Health IT developers, may need to support participation in multiple QHINs and would be burdened by variations in requirements. We encourage the development of some basic "rules of the road" for intra-QHIN exchanges.
Page 14	QHIN Targeted Query: a QHIN's electronic request for EHI (sometimes referred to as a "pull") from specific QHINs in the context of the Common Agreement to the extent permitted by the Common Agreement and Applicable Law.	Since IIS consolidate data from many sources over an individual's lifespan, data are constantly changing and being updated. To ensure queries result in the most current and "fresh" record, we would recommend that re-query be considered as a requirement or strongly recommended provision within TEFCA, and that caching data (which could quickly become outdated or "stale") be strongly discouraged.
Page 15	The Exchange Purpose described as Individual Access in TEF 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 now includes a corresponding requirement for non-HIPAA entities that elect to participate in the Common Agreement. We request comment on the scope of these Exchange Purposes.	It is important to note that some public health laws and rules do not allow individuals to access their own data or restrict how access is obtained. We request that public health be provided a specific and explicit exemption from this requirement as HIPAA does. A suggestion is to update 8.21 on page 67 to extend the exemption provided to federal agencies there to state and local agencies. We strongly support the need for written authorization procedures, but recommend ONC work with public health organizations to further develop appropriate security labels.
Page 16	In order to meet the goals of the Cures Act as well as to help address these concerns and encourage robust data exchange that will ultimately improve the health of patients, the Common Agreement requires non-HIPAA entities, who elect to participate in exchange, to be bound by certain provisions that align	TDH urges ONC to provide clarity regarding when non-HIPAA covered entities or business associates are subject to all HIPAA privacy and security provisions. The applicability of these provisions is not fully evident in the MRTCs. It is not clear what this might mean for non-

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	with safeguards of the HIPAA Rules. This will bolster data integrity, confidentiality, and security, which is necessary given the evolving cybersecurity threat landscape.	covered entities in Public Health and the Public Health exclusion for HIPAA disclosures – please articulate more fully. We would recommend an explicit exclusion for non-covered entities in Public Health. In addition, if an IIS does provide Individual Access Services, we are not sure this should be subject to HIPAA, as this is a public health function.
Page 17	Therefore, 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.	Meaningful Choice is a complex concept that does not exist and will require considerable effort for both public and private sectors to implement effectively. The development of Meaningful Choice options will require the carefully consideration to develop a timeline for implementation. Given Meaningful Choice issues relate to important issues of privacy and security, we suggest that ONC allow less global Meaningful Choice than proposed initially, and then refine these working with the community and the RCE to provide support for more granular Individual choice about recipients, information content, and information confidentiality, especially as increasingly robust data segmentation is more widely adopted. We would also like to acknowledge the comments of HL7, AIRA and Interoperability Task Force.
Page 19	Labeling shall occur at the highest (document or security header) level.	The ONC proposed rule calls for security labeling at a more granular level. Should these two proposals by harmonized?
Page 19	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: • At a minimum, such EHI shall be electronically labeled using the confidentiality code set as referenced in the HL7 Version 3	It's not clear where/how this HL7 V3 code set would be used in non-V3 EHI exchanges such as V2 or FHIR. Also, please clarify what "at a minimum" means. Are there examples of things that are better than this suggested floor which could be used?

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	Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1 (DS4P IG), Part 1: CDA R2 and Privacy Metadata;	
Page 20	• QHINs have 12 months to update agreements and technical requirements. Was changed to: • QHINs have 18 months to update agreements and technical requirements.	TDH supports the extended compliance timeline and views this as an achievable and a very reasonable timeline.
Page 20	• QHINs may not charge other QHINs to respond to queries for Individual Access, Public Health, or Benefits Determination. Was changed to: • QHINs may not impose any other fee on the Use or further Disclosure of the EHI once it is accessed by another QHIN.	TDH is concerned about removal of language present in TEFCA Draft 1 regarding fees applied to queries for public health purposes. It is not clear what the implication is if public health related queries are not exempted from fees. Does this change mean that: • Public health entities may need to pay for access to data held by QHINs and their participants? • Public Health entities may charge users for access to data held by the entity? Given the critical role of public health data in maintaining healthy populations, TDH would like to recommend that the MRTCs clearly state public health entities may not be charged fees to access or receive data.
Page 28	To support accurate matching, HINs should agree upon and consistently share a core set of demographic data each time that EHI is requested. Likewise, participants of HINs should ensure that the core set of demographic data is consistently captured for all individuals so that it can be exchanged in a standard format and used to accurately match 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 all experience.

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		HL7 recommends using a broader set of specified patient demographic elements to resolve patient identity especially given that with a wider demographic pool, the chances of mismatch will increase on a small number of elements. We recommend that ONC conduct further work to gain consensus on a broader set a of specified patient demographic elements and permit flexibility at the QHIN level to add additional matching parameters, as populations served may need an expanded list.
Pages 9, 10, 34	The TEFCA Draft 2 document outlines an updated version of Minimum Required Terms and Conditions (MRTCs) to ensure that signers of the Common Agreement accede to common practices and align to the principles and objectives contained in the TEF. ONC intends to update and release a Final TEF, while working with the RCE and industry stakeholders to modify and update the MRTCs Draft 2 and the QTF Draft 1. Pg. 34: The Common Agreement shall consist of (a) the Minimum Required Terms and Conditions, (b) the Additional Required Terms and Conditions, and (c) such other terms as the RCE and the QHIN mutually agree upon;	TDH would like to see ONC emphasize and employ a fully collaborative approach in working with a wide range of healthcare and industry stakeholders including SDOs, to modify and update the MRTCs Draft 2. We believe that a hands-on, interactive approaches the best avenue to ensuring MRTCs reflect market realities and facilitate an optimal, orderly and smooth glide path to healthcare change. ONC's work and consultation with RCE on the MRTCs is also critical. The RCE should have a key role in finalizing the MRTCs.
Page 34	Electronic Health Information (EHI): Electronic Protected Health Information, and any other information that identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual and is transmitted by or maintained in "electronic media," as defined at 45 CFR § 160.103, that relates to the past, present, or future health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.	As in the ONC Notice of Proposed Rule Making (NPRM), there is some confusion in the inclusive definition and scope of Electronic Health Information (EHI). It is critical that this key definition and its relationship to the emerging US Core Data for Interoperability (USCDI) be reconciled.
Pages 34-35	Health Information Network (HIN): an individual or an entity that satisfies one or both of the following-	The definition of who could be a HIN or QHIN is vague – unclear on if an IIS or local health department would/could/should

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	1) Determines, oversees, administers, controls, or substantially influences policies or agreements that define business, operational, technical, or other conditions or requirements for enabling or facilitating access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities; or 2) Provides, manages, controls, or substantially influences any technology or service that enables or facilitates the access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities.	qualify? Also unclear how many QHINs ONC envisions operating at one time.
Page 35	Meaningful Choice: an Individual's choice with respect to the Use or Disclosure of EHI in the context of the applicable Framework Agreement that is: (i) made with advance knowledge as provided by the written privacy summary described in Sections 6.1.5, 7.6, or 8.6, as applicable; (ii) not used as a condition for receiving medical treatment or for discriminatory purposes; and (iii) revocable on a prospective basis if an Individual gives written notice to a QHIN, Participant, or Participant Member.	Despite this definition, it is still unclear how consent is registered via manual or automated data feeds, where consent is maintained, how consent is updated over time, and how consumer/patient consent interacts with reporting mandates and opt-in/opt-out provisions for participation. We recommend more consideration and description on these concepts.
Page 46	2.2.12 Termination of Participation in the Common Agreement. In the event that a QHIN's Common Agreement is terminated due to a material breach of its terms by the QHIN without cure, then the QHIN shall, to the extent required by the Common Agreement, return or destroy all EHI received from, created by, or received by the QHIN that the QHIN still maintains in any form and retain no copies of such EHI except as provided below.	The document outlines requirements upon the termination of a QHIN from the Common Agreement, but there is no mention of the QHIN's relationship to Participants and Individual Users in this case. Are the Participants and Individual Users released from any obligations to the QHIN? If the Participants or Individual Users were required to pay any upfront fees for joining the QHIN, are those fees refunded? Clarification might be helpful.
Page 48	5.2.1: Reasonable and Non-Discriminatory Fees. A QHIN must use reasonable and non-discriminatory criteria and methods in creating and applying pricing models if it charges any	This section seems to contain two contradictory statements. The first sentence (A QHIN must use reasonable and non-discriminatory criteria and methods in creating and applying pricing models if it

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	Fees or imposes any other costs or expenses on another QHIN. Nothing in these terms and conditions requires any QHIN to charge or pay any amounts to another QHIN.	charges any Fees or imposes any other costs or expenses on another QHIN.) implies that a QHIN may impose a fee on another QHIN. Yet the second sentence (Nothing in these terms and conditions requires any QHIN to charge or pay any amounts to another QHIN.) seems to say that no QHIN is obligated to pay such a fee. Please clarify this meaning of this section.
Page 70	The QTF specifies the technical underpinnings for QHIN-to-QHIN exchange and other responsibilities described in the Common Agreement.	Most of the standards (both content and transport) in the document are QHIN to QHIN requirements. TEFCA doesn't appear to be explicit regarding QHIN-to-Participant or Participant-to-Participant Member. It's unclear what the vision is for those exchanges. Are they going to remain using their tried-and-true methods or will they be required to transition to QHIN preferred standards? This would be a considerable lift for IIS (which would require significant funding and time to implement).
Page 72	A QHIN Query typically involves two major workflows, patient discovery via IHE XCPD and document location/retrieval via IHE XCA.	These sections outline the adoption of IHE profiles but not FHIR or other existing standards. Many existing data exchanges in Public Health use standards other than IHE profiles. If the emphasis is to be on "existing, deployed technical infrastructure" then the adoption of existing HL7 v2, CDA and FHIR standards should be required. As well, given the focus of the ONC and CMS proposed rules on FHIR, adoption of FHIR within TEFCA should be a priority.
Page 82	QHINs MUST be capable of sending and receiving message delivery acknowledgements to and from QHINs and First Degree Entities.	We appreciate that acknowledgment messaging is called out in the actual TEFCA document, but it does not appear in the user guide. We want to ensure that a response to a submitted message is always required.
Page 82	Specified standards for Message Delivery are included in Table 8… • Responding QHIN(s) MUST be capable of processing XCDR transactions to send documents and associated metadata to the appropriate First Degree Entity(ies)	The standards referenced are IHE XCDR profile to get the data from QHIN A to QHIN B, but it doesn't define the standards on the far left and far right of the swim lane. It does use the words "document and associated metadata", which is concerning. We want the expected appropriate standard to be used regardless of the communication method, so V2 messages for those things currently

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	Table 8. Specified and Alternative Standards for Message Delivery: Specified Standard/Profile: IEH XCDR	interfaces with V2 messages, like syndromic, ELR, immunizations…. We want CDA for those things expected in documents, like eICR, and other case reports… No V3 messages.
Page 82	Initiating QHINs MUST be capable of receiving Message Delivery Solicitations from a First Degree Entity	It is not clear who is responsible for consolidation, deduplication, verification, reconciliation into the new system, etc. Do these activities all happen at the smart phone app (in this example)? There are some critical policy/functional decisions and standards which need to be put in place to both reduce variation and safeguard disclosures when incorrect patient matches are made during queries.
N/A	To help further explain the new TEFCA draft, ONC has provided a User's Guide slide deck, plus a series of 2-page information sheets for different stakeholder groups including state government and public health.	All of the TEFCA documents written well well, and the supporting material from ONC is well written and useful.

Again, we are appreciative ONC' efforts to increase innovation and improve access to patient records for patients and their healthcare providers through the proposed rule and we are thankful for the opportunity to comment. We would like to support comments submitted by CSTE, HL7 and AIRA.

If there are any questions or concerns we are available by way of email or phone at TDH.Informatics@tn.gov or 61-253-8945.

Sincerely,

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