UHIN
DRIVING HEALTHCARE SOLUTIONS FORWARD

June 17, 2019

Donald W. Rucker, MD
National Coordinator for Health Information Technology
Office of the National Coordinator
U.S. Department of Health and Human Services
330 C Street SW
Washington, DC 20201

Re: Response to Trusted Exchange Network Common Agreement (TEFCA) Draft 2

Dear Dr. Rucker,

UHIN appreciates the opportunity to comment on TEFCA draft 2. UHIN celebrates the 10th year of its health information network, CHIE. We are actively working on building interoperability throughout the community by creating a trusted exchange. Our standards-based approach towards building on use cases that the community embraces has allowed us to care, protect and appropriately exchange over 6 million patients' medical records. We understand the need for data to move outside of our HIN/HIE and as such have connected with over 20 other HIEs to ensure the data safely follows the patient. We ask that ONC thoughtfully implements TEFCA to not impede the progress we have already made.

ONC must realize that a single on-ramp to nationwide connectivity will not be possible. Even with the common agreement, TEFCA already acknowledges that the QHINs will create additional services based on their community needs, which will create additional agreements. Hospitals will maintain their results delivery connections to providers to maintain their business relationships. States will continue to maintain their governance on the sharing of information and any new contract will need to include the need to respect their governance. Lastly, states have set up their own registries such as cancer, immunization, trauma and EMS that are currently with separate on-ramps. Unless there is a requirement for state registries to connect to a QHIN, the provider will need to continue to maintain those connections.

We ask that ONC exercise minimal regulation with the MRTCs and ARTCs to continue to allow local governance over data. As per the Information Blocking rule, costs of doing business should be allowed as reasonable and not governed or dictated by an ARTC (page 11).

It is the HINs that have worked with their communities to create the governance necessary for data to flow, the normalization of data, and to create standards of exchange. The proposed TEFCA

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takes the successful current HIN model but adds another layer. The proposed rules will require additional resources to update agreements, set up another layer of HIN and meet several requirements. This will come as a cost to the community. While ONC has set up funding to do the initial work of the RCE, we would strongly suggest similar funding will need to be in place to set up the QHINs.

UHIN agrees with the attributes required to apply as a QHIN but asks for further clarification on the provisional cohort. What value is the cohort providing? What requirements are in place on the RCE to adjudicate the QHIN application in a timely manner? Why not eliminate the Provisional QHIN status and instead condition the QHIN application and approval process on implementation of the requirements of the Common Agreement? Why does the RCE need to know and adjudicate the necessary personnel and technical infrastructure of the QHIN? This information will not stay current and will add more burden to the documentation required. Also, it needs to be clear that no response is required if the patient has opted out of their meaningful choice to share their records (item 2.2.ii). Moreover, we take exception to the section regarding the need for a signed Participant with signed agreements from at least two Participant Members exchanging. This seems overly prescriptive and unnecessary for QHIN approval.

UHIN agrees with the delay of the modality of population-level data exchange. The technology is not mature and there are several privacy and security issues to be reviewed. UHIN would ask that current groups such as SHIEC and WEDI provide input and testing for the RCE to help refine this use case and its requirements. UHIN agrees with the other exchange modalities and would add clarification that the broadcast query is based on query of **an individual** (so not to be confused with the population-level data exchange) and that message delivery is based on **an event** (patient discharge, results completed, etc.).

However, we disagree with the intent to not include all payment reasons defined under HIPAA as an exchange purpose. This change in exchange purposes flies in the face of the Information Blocking rule released earlier this year. We believe alignment with HIPAA would serve interoperability progress better. We would further recommend that federal agencies that sign on to the TEFCA be required to comply with all provisions included in HIPAA. In addition, we would suggest that life insurance payers should be added to the use case of benefit determination rather than restricting this modality to only the federal and state agencies. This use case and stakeholder has been successfully exchanging data to increase the timeliness of benefit determination of life insurance policies under the DURSA for many years. Also, once data have been pushed for an exchange purpose, it will be difficult to maintain its future use for the approved purposes. For example, the provider may receive the data as part of the treatment purpose, but in the future, exchange it with its vendor for population health purposes.

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We agree with the Privacy and Security provisions but would recommend that the QHIN be responsible to contact only the RCE and those participants, participant members and individuals with whom they have a direct relationship, not all of these stakeholders as contemplated on page 17. It is important that annual risk analysis is done. At some point there will need to be merging of HIPAA and CUI regulations to promote consistency. As federal agencies continue to participate in the bi-directional data flow, this data will exist in multiple databases and all will be responsible to monitor the privacy and security of the data. We agree that Consent2share sensitivity sets should be labeled and when the EHRs have upgraded to the proposed 2015 EHR criteria and includes these labels, then the QHIN can implement.

UHIN believes that standardization is key to interoperability. We recommend that the approved standards be in one place – the ISA – and that the ISA would include all standards approved by HHS and proposed standards version advancement process. The acceptance and implementation of the USCDI will assist in common demographics to assist in patient matching. The HIN/HIEs have expertise in patient matching and SHIEC with its Patient Centered Data Home project has implemented a process to ensure patients' data is correctly linked across disparate geographic sources. SHIEC can be a resource as ONC seeks to improve patient matching.

We agree that individuals should not be charged for their data. However, we caution ONC to monitor entities that will exploit the individual to get around the appropriate reimbursement of reasonable fees for their own business model/gain. Also, it is important to note that individual access through a third party will require that the third party has been adequately vetted to ensure that they are working on behalf of the individual. ONC may want to consider a process that HIN/HIEs and QHINs can verify third parties for transparency, appropriate care and authentication of the individual. Before an individual's data is released, there needs to be some assurance that the third party is indeed working for the individual.

We respectively ask that ONC review the level of specific details in the requirements. We believe listing of personnel of the QHIN and their vendor is overreach and would not stay current. While the RCE should require that the QHIN meet certain requirements, it should not be in their purview to review the participant and the participant member agreements. The QHIN is obligated to ensure that they meet the requirements and will need to have flow down language, but the RCE should not be governing the participants and their members. Lastly, QHINs will remain in business with good service, including patient matching techniques. It is not necessary that the RCE monitor that the QHIN has evaluated their data management on an annual basis.

We agree that the individual should have meaningful choice of how their data will be exchanged. However, we believe that sending their identifying demographics throughout the network is not respecting their choice if they have asked that data not be shared. Rather, we would recommend

that only when the patient is queried that a response be sent back that data is not being shared due to meaningful choice.

We are a global economy and we will need to let data flow outside of the United States. We would recommend that consideration for data sharing be made for those countries that have implemented the General Data Protection Regulation (GDPR) to ensure protection of individuals.

ONC Request for Comment #3: QHINs should not be required to transmit other authorization roles and security labels. QHINs are required to monitor their participants to ensure they are exchanging for the permitted purposes.

ONC Request for Comment #5: To assist the QHIN in filtering the documents to what the requestor wants, we would favor the QTF support at minimum the following:

- FindDocuments – it would be beneficial to require the support of the following:
    - $XDSDocumentEntryPatientId
    - $XDSDocumentEntryClassCode
    - $XDSDocumentEntryTypeCode
    - $XDSDocumentEntryHealthcareFacilityTypeCode
    - $XDSDocumentAuthorPerson
    - $XDSDocumentEntryFormatCode
    - $XDSDocumentEntryType
- GetDocuments

ONC Request for Comment #6: There is already work around HL7 FHIR to perform granular queries and we would recommend working with the HL7 FHIR community to avoid duplicating any work.

ONC Request for Comment #12: UHIN recommends using the FHIR Consent Resource as that is what most organizations are moving towards. The identity should already be resolved before the notice is sent so we don't see a need to resend any information beyond the patient identifier.

ONC Request for Comment #13: Eventually, UHIN would agree that a function to support the exchange of individual's privacy preference is needed, but more standardization is required in this area.

ONC Request for Comment #14: UHIN believes that the Audit Trail and Node Authentication (ATNA) framework for the IHE Profiles would be a good start towards documentation for audible events.

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UHIN has worked tirelessly to promote interoperability for all stakeholders in our community. We appreciate the work that ONC has done in accelerating nationwide interoperability. Please do not hesitate to reach out to me or my organization if you have any questions.

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