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SOLUTIONS THAT MATTER. HEALTH CARE THAT WORKS.

June 13, 2019

National Coordinator for Health Information Technology
US Department of Health and Human Services
330 C St. SW
Washington, DC 20201

To whom it may concern,

On behalf of Altarum, we are pleased to submit comments on **Draft 2 of the Trusted Exchange Framework and Common Agreement (TEFCA)**. Altarum is a non-profit committed to solutions that improve the health of vulnerable populations. Our work spans 50 years of solving critical health IT problems, including capturing clinical data from Electronic Health Record (EHR) systems across a wide array of products and settings; utilizing tools built to collect patient-reported outcomes in multi-site global registries; and developing and successfully deploying registries and clinical decision-support tools used by physicians and clinical researchers alike. Our experience ranges from facilitating some of the earliest health information exchange (HIE) planning projects to directly supporting provider adoption of electronic health records (EHRs) as the boots on the ground for Michigan's Regional Extension Center and developing national standards for information exchange and public health reporting today.

Given our experience, we respectfully submit the following comments. Please contact Craig Newman (Craig.Newman@altarum.org), Altarum's interoperability standards analyst, with any questions.

Sincerely,

Rick Keller, Director for the Center for Connected Health

Page Number	Excerpt	Comment
n/a	n/a	We greatly appreciate the explicit inclusion of public health as a key stakeholder and important contributor to the TEFCA concept.
n/a	n/a	We applaud the inclusion of the QHIN Message Delivery modality as this accommodates many existing Public Health workflows today and will be critical to the participation of public health in TEFCA.
n/a	n/a	In general, Draft 2 is silent on which entity is responsible for deduplication of patient records and collation of clinical data. Is this a task for the querying QHIN or for the application initiating the query? Guidance should be provided to reduce variation in how systems handle these

		complex tasks and to ensure privacy and clinical safety when incorrect patient matches are made.
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.	The wording of the MRTC section is contradictory, in that MRTCs are described as "mandatory" but that QHINs "may voluntarily agree to comply". Please clarify if the MRTCs are binding on QHINs.
Page 13	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" or a floor for participation for intra-QHIN exchanges.
Page 14	commenters expressed concern regarding the relative maturity of Population-Level Data Exchange	Population level data (particularly geographic populations) is of critical importance to public health and we encourage ONC to include explicit population query requirements as soon as feasible. Until such time, it is critical that TEFCA not introduce barriers to population level data exchange by authorized parties. We strongly support the inclusion of population-level data exchange in the principles of the Trusted Exchange.
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.	It is critical to ensure clarity about right to opt out vs required reporting laws, and where patient consent is stored. It will be very difficult to reconcile those competing concerns across state lines. These issues suggest that there may be a level of detail not yet identified or addressed in these documents.
Page 19	Labeling shall occur at the highest (document or security header) level	The call for security labeling at the document level is at odds with calls in the recent ONC proposed rule that calls for more granular levels of security labeling. Given that many of the same players will be implementing both the ONC rule and TEFCA, we suggest that these two sets of requirements be harmonized relative to security labeling.
Page 20	QHINs may not charge other QHINs to respond to queries for Individual Access, Public Health, or Benefits Determination.	The removal of the language relating to fees for public health queries creates ambiguity. Does this mean that a Public Health entity may need to pay for access to data held by QHINs and their participants? Does this mean that a Public Health entity may charge users for access to data held by the entity? Given the important role Public Health data plays in maintaining healthy populations, restoration of the prior protection

		for public health access to data would seem to be appropriate.
Page 25	n/a	Beginning in Appendix 1, "HIN" is used rather than "QHIN". Is there a significance to the use of "HIN" rather than "QHIN"?
Page 33	n/a	Appendix 2 defines Common Agreement as not including the QTF while pages 9 and 10 do include the QTF as part of the Common Agreement. The document should be consistent in this regard.
Page 45	In the event that a QHIN's Common Agreement is terminated due to a material breach of its terms by the QHIN without cure	Section 2.2.12 describes the terminated QHIN's responsibility with regard to EHI, however it does not describe any responsibilities it has towards its participants, members and individual users. 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 fee refunded? Do individual users have any recourse if their health was impacted by a QHIN bad behavior? Clarification in TEFCA or by the RCE will be helpful.
Page 47	A QHIN must use reasonable and nondiscriminatory criteria and methods in creating and applying pricing models if it charges any 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.	Section 5.2.1 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 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 and expectations with regards to fees.
Page 82	Comments are requested on other appropriate standards to consider for implementation to enable more discrete data queries, such as emerging IHE profiles leveraging RESTful APIs and/or use of HL7 FHIR.	The IHE profiles required by this draft are not employed in many Public Health domains. Given the emphasis on FHIR APIs in other proposed rules, it makes sense to coalesce around a single set of standards (FHIR APIs and USCDI) in all interoperability programs.