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June 10, 2019

Dr. Don Rucker  
Department of Health and Human Services,  
National Coordinator for Health Information Technology  
Mary E. Switzer Building, Mail Stop: 7033A  
330 C St. SW  
Washington, DC 20201

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

Dear Dr. Rucker,

HLN Consulting is pleased to submit the attached comments in response to the above mentioned document. HLN is a leading public health informatics consulting company and as such our comments are offered from this public health perspective.

#### *General Comments*

In general, we are quite supportive of the clarifications made in this new version of TEFCAs. Public health continues to play a conspicuous role in this proposal, whether it's explicit presence in the list of stakeholders, inclusion in the exchange purposes, and recognition of the role of existing state and local consent laws as they affect information exchange. The document continues to read well, and the supporting material from ONC is well written and useful. Separation of the technical framework from the TEF into the QTF is also a big improvement, though the contents of the QTF are still problematic (see below). The general rubric of how the Common Agreement will work – it's essential hub and spoke design – is cleanly laid out and relatively straightforward, though the draft still leaves one wondering just how many QHINs ONC envisions operating at one time.

#### *"Push" Exchange Modality*

Perhaps the most dramatic improvement is the inclusion of a "push" transaction among the exchange modalities. This is a major win for public health conceptually. Though neither the QTF chapter nor the slides used by ONC during an April 23, 2019 webinar show a public health interoperability scenario, the User's Guide made available by ONC did show a "push" transaction involving a primary care provider submitting an immunization record to an Immunization Information System (IIS).

However, ONC has made it very clear that initial implementation as guided by the QTF is expected to rely almost exclusively on Integrating the Healthcare Enterprise (IHE) standards and transactions which are largely document-centered (as opposed to message-centered) and which do not represent the majority of health information exchange implementations today. There is 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 Notice of Proposed Rulemaking on Interoperability with its fairly aggressive proposed timelines it seems surprising that ONC would not circle the wagons around that strategy and advocate for FHIR more strongly. In a recent meeting of the Trusted Exchange Framework Task Force, ONC clarified that they thought of the specific standards and technologies identified in the QTF as a starting point for discussion, and that the RCE when it is selected will continue the conversation and select the appropriate technologies.

Even more so, most public health transactions – certainly interoperability with IIS – are not currently implemented with IHE technologies. In all fairness, TEFCA only maintains that the QHIN to QHIN interoperability use this type of transaction; the QHINs at either end (or both ends) of the transaction could receive and forward messages in the manner that seems natural to both the provider and the IIS with existing standards-in-use (in the case of IIS, web services, steps 1 and 3 in the diagram above) and leave the IHE transactions to be between the QHINs alone transparent to the other participants (step 2 in the diagram above). But the intermediation by the QHINs would be complicated to track in this type of transaction. It is worth noting, on the other hand, that the national implementation of electronic case reporting (eCR) does support IHE XDR (the basis for IHE XCDR) according to Digital Bridge technical documentation.

### *EHI*

The February 2019 ONC Notice of Proposed Rulemaking on Interoperability has trouble defining Electronic Health Information (EHI), but TEFCA does not seem to have an easier time. It is critical that this key definition and its relationship to the emerging US Core Data for Interoperability (USCDI) be reconciled.

### *HIPAA and Public Health*

TEFCA proposes to extend HIPAA privacy and security regulations to all TEFCA participants, even those who are not covered entities or business associates under that law. It is unclear how the public health exclusion in HIPAA will be treated within TEFCA, and we recommend explicitly excluding public health transactions from this expanded HIPAA umbrella.

### *Patient Matching*

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 MRTTC 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. 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 as they have been in the past including the most recent NPRM.

#### *Individual Access Services*

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. TEFCAs 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; the TEFCAs 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 (see definition on p. 33), 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. Perhaps ONC should issue a clarification on this issue.

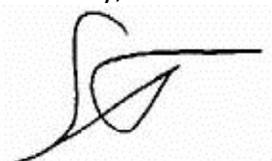
#### *Meaningful Choice*

Patients can make a “meaningful choice” to have their data transmitted through this network and can revoke the right for future transmission of their data. This is an “all or nothing” action – it applies to all their data and is not selective. While patients cannot prevent transmissions that are required by law (like some public health reporting), there is some concern that they may inadvertently prevent transmission of their data to public health registries through this “all or nothing” meaningful choice, essentially throwing out the baby with the bath water.

We also support strongly the comments put forth under separate cover by the American Immunization Registry Association (AIRA) and other public health membership organizations and agencies.

HLN greatly appreciates the opportunity to comment on these proposed guidelines, and we look forward to continuing to collaborate to ensure high-value health IT interoperability with our many partners. I want to thank ONC for continuing to allow me to serve on the HITAC Trusted Exchange Task Force.

Sincerely,

A handwritten signature in black ink, appearing to be 'Noam H. Arzt', written over a light gray dotted background.

Noam H. Arzt, PhD, FHIMSS, FAMIA  
President