

June 17, 2019

Donald Rucker, M.D.
National Coordinator for Health Information Technology
Office of the National Coordinator for Health IT (ONC)
200 Independence Avenue, S.W.
Washington, DC 20201

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

Dear Dr. Rucker:

We are writing on behalf of the undersigned national public health associations which represent the broad spectrum of public health policy and practice in the United States of America. We appreciate the opportunity to submit comments on the: *Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2*.

Data exchange and interoperability between health organizations and public health agencies is a critical part of public health practice and directly serve to protect the nation's health. The inter-network connectivity, single on-ramp, and public health permitted purpose of both the first and second TEFCA drafts can be critical in supporting exchanges electronically now that electronic health records (EHRs) are prevalent. We previously commented that the potential value of TEFCA to supporting public health is very dependent on both the trust and technical aspects of the proposal so as to manifest reporting, surveillance, and other public health activities mostly through "push" transactions. We appreciate that ONC heard these and other comments and added "push" to the new TEFCA draft. We strongly support the addition of "push" data exchange in this second TEFCA draft.

We are now offering additional comments on the second TEFCA draft to ensure that public health interests and needs are made manifest in an ongoing way. Public health is a critical component of the nation's health infrastructure and earlier and more engaged participation by public health in designing the policy and technical underpinnings of that infrastructure will be needed to support it going forward.

The comments listed below are based on the TEFCA version 2 draft posted to <https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement>:

- TEFCA should make clear that public health must be represented in the governance of the Recognized Coordinating Entity (RCE) and TEFCA moving forward. Public health is a government-organized and population-focused activity that has both a different legal basis and different needs than purely patient or provider-orientations. In the TEFCA, as in a number of the places in the recent CMS and ONC "Blocking" Notices of Proposed Rulemaking (NPRMs), processes are cited that will impact public health, but in which public health has had no representation and, in some circumstances, has been actively excluded.

- Although public health is all about taking care of people, many public health activities need to be recognized as different from the activities of patients and healthcare providers and should not always be held to all the same considerations:
 - HIPAA and the Common Agreement (pages 16, 18-19, 46) – HIPAA contemplated the roles of government agencies and public health in great depth and carved out considerations as a result. Additional provisions from HIPAA, that do not currently apply to public health, should not now become incumbent on public health agencies who were explicitly excluded from these HIPAA considerations previously. Public health agencies are health oversight agencies under HIPAA and, in conjunction with federal, state, and local supporting laws, are allowed to receive and transmit patient data without consent in order to assure health security and protect the health of the population. TEFCAs should not try to extend HIPAA to these public health organizations or impact the access and exchange of health information for public health and surveillance where agencies or their agents do not participate in patient access services.
 - Specific language in this draft that releases federal agencies from HIPAA should be extended to include state and local government public health agencies as well. Similar rationales to those that exclude federal agencies, including sovereign immunity and other applicable law also apply:

*A federal, **state, or local** agency that is serving as a Participant and is not otherwise subject to the HIPAA Rules is not required to comply with the HIPAA Privacy and Security Rules referenced in these MRTCs. The federal, **state, or local** agency will comply with all privacy and security requirements imposed by applicable **state and** federal laws.*

HIPAA also specifically authorizes sharing data with foreign governments, in conjunction with US-based public health agencies. This sharing can, at times, be critical in addressing cross-border issues and disease control. Draft 2 of TEFCAs appears to limit even this important international access to data. We believe that the HIPAA exceptions for public health in 45 CFR §164.512 should continue to apply and that public health should be permitted to share information internationally as needed when conducting specific public health activities.

It should also be made clear in TEFCAs that the provisions for individual access services do not apply to public health registries. For established reasons, not all public health information systems currently support direct individual access for patients. In addition to conflicting workflows, at times doing so would conflict with parents' and legal guardian's rights and prohibitions data access. The TEFCAs draft is now silent on how an individual may initially establish a validated identity and how that identification becomes verifiably associated with data stored in secondary and tertiary locations. The workflow and cost impact of these new expectations cannot be ignored.

- In fact, TEFCAs exchange, more than just not violating state (and federal) laws, should explicitly require that "Participants," "Participant Members," and QHINs comply with, and support, state laws. As we noted in our comments on the recent ONC "Blocking" NPRM,

public health needs stronger incentives and support to ensure that state laws are complied with in an ongoing way and federal regulations should be a cornerstone of this compliance.

- We support the ongoing inclusion of a public health permitted purpose in the Common Agreement and request that stronger support of existing laws be advanced rather than additional requirements that would carry new costs for public health agencies that have not been quantified or accounted for.

State and local public health agencies are resource constrained making system modifications to meet technical requirements in federal rules that do not align with new federal funding very difficult. At times these modifications may require substantial effort by public health agencies, many of which must use custom software that limits their ability to share costs and system modifications.

- Individual Exercise of Meaningful Choice (pages 17, 54-55) – While this section says that applicable laws can allow disclosure of information despite someone exercising a “Meaningful Choice” decision to not disclose, more specific language should be added to indicate that QHINs, participants, and participant members need to consider these disclosures and state laws from the beginning as “Meaningful Choice” implementation approaches are advanced. More than not violating state laws, this federal activity should be helping to support their implementation even while advancing standards and infrastructure for “Meaningful Choice.”
- QHIN Fees (page 20) – In a change from the first draft of TEFCA, public health is no longer excluded from paying for QHIN transactions. Public health cannot, and should not, be expected to pay charges for QHIN data exchanges made in support of state laws. These charges would be above and beyond the health information network membership charges for public health agencies that are already difficult for public health to support. The new charges would, among other things, obstruct public health agencies from using data for surveillance work to address disease control, handle emergency response, and develop public policy. The changes made to allow these charges to public health in this second draft of TEFCA should be rescinded. Ensuring the support of public health activities is an inherent government responsibility and should not be left up to decisions of the RCE.
- “Push” data exchange is important to public health, but it is also important to many healthcare and patient data exchange needs as well. The existence of Direct and DirectTrust speaks to the importance of “push” in health information exchange and makes a compelling case for including the Direct health information network in the same trust fabric and single on-ramp as the rest of health information exchanges in TEFCA. Direct needs a more robust trust framework to eliminate point-to-point data use agreements and TEFCA needs Direct to ensure the single on-ramp that is a critical goal of the TEFCA.
- Aside from Direct, the other large health information networks have moved to advance strong trust frameworks. Both the eHealth Exchange and CommonWell now manifest HIPAA Business Associate

authorities across their participants. Important public health activities like electronic case reporting (eCR) and electronic laboratory reporting (ELR) make use of common services platforms that use Business Associate and operations authorities to ease clinical – public health interoperability. TEFCA should extend its trust framework such that HIPAA Business Associate authorities and operational needs can be supported as well.

- The QTF should separate transport and payload standards for “push” exchange. The specific standards used for QHIN to QHIN “push” transport could be executed in several different ways, but TEFCA should insist that for any of them a variety of payloads are allowed (HL7 v2, CDA, and FHIR bundles) and that the “header” information of each of these payloads be kept intact and unaltered through the multi-hop process described in the TEFCA draft.
- In fact, the HL7 FHIR API standards as specified in the QTF do not adequately support “push” messaging through an intermediary because they do not specify a message header. “FHIR Messaging” needs to be specified in addition to the basic FHIR API to support the “push” use through intermediaries that is detailed here. Additional language ensuring that content is delivered to the ultimate participant / individual is also needed.
- Some functional and technical considerations need to be standardized and applied to the participants and participant members that are “behind” QHINs. An example is the consideration for how frequently QHIN data caches will be refreshed to deliver current, up-to-date, query-response data. QHINs should also not completely independently “specify the format and content of acceptable Message Delivery Solicitations.” There should be shared standards for this to be fully functional for “push” messages. There should also be consideration of approaches to patient matching algorithms used by QHINs to help ensure consistency in patient matching strategies and the reliability of any match activity. This strategy must address multiple matching activities as data flows between QHINs.
- ONC will not be able to, and should not, tease out all of these issues that are provided to the RCE, but the RCE should be enabled to develop them in accordance with the industry as it moves forward with its activities. ONC should help establish principles for the RCE including maintaining unbiased relationships with QHINs and other important guardrails.
- The “standards hierarchy” ONC defines of:

Adhere to applicable standards for EHI and interoperability that have been adopted by the U.S. Department of Health & Human Services (HHS), approved for use by ONC, or identified by ONC in the Interoperability Standards Advisory (ISA).

needs to be reconsidered.

Part of the reason for having an (at least semi-) independent RCE, for separating the QTF standards, and for abiding by the National Technology Transfer and Advancement Act, is to avoid individual program and government choices that don’t always represent broad community participation in the way that consensus-based standards development processes do. The ONC “Blocking” NPRM seeks multiple exceptions for ONC from NTTAA requirements to use consensus-based standards and the

standards hierarchy identified here does not adequately ensure public health participation going forward either.

Thank you for listening to some of the public health comments that were suggested for the first TEFCA draft. We would now like to fully engage public health in the organizations, standards, and processes for TEFCA moving forward to ensure that essential public health services can be provided nationally.

Sincerely,

American Immunization Registry Association

Association of Public Health Laboratories

Association of State and Territorial Health Officials

Council of State and Territorial Epidemiologists

National Association of County and City Health Officials