



STATE OF WASHINGTON
DEPARTMENT OF HEALTH

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June 17, 2019

The Honorable Donald Rucker, MD
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C Street SW, Floor 7
Washington, D.C. 20201

Dear Dr. Rucker:

RE: Request for Comments, “Trusted Exchange Framework and Common Agreement Draft 2”

The Washington State Department of Health (DOH) submits the following comments on Appendices 1, 2, and 3 of the Trust Exchange Framework and Common Agreement (TEFCA). As a public health agency, DOH has many programs that receive and send data to clinical data partners through their health IT systems. DOH strives to make transacting data with public health information as seamless and efficient as possible for health care providers. Our agency has embraced the interoperability standards set forth by ONC for public health measures and believe this work has been essential to make public health reporting more efficient for both healthcare providers and public health agencies. DOH asks that ONC consider the vital work of public health when defining how TEFCA operates. TEFCA should help further streamline and benefit the exchange of data between healthcare providers and public health.

The ONC proposed rule on interoperability requests information on TEFCA. In light of that request, DOH does see benefit in requiring health IT developers, health information networks and health information exchanges to participate in TEFCA. Having a common framework to ensure data exchange can happen securely and in a standardized way to reduce costs is important. However, DOH requests that many TEFCA requirements not be put on public health agencies due to lack of resources available to meet such requirements (*see details below*). In addition, those requirements should not fall on vendors contracted to operate public health registries, as those costs would likely be passed on to public health agencies.

DOH’s specific comments listed below reference page numbers based on the updated TEFCA draft 2, posted online [here](#)¹:

- Qualified Health Information Network (QHIN) Fees (page 20) – Given the importance of public health reporting, and its requirement in state or federal law, DOH strongly objects to removal of the provision that prohibited a QHIN from charging a fee to respond to queries

¹ <https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement>.

for public health. DOH strongly requests the language from TEFCA 1.0 be reinstated to clarify that fees cannot be charged for public health data exchanges. This is critical to support the ongoing population health work of public health, protect our ability to receive standards-based health IT messages of disease reporting (advanced in eCR, public health registries, and electronic laboratory reporting), as well as responses to queries regarding non-notifiable conditions, such as federated queries regarding hypertension and diabetes, and other non-notifiable conditions, such as neonatal abstinence syndrome and acute flaccid myelitis. DOH is concerned that fees, even if reasonable by HIT standards, would quickly become onerous and decrease the data exchange on which modern public health departments depend.

- QHIN Technical Framework (pages 69-86) – The framework relies almost completely on Integrating the Healthcare Enterprise (IHE) standards and transactions, which do not represent most health information exchange implementations today. Most public health transactions (for example, immunizations) are not currently implemented with IHE technologies. DOH is concerned that this framework may make it difficult to ensure public health transactions can be easily sent between two QHINs and would suggest that standards-based implementations in use today, such as HL7 standards, be supported. DOH recommends end-to-end encryption to ensure the privacy and security of patient information. DOH recommends that QHINs be required to follow national standards set by ONC for public health exchange in the ISA. This proposal may impose costs on public health to receive and parse messages not transmitted in a standard currently in use.
- Individual Access Services (pages 15, 35, 41-44, 48, 53-54, 58, 61-62, 65-68) – DOH appreciates the goal of ensuring patients have access to their own information. However, public health has not been provided with adequate resources to ensure it could respond through a QHIN to an individual’s access service request. Additionally, public health agencies are not covered entities or business associates under HIPAA and should not be treated as such. Some public health laws and rules do not allow individuals to access their own data or restrict how access is obtained. (For example, a state rule requires the patient to come in-person with photo ID for identity proofing.) DOH requests that public health be provided a specific exemption from this requirement as HIPAA does. We suggest updating 8.21 on page 67 to extend the exemption provided to federal agencies to include state agencies, and to clarify that such agencies may respond to individual requests only when laws allow and via methods they have resources for. DOH is also concerned that the framework does not indicate clearly who is responsible for tracking the requests and ensuring responses reach the individual.
- Individual Exercise of Meaningful Choice (pages 17, 54-55) – While this section states that applicable laws can allow disclosure of information despite an individual exercising the right to not disclose, DOH would like to see specific clarity for public health reporting. Lack of clarity is detrimental to public health agencies’ core mandates to prevent and control diseases and would put the population of every state at risk. Public health has specific provisions under HIPAA as a “health oversight agency” that allow the collection of data without patient consent and this provision must be echoed and supported in the TEFCA more clearly.

- Public Health Definition (pages 38-39) – DOH appreciates that the draft defines public health exchange purposes in light of the permitted disclosures HIPAA allows to health oversight entities. It is vital the exchange supports public health purposes and activities. It is also vital that public health not be held to the same requirements as covered entities or business associates with regards to issues such as patient consent and charges for responding to public health queries. Public health agencies use aggregate data for surveillance work to help address disease control, prevention and policy analysis. Public health also has programs that deal directly with identifying patient information for case management, care coordination, and helping providers make informed treatment decisions.
- Definition of Electronic Health Information (page 34) – DOH asks that this key definition is reconciled fully with the proposed rules for interoperability and the U.S. Core Data for Interoperability (USCDI).
- Exchange Purposes (pages 14-15) – DOH appreciates having public health listed as a required purpose of the exchange. It is essential work that public health leverage the exchange to receive and send data to our clinical partners. This is sometimes a bi-directional exchange that helps providers with patient care and helps public health carry out our important responsibilities.
- QHIN Message Delivery “push” (page 14, 39-44) – Public health has many registries that have laws in place mandating reporting. Having a “push” based query added to the exchange framework is important to help clinical partners meet these mandates to submit data automatically when an appropriate code indicates the condition is notifiable. The definition of the QHIN Message Delivery seems mostly adequate, except that it is defined too vaguely about whether or not a receiving QHIN must ensure the message is delivered to the required participant or individual. The definition states there is no obligation to further transmit it, which is not clear. DOH suggests clarifying that if a QHIN receives a push request, it should ensure delivery within its network to the requestor or ensure it goes to the QHIN where the requestor is a member. DOH also asks that DirectTrust/Direct be added as a method by which data can be pushed to public health agencies. This is in use already and would ensure the trust framework applies to Direct. DirectTrust/Direct would also help promote the single “on-ramp” concept in the network.
- Initial Application, Onboarding, Designation and Operation of QHINs (pages 39-41) – DOH appreciates the robust process outlined to properly vet and approve QHINs. This is vital to ensuring the trusted exchange meets its goals. There is still some clarity needed in understanding what types of entities can and cannot apply to become a QHIN, particularly what type of relationship a QHIN applicant could have with the approving recognized coordinating entity (RCE). The RCE must remain unbiased in its review and approval process.
- Health Care Stakeholders (page 10) – DOH appreciates and approves of public health agencies being specifically included as stakeholders. Public health agencies have an important role in helping achieve population health and individual health. DOH requests that

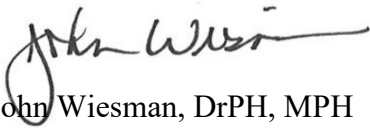
public health be formally invited to workgroups and other meetings in the future that will continue this work. DOH encourages ONC to ensure collaboration with important federal partners, such as CDC, which operates several systems that public health agencies use. These systems could likely be impacted by TEFCA and may need to be enhanced.

- Recognized Coordinating Entity - RCE (pages 10-11) – DOH recommends language be added in the TEFCA to address how the RCE will handle issues when an approved QHIN is found in violation of any required components of TEFCA. While work is done up-front to approve their practices before qualifying them, the proposal thus far does not cover how breaches of compliance will be handled. DOH feels this is important to ensure privacy, security and interoperability. DOH recommends the formation of an advisory council, including public health, to the RCE and ONC to help establish the initial framework and conduct oversight. Federal funding should be used for travel costs to ensure all stakeholders can attend. DOH also recommends funding be made available to the RCE to establish a technical assistance center that could provide consultation to public health and others trying to utilize the framework. The previously funded regional extension centers for HITECH may be an avenue for this type of technical assistance.
- The Common Agreement's Relationship to HIPAA (pages 16, 18-19, 46) – Public health agencies are specifically listed as health oversight agencies under HIPAA and are allowed to receive and transmit patient data without consent. DOH requests specification that the minimum necessary requirements from HIPAA will not apply to public health agencies participating in a QHIN and that the ability of public health to receive and transmit patient data without consent will continue in TEFCA. TEFCA should more explicitly speak to how the framework can help with meeting reporting requirements under federal and state laws, including reporting to public health.
- 6 Principles (pages 24-30) – DOH appreciates the layout of these principles to guide TEFCA. DOH especially supports the call to adhere to standards in the ONC Interoperability Standards Advisory (ISA), making terms, conditions and contractual agreements public, ensuring HINs do not treat EHI as an asset for competitive advantage, and the ability to obtain multiple patient records.
- Patient Identity Resolution (page 83) – DOH believes patient matching is critical for promoting improved patient safety, better care coordination, advanced interoperability and for improved public health surveillance. DOH would welcome ONC taking on a role in standardizing how master person indexing is done, including support of CMS' RFI to require a CMS-wide identifier and standardization of data elements for matching. Ensuring interoperability between public health, insurance companies and clinical providers is a critical long-term effort that is built on robust and flexible patient matching, including adjustable deduplication controls built-in for jurisdiction-specific choices. DOH requests that public health is represented in any stakeholder work performed. DOH recommends the same approach taken by CMS for Medicaid and Medicare. If TEFCA cannot at this time address patient matching, DOH would encourage this draft to require the RCE to establish standards for QHINs to follow.

DOH strongly supports continued required reporting in the areas of immunization, syndromic surveillance, vital records, case reports, disease and clinical registries and others. Federal support for public health reporting must remain strong. DOH also recommends the TEFCA framework strengthen strong public health surveillance to protect the public.

DOH looks forward to partnering with HHS to further this important work. Thank you for the opportunity to provide comments on this draft.

Sincerely,

A handwritten signature in black ink, appearing to read "John Wiesman", with a long horizontal flourish extending to the right.

John Wiesman, DrPH, MPH
Secretary of Health