

June 17, 2019

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

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

Dear Dr. Don Rucker:

The Digital Bridge initiative is pleased to submit the following comments in response to the Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2.

A partnership of key decision makers in health care, public health and health information technology (IT), Digital Bridge creates a forum for these stakeholders to collaborate on ideas and solutions for a nationally consistent and sustainable approach to using electronic health data. Through this collaboration, Digital Bridge fosters a better connection between health care and public health, a relationship that is integral to efficient public health surveillance. For the initial use case, Digital Bridge partners aim to build a multi-jurisdictional approach to electronic case reporting (eCR), reducing the manual burden of public health reporting by automating the data exchange process and implementing a single standard for reporting criteria.

Attached is additional background on this initiative and comments on the issues and challenges related to the current state of data exchange between health care and public health. The Digital Bridge governance body¹ commends ONC's efforts to create the technical and legal requirements for sharing electronic health information at a nationwide scale across disparate health information networks.

Data exchange between and with health care organizations enables a critical part of public health practice. The inter-network connectivity, single on-ramp, and public health permitted purpose of both the first and second TEFCA drafts can be critical elements of supporting these exchanges electronically now that electronic health records (EHRs) are prevalent. The potential value of TEFCA in supporting public health is dependent on both the trust and technical aspects of the proposal 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 this addition of "push" data exchange in this second TEFCA draft.

¹ Allscripts, American Medical Association (AMA), Association of Public Health Laboratories (APHL), Association of State and Territorial Health Officials (ASTHO), Cerner, Council of State and Territorial Epidemiologists (CSTE), eClinicalWorks, Epic Systems, Health Partners, Intermountain Healthcare, Kaiser Permanente, Meditech, National Association of County and City Health Officials (NACCHO), Robert Wood Johnson Foundation

We believe ONC must be careful to strike a balance between an initiative that is industry-driven and one that is government-driven. In regards to leadership, we recommend that private industries play this role opposed to government. For example, the Recognized Coordinating Entity (RCE) should be given more autonomy and be less beholden to ONC.

Further, we recommend a modification to the approach and urge ONC to consider a governance structure that is open, transparent and participatory to ensure ONC and the RCE will not make unilateral decisions related to the Trusted Exchange Framework (TEF). Public health—among other stakeholders—must be represented in the governance structure. Public health is a critical component of the nation’s health infrastructure, and its early and engaged participation in the electronic underpinnings of that infrastructure will be needed going forward to support it.

We urge ONC to architect the TEFCA in a manner that avoids over-engineering the health information exchange and health information network ecosystem. The entire TEFCA should be rethought and restructured to eliminate granular, prescriptive, and restrictive elements and focus on defining guardrails that foster competition, flexibility and innovation for health information networks to operate under. Failure to do so may result in an elective framework where too few entities choose to participate due to concerns of high risk and low benefit.

The economic impact of the TEF and Minimum Required Terms and Conditions Draft 2 are troublesome and warrant further examination. For example, Draft 2 appears to suggest that Qualified Health Information Networks (QHINs) may charge other QHINs to respond to queries for public health. We find such a fee structure concerning and counterproductive to the mission of protecting the public’s health.

Please send any questions or concerns to info@digitalbridge.us.

Sincerely,

A handwritten signature in black ink that reads "Vivian Singletary".

Vivian Singletary, MBA, JM
Public Health Informatics Institute
Co-Principal Investigator, Digital Bridge

About Digital Bridge

Digital Bridge is a public-private partnership among health care delivery systems, health information technology (IT) developers and public health agencies to enhance bidirectional information flow between health care and public health.

As its first project, Digital Bridge has designed a nationally scalable, multi-jurisdictional approach to electronic case reporting (eCR), the automated generation and transmission of case reports from the electronic health record (EHR) to public health agencies for review and action. To effectively test the technical approach, Digital Bridge is coordinating eCR implementations at selected demonstration sites through 2019.

More details and a list of participants are available at digitalbridge.us.

Digital Bridge comments

Digital Bridge is invested in identifying and leveraging legal, policy and regulatory frameworks that minimize risks to the privacy and security of protected health information while also fostering increased data sharing to promote a culture of health. Our demonstration of an automated and standardized approach to eCR ([details here](#)) testifies our resolve and the depth of our experience. Our comment to the ONC offers our unique perspective and experience and highlights opportunities.

We offer specific comment on ONC's Draft 2 of the Trusted Exchange Framework and Common Agreement (TEFCA) released on April 19, 2019 with regard to the following:

- Introduction to the Trusted Exchange Framework and Common Agreement (TEFCA)
- Appendix 1: The Trusted Exchange Framework (TEF)
- Appendix 2: Minimum Required Terms & Conditions (MRTCs)
- Appendix 3: Qualified Health Information Network (QHIN) Technical Framework (QTF)

Comments on Introduction to the Trusted Exchange Framework and Common Agreement (TEFCA)

An "On-Ramp" for Data Exchange

We support the three overarching goals laid out for the TEF and Common Agreement to provide a single "on-ramp" to nationwide connectivity, enable electronic health information (EHI) to securely follow the patient when and where it is needed, and support nationwide scalability. An additional goal of TEFCA should be to empower market-driven solutions in support of health information exchange.

The Trusted Exchange Framework (TEF)

Digital Bridge partners believe interoperability should be added to the common set of principles designed to facilitate trust between HINs. Another additional principal should be that of open, transparent and participatory governance.

The Common Agreement

We caution that the Minimum Required Terms and Conditions (MRTCs) are too extensive, complex and granular as currently written and may discourage voluntary participation.

Recognized Coordinating Entity (RCE)

We applaud ONC's recognition of the importance of public-private partnerships and setting forth the cooperative agreement.

We applaud transparency and openness to avoid unilateral decision making. To create a true private-public partnership and an open, transparent and balanced participatory governance structure and process, ONC should involve representation from all affected stakeholders, including public health. Public health is a government-organized and population-focused activity that has both a different legal basis and needs than purely patient or provider-orientations. In the TEFCA, processes are cited that will impact public health but in which public health has had no representation.

An additional role of the RCE should be to assess the readiness of the industry to implement the suggested technical and legal requirements for sharing EHI.

Qualified Health Information Networks (QHIN)

We urge ONC (and the eventual RCE) to ensure that QHINs are open to all participants and that the technical capability requirements do not represent burden that will effectively exclude certain groups of health information networks.

Is the intent that QHINs can exclude certain stakeholders from participating in their network? If they are expected to be open and transparent, they might be at risk of violating non-discriminatory practices if they exclude certain entities and individuals as participants.

Participant, Participant Members and Individual Users

Are participants in a QHIN required to be open and transparent? If so, they might also be at risk of violating non-discriminatory practices if they exclude certain organizations or individuals from becoming a participant member.

If individual users are going to have direct relationships with the various QHINs, the QHINs will potentially have to manage many layers of participants (e.g., many HIEs, health care organizations, vendors, and individual users). This burden may be detrimental for the operation of the QHINs and preclude them from delivering on their other responsibilities, particularly if the individual user to QHIN connection is high volume. Individual users may be at risk of being overshadowed by other larger and more complex participants of the QHIN, and the QHIN might not be able to appropriately address individual user needs. Should QHINs instead be kept at a higher level of this structure, as to avoid having a QHIN connected to individual users? At a minimum, if QHINs will be connected to individual users, the governance and infrastructure to enable this must be addressed to avoid overwhelming burden and perhaps be allowed but not encouraged.

Exchange Modalities

Digital Bridge applauds ONC's inclusion of QHIN Message Delivery as one of the required exchange modalities. "Push" data exchange is important to public health, but it is also important to many health care and patient data exchange needs as well.

We recommend ONC clarify if or how the principle of population level data exchange will be achieved within the confines of the remaining exchange modalities, now that the population-level data exchange has been removed.

It seems there are really two types of QHIN exchange modalities: pull and push. Each of these two modalities can be used for one specific individual or a group of individuals, and can be used with one other specific QHIN or with multiple QHINs at once, creating a matrix of options to combine pull or push, for an individual or a group, and by a single or multiple QHINs. The importance of this is that it eliminates the concept that there are "only" three exchange modalities to be supported, missing the critical interdependencies between the key elements of individual/multiple individuals and single/multiple QHINs.

Exchange Purposes

We commend the continued inclusion of public health as one of the six exchange purposes.

The identification of selected administrative exchanges (benefit determination, subset of payment information) seems unfounded. QHINs should be free to support any and all treatment, payment, operations, public health, research and other purposes.

Phased Approach

We have concern that ONC intends to control the evolution of the TEF and unilaterally decide phasing in new exchange modalities and purposes. Again, we emphasize the importance of establishing a strong open, transparent and participatory governance structure and process.

As currently written, QHINs could have incredibly detailed requirements put upon them. We encourage ONC and the RCE not to micromanage what would otherwise be a market-driven process.

Common Agreement Relationship to HIPAA

The sheer number of mandatory requirements, granularity of them, complexity and level of burden they create calls for a complete overhaul of the approach. These requirements will discourage and create barriers, rather than encourage HINs, participants and participant members to participate voluntarily.

We have strong concerns about the intent, purpose and unintended consequences of the meaningful choice requirement. This seems to go beyond a simple opt-out from having a patient's data be exchanged via a HIE, to affect all EHI being used and disclosed via the Common Agreement, which may affect much of the data that health care providers might exchange.

Meaningful choice is one of the more complex requirements, imposing a sort of 'consent' or 'authorization' for any access, use or disclosure by and from any QHIN, participant and

participant member. As currently written, it is an "all or nothing" activity: an individual cannot selectively withhold certain data while allowing other data to flow. This may be necessary due to technical limitations, but it has the potential to block mandatory reporting to a public health agency in jurisdictions where patients are allowed to opt-out.

Meaningful choice represents such a significant national topic that we recommend such a change not be ordered and required through a contract. We believe this would be best handled appropriately by congress via law and by the Office of Civil Rights via regulation—not by ONC via contract provision. We recommend meaningful choice be limited to consent for an individual's data to be exchanged via the TEFCAs.

We support breach notification being consistent with the HIPAA breach rule.

We note that the written notice requirement overlaps with the Notice of Privacy Practices for covered entities and creates a new level of requirement in terms of consumer privacy. What is the motivation for creating two levels of expectations?

We believe that the minimum security requirements for QHINs should be consistent with the HIPAA Security Rule and should avoid adding, modifying or overlapping requirements from the HIPAA Security Rule. We are concerned that some of these minimum security requirements would not apply to Participants or Participant Members. Whether an entity is handling data on the entire country or one individual—the bar should be set at the same level, and that should be a high bar.

While we are supportive of the idea that the HIPAA Security Rule should apply to QHINs, participants, and participant members, additional provisions from the HIPAA Privacy Rule should not now become incumbent on public health agencies that were explicitly excluded from these considerations previously. Public health agencies are health oversight agencies under HIPAA and, in conjunction with supporting laws, are allowed to receive and transmit patient data without consent. TEFCAs should not try to extend the HIPAA Privacy Rule to these organizations where they do not participate in patient access services.

Moreover, TEFCAs exchange, more than just not violating state (and federal) laws, should explicitly require that participants, participant members and QHINs should comply with, and support, state laws. 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.

Regarding the requirement that no EHI be used or disclosed outside of the United States, while the consumer has control over the decision to use or disclose their EHI outside of the US, there must be consideration of situations when the best interest of the patient prevails even if the patient is unable to make such a decision. A blanket prohibition included in the MRTCs seems excessive and inappropriate.

We have concerns with a requirement to adopt SAMHSA's Consent2Share sensitivity value set as well as Data Segmentation for Privacy. This concern could potentially be mitigated if these

guidance documents were appropriately vetted and if other approaches to solve this issue were considered.

Comments on Appendix 1: The Trusted Exchange Framework (TEF)

Overview

Digital Bridge partners express strong support for each of the six principles for trusted exchange. We additionally recommend ONC consider two more principles:

1. Principle of Interoperability: Use of standards and technologies that support interoperable exchange of individual and population level information.
2. Open, Transparent and Participatory Governance: Establishing a governance structure that is open, transparent and participatory and that is ultimately responsible for decision making on all TEFCA matters.

Principle 1 – Standardization: Adhere to industry and federally recognized technical standards, policies, best practices and procedures.

The standards adherence hierarchy outline is helpful. However, we encourage greater input from consensus-based standards development organizations to influence the decision of which standards must be used within the context of TEFCA. Doing so would create an opportunity for ONC to encourage open, transparent and participatory governance.

Principle 2 – Transparency: Conduct all exchange and operations openly and transparently.

We applaud the inclusion of transparency as a critical principle. This principle should apply not only to the HINs, but also the governance of the entire TEFCA.

Principle 3 – Cooperation and Non-Discrimination: Collaborate with stakeholders across the continuum of care to exchange EHI, even when a stakeholder may be a business competitor.

We agree with this principle; however, cooperation and non-discrimination should apply to all entities involved. There should be non-discriminatory practices regarding participation in the HINs.

Principle 4 – Privacy, Security, and Safety: Exchange EHI securely and in a manner that promotes patient safety, ensures data integrity and adheres to privacy policies.

Consumers/individuals should be able to exercise meaningful choice within the terms of the law (federal and state) and should primarily be limited to choosing to have their data exchanged via the common agreement. Our concern, as noted above, is the degree to which the meaningful choice requirement implements a 'consent' or 'authorization' across the board—by all QHINs, participants, and participant members—to access, use or disclose any patient data and elevates the bar from current HIPAA policies that exempt treatment, payment and operations from patient consent. This significant change should not be done via a provision in a contract.

Principle 5 – Access: Ensure that individuals and their authorized caregivers have easy access to their EHI.

We agree with this principle and encourage its expansion to more than just individuals' access, but also access by other entities, when appropriate and necessary.

Principle 6 — Population-Level Data: Exchange multiple records for a cohort of individuals at one time in accordance with applicable law to enable identification and trending of data to lower the cost of care and improve the health of the population.

This principle seems to be misplaced; it should be a supported purpose, rather than a principle. Also, there should not be a limit or maximum number of records at one time.

Comments on Appendix 2: Minimum Required Terms & Conditions (MRTCs)

Definitions

We believe TEFCAs do not yet adequately define EHI. As in our recent comment letter to ONC regarding the 21st Century Cures Act, we recommend that EHI should have the same content definition of protected health information (PHI) under HIPAA and that the only difference is in *who* holds the data. In other words, the same data considered PHI in the hands of a covered entity would be EHI if in the hands of a non-covered entity.

Regarding the definition of a health information network (HIN), we are concerned that the definition refers to “an individual or entities” when it should really only refer to entities. Additionally, we raise the concern that the definition states “...define business, operational, technical, or other conditions or requirements for enabling access, exchange or use of EHI between or among two or more unaffiliated individuals or entities.” This inclusion is too broad, and could encompass, for example, entities that define operational requirements for use of EHI – which can hardly be considered a HIN. We recommend dropping “use” from the HIN definition in both instances where it appears.

Regarding meaningful choice, we echo the sentiments expressed earlier in this letter. This definition is setting a new level of policy regarding consumer ‘authorization’ beyond an opt-out from having their data be exchanged via the TEFCAs framework. Our main concerns are summarized below:

1. Creating a new level of consumer ‘consent’ or ‘authorization’ at this level and with such profound implications is a shift that should be established via legislation, not via a voluntary contractual agreement.
2. It seems to apply to not just HINs, but participants and participant members, which would extend into health care organizations and their current practices.
3. It applies to use or disclosure of EHI, with the use part having many unforeseen consequences for participants and participant members.

2. Initial Application, Onboarding, Designation, Operation of QHINs

Section 2.2 (QHIN Operations) defines granular and prescriptive details for each and every one of the functions, actions, roles, responsibilities, limitations and options of the operations of a QHIN. Statements like “the QHIN Query is only for one or more of the Exchange Purposes and is initiated in one of the following ways...” demonstrate the prescriptive and restrictive nature of the approach. This entire section should be restructured to eliminate all granular, prescriptive and restrictive elements, and focus on defining guardrails that foster competition, flexibility and innovation for health information networks to operate under.

The ability of a QHIN to have direct relationships with individuals is a concern, as they might end up serving hundreds of thousands or even millions of individual members, diluting and constraining their ability to serve their participants and participant members.

3. Data Quality and Minimum Necessary

The Minimum Necessary provisions that are intended to be applied to QHINs for any request, use or disclosure of EHI do not take into account that under HIPAA there are certain exceptions of the applicability of Minimum Necessary – for example, when the purpose is for treatment.

Regarding the applicability of individual access services to public health agencies, agencies have not been provided with adequate resources to ensure they could respond to an individual’s access service request through a QHIN. Also 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 (e.g., a state rule requires the patient to come in person with photo identification for identity proofing). We request that public health be provided a specific exemption from this requirement as HIPAA does. A suggestion is to update 8.21 on page 68 to extend the exemption provided there to federal agencies to state and local agencies as well.

5. Cooperation and Non-Discrimination

In a change from the first draft of TECCA, 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 TECCA should be rescinded.

6. Privacy, Security and Patient Safety

Regarding breach notification, there are already federal and state requirements to comply with, which include giving notice to individuals (even if the QHIN does not have a direct relationship), state attorney generals, and others.

We understand in section 6.1.5 that the Written Privacy Summary is supposed to be modeled on the ONC Model Privacy Notice, with additional information. Yet, in another part of this section, it says that QHINs must comply with all HIPAA regulations (which include a Notice of Privacy

Practice). For simplicity, we recommend that the Written Privacy Summary should be simply equated to the Notice of Privacy Practice under HIPAA.

Regarding minimum EHI security requirements, why not simply state that QHINs must comply with all HIPAA security requirements? As written, the minimum EHI security requirements seem to be less rigorous than those required by covered entities.

7. Participant Minimum Obligations

The goal of this section should, again, be to establish appropriate guardrails rather than micromanage the various interactions of participants.

9. Individual Rights and Obligations

The content of the summary section does not seem to exclude disclosures made for treatment, payment or operation except to say that if it is a covered entity, the requirement is met by meeting the HIPAA Accounting of Disclosure requirement. This provision is confusing and could be misleading for consumers.

Comments on Appendix 3: Qualified Health Information Network (QHIN) Technical Framework (QTF)

Overall, the section is also over prescriptive. It currently reads not as a framework, but rather a prescriptive manual of every element with which a QHIN must comply. We fear that this many detailed, granular, prescriptive and restrictive requirements will, by themselves, discourage any HIN from voluntarily becoming a QHIN and a part of TEFCa. We instead encourage ONC to eliminate all the prescriptive requirements and establish guardrails for QHIN implementation.

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.” ONC will not be able to, and should not, tease out all of these issues. Rather, as ONC has stated, the RCE should be enabled to develop them as it moves forward with its activities.

The issue of patient matching across the health care ecosystem continues to be a serious obstacle to interoperability. The description of patient matching for query purposes within the MRTCs presents a simplistic view of patient matching with no recognition of the complexity of uncertain matches, multiple matches and similar challenges. 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 practical difficulties.