Comment Letter to the Office of National Coordinator on the Proposed Trusted Exchange Framework and Common Agreement Draft 2

JUNE 14, 2019

Dr. Donald Rucker, National Coordinator for HIT
Office of National Coordinator
U.S. Department of Health and Human Services
330 C St SW
Floor 7
Washington, DC 20201

Subject: Proposed Trusted Exchange Framework and Common Agreement Draft 2 Comments

Dear Dr. Rucker:

On behalf of HealtHIE Nevada, the state-wide health information exchange in Nevada, I have prepared these comments on the Proposed Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2. I am the Executive Director of HealtHIE Nevada and the former Chief Technology Officer for Vermont Information Technology Leaders. I have over 15 years of direct experience in health information exchange from both technical and executive leadership perspectives.

Overview

Core Comment 1: I continue to support the ONCs efforts to create a framework for nationwide clinical data interoperability. The changes made in this Draft 2 of the TEFCA are a major improvement and address many of the comments I made in the first draft. Specifically the addition of QHIN Targeted Query and QHIN Message Deliver to the new draft are a major improvement. Although not specifically part of the TEFCA the requirement that health IT vendors publish open APIs is also a major step forward.

I believe that the concept of “empowering individuals to use their Electronic Health Information to the fullest extent” is a laudable goal but I do not think that many patients will be engaged enough to personally take control of their health data. Many patients believe that clinical data exchange already happens between providers and only when they experience the lack of exchange firsthand do they recognize the problem. We have a few patient success stories here in Nevada about effective exchange of data but far more that demonstrate the lack of exchange. On the other hand, if we can successfully market the effectiveness of the HealtHIE Nevada exchange to consumers as a capability that makes data exchange happen and get patients to sign a “consent” form which requires their data to be sent to the HIE, then we can enable the exchange of health data across the state.
The adoption of the USCDI 2.0 as a standard for exchange of information with associated terminology standards is a reasonable incremental step towards creating a base set of data elements that must be shared. I see this as an improvement over the CCD C32 or C-CDA albeit a small one.

**An On-Ramp for Data Exchange**

The ONCs mentions three high level goals of:

- Provide a single “on-ramp” to nationwide connectivity.
- Enable Electronic Health Information to securely follow the patient when and where it is needed.
- Support nationwide scalability.

Comment 2: The idea that there is a single “on-ramp” to national exchange makes sense theoretically but in practice may not produce the most effective nationwide network. I worry that providers will take the cheapest route not the most effective one and will only meet the minimum qualifications of exchange. If a provider is offered a free service from an EHR vendor which only does basic (broadcast) query-response and messaging using Direct that would probably meet the letter of the law, and they would not be deemed to be “information blocking.” But this solution might only be marginally effective if there is no master patient index or recipients are expected to send and receive messages with Direct. On the other hand, if they are offered access to an HIE that can provide services such as lab results delivery, event notification, an indexed community record and interoperability with other HIEs but there is a cost for this service, many providers will choose the cheaper option rather than the one that provides the most value to patients. In the Nevada market fee-for-service is still the most prevalent payment program for hospitals and providers and most of them are for-profit. Without incentives to provide more effective exchange of data most providers will view this as an additional burden and cost.

Comment 3: I whole heartedly support the second goal as this is the core mission of HIEs. But as mentioned in Comment 2 if many providers take the less expensive “on-ramp” then we may not meet this goal. Most healthcare delivery is local.

Comment 4: We collectively should be looking at and planning for nationwide extensibility as well.

**Qualified Health Information Networks**

Exchange Modalities
Comment 5: I don’t think population level data exchange should be removed but it could be optional and planned to be required in the future. Those organizations that apply to be QHINs would get “extra credit” for having this capability now but it would not be a requirement. The RCE should measure the maturity of interoperability of each QHIN and while there would be a set of requirements at the floor there would also be more advanced levels of use cases perhaps mimicking what Beckers described as functional, structural and semantic.

Comments 6: We strongly support and appreciate the addition of Targeted Query and Message Delivery to this draft.

Exchange Purposes

Comment 7: We generally support the modifications to the Exchange Purposes especially the modification to Individual Access Services which allows for an individual to obtain a copy of their records as opposed to being able to view them online.

Phased Approach

Comment 8: The phased approach makes sense but perhaps an approach that has both required and optional exchange modalities and use cases would be a consideration. Optional exchange modalities and use cases would eventually become required over time and those QHINs that implement more advanced use cases would be “scored” as a higher level.

The Common Agreement’s Relationship to HIPAA

Comment 9: App developers and other users of EHI must now sign Business Associate Agreements so this practice should become a requirement for use of EHI.

What Privacy and Security Requirements are Included in the Common Agreement?

Meaningful Choice and Written Privacy Summary

Comment 10: Here in Nevada we require a patient to Opt-In for viewing their EHI by participants and are considering changing to Opt-Out. Opt-In creates a significant burden on providers and patients and does not improve the privacy of EHI. Patients who wish to Opt-Out can still do so. Data we have collected over the last 3 years shows that approximately 95% of Nevada patients Opt-In when asked but unfortunately, we have only asked about half of the 3.5M patients in our MPI. From our research only about 6 states have consent regulations or polices which require Opt-In or something more stringent. We strongly recommend that ONC creates a nationwide standard for Meaningful Choice of Opt-Out for Use and Disclosure (with some additions for 42 CFR Part 2 data) and does not impose any Individual restrictions on the transmission of the data to any Participant Member or QHIN. If an Individual is allowed to restrict the transmission of data to a Participant Member or QHIN it can lead to gaps in their medical record which can be nearly impossible to obtain at a later date.
Minimum Security Requirements

Comment 11: I do not believe that the proposed security requirements for QHINs are enough. The minimum requirements should be an accreditation by EHNAC with a preferred for HITRUST. This will eliminate some organizations from being QHINs but the bar should be high for QHIN security.

Security Labeling

Comment 12: Security labeling should not be implemented in this version of TEFCA. There are going to be numerous issues with this that will not be implemented in EHRs in a way that allows for surgical precision. Rather you are recommending that the labeling happens at the highest level of the document. Too many EHRs have text-based sections of their documents that could contain notes relating to mental health, substance abuse and STDs. This will end up limiting access too many documents and medical records that really should not be labeled as sensitive. We strongly recommend that you only impose this limitation on specific data for 42 CFR Part 2 and not extend the limitation to mental health, basic substance abuse and STDs.

Major Updates to Draft 2 of the TEF and MRTCs

Comment 13: Separating the standards into the QTF is a good idea. It provides more flexibility.

Trusted Exchange Framework

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

A. 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).

Comment 14: Standards are sometimes tricky to implement in a HIN. As you are well aware the issue is not that standards don’t exist but that they are not universally adopted. HINs need to be flexible enough to collect data using almost any method needed but then need to communicate with other QHINs using standards. Also, the most adopted and universal standards may not be the most recent and functional. There should be a minimum set of requirements, but newer standards should be allowed. Standards must not become the “lowest common denominator” for interoperability but should be the minimum requirements for participation.

B. Implement technology in a manner that makes it easy to use and that allows others to connect to data sources, innovate, and use data to support better, more person-centered care; smarter spending; and healthier people.
Comment 15: Technology should be easy to use but, in this case, we are talking about access to data vs. use of a service like a web portal. I would slightly rephrase and change the context of this to technology is easy to use, data is available to access and data quality is managed in a way that supports better, more person-centered care; smarter spending; and healthier people.

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

Comment 16: No specific comments

**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.

A. Do not seek to gain competitive advantage by limiting access to individuals’ EHI.

Comment 17: I completely agree with the principle, but the implementation must be well thought through. HealthIE Nevada is a state wide HIE and gets very little state and federal funding. We have invested millions to build the network over the last 8 years and I must be able to sustain my operations and have enough revenue to build new services. I do this by providing value added services to my participants that they are willing to pay for. The key phrases are “business competitor and “competitive advantage.” In the context of a provider organization withholding EHI from another provider who also is treating the patient then the context of open sharing is acceptable, and we already do this as part of our mission. But in the context of sharing data with an application provider who competes with a service I also provide (e.g. event notification services) then I need to be able to charge a significant fee. If they want to develop a competing HIE infrastructure, then that is a fair competitive practice. But if I am expected to provide them with aggregated, indexed, standardized, and normalized data that they can collect and store then the fee is going to be very high. Even if they are not allowed to aggregate the data, the transaction fee must be significant. So, the key here is a better definition of “business competitor.” Participants in my HIE or other HIEs that cover different geographies are not my business competitors. But application providers who compete with me for services within my geography are business competitors.

**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.

A. Ensure that EHI is exchanged and used in a manner that promotes safe care, including consistently and accurately matching EHI to an individual.

Comment 18: This is a complex topic and will be challenging to fix with just your recommendation about how “HINs should agree upon and consistently share a core set of demographic data each time that EHI is requested.” We can agree within my HIN with the required fields in an ADT message but how do we ensure the data accuracy and
quality of these fields? We are at the mercy of low paid registration clerks at health care organizations of all shapes and sizes. We can all agree to send a phone number but when the number comes across as “999-999-9999” what good is that? No matter how sophisticated the algorithm it cannot resolve inaccurate data entry. And since there are no incentives for providers to make this process effective (it doesn’t impact their ability to bill for services) the chances of this being fixed in this manner are low. We need a more effective solution, and I can see one carrot approach and one stick approach. The carrot approach would be to fund HINs to implement some form of biometrics to aid in patient identification. It could be as simple as a driver’s license or taking a picture of the patient or something more complex like iris scans. ONC or CMS could fund some demonstration projects that show improvement in patient matching rates and then pick one or more methods that could be adopted. Funding this would be a major help. The stick approach is to require improved data entry from each HIN participant and then measure how well they do. If they do not meet the requirements, then this could be considered “information blocking” and they would be subject to the associated penalties.

B. Ensure providers and organizations participating in data exchange have confidence that individuals have the opportunity to exercise meaningful choice, if and when it is needed, prior to the exchange of EHI.

Comment 19: I mentioned Meaningful Choice earlier and will paraphrase my response here. ONC/CMS should standardize on Opt-Out as the nationwide model. Data strongly support that the vast majority of patients want their data to be shared with their treating providers and those that do not want it shared can Opt-Out. Make clear that transmission of data to any HIN does not require consent.

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

A. Do not impede or put in place any unnecessary barriers to the ability of individuals to access and direct their EHI to designated third parties, and to learn how information about them has been access or disclosed.

Comment 20: Please make clear that “access” does not require the HIN to stand up a patient portal. Access can be via electronic delivery or hard copy.

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.

A. Enable participants to request and receive multiple patient records, based on a patient or member panel, at one time.

Comment 21: We support this requirement as long as the mechanism for delivery of the multiples of patient records is somewhat flexible. I would not support a multiple patient
Targeted Query as the only mechanism but would prefer to expose an API or spin off a data set for analysis with an associated data dictionary.

**Minimum Required Terms and Conditions**

1. Definitions
   
   **No comments**

2. Initial Application, Onboarding, Designation and Operation of QHINs
   
   **No comments**

3. Data Quality and Minimum Necessary
   
   **Comment 22:** Should be more detail on minimum necessary specifically on patient demographics for matching as mentioned in previous comments above.

4. Transparency
   
   **No comments**

5. Cooperation and Non-Discrimination
   
   **No comments**

6. Privacy, Security, and Patient Safety
   
   **No comments**

7. Participant Minimum Obligations
   
   **Comment 23:** The right of an IT Developer (Participant) to obtain and retain information from a Participant Member such as an HIE could pose significant issues. For example, if an Individual requests that all of their data be sent from the HIE to an application of their choosing our HIE must be able to charge for this. We have invested a significant amount of money in building a network of aggregated, indexed and standardized data and cannot simply give this away to some IT Developer who has not invested in the technology to collect and manage this data. I can envision IT Developers creating free apps with “click through” Individual acceptance which would require that the HIE share this data. If an IT Developer wants to collect Individuals data from each provider, then that should be open and “free.” But if they want an Individuals data from multiple sources (as they would get in a HIN) then a fee should be allowed for this access since the HIN provides a value-add.

8. Participant Member Minimum Obligations
   
   **No comments**

9. Individual Rights and Obligations
Qualified Health Information Network Technical Framework

1. Definitions

No comments

2. Example QHIN Exchange Scenarios

No comments

3. Functions and Technology to Support Exchange

No comments except for:

Message Delivery

Comment 24: Message delivery should also include the delivery of clinical data via means other than Direct. In our HIE Direct would not be the preferred choice.

Patient Identity Resolution

* ONC Request for Comment #7: The IHE XCPD profile only requires a minimal set of demographic information (i.e., name and birth date/time). Should QHINs use a broader set of specified patient demographic elements to resolve patient identity? What elements should comprise such a set?

Comment 25: At a minimum include phone number. More and more people including many indigents have cell phones and this can be used as a form of identification.

* ONC Request for Comment #8: There are many possible approaches to Patient Identity Resolution, each with its own benefits and risks. For example, a centralized index of patient identity information may be more efficient for resolving patient identities across disparate communities, but also poses a greater risk to privacy if the system is compromised. Federated approaches may be less susceptible to external threats like cyberattacks, but harder to scale across many communities. Recognizing that new technologies and business entities with robust identity matching solutions may disrupt traditional approaches, should the QTF specify a single standardized approach to Patient Identity Resolution across QHINs?

Comment 26: Centralized approach with biometrics.

* ONC Request for Comment #9: Different communities tolerate different degrees of risk with respect to accurately matching patient identities. Should QHINs meet a minimum performance standard (e.g., a minimum acceptable matching accuracy rate) over a specified time period? Likewise, different algorithmic techniques for matching patient identities use different approaches and must be tuned to the applicable patient population and continuously refined over time. Should QHINs measure and report on the performance of the algorithm(s) they rely on (e.g., by calculating precision, recall, etc.)?
Comment 27: QHINs should not be required to meet a minimum set of performance standards unless source organizations are required to meet data quality standards. Regular review and assessment of the MPI should be done by HINs and QHINs.

Record Location

* ONC Request for Comment #10: Recognizing there are different ways to implement Record Location services, should the QTF specify a single standardized approach across QHINs?

Comment 28: No, you should not impose a single standard approach since this is likely to be a “lowest common denominator” approach. Instead as I have mentioned several times in other sections develop a lowest level of acceptable matching and then allow for more advanced ones.

Directory Services

* ONC Request for Comment #11: Should the QTF require QHINs to implement Directory Services? Recognizing there are many possible approaches for implementing Directory Services, should the QTF specify a single standardized approach? If QHINs implement Directory Services, which entities should be included in directories? Should directories be made publicly accessible?

Comment 29: Directory services are a good idea but perhaps these should be a future capability or part of a set of “levels” of capabilities. Directory services should really be an Entity and Person Directory not just a Provider Directory. Assigning Providers to Entities is almost as significant an issue as Patient-Provider attribution. Often a Patient is only attributed to a Provider at a particular Entity. This is especially true of Providers who practice at multiple Entities.

Individual Privacy Preferences

* ONC Request for Comment #12: Future drafts of the QTF will specify a format for Meaningful Choice notices communicated between QHINs. Which standard/format should the QTF specify? What information should be included in a Meaningful Choice notice (e.g., should a notice include patient demographic information to enable QHINs to resolve the identity of the Individual that exercised Meaningful Choice)?

Comment 30: No comment at this point on the format for exchange of consent but the format should include demographics and biometrics if available.

* ONC Request for Comment #13: In addition to enabling Meaningful Choice, the Common Agreement requires QHINs to collect other information about an Individual’s privacy preferences such as consent, approval, or other documentation when required by Applicable Law. Should the QTF specify a function to support the exchange of such information through the QHIN Exchange Network? Which standards and/or approaches should the QTF specify for this function?

Comment 31: Establish a single consent option of Opt-Out nationwide and eliminate differences in state-based consent.
Auditing

* ONC Request for Comment #14: QHINs may participate in a variety of activities and transactions involving First Degree Entities and/or internal operations, including receiving and processing Query and Message Delivery Solicitations, performing Patient Identity Resolution, performing Record Location, sending EHI, receiving EHI, performing queries, granting/revoking access credentials, etc. Future versions of the QTF may specify a list of events a QHIN must record involving First Degree Entities and/or internal operations. Which activities and transactions should the QTF specify as auditable events? What information should the QHIN record about each event?

Comment 32: All of the events you list should be audited and tracked by HINs and QHINs. The minimum requirements should be sender, recipient, date/time, user or organization (as applicable), message or request type, and patient.

Error Handling

* ONC Request for Comment #15: Should the QTF specify a consistent set of error messages for interactions between QHINs? Which error messages should the QTF specify? Should the QTF specify a consistent format for error messages?

Comment 33: Yes but I have no immediate comment on which errors should be reported.