



June 17, 2019

Donald Rucker, MD
National Coordinator for Health Information Technology
Office of the National Coordinate for Health Information Technology (ONC)
US Department of Health and Human Services (HHS)
330 C Street, SW
Washington, DC 20201

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

Dear Doctor Rucker:

Kno2 is pleased to provide comments in response to the ONC's second draft of the Trusted Exchange Framework and Common Agreement (TEFCA). It is our hope that these comments provide support for a roadmap that ensures current industry efforts toward interoperability are considered and fully leveraged and does not hinder progress currently being made. We look forward to meeting with you to further our discussions about the value of an interoperable health care system that enables patients, providers, payors, and others to have access to secure medical information.

Kno2's corporate mission since our founding has been the elimination of fax from healthcare. We are best known for working with providers who did not receive government incentives to implement electronic health records (EHRs) and were left behind in the transition to interoperable electronic exchange, including providers in the post-acute, long-term care, skilled nursing, and therapy settings. We also represent over 60% of emergency medical services, and are working with dental, vision, and others as well.

Kno2's Interoperability as a Service™ allows clinicians to utilize multiple methods of exchange all in one place, including cloud faxing, Direct messaging, referral networks, and also query-based record exchange through frameworks such as Carequality, CommonWell Health Alliance, state and local HIEs. We also work with some larger health systems and provider organizations that are using big-name certified EHRs, but still have interoperability gaps that we help them close,

enabling them to eliminate all forms of fax and transition entirely to interoperable exchange of data.

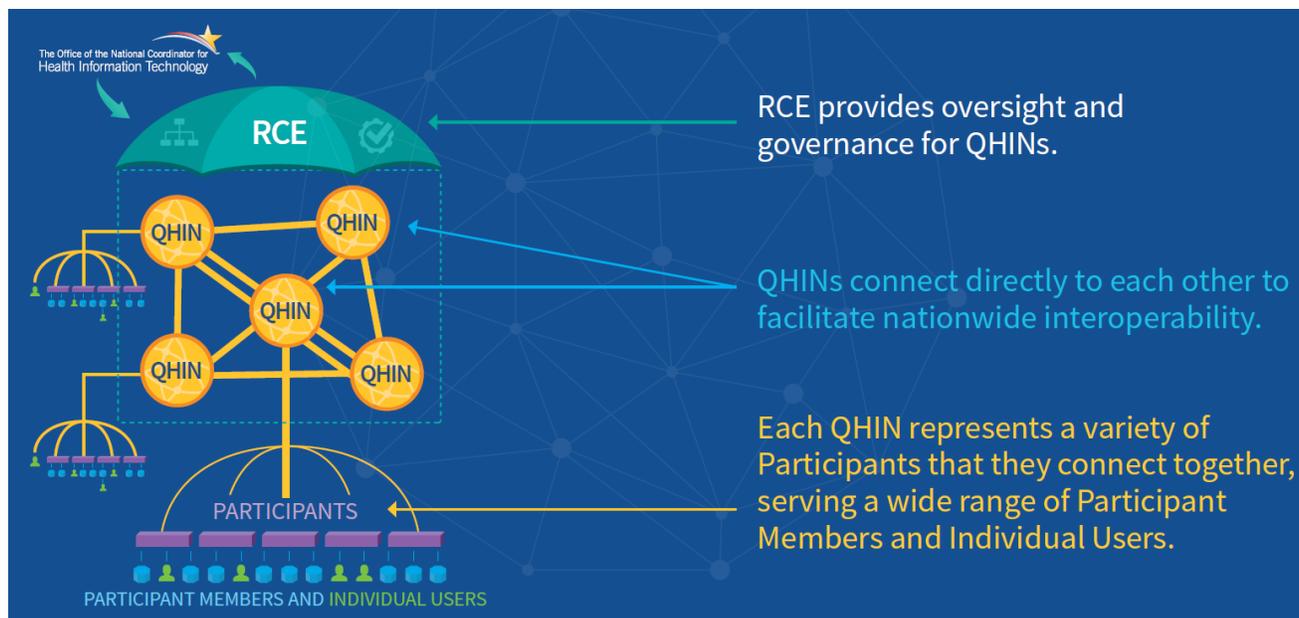
We applaud the current focus of ONC to push interoperability forward, building upon innovation from current industry interoperability frameworks and networks, along with interoperability focus from CMS in its recent proposed rule, and the requirements from Congress in the 21st Century Cures Act. We are also pleased with the significant improvements made in draft 2 of the TEFCA, compared to draft 1. Yet we are concerned that the specifics of ONC's proposals within TEFCA may hinder progress that is already being made in the industry and disrupt exchange that is currently happening.

In the 21st Century Cures Act (Sections 4003(b)(9)(A) & 4003(b)(9)(B)(i)), ONC is given the task to “develop **or support** a trusted exchange framework” (emphasis added). Section 4003(b)(9)(F)(iii) goes on to specifically state that “the trusted exchange framework and common agreement...shall take into account existing trusted exchange frameworks and agreements used by health information networks to avoid the disruption of existing exchanges between participants of health information networks.”

Organizations like Carequality and CommonWell already have wide adoption and are realizing nationwide interoperability for query-based document exchange. Carequality currently reports more than 19 Million patient records exchanged on a monthly basis. That exchange today is largely provider-to-provider, but does also include some payors, patient/consumer applications, ACOs, and even extends to providers previously ignored by federal interoperability initiatives—long-term care, therapies, behavioral, vision, emergency medical services, and others. Current work from Carequality and CommonWell seeks to further expand to bring in additional payors, patients, and others. Both are also in the process of adding additional exchange methods, expanding beyond their start with query-based document exchange, to include FHIR-based exchange, subscription-based Event Notifications, document content improvements, and other use cases as directed by industry need.

Push-based messaging, which was previously ignored in TEFCA draft 1 but has been added to draft 2 is largely facilitated today by DirectTrust™, which currently reports more than 1.9 Million DirectTrust trusted addresses nationwide, with more than 164 Million Direct message transactions sent/received in Q1 2019. Direct messaging, like queries through Carequality and CommonWell, has largely focused on provider-to-provider exchange to date. But work is already occurring to expand to payors, patients, and others throughout the care continuum.

The picture that is often used by ONC (pasted below for reference) looks like it could be a representation of how Carequality works – replace “RCE” with “Carequality”, “QHIN” with “Implementer”, and “Participants”/”Participant Members” with “Carequality Connections”. However, the actual written requirements of TEFCA draft 2 (particularly the MRTCs and QTF) change that structure used by Carequality and in many cases would be incompatible with how Carequality currently works.



ONC diagram of TEFCA organizations – RCE, QHINS, Participants, Participant Members, and Individual Users

We urge ONC to reconsider its direction in complying with the congressional mandate to “develop **or support** a trusted exchange framework” by looking to the work already taking place in the industry today, and supporting, rather than starting over and developing, a trusted exchange framework, in order to continue pushing forward nationwide interoperability while still following the additional congressional mandate to “avoid the disruption of existing exchanges between participants of health information networks.”

Recognizing that TEFCA draft 2 represents ONC’s current direction, and given that it does include many specific requests for comment, this letter will proceed with comments based on the model proposed in this draft, with the hope that these comments may ultimately not be needed should ONC reconsider its model and move to instead support an existing trusted exchange framework.

Single On-Ramp

The goal of providing a single “on-ramp” for data exchange continues as a fundamental basis from draft 1 of TEFCA into draft 2. However, it is important to note that the explanation and justification provided in draft 2 retain the inaccurate view of current interoperability efforts that was included and commented on in draft 1.

“There are more than 100 regional health information exchanges” (*TEFCA page 7*) – With the expanded definition of QHIN in TEFCA draft 2, there could be more than 100 QHINs. We are glad to see that broadened definition and do approve of expanding the definition of a QHIN from the very narrowly defined version in TEFCA draft 1. However, the number of HIEs/HINs/QHINs in existence is irrelevant. What matters is the number of those that a given provider must connect to in order to achieve needed interoperability.

A research study is cited showing that “a majority of [responding hospitals] indicated that they require three or more methods for exchanging data and about three in 10 hospitals used five or more methods to be interoperable.” The context of that research study is left out, and thus a critical piece to understanding those numbers is missing. Those “methods of exchange” are not counting individual point-to-point connections, or multiple HIEs/HINs, but rather different exchange specifications/types (e.g., query, Direct, HL7v2). The survey also only looked at a single hospital-to-hospital exchange of data. The survey results clearly show that the proposed single query-based on-ramp is not enough. Providers have multiple additional exchange methods they must support even for hospital-to-hospital exchange, not counting exchange for e-Prescribing, state registries, etc. The study supports the need for a “single on-ramp” for queries, and a “single on-ramp” for pushes, a “single on-ramp” for FHIR, etc., etc. But the study does not support the idea that all of a hospital’s exchange methods will go away based on anything proposed within TEFCA.

Where we do see organizations legitimately forced to connect to multiple HINs *for the same exchange method*, it is most often due to state laws requiring connectivity to local HIEs. This is another issue that TEFCA will not solve. In some states, such as New York and North Carolina, providers are required to connect to their state HIE. In most cases those providers already leverage other exchange frameworks for their actual interoperability needs—Carequality, CommonWell, DirectTrust, etc.—but now must additionally connect to an HIE, or multiple HIEs, due to a requirement within their state.

Unless those state laws are changed, providers who connect to a QHIN and fully participate in TEFCA-based exchange would still be required to maintain multiple HIE connections outside of TEFCA. This is a huge problem, leading to duplicative efforts for organizations and wasted expense for time and development of each connection. A “single on-ramp” for any given exchange method could solve this, if allowed for in state laws, but that is different from various “on-ramps” needed for each additional method of exchange.

With the expansion of TEFCA draft 2 to include both push (QHIN Message Delivery) as well as query/pull (QHIN Targeted/Broadcast Query), for providers in large health systems this “on-ramp” for exchange may reduce some point-to-point connections where they have reached out individually to nearby trading partners to set up those types of connections today, but they’ll still have to maintain all of their other connections. For providers outside of acute/ambulatory, they largely are not utilizing query-based exchange today, in part because their EHR systems were not part of past government incentive programs to promote interoperability, though many are beginning to connect through Carequality and CommonWell, and many have begun using Direct messaging. Those organizations/providers will still need all of their other existing connections, and if they aren’t already doing query or Direct, then TEFCA will eliminate nothing and is a net new add for connectivity, requiring additional work, time, and money beyond existing connections.

Lastly, TEFCA draft 2 largely ignores FHIR-based exchange (even though the Executive Summary does mention APIs “that can be used without special effort”). Given current industry focus on FHIR based exchange, patient access to data, and the recent CMS and ONC proposed rules requiring FHIR APIs from providers and payor, it is very odd that TEFCA would limit its “on-ramp” to query and push messaging, without inclusion of those FHIR APIs. A major concern with Information Blocking in the recent ONC proposed rule is how will provider organizations deal with the potentially massive burden of vetting consumer apps. Consumer apps need to be included in TEFCA. Once an app has been “validated” as TEFCA-compliant, and is live on a QHIN (directly, through a Participant, etc.) any other organization available through TEFCA exchange must exchange with that consumer app, at the patient’s direction. An information blocking exception could be added such that if a patient uses an app that is not a party of the TEFCA (bound to the Common Agreement), the provider would not be an information blocker for refusing to exchange with that app. Without FHIR inclusion for consumer apps in TEFCA, and without that exception, every provider organization will be required to individually vet every possible consumer app. That is entirely infeasible. A vetting of apps through QHINs, under the direction of the RCE and ONC, would remove that burden entirely from the provider

organizations (and payors, and anyone else a consumer app would want information from), allowing patients to trust that any consumer app of their choosing will be able to connect, as long as it is “certified”/“TEFCA compliant”/whatever label is given to those apps.

Exchange Modalities

We are pleased with the inclusion of QHIN Message Delivery in TEFCA draft 2. We are concerned, however, that this is duplicative of work already facilitated by DirectTrust but using a different communication standard than is currently widely used today for Direct messaging. We recommend that ONC look at the standards already in use for Direct messaging and how that can be incorporated into the TEFCA exchange ecosystem, rather than introduction a new, duplicative standard, “to avoid the disruption of existing exchanges between participants of health information networks.”

The current proposal for a QHIN Targeted Query is too broad. If a patient knows they were recently seen at Hospital XYZ, a provider treating the patient should be able to target a query to Hospital XYZ. The current method of “targeted” query would instead be to Hospital XYZ’s QHIN and would return results from any other organization within that QHIN that also knows the patient. If the provider wanted all of that additional information, he could have instead done a QHIN Broadcast Query. There does not seem to be any reason that you would do either a full broadcast or a mini broadcast (targeted to a full QHIN). What is needed is the ability to either do a full broadcast, or target of a specific organization (hospital, health system, provider organization, etc.) that information is specifically needed from.

Population-Level Data Exchange

We are pleased to see ONC remove TEFCA draft 1’s exchange modality of population-level data exchange from draft 2. While we believe population-level data exchange will be critical to many of the goals of an interoperable healthcare ecosystem, we agree with ONC’s assessment regarding the relative maturity of population-level data exchange.

However, Population-Level Data is still included in the TEF as a Principle for Trusted Exchange. This is odd given that population-level data exchange has been removed from the Exchange Modalities. Also, Principles for Trusted Exchange #1-5 are actually principles of trust. #6: Population-Level Data does not have anything to do with trust and does not fit in with the others. We suggest that it be removed from the Principles for Trusted Exchange and instead simply referenced as a future Exchange Modality.

Exchange Purposes

An exchange purpose of "Benefits Determination" is defined specifically for federal or state agencies determining benefits (e.g. SSA disability benefits). In other exchanges such as Carequality, that similar exchange purpose (called Coverage Determination in Carequality) includes not only SSA, but also life insurance or other insurance or similar benefits. We request clarification if life insurance and other non-state or federal benefits determinations are intentionally not included in TEFCA, or does ONC envision those organizations leveraging one of the other allowed Exchange Purposes?

EHI Used or Disclosed Outside the United States

We understand that there are concerns with exchange with organizations outside of the United States, or US-based exchange information being stored outside the United States. While the initial phase of TEFCA likely should not tackle health information being exchanged internationally, it must at least recognize that international exchange of patient information is a reality today and will continue to grow with medical tourism and increased international travel for work and pleasure. Additionally, there are non-US-based EHR vendors operating in the United States. As more vendors move to cloud-based services, a requirement to "only utilize cloud-based services that are physically located within the United States" could be detrimental to any healthcare organization currently using an EHR from a non-US-based vendor. We propose that wording instead be included in the Common Agreement such that anyone who agrees to it must meet privacy and security standards set forth in US law, as well as the technical terms of the MRTCs, ARTCs, and QTF. This would allow organizations outside the United States to participate, being bound to the same terms within the Common Agreement as US-based organizations, even if they would otherwise not have the same accountability to US law.

Health Information Network (HIN)

For clarity in reading the TEFCA, we ask that ONC look at how "HIN(s)" is used throughout the document and potentially separate out a different word to clarify what is actually being referenced. Health Information Networks is a term used in the Cures Act. It then gets used throughout TEFCA, but at times means different things. For example, an organization must be a HIN to apply to become a QHIN. Yet a HIN could instead be a Participant of a QHIN. The TEF generally refers to exchange between HINs—the Principles for Trusted Exchange, for example are all about what HINs should do. Is that meaning a QHIN? Or does it mean a HIN that could be either a QHIN or a Participant of a QHIN, but is not talking about other non-HIN Participants of a

QHIN? Or is it a broader definition of HIN that may sometimes encompass QHINs, HINs, and other Participants and Participant Members?

Adherence to Application Standards

We agree with the requirement that HINs adhere to federally adopted standards, looking first to standards adopted by HHS, then those approved by ONC as part of the Certification Program, and finally, those identified in the ISA. While the ISA is not part of this TEFCA draft 2 or subject to this round of comments, we recommend that if TEFCA does point to ISA, future cleanup of ISA should be considered by ONC. We appreciate the work ONC has put into ISA and compiling the various standards that are available for use. Our concern is that there are often multiple standards listed to complete the same task. As the industry evolves and new standards are created, the old standards are still part of ISA. If a health IT developer were to use ISA as a starting point, looking for an applicable standard to solve a specific need, they would be presented with multiple available standards to pick from, some of those standards being ones that are no longer widely used and should likely not be developed by new health IT developers. The ISA needs to remove old standards that should no longer be used and become a reference that can be used to find available widely used or upcoming standards.

Role of RCE: TEF, MRTCs and ARTCs, and QTF

The organization selected as the Recognized Coordinating Entity (RCE) should be one with expertise in developing and supporting common agreements and use-case-specific implementation guides, like The Sequoia Project and Carequality have been doing successfully for years. Throughout draft 2 of TEFCA, there are some areas that specify future input and finalization from the RCE and others that are intended to be finalized solely by ONC (such as the Minimum Required Terms & Conditions (MRTCs) from ONC, with Additional Required Terms & Conditions (ARTCs) being added by the RCE).

Given the complexity of TEFCA as a whole, and the intention that the RCE be that facilitating organization long-term, we urge ONC to work with the RCE from the beginning before anything within TEFCA is finalized, instead of ONC creating initial requirements that the RCE cannot change but must add to. The RCE should be involved with ONC in the creation of all requirements to ensure appropriate industry input and long-term viability.

SAML Tokens in the QHIN Technical Framework

In existing exchange frameworks, SAML assertions are used both for passing information needed to determine whether a release is authorized, and also for auditing purposes.

Information like the ID of the message-initiating organization and the exchange purpose can be used to determine whether anything additional is needed (e.g., patient consent) before releasing information. Information such as the specific user initiating the request and the user role are beneficial for auditing purposes but should not be used for determination of a release of information because specific user information is not indicative of who will actually have access to the released information. For example, in a clinical setting, queries are often initiated by a front desk user even though that user will never see the clinical content returned in response to the query. The returned clinical data will be available to the provider when he is seeing the patient. The organization being queried should not restrict release of information to only users with a clinical role but should respond regardless of the specific user or role, knowing that information will ultimately be available to any clinical user within the represented organization.

Exchanged Content/Structure

TEFCA draft 2 and the QTF are largely silent on actual content or structure of exchanged data. The query Exchange Modalities leverage XCA, which is commonly used to exchange documents today, though not technically limited to document exchange. The ONC C-CDA scorecard is referenced for validating documents. But nothing actually requires the use of C-CDA documents. USCDI is specifically required, along with numerous references to access of EHI. Only a small subset of EHI is currently included in USCDI, and even within the Document Templates for C-CDA only a subset of EHI fits in the defined C-CDA sections. In order for a recipient (of a query response or a message delivery) to accept and appropriately handle the exchanged data, it must be in an expected and recognized format. Clarification is needed around the use of C-CDA, how USCDI fits in those documents, handling of EHI that is not part of USCDI, and any relation to FHIR resources once those are added into the TEFCA framework.

Patient Identity Resolution

One of the biggest challenges to interoperable exchange today is patient matching. We are optimistic of the possibility that Congress may allow federal funding to support the development of a National Patient Identifier. Without a standard way to identify patients, consistent demographic information collected about patients, or any form of reliable patient identifier, health IT developers are required to create their own matching algorithms to achieve an acceptable “likelihood” for patient matches. Some vendors have complicated algorithms that give point values to all provided demographic elements, looking for a patient with a high enough score to determine a match. Others use simple string matching (“123 Main Street” does

not match “123 Main St”). If we are to achieve true nationwide interoperability, without significantly increasing provider burden, we must address the issues of patient matching.

The larger issue is patient identity management as a whole, not just patient matching during interoperable exchange. There are large numbers of merges, unmerges, patient record overlay corrections, incorrectly entered demographics, etc. within a single organization. All of those issues then impact patient matching when cross-organization interoperable exchange relies entirely on demographics to match a patient. Issues with patient identity management are larger than TEFCA but need to be solved.

Within the scope of TEFCA, we recommend working with industry groups to create a best practice for baseline patient matching. Commonly exchanged elements are patient name, date of birth, sex, address, and phone number. How should those be compared, differences in spelling, inverted digits, etc.? How should they be weighted, are certain elements more important to match than others? And what additional information should be included, such as insurance ID numbers, Medicare/Medicaid numbers, Social Security Number, birth order for multiple births, Race and Ethnicity from USCDI, etc.? There have been many industry workgroups that have worked on this issue in the past—for example the Sequoia Project’s whitepaper, *A Framework for Cross-Organizational Patient Identity Management*. We recommend working with these industry groups to identify or define a best practice baseline to include in TEFCA.

Meaningful Choice

As it works in TEFCA draft 2, a patient’s “Meaningful Choice” is not actually very meaningful. True Meaningful Choice must be more than a global opt-in or opt-out. Patients need the ability to meaningfully choose what information will be shared with whom.

Differences in requirements around patient consent (e.g., state laws that are more restrictive than HIPAA, organizational interpretation of state and federal laws) are a major issue today that is blocking information exchange. With point-to-point connections, such as through Carequality, a requestor can assert to a record holding organization that necessary consent is on file (with various ways how that consent may have been collected). TEFCA’s structure of user to Participant to QHIN to other QHINs and down to their Participants makes any assertion of Participant-specific consent very difficult. But a patient’s consent for release of information should be managed at the Participant level (or Participant Member), allowing patients to

consent to information being released from one Participant (or Participant Member) while restricting others, even within the same QHIN.

QHIN Fees

QHINs are allowed (not required, but are allowed) to charge other QHINs for exchange, even though all QHINs are required to exchange with all other QHINs, and are not allowed to enter into separate agreements between QHINs for purposes covered by the Common Agreement. This is not a sustainable model. A QHIN that initially doesn't charge, but gets charged fees from other QHINs, will likely start charging other QHINs to recoup that money. Ultimately, it becomes a zero-sum game with each QHIN only recovering the amount payed out to other QHINs.

QHINs should not be allowed to charge each other solely for the exchange of data. They should have a sustainability model based on charging their Participants and Individual Users for access to the QHIN services, with various QHINs differentiating themselves with additional services, standards supported, and fees. A great example of this working today is the Carequality framework, which currently allows Implementers to charge each other only for non-treatment-based exchange, and how much a Carequality Connection is charged by its Implementer varies Implementer to Implementer. Allowing QHINs to charge for data that they make available for non-treatment purposes, or who have a business model built around that data, might make sense, but at least treatment-based exchange should to be without cost between QHINs.

We appreciate your consideration of our comments and welcome the opportunity to meet with you to discuss these and other issues in greater detail.

Sincerely,



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