



2800 Rockcreek Parkway  
Kansas City, MO 64117  
Direct: (816) 201-1024  
Fax: (816) 474-1742

June 14, 2019

Donald Rucker, MD  
National Coordinator for Health Information Technology  
U.S. Department of Health and Human Services  
Attention: RIN 0955-AA01  
200 Independence Avenue, SW  
Washington, DC 20201

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

Dear Dr. Rucker,

Cerner Corporation appreciates the opportunity to submit public comment on the proposed approach to establish a Trusted Exchange Framework and Common Agreement in support of the 21<sup>st</sup> Century Cures Act provisions.

We fully support the need for a national trusted exchange framework as called for in the 21st Century Cures Act which states “The National Coordinator shall, in collaboration with the National Institute of Standards and Technology and other relevant agencies within the Department of Health and Human Services, for the purpose of ensuring full network-to-network exchange of health information, convene public-private and public-public partnerships to build consensus and develop or support a trusted exchange framework, including a common agreement among health information networks nationally. Such convention may occur at a frequency determined appropriate by the Secretary.” Having a national trusted exchange framework with a common agreement and common architecture can enable all stakeholders to access and exchange a growing data set within EHI based on the U.S. Core Data set for Interoperability (USCDI), using a variety of access methods and payloads such as documents, individual data elements, or large data sets.

We appreciate the progression from the first draft of ONC’s TEFCA distributed January 5, 2018, followed by the second draft on April 19, 2019, that took much of the feedback provided on the first draft into consideration. We underscore the importance of nationwide interoperability and our commitment to it, as evidenced by our central role in establishing the CommonWell Health Alliance, CommonWell’s growth since 2014, and the further reach that has been achieved since the first TEFCA draft was published. This has been achieved by connecting Carequality implementers to the degree that now enables connecting virtually every provider in the country using standards-based document exchange, while continuing support for exchange of documents using Direct in situations where the networks do not fully extend or where a directed exchange is most appropriate. We are now also at the forefront of expanding access to the data element level and to large data sets using the HL7® FHIR® based API approach through these networks to not only providers but also with capabilities aimed at consumers, payers, and other stakeholders. Agreements across and within networks to enable scaling helps our clients to connect to one network which immediately connects them through that same network to other connected networks under the same terms. Together with many other stakeholders, we have been able to build a strong foundation to scale and expand participation across all relevant stakeholders and introduce new capabilities into these networks.

Based on our experience helping to establish and build a nationwide exchange framework and network, and supporting our clients to connect with the most appropriate network that meet their goals (e.g., CommonWell, local HIEs, eHealthExchange, and now also to other Carequality Implementers), we believe the focus should be to build on this existing exchange and to minimize disruption and to avoid overly prescriptive approaches to realize the trusted exchange framework envisioned in the 21st Cures Act. It should be acknowledged that since the 21st Century Cures Act was enacted in 2016, technology the industry has changed significantly while the market has already been addressing many of the stated goals on its own.

June 14, 2019

Page 2

We appreciate the flexibility that Congress is allowing for in the progression towards that vision as Congress recognized the key to progress by calling on ONC to “...convene public-private and public-public partnerships to build consensus and develop or support a trusted exchange framework...”. The efforts by various partnerships enabling functioning operational networks (e.g., CommonWell, eHealth Exchange, HIEs) and virtual frameworks (e.g., Carequality, Direct, SHIEC) with increased collaboration demonstrates clear progress and common direction as they have established workable legal governance and technical architectures and standards that enable open, transparent access to an increasing set of common data. As ONC considers selection of the Recognized Coordinating Entity (RCE), this level of expertise and experience as demonstrated by organizations such as The Sequoia Project and Carequality, should they apply to be the RCE, is essential to provide continued growth and progress towards the shared goals expressed in the 21st Century Cures Act.

We urge ONC to make full use of such existing efforts, governance and infrastructure to progress this path and refrain from unnecessary re-development that would create uncertainty, duplicate current efforts, yield re-work, and delay the progress that can and should be made as stakeholders not yet involved may stay on the sidelines until the re-work has settled. We urge ONC to define their onramp cognizant of the need to meet potential participants where they are, and to encourage (rather than discourage) onboarding by embracing participants where they are for the level of abilities they (and their HIT) have to participate in trusted exchange. This is critical to broaden the participation by those stakeholders who have to date stayed on the sidelines because they are discouraged by the level at which the bar is set for participation.

Our perspectives on the current proposed approach can be summarized as follows:

#### ***Trusted Exchange Framework Principles***

We support the basic principles of TEFCA Draft 2 as reasonable and appropriate but emphasize these are largely in place in current HINs active in current trusted exchange frameworks.

We appreciate that various elements and QHIN responsibilities, such as those focused on consent, have either been moved to the Minimum Required Terms & Conditions and/or QHIN Technical Framework where they can be more specifically addressed and evolve, while the principles remain stable and fundamental.

#### ***Common Agreement (CA) / Minimum Required Terms & Conditions (MRTC)***

While the definitions of participants and participant members provide further clarity on intended roles, we are concerned these may be too restrictive. Our concerns include:

- There may be multiple levels of participant and participant members, not just two;
- Certain HIT Developers may never be Participants or Participant Members as they may only be supporting providers who are the actual Participants or Participant Members such as in eHealth Exchange or many HIEs;
- Responsibilities of “actors” may be distributed differently than ONC proposes;
- Technology infrastructures may be more decentralized/federated or more centralized.
- There needs to be clarity of the embrace for meeting participants where they are and to encourage increased adoption of capable HIT over time, especially providers in market segments grossly underrepresented in trusted health exchange historically.

Given those variations and our experience connecting clients across those diverse environments, we suggest ONC not focus on definitions with prescriptive/implied responsibilities to specific roles, but rather that within the QHIN governance, responsibilities, and technical infrastructures address specific participation requirements of the QHIN as whole, where the QHIN determines what kind of entity supports what requirement to collectively operate as a QHIN.

We appreciate the wider variety of HINs that can qualify to be a QHIN, recognizing the variety of networks and formats that can make for a successful trusted exchange framework without a substantial first big step to become a QHIN. We also urge ONC to allow for QHINs to play distinct purposes as to purposes of exchange based on their function and scope where possible.

We are very concerned with the impression left by the wording on intent of the MRTC that the proposed language, once finalized between the RCE and ONC, is expected to be included “as-is”, thus effectively replacing any existing agreement language that current trusted exchange frameworks have in place (such as Cerner participating in the CommonWell Health Alliance, which in turn connects with other networks within the Carequality framework, and other like arrangements). Change to current agreements, just for the sake of adoption of such prescriptive language, could re-open evaluation of participation by many current members of existing networks, cause stakeholder re-education, induce unnecessary re-alignment, and create re-work without substantial value add. We urge ONC to re-consider its approach and assess the role of MRTC as best-practice language, while encouraging existing networks to fill any identified gaps of current agreements over time. Some form of scoring method to compare existing language to best practice language may sufficiently inform the stakeholders in their decisions to join, while enabling the industry to continue the solid progress made to date.

#### **QHIN Technical Framework (QTF).**

We appreciate the separation of the standards requirements from the Common Agreement into a set of implementation specifications within a QHIN Technical Framework. This will be beneficial to maintain a more stable CA/MRTC while the technology can evolve on a separate track at its own pace.

We support that the QTF primarily focuses on QHIN-QHIN interactions and capabilities enabling the QHINs to have variant approaches that best suit their respective environments. We recognize some of the requirements to enable QHIN-QHIN interactions may need to trickle down to the QHINs and through to their Participants and even Participant Members.

We are concerned that the Exchange Modalities language remained in the MRTC section from the original TEFCA draft and suggest this be moved to the QTF instead. The MRTC language assumes a singular architecture across different access and exchange methods. While the current scope is focused on document exchange, the MRTC language is not specific to that. It is likely that the approach to enable FHIR based access and exchange will not be configured similarly and may not require the same level of centralized capabilities that the MRTC currently implies. This may result in less exchange brokered through the QHIN but rather use direct connections once the relevant endpoints have been identified for the patient(s) at hand. We suggest that the Exchange Modalities considerations be fully moved to the QTF as well, and that these be addressed in the context of specific access and exchange use cases to establish the appropriate architecture and configuration. Considering that, the various diagrams that show data flowing through the QHIN should be replaced with diagrams that are agnostic as to whether the data flows through a central QHIN network, or from any of its parts. Evolution of the QTF will identify what must be centralized when for a given use case.

As with the CA/MRTC we are concerned that the QTF will be re-creating much of the implementation guidance already in place and re-establish the basic infrastructure and plumbing that already demonstrates how a trusted exchange framework works. We understand that the RCE may opt to select something that already exists, but we note that the process that the RCE and ONC are proposed to go through essentially re-opens all the discussions again. We suggest that the final ONC adoption be re-focused where the role of the RCE is to continue facilitation and mediation where needed among existing networks that reflect the principles and essence of the MRTC to bridge and/or align the approaches to enable data to flow more broadly. We note the current FAST initiative and the alignment discussions that

June 14, 2019  
Page 4

are beginning to form between Carequality, CommonWell, and FAST as a good example of how progress can be stimulated without re-working what already enables data to flow.

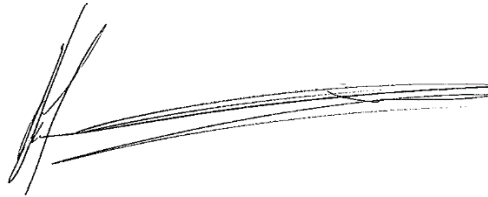
In addition to the above summary, we offer the attached detailed suggestions for each of these topics and strongly urge ONC to embrace building on existing initiatives that already contributes to a nationwide trusted exchange framework rather than to develop one from scratch that is full replacement to what already works.

We look forward to the continued discussion and would be happy to discuss any questions you may have.

Sincerely,

A handwritten signature in black ink, appearing to read 'John Travis', with a stylized, cursive script.

*John Travis*  
Vice President & Regulatory Strategy Executive  
Cerner Corporation

A handwritten signature in black ink, appearing to read 'Hans J. Buitendijk', with a stylized, cursive script.

*Hans J. Buitendijk*  
Director, Interoperability Strategy  
Cerner Corporation

## Detailed Responses

### General

#### Single or Multiple Onramps

The trusted exchange framework seeks to establish a single on-ramp to "...access one network, which then becomes a gateway to all other networks..." [TEFCA Draft 2, Page 8]. We remain concerned that given networks best serve different purposes one network will not provide access to all EHI for all purposes of exchange for both individuals and populations. Rather, participation in multiple networks, each with different purposes should remain permissible, particularly during any transition, to support the necessary variety of needs and capabilities.

#### Data follows the Patient

We fully support the goal of enabling EHI to effectively follow the patient and enable a stakeholder to access a patient's data wherever it may be located considering appropriate consent permissions and access controls. Record locator services, such as those used by CommonWell are essential, which includes the need to enable such services to be informed of when patients are seen across providers who may connect through different networks. Patient event notification capabilities are essential for all participants to support.

#### Separation of Concerns

We support the separation of the QTF from the CA/MRTC to enable increased flexibility to progress the technical capabilities under a consistent set of governance.

#### Focus on Support

The document states that "The TEF and the Common Agreement are distinct components that aim to create a technical and legal infrastructure for broadly sharing EHI across disparate HINs to enable nationwide data exchange." We suggest that the notion of "create" should be replaced by "build and expand upon existing" to reflect the intent of the 21<sup>st</sup> Century Cures Act and enabling building on what we have.

#### Support Successful Initiatives

Carequality is already akin to the role of the RCE and has established an agreement framework, similar to the Common Agreement/MRTC, and a technical framework, like the QTF, that would require substantial review and revision to replace current terms and condition language with those proposed. That would serve to re-open existing implementation guidance to establish a new set of national level document exchange guidance at the time eHealth Exchange is progressing through the efforts to enable their participants to communicate through Carequality with other Carequality Implementers, including CommonWell participants, who already aligned their agreements and document exchange capabilities. We suggest that ONC adopts the Carequality agreement framework and technical guidance process as the baseline for the trusted exchange framework and collaborate through that community to progress connectivity with any other HINs. The CommonWell - Carequality alignment has clearly demonstrated how different HIN approaches can be connected, yet did not require introduction of a replacement process for existing agreements.

#### Data Exchange Purposes

We support the updated clarifications to the supported purposes, particularly focusing on a subset of Payment and Health Operations purposes. We suggest that current initiatives are progressing in that direction but need assistance to get clarification on what data can be shared with whom for what purpose. We suggest that ONC should focus on collaborating with CMS, OCR, respective data holders, and the existing networks to establish clarity. This initiative does not require an RCE to inject such guidance into efforts in progress to enable them to improve on the appropriate flow of data.

We understand that a QHIN does not have to support all exchange purposes. We support such an approach, which would still enable a single on-ramp for particular purposes and use cases. We do suggest though that

June 14, 2019

Page 6

the proposed timeline from the signing of the QHIN agreement to having the relevant scope in place would be severely impacted if the expectation is that a single QHIN does need to support all purposes.

We also understand that a Participant may support fewer purposes and only certain use cases. We support such flexibility to enable HINs to grow and focus on areas they serve best, rather than being required to be a one stop shop for everything.

#### **EHI outside the United States**

We appreciate the clarifications provided that EHI cannot be communicated outside the United States without express consent by the patient or their representative. Even with increased travel and increases in telehealth that both cross borders, we believe this to be a reasonable and necessary requirement.

### **Trusted Exchange Framework Principles**

Generally, we support the principles as outlined. We provide specific considerations below for each of the principles. We suggest clarification generally that these principles apply to HINs that wish to become a QHIN, as well as HINs that wish to be a Participant of a QHIN.

#### **Principle 1**

We support that HINs should consider the Certification program, Standards Version Advancement Process (SVAP), and the Interoperability Standards Advisory (ISA) when selecting standards and implementation guides for various interoperability use cases. However, we do not support that they must be restricted to those sources. A process that insists HINs should first look at the standards adopted by HHS, then those in the SVAP/Certification Program, and *finally* the ISA is too restrictive. Innovation occurs by breaking down barriers and boundaries in non-conventional ways. That includes choosing different paths. We do agree that the QTF applies to QHINs only and HINs should be allowed to make their own architectural choices. That should include choices of standards with the only constraint that they provide bridging capabilities where necessary. This is not to say that HINs should not be encouraged to use common standards wherever possible but that they not be limited to that. We also note that the QTF should not be restricted to using the Certification program, SVAP, and ISA either. It is more important that standard is mature and being maintained by an SDO.

We support the need for testing tools to be available for HINs, QHINs, and across QHINs. We suggest however ONC emphasize more strongly the need for common test tools focusing on content validation (e.g., HL7 CDA C-CDA validation or HL7 FHIR resource validation). Inconsistencies across content creators contributes to user satisfaction issues and they should be a key focus of an RCE function to manage at all levels of the trusted exchange framework.

#### **Principle 2**

We appreciate the removal of the requirement that a (Q)HIN must have the capability to enable capture of patient consent or authorization if required by law rather than address it through Principle 2.C.4. As models for capturing and managing consent, the methods and specific role of the HIN as QHIN, Participant, or Participant Member can be further clarified through the QTF. We offer further comments later in the context of the CA/MRTC and QTF.

We appreciate and support the inclusion of an arbitration process to be available.

#### **Principle 3**

We support this principle and reflect on the experience to date in CommonWell, Carequality, eHealth Exchange, and many HIEs where this principle is clearly practiced.

#### **Principle 4**

We support this principle and appreciate it calls out exchange with non-covered entities. In this context we reiterate our comments to ONC's Information Blocking and Conditions/Maintenance of Certification proposed rule where we recommend that the data classes in scope of EHI should be the exact same as the data classes

June 14, 2019

Page 7

in scope of ePHI. Use of HIPAA's definition of ePHI as the basis for the EHI scope enables us to reference the exact same data classes set independent of HIPAA. We appreciate the notion further in the proposal that HINs can require non-covered entities to be bound by certain provisions by agreement that protect patient privacy, including stipulations in ONC's Model Privacy Notice.

#### Principle 5

We support this principle and appreciate the removal of the required QHIN capability for a patient to directly withdraw or revoke his or her participation in the QHIN. Such actions are typically best performed through their (non-)covered entity, while the (Q)HIN may have a role in further managing such actions as described in the QTF.

#### Principle 6

We appreciate and support the update to the principle wording to focus on Population-Level Data rather than Data-driven Accountability. We also support that HINs may not all be required to support this capability as certain population level access use cases may be best served by specialized HINs. We do suggest to provide clarity that the intent is address population level data access and exchange at a future stage, rather than drop it from the scope of the trusted exchange framework as currently implied.

## Common Agreement/Minimum Required Terms and Conditions

### Scope

We understand that the current scope of the QTF is document exchange. We suggest that this be made more explicit in the opening paragraphs that it is limited to that while approach and architectures for other methods of access and exchange are not intended to be bound by currently proposed approach and architecture. We are providing further specific comments in this context in subsequent sections.

### Definitions

- *Health Information Network (HIN)*  
While we appreciate a broader definition of a HIN to capture a variety of different relevant stakeholders, we believe the proposed definition of HIN is overly broad. We suggest this should be constrained to those organizations likely to be QHINs, Participants, or Participant Members, (e.g., exclude an HL7 or CARIN) while also recognizing that for a number of organizations that technically would qualify there is no expectation to join, at least not in the short term (e.g., school-based clinics).
- *Participant / Participant Member*  
The definitions of Participant and Participant Member indicate that a QHIN may have different amalgamations of Participants and Participant Members. We suggest clarification that this may include multiple levels between a Participant and certain Participant Members. It also would be helpful to clarify that depending on the approach of a QHIN, such as if a HIN like eHealth Exchange becomes a QHIN, that a HIT Developer may never be a Participant or Participant Member as their client (e.g. a provider entity) would actually be in that role. While in those situations the HIT Developer is not a Participant or Participant Member, they are critical to the success of the trusted exchange framework.
- *Qualified HIN*  
The definition of a QHIN is ambiguous. On page 9 it states "**Minimum Required Terms and Conditions (MRTCs):** ONC will develop the MRTCs, which will consist of mandatory minimum required terms and conditions with which Qualified Health Information Networks (QHINs) may voluntarily agree to comply." Without being required to adopt the MRTCs, what makes a HIN a QHIN? Note that on page 12 it states "A QHIN must meet the definition of a Health Information Network (HIN) and satisfy all of the

conditions of the Common Agreement and accompanying QTF.” We ask that the conflict in the use of “may” and “must” in the respective statements be resolved.

### **Exchange Modalities**

We are concerned that through section 2.2.1, the MRTC requires specific exchange modalities to be supported by the QHIN rather than these being specified through the QTF in the context of specific use cases (e.g., document exchange-based use cases or FHIR based use cases). While for document exchange the proposed exchange modalities reflect a common approach for a HIN to support where HINs are typically functioning in a broker function in that context, for the anticipated FHIR based exchange the expected role of a QHIN is likely to be more limited and not broker the actual access/exchange. Thus, the role of the QHIN is much more dependent on architectural and technology choices than on a legal governance framework. Specific exchange modalities should not be included for any use case even as predominant as a particular approach may be. We suggest that architectural choices, including permissible options/variations, are made through the QTF.

### **Non-Covered Entity Participation**

We appreciate non-covered entities are to be bound by certain provisions of the Common Agreement. This approach can increase trust with data holders such as providers, as well as their patients, particularly in the use of consumer facing Apps. We suggest that clarity on networks’ ability to include such provisions like adherence to ONC’s Model Privacy Notice and/or CARIN’s Code of Conduct could be achieved without having to create an RCE. Rather, reporting and transparency what each network requires would be sufficient for stakeholders to make informed decisions to either connect through a network, or pursue access directly with each relevant data holders open APIs.

- **Terms and Conditions Pass-Through**

While the Common Agreement and MRTCs are primarily between the RCE and the QHIN, the QHIN will need to pass on certain elements to their Participants, who in turn must pass certain elements on to their members. While the proposed/anticipated Common Agreement/MRTCs are likely very similar to what current agreements already address, effectively all agreements have to be revisited, updated, and re-executed if these are adopted as wholly new. This is a substantial effort where the value is not clear.

We recognize three paths for HINs to become a QHIN given the MRTCs, and further ARTCs, “as-is” (all with the effect that TEFCA amounts to a distinct framework from what exists that compels HINs to completely create new or substantially rework their existing framework to become a QHIN).

- A current HIN that becomes a QHIN converts all its agreements with its members/implementers/endpoints to the ARTC/MRTCs with one switchover.
  - This would enable intra-QHIN access/exchange to operate on one set of agreements at any point in time and moving forward.
  - There would be a need to address agreements the QHIN would continue to have to communicate with other HINs that have not joined TEFCA to allow them to continue. This would seem to require existing agreements to persist until the any such HINs have switched as well.
- A current HIN that becomes a QHIN converts its agreements with its members/implementers/endpoints to the ARTC/MRTCs over time.
  - This would still persist the challenge of what agreements govern communication within the QHIN as participants join TEFCA over time.
- A current HIN would create effectively a parallel HIN that would become the QHIN and the HIN migrates its members/implementers/endpoints to this parallel QHIN over time from existing agreements.
  - This is akin to the first path, but with an extra, new HIN organization in place alongside the existing HIN to support transition, which per the definition could actually not happen since a QHIN must be an existing HIN, not a new HIN.



These paths demonstrate the complexity of migration and governance resolution of a mixed environment as transition occurs if the proposal is to require adoption of the ARTC/MRTCs as-is in a voluntary environment where governance and infrastructures are already in place. It would require substantial time and effort to make this successful to establish and maintain parallel frameworks for an extended period of time. It is also not realistic to assume that all putative participants and participant members would switch at the same time given that they all have their own discretion to participate in the proposed trusted exchange framework given that it is voluntary.

This reinforces our suggestion to progress based on what exchange agreements and governance is already in place and use the ARTC/MRTC as informative to drive ongoing enhancement to existing agreements and governance that can be adopted by the community through an update process rather than a replacement or redo process. We specifically suggest that the RCE work in close coordination with (aspiring) QHINs, Participants, and Participant Members to identify gaps in existing agreements and establish a roadmap for adoption of the intent of the MRTCs over time at a sustainable, practical pace. This must occur in a highly collaborative, iterative approach as demonstrated through experience with existing exchange initiatives where parties were motivated to work together to make interoperability operational at a national level. Close collaboration can identify short term wins while thoughtfully progressing towards resolving the more challenging gaps.

#### **Timelines**

We understand that from the moment a Provisional QHIN is recognized as a QHIN, they have 18 months to be fully operational having propagated the applicable capabilities of the CA through their Participants and Participant Members. We believe this timeline may not be realistic particularly if all permitted purposes and exchange modalities would have to be available according to the then agreed to QTF if said QTF is substantially different from current implementations. Certain changes may be able to be achieved faster while other requirements may need more time to develop and deploy particularly if the QHIN's Participants and Participant Members have substantial work to do as well. We suggest that support of current enhancement and rollout approaches in HINs provides for adequate flexibility and practical implementation approaches without one-size-fits all arbitrary timelines.

#### **Minimum EHI Security Requirements**

We suggest ONC clarify sections 6.2.1 through 6.2.5 to focus on the process and policy elements of the standards referenced and not the actual technical implementation standard. The latter would be addressed in the QTF that focuses on any of the technical implementation choices that are to be harmonized.

### **QHIN Technical Framework**

#### **Definitions**

We are concerned with the broad scope of a First-Degree Entity as the definition includes individual users yet does not mention Participant Members. We suggest clarifying that the primary focus is on Participants (and their HIT Suppliers) interacting with the QHINs, while Participant Members are less likely to be First Degree Entities, depending on how the QHIN operationalizes various of its functions.

#### **Implementation Guidance**

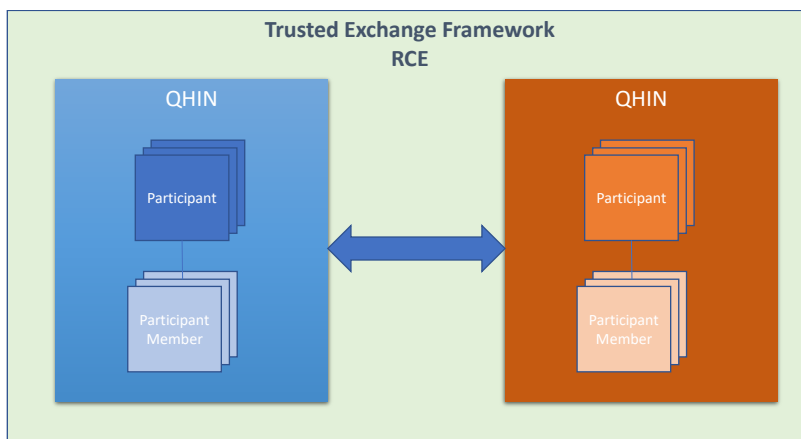
With the focus on document exchange, we agree with the standards/profile stack proposed but we believe the IHE profiles are not sufficiently specific enough to enable consistent, compatible implementations. Further profiling of them was needed in development of the Commonwell specifications to support its model, while Carequality created the Query-Based Document Exchange Implementation Guide to harmonize cross-Implementer document exchange. These models have demonstrated the ability to co-exist and transition from one to another. We therefore suggest starting with the Carequality implementation guide rather than rebuilding the implementation guidance that is necessary beyond the base profile documentation referenced.

#### **Architectural Approach and Responsibilities**

We note that in the MRTC (and in the CA/MRTC section above), as well as in the QTF, the QHIN is required to

support all exchange modalities and be part of every communication. We suggest that is too restrictive if meant to be an actual rather than an abstract model. Based on work progressing beyond document exchange, there likely will be less centralized brokered exchange, and more direct access and exchange where a QHIN would primarily focus on directory services (e.g., endpoint discovery). We suggest the architectures and the role of a physical, centralized QHIN network infrastructure be carefully considered as part of each use case. That also would require that any functions of the QHIN be clarified to represent functions of the QHIN as a whole and not just the capabilities of a central network infrastructure provided by the QHIN.

In that context, we offer the following diagrams to further visualize the suggested approach that data does not literally flow through the QHIN, but rather from a QHIN environment where the internal configuration is up to the QHIN on where what data actually flows.



### Query Scenarios

We note that the Query Scenarios call out FHIR Based Document Exchange methods, e.g., IHE MHD, as an alternative/emerging approach, while also using other FHIR based capabilities for auditing. Generally, we support the directional statement that FHIR provides an opportunity to provide an alternative to augment or even replace various of the current standards/profile stack in wide use. We suggest that this not be limited to FHIR based RESTful APIs, but that other transport protocols may be considered as well. Additionally, while there are implementations in progress at the network level including operational capabilities (e.g., CommonWell's patient registration capabilities – double check what exactly we can reference is live), further implementation guidance must still be developed beyond the base standard references to make this a reality, including the use of IHE MHD if decided to be the starting point.

### Message Delivery Scenario

We note that the message delivery standard reference IHE XCDR and Direct is listed as an alternative/emerging standard. We suggest that Direct should be the primary focus as it has very wide adoption and can be used between networks as well as directly with individual HINs (including an HIN of a one doctor practice if necessary). IHE XCDR should only be an alternative that can be deployed where certain QHINs agree to do so.

### Development Approach

We understand that the process for further developing the QTF may be similar to how the ISA is being maintained or how input to a certification program is managed. Such an approach would be concerning as it is insufficiently interactive between the principle stakeholders that need to realize the finalized architecture and to continue to maintain and enhance it. We note that the approaches used in CommonWell and Carequality should be the model used to get the right parties fully engaged focusing on those stakeholders that actually have to make it happen. Any approach that is not so focused and is not inclusive of the primary stakeholders

will result in impractical solutions that cannot be sustained.

### **Certificate Policy**

We support the intended direction and types of standards, recognizing that as the capabilities move beyond document exchange, the applicable approach and standards may change.

### **Secure Channel**

RfC #1: *Should the QTF specify additional standards or approaches for securing QHIN Exchange Network transactions (e.g. OASIS Web Services Security)?*

- We support the need to address this topic with the (potential Q)HINs, recognizing our earlier comments that based on the actual access and exchange approach (e.g., document vs. data element/set) the QHIN is not assumed to be reflected through a centralized server.
- We note that some protocols may not need or support transport layer security, but may be done at the application level. For example: Direct Project uses non-secured TPC connection for SMTP traffic, but the payloads are protected using the S/MIME application layer security requirements of Direct.

### **Mutual QHIN Server Authentication**

We note that not all services will use Mutual TLS or even transport level security, but participating servers should use some approach of mutual authentication to ensure that both sides of the conversation establish trust with each other. This should be defined through further use case specific implementation guidance.

### **User Authentication**

RfC #2: *What specific elements should a SAML assertion for User Authentication include?*

- We suggest that Carequality's Query-Based Document Exchange Implementation Guide, which was inspired by eHealth Exchange's NHIN Authorization Framework, provides a reasonable starting point to begin with.

### **Authorization & Exchange Purpose**

RfC #3: *Should QHINs be required to transmit other authorization information (e.g., user roles, security labels) in addition to Exchange Purpose and any information required by IHE XUA? What specific elements should a SAML assertion include?*

- **SAML Assertions**  
We suggest that the ability to include authorization tokens/tags is generally appropriate. We note that, while the Carequality's Directed Document Query guide includes a list that has been substantially extended during the last revision, uptake of the initial set to also assert level of consent has not yet been widely adopted. We suggest that list should be used as a starting point to establish a roadmap for progressively supporting the various tokens/tags.

The IHE IUA and NHIN Authorization Framework would need more work to be worthy of consideration.

- **Security Labeling**  
We appreciate the initial focus of the MRTC to be on document level security labelling given document exchange is the primary initial focus. As also indicated in our response to ONC's Information Blocking and Conditions and Maintenance of Certification proposed rule, we are concerned with the proposed data element level security labeling approach being pursued in the absence of clear standards on how to map security policies with corresponding security labels. We also suggested ONC review alternative approaches on policies that can simplify security labels to ensure the process is practical, computable, and easily explained to patients who then can base their consent directives on those policies. If pursued as proposed without such critical improvements, data will be shared where the expectation was not to share, or will not be shared where it should have been.

As for other standards, any security labeling standards and associated consent management standards should be referenced in the QTF, not the CA/MRTC.

We urge that the framework should (strongly) encourage opt in as the default as it has been demonstrated to get wider participation faster.

### Query

RfC #4: *The Query function above describes a general workflow and set of capabilities for QHINs conducting query-based, inter-network document exchange. However, implementations may vary and result in divergence from the basic workflow. For example, a QHIN might fail to definitively resolve patient identity and consequently rely on a participant or Participant Member to determine the correct match. Likewise, Carequality's Query-Based Document Exchange Implementation Guide describes a number of alternate flows based on a "nominal flow." To inform subsequent work with the RCE to develop more specific technical guidance to address variation, comments are requested on the basic function presented and potential variations to consider.*

- We note that resolving patient identity and matching may not be done in every QHIN at a QHIN level common patient index thus immediately relying on the Participant or Participant Member to have to resolve it.
- We look forward to work with the final RCE and initial QHINs to progress the work to date, starting with Carequality's Query-Based Document Exchange Implementation Guide to expand and refine.

RfC #5: *The IHE XCA profile supports a number of defined queries (e.g., FindDocuments, GetAll, GetDocuments, GetRelatedDocuments, etc.). Each query includes a number of optional parameters. Should the QTF specify which queries/parameters a QHIN must support? Which queries/parameters are most widely implemented and/or useful today?*

- We have identified the following as most common query parameters to Find Document/Get Documents
  - XSDDocumentEntryPatientId
  - XSDDocumentEntryStatus
  - XSDDocumentEntryType
  - XSDDocumentEntryServiceStartTimeFrom
  - XSDDocumentEntryClassCode
  - XSDDocumentEntryFormatCode

RfC #6: *The IHE XCA profile is content-agnostic; it enables queries for documents based on metadata about the document but not the contents of the document itself. Therefore, the XCA profile does not necessarily support more granular queries for discrete data (e.g., a request for all clinical documents about a patient that contain a specific medication or laboratory result). Comments are requested on other appropriate standards to consider for implementation to enable more discrete data queries, such as emerging IHE profiles leveraging RESTful APIs and/or use of HL7 FHIR.*

- We appreciate queries for documents are limited to metadata on the document and not more granular. FHIR based implementation guides are best suited to support expansion of use cases to address data element level queries or data set level queries. FHIR based implementation guides are emerging to support the ability to query synchronously and a-synchronously for more specific data sets. We suggest that this not be limited to IHE profiles. Current efforts in progress to establish the essential infrastructure to enable FHIR based access and exchange would enable a choice of implementation guides to be endorsed and deployed on the networks, whether from Argonaut, Da Vinci, CARIN, Gravity, PACIO, IHE, or from other sources of emerging use case specific guidance. We strongly urge not to attempt to use XCA beyond its current capabilities.

### Message Delivery

As previously stated, we suggest that Direct should become the primary focus and requirement for Message Delivery implementation as it has very wide adoption and can be used between networks, as well as directly with individual HINs (including an HIN of a one doctor practice if necessary). Rather than require IHE XCDR, it should instead become an alternative to Direct that can be deployed where certain QHINs agree to do so. We believe this approach better addresses the first three stated goals of "build on and extend existing work done by the industry" (e.g. DirectTrust community represents 1.9M+ endpoints), "provide a single 'on-ramp' to

June 14, 2019

Page 13

interoperability for all” (use of Direct removes optionality in implementation) and “be scalable to support the entire nation” (e.g., DirectTrust community supported 164M+ nationwide messages in Q119).

### **Patient Identity Resolution**

RfC #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?*

- We suggest starting with the set currently indicated in Carequality’s Query-Based Document Exchange Implementation Guide. Updating this with applicable standardization of format, while adding the opportunity to use validated phone numbers (particularly cell phone numbers) would be a natural progression.
- We caution expanding the list too far until there is enough evidence that the above steps are insufficient as increasing the demographic data set inherently exposes more PHI than strictly necessary to arrive at a good match. In that context, we suggest that more focus should be placed on improving provider registration and patient look-up processes to take advantage of the technologies available and recognizing that the extra effort has substantial value downstream with less records to be matched later or missed opportunities to having access to the full patient record. Our experience with CommonWell has shown that such processes are quite valuable, but are hard to achieve given the initial effort to enter data correctly, to review potential matches more carefully or to deal with other similar efforts.
- We strongly support a direction of using stronger, unique identifiers already in use that in combination with a few other demographic data elements can yield substantial improvements. For example, a validated cell phone number uses an existing identifier that many people already have. We recognize that either this identifier, a driver’s license number, or Medicare Beneficiary Number, or like identifiers cannot cover all use cases but would still provide substantial benefit if the registration process captures at least one of them.

RfC #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?*

- Based on the variety of use cases, the QHIN should not be required to have a centralized patient index. Rather it should have the ability in its network “collectively” to resolve patient or record subject identities based on an agreed to data set that is used across QHINs.

RfC #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.)?*

- We suggest as a general practice that HINs provide agreed to matching rate reporting and share best practices on how to continuously improve these matches. As noted before, the QHIN may not have sufficient central data to report on, relying instead on their Participants and Participant Members to provide that. This may be a good quality measure to consider for various initiatives that thus can help re-enforce necessary improvements.

### **Record Location**

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

- There are substantial benefits by having a common Record Location Service (RLS) for a QHIN, as demonstrated by the success of the CommonWell Health Alliance that includes an RLS. The combination of interactions between CommonWell members' client systems and the common RLS in CommonWell has substantially improved the ability to identify where the patient has records and to reduce the volume of point-to-point queries to determine if the patient is known at a certain endpoint on the network. However, we do not believe that it is required that a QHIN provides the RLS itself but rather that choices are available to their Participants. In Carequality there is no RLS prescribed by Carequality. (Potential Q)HINs identify their own strategy that optimizes finding a patient's records. Market dynamics and learning will find the right balance, thus not requiring a prescriptive approach in the QTF.

We suggest it is important that all RLS services available across QHINs can interact using common event notification standards enabling informing all RLS services, thus improving the efficiencies of record location services and patient matching capabilities.

### Directory Services

RfC #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?*

- Directory services are essential to enable endpoint and capability discovery for various exchange modalities. An agreed to core set of data will be needed to enable such discoveries across networks. We support aggregating and making available information helpful to establishing connection between entities to achieve a scalable network. However, the traditional issues plaguing these efforts must also be addressed: authority, optionality, and governance. Cerner does not believe the QTF should require QHINs to implement Directory Services and instead should continue following ONC and CMS supported efforts to implement a single authoritative directory. While we recognize no one directory can solve for all use cases and not every entity will always be included, the current ONC and CMS indicated efforts at least align with the use cases being contemplated in the TEFCA Draft 2 as a starting point.

Whether a federated approach with a central source of truth will be used should be part of the RCE's charter to establish with (potential Q)HINs in collaboration with CMS and ONC to support the 21<sup>st</sup> Century Cures Act requirement for a Provider Digital Contact Information Index (PDCII) to be stood up. The core directory data set should be shareable across the networks and such a PDCII should use common standards (e.g., FHIR based APIs) while recognizing that networks may need more data to augment that directory data set in support of features they offer to their participants/members. Actual updates may flow up from directories maintained in the networks as new endpoints are being established or flow down as a central directory that is authoritative to certain attributes is updated. Therefore, to the question of specifying a single approach to implementing Directory Services, Cerner supports removing optionality and suggests use of the referenced FHIR-based specification as the starting point given its contemporary architecture. The IHE Healthcare Provider Directory (HPD) profile utilizes outdated technologies reflective in the lack of implementation. If ONC should choose to require QHINs to each implement their own Directory Services, following a standardized approach would at least ease the effort with which interested parties can obtain and use information from the various directories. Lastly, specific policy and governance must be present to address items such as expected entities for inclusion, attributes of those entities, intended use, expected frequency of updates, how to deal with bad actors and for other matters. Cerner believes this policy should require information to be public and allow for inclusion of any entity within the care continuum including physicians, nurses, support staff, care team members, and payers. We encourage ONC to leverage existing directory efforts such as those within the CommonWell and DirectTrust communities as reference models for establishing governance.

Any directory infrastructure must be based on a single standard and format for a core data set as

multiple directories will be required to satisfy different needs that can interact to sync up or down for the common set.

### Individual Privacy Preferences

RfC #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)?*

- Depending on the level of granularity envisioned to express meaningful choice, further efforts are required to establish, validate, and deploy such capabilities. Today, patients can opt in/out of data sharing beyond their provider through a network, where an opt-in default yields the most participation and value. When patients opt out, data is not shared with the network. We are concerned with the proposed requirement that this be communicated to all other networks as that effectively discloses information about the patient's choice. Therefore, consideration should be given to an agreed to interaction with edge systems where the patient's data is available on how to (not) react to requests for information for a patient who wishes not to have his/her data shared. There should not be a requirement that a QHIN must maintain such data centrally.

RfC #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?*

- Similar to Meaningful Choice, and given consent preferences could be expressed more granularly, there should not be a requirement for a centralized approach within a QHIN. Rather the focus should be based on standard interaction with the actual data holder, which may be the edge system, an HIE, or the QHIN itself. This should address how to manage data segmentation and associated consent management. As indicated in our response to ONC's Information Blocking and Conditions and Maintenance of Certification proposed rule, we are concerned that current proposals are too granular and should be limited to manage data segmentation at the document section, entry, or FHIR resource level. Not only is there a current lack of standards but complexities would make the standards practically unimplementable. We suggested alternatives to segmenting data be explored to provide a simpler, more practical approach such as may be modeled after 42 CFR Part 2 where patient can determine whether any data originated by a particular provider can be shared based on permissions that allow none, some, or all to be shared. Most other techniques lack clear mapping between well-defined policies and security labels, and/or have an inability to address secondary sources that effectively still reveal the private data when not properly labeled.

### Auditing

RfC #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?*

- We suggest that the audit should be consistent for an interaction using the same data set across QHINs. We suggest this be further defined between the RCE and (potential Q)HINs.

### Error Handling

RfC #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?*

- We suggest for document exchange to start with Carequality's Query-Based Document Exchange Implementation Guide, while for message delivery, assuming Direct to be the primary standard/method, to use the Direct Protocol's error messages.