2800 Rockcreek Parkway
Kansas City, MO 64117
816.201.1024 Tel
816.474.1742 Fax

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Mariann Yeager
Chief Executive Officer
The Sequoia Project
8300 Boone Blvd.
Suite 500
Vienna, Virginia 22182

RE: Trusted Exchange Framework: Common Agreement Elements and QHIN Eligibility Criteria

Dear Mrs. Yeager:

On behalf of Cerner, we are writing to provide input to the Technical Exchange Framework (TEF) Common Agreement (CA) Elements and related QHIN Eligibility Criteria proposals.

We strongly support the availability of a national trusted exchange framework as set out in the 21st Century Cures Act and the opportunity to build on experiences in similar initiatives such as CommonWell and eHealth Exchange as national networks with Carequality enabling a cross-network trust framework. We recognize many similarities between those respective agreements and the TEF CA Elements and appreciate that progression. Cerner has provided feedback and participated in various listening and discussion sessions on the Trusted Exchange Framework (TEF), Cooperative Agreement (CA), and QHIN Technical Framework (QTF) to date and would like to provide further feedback on the proposed TEF CA Elements and QHIN Eligibility Criteria in light of our participation in enabling national frameworks to date and considering ONC's goal to formally start the implementation of a trusted exchange framework in 2022. Our comments and suggestions build on our feedback provided in prior versions of both the TEF CA and QTF and are provided below for each of the elements.

Definitions

QHIN Scope - We note that when referencing the term "QHIN" it is not always clear whether a reference is solely to the organization that is providing the QHIN services or is inclusive of all its participants and sub-participants as well. For example, when it is stated in Section 13, Fees, that QHINs cannot charge each other, is that solely the organizations providing the QHIN services, or inclusive of any of its participants and sub-participants? We suggest emphasizing that when referencing a QHIN, clarifying that the requirement is intended to only include the organization that is providing the QHIN services, unless it is specifically expanded to cover all its participants and sub-participants.

Available Information - We note that the use of the term "available information" is not clear and should be defined. While the definition of Required Information is providing a clear boundary (ePHI created, received, transmitted, or retained), it is not clear what information within that data set is to be considered "available". For example, if a participant has data in a system that is not (yet) connected and accessible under TEF, is that considered unavailable? Or is it expected to be available on day one as it contains ePHI that may not be available in any other system of that participant? Is the concept meant to align with information blocking exception definitions where such data is not available because the participant does not yet have the necessary technology to make it available? We understand that the intent of the TEF is to meet the

participants and sub-participants where they are at without requiring everything to be immediately available. We suggest that this be further defined in the context of information blocking expectations and from a timing perspective as to when the Required Information and available information is required to be shared. We suggest that, while that may need to be partially addressed for specific use cases under the applicable QTF elements, there also needs to be clarity in the TEF CA on the overall intent of "available information". I.e., the distinction between what is available from a participant or sub-participant vs. what should be sent (Required Information), vs. what is actually send (TEFCA Information) should be clear without mandating upgrades or other incremental investments.

Required Information – We note that the definition of Required Information does not include the notion of Applicable Laws that may restrict what information is required. Rather, that is done in other places. We suggest that the definition of Required Information explicitly excludes any ePHI that is not allowed to be sent under Applicable Law. We suggest that only information that is required under Applicable Law and available should be considered Required Information, while we suggest clarifying the meaning of "available information" as we also further highlight in the section on TEFCA Information and Required Information.

TEFCA Information (TI) – TEFCA Information is defined as "any information that is exchanged between QHINs for one or more of the Exchange Purposes pursuant to any of the Framework Agreements." We are concerned with this concept as it introduces the potential need for participants and sub-participants to flag any data that was sent or received under TEF distinct from any other data to ensure any current and future obligations on the management of TI is managed appropriately. Additionally, it may require a QHIN to persist more data than necessary to understand the actual data that is considered TI to enable compliance with current or future obligations under TEF CA and its corresponding SOPs.

We believe the intent is to ensure that entities that are not currently regulated by HIPAA, manage TI in accordance with HIPAA and consistent with the policies of covered entities and business associates that govern the handling of any received data. However, in attempting to achieve that, an unintended consequence of having a unique definition of TI, which has its own set of rules and requirements under the TEF CA and the corresponding SOPS, such that two separate governing rules may apply to the same set of information. An example of this is that the TEF CA Elements indicate the need for encryption, but HIPAA does not. We suggest that the TEF CA not purport to govern the data that HIPAA covered entities and their business associates receive under this framework. Rather, the additional requirements around governance of the TI data ought to extend only to entities that are not currently regulated in their use, access and exchange of TI.

Exchange Purposes

We support the objective of TEF to enable a wide range of Exchange Purposes that all QHINs should support. We are concerned with the ambiguity across the documents (TEF CA, QTF, and QHIN Eligibility Criteria) that raises the following questions:

- Should a QHIN support all Exchange Purposes currently enumerated in the TEF CA on day one of being a designated QHIN, or can they phase them in considering their current state as a candidate and their commitment to deploy them all?
- Can a QHIN opt to only support some but not all Exchange Purposes? I.e., could a specialized network remain a specialized QHIN?

- Should a participant and sub-participant similarly be required to support all Exchange Purposes the moment they sign up with a QHIN under TEF, can they have discretion support those Exchange Purposes relevant to them or can they phase in support considering their current state capabilities, e.g., the enabling HIT supplier does not provide certain capabilities yet?
- What expectation is set for new Exchange Purposes in terms of it being adopted through an SOP that is managed through the proposed governance process.

We note that in addressing these questions we should consider what "available information" implies as raised in the Definitions section above, as well as the absence of clear guidance in the QTF as to what data is specifically expected to be exchanged when and how (e.g., which document types, what sections, etc.) under the various Exchange Purposes and within those the supported use cases.

We suggest the following clarifications to address these concerns:

- Introduce support for new Exchange Purposes as amendments to the TEF CA rather than an SOP, considering any new Exchange Purpose would be material in nature.
- Provide adequate implementation time and a phased approach for QHINs to support the initial and any subsequently adopted Exchange Purposes and use publication of the applicable QTF elements to set adoption timelines. We note that based on ONC's certification program, from availability of specifications to starting wide deployment typically takes 18-24 months, depending on other regulatory requirements.
- Start the TEF CA with an initial implementation supporting Treatment and Individual Access Services while allowing for more development time and maturation to ensure there is clarity of what information to exchange how and when for the other Exchange Purposes. We support an opt-in approach to future Exchange Purposes, such that all participants can balance the exchange and corresponding controls and assurances around the exchange to ensure that they are able to meet all Applicable Laws, contractual obligations and patient/consumer expectations, in authorizing the exchange.
- Clarify whether specialized QHINs are permitted, or that a QHIN must commit to all current and future Exchange Purposes and associated use cases as they are being adopted through the proposed governance process, considering adequate and reasonable implementation time frames.
- Clarify that the QTF will provide the necessary guidance on what is the subset of the Required Information and what "as available" to be shared means for each of the use cases within an Exchange Purpose and according to what format, e.g., specific document types, templates, structured or unstructured, etc. to avoid to a default send everything always. We note that this could be clarified and summarized as it is being completed with simple summary grids as well to indicate for all the data overall in scope of TEF (and in particular highlighting USCDI prioritized data) which Exchange Purpose/use case should include such data. This can further alleviate concerns around minimum necessary data sets for certain use cases that otherwise would default to everything always.

The section states "...shared through QHIN-to-QHIN exchange..." and "Requests: TEFCA requests would be transmitted via a QHIN's Connectivity Services…". These give the impression that all exchange must physically flow through QHIN servers, i.e., be fully brokered. We are concerned that this is limited through the TEF CA rather than through the QTF for those use cases where brokering is the only workable technology approach. We recognize that with brokering one gains various benefits such as measuring volumes and certain performance. Data for reporting can be centralized rather than aggregated from multiple sources. However, those should not be the main driver, rather technical effectiveness and efficiency should, as well as speed to solution. Many times, measurements are good to understand uptake, but beyond a certain point that is overtaken by user experience: does it work, do I get what I need, etc.

We note two use cases expressed in the QTF Draft 2 that would benefit from not being restricted to brokered exchange: message delivery and FHIR based exchange beyond document exchange. Message delivery has demonstrated under the Carequality umbrella that the legal framework with a directory entry is sufficient to make that happen. If it had to be brokered speed to value would have been very slow. As a result, Cerner was able to deploy eCR Now in less time and start to contribute to improved public health reporting sooner. Other scenarios where the receiver is known to the sender and only may need a patient discovery and directory look up for an address to deliver the message is sufficient. The message itself need not to be brokered. A second example is the use of FHIR where all current network-based initiatives start with a hybrid approach. That process has the opportunity to take advantage of not only the legal framework, patient discovery services, and establishing trust (authentication, authorization, and registration through a shared environment), while the actual FHIR-based access and data exchange is directly between the client and server of the (sub-)participants, not through a QHIN server. A QHIN may opt to do so but should not be required to. We urge the RCE and ONC that the TEF CA does not impose an architectural decision that needs to be driven by the technology, thus the QTF, much like the suggestion that a QHIN need not use a central RLS or eMPI. The focus should be on the performance of the solution where some use cases may greatly benefit from brokering while others don't. The TEF CA should enable TEF to be a framework that reduces the number of point-to-point data sharing agreements that otherwise would be necessary, while enabling a variety of technologies to solve use cases as they came about and evolve.

In the Responses bullet, we note that of the parties listed that are given an exemption from responding to a request for health information, various parties would have data of great value when responding to a request for information, including for treatment. For example, it is unclear why a Public Health Authority would not be under the same obligation to respond to valid requests for information. As we explore use cases not limited to ePHI, but involving de-identified and/or aggregated data, for all the potential interests even within the currently proposed Exchange Purposes, the suggested approach would be limiting. The required exchange of health information by Public Health Authorities, on patients individually or in aggregate, could enable a provider to provide better care for a specific patient or population or a consumer/patient obtaining their health data from that same agency. Another example is whether an IAS Provider must or may respond to a request by another IAS Provider where the patient has data and has consented to exchange. Similarly, if a patient consents to sharing their data with a provider held by an IAS Provider, what is the obligation of the IAS Provider to enable the access or exchange. Generally, we suggest that underlying value of the TEF is bi-directional exchange and that only in specific use cases a party may be deemed not to have to respond.

In addition, the requirement to respond to any requests, unless prohibited by law, assumes trust with the requestor. It is unclear how this trust is established and, if that trust is broken, who ultimately is responsible for the violation. While we fully support the objectives of universal interoperability, we do not see that enough attention has been paid to the custodian of the information's obligations to maintain the privacy of the information. On one hand, covered entities and their business associates each have extensive potential exposure for wrongful access to or disclosure of personal health information. On the other hand, these same entities face additional exposure under the information blocking rules of the Cures Act, and this Common Agreement, as they are required "to respond to a request for certain health information for any of the Exchange Purposes." While this proposed agreement (and the information blocking rules) each say that information can be restricted if the exchange is prohibited by Applicable Law, there is no safe harbor under HIPAA (or other federal and state privacy rules) for disclosures made under this Common Agreement, in good faith and in reliance on the TEF.

Participants and Sub-Participants
We appreciate and support the recognition of participants and sub-participants that reflect the potential organizations involved in enabling a national network infrastructure.

Required Flow-Down Provisions
While generally we agree with the need for flow downs, for participants and sub-participants that would raise a particular concern around what Exchange Purposes they must support and when, and the required data they are expected to share for each of the Exchange Purposes and use cases within that. Especially on day one, it is not practical that each participant and sub-participant is expected to share all Required Information for all Exchange Purposes and every use case within that in order to participate under TEF. Participants and sub-participants should be able to participate in TEF based on their business interests, the technical capabilities of their systems, and the Required Information that is relevant to what they maintain in their systems as a matter of the normal course of their business. We suggest this is acknowledged and clarified to enable a practical adoption progression. See also other comments in the Definition and Exchange Purposes sections.

TEFCA Information and Required Information
We note that the Required Information uses ePHI as the criterion for inclusion, but not EHI as is done for the information blocking rules. At the same time, we note that valuable use cases exist where ePHI is not the data of interest. For example, these use cases include those for de-identified and aggregate data, as well as certain operational data, such as for directory services and availability data to aid in referral processes and exchange using message delivery and upcoming FHIR based access and exchange.

This would imply that the Required Information scope should be larger than ePHI or EHI. This challenge highlights that we must be cautious in defining the scope of data that is required to be accessed and exchanged in the TEF CA, rather than through the QTF and SOPs. We need to avoid setting expectations that we would have to share everything always as the current definitions imply, while other data beyond ePHI is not being contemplated. We suggest there be clarity provided on the use of ePHI vs. EHI and acknowledge the need to address non-ePHI/EHI for various use cases by clarifying the role of QTF elements to specifically address what data to share when and how in line with our prior commentary in the Required Information and

Exchange Purposes sections. This will also help to establish a more stable TEF CA that would not require frequent updates.

Governing Approach to Exchange Activities Under the Common Agreement
We support the general approach outlined to govern updates to the TEF CA, QTF, and SOPs and appreciate all stakeholders are involved and can contribute.

QHIN Designation and Eligibility Criteria
We note there is apparent ambiguity in the term Signatory as used in the QHIN Eligibility Criteria. On the one hand, the criteria imply that the signatory already can support all Exchange Purposes and capabilities according to the QTF (Section 2.a.i) at the time it signs the TEF CA while on the other hand, when signing the TEF CA, the signatory only needs to share what it currently can do (Section 2.b and 2.c) as it is only at the start of the process to become a QHIN. We understand there is a process where an interested network makes a statement of intent to want to become a QHIN and needs to submit its qualifications and plans to address any gaps to becoming a designated QHIN (e.g., expanding support to all use cases, improvements on process, and/or performance criteria), and is finalized as a designated QHIN upon acceptance of demonstrable capabilities. We suggest separation of these stages and clarity as to what is expected when, including a requirement for plans on how and when to address any gaps, and that requirements of the application and preparation phase are clear, vs. what is committed once the network is designated as a QHIN.

We also suggest that section 2 is clear on the point about whether or not there can in fact be QHINs that can specialize based on specific Exchange Purposes and use cases. If a network seeking to become a QHIN is a specialized network, is the fact that they are asked to provide documentation of their specialty indicative that they can become a specialty QHIN? Or must they address how they will take on all Exchange Purposes, as do other QHINs? And if so, does that also mean they can only become a provisional QHIN until such time as they can support all Exchange Purposes and use cases? It also has been our understanding that, while a specialized network may be a candidate QHIN, a designated QHIN cannot be specialized by any of these characteristics as it needs to be able to support all agreed to Exchange Purposes and use cases as they are phased in. We suggest that this is further clarified in section 2.

While the initial Exchange Purposes are identified and eligibility criteria are being established that assume all initial Exchange Purposes must be supported as the scope, it is not clear how adoption of subsequent Exchange Purposes will be considered. We suggest this process is clarified and whether a QHIN is obligated to adopt any further Exchange Purposes as they are added to the TEF, or whether all QHINs must always agree to adopt any new Exchange Purpose, or they jeopardize their QHIN standing if they do not. As mentioned above, we suggest an opt-in approach to future Exchange Purposes.

We noted in our response to the TEF QTF the need for clarity on performance objectives, e.g., response times, patient matching quality, time-outs, etc. around patient discovery in particular. We note that in Section 5 of the QHIN Eligibility Criteria there is mention of an SOP, but that SOP has not yet been defined. We believe it is important that as part of assessing whether an interested network has a reasonable opportunity to be successful to be a designated QHIN, and for any network that is about to be designated as an approved QHIN that has demonstrated it can support the necessary performance criteria, such criteria are well defined. We look forward to review specifically the target performance goals and provide further input at that time. This is a critical element for all parties across TEF to establish the necessary expectations and trust.

Cooperation and Nondiscrimination
We agree with the basic tenants of cooperation and non-discrimination to achieve a trusted exchange framework. In that context, data sharing should be the default behavior, which means to enable bi-directional access and exchange across participants and sub-participants, not limiting response requirements to some classes of participants, sub-participants and Exchange Purposes. As indicated in other sections, we suggest that Applicable Law, availability of information and readiness for supporting the required Exchange Purposes and use cases, as further reflected within the consent directives of a patient, define who is expected to share data and when such data should be accessible.

RCE Directory Service
We appreciate the inclusion of a singular directory service that reflects all the relevant QHINs, participants, and sub-participants with their official endpoints/addresses for the various purposes that can be used in combination with the QHINs patient discovery services to find the correct endpoints/addresses easily and reliably.

Individual Access Services (IAS)
We understand that QHINs, participants, and sub-participants are not required to provide Individual Access Services, but conversely, a QHIN, a participant or a sub-participant must honor a request from an IAS Provider where they have information for that individual. We support that approach. In this context, we want to highlight where an IAS Provider may have relevant data and the individual has provided the necessary consent for the requester to access that data. We suggest that rather than explicitly stating that an IAS Provider need not respond to such requests, that the IAS Provider is considered no different than other participants and sub-participants and this is addressed through clearly defining what constitutes "available information" as discussed in the Definitions section. We suggest that managing patient consent in this situation need not be different than requests from other parties, which still requires much attention as we will highlight in the Special Requirements (including Consent) section. We also recognize that the relevant specifications to enable this use case may need further updates before this capability can be deployed, yet the TEF CA should encourage adoption of those capabilities at that time.

Privacy and Security
Privacy and security are critical components when creating a truly trusted exchange framework. As TEF is intended to encompass both HIPAA covered entities and non-HIPAA entities, all parties must be held to the same level of secure exchange, within the privacy policies across the various jurisdictions and a patient's consent directives, with clear understanding and transparency how the data is to be used by the connected stakeholders.

Special Requirements (including Consent)
This element requires IAS Providers to obtain patient consent which we agree is essential to establishing trust. However, in the absence of a computable consent and policy assertions and assessment capabilities, trust in consent assertions or sharing of non-computable consent directives to demonstrate authorization to request data on behalf of the patient or enable responses for other requesters is limited.

In the QTF there is a capability described that enables consent to be asserted or exchanged as part of the document exchange process. While that provides the potential for managing consent, it is insufficient in itself to scale at the level of TEF due to lack of computable, standard vocabulary for privacy policies across jurisdictions and patient consent directives. There

furthermore needs to be an ability to clearly identify the requester (individual or organization) in the context of their class, e.g., the relevant Exchange Purpose, or to provide further authorization granularity, e.g., emergency declaration, to assess whether the request can be fulfilled. There is also a need to understand how to manage revocation of a consent or to address incorrectly asserted consent. These and other complexities make it challenging to enable computable privacy and consent assertions and assessments at a national scale.

We suggest that without a concerted effort to address these gaps, the proposed element will be limited in enabling and driving wider data sharing, particularly for Exchange Purposes beyond TPO among HIPAA covered entities. We urge the RCE and ONC and the community at large to address these challenges, while establishing audit capabilities in the meantime to address incorrect consent assertions for non-HIPAA covered entities and outside of TPO.

Fees

We appreciate and support the suggestion that QHIN service providers cannot charge each other for TI transactions. That works when all QHIN service providers are required to support the same Exchange Purposes and use cases as this involves bi-directional exchange among the QHINs. However, for interactions between participants and sub-participants, whether brokered or not through the QHIN, the nature of these data sources may be such that the interactions are more unidirectional. For example, requests for Benefits Determination would not be reciprocal. We suggest therefore, other than for QHIN-to-QHIN and for the Exchange Purposes of Treatment and Individual Access Services, the TEF CA is clear that fees can be charged among parties across the TEF in accordance with Applicable Law. We note that if specialized QHINs are permitted, interactions may become primarily unidirectional between specialized QHIN and "comprehensive" QHINs and that fees should be permitted to enable cost sharing of the necessary infrastructures. If the intent is that all transactions under TEF are free, then other funding methods must be established for data sources to enable the essential infrastructure to support all Exchange Purposes and use cases.

Please do not hesitate to contact us if we can be of further assistance.

Sincerely,

Hans J. Buitendijk, M.Sc., FHL7
Director, Interoperability Strategy

John Travis
Vice President & Product Regulatory Strategist