



June 17, 2019

Donald Rucker, M.D.
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

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

Dear Dr. Rucker,

On behalf of Change Healthcare, I am pleased to submit our comments in response to the Office of the National Coordinator's ("ONC") requests for comment and information on the Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2 ("TEFCA 2.0").

Tackling the significant task of defining the framework for a safe and effective health information exchange and the appropriate agreements is critical to moving the needle forward for interoperable health information systems in the United States. We applaud the ONC's efforts as we know there were many industry comments submitted and considered in response to the first draft of the TEFCA. Thank you for your time and efforts in crafting this second draft.

Change Healthcare is a leading independent healthcare technology company that provides data and analytics-driven solutions to improve clinical, financial and patient engagement outcomes in the U.S. healthcare system. We are a key catalyst of a value-based healthcare system, accelerating the journey toward improved lives and healthier communities. We are one of the largest clearinghouse operators in the U.S. with a network connecting more than 800,000 providers and 2,100 payers. Leveraging our Intelligent Healthcare Network™, Change has grown to be the single largest financial and administrative network serving the U.S. healthcare system, helping payers, providers, and other stakeholders operate more effectively and efficiently.

Change Healthcare is dedicated to accelerating the journey toward improved lives and healthier communities by partnering with our customers to help reduce their costs, create efficiencies, and effectively manage complex workflows. In carrying out our mission, Change Healthcare serves as the service provider to many Health Information Networks

(HINs), most notably the CommonWell Health Alliance, which serves 13,000+ provider sites and 50 million unique individuals, with over 29 million records retrieved. ¹

Below you will find Change Healthcare's comments on TEFCA 2.0. We support many of the initiatives outlined in TEFCA 2.0 including use of a single "on-ramp" to information exchange, as well as the engagement of a non-profit organization within the industry to serve as the Recognized Coordinating Entity (RCE). In addition, we are encouraged by the attention that this version of the TEFCA gives to the minimum security and privacy requirements that relate and flow down under the Minimum Required Terms & Conditions (MRTCs) to all Participants and Participant Members, including entities that are not subject to HIPAA's privacy and security requirements like direct-to-consumer companies that provide a personal health record application.

Coupling TEFCA 2.0's security and privacy requirements with the ONC's goal of expanded interoperability presents an opportunity to ensure that many more participants in the exchange of health information agree to appropriate data protection and stewardship principles. To ensure that the principles and appropriate data protections are implemented, we urge the ONC to exercise its authority under section 4003(b) of the 21st Century Cures Act, to consult with the National Institutes of Standards and Technology (NIST) to conduct pilot testing and to provide technical assistance. We recommend the ONC take the time to test and provide follow-up technical guidance to help ensure the careful, deliberate and methodical roll-out of a fully-functioning national Health Information Network on day one. Such a pilot test phase could also provide the ONC the opportunity to confirm the efficacy of the terms and conditions in the Common Agreement in real-world environments, and that the Trusted Exchange Framework is indeed secure and trusted.

1) Comments on The Trusted Exchange Framework (TEF)

In TEFCA 2.0, the ONC has proposed three primary goals it seeks to achieve:

- 1) a single "on-ramp" to nationwide connectivity,
- 2) secured data availability when and where patients need it, and
- 3) nationwide scalability.

We support these three goals and appreciate the ONC's further articulation in this draft of a single "on-ramp" to information exchange. While we support the three goals, we caution the ONC against trying to make the TEFCA fit every use case and user, as this

¹ Source: CommonWell Health Alliance, <https://www.commonwellalliance.org/>

may ultimately slow overall progress toward adoption of a national network, because of the time and effort required to contemplate and accommodate every unique use case and user at the onset. We also support the general principles articulated in the Trusted Exchange Framework (TEF) and believe all HINs should follow these principles.

We understand the FHIR standard to support population level data queries and exchanges is currently in development. While we do not support immediate inclusion of this new standard in the TEFCAs, we were surprised by the ONC's removal of a future state standard from TEFCAs 2.0. As we will discuss in a later section, we believe the FHIR standard has matured since the first comment period for TEFCAs, and it should be included in the TEFCAs 2.0, and be the standard used by Qualified HINs (QHIN).

2) Comments on The Common Agreement (CA) – Minimum Required Terms and Conditions (MRTCs)

There are many of the same defined terms in both the MRTCs and in the ONC's proposed rule on information blocking ("Proposed Rule"). To avoid confusion, the defined terms used in TEFCAs 2.0 and the Proposed Rule must match. Consequently, we would like to reiterate our comments on the definitions of Electronic Health Information (EHI) and HIN to the ONC. We believe that both definitions are overly broad and will have unintended consequences on the industry. We provide more specific comments on each of these definitions below that align with the comments that we submitted on the *Proposed ONC Interoperability, Information Blocking and ONC Health IT Certification* regulations ("CHC Letter") on June 2, 2019.

- **EHI Definition:** We suggest that the ONC limit the scope of what constitutes EHI, as well as the timelines and modalities for exporting such data. The definition of EHI should be limited to include only the clinical and financial information related to a patient's care. EHI as defined should exclude data that is derived from value-added analytic services or otherwise algorithmically derived. We encourage the ONC to also consider limiting the definition of EHI to a "designated record set" based on the U.S. Core Data for Interoperability (USCDI), as defined under Health Insurance Portability and Accountability Act (HIPAA). This USCDI-based designated record set should be the "floor" for moving forward with the regulations and the scope of EHI can be re-examined in the future with the goal of adding more health data types and data sources on this journey toward greater interoperability.

We recommended in our CHC Letter that the ONC limit the EHI definition to Individually Identified Health Information (IIHI) maintained electronically in a

designated record set. Constraining EHI to IHHI maintained electronically within a designated record set would better capture the universe of IHHI that Congress sought to protect in 21st Century Cures Act. In other words, EHI should be limited to (i) clinical information which is maintained within electronic health record and claims management systems, and (ii) needed by health care providers and health plans to make treatment and payment decisions about patients.

- **HIN Definition:** While HIN *entities* - such as the national networks like CommonWell or eHealth Exchange – are the organizations that manage, control, and influence the technologies they use to facilitate interoperability, such HIN entities may source the information exchange technologies from technology vendors. Because these traditional HIN organizations oversee general governance in addition to managing supporting IT vendors, modifying the HIN definition to exclude specific vendors would still include organizations the industry traditionally thinks of as HINs, while appropriately excluding “best of breed” vendors, such as interface/middleware technologies and MPI services. As per our comments in the CHC Letter, we recommend the ONC edit the definition of HIN accordingly to exclude Health IT vendors such as interface/middleware developers, MPI and patient matching vendors, and clearinghouses.

We also recommend the following definition for qualified health information network (QHIN):

- **QHIN Definition:** The new definition under TEFCA 2.0 states that a QHIN is “...a *Health Information Network that is a party to a Common Agreement signed by the RCE and has been Designated a QHIN by the RCE after satisfying all the conditions of the Common Agreement and the QHIN Technical Framework.*” While the ONC has modified the QHIN definition from the original draft and removed many of the requirements for QHIN designation, we are primarily concerned with the removal of the connectivity broker quality. By removing connectivity broker quality from the definition of QHIN, TEFCA 2.0 appears to have dropped the requirement that QHINs provide a record locator service (“RLS”). **We do not support the removal of the RLS requirement.**
 - As proven through our experience with CommonWell Health Alliance, an RLS supports patient and document location at scale. RLSs enable systems to routinely capture patient location data and store it for when a patient actually needs their data. Without an RLS, each querying node

needs to either know where to look for data, or blindly query end points in search of a patient's records. This is not suitable or efficient to support business-to-business transactions, as each querying node would most likely:

- come up with their own method for locating records,
- need to rely on data stored within their individual business systems versus leveraging all patient locations learned by an entire network to locate records, or
- lead to queries not being as performant, because it may not connect to information indexed on the network.

Even for a patient access use case, the RLS is essential as patients are not going to be able to remember all the locations they visited in the past, nor would it be efficient to blindly query end points when a patient wants to do a broad search. The removal of this requirement threatens the scalability and efficacy of the TECA and, therefore, the ability to attain one of the ONC's stated goals.

We are also concerned that the breadth of the proposed QHIN definition will lead to too many HINs participating in the larger network, which can also threaten overall scalability. We suspect that too many initial QHINs may decrease greater adoption levels by creating too many choices by which to connect. In our experience with CommonWell Health Alliance and CareQuality, we have observed that members are only able to leverage a minimum set of capabilities due to competing roadmaps within their own organizations. We suspect that with a greater number of QHINs, members will be challenged to join and maintain multiple connections for useful integration.

Further, allowing an abundance of HINs to become QHINs will make it difficult to gain consensus when defining processes, policies, and standards, and could slow new use case deployment. We believe the industry needs to move slowly with a few QHINs initially to gain momentum and then speed up over time.

3) Comments on the Initial Application, Onboarding, Designation, and Operation of QHINs

The ONC laid out a general process in the MRTCs for how a HIN would apply, onboard, and qualify for QHIN designation. However, the MRTCs are not clear about which exchange modalities a QHIN would need to support at the qualification stage. For example, the MRTCs state that a QHIN must be "live" in a clinical environment but does

not specify whether all exchange modalities must be supported at that time or just a subset, such as only targeted and broadcast queries or push messaging. While we suggest the ONC remove push messaging from the MRTCs, we ask that ONC clarify which exchange modalities must be “live” in a clinical environment in order for a HIN to be onboarded to the Common Agreement.

We support the removal of the population level query at this time from the MRTCs since the FHIR standard is still being developed, and we support both the targeted and broadcast queries modalities. However, we are concerned about the ONC’s inclusion of push messaging in MRTCs 2.1.1 iv, v, and vi. We recommend that the ONC remove this requirement from the MRTCs.

a) Comments on Data Exchange Purposes

In TEFCA 2.0, the ONC has narrowed down the exchange purposes and maintained the data reciprocity requirements. We believe the data exchange purposes should be further narrowed to Treatment, Individual Access, Utilization Management, Quality Assessment and Measurement, and Benefits Determination. We also ask the ONC to clarify whether all QHINs, Participants, and Participant Members must support **all** of the exchange purposes. While we understand why participation in all seven should be mandatory for all participants, (if organizations can pick and choose which purpose to respond they will likely default to treatment, which is the current state), we believe individual access should be treated differently. There are a number of organizations who may wish to support the individual access use case only, such as those creating portals and apps for patients. We believe requiring such organizations to respond to queries for **all** exchange purposes will limit overall participation in the Common Agreement. We ask that the ONC clarify that a QHIN, Participant, or Participant Member can support only one, such as individual access exchange purpose, or a subset of the ratified exchange purposes.

Further, we support the ONC’s MRTCs that stipulate that EHI can be reused for any of the exchange purposes once it has been provided to the data requestor. We also strongly support allowing individuals to control and limit disclosures of the EHI that was made available to such individual through the Individual Access Services exchange purpose. It is vitally important that individuals have the opportunity to understand and make informed choices about where, how, and with whom their EHI is shared. Therefore, individuals must understand and explicitly consent to how their EHI is used when it is obtained directly on their behalf. We believe that the MRTCs that limit the reuse without such explicit consent will provide appropriate protections for individuals and ensure they can trust the networks who are accessing their data.

In MRTC 2.2.1 (ii) the ONC indicates that a QHIN must respond with the EHI it has: *"If the QHIN stores or maintains EHI, the QHIN shall also respond by providing all of the EHI in the then applicable USCDI to the extent that all of the following conditions are satisfied."* This clause seems to conflate EHI and USCDI, and it is confusing whether QHINs must at a minimum be able to exchange all EHI or just the USCDI. We suggest the ONC reword the clause to indicate that a QHIN shall also respond by providing the then applicable USCDI to the extent that all the conditions that follow are satisfied. We believe modifying this clause and the accompanying flow down clauses to obligate Participants and Participant Members in Sections 7 and 8, respectively will alleviate confusion.

b) Comments on Data Outside the U.S.

Finally, in this section the ONC has included a clause that limits not only the storage of EHI in cloud-based systems that are outside of the U.S., but all uses and disclosures of EHI outside of the U.S. We understand this limitation is intended to protect national security and ensure that foreign governments do not gain inappropriate access to the health information of U.S. citizens. We support the requirement that EHI be hosted within the U.S. and encourage the ONC to finalize that portion of the clause. However, we are concerned with the restriction that data may not be used or disclosed outside of the U.S., particularly since these terms are defined quite broadly.

Change Healthcare, like many other technology vendors that will support QHINs, often uses offshore resources who can access Protected Health Information (PHI) and provide remote services from a secured location (a vault-like area that prohibits cameras and removable storage) via a Virtual Desktop Infrastructure (VDI) but cannot download, save, or store such PHI to that remote location. In other words, the VDI access from a secured location enables offshore resources to perform services without storage of any PHI at that offshore location. However, the ONC's restriction on Use and Disclosure outside of the US would prevent companies from utilizing offshore resources in this manner.

We believe that this could have an unintended effect on the market, such as driving up costs and prices, and limit the vendor options QHINs can choose from to provide their technology stack. We encourage the ONC to either redefine "use and disclose" to indicate that data is downloaded or stored or use different terminology that would not limit offshore resources from accessing PHI via VDI. For example, 2.2.11 could be reworded to state that no QHIN shall allow for the download or storage of any EHI outside of the U.S., except as required by Applicable U.S. Law or as provided below. In Section 2.2.11 (i) of the MRTCs, the ONC could modify the clause to state that QHINs

shall not allow for the download or storage of EHI by any person or entity outside the U.S., except to the extent that an Individual User requires his or her EHI to be downloaded or stored outside of the U.S.

c) Comments on Cooperation and Non-discrimination

Section 5.2.1 of the MRTCs includes the following: “A QHIN must use reasonable and nondiscriminatory criteria and methods in creating and applying pricing models if it charges any Fees or imposes any other costs or expenses on another QHIN. Nothing in these terms and conditions requires any QHIN to charge or pay any amounts to another QHIN.” We support ensuring that QHINs do not use varying fees to discriminate against some QHINs that may be a competitor. However, “reasonable and nondiscriminatory” is not defined in the MRTCs. In the Proposed Rule, ONC proposed information blocking rules that licensors must use “reasonable and non-discriminatory” (RAND) pricing terms. It is unclear whether the ONC is intending to use the same policy from the Proposed Rule but applied to QHINs for all QHIN’s services. If so, in alignment with the comments we submitted in our response to the Proposed Rule, we strongly disagree with imposing a blanket limit on fees on all services.

We support reasonable, transparent fee structures for patient and document location, document query, document retrieval, and message delivery. However, each QHIN should be able to charge market rates for any value-add solutions which go beyond foundational, required capabilities. Likewise, a QHIN should be able to charge for secondary use if the data is treated in some way to meet the secondary use case (i.e., data quality enhancement, use of analytics, etc.). We ask that the ONC modify the MRTCs or define the terms “reasonable and non-discriminatory” to allow for market pricing of value-add services.

d) Comments on Privacy, Security, and Patient Safety

- i) Privacy Requirements – Generally.** We urge the ONC to continuously monitor and harmonize the Privacy Requirements set forth in the MRTCs with all applicable federal privacy laws, any rules, regulations or guidance that is promulgated by HHS now and in the future, including the Proposed Rule. There is no “one-size-fits-all” solution that will apply uniformly to every QHIN, HIN, Participant, Participant Member or Individual User who will exchange information within a national health information network. However, the MRTCs are an improvement as they address each of the Fair Information Practice Principles and lay a foundation that recognizes

vulnerabilities exist, encourages cooperation to resolve threats and encourages trust to allow EHI to flow when and where it matters most.

- ii) **Breach Notification Requirements and Security Incidents.** We agree with the proposed breach notification requirements and obligations for reporting security incidents in this section.
- iii) **Law Enforcement Exception to Breach Notification.** Notwithstanding Section 6.1.1 above, if a QHIN is notified, in writing or by oral statement by any law enforcement official or by any other governmental agency (e.g. Federal Trade Commission), that a Breach notification would impede a criminal investigation or cause damage to national security, and the statement has been documented consistent with 45 CFR 164.412(b), then the QHIN shall delay the Breach notification for the time period specified by the law enforcement official.

e) Application of NIST Standards and ONC/OCR Security Risk Assessment Tool

(i) HIPAA Security Rule Crosswalk to the NIST Cybersecurity Framework and ONC/OCR Security Risk Assessment Tool.

We suggest refining Section 6.2.1 (i) of the MRTCs with examples of how to use the tools referenced in that section. We suggest the following:

“Each QHIN shall use as part of its security program on at least an annual basis, the most recently published version of the ONC/OCR HIPAA Security Risk Assessment Tool to help the QHIN ensure its compliance with the HIPAA Rules. In addition, and as part of ongoing risk management and analysis, each QHIN shall follow the HIPAA Security Rule Crosswalk to the NIST Cybersecurity Framework or NIST Special Publication 800-30.”

(ii) Protecting the Confidentiality of Controlled Unclassified Information (CUI) in Non-Federal Systems and Organizations.

We support the proposed guidance set forth in Section 6.2.1 (ii) of the MRTCs and suggest the addition of the following:

“Each QHIN shall also develop and implement an action plan to comply with all standards and implementation specifications of the HIPAA Security Rule”.

We suggest that the ONC consider the use of more robust security control frameworks, such as NIST SP 800-171 or NIST SP 800-53 for Moderate systems.

iii) Auditable Events.

We have concerns regarding the following requirement set forth at Section 6.2.8(ii) in the MRTCs:

"An audit log including records for all auditable events required by the QHIN Technical Framework. A QHIN shall retain all audit logs (both electronic and non-electronic) in accordance with Applicable Law and make such audit logs available during any audit"

We do not view this scenario as feasible in a shared services or multi-tenant IT environment where a single set of information systems, (including a single set of audit logs for such single set of information systems) is offering one or more products and/or applications to hundreds or thousands of customers concurrently. We see the suggested scenarios as very burdensome on the Health IT vendor powering the QHIN exchange, and there would be a significant possibility that audit logs for the Health IT vendor's other operations, wholly unrelated to ONC's Trusted Exchange Framework, could be accidentally included in an audit report under TEFCFA. The recommendation is to strike this requirement.

iv) Right to Receive Summary of Disclosures of EHI.

We agree with the requirements set forth in Section 9.5 of the MRTCs.

f) Comments on The Recognized Coordinating Entity (RCE)

We support the ONC's intent to choose a non-profit organization from the industry to serve as the RCE. We believe that an industry organization is most qualified to complete and operationalize the Common Agreement. With respect to the QTF, we suggest that the ONC edit the QHIN Technical Framework (QTF) to provide more deference to the RCE, with clearer functional requirements defined in the MRTCs. We urge the ONC to lean towards providing the RCE with the maximum amount of autonomy possible as it develops the Additional Required Terms and Conditions (ARTCs) and the QTF with the industry. We understand that the ONC may be tempted to overrule the industry and the RCE on some points, but we urge the agency not to do so. The RCE should be allowed to work collaboratively with a broad group of stakeholders to ensure we reach a final Common Agreement that best supports industry needs.

g) Comments on the QHIN Technical Framework

The RCE should be primarily responsible for developing the QHIN Technical Framework , which should ultimately be an implementation guide that QHINs can use to build their services. We urge the ONC to allow the RCE primary authority over this document. Consequently, we believe the RCE should take the following comments into consideration as they develop the QHIN Technical Framework.

We have a number of concerns about the technical stack suggested in the QHIN Technical Framework. First, the ONC seems to have removed the RLS requirements that were present in the first iteration of TEFCA. The exchange modalities that ONC has proposed cannot scale without RLS being a requirement for QHINs, particularly the Broadcast Query. The ONC included a requirement that “A QHIN *MUST* be capable of accurately identifying the location of all appropriate patient EHI prior to responding to a QHIN Query.” However, this does not necessitate that a QHIN run an RLS, and we are concerned that some QHINs may try to take a federated approach which likely would not scale, impacting the viability of the entire network.

A second concern is the inclusion of push messaging as a required exchange modality. The ONC has indicated that it included push messaging to support public health reporting and delivery of clinical summaries upon a transition of care. We believe that both use cases are already well covered outside of the TEFCA, including them as required exchange modalities is duplicative, and their inclusion may be asking too much from QHINs that do not already support push messaging. Direct messaging is widely used for delivering care summaries, and healthcare providers have had to report data to public health registries since 2011. We urge the ONC not to try to make the TEFCA cover every single possible use case, at least not initially. We recommend that push messaging be removed as a required exchange modality. If the ONC does not remove this requirement, then at a minimum it should specify standards for push messaging that are already in use in the industry, which is not in the current proposal.

We are also concerned that the standards stack is limited to legacy IHE standards and does not include FHIR in any capacity (i.e., the HL7 stack or the IHE specs). The FHIR R4 standard is stable for clinical information and currently in widespread use, including by CommonWell and Apple. We are concerned that removing FHIR as a requirement could stagnate further growth as new standards or various standards would need to be met versus leveraging and building off existing and matured standards. We urge ONC to include FHIR as part of the standards stack, or at a minimum not prevent the RCE from using FHIR.

Finally, the ONC required that QHINs in the MRTCs share patient consent. While we agree that QHINs will need to be able to exchange consent to ensure patients trust the QHINs, we are concerned that the QHIN Technical Framework does not include any standards for exchanging that patient consent. It is unclear how QHINs will, or should, accomplish this requirement without a standard being specified in the Technical Framework.

Lastly, we would like to reiterate our support for many of the goals in the Proposed Rule. It would be remiss of us to not highlight one way to incentivize participation in TEFCA 2.0: ONC should expressly provide a safe harbor in the Proposed Rule for those entities participating in TEFCA, or in the alternative, expressly provide in TEFCA that an entity's participation in TEFCA is an affirmative defense regarding the applicable portions of the information blocking rule. The latest draft of the Proposed Rule is written broadly without much specificity and punishes entities that violate information blocking rules. With some uncertainty among current HIT and certified HIT developers whether any of their practices implicate the information blocking rules, ONC has the opportunity here to not only provide certain assurances to certified HIT developers that their participation in TEFCA is a strong indication of compliance with select portions of the information blocking rules, it will also send a message to future innovators that participation in TEFCA will give them a head start on compliance with the Proposed Rule.

Conclusion

We applaud the ONC for their comprehensive effort to create a thoughtful approach to trusted health information exchange and the agreement frameworks that will govern Health Information Networks. We are happy to answer questions or discuss our comments in greater detail, and I may be contacted at Deanne.Kasim@changehealthcare.com or at (301) 807-8567.

Sincerely,



Deanne Kasim
Senior Director, Health Policy Strategy