

February 20, 2018

Donald W. Rucker, MD
National Coordinator for Health IT
Office of the National Coordinator
Department of Health and Human Services
Mary E. Switzer Building
330 C Street, SW, Office 7009A
Washington, D.C. 20201

Re: Trusted Exchange Framework & Common Agreement

Submitted via email to exchangeframework@hhs.gov

Dear Dr. Rucker,

CommonWell Health Alliance (the Alliance) appreciates the opportunity to submit comments regarding the *Draft Trusted Exchange Framework (TEFCA)* published on January 5, 2018, as well as the accompanying *US Core Data for Interoperability (USCDI)* draft.

By way of background, CommonWell Health Alliance is a not-for-profit trade association made up of diverse health care and health IT stakeholders across the care continuum, dedicated to the notion that the individual's data should be available to themselves and their caregivers, regardless of where care has occurred. To accomplish this Vision, our Mission is to create secure, authorized, universal access to health data via a person-centered, nationwide network. Alliance members represent more than 20 care settings, including two-thirds of the acute care EHR market^{*}, more than one-third of the ambulatory care EHR market[†], technology leaders in post-acute care, patient portals, imaging, pharmacy, population health, emergency services and others; and other key organizations across the health care spectrum such as State and Federal Agencies, Not-For-Profit Organizations, and of course clinical providers. The Alliance and its members are committed to the belief that access to health data must be built into information technologies at a reasonable cost for use by a broad range of health care providers and by individuals to best manage their health. Over the past three years, we have driven adoption of nationwide interoperability among more than 8,000 care locations, enabling more than 100 million transactions for more than 23 million unique patients.

[A] Statement of Support for TEFCA

CommonWell Health Alliance is very supportive of the goals and direction articulated by TEFCA. We agree that a single on-ramp will increase access to data across the US. In line with the mission of the Alliance, we are optimistic about the potential for TEFCA to increase the level of empowerment by individuals and their care providers by enabling them to get the data they need to make the best care decisions.

¹ KLAS – 2016 Hospital EMR Market Share, May 2016. © 2016 KLAS Enterprises, LLC. All rights reserved. www.KLASresearch.com

^{*} SK&A, a Cegedim Company – “Physician Office Usage of EHR Software” SK&A. February 2016.

At the center of our support is the notion, formalized in our own vision and emulated by TEFCA, that person-centered data exchange should be the minimum standard for nationwide interoperability, allowing a person's information to be found and retrieved with "no blind spots".

The architectural concept espoused by TEFCA, calling on a federated query model that leverages an enterprise master patient index, record locator services and a query broker, builds on the approach that the Alliance has successfully delivered to the market nationwide. CommonWell Members already know the benefit of moving away from the world where they have to support – legally, organizationally, and technically – thousands of point-to-point interfaces. Their participation in the CommonWell network underscores their commitment to that idea.

We also applaud ONC for reflecting upon and appropriately incorporating our previously submitted comments (August 25, 2017) during the initial comment solicitation phase last summer. In particular, we are pleased to see that TEFCA aligns with two of our recommendations: it raises the bar on interoperability so that the industry matures in a direction that is truly transformative to healthcare; and it provides clear direction to "unfreeze" the marketplace, so that healthcare and health IT organizations can take definitive steps towards interoperability.

With these statements of support in mind, we conclude this section of commentary by stating here that **CommonWell Health Alliance intends to become a Qualified Health Information Network (QHIN)**, subject to reasonable improvements that we expect will be incorporated into the final Framework. In addition, CommonWell intends to play an active role in the finalization of the Recognized Coordinating Entity (RCE), and would expect to **participate as an active stakeholder in RCE deliberations**.

[B] Overview of Feedback on TEFCA

On the whole, while TEFCA is arguably prescriptive in some areas, the Congressional mandate in 21st Century Cures was for a government-defined framework and common agreement, and in light of that requirement, our point of view is that ONC executed on that requirement admirably in this draft Framework. We particularly applaud the intention to make a flexible framework that relies more on private-sector leadership than government action.

In fact, we encourage ONC and its sister agencies to double-down on TEFCA by creating further motivation for marketplace engagement. Indeed, as an entirely voluntary Framework that creates new burdens and few incentives to get adopters over the initial thresholds for effort, there is significant risk that the momentum fizzles out early. As such, we recommend that TEFCA be incorporated into relevant government initiatives that may give it a further nudge into reality. For example, we would expect that, at a minimum, the upcoming information blocking rules would posit that participation in TEFCA via a QHIN would provide some degree of "safe harbor". Additionally, engagement with federal agencies that provide health and care services (Department of Veteran's Affairs, Department of Defense, Indian Health Service, National Institutes of Health, Centers for Disease Control, and others) probably should require that data exchange requirements be met through a QHIN (where applicable).

The rest of this commentary provides feedback into the draft Framework as currently written. Indeed, **it is a common opinion across a broad swath of our Alliance that several details of the draft TEFCA will need clarification or even major revisions**, in order to be feasible on the front-lines of interoperability. We organize our feedback into three key categories, with the details articulated in the sections that follow:

- (1) **Feedback to improve operational feasibility and success of QHINs.** Overall, as indicated above, we believe that this is a sensible approach, though we have some concerns about technical scalability and business models, which we have detailed below.
- (2) **Feedback to improve operational feasibility and success of the RCE.** Overall we believe that this too is a reasonable approach, assuming that proper stakeholder participation and assiduous neutrality is achieved. We posit that no appropriate entities exist today that are structured appropriately to fulfill this purpose, but on the other hand, ONC can absolutely build upon the community of work that has already been done to move relatively quickly.
- (3) **Feedback on the use of standards.** This applies to TEFCA overall, and includes (but is not limited to) feedback on the accompanying US Core Data for Interoperability (USCDI) draft.

[C] Feedback to improve operational feasibility and success of QHINs.

(1) Consider a phased approach that gradually increases the scope of minimum necessary use-cases to be supported by QHINs

The market now had nearly three years of experience with reciprocal interchange among provider organizations in support of HIPAA-defined direct “treatment” relationship, as well as some degree of experience with the “individual access” purpose of use. TEFCA should consider starting with these two use cases as the minimum necessary use cases to be supported by QHINs. Even for these better-known use cases, most of the valuable operational learning lies ahead rather than behind, and the new QHIN-based approach may unearth entirely new challenges (such as unexpected corner cases, instances of “bad” marketplace behaviors, unanticipated scaling issues, etc.) that will require governance and operational focus.

This is not to say that other use cases should be ignored – in fact we support the notion that the other use cases be duly supported, and to a large degree have either started or intend to start supporting them in limited deployment over the coming two years. However, that is quite different from approach implied in the draft TEFCA, where several QHINs may all be forced to support brand new untested use cases out of the gate. We argue that a phasing approach is much more rational, and should be in line with (and help drive) the maturity of both technical standards and operational/empirical experience, as none of these use cases have been deployed at national scale in a federated query model. In particular, use cases that necessitate large data loads on a single transaction stream – such as population health or public health – have been largely untested in a federated model. As we discuss in (2) immediately below, it is likely that a pure broadcast model will not work for such use cases, without some as-yet-untested tweaks and innovations.

(2) In general, we suggest adopting an outcomes-oriented approach rather than an explicit architecture per the TEFCA draft, but this is especially true for the less-mature use cases.

Specifically, the notion that QHINs “broadcast to all other QHINs” may have serious implications on both the feasibility of QHINs and to the load on the network itself, because patterns of access to nationwide population health and public health queries are largely – if not totally – unknown. In several realistic scenarios that we simulated, this requirement may effectively create nationwide Distributed Denial of Service (also known as a “DDOS” attack).

As such, we suggest that the RCE and QHINs work together to decide on operationally feasible pathways that meet clearly defined outcomes. For example, TEFCA implies that the desired goals are that the locations of any specific patient’s electronic data are always identifiable and accessible, and

that the corresponding records can be retrieved electronically with no special effort. To achieve this, the RCE and QHINs should be allowed to devise alternate or complementary approaches to the general “broadcast” proposal in the TEFCA draft, for example: a global RLS-sharing mechanism; a more sophisticated cache-management architecture that allows QHINs to avoid re-querying for data that the requestor already possesses; rules for timing and frequency for certain types of queries and corresponding retrievals; a test-and-learn/pilot/ramp-up approach to determine operational feasibility of different approaches, etc. Again, we are supportive of enabling all of the use cases articulated by TEFCA, and want to ensure that we do so in a manner that is operational feasible for the success and longevity of TEFCA itself, such as by using a phased-in approach as noted above.

(3) Clarity of expectations and requirements for QHIN formation.

ONC has stated on webinars and other forums – outside of the draft TEFCA itself – that it expects a handful (presumably 5-6) entities to provide QHIN services, and that EHR vendors and HIEs would have to join with others to create a QHIN. ONC has also shared that EHR-specific (“proprietary”) networks would not qualify as QHINs, and neither would individual regional HIEs. Despite these forums, on the basis of the draft TEFCA itself it is clear that dozens of organizations are examining the notion of becoming QHINs, including EHRs, HIEs, Patient Portals, extant proprietary networks, etc. Our view is that such broad participation in the QHIN market could create an over-complicated connectivity layer, making it operationally infeasible. In fact, the scalability challenges of broadcast among (and operational coordination of!) a very large number of QHIN participants may actually create more inefficiencies than it solves.

It is likely that several such potential QHIN participants are misinterpreting the responsibilities and operational burdens of providing QHIN services, and that a massive market fall-out could occur post-formation of their QHINs, creating a much bumpier ride en route to steady state than necessary. While competition and creative destruction are usually positive indicators of a healthy market, one presumes that an orderly market is a desired outcome of TEFCA – as opposed to tectonic failures, as we have seen elsewhere in health data exchange. To that end, **we suggest that the Framework clarify the expectations and requirements of QHINs upfront**, so that the broad variety of potential market entrants can make rational decisions as how to participate in the Framework.

A separate concern that needs to be addressed upfront is the restrictions to the potential business models that a QHIN may pursue. Here are the specific questions which we found to be ambiguous at best in the current draft of the TEFCA – answers to these questions would better-illuminate the requirements on QHINs, and enable potential market entrants to make informed decisions:

- a) What is the correct interpretation of the requirement articulated by Section 5.4? Will QHINs be able to provide different levels of service (i.e., QHIN services vs. other interoperability services) to different participants? Will they be able to provide such differing levels of service to other QHINs?
- b) Are there corner cases that an unscrupulous player might utilize to game the system and avoid the burdens borne by others? We recommend that TEFCA identify some of the anticipated scenarios upfront, and subsequently work with the RCE to identify unanticipated abuses. Some examples:
 - Asymmetric QHINs, i.e., an organization that sets up a querying gateway that has no data sources of its own.
 - Near-asymmetric QHINs, e.g., a small clinical practice that sets up its own QHIN that always responds to other QHINs with the equivalent of “no data found” except in the case of a small set of patients actually seen by the provider? Such an approach, if acceptable, can drive a proliferation of QHINs, each of which have an essentially

“hardcoded” eMPI/RLS that serves only their narrow interests, while contributing little to the Framework except topological complexity.

(4) Clarify the consumer-facing requirements.

Since inception, the Alliance has advocated for patient empowerment, including enabling the “individual access” purpose of use over two years ago. As such, we are philosophically aligned with TEFCA as written today. However, some of the expectations for QHINs in their support of consumer engagement seem unusual for a backend interoperability network.

A key question is whether or not QHINs must themselves support direct-to-consumer activity, or whether the mandatory support for “individual access” can be mediated by a QHIN’s Participants, as long as the QHIN itself does not block or prohibit that use-case. This question applies to several aspects of the individual access related functionality articulated by TEFCA:

- a) APIs and app support for individuals: do QHINs have to directly support Apps? Per the above, we recommend that this not be required by the QHIN itself, as this is not typically a competency of a backend service.
- b) Similarly, does the QHIN directly manage the HIPAA release of records request, routing data to third parties? Again we would expect Participants to enable such controls and experiences.

Separately, we recommend that TEFCA clarify what Individual Access includes and does not include. Specifically, we believe that there should be a distinction between two different purposes of use (including phasing, ability to charge, and potentially technical requirements): individuals consciously acting on their own will, which we regard as truly “individual access”; versus “aggregator” sites that collect individuals and then query for data on behalf of them, thus creating a substantial unfunded operational burden on the network and possibly violations of patients’ rights as well. **TEFCA should make the distinction clear.**

(5) Be flexible with the economic models or risk unintended market behaviors.

The TEFCA requirements currently state (or seem to state) that QHINs have to query all other QHINs; and yet the responding QHINs will be able to charge differing amounts for these transactions, limited only by the vague notion of “Attributable Costs”. There is a real concern here that QHINs will try to “stuff” as much into those Attributable Costs as possible, and that this economic incentive could actually drive upwards-spiraling prices. For example, a QHIN with near-monopolistic control over a critical section of the provider market (such as the VA, or academic medical centers) could essentially demand whatever price it sets.

As an early indicator of the validity of this concern, it is clear that some organizations are expecting to enter the QHIN business specifically as a source of revenue enhancement. While revenue-seeking for sustainability is no sin, the notion that this market will be a source of deep revenues is certainly worrying when the intention should be to **drive down** the costs of interoperability.

A separate economic issue is the notion that some purposes of use can be charged for and not others, which creates perverse incentives to either blur the lines between purposes of use or/and to create corner cases that allow inequitable access to the QHIN connectivity layer. As an early indicator of the validity of this concern, it is clear that several patient aggregation “portal” companies are planning to enter the QHIN business as it allows them to access patient data for free, without any financial burden and without the burden of responding to other QHINs except to say “no data here”. The asymmetry of the exchange, coupled with the mandate that the transaction be free could create

perverse outcomes. The provider organization, EHR and QHIN bear all the burden and none of the reward that some other organization reaps by charging patients/others for that data access. Again, we have no issue with the notion that an individual can access their records for low cost (or even for free); it is more the concern that market participants will try to abuse such a construct.

Similarly, but more narrowly, the draft rule would enable the Social Security Administration (which currently pays for approved documents) to form their own QHIN, and all QHINs would have to respond to that QHIN's queries at no cost[‡]. As in the individual access purpose of use, and for that matter the public health purpose of use, the burden is not borne by the responding QHIN and the source system (presumably EHR), but also on all other QHINs, Participants and End Users, as the cost basis on all other "chargeable" purposes of use (i.e., treatment, payments and operations) would have to be ramped up to cover these unfunded costs. This creates a market-wide **disincentive** for participation in those other chargeable purposes of use. In effect, the proposed system amounts to a substantial tax on providers, as the only use cases with allowed pricing are those that providers and health plans would pay for, inequitably increasing the costs of business for both.

[D] Feedback to improve operational feasibility and success of the Recognized Coordinating Entity (RCE).

We are supportive of the notion of the RCE, insomuch as it provides a mechanism for strong public- and private-sector input into the governance of TEFCA. We underscore that the RCE should be a neutral, transparent, and objective governance body, working closely with ONC to fulfill the vision described by TEFCA. The governing body should be balanced so that all stakeholders are adequately represented.

In particular the RCE should:

- a) Have relatively equal weighting of participants from across the care spectrum, particularly:
 - I. Small provider organizations (e.g., IPAs), monolithic single-EHR academic medical centers (AMCs), and multi-regional/multi-EHR health systems;
 - II. Ambulatory, acute care and post-acute care technology innovators;
 - III. Representatives of the various intended use cases, where not already covered by I and II, e.g., the patient interest; the Social Security Administration.
- b) Include a representative set of QHINs, complementary to (a) above. In fact we would be concerned about an RCE that has too much "industry stakeholder" representation and not enough "implementer" representation, and vice versa.
- c) The RCE should not run, operate, or govern a particular exchange, as that creates irremediable conflicts of interest.

We feel strongly about the need for balance, as articulated above, and re-emphasize that no existing organization meets these requirements today, although several organizations have pieces of the puzzle and can be brought together or restructured to constitute an appropriate body.

We also recommend that ONC re-consider the timing of the RCE selection process. The currently articulated timing would create an RCE before TEFCA is finalized, effectively selecting stewards without knowledge of what is being stewarded – this seems to be a "cart before the horse" process. Judicious

[‡] We will note that, at this time, the Social Security Administration has not indicated any intention to change their current or expected business arrangements, but rather that this rule gives them the opportunity – and possibly the incentive – to do so. It is because of this type of new uncertainty, needlessly created by the economics articulated by TEFCA, that we are concerned about all the purposes of use, including but not limited to "benefits determination".

government requires that ONC internalize and respond to comments — which will include comments on both RCE requirements specifically and TEFCA requirements generally — before selecting the RCE.

[E] Feedback on the use of standards.

- (1) There are places throughout the common agreement where ONC prescribes specific standards, whereas in other places it relies on a reference to the ISA, and other places that it relies on standards and specifications adopted by HHS in the future – and in some cases (detailed below), it seems to use more than one mechanism for the same functional requirement. This tangled web of recommendations is opaque, confusing to navigate, and most importantly, inflexible.

Our perspective is that stakeholders should select standards that actually work for the use case, and that all participants agree to use, preferably based on their actual experience with the standard. Therefore, we recommend that ONC should work with the RCE on creating the functional requirements, and then **let the RCE and effected stakeholders (QHINs) select the best standards**. This may include inventing/piloting new ones for use cases that did not broadly exist before TEFCA, much as the Alliance did with the at-that-time-unknown “FHIR” standard that has since become mainstream.

If ONC were to stick to the current web of various standards references in TEFCA, the question will become as to how these will be reconciled and updated? Will collaboration between the RCE and potential QHINs be ultimately responsible for filtering out and tackling negative overlap between differing standards recommended by named entities and those implemented by QHINs and their Participants?

Some examples of standards references that can lead to confusion:

- Referential language on pages:
 - Page 14 -- Principle 1 – Section A
 - Page 20 -- “accessing individuals’ Electronic Health Information via an API”
 - Page 31 – 3.1 Connectivity Broker (Broker) Capabilities
- 3.1.3 – references to
 - § 45 C.F.R. Part 170, Subpart B
 - § 2015 Edition
 - § other: “(or any applicable standards and implementation specifications adopted in the future by HHS)”
- 3.1.7 – “in accordance with both the IHE XCA standards then most recently formally adopted and the certification criterion specified at 45 C.F.R. 170 Subpart B as applicable and referenced in the 2015 Edition (or any then applicable standards and implementation specifications adopted in the future by HHS).”

- (2) We also specifically recommend that a more formal definition is needed to provide sets of constraints around “Population level exchange” (page 21 & 8.1 – note that this latter references 4.1.5 in the draft, but we presume that it actually intended to reference 3.1.5)

- (3) Several questions are raised by the sections addressing auditing, privacy, & identity proofing:
 - a. Auditable Events (3.1.6 & 6.2.10): Will there be guidance published on record retention lifespan of auditable events and their availability to Individuals?
 - b. Identity Proofing (6.2.4 – QHIN, 9.1.4 – Passed down to Participants, 10.1.3 – Passed down to End Users): despite the indication of pass-through terms, the wording in this

section is confusing. Is it the responsibility of the QHIN to proof at a minimum of IAL2 for Participants, End Users and either Individuals directly or through a Participant staff trusted referee? This seems like an extremely unusual requirement for a backend non-user-facing service. We would expect the QHIN Participants to be responsible for this proofing. Further, we recommend that ONC and the RCE validate the timeframe under which the industry will be ready to make a shift to 2-Factor Authentication; our experiences suggest that this is a much heavier industry lift than ONC may be anticipating.

- c. Authentication (6.2.5 – QHIN, 9.1.5 – Passed down to Participants, 10.1.4 – Passed down to End Users): Is it the responsibility of the QHIN to authenticate (to a minimum of AAL2) End Users, and Individuals? Again, we would expect the QHIN Participants to be responsible for authenticating End-Users and Individuals.

(4) Finally, we provide some feedback on the USCDI:

- USCDI does not cover “payer data” like claims and coverage rules. That seems unidirectional, unfair and exploitable.
- Provenance is exceedingly helpful in a network-of-networks environment, as it can help the QHIN and its Participants and End-Users to reduce the challenge of figuring out what data is new versus previously-seen. It could also be used to make the network more efficient, if for example, the provider’s query can present what they already know so that the remote system can respond with the technical equivalent of “I don’t have anything you don’t already know”, analogous to how caching works on the Internet.
 - We acknowledge that some of the challenges with provenance will certainly require collaboration and focus, and even then may need some time to yield consensus.
 - Some of the key issues include: the level of granularity at which to attach provenance; how to encode the provenance (just a digital signature, deep information on the original source, information on secondary pass through sources, etc.); how to treat aggregations of data that combine many sources of data into a longitudinal view; how will the transport mechanisms (XDS and CA) support provenance if there are no equivalent meta-data attributes.
 - Our point of view is that a simple, not-overly-engineered approach with straightforward rules can help solve 80% of the challenges faced by a lack of provenance today, and not create excessive delay of this valuable attribute. At the least, document-level provenance – that persists as long as long as the document is not altered – would be an achievable goal and prevent some of the easy-to-anticipate issues that inter-QHIN connectivity will create.
- In terms of standardization of clinical notes as well as the commonly-used structured sections of the CCD, we eagerly support that notion and recommend that ONC monitor the developments of the “Joint Document Content Workgroup” hosted by Carequality, which is a result of the merger of an existing Carequality document content workgroup and parallel workgroups hosted at CommonWell Health Alliance and the Argonaut Project, now all (largely) merged into that one joint forum.
- From an Individual Access perspective, and in light of the increasing availability and usage of artificial intelligence, we posit that access to the complete record in unstructured format should also be available, in addition to the ever-increasing structured and standardized data.
- We recommend that ONC pay attention to the commentary of EHR vendors in articulating the near-term and longer-term requirements of the USCDI. For instance, despite our feedback above as a network, the feedback we have received from EHRs is that the notion of adding clinical notes and provenance to the MU common data set for the initial phase in USCDI seems aggressive.

[F] Concluding Remarks

In conclusion, we remind ONC that CommonWell Health Alliance is dedicated to universal person-centered access to health data. As ONC embarks upon its journey to implement TEFCA, we hope that our feedback is perceived in light of our willingness to support and improve the operational feasibility of the vision articulated by TEFCA. A bright path lies ahead!

On behalf of the CommonWell Health Alliance, thank you again for the opportunity to comment on the *21st Century Cures Act DRAFT Trusted Exchange Framework and Common Agreement*. For more information, please contact me at jitin@commonwellalliance.org.

Respectfully submitted,



Jitin Asnaani
Executive Director
CommonWell Health Alliance