June 17, 2019

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 and Common Agreement (TEFCA)

Dear Dr. Rucker,

CommonWell Health Alliance (the "Alliance") appreciates the opportunity to submit comments regarding Draft 2 of the Trusted Exchange Framework and Common Agreement (TEFCA), published on April 19, 2019. The Alliance appreciates the effort undertaken by the Office of the National Coordinator for Health IT in the preparation of the second draft of this important rule, and we support ONC in its ongoing commitment to enable ubiquitous nationwide interoperability.

By way of background, CommonWell Health Alliance is a not-for-profit trade association comprised 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. Alliance members represent more than 20 care settings, including technology leaders in acute care, ambulatory care, post-acute care, patient portals/PHRs, 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. To that end, we have enabled secure, authorized, universal access to health data via a person-centered nationwide network. Over the past four years, we have driven adoption of nationwide interoperability among more than 13,000 care locations, enabling over 200 million transactions for more than 50 million unique enrolled patients.

[A] Scope of this Comment Letter

Although CommonWell Health Alliance is an association whose Members span the breadth of health IT, we are focused on a single vision and mission, namely to enable a vendor-neutral nationwide infrastructure that enables person-centered exchange. As such our comments are not accretive of all of our Members' commentary, but rather unique feedback from the perspective of our very specific vision and mission. Note also that the comments in this letter are not intended to endorse nor refute any commentary made by CommonWell Members or supporters through their own specific comment letters to ONC, except where specifically highlighted as such.

[B] 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.

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, 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.

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 the evolution and governance of the RCE**.

[C] Feedback on TEFCA

We applaud ONC's effort to thoughtfully incorporate TEFCA into the 21st Century Cures Act Information Blocking Exceptions. With much still to be decided in terms of the ARTCs and the further finalization of all the Cures Act proposed rules, it behooves ONC to artfully piece together the right building blocks for scalable nationwide exchange, of which TEFCA is one major component.

Our primary concern is that there is significant risk that TEFCA will fail if:
(1) the value is unclear,
(2) the burden to execute is too high, or
(3) it fails to solve the problems that it purports to address (i.e., mismanages expectations).

In terms of Issue #1, we refer back to our response to the Information Blocking NPRM, wherein we shared our recommendations towards bolstering **the need for TEFCA as a means to meet the spirit and word of the anti-Information Blocking behaviors** that Congress desires.

In terms of issue #2, we are concerned with the construction of the QHIN Technical Framework (QTF) as we believe unnecessarily increases the burden of implementation. While we wholly agree that separating the QTF from the rest of the requirements (MRTCs, ARTCs) is prudent, our concern is that the set of standards specified in the QTF is misguided. **In particular, the standards generally point to legacy IHE SOAP-based profiles, which the bulk of the industry is already moving well past.** This is compounded by the fact that it will be some years until TEFCA is implemented, virtually guaranteeing that the QTF as written will be obsolete at the time it becomes effective. We suggest that ONC work with the future RCE to determine the appropriate standards at a time closer to the implementation of TEFCA. We

further suggest that, in all cases, ONC keep a bias towards the RESTful-based standards that are increasingly becoming the norm in the industry – our experience is that even incumbent EHR vendors are moving in this direction, while emerging technology companies almost universally prefer RESTful interfaces, preferably aligned with Argonaut Project recommendations (where applicable) and/or well-adopted profiles like the IHE MHD profile. Cooperation and coordination with the RCE on the QTF will also ensure that the TEFCA framework drives towards standards that are biased towards live and scalable data exchange rather than unproven or poorly-adopted standards – for example, the use of REST or Direct Project protocols over the choice of XCDR, which is the most baffling choice of standard postulate in the QHIN given the pervasive lack of awareness and adoption of XCDR by the industry.

Our biggest concerns with the current draft of TEFCA relate to Issue #3 above, namely that the whole program has been set up for failure as currently articulated. **Specifically, we are concerned that TEFCA, as written, sets an unrealistic expectation for the scope of interoperability issues than it aims to solve.** We think this expectation can be managed and that TEFCA can, over time, indeed solve the breadth and depth of problems that it aims to address – but if stakeholders "latch onto" the expectations implicitly set in this NPRM too early, then this Framework will be a political failure, and we as an industry will find ourselves in the unfortunate position of starting from scratch all over again in 3-5 years' time.

There are three major issues implied by this TEFCA NPRM that specifically engender this concern:

1. **Lowering the bar for becoming a QHIN:** this draft of TEFCA ostensibly lowers the bar for an industry participant to become a QHIN by removing the need for a Record Locator Service and Connectivity Broker – both of which create high scalability to search and retrieve person-centered data – and by increasing the leniency for qualification to form a QHIN.
   On the one hand, we acknowledge that this may enable more organizations to instantiate legitimate QHINs than the previous version, which is obviously a good outcome. The issue is that this will also encourage a substantial number of unqualified organizations to take the step of becoming QHINs and attracting Participants and Participant-Members to work with them, only to discover post hoc that they cannot meet the highly demanding performance needs of a scalable real-time national data-brokering service. This is likely to create an artificially inflated bubble of potential QHIN market entrants, followed by the "long, slow death by attrition" of the QHIN market until it stabilizes around a small number of performant QHINs, creating ill-will and political churn all along the way.
   Of course, to be clear, we are not suggesting a specific limit to the potential QHIN participants or some sort of "picking winners" strategy, as we do not want to inhibit competition among QHINs. Rather, what we want – and what the whole industry needs – is an ecosystem of QHINs that can be relied upon to deliver on the performance needs of nationwide exchange. To that end, we strongly suggest that ONC – either through this rulemaking directly, or through collaboration with the RCE subsequently – **articulate a set of requirements (MRTCs or ARTCs) that make the performance requirements of the QHIN clear, including the Service Levels** such as query response times, network uptime, and other relevant metrics, at the scale of nationwide data exchange (i.e., from hundreds of millions to billions of documents per year).

2. **The inclusion of QHIN Message Delivery:** we were surprised by the unexpected inclusion of "Push" capabilities into QHIN stack. As an aspiring QHIN, we have been planning to enable valuable push-based workflows within our community, and in fact are expecting to go live with Event Notifications this summer. However, in terms of this TEFCA draft, the potential value is greatly outweighed by two issues: creating too many moving parts too quickly, and lacking clarity and specificity of the target use cases.
   On the first item, TEFCA is likely asking QHINs to "run before they can walk" by requiring too very

different modalities (push and pull) in initial production. For some QHINs who have already had experience with nationwide exchange along these two modalities, it may not create overall network performance or support issues; but for the broader ecosystem of QHINs (especially given the lowered bar for QHIN formation), the current approach may result in tremendous churn (i.e., support requests) both for themselves and to the larger ecosystem of QHINs connected to them, because TEFCA is only going to be as strong as its weakest link. It would be far more prudent to enable push-based capabilities to be brought online after some period of time during which nationwide federated query/pull (QHIN Broadcast Query, QHIN Targeted Query) have stabilized in production.

The more significant issue is the lack of specificity in the current TEFCA, which requires "QHIN Message Delivery" while providing less-than-minimal articulation of the Use Cases to be expected. This can lead different stakeholders to have very different expectations of what is going to be delivered (e.g., submission to public health registries vs. physician referrals) by both their QHIN and by TEFCA overall (i.e., all the other QHINs in the community). It also assumes that all "Push" workflows are equivalent, which is simply not true – a workflow and complementary set of services and technologies that are optimized for public health reporting are probably going to have (at best) *partial* overlap with those needed to create effective referral management. **This lack of specificity will need to be addressed by the TEF or by the RCE through the selection of a series of prioritized use cases, else the implementation of TEFCA is going to engender widespread discontent through failed expectations.**

3. **Patient Matching:** this NPRM rightly calls for input into patient matching. While we believe it is better for the industry to be able to continue to evolve patient matching techniques and strategies, a "rising floor" of patient matching capability is clearly required.

   We refer ONC back to our comments on the Information Blocking NPRM. To summarize, we specifically support the mandatory usage of a more robust set of demographic elements nationwide for patient-matching purposes, in particular the use of USPS-standardized addresses, email addresses and mobile numbers immediately where available, as well as the subsequent use of strong identifiers and other techniques. We support the notion of transparent measurement of the patient matching accuracy for QHINs, but defer to future consensus (presumably facilitated by the RCE) in terms of what measures and thresholds would provide a meaningful floor to performance expectations.

[D] Comments on the Recognized Coordinating Entity

We are supportive of the notion of the Recognized Coordinating Entity (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, advocates or representatives from across the care spectrum, particularly:
   I. Small and very small provider organizations (e.g., physician practices of <10 clinicians, independent physician associations), community and critical access hospitals, academic medical centers, and 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., patient advocates; federal agencies; state agencies; payers; etc.

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, or vice versa.

c) We agree with the Notice of Funding Opportunity (NOFO) requirements that 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 some organizations have pieces of the puzzle and can be brought together, restructured and/or re-shaped to constitute an appropriate body. We encourage ONC to acknowledge that bringing such balance and neutrality will be a critical aspect of their unique role in partnering with the RCE.

[E] Concluding Remarks

In conclusion, we remind ONC that CommonWell Health Alliance is dedicated to ubiquitous 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.

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,

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