August 2nd, 2022

Micky Tripathi
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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: Concerns Regarding Record Location Objectives of TEFCA and the QHIN Technical Framework Version 1.0

Dear Dr. Tripathi,

Thank you for the opportunity to speak with the ONC on July 13th, 2022. As we discussed, CommonWell has concerns about a change to the QTF introduced between the final draft and the publication of v1.0 that was not well explained until very recently. We appreciate your explanation, but remain concerned about the impact of the language introduced by the ONC.

After our call, we walked away with an understanding that the change was not intended to have the negative consequences we believe it is likely to create. That said, we still believe the new language in QTF-070 creates a fatal flaw in the technical framework for TEFCA that destroys a central tenant of TEFCA's intended benefits for providers participating in the framework. On behalf of the Alliance and its Members we request the final approval of QHIN applications not occur until this flaw is resolved. At a minimum we request an open, transparent process be conducted to explain the new language and its implications to expected participants and allow for feedback before the process continues any further.

The original and changed language change under discussion is the following:

Excerpt from 2021 Final Draft of the QTF[1]:

> *QTF-066 A QHIN MAY delegate the patient identity resolution function to Participant(s).*

Excerpt of the Equivalent section of the Final QTF[2]:

> *QTF-070 A QHIN MAY use other innovative methods or delegate the patient identity resolution function to its Participant(s).*

Note: While the QTF numbering changed due to the introduction of new requirements (QTF-066 became QTF-070), the only change due to this requirement is highlighted in yellow above.

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[1] 2021 Draft (Draft 2) of the QTF: https://rce.sequoiaproject.org/wp-content/uploads/2021/07/QTF-V1-Draft.pdf
[2] QTF Version 1.0: https://rce.sequoiaproject.org/wp-content/uploads/2022/01/QTF_0122.pdf

While TEFCA has the potential to rapidly expand the use cases serviced by nationwide interoperability, it can only do so if health care providers participate. To encourage adoption, providers and patients need to feel TEFCA is a better interoperability solution than what they have today for Treatment and Individual Access use cases. TEFCA, as originally designed, did include a compelling differentiator in its required availability of coordinated record location. All QHINs were to be responsible for being capable of locating ALL the records for a given patient within their community of connected endpoints. TEFCA was designed to assist in obtaining a comprehensive view of a patient's full clinical history. The QTF itself says it well:

> *RECORD LOCATION The exchange functions enabled by QHIN-to-QHIN exchange depend on accurately determining which entities maintain relevant information. Query functions, in particular, rely on accurate and comprehensive record location. This QTF does not specify a particular technology or standard for QHINs to use to locate patient records.*

> *QTF-072 A Responding QHIN MUST be capable of identifying which, if any, of its Participants and/or Subparticipants are the Responding Source.*

The language added to QTF-070 does not pose a problem to TEFCA unless considered within the context of why the ONC added it. When CommonWell and its Members read the modification, it looked as if the ONC was emphasizing its intended goal of QHIN autonomy. QHINs would be free to innovate and use whatever technology they wanted on the inside – the QTF would solely focus on technology standards used between QHINs. This point was made on many learning sessions hosted by the ONC, Sequoia and Carequality. While we were initially concerned that QHINs without an RLS/MPI would be unable to perform at QHIN scale, we could not argue with the idea that there might be alternative, potentially better methods to resolve patient discovery lookups within a QHIN. In the end, we agreed the compromise position would be an SLA that would be referenced by the QTF. This SLA would ensure that regardless of the method of patient discovery used internal to the QHIN, the outcome of a query would be consistent across the framework: reliable, high-performance availability of a comprehensive list of record locations for a given patient through a singular query. The QTF did make reference to an SLA, but as of today the SLA has not been published in final nor draft form.

Unfortunately, we learned from the July 13th call that our understanding of the added language was wrong. It was explained to us that the change was in direct response to a request from a candidate QHIN seeking to be allowed to do partial patient discovery searches, instead of comprehensive searches, within its QHIN community. Not as an alternative, additional choice for the originating source, but the only method by which the QHIN would support patient discovery and record location, thus requiring multiple queries to cover any potential record locations. The new language was in reaction to comments to the draft QTF made by eHealth Exchange.

In its comments to the Final Draft of the QTF, eHX stated:

As an alternative to broadcast and RLS options, the QTF should permit geospatial queries. It's well known that most healthcare is provided locally to the patient. Queries have a point of diminishing returns outside of a 50-mile radius of the patient's primary residence. The QTF should allow organizations the ability to query a geographical region containing the patient's primary address as an alternative to broadcast or RLS queries. This could, perhaps, be augmented by a QTF policy indicating that periodically a QHIN should broadcast a query to all Participants in that QHIN to detect care provided outside the patients' home region.[3]

Allowing for the kind of "innovative methods" expressed by eHX for record location is in direct conflict with TEFCA and the QTF. Geofencing techniques are not an attempt to be comprehensive. They are a technical compromise that attempts to find data as efficiently as possible from a computing perspective when one does not have record location (which is what TEFCA is supposed to support in principle). This compromise intrinsically misses data—some of which may be incredibly important to patient care and individual access. Geofencing is how many, including CommonWell, locate records in Carequality today and we know from our own experience that it regularly misses data. While we do not argue that the volume of clinical data diminishes with distance from your home, there is no general understanding on whether the quality of the data is lower and should be discarded or ignored. If we assume 95% of your health care is local (within the 50 miles eHX describes above), is the 5% irrelevant?

Our belief is the 5% is often critically important and the effect of ignoring this will have an outsized effect on individuals who already have issues with patient access and the care they can receive. This problem is especially acute for patients that move a lot or need to travel long distances for care including but not limited to migrants, people living in rural communities, active service and retired veterans, people moving for their education or work, and later moving to live near family, people with more than one home, people traveling distances to receive specialty health care or people simply traveling for leisure or to visit friends and family. TEFCA was conceived to address all these dynamics. The concept of "comprehensiveness" addresses these dynamics by promising a single on-ramp for nationwide (not region-wide) interoperability. Failing to account for these dynamics undermines the heart of TEFCA. Allowing the pathway that, by intent, limits nationwide interoperability will have a foreseeable and negative impact on these and other groups. As we address health equity nationwide, we need to consider all these dynamics and equity factors, to ensure there is no widening of the equity gap created by even the best-intentioned programs and instead strive to tackle these issues, not exacerbate them.

Is the broken arm sustained while visiting family 90 miles away from your home important to your future clinical care? Likely not. But what about that same person experiencing an acute asthma attack resulting in them being rushed to the emergency department (ED) in an ambulance with crashing blood oxygen levels and unable to breathe. Interoperability is critical in that ED when that patient cannot speak but can

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[3] Full set of comments, including eHX's, to the 2021 QTF Final Draft: https://rce.sequoiaproject.org/qhin-technical-framework-feedback-comments/

nod yes or no to a current medication list available only through interoperability. This 5% of their record is also critically important two weeks later when that patient follows up with their pulmonologist. Or in another example, take the rural patient who has to travel hundreds of miles to get treated for cancer because their local health systems did not have the specialty care they needed. What happens when they end up in their local hospital's ED and those ED clinicians have no knowledge of their cancer care being done 600 miles away? Both of these examples are real-life scenarios, and these types of scenarios are too pervasive to call them exceptions. The loophole created by QTF-070 serves to undermine the TEFCA goal of a comprehensive view of a patient's clinical history—which is one on-ramp to ALL the data.

Keep in mind, this need for comprehensive data is equally if not more important for patients and those they depend upon to help them gather and explain their medical history. TEFCA already indicates it will expand into Public Health and Individual Access both of which will directly benefit from the ability to collect complete data through the assistance of comprehensive record location. A consistently applied interoperability standard is needed to meet patient and provider expectations that they can acquire all their medical data, to empower patients as advocates in their care and to increase the abundance of data available for clinicians to make decisions affecting their patients' care. Meeting these expectations is foundational to the core principle of TEFCA: to build Trust.

The flexibility added into QTF-070 to accommodate less than comprehensive discovery is simply going too far. If it remains, it erodes Trust and value which are vital to the success of TEFCA. Requestors querying QHINs for data will simply have no knowledge of the scope of the search performed by the responding QHIN. They won't know if it was comprehensive or not. The only solution for a querying QHIN to obtain a comprehensive list of available data source would be to do directed patient queries to every participant in TEFCA outside its own community. Technically, this is a capability already available within Carequality, one of TEFCA's reference frameworks. In practice, in Carequality we all use geofencing similar to what is described in eHX's comments. This is not because it is comprehensive, but because we know it is computationally impossible to query every endpoint – broadcasting at this scale would crush both responder and querying servers and network equipment. Even more troubling, the problem gets worse as we increase adoption of interoperability nationwide and we still have many endpoints to which we need to connect. Working with another RLS capable network in Carequality, this past May we proved that a comprehensive RLS capability is computationally efficient and yields more data to the requestor. Switching from directed queries to a single query to a community based RLS dropped our total queries across all Carequality endpoints by 50% with no drop in available data to our Members and their end users – in fact, data availability went up as their RLS helped us find data we weren't finding with geofencing techniques. TEFCA's introduction of an RLS capability at the edge of the QHIN was a building block for the industry to work smarter, not harder while we grow adoption and expand into new use cases. Public Health and Patient Access are both examples of new use cases that will benefit from getting complete data only by using an RLS. Without this fundamental building block, TEFCA will be restricted in its growth as well its creation and maintenance of Trust.

Given this new understanding of the QTF-070 language we request the ONC address the conflict in the QTF. There are many ways to address the loophole. Here are two possible approaches.

1) Revert the language in QTF-070 to what was in the 2021 draft QTF.
2) Draft and release a performance SLA that serves to define the term "comprehensive" in the context of TEFCA and/or set performance obligations based on the performance needs of the requesting party.

For the SLA option, one example SLA could be the following:

1) Full QHIN community search: 15 seconds
2) Smart queries (result may be partial): 10 seconds
3) Directed queries: 8 seconds

The above could be linked to a performance requirement that all QHINs must at a minimum present a comprehensive, full QHIN community search endpoint available for a querying QHIN to use. The full search can be driven by an RLS as specified in QTF-069 or use an innovative patient discovery brokering approach that delegates the patient identity resolution function to its Participant(s) to respond individually as is described under QTF-070, the optional alternative to QTF-069. QHINs may then optionally have a faster, but partial response endpoint that may use geofencing or other smart query technology. The requesting party, not the responding one, should make the decision on the completeness of the patient record discovery process as driven by the querying party's use case. This SLA suggestion is in line with TEFCA's objective of "*Query functions, in particular, rely on accurate and comprehensive record location*", as stated in the QTF, while allowing innovation and allowing the broad market to test the benefits of speed vs. completeness.

We do firmly believe the ONC and RCE need to define "accurate and comprehensive record location" in light of the ambiguity embedded in QTF-070 before QHIN applications are able to be submitted. We understand addressing the issue has the potential to negatively impact the desired timeline for rollout of TEFCA. We support a speedy rollout of TEFCA and believe the process could continue on schedule with a draft version of the SLA and/or specific questions added to the QHIN application for QHINs to better explain how they expect to satisfy the requirement of a comprehensive, QHIN level, patient record location discovery capability. We welcome the opportunity to discuss ways to keep the process on track while making sure that prospective QHINs are well informed of expectations of themselves and all QHINs in the framework.

In the July 13th meeting, representatives of the ONC explained they believe the Transition Council, which is made up of the initial wave of provisional QHINs, could fix this flaw this by collaboratively developing QTF v1.1. Unfortunately, this is not likely a fixable problem once the ball is rolling. We already know of at least one QHIN candidate beyond eHX that plans to exploit this loophole and once it is used by many, it is less likely to be able to be eliminated. TEFCA needs to start with a solid foundation not one that disrupts

Trust and causes confusion and finger pointing. Changing this back after we start up TEFCA through the governing councils is also unfair. QHINs, including CommonWell, need to plan out their TEFCA technology roadmap. This seemingly small change (by word count) is a massive change to Trust and vision — reversing later will likely be detrimental to the QHINs that assumed this exploit would stay in place. This could force the exit of a QHIN early in the TEFCA roll out or force a reshuffling of the framework that could lead to TEFCA's early demise. QHIN candidates need to plan their TEFCA strategy based on a stable set of expectations in order to make an informed decision on whether to apply, partner or simply not participate and how to structure themselves as a QHIN if they do apply.

Thank you for your consideration in this important matter. We look forward to your response and next steps to address this collaboratively. For any clarification or comments, please feel free to contact me at paul@commonwellalliance.org.

Sincerely,

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cc: Marian Yaeger, CEO at The Sequoia Project (the TEFCA Recognized Coordinating Entity)
Steven Posnack, Deputy National Coordinator for Health Information Technology at ONC
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