HLN Consulting's Report on the 2019 Annual Meeting of The Sequoia Project

On December 5, 2019, HLN participated in The Sequoia Project's day long annual meeting which was held just outside of Washington, D.C. at the Gaylord National Resort & Convention Center. After the meeting, HLN produced the following report. In addition, The Sequoia Project posted the proceedings of the meeting online, including both the recorded discussions and the slides that had been presented.

Key Takeaways

1. The Sequoia Project, which was recently selected as the ONC's Recognized Coordinating Entity, is following in the footsteps of the ONC's own approach to developing The Trusted Exchange Framework and Common Agreement (TEFCA) which was spawned by the 21st Century Cures Act and will be the ground rules for participating in a nationwide network of health information networks. They have an open mind, are eagerly seeking feedback from stakeholders, and are listening. They didn't wait long - jumping immediately into a presentation and extensive feedback session throughout the afternoon portion of their annual meeting. They have a stakeholder engagement plan and will soon be reaching out to public health stakeholders and to other groups (health plans, consumers, government) to invite them to participate in targeted stakeholder feedback sessions that will be conducted in January. Public health organizations that are on the list that is being provided by ONC should expect to hear from The Sequoia Project soon.
2. Adopting the FHIR standard into the QHIN Technical Framework portion of TEFCA appears to be a question of when, not if. The (as yet unanswered) question is - should the FHIR standard be incorporated in the initial release of TEFCA, or should we wait until a significant number of additional FHIR resources become normative (meaning that backward compatibility will be assured going forward) in later versions?
3. Health care providers should begin mobilizing now to comply with the final Information Blocking Rule, a separate part of the 21st Century Cures Act. The final rule will be published in a matter of weeks and is expected to make a HIPAA-sized wave.

Meeting Overview

The non-profit Sequoia Project was founded in 2012 and has supported the launch of the eHealth Exchange ("the largest query-based, health information network in the country") which became an independent body in 2018, as well as an initiative called Carequality which interconnects data sharing networks and was relaunched as an independent nonprofit last year.

The most significant elements of The Sequoia Project's day long annual meeting included:

- TEFCA Feedback Sessions
    - QHIN Technical Framework (QTF) Feedback Session
    - Minimum Required Terms and Conditions (MRTCs) Feedback Session
- Information Blocking Workgroup Panel Presentation
- Panel Presentation about the PULSE Project (a health IT disaster response platform)
- Keynote Address from Dr. Donald Rucker, National Coordinator for Health IT
- Speech from Steven Poznack, Assistant National Coordinator for Health IT

In his keynote address, Dr. Rucker provided his updates and perspective on TEFCA, Information Blocking, and API's "without special effort" - another requirement included in the 21st Century Cures Act. In the subsequent speech, Mr. Poznack provided some history about policy and governance in the years leading up to the 21st Century Cures Act, and then he walked through a high level overview of TEFCA with slides. (Mr. Poznack was filling in for Eric D. Hargan, Deputy Secretary, U.S. Department of Health and Human Services who had been scheduled to speak that afternoon, but was needed at the White House that day).

For each of the speeches and presentations throughout the day, an extensive period of time was dedicated to engagement with the meeting participants through Q&A and through robust and unrushed feedback sessions, where the questions and comments were initiated in both directions. The various speakers were willing to let the discussions play out, at the expense of ending the meeting without having gotten to all of the topics that they had hoped to cover - most notably, the feedback session on the TEFCA Additional Required Terms and Conditions (ARTCs) which was canceled and rescheduled.

TEFCA

In September 2019, the ONC selected the Sequoia Project to be the Recognized Coordinating Entity (RCE) that would oversee the implementation of the Trusted Exchange Framework and Common Agreement (TEFCA) provision from the 21st Century Cures Act.

A very good overview of TEFCA can be found in the TEFCA Draft 2 User Guide, and public health stakeholders should also see the Highlights for State Governments and Public Health information sheet that was produced by ONC (see HLN's comments in our own blog entry).

- The Technical Exchange Framework will list the principles.
- The Common Agreement is the agreement that HINs will be required to sign and abide by in order to become a Qualified HIN (*i.e.,* a QHIN). The Common Agreement will incorporate by reference
    - The ONC's Minimum Terms and Conditions
    - The Additional Terms and Conditions that will be developed by the RCE

- The QHIN Technical Framework which will specify the functional and technical requirements for the QHINs

In his keynote address, Dr. Rucker stated that TEFCA was spawned by the many complaints that Congress had received about healthcare providers being compelled to join multiple networks, and pay multiple charges. He indicated that the QHIN concept was a policy construct for the REC to flesh out, and was not something handed down by the computing gods. He also revealed that much earlier in his career he had frequently been in the position of reviewing and submitting comments in response to various proposed rules. At the time, he had wondered what really happened to those comments, and he attested now that (at least at the ONC) every single one of the 2,000 comments was meticulously reviewed and was also mapped to the relevant portions of the proposed rule.

Dr. Rucker made several comments about risks related to competition. He wants a fair playing field and is concerned about providers faced with the prospect of buying into single vendor ecosystems without any competition. He wants all of the health care institutions to be able to participate in the networks, including free standing ERs, low cost imaging centers, etc. He also commented on the importance of social determinants of health, and secondary uses of data.

In his speech, Steve Poznack said that the articulation of the use cases in the proposed rule's QHIN Technical Framework was simply the ONC's description of how the ONC understood data exchange to be working today and that through the commenting process, they were seeking confirmation and feedback that their understanding was correct, and also seeking information about other types of exchange that were not included in that description. The ONC doesn't have a prediction or a goal for specific number of QHINs. They don't expect that there will be hundreds. They want to support the market in the direction that it is already moving. They perceive that becoming a QHIN will be a natural next step for some "Super HINs" who want to grow.

Mariann Yeager, CEO of The Sequoia Project, emphasized that ONC has been very collaborative,flexible, and open minded. Keep in mind that until recently, The Sequoia Project was on the same side of the fence as the rest of us (so to speak), and had submitted its own substantial set of comments in response to both ONC TEFCA Draft 1 and ONC TEFCA Draft 2 . Since that time, Ms. Yeager has been able to see a red line version of the MRTCs that incorporate feedback from the public comments. Based on what she saw, she enthusiastically reported to the meeting participants that "they [the ONC] are listening", and that we all now have a "tremendous opportunity."

In addition to the targeted stakeholder feedback sessions planned for January 2020, there will be a Common Agreement public stakeholder feedback session on January 9, and ONC Annual Meeting (1/27 - 1/28). In February 2020, there will be a public information call, and in March 2020, there will be face-to-face stakeholder sessions at the HIMSS Conference.

Ms. Yeager indicated that they would want early feedback on an early draft of the Common Agreement because “words matter” to lawyers, business owners, etc. Therefore, the Sequoia Project will be forming a Common Agreement Task Force. Potential QHINs, participants, and participant-members who participate would be shown draft language for the Common Agreement and asked to provide feedback. Organizations would have to apply to participate in the task force and something akin to a non-disclosure agreement (NDA) and/or memorandum of understanding (MOU) would be necessary.

It was revealed that Carequality is a “subrecipient” of The Sequoia Project’s cooperative agreement with the ONC. Dave Cassel, the Executive Director of Carequality indicated that Carequality has been tasked with developing the QHIN Technical Framework (QTF) and is expected to play a role in the review and approval of QHIN applications and the monitoring of QHIN activities. Mr. Cassel, along with David Pyke from Ready Computing, facilitated the QTF feedback session with the meeting participants. Query, message delivery, FHIR, record locator services, patient matching, and privacy were a few of the topics discussed during the QTF feedback session.

QHIN Query

It is expected that the QTF standards for QHIN query (at least with respect to SOAP-based document exchange via IHE transactions) will largely mirror (with some minor variances) what is currently implemented in Carequality. For example, they may point to the newer versions of the IHE profiles than the versions that Carequality is currently pointing to. A discussion about if/when to adopt FHIR, and for what (just for document exchange or for FHIR resources as well), exposed a tension between the desire to use this opportunity to promote interoperability using the best (most current) technologies and standards, and the notion of simply “meeting the industry where it is today” in order to get to national interoperability quickly and efficiently.

QHIN Message Delivery

With regards to QHIN message delivery, the question was - Should the QTF standard for message delivery be XDR (which has been widely implemented and used, and is what Direct is built upon), or should the QTF adopt XCDR/ITI-41 (which is more suitable for cross community document exchange but is newer and much less common), or should some sort of FHIR mechanism be used? The CEO of Direct Trust expressed his opinion that if/when Direct is eventually replaced, it should be replaced with FHIR. The Associate Chief Medical Information Officer at Stanford Healthcare (and Vice Chair of the Sequoia Board) indicated that his organization is now using ITI-41 to send messages and thinks that it is great. He felt that it is poised to take off and be implemented by other organizations. Two downsides of Direct that were discussed were directory management (where is the single authoritative directory?), and costs of certificates. The CEO of Direct Trust said that 15 of the top 20 EHRs would be meeting with Direct Trust the following week to discuss the problems with managing a directory. They know that it is a problem and they are taking responsibility to fix it, but they need the EHRs involved. As for certificates, he felt that the costs would come down as they become ubiquitous

(which happens with all goods that become ubiquitous). Finally, another participant stated that "providers are dying from CCDAs" and that getting information to the providers in a usable format that they can easily digest is essential, which means taking advantage of emerging technologies like FHIR in order to support improved usability.

The discussion during the Information Blocking portion in the morning and then the TEFCA portion in the afternoon made clear the tension between the two initiatives and the competing concerns. Patients want their providers to make their data accessible to the patient and to the patient's other healthcare providers in all of the appropriate ways, but they also demand that the privacy of their health data to be very tightly preserved in every other way. Furthermore, there is a third complicating factor. During the feedback session about the MRTCs and the discussion of the Meaningful Choice provisions, the HLN representative at the meeting commented that any implementation must take into account that some data will still be required to be exchanged with public health agencies in accordance with state laws even if/when the patient exercises their meaningful choice to opt out.

Near the end of the meeting, Ms. Yeager voiced optimism, touting The Sequoia Project's experience with piloting new processes in interoperability.

Information Blocking

The morning portion of the meeting was devoted to the ONCs proposed rule on Information Blocking, which is a separate provision of the 21st Century Cures Act. The Sequoia Project's Interoperability Matters cooperative had formed an Information Blocking workgroup which had been meeting since March 2019 and had thoroughly reviewed the ONCs proposed rule on Information Blocking. At the annual meeting, leaders of the workgroup reported their findings, provided recommendations for a compliance framework, and facilitated a Q&A session.

They warned the participants that this new Information Blocking rule will have a broad impact on many organizations in the healthcare community and on many parts of those organizations. The message delivered was that - like HIPAA - this will not "blow over" and organizations should immediately begin preparing for compliance. It is expected that most provisions of the proposed rule will go into effect 60 days after the final rule is published (with other provisions going into effect 26 months after publication), and that the final rule will be published sometime in late December or in January.

Chief concerns about the proposed rule include – liability and potentially significant fines for each violation (up to $1 million), constraints on the fees that may be charged for implementing APIs (fees must be "reasonably related" to the costs of providing API-based access to the data), and the natural tension between existing mandates to protect the privacy of health information and the new mandate to not engage in information blocking. Concerns were compounded by the feeling that some definitions in the proposed rule were ambiguous. During his keynote address, Dr. Rucker expressed awareness of that particular criticism, and even referenced the

fact that the word “reasonable” appears in the proposed rule a couple hundred times (literally), but he explained that the word was chosen intentionally and that it was appropriate.

Related Resources

- 21st Century Cures Act, Public Law 114-255, December 13, 2016
- The Trusted Exchange Framework and Common Agreement (TEFCA) Resources
- Information Blocking Resources
- HLN Consulting’s Reaction to TEFCA
    - HLN's Comments on Draft 1 and related Blog Post
    - HLN's Comments on Draft 2 and related Blog Post
- Other Responses to TEFCA Draft 2 that HLN Contributed to
    - American Immunization Registry Association (AIRA)
    - American Medical Informatics Association (AMIA)
    - Digital Bridge Project
    - Health Level Seven (HL7)
    - Healthcare Information and Management Systems Society (HIMSS)
    - Joint Public Health Informatics Taskforce (JPHIT)
- Framework for Cross Organizational Patient Matching - produced by the Interoperability Matters cooperative prior to their most recent work on Information Blocking