September 17, 2021

Ms. Mariann Yeager
Chief Executive Officer
The Sequoia Project
8300 Boone Boulevard
Suite 500
Vienna, VA 22182

Dear Ms. Yeager,

On behalf of the Healthcare Information and Management Systems Society (HIMSS), we are pleased to provide written comments on the Draft Qualified Health Information Network (QHIN) Technical Framework (QTF). HIMSS appreciates the opportunity to leverage our members' expertise in offering feedback on the Trusted Exchange Framework and Common Agreement (TEFCA) as well as QTF and we look forward to continued dialogue with the Office of the National Coordinator for Health Information Technology (ONC) and The Sequoia Project on these critical topics.

HIMSS is a global advisor and thought leader supporting the transformation of the global health ecosystem through the power of information and technology. As a mission driven non-profit for more than 60 years, HIMSS offers a unique depth and breadth of expertise in health innovation, public policy, workforce development, research and analytics to advise global leaders, stakeholders and influencers on best practices in health information and technology. With a community-centric approach, our innovation engine delivers key insights, education and engaging events to healthcare providers, governments and market suppliers around the world. HIMSS serves the global health ecosystem with focused operations across North America, Europe, the United Kingdom, the Middle East and Asia Pacific. Our members encompass more than 105,000 individuals, 480 provider organizations, 470 non-profit partners and 650 health services organizations.

For our public comment, we offer the following thoughts and recommendations:

TEFCA is a helpful tool to utilize on the journey to nationwide interoperability, but the community needs more specifics to buy-in

HIMSS appreciates ONC's work to create TEFCA and establish a floor of universal interoperability across the U.S. We also thank The Sequoia Project for its ongoing work as the Recognized Coordinating Entity (RCE) and leadership on drafting QTF.

As the U.S. implements the interoperability regulations from ONC and CMS and moves closer to ubiquitous data exchange across the care continuum, we need TEFCA and the broader interoperability that it enables as an available tool. The true value of the TEFCA Network should be that all healthcare organizations are able to participate in nationwide data exchange, and that more sharing and consumption of patient

information across the ecosystem produces better outcomes for patients. Ultimately, HIMSS wants to ensure that broader interoperability benefits patients and supports their care and planning needs in a safe and secure manner.

However, the community has been primed for more structural and functional information about TEFCA for two plus years. It is imperative that ONC and The Sequoia Project move forward with their planned public engagement webinars on TEFCA in the near-term, and use them as an opportunity to build understanding and interest from all potential participants. The aggressive timeline that ONC and The Sequoia Project have presented to operationalize TEFCA in the first quarter (Q1) of calendar year 2022 will require broad community buy-in to meet its goal, and more public education will serve to support it.

The healthcare community is seeking greater clarity on how TEFCA will be structured, which is creating a level of uncertainty about whether organizations will ultimately want to participate in the Network. Some questions were answered by the details included in the Draft QTF, and future publication of what QHINs must fulfill under the Common Agreement as well as what is required to meet the Standard Operating Procedures (SOPs) will include more information. In the meantime, organizations are deliberating whether their existing business models fit into TEFCA and if they have a willingness as well as the resources to change their structure and direction to participate in TEFCA.

We want to help ONC and The Sequoia Project meet its stated goal to have the new network open for participation in Q1 of 2022. Community-wide education and buy-in will be key components of this effort, and HIMSS can support your work to operationalize TEFCA.

Building TEFCA on a foundation of IHE Profiles is the right place to begin

ONC and The Sequoia Project should be commended for building the TEFCA Network on existing infrastructure and leveraging Integrating the Healthcare Enterprise (IHE) Profiles, as well as planning for the conversion of IHE Profiles to the Health Level Seven International (HL7®) Fast Healthcare Interoperability Resources (FHIR®) Standard in the future.

It is critical to ensure the healthcare community is continuously leveraging existing and emerging standards, data formats, and use cases to achieve greater health data interoperability in support of improved health outcomes. A comprehensive integrated approach to care can recognize and build upon the many mature, consensus-based standards and profiles already in place, while allowing innovation to pilot and incorporate new and emerging standards.

IHE Profiles provide the backbone to much of the health data exchange occurring across the health ecosystem today. The IHE Profiles that were identified in QTF are open standards and are working successfully across the community. They are the appropriate standards to use from the onset as QTF seeks to facilitate the immediate availability of QHIN services.

Moving forward, a potential resource to ONC, The Sequoia Project, QHINs, and all TEFCA participants is the work of HIMSS, in partnership with HL7 and IHE International, through the creation of the [Global Consortium for eHealth Interoperability](#). The principal work of the Consortium is to capitalize on FHIR—its focus is on engaging in and conveying real world testing guidance such as test plan development, sharing their roadmaps and interoperability vision for global community benefit, and developing online resources to share best practices, use cases as well as interoperability strategy planning.

In addition, we highlight the productive work undertaken by ONC to partner with IHE USA in a multi-year [cooperative agreement](#) to accelerate the adoption of FHIR-based IHE integration profiles to drive the adoption of the FHIR standard in compliance with the [21st Century Cures Act (Public Law 114-255)](#).

The 21st Century Cures Act requires developers of certified health IT to publish application programming interfaces (APIs) and adopt certification criteria that require standardized API access for single patient and population services using the FHIR standard. The objectives of the work being done by the IHE USA Cooperative Agreement project team focus on:

- o Cataloging IHE Profiles that utilize the FHIR standard to enable cross community health information exchange
- o Identifying and prioritizing new profiling opportunities to leverage the FHIR standard
- o Accelerating the development of robust, real world testing processes and adoption of the updated FHIR-focused IHE Profiles and HL7 implementation guides
- o Actively engaging with ONC, HL7, and IHE International on lessons learned through profiling improvements and real-world testing
- o Strengthening and streamlining cross-organizational collaboration efforts between SDOs, interoperability test tool developers, FHIR champions, and other vital stakeholders

Require the QHIN Message Delivery modality in QTF using IHE Cross-Community Document Reliable Interchange (XCDR) profile with a future transition to FHIR

HIMSS recommends that The Sequoia Project move forward with "Option 1" on its question related to if QTF should include message delivery—requiring the QHIN Message Delivery modality in QTF using the IHE XCDR Profile with a future transition to FHIR. From the technical perspective, it is important to use an open standard for message delivery and the IHE XCDR protocols are in line with what is being used across the community today. In addition, when positioning QTF for the future, all IHE protocols, including XCDR, are very much designed to co-exist with FHIR, i.e., support Representational State Transfer (RESTful) architecture.

Overall, several factors compel us to require the inclusion of message delivery. If the TEFCA Network is truly going to serve as a means to facilitate nationwide

interoperability, we need the network to embrace multiple exchange modalities beyond "query" in order to appeal to all current and future health system participants.

For example, state and local public health departments rely on push messages for many required public health reporting measures, including for syndromic surveillance. immunization registries, electronic cases, and laboratory results. Given that much of our nation is still in attempting to fully address the COVID-19 Public Health Emergency (PHE), more reporting on these measures will figure prominently in helping us emerge from the pandemic. Such a step will establish continuity in the broader federal COVID-19 response and improve coordination as it relates to health data.

CMS recently finalized the [2022 Inpatient Prospective Payment System (IPPS) Regulation](#) that requires eligible hospitals and critical access hospitals to report a "Yes" on four of the existing Public Health and Clinical Data Exchange Objective Measures (Syndromic Surveillance Reporting, Immunization Registry Reporting, Electronic Case Reporting, and Electronic Reportable Laboratory Result Reporting) of the Medicare Promoting Interoperability Program beginning with the electronic health record (EHR) reporting period in 2022. As CMS has described, reporting on these measures would put public health departments on stronger footing for future health threats and a long-term COVID-19 pandemic recovery by strengthening three important public health functions: (1) early warning surveillance, (2) case surveillance, and (3) vaccine uptake.

In addition, CMS proposed as part of its [2022 Physician Fee Schedule](#) to require eligible clinicians to report a "Yes" on two of the measures (Immunization Registry Reporting and Electronic Case Reporting) associated with the Public Health and Clinical Data Exchange Objective.

It is also important to note that HIMSS continues to advocate for and emphasize the foundational investments necessary to upgrade the nation's public health data systems infrastructure through the [CDC's Data Modernization Initiative](#). The COVID-19 PHE has underscored the critical need for a large-scale upgrade to the US public health infrastructure. It is essential that our nation bolster our broader public health infrastructure to optimize data collection and state/local health department access to critical data to manage ongoing and emergent public health crises.

As we discuss a use or business case for including message delivery in QTF, CMS has helped push this concept forward with the reporting requirements for these public health measures. Moreover, as the community gears up for TEFCA to be open for participation in Q1 of 2022, the new reporting requirements can serve as the catalyst for ensuring the policy and technical infrastructure is in place to support TEFCA participants that need a means to support this necessary public health data collection, reporting of this data, and contributing to broader societal PHE-related goals.

Set robust expectations for patient matching algorithms across QHINs

HIMSS recognizes the importance of matching algorithms and the autonomy granted in QTF for QHINs to choose their own internal processes. The requirement prescribed by QTF should be focused on each QHIN being able to correctly identify the patient, and serve as a differentiator based on the different methods that they deploy for matching as well as what they require of their participants. A high-quality patient matching process is necessary to preserve patient safety and establish trust across the TEFCA Network. We ask The Sequoia Project to look closely at this issue and set clear and robust expectations for QHINs as well as require periodic and regular reporting on the quality of patient matching rate performance.

QTF outlines several performance measures that QHINs will submit to The Sequoia Project in its RCE role. Monthly submissions from QHINs on the raw count of successful and erroneous inter-QHIN transactions will be helpful, but running patient discovery tests not only during onboarding but also on a periodic basis over the course of the year should help the network provide assurances to its participants and other QHINs about how well its matching algorithms are performing. This information can also be used to establish benchmarks on patient matching applications across QHINs, so they are striving to improve over their previous match rates.

In addition, given the work occurring across the community to improve processes and supplement the data points used for matching, we encourage The Sequoia Project to ask QHINs about their non-proprietary methods and additional attributes as well as data points that they are regularly using to help match patient records. The Sequoia Project should compile this information on an annual basis and publish it to support sharing and learning across the TEFCA Network. As part of this effort, HIMSS recommends that The Sequoia Project allocate resources toward educating the community on underutilized attributes that could be used to improve matching rates. For example, there is information circulating community-wide on "preferred" attributes and data points that are successfully being used for matching (such as email addresses and mobile telephone numbers)—if more data and use cases were available on the value of these additional data points, other QHINs and participants may be able to improve their matching rates, and the entire network could benefit.

Overall, the safety of patients is paramount—successfully matching patients with their information across the entire network will help continually reinforce the value in participating in TEFCA and ensure that stakeholders exclusively rely on their QHIN to exchange information.

Provide more details on the responsibilities for TEFCA participants and subparticipants

The Draft QTF provides detailed information on what is required on the part of QHINs as well as how they are expected to interact with and exchange information with other QHINs. There is also some information on the constraints for participants and

subparticipants, and assurances that they provide information necessary for QHIN functions.

We expect more details on what is required of participants and subparticipants in the Common Agreement and SOPs, but there is information included in the QTF Performance Measures that are helpful steps to build on moving forward. Of particular interest are service level agreement requirements and parameters that will be adopted by The Sequoia Project in its RCE role for QHIN-to-QHIN exchange. We anticipate that some of these requirements will flow down from QHINs to participants and subparticipants, but more specifics about what is required would be helpful.

As QTF states, protecting the privacy and security of health information is essential for building trust among participating entities. What is included for QHINs from the security perspective is informative, and QTF should ensure participants and subparticipants are adopting all these protocols as well in their work across the TEFCA Network. For example, QHINs must provide a secure channel to ensure transport-level security for all transactions under their domain. In addition, QHINs are encouraged to take advantage of testing resources such as tools provided by the National Institute of Standards and Technology (NIST), testing platforms maintained by private organizations, and IHE Connectathon events. The Draft QTF also specifies mutual authentication for all QHIN-to-QHIN and QHIN-to-Participant communication.

On the privacy side, fewer details are included in this document. QTF states that actors have the ability to choose if/how to allow a transaction to proceed based on privacy policies, security details, and the requirements of the Common Agreement. HIMSS requests that the Common Agreement and SOPs provide more substantive information on how TEFCA will be operationalized with Health Insurance Portability and Accountability Act of 1996 (HIPAA) requirements. In addition, given the impact of state privacy laws in this space, more details are needed about how TEFCA will accommodate different state laws and ensure QHINs, participants, and subparticipants are abiding by all applicable privacy laws before exchanging any protected health information.

Moreover, ensuring the inclusion of patient consent across the Network is also critical when discussing the overlap and impact of different state laws and regulations. The information included in the Draft QTF is helpful, but QHINs, participants, and subparticipants will need to be educated to ensure alignment on how patient consent is incorporated into the query as well as message delivery modalities across the TEFCA Network.

In our public comments on the [Proposed Modifications to the HIPAA Privacy Rule To Support, and Remove Barriers to, Coordinated Care and Individual Engagement](#) earlier this year, HIMSS called for harmonized privacy regulations that are clear and concise, and avoid any redundancies, conflicts, or inconsistencies that may result in confusion and impede progress toward broader alignment. We want rules that collectively encourage innovation and provide the right balance concerning the sharing of information to enable care coordination and interoperability. ONC and The Sequoia

Project have the opportunity to use QTF, the Common Agreement, as well as the SOPs to provide more privacy information to bolster health data exchange and support the tenets of TEFCA.

Glidepath to incorporate FHIR should focus on driving specific use cases

We recommend The Sequoia Project move forward with plans to incorporate FHIR into future iterations of QTF. The FHIR Roadmap under development as part of the process to finalize the Draft QTF should focus on driving specific use cases that utilize FHIR Documents, rather than a "date certain" when FHIR should be incorporated in QTF.

As we have previously discussed, QTF should be built on existing infrastructure and leverage IHE Profiles at this time, but future versions of QTF should point to the broader use of the FHIR Standard. The idea we recommend is a "fast follow" approach by building QTF on IHE infrastructure that allows for incorporating FHIR when those standards are performing at scale and can be appropriately integrated.

A bridge between the use of IHE and FHIR Standards could be to encourage organizations to leverage the consolidated-clinical document architecture (C-CDA) content specification as it does not restrict the use of FHIR. The technical encoding's metadata can be structured to include the same content in two different formats to ease the transition from IHE Profiles to FHIR Documents. As described by a Standards Architect, the International Patient Summary (IPS) is a FHIR Document that covers the same needs as the C-CDA Medical Summary and for those that want a FHIR content format, the choice would be the IPS rather than the C-CDA. The metadata would indicate to organizations that entries exist in both IPS and C-CDA, and they could choose which to consume. As FHIR matures and begins performing at scale, QTF could encourage organizations to transition to consuming the IPS entry.

Another opportunity to consider on the glidepath to incorporating FHIR is to encourage QHINs to pilot the broader use of FHIR in their work with participants and subparticipants. As QTF focuses primarily on the technical and functional requirements for interoperability among QHINs, future iterations of QTF could empower QHINs to more broadly use FHIR Documents for queries and message delivery "downstream" to their participants. The QHIN-to-QHIN exchange of health information would still utilize IHE Profiles at present, but other work within the TEFCA Network could focus on using FHIR Documents. Such a step will provide a testbed for the FHIR Roadmap, and help FHIR continue to mature and ensure the implementation community grows more quickly. In interactions with their participants and subparticipants, QHINs have a real opportunity to support the further development of emerging standards and allow the pace of standards adoption to move forward more quickly across the entire ecosystem.

Finally, moving toward full implementation of the ONC and CMS Interoperability Regulations across the community provides another opportunity to embrace FHIR and parlay organizational regulatory obligations into demonstrating a commitment to the future use of FHIR in QTF and across the TEFCA Network. ONC and CMS have prioritized the use of FHIR to better serve the needs of patients. Overall, the FHIR Roadmap's

implementation expectations should coincide with the requirements placed on the community to adopt these regulations.

We would welcome the opportunity further to discuss these issues with you and your leadership team. Please feel free to contact Jeff Coughlin, Senior Director of Government Relations, at jeff.coughlin@himss.org, with questions or for more information.

Thank you for your consideration.

Sincerely,

Harold F. Wolf III, FHIMSS
President & CEO