



October 21, 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 [Elements of the Common Agreement](#) and [Draft Qualified Health Information Network \(QHIN\) Eligibility Criteria](#). HIMSS appreciates the opportunity to leverage our members' expertise in offering feedback on the Trusted Exchange Framework and Common Agreement (TEFCA) as well as both of these documents, 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.

HIMSS supports the goal of the Common Agreement to establish a floor of universal interoperability across the U.S. for health care and how it would provide the governing approach necessary to connect and scale interconnected QHINs. In addition, we appreciate the attention included in the Common Agreement on privacy and security in the TEFCA Network. It is a positive step that the Elements of the Common Agreement state that QHINs, Participants, and Subparticipants would be subject to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Rules, how the Common Agreement and its Required Flow-Down provisions would not replace the obligations of HIPAA Covered Entities and HIPAA Business Associates to comply with the HIPAA Rules, and the Common Agreement's extension of many of the requirements of the HIPAA Rules to health care providers that are not Covered Entities.

Similarly, with respect to HIPAA security, HIMSS endorses the idea that QHINs would be expected to meet and maintain third-party certification to an industry-recognized cybersecurity framework and undergo annual security assessments. We also appreciate that the Common Agreement would require flow-down contract provisions

for all Participants and Subparticipants to enact security measures that align with the HIPAA Security Rule (at a minimum), even if the participants are not HIPAA Covered Entities or Business Associates.

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

Leverage Existing Infrastructure in TEFCO Creation to Avoid Disruption of Existing Exchange

As [HIMSS stated in its TEFCO Draft 2 Public Comment Letter from June 2019](#), TEFCO infrastructure should not disrupt existing successful health data interoperability processes, including the business models of state and regional health information exchanges (HIEs) and health information networks (HINs) as well as other exchange entities. TEFCO should build upon their innovations, partnerships, and successes that are already in place. We encouraged ONC to use the current HIE and HIN infrastructure as a foundation to empower information exchange by enabling market-driven solutions and removing participation barriers.

[Section 4003 of The 21st Century Cures Act](#) states:

(F)(iii) Existing frameworks and agreements.--The trusted exchange framework and common agreement published under subparagraph (C) shall take into account existing trusted exchange frameworks and agreements used by health information networks to avoid the disruption of existing exchanges between participants of health information networks.

We ask The Sequoia Project to work with ONC to reach out to health system stakeholders and potential TEFCO Network participants to gather specific feedback on how TEFCO could be structured to ensure that creation of the Network avoids disruption and appropriately leverages existing exchange processes, including state and regional HIEs and HINs.

Require Qualified Health Information Networks (QHINs) to Provide Individual Access Services (IAS)

The document states that delivering IAS is "optional" for QHINs, Participants, and Subparticipants to offer to individuals with whom they have a direct relationship. HIMSS believes that QHINs and their networks should be required to provide IAS to individuals—it should be up to the individual to have the option to utilize a QHIN for such services, or if they have a more direct relationship with a Participant or Subparticipant to a QHIN, access IAS through that means. Either way, TEFCO should require that these services are available to empower individuals with control of and access to their personal health information. We want to ensure that TEFCO reduces the friction that an individual may encounter in trying to compile their own information, and that individuals are better positioned to use that information to make more informed health care decisions.

With the implementation of the [ONC](#) and [CMS](#) interoperability regulations underway, we are on a pathway to broader and more meaningful health data exchange, as well

as greater empowerment of patients with more control over their data. HIMSS encourages the interoperability regulations, TEFCA, and other regulatory vehicles to foster two-way, individual access to information, and clearly present the value proposition for all health ecosystem participants related to the collection and exchange of data. Such dialogue will clarify why individuals should control their health information and how health and wellness outcomes improve as data moves effortlessly across the continuum of care.

In addition, we are very encouraged by the steps underway in Congress to remove Section 510—a longstanding ban prohibiting federal funds for the promulgation or adoption of a unique patient identifier—from the Labor, Health and Human Services, Education, and Related Agencies (Labor-HHS) appropriations bill. A narrow interpretation of this archaic ban has prevented HHS from leading on efforts to advance a national patient identification strategy. HIMSS remains committed to working with Congress, HHS, and the broader stakeholder community to move forward with developing this strategy. This endeavor would enhance patient matching to support secure information sharing as part of the expansive effort to improve care quality, effectiveness, affordability, and safety.

We also see TEFCA and IAS as expanded means to support the ability for consumers to contribute personal health data to their health records. As IAS satisfies an individual's ability to use a QHIN to access, inspect, or obtain a copy of their TEFCA Information, we want to ensure that the compilation of an individual's health information includes any additional information that they choose to incorporate. Such a step will help provide an individual and their care team with a comprehensive, 360° perspective on their healthcare journey, and serve to advance their overall empowerment.

Retain the Six Exchange Purposes Included in the Draft Elements of the Common Agreement

For the initial rollout in the first quarter of 2022, HIMSS supports the inclusion of the six Exchange Purposes detailed in the document: Treatment; Payment; Health Care Operations; Public Health; Benefits Determination; and, IAS. We agree that these are the only purposes that should be allowed under the Common Agreement during the first year of TEFCA.

HIMSS supports The Sequoia Project initiating a predictable, transparent, and collaborative process for consideration of new Exchange Purposes in TEFCA Year 2. A model to contemplate is the process that ONC uses for the [United States Core Data for Interoperability \(USCDI\)](#), which allows health IT stakeholders to submit new data elements and classes for future versions of USCDI. ONC's USCDI process also provides an extensive runway for the community to understand new candidate data classes and elements under consideration, when they would be included in the new version, and specifics on what organizations need to prepare for their inclusion. ONC and The Sequoia Project should solicit new Exchange Purposes by a similar deliberative process annually.

We recommend the first additional exchange purpose to consider for TEFCA Year 2 should be requesting or sending information to support biomedical research. Inclusion

of support for biomedical research as an exchange purpose would provide medical researchers with greater access to information to enhance their research projects as well as demonstrate the additional value that a robust TEFCA infrastructure could provide to the community.

Allow QHINs to Charge Fees to Participants, but Examine an Alternative Rate Structure for Public Health Agencies and Safety Net Organizations

HIMSS agrees with the plan to prohibit QHINs from charging fees to other QHINs for activities under the Common Agreement. As TEFCA will be built on QHIN-to-QHIN exchange, and QHINs may vary in size across the network, fees should not factor into the query or message delivery modalities at the QHIN level of exchange.

In addition, we also understand the need for QHINs to charge fees to their participants to support their business models. We expect fees to all participants to be market-driven, which will help ensure that they are reasonable and cost-based fees. [ONC's Fees Exception in the Information Blocking Regulation](#) provides a meaningful framework model for The Sequoia Project on how to structure fee requirements in TEFCA. Under the Information Blocking Fees Exception, regulated actors are allowed to charge fees that lead to a reasonable profit margin for accessing, exchanging or using electronic health information (EHI). However, the fees must be based on objective and verifiable criteria that are uniformly applied for similarly situated people as well as requests, and reasonably related to the costs incurred by the actor. These same principles could be applied to TEFCA's QHIN-to-participant fees and help guide the network's design of an appropriate fee structure.

HIMSS encourages The Sequoia Project to look closely for opportunities to charge certain QHIN Participants lower or no fees for taking part in data exchange on the TEFCA Network. We envision that public health-related transactions would occur under TEFCA through an alternative fee structure. In addition, federally qualified health centers (FQHCs) and other safety net organizations should be permitted to participate in TEFCA with similar fees. As TEFCA works to establish a floor for universal interoperability across the U.S., there is considerable value to the overall health system in having more public health-related transactions and FQHCs on the TEFCA Network. HIMSS recommends The Sequoia Project implement fees do not inhibit all health system stakeholders from participating in the network or limit any critical transactions from occurring on the network.

As we attempt to address the COVID-19 pandemic, the immense importance of public health data exchange, at present as well as for future outbreaks, becomes readily apparent. HIMSS wants to ensure there are as few barriers as possible to receiving the essential data public health needs to perform surveillance and control disease spread. Similarly, with the limited resources of FQHCs, we want to ensure that safety net organizations are broadly sharing data across their communities to help deliver better outcomes to patients. Fees for participating in TEFCA data exchange should not stand in the way of these organizations joining the network.

Ensure Opportunities Exist for New Market Entrants and Innovators to the Data Exchange Space

We understand that to be designated as a QHIN, an entity needs to have been operating and supporting query functionality as outlined in the QHIN Technical Framework (QTF), or another functionally comparable exchange method for at least 12 calendar months. HIMSS recommends The Sequoia Project provide more details on the provisional QHIN status process and designation to ensure that the designation encourages new market entrants and innovators to join the network and participate in TEFCA data exchange. Innovators in a separate but related field could inject fresh ideas and perspectives into health data exchange that could lead to even broader health care interoperability in the U.S. The Common Agreement should provide guidance on how a new entrant with novel ideas, but minimal functional history in health data exchange, could become a provisional QHIN with a route to full QHIN status.

For example, there may be opportunities for a new entrant to be designated as a provisional QHIN and participate in the TEFCA network on a smaller scale as it develops a record of accomplishment in health data exchange that places it on a pathway toward full-fledged TEFCA participation as a QHIN. We want to ensure that the Common Agreement does not preclude the inclusion of new market entrants and innovators in the TEFCA Network, and that aspirant organizations understand the objectives that must be met to become a QHIN.

Moreover, we encourage The Sequoia Project to think through the idea of creating a type of "matching service" for entities that do not currently meet the threshold to be designated as a QHIN, but are open to potential partnership or collaboration opportunities. For example, The Sequoia Project could facilitate combining two or more entities that are interested in serving as a QHIN, and fill a niche in the TEFCA Infrastructure, to collectively provide an appropriate track record in the health data exchange space and serve as a QHIN. This type of function could be compelling resource for The Sequoia Project to pursue.

We 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,

A handwritten signature in black ink, appearing to read "Harold F. Wolf III". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Harold F. Wolf III, FHIMSS
President & CEO