



September 17, 2021

Mariann Yeager
Chief Executive Officer
The Sequoia Project
8300 Boone Blvd.
Suite 500
Vienna, Virginia 22182

Submitted via email to: rce@sequoiaproject.org

Dear Ms. Yeager:

WEDI commends the Office of the National Coordinator for Health Information Technology (ONC) and the Recognized Coordinating Entity (RCE) for the release of the latest draft of the Qualified Health Information Network (QHIN) and QHIN Technical Framework (QTF) and for the open and transparent process for development of the Trusted Exchange Framework and Common Agreement (TEFCA). We are pleased to offer comments and recommendations on the proposed QHIN Technical Framework and TEFCA.

WEDI was formed in 1991 by then Secretary of the Department of Health and Human Services (HHS) Dr. Louis Sullivan to identify opportunities to improve the efficiency of health data exchange. WEDI was named in the Health Insurance Portability and Accountability Act (HIPAA) as an advisor to the Secretary of HHS. Recognized and trusted as a formal advisor to the Secretary, WEDI is the leading authority on the use of health information technology (IT) to efficiently improve health information exchange, enhance care quality, and reduce costs. With a focus on advancing standards for electronic administrative transactions, and promoting data privacy and security, WEDI has been instrumental in aligning the industry to harmonize administrative and clinical data.

Overall, WEDI is strongly supportive of establishing a framework for the trusted exchange of electronic health information. TEFCA represents another phase of ONC's efforts to advance interoperability across the nation's health care system in support of the access, exchange, and use of electronic health information.

WEDI commends the work of the ONC and RCE to advance the interoperability of electronic health information. The 21st Century Cures Act pushed for interoperability to be a priority for the industry and TEFCA represents an important step towards achieving this goal. As ONC further develops their approach to advancing interoperability, we encourage the collaboration with the Centers for Medicare & Medicaid Services (CMS), as well as industry stakeholders such as WEDI.

WEDI has the following comments and recommendations TEFCA and the draft QHIN framework:

- We recommend that participation in TEFCA continue to be voluntary.
- The HIPAA privacy framework has been a fixture in our health care system for more than two decades. Patients rely on HIPAA to ensure that the confidentiality of their information is maintained. Ensuring that TEFCA facilitates trust in the privacy and security of the information being exchanged as well as improved health outcomes for individuals will be critical to its success.
- For health care data exchange to happen in an interoperable manner as called for under the 21st Century Cures rules, there must be confidence that participants meet a minimum level of privacy and security. We recommend ONC and the RCE explore requiring each participant within the exchange environment to complete an appropriate and independent third-party privacy and security accreditation.
- WEDI recommends ONC and the RCE consider delaying the launch of TEFCA and explore identifying Fast Healthcare Interoperability Resources (FHIR)-based standards as a more secure and scalable option for interoperable exchange of health information.

Leveraging new standards and technologies, including FHIR and HL7 Unified Data Access Profiles may offer a method to resolve the current registration challenges and inability to scale solutions. We also note that the industry shift toward FHIR includes CMS and ONC regulatory requirements. As a result of these mandates, we are concerned that health plans and other impacted stakeholders have and will make a considerable financial and human investment in this new approach. Requiring an older unsupported standard would force stakeholders to potentially incur the financial cost of supporting two standards and necessitate the challenging task of identifying and hiring staff with expertise in the older standard. Overall, forcing stakeholders who otherwise would be interested in participating in the exchange framework to support multiple exchange standards could have the unintended consequence of limiting participation.

Further, there appears to be concern regarding the “maturity” level of FHIR for use in an exchange framework. As evidenced by the ONC FHIR at Scale Taskforce (FAST), HL7 Da Vinci, and Argonaut initiatives, considerable progress has been made in developing FHIR-based exchange protocols. ONC and the RCE should ensure that TEFCA and the

ongoing work of ONC FAST, HL7, and the FHIR accelerators are aligned and leveraged. Impacted stakeholders must work together to create a unified, integrated and agreed upon approach to move forward and establish a common exchange process implementation roadmap. We expect that avoiding duplication of effort and requiring multiple standards will result in greater participation in the exchange network and this in turn will lead to a greater impact on patient care.

- Regarding the issue of whether the QTF should include QHIN Message Delivery, there are three options proposed:
 - Option 1: Require “QHIN Message Delivery” modality in QTF using the Integrating the Health Care Enterprise (IHE) Cross-Community Document Reliable Interchange (XCDR) profile with a future transition to FHIR; or
 - Option 2: Defer “QHIN Message Delivery” from QTF until a FHIR based solution is readily available; or
 - Option 3: Include “QHIN Message Delivery” using XCDR as optional in QTF until a FHIR based solution is readily available.

We support Option 2 as we believe that the industry may not need to wait for FHIR to mature as use cases and standards are already prepared and can be leveraged. We encourage a coordinated effort to identify and implement appropriate standards as they continue to evolve.

We appreciate the opportunity to share our perspectives regarding TECCA and the exchange framework proposals put forward by ONC and the RCE. Exchanging data in a standardized and efficient manner will result in patients, providers, health plans, and other stakeholders receiving better data, faster. WEDI looks forward to working with ONC and the RCE as the TECCA process moves forward and we will continue to educate the industry on this important initiative. Should you have any questions regarding this letter, please contact Charles Stellar, WEDI President and CEO at cstellar@WEDI.org.

Sincerely,
/s/
Nancy Spector
Chair, WEDI

cc: WEDI Board of Directors