



February 16, 2018

Don Rucker, M.D.  
National Coordinator for Health Information Technology  
Department of Health and Human Services  
330 C St. SW Floor 7  
Washington, D.C. 20201

Dear Dr. Rucker:

The Healthcare Leadership Council (HLC), a group of leaders across all sectors of American healthcare, appreciates the opportunity to comment on the Trusted Exchange Framework and Common Agreement (TEFCA) released by the Office of National Coordinator (ONC). We applaud the vision of this framework and ONC's leadership on advancing interoperability.

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century health system that makes affordable, high-quality care accessible to all Americans. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, pharmacies, post-acute care providers, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach.

The Healthcare Leadership Council supports ONC's intent to advance interoperability to increase access to health information between and among patients, payers and providers, irrespective of location, to provide a longitudinal health record and deliver high quality care. We commend the concepts and precepts of this effort. HLC has questions, however, about how the entities established and participating in this framework will transfer and deliver health information to all stakeholders across the continuum of care.

HLC seeks clarification surrounding the Recognized Coordinating Entity (RCE), its implementation of the common agreement and the way in which it will operationalize the Trusted Exchange's Framework. HLC also seeks clarification on the framework's relationship to HIPAA, as well as, more clarity surrounding stakeholder participation in the framework. There is considerable detail in the appended documents to the TEFCA framework but clarifying these areas to avoid complications as implementation occurs will be helpful.

HLC also recommends that the ONC synchronize definitions and terms across TEFCA and US Core Data for Interoperability documents (USDCI). More specifically, we respectfully request that ONC consider connecting various features across TEFCA and USDCI development, namely, the implementation of application programming interfaces (API's), interoperability standards, the definition of what 'open API' really means as requested in the 21st Century Cures Act, the semantic standards for electronic health records (EHR's) reporting and data

transfer, and clear distinctions between business and political based information blocking and technical impediments to database access and understanding due to terminology ambiguity. Lastly, we seek greater clarity related to patient matching, user identity authentication, user cases, permitted purposes and queries.

Specifically, we seek answers from ONC to the following questions:

### **RCE/Common Agreement**

- How will the RCE be structured? What are the roles and responsibilities of the RCE? We recommend that the RCE should be neutral, transparent, and objective as it governs a network of QHINs (Qualified Health Information Network). The governing board should be balanced so that all stakeholders are adequately represented.
- How much funding will be allocated to the RCE?
- What barriers will the RCE and common agreements address?
- How was the analysis conducted to assess current regulatory authority and legal standards? How does this analysis enable and promote interoperability?
- What are the details of the common agreement and how will it be developed?
- There is clearly a need for standardization to which all participating entities should adhere; How does ONC plan to address, certify and monitor use of such standards?
- We are generally supportive of the requirements for the QHIN. We recommend that ONC define the functional requirements for a QHIN and allow the neutral-bodied RCE and QHINs to define the technical requirements.

### **HIPAA**

- Does participation by non-HIPAA covered entities require them to be covered under HIPAA in the TEFCA framework?
- How does the TEFCA framework handle data requests that do not fall under HIPAA?
- Who will manage consent under the TEFCA model?
- How will ONC work with industry to ensure the accounting of disclosures requirement under TEFCA is realistically feasible for industry? (HLC strongly opposes the access report provision of the HIPAA Accounting of Disclosures NPRM 76 FR 31426).

### **Participants/Stakeholders**

- What are the overall costs to those who participate? We recommend that attributable costs be driven by market factors and not regulated by ONC through TEFCA.
- What are the fees and fee structures for services?
- Will stakeholders need to make substantial investments in infrastructure and in changes/upgrades?
- What is the likelihood federal agencies will require TEFCA participation?
- Is it reasonable to expect participants to ensure every patient's medications and medical information are up to date prior to data exchange with other organizations?
- What incentives for participation can be provided? History has shown that the business model for wide-ranging health exchange networks is challenging, and while ethically and morally the right thing to do, such network unification, maintenance is often not fiscally rewarding enough to encourage participation.

**Other general questions:**

- How do new regulations related to medical devices in information technology, such as US Device Innovation (USDI), fit within the TEFCA framework?
- How does the Unique Device Identifier (UDI) relate (or not) to other existing and in process data model efforts?
- Does ONC believe previous experience is sufficient to suggest TEFCA will be successfully scaled, or should consideration be given to conducting a pilot study to determine scalability?
- Should ONC collaborate with the National Institutes of Standards and Technology (NIST) and RCE to design a pilot program, with the pilots completed before TEFCA is finalized?
- Individuals who previously agreed to share information via the framework may withdraw their consent in the broader contextual effort, and if an individual decides to cease sharing information, how will the data already shared across all networks be affected?
- Lastly, how will the framework impact value-based care initiatives and the Merit-based Incentive Payment System (MIPS) program?

The Healthcare Leadership Council believes the Trusted Exchange Framework and Common Agreement will help to build a solid foundation to increase access to health information and improve communication among all stakeholders within healthcare. We applaud the intent of ONC to produce a framework aimed at supporting interoperability and increasing the flow of information among interrelated healthcare entities, and we respectfully request ONC consider our questions and suggestions to improve upon the framework's foundation. HLC stands ready to assist ONC with an approach to increasing access to healthcare information across all stakeholders. Should you have any questions, please do not hesitate to contact Tina Grande at (202) 449-3433 or [tgrande@hlc.org](mailto:tgrande@hlc.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Mary R. Greal". The signature is fluid and cursive, with a large initial "M" and "R".

Mary R. Greal  
President