MAYO CLINIC

SUBMITTED ELECTRONICALLY

June 17, 2019

Donald Rucker, MD
National Coordinator for Health Information Technology
US Department of Health and Human Services
330 C Street, SW
Washington, DC 20201

Dear Dr. Rucker:

We appreciate the opportunity to provide comments on the Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2.

Mayo Clinic is a not-for-profit health care system dedicated to medical care, research and education. With more than 3,600 physicians and 60,000 employees, Mayo Clinic demonstrates a relentless and unwavering commitment to excellence which has spawned a rich history of health care innovation. Each year, more than 1,000,000 people from all 50 states and 140 countries come to Mayo Clinic to receive the highest quality care at sites in Minnesota, Arizona and Florida. In addition, Mayo Clinic Health System, a family of clinics, hospitals and health care facilities, serves communities in Iowa, Minnesota and Wisconsin. Over 100 year ago, when a Mayo physician devised the first unified medical record, or just last year when we undertook an enterprise-wide technology upgrade to enhance our capabilities to streamline and share patient records across provider groups, our staff continuously strive to put the needs of the patient first.

Mayo Clinic is very supportive of the goals set forth in the TEFCA proposal. The establishment of a single set of overarching policies and technical framework nationwide is a significant step forward for health information exchange within the U.S. Taken in context with the previous ONC and CMS proposals, the new exchange solution will enable Mayo to connect once and send and receive a wealth of patient health information needed to support direct patient care. The inclusion of the HL7® FHIR® standards and its support using this infrastructure sends a clear signal, that patient health information must be portable, accessible and standardized into order to meet these goals and to enable patients to effectivity engage and manage their health and health care. We look forward with working with the ONC and other leaders in the industry to see this strategy mature and succeed.

Meaningful Choice
We encourage that Meaningful Choice be clear, concise and easy for patients to ensure their privacy rights. Patients are often confused about where they need to exercise Meaningful Choice (opting out). Today, they must elect to opt out at every location as opting out at one entity does not apply to all. This system must be clear and user friendly for the patient.

In addition, we believes that TEFCA and all polices, and procedures developed by the Recognized Coordinating Entity (RCE) should align with the Health Insurance Portability and Accountability

Act (HIPAA), including the presumed consent for the exchange of protected health information for treatment and minimum necessary information exchange for payment and health care operations. We agree with ONC in that individuals should have the opportunity to understand and make informed choices about where, how, and with whom their electronic health information is shared; however, we suggest that ONC define Meaningful Choice in a way that applies only to the exchange of health information that does not fall under the definitions of treatment, payment and operations (TPO) as established by HIPAA. Establishing a new choice standard for TPO would be inappropriate for HIPAA Covered Entities and Business Associates, as the current implied consent model for TPO is an ingrained standard that has served patients well. We ask that ONC clarify that Meaningful Choice applies to data sharing that is not contained within the HIPAA TPO construct. This clarification is essential for HIPAA Covered Entities' and Business Associates' participation in TEFCA.

Below, Mayo Clinic offers input on specific questions and comments posed in the Framework:

Should the QTF specify additional standards or approaches for securing QHIN Exchange Network transactions (page 78)?

Mayo Clinic response: The support of secure channels via a certificate framework with policies supporting biennial re-certification, conformance testing and systematic and independent audit reviews seems appropriate. However, there needs to be clear guidelines about encryption of data at rest and the use of two factor authentication for all access by users and support staff of this key national infrastructure.

Should the QTF specify which queries/parameters a QHIN must support? Which queries/parameters are most widely implemented and/or useful today (page 82)?

Mayo Clinic response: We strongly encourage the QTF to specify the precise queries and parameters along with the associated codes or values that *shall* be used for document query across the QHIN network. Only by ensuring uniform functional specifications can a reasonable national solution be deployed.

Comments are requested on other appropriate standards to consider for implementation to enable more discrete data queries, such as emerging IHE profiles leveraging RESTful APIs and/or use of HL7 FHIR (page 82).

Mayo Clinic response: When the goal is to query discrete data from a source, the use of FHIR queries with appropriate profiles, HL7 or IHE would be strongly encouraged. Regarding FHIR, due to the differences in implementations between vendors, Mayo strongly recommends that a set of required queries be explicitly enumerated. The document query capabilities should be leveraged when access to summaries or physician (care giver) documentation inclusive of their impressions, report, and plans are desired.

Should QHINs use a broader set of specified patient demographic elements to resolve patient identity? What elements should comprise such a set (page 85)?

Mayo Clinic response: Accurate identification of a patient in the context of querying electronic health information for the purpose of clinical care is essential. Current algorithmic based strategies utilizing patient demographics will likely fail to deliver dependable match rates required for clinical care use cases on a nationwide basis. All large healthcare organizations utilize unique patient identifiers to ensure proper patient identification and do not rely on demographic queries to manage financial information. We encourage ONC to reference the learnings from "A Framework for Cross-Organizational Patient Identity Management" a study by InterMountain Healthcare, available by the Sequoia project https://sequoiaproject.org/resources/patient-matching/ which identifies patient matching best practices.

Should QHINs meet a minimum performance standard (e.g., a minimum acceptable matching accuracy rate) over a specified time period? Likewise, different algorithmic techniques for matching patient identities use different approaches and must be tuned to the applicable patient population and continuously refined over time. Should QHINs measure and report on the performance of the algorithm(s) they rely on (e.g., by calculating precision, recall, etc.) (page 85)?

Mayo Clinic response: If QHINs utilize algorithmic approaches to patient matching, they should not only establish minimum performance standards, but also be required to establish procedures to correct all patient misidentification issues identified on continuous basis. Once a patient misidentification has been detected and a proper match has been established, the system should retain this information and avoid the same mismatch into the future. In addition, when mismatches do occur, systems that received the mismatched information will need to be notified, so that appropriate cleanup can be made in their receiving clinical systems and notifications can be shared with their local providers.

Recognizing there are different ways to implement Record Location services, should the QTF specify a single standardized approach across QHINs (page 86)?

Mayo Clinic response: We encourage the QTF to specify a single standardized approach for the base record location services to be supported. Extensions should be allowed and used to identify enhancements moving into the future. However, a base set of capabilities will be required to ensure uniform functional capabilities at a national level.

We appreciate the opportunity to comment on this important proposal. For more information, please feel free to reach out to me or contact Mayo Clinic Government Relations Policy Director Randy Schubring at schubring.randy@mayo.edu or 507-293-0966.

Thank you for your attention.

Sincerely,

Christopher J. Ross
Chief Information Officer
Mayo Clinic