



June 17, 2019

The Honorable Donald Rucker, MD
Office of the National Coordinator (ONC) for Health
Information Technology
Mary E. Switzer Building
Mail Stop: 7033A
330 C Street SW
Washington, DC 20201

RE: Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2

Dear Dr. Rucker:

RadNet appreciates the opportunity to comment on the latest version of the ONC's Trusted Exchange Framework and Common Agreement (TEFCA) announced on April 19, 2019. It is our understanding that TEFCA: (1) outlines a common set of principles, terms, and conditions that would help enable nationwide exchange of electronic health information (EHI) across disparate health information networks (HINs) and (2) is designed to scale EHI exchange nationwide and help ensure that the various stakeholders have secure access to their electronic health information when and where it is needed.

About RadNet

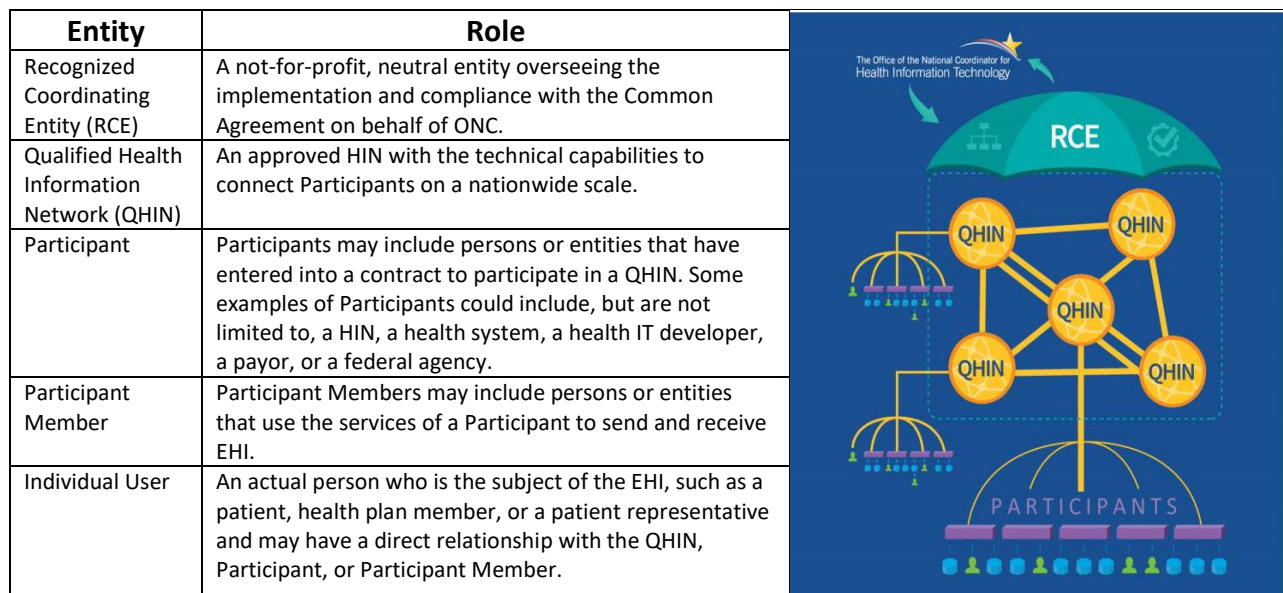
RadNet, Inc., with a network of 323 imaging centers and nearly 800 radiologists in six states, is the leading national provider of freestanding, fixed-site diagnostic imaging services in the United States based on the number of locations and annual imaging revenue. We are the alternative to hospital-affiliated imaging and our goal is to deliver convenient access to high-quality, affordable outpatient imaging services. In addition, RadNet provides radiology information technology solutions, teleradiology professional services, and other related products and services to customers in the diagnostic imaging industry.

The interoperable exchange of electronic health information (EHI) is required in order to transform the U.S. healthcare system from its current fragmented, siloed state to one that is more patient-centric, effective, and efficient. RadNet is doing its part towards achieving this outcome. Our affiliated practices and imaging centers participate in several HINs. One such network is CRISP (the Chesapeake Regional Information System for our Patients) which exchanges health data among Maryland physicians, hospitals, and other healthcare organizations and providers. In addition, RadNet has developed HL7 interfaces with a variety of partners including hospitals and health systems as well as providing portals for physicians and patients to access and share imaging studies.

TEFCA Draft 2

The TEF and the Common Agreement are distinct components that aim to create a technical and legal infrastructure for broadly sharing EHI across disparate HINs to enable nationwide data exchange. The TEF¹ creates a common set of principles that are designed to facilitate trust between HINs and enable widespread data exchange. Those principles are: (1) standardization, (2) transparency, (3) cooperation and non-discrimination, (4) privacy, security, and patient safety, (5) access, and (6) data driven accountability. The Common Agreement is intended to provide the governance necessary to scale a functioning system of connected HINs (a “network of networks”). In Draft 2, the Common Agreement has three parts: (1) Minimum Required Terms and Conditions (MRTCs)², (2) Additional Required Terms and Conditions (ARTCs)³, and (3) the QHIN Technical Framework (QTF) Draft 1.⁴

The TEF and the Common Agreement follow a “network of networks” structure (as envisioned below), which allows for multiple points of entry and is inclusive of many different types of health care stakeholders. Based on the proposed TEFCA network structure, we anticipate being designated a Participant or Participant Member.



¹ See TEFCA draft 2 -- Appendix 1

² See TEFCA draft 2 -- Appendix 2

³ Pending selection of the Recognized Coordinating Entity (RCE)

⁴ See TEFCA draft 2 -- Appendix 3

RadNet’s Comments on TEFCA Draft 2

I. Timeline

RadNet seeks further guidance on: (1) how the proposed timeframe of 18 months for QHINs to implement various provisions of TEFCA Draft 2 impacts Participants, Participant Members, and Individual Users and (2) how Participants, Participant Members, and Individual Users should transition if their HIN is approved as a QHIN.

TEFCA Draft 2 gives QHINs 18 months to update agreements and technical requirements such as: (1) supporting the exchange of the latest U.S. Core Data for Interoperability (USCDI), (2) updating Participant-QHIN Agreements, (3) complying with updates to the QHIN Technical Framework, and (4) evaluating the quality of their data.

It is unclear to us how Participants, Participant Members, and Individual Users fit into this deadline and what will be expected of them as part of the transition. The proposed 18-month timeframe could be interpreted in one of two ways: (1) take the steps necessary and be ready to comply with the new requirements within 18 months or (2) perform the necessary updates and apply them to the affiliated entities as applicable. The latter scenario accelerates the time constraint. RadNet currently participates in several HINs and 18 months may not be sufficient time to update policies and procedures and begin on-boarding existing clients. We believe that the 18-month timeframe should apply only to readying the necessary changes and not to roll-out or execution.

II. Fees

RadNet believes that providers should not have to pay to contribute health information to the QHIN or other TEFCA entity; rather payment should come from those who use the data and reflect “value-added” services.

TEFCA Draft 2 defines fees as “any present or future obligation to pay money or provide any other thing of value charged by a QHIN. Fees may include, but are not limited to, one-time membership fees, ongoing membership fees, testing fees, ongoing usage fees, transaction fees, and data analytics fees.” Regarding the applicability of fees, TEFCA Draft 2 stipulates that QHINs: (1) must use reasonable and non-discriminatory criteria if it charges any fees to another QHIN, (2) may not charge another QHIN any amount to exchange EHI for Individual Access Services, and (3) may not impose any other fee on the use or further disclosure of the EHI once it is accessed by another QHIN.

We agree with the ONC that fees, if charged, should be reasonable, non-discriminatory, and should not interfere with, prevent, or materially discourage the access, exchange, use, or disclosure of EHI. RadNet feels strongly, however, that providers should not have to pay to contribute EHI to a network or other TEFCA entity. Fees of this nature would present a significant barrier to interoperability. Interface fees are another concern. Clinicians and hospitals are charged for interface: (1) creation, (2) maintenance, and (3) use. Depending on the size and complexity, interface fees range from \$500 to \$100,000 to create. EHR and technology vendors also may charge an annual maintenance fee (e.g., 18 percent) based on the initial interface cost. Finally, there are “per click” costs to send or receive information. For high volume referral-based specialties like radiology, total interface-related fees can be significant and represent an obstacle to full interoperability.

We recognize that to be sustainable over the long-term, networks need to be financially viable. Fees based on end-use and added value would be much more acceptable than those based on data contribution. We believe that there would be a market for technology that facilitates access to EHI, enhanced data analytics (e.g., benchmarking, clinical pathways), technical support, etc.

III. Meaningful Choice

QHINs should manage patients’ choices over their EHI disclosures; a consent management API or centralized resource could be a solution.

Meaningful Choice is intended to provide individuals with a reasonable opportunity and capability to make informed decisions about the collection, use, and disclosure of their EHI. In TEFCA Draft 2, QHINs, Participants, and Participant Members would be required to provide Individuals with the opportunity to exercise Meaningful Choice -- to request that their EHI not be Used or Disclosed via the Common Agreement, except as required by Applicable Law. Participants and Participant Members would be responsible for communicating an Individual’s Meaningful Choice to the QHIN who must then communicate the choice to all other QHINs. This choice must be respected on an ongoing basis.

We believe that patients should have a reasonable say in how their EHI is collected, used, and disclosed. However, the potential problem comes with having providers manage the various disclosures and non-disclosures. A system of layer selective access or non-disclosures will be difficult to track and maintain and could present a barrier to provider participation. To minimize the effort of managing and maintaining patient disclosures, patients should be given two options initially either to opt-in or opt-out. Moreover, these two choices are applicable to the highest, broadest data level and not individual types of data. Second, QHINs should be responsible for data consent management and dissemination rather than providers. By channeling consents through QHINs, the



need for individual providers to collect this information would be eliminated thereby reducing redundancies and the chance for discrepancies and variability from patients. Also, given that QHINs will exchange EHI with one another, they are better able to control the information being shared based on patient preferences. Consent management over time could move to an API or other centralized solution as proposed by the ONC as a 2015 Edition certification criterion. But before an API strategy went into effect, it would need to be: (1) tested thoroughly across different types of providers, practice settings, and EHR systems, (2) affordable, and (3) easy to implement and use and not impose any undue burdens.

In closing, RadNet believes strongly in promoting interoperability and, thus, appreciates the opportunity to comment on the ONC's TEFCO Draft 2. We stand prepared to meet and discuss our comments directly with you and your colleagues at the ONC. If you have any questions or need additional information, please contact Michael Mabry, RadNet's Director of Public Policy and Economic Analysis at 443.810.4798 or Michael.Mabry@RadNet.com.

Sincerely,

Susan Hollabaugh

Vice President, Regulatory Analysis and Conformance
RadNet

cc: Ranjan Jayanathan, RadNet
Michael Mabry, RadNet