

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

Comments submitted at: <https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement>

[Intelligent Medical Objects \(IMO\)](#) appreciates the opportunity to comment on this ONC's Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2.

IMO is the leading provider of clinical terminology content and services to support clinical workflow in hospitals and medical offices. Currently, IMO is installed in over 85% of EHRs nationwide and has over 550,000 primary clinician users, however, there are countless downstream users and beneficiaries that leverage our IMO terminology solutions.

IMO enables and supports the accurate capture and preservation of clinical intent for clinical documentation, decision support, reimbursement, reporting, data analysis, research, and health education. We actively participate in the advancement and adoption of healthcare standards supporting health information integrity and semantic interoperability.

We have eased the terminology implementation challenges in the majority of EHR installs across the country helping to facilitate the growth trajectory of EHR implementations that have occurred since the start of the Meaningful Use and EHR Incentive Programs.

Comments

Recognized Coordinating Entity

TEFCA Text

Through a Cooperative Agreement, ONC is seeking eligible applicants to become the RCE and receive funding from ONC to 1) Develop a Common Agreement that includes the MRTCs and ARTCs, for ONC approval and publication to HealthIT.gov and in the Federal Register; 2) Virtually convene public listening sessions that will allow industry stakeholders to provide objective and transparent feedback to the RCE; 3) Identify and monitor QHINs that voluntarily agree to sign and adopt the Common Agreement; 4) Implement an ONC-approved process to adjudicate QHIN noncompliance with the Common Agreement, up to and including removal from ONC's public directory on HealthIT.gov; 5) Implement a process to update the Common Agreement, as needed, for ONC final approval and publication to HealthIT.gov and in the Federal Register; 6) Modify and update the QHIN Technical Framework Draft 1, for ONC approval, to detail proposed technical components for exchange among QHINs as required by the latest version of the MRTCs; and 7) Propose strategies that an RCE could employ to sustain the Common Agreement at a national level after the expiration of the term of the Cooperative Agreement.

IMO Comments

- IMO agrees with ONC that an experienced private sector RCE should implement and monitor compliance with the Common Agreement.
- We recommend ONC release a more detailed roadmap and implementation plan to help stakeholders better understand how the TEFCA and USCDI are meant to be operationalized.
- We believe the TEFCA Cooperative Agreement should stipulate that the RCE have a governance structure that includes a broad array of stakeholders, including representatives from the informatics

community, standards developers, clinical terminologists, health IT professionals, clinicians, public health, payers, HIEs, and individual/patient advocates.

Participants, Participant Members, and Individual Users

TEFCA Text

The TEF and the Common Agreement seek to serve many different stakeholders across the country who have unique needs and constituencies. As such, the TEF, MRTCs, and QTF do not dictate the internal requirements or business structures of QHINs, but rather provide QHINs flexibility to provide different services and support different stakeholders.

IMO Comments

- IMO concurs with ONC that the TEFCA should not dictate internal requirements or structures of QHINs or their components.
- We appreciate how similar organizations and entities (e.g. health systems) may be designated as different stakeholder types, depending on their relationship to the QHIN. We anticipate that confusion will remain high among some stakeholder groups, and we encourage ONC to develop additional examples and educational materials to provide guidance.
- We caution ONC to be very mindful the Congressional intent that the TEFCA avoid disruption and duplication of “existing exchanges between participants of health information networks.”

Exchange Modalities

TEFCA Text

ONC received a number of requests from commenters to include a “push-based” exchange modality in the TEF and the Common Agreement. Commenters noted that push transactions play a vital role in supporting transitions of care and public health use cases and would be necessary to fully support required Public Health reporting. Therefore, ONC has included QHIN Message Delivery, which supports instances where a QHIN sends EHI to one or more QHINs for delivery. We request comment on the inclusion of QHIN Message Delivery and its definition.

IMO Comments

- IMO supports the initial exchange modality set.
- IMO specifically supports the inclusion of QHIN Message Delivery (push modality) in the TEFCA. This modality is a key part of interoperability, and especially important for the public health community, and will likely be important to the TEFCA’s success.
- IMO recommends that the HL7 FHIR Standards identified for “push messaging” in the future include “FHIR Messaging” (bundle and message header), if messages are to be routed through the QHIN.
- We emphasize to ONC that HL7 has developed security labeling syntax for its main product families, HL7 Version 2, CDA, and FHIR, using the same security label vocabulary established by the HL7 Privacy and Security Healthcare Classification System (HCS).

Exchange Purposes

TEFCA Text

Draft 2 requires exchange for only a subset of activities in Payment (Utilization Review) and Health Care Operations (Quality Assessment and Improvement, and Business Planning and Development) as defined in the HIPAA Privacy Rule. In addition, Individual Access as defined in Draft 1 has been modified to Individual Access Services, which includes the HIPAA Privacy Rule right for an individual to view or obtain a copy of his or her

Protected Health Information from Covered Entities. The Individual Access Services Exchange Purpose also now includes a corresponding requirement for non-HIPAA entities that elect to participate in the Common Agreement.

IMO Comments

- IMO supports the effort to make supported Exchange Purposes transparent, we seek clarification on how the discussion accompanying this principle aligns with prohibition against information blocking in the recent ONC NPRM as well as with Minimum Required Terms and Conditions (MRTC) requirements for QHINs to support all Exchange Purposes and for Participants, and Participant Members to respond to queries for all MRTC-designated Exchange Purposes with EHI that they have available, subject to certain conditions (e.g., compliance with law and “minimum necessary”).

Phased Approach

TEFCA Text

Agreement to support additional use cases. ONC intends to work with the National Institute of Standards and Technology (NIST) and the industry on pilots focusing on use cases of the TEF and the Common Agreement.

IMO Comments

- IMO supports the phased approach, but we request that ONC work with the RCE to publish an implementation roadmap to help all stakeholders prepare for each phase.

Phased Approach

TEFCA Text

The MRTCs Draft 2 requires that QHINs, Participants, and Participant Members 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 are responsible for communicating this Meaningful Choice up to the QHIN who must then communicate the choice to all other QHINs. This choice must be respected on a prospective basis. Additionally, all QHINs, Participants, and Participant Members who provide Individual Access Services must publish and make publicly available a written notice describing their privacy practices regarding the access, exchange, Use, and Disclosure of EHI. This notice should mirror ONC’s Model Privacy Notice and include an explanation of how an Individual can exercise their Meaningful Choice and who they may contact for more information about the entity’s privacy practices.

IMO Comments

- IMO supports the concept of “Meaningful Choice.” However, this is a complex new concept that will require considerable effort from both the public and private sectors to implement effectively.
- Unfortunately, the industry is not yet ready to support individuals’ “Meaningful Choices” electronically with consistency and accuracy. This is true at every level of the TEF, from Participant Members to QHINs, and the millions of patients with whom they will interact. ONC acknowledges this on page 84 of Draft 2 noting, “...the healthcare industry has not established a common approach for electronically managing patient privacy preferences.”
- IMO encourages the ONC to engage with HL7 Privacy and Security standards experts and AMIA policy experts going forward to develop a harmonized nationwide standards-based approach.

EHI Used or Disclosed Outside the United States

TEFCA Text

ONC seeks public comment on how the Common Agreement should handle potential requirements for EHI that may be used or disclosed outside the United States. For example, there are federal agencies and other multinational entities that have employees receiving care outside the United States, and their health care providers may want to request the patients' health care records that are located within the United States. Currently, the MRTCs Draft 2 does not permit QHINs to Use or Disclose EHI outside the United States, except to the extent that an Individual User requests his or her EHI to be Used or Disclosed outside of the United States. **ONC requests comment on reasonable applicability of similar limitations to preserve the security and privacy of EHI sent, stored, maintained, or used by Participants and Participant Members while also preserving the rights of each individual with respect to that EHI.**

IMO Comments

- IMO believes that the Common Agreement should abide by a general principle of patient-centeredness. If an Individual User requests his or her EHI to be shared, it should be shared with providers regardless of whether a provider is within or outside the United States. It may be important to negotiate such use and disclosure with neighboring countries, but this is likely outside ONC's immediate purview
- Healthcare is now more globally provided due to international employment situations, healthcare tourism and other scenarios, IMO encourages ONC to undertake a forward-thinking approach to TEFCA policies in this area. Short-term, IMO suggests that ONC develop guidance for responding to "Break the Glass" scenarios where cross-border information flows are imperative for patient health and safety, particularly in cases of international health crises like Ebola, or a patient's incapacitation or unconsciousness.

Privacy, Security, and Safety: Exchange EHI securely and in a manner that promotes patient safety, ensures data integrity, and adheres to privacy policies.

TEFCA Text

In addition to the importance of the integrity of demographic data, overall EHI integrity is a key component of promoting patient safety in electronic exchange. Where possible, standard nomenclatures should be used and exchanged in a data format that is consumable by a receiving system, such as a C-CDA or via FHIR APIs. Further, clinicians should update individuals' EHI in their EHR to ensure that medications, allergies, and problems are up to date prior to exchanging such data with another organization. To the extent possible, HINs should utilize testing and onboarding processes for their participants that seek to establish a high level of data quality.

IMO Comments

- We encourage ONC to consider emphasizing the importance of vocabulary normalization across all exchanges and to encourage the capturing and sending of the term selected by clinicians in their EHRs **along with the standard nomenclatures** to aid in the accuracy and avoid loss of clinical data.
- Both FHIR and CDA provide fields for communicating local and/or proprietary terminologies that capture the terms clinicians select in their EHRs which are often more granular than the available codes found in the standard terminologies.
- In FHIR, `codableConcept` allows for identification of a user selected term (<https://www.hl7.org/fhir/datatypes.html#CodeableConcept>): "...A typical use of `CodeableConcept` is to send the local code that the standard code system concept was coded with, and also one or more translations to publicly defined code systems such as LOINC or SNOMED CT. **Sending local codes is useful and important for the purposes of debugging and integrity auditing (and normalization).**"
- In CDA this can be captured in `OriginalText` and in `Translation`.