Pharmacy Health Information Technology Collaborative

Via Electronic Submission to: https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement

June 17, 2019

Donald Rucker, MD
National Coordinator
Office of the National Coordinator
for Health Information Technology
330 C Street, SW, Room 7033A
Washington, DC 20201

Re: Draft 2 – Trusted Exchange Framework and Common Agreement

Dear Dr. Rucker:

On behalf of the membership of the Pharmacy Health Information Technology Collaborative (Collaborative), we appreciate the opportunity to submit comments on the *Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2.*

Pharmacists provide essential pharmacy and health-related services to patients. Additionally, pharmacists are users of health IT, and in particular, e-prescription and EHR systems. The Collaborative supports the use of these systems, which are important to pharmacists in working with other health care providers to provide needed medications and transmit patient information related to overall patient care, transitions of care, immunization (historical and administered), immunization registry reporting, medication lists, medication allergies, allergy reactions, patient problem lists, smoking status, reporting to public health agencies, clinical decision support services/knowledge artifacts, drug formulary checking, and electronic prescribing.

The Collaborative has been involved with the federal agencies, including the Office of the National Coordinator (ONC) and the Centers for Medicaid and Medicare Services (CMS), in developing the national health information technology (HIT) framework and standards since 2010.

The following are our comments regarding the *Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2*.

Three High-Level TEFCA Goals

The Collaborative supports the three high-level goals of TEFCA developed by the ONC: provide a single on-ramp to nationwide connectivity; enable electronic health information (EHI) to securely follow the patient when and where it is needed; and support nationwide scalability. The Collaborative also supports the six TEF principles established to facilitate trust between HINs for exchanging electronic health information.

Meaningful Choice and Written Privacy Summary

The Collaborative supports the Minimum Required Terms and Conditions (MRTCs) Draft 2 requiring Qualified Health Information Networks (QHINs), participants, and participant members 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 laws, as well as being required to publish and make publicly available a written notice describing their privacy practices regarding the access, exchange, use, and disclosure of EHI.

Breach Notification Requirements

The Collaborative supports MRTCs Draft 2 requiring QHINs, et al, to comply with the breach notification requirements of the HIPAA Breach Notification Rule at 45 CFR §164.400-414, regardless of whether they are a covered entity or business associate. Notifications are to be sent to individuals no later than 60 days after discovery of a security breach and posted on the home page of the entity involved for 90 days. We have a question about reporting and enforcement requirements of this section, and ask ONC for clarification. HIPAA requires breaches to be reported to the Secretary of Health and Human Services. As this proposal requires a QHIN to report a breach to the Recognized Coordinating Entity (REC), who would then be required to report the breach to the secretary? The REC? The QHIN? Or both?

Minimum Security Requirements

The Collaborative supports MRTCs Draft 2 requirements for QHINs to comply with HIPAA Privacy and Security Rules pertaining to EHI; evaluate their security programs for the protection of controlled unclassified information (CUI); develop an action plan to comply with the security requirements of the most recently published version of NIST Special Publication 800-171 (Protecting Controlled Unclassified Information in Non-federal Information Systems and Organizations); review the most recent version of the HIPAA Security Rule Crosswalk to the NIST Cybersecurity Network; implement appropriate security measures consistent with industry standards and best practices; and evaluate their security programs on at least an annual basis. As noted in the previous section, does ONC have a plan to review and monitor compliance of QHINs with regard to security requirements, since participation in TEFCA is voluntary? Will there be an enforcement mechanism?

No EHI Used or Disclosed Outside the United States (Request for Comment)

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, although MRTCs Draft 2 currently does not permit QHINs to use or disclose EHI outside the United States. The Collaborative notes that ONC appears to be focusing this possibility solely on federal agencies or other multinational entities that have employees receiving care outside the U.S. (the presumption being they are living outside of the U.S.) and EHI leaving the U.S. if requested by the employee. An aspect that appears to be missing from consideration is that EHI exchange would need to be bidirectional across borders. That is, an employee may also need to have health records from outside the U.S. where care is received sent to the employee's health care provider in the U.S. Concerning the latter, the European Union and other countries' laws and regulations would govern that and may impact the bidirectional exchange of EHI. Though it's not specifically mentioned, the example presented by ONC would also appear to be applicable to foreign agencies and foreign multinational entities that have employees receiving care in the U.S., which also needs to be considered. The Collaborative suggests that ONC look at this more broadly, as it will apply to other individuals. This may involve more than just an individual requesting and authorizing an EHI exchange outside the country.

Before moving forward and possibly changing the MRTCs to allow this EHI exchange, the Collaborative recommends that ONC survey and review the data protection laws and regulations of other countries, particularly the EU General Data Protection Regulation.[1] Additionally, to accomplish an exchange of electronic health records (EHR) with Europe and other countries, the exchange format used by a QHIN would need to be compatible with EU exchange formats, as well as ensuring the secure exchange of EHI across borders. The European Commission has adopted a Recommendation on European Health Record exchange format for secure access to health data across EU borders.[2]

Lastly, if the current MRTCs Draft 2 does not permit QHINs to use or disclose EHI outside the U.S., would this be in conflict with 7.3 Individual Exercise of Meaningful Use of Draft 2, if allowed by applicable law?

Security Labeling

The Collaborative supports the new proposed requirements regarding security labeling as follows: Any EHI containing codes from one of the SAMHSA Consent2Share sensitivity values in Value Set Authority Center (VSAC) shall be electronically labeled; any EHI patients considered to be minors shall be electronically labeled; the data holder responding to a request for EHI is obligated to appropriately apply security labels to the EHI; at a minimum, such EHI shall be electronically labeled using the confidentiality sets as referenced in the HL7 Version 3 Implementation Guide: Data Segmentation for Privacy (DS4P) Release 1 (DS4PG), Part 1: CDA

[1] EU General Data Protection Regulations, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32016R0679

[2] "Exchange of Electronic Health Records across the EU," Digital Market, https://ec.europa.eu/digital-single-market/en/exchange-electronic-health-records-across-eu

R2 and Privacy Metadata; and labeling shall occur at the highest (document or security header) level. It is understood that the DS4P Implementation Guide has yet to reach wide adoption.

Principles for Trusted Exchange

The Collaborative supports the six principles for trusted exchange and requiring HINs to adhere to them.

Minimum Required Terms & Conditions

In general, the Collaborative is supportive of the proposed minimum required terms and conditions for QHINs. Specifically, the Collaborative supports 2.2.5 Mandatory Updating of Technical Capacity with a new version of USCI if it is approved by the national coordinator.

Transparency

4.1.2 Fee Schedule

QHINs will be required to file its schedule of fees with the RCE within 30 days after signing the Common Agreement. Does this mean the RCE approves the fees? Is there a mechanism in place to review fees to ensure they would not become part of information blocking? The proposal is not clear in this regard. We ask ONC for additional clarification.

Cooperation and Non-Discrimination

The Collaborative supports the cooperation and non-discrimination requirements.

Privacy, Security, and Patient Safety

The Collaborative supports the privacy, security, and patient safety requirements.

Participant Minimum Obligations

The Collaborative is supportive of the participant minimum obligations.

As mentioned previously in No EHI Used or Disclosed Outside the United States, it's unclear whether the MRTCs Draft 2 not permitting this would be in conflict with 7.3 Individual Exercise of Meaningful Choice if and EHI exchange is requested by the individual.

8.5 Non-Discrimination – A participant member shall not unfairly or unreasonably limit exchange or interoperability with any QHIN, participant, other participant member, or individual user…or by other means that limit the ability of a participant member to send or receive EHI with a QHIN, et al. The phrase "unfairly or unreasonably limit" is broad. Anyone

can create their own definition or parameters for what constitutes "unfairly or unreasonably limit," which could lead to information blocking. Further guidance in this area is needed.

Qualified Health Information Network (QHIN) Technical Framework

Query and Message Delivery

The Collaborative supports the use of IHE XCA, IHE XCPD, IHE XDR, as well as the listed alternative standard, HL7 FHIR RESTful API, for queries and message delivery.

Patient Identity Resolution

ONC Request for Comment #7: The IHE XCPD profile only requires a minimal set of demographic information (e.g., name and birth date/time). Should QHINs use a broader set of specified patient demographic elements to resolve patient identity? What elements should comprise such a set?

The Collaborative suggests a broader set be used. The Collaborative believes patient identifiers should not be restrictive but more inclusive to ensure the patient is securely matched with the correct patient record Additional elements such as a patient's address and telephone number, identifiers based on commercial solutions (e.g., NCPDP's Universal Patient Identifier vendor-neutral solution), or any patient identifier a QHIN deems appropriate should be part of the set.

Directory Services

ONC Request for Comment #11: Should the QTF require QHINs to implement Directory Services? Should the QTF specify a single standardized approach? If QHINs implement Directory Services, which entities should be included in directories? Should directories be made publicly available?

The Collaborative believes QHINs should implement health care provider directory services. Such directories should include relevant public information about health care providers and organizations (e.g., name, workplace, location, type of practice, years in practice, ratings, etc.).

Error Handling

ONC Request for Comment #15: Should the QTF specify a consistent set of error messages for interactions between QHINs? Which error messages should the QTF specify? Should the QTF specify consistent format for error messages?

The Collaborative believes the Qualified Technical Framework (QTF) should specify a consistent set of error messages and generate error messages when activities and

transactions fail. The messages should clearly communicate the cause of the error and provide details to resolve the issue, particularly to first-degree entities (e.g., participants and individual users). Error messages should be presented in a consistent format. The Collaborative also suggests that ONC consider including error handling in audit records.

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The Pharmacy HIT Collaborative comprises the major national pharmacy associations, representing 250,000 members, including those in pharmacy education and accreditation. The Collaborative's membership is composed of the key national pharmacy associations involved in health information technology (HIT), the National Council of Prescription Drug Programs, and nine associate members encompassing e-prescribing, health information networks, transaction processing networks, pharmacy companies, system vendors, pharmaceutical manufacturers, and other organizations that support pharmacists' services.

As the leading authority in pharmacy health information technology, the Pharmacy HIT Collaborative's vision and mission are to ensure the U.S. health IT infrastructure better enables pharmacists to optimize person-center care. Supporting and advancing the use, usability, and interoperability of health IT by pharmacists for person-centered care, the Collaborative identifies and voices the health IT needs of pharmacists; promotes awareness of functionality and pharmacists' use of health IT; provides resources, guidance, and support for the adoption and implementation of standards driven health IT; and guides health IT standards development to address pharmacists' needs. For additional information, visit www.pharmacyhit.org.

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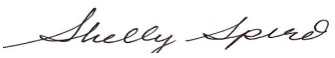
On behalf of the Pharmacy HIT Collaborative, thank you again for the opportunity to comment on the *Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2*.

For more information, contact Shelly Spiro, executive director, Pharmacy HIT Collaborative, at shelly@pharmacyhit.org.

Respectfully submitted,



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