June 17, 2019

Don Rucker, M.D., National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology (ONC)
U.S. Department of Health and Human Services
330 C Street SW
Floor 7
Washington, DC 20201

Submitted via the HealthIT.gov Web Portal, https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement

RE: Trusted Exchange Framework and Common Agreement Draft 2

Dear Dr. Rucker:

I am writing on behalf of the Workgroup for Electronic Data Interchange (WEDI), the nation's leading nonprofit authority on the use of health IT to create efficiencies in health care information exchange. We want to commend you for the work the Office of the National Coordinator for Health Information Technology (ONC) has undertaken to advance the interoperability of electronic health information. The 21st Century Cures Act pushed the for interoperability to the forefront of the industry and the Trusted Exchange Framer and Common Agreement (TEFCA) is a step towards achieving this goal.

As ONC further develops their approach to advancing interoperability, we encourage the collaboration with the Centers for Medicare & Medicaid Services (CMS), as well as industry stakeholders such as WEDI. As an advisor to the Secretary of the Department of Health and Human Services (HHS) and a multi-stakeholder organization comprised of health plans, providers, vendors and SDOs, WEDI offers the structure for intra-industry collaboration. WEDI has proven leadership engaging the industry to address the most impactful changes of our time, including the National Provider Identifier, ICD-10, health claim attachments and prior authorization.

WEDI supports establishing a framework for the trusted exchange of electronic health information. The Trusted Exchange Framework and Common Agreement is another phase of ONC's efforts to advance interoperability across the United States (U.S.) health care system in support of the access, exchange and use of electronic health information. This letter focuses our comments on those provisions specifically of interest to WEDI's membership.

The comments contained herein have been reviewed and approved by the Executive Committee of the WEDI Board on June 17, 2019. On behalf of the WEDI Board of Directors, I am sending them to you for review and consideration. WEDI appreciates the opportunity to collaborate with ONC and stands ready to assist in clarifying the attached as needed. Charles Stellar, President and CEO of WEDI, or I would be pleased to answer any questions pertaining to WEDI's recommendations, which are enclosed herein.

Sincerely,

/s/

Jay Eisenstock
Chair, WEDI

cc: WEDI Board of Directors

About WEDI

WEDI was formed in 1991 by then-Secretary of HHS Dr. Louis Sullivan. Named in the bipartisan Kassebaum-Kennedy HIPAA legislation as an advisor to the HHS Secretary, we have worked closely with every Administration. WEDI is a multi-stakeholder organization, whose membership includes ambulatory providers, hospitals, health systems, health plans, health information technology standards organizations, health care information technology vendors and government entities. We continue our role of working with both the public and private sectors to reduce health care administrative costs and facilitating improvements in information exchange through voluntary collaboration.

WEDI has been an instrumental force in establishing and later enhancing HIPAA standards for electronic administrative transactions, data privacy and data security; driving down the costs associated with manual, paper-based transactions and increasing the confidentiality of patient information. Our robust workgroups, white papers and other industry guidance, informative conferences, surveys and online webinars provide critical industry education and foster collaborative partnerships among diverse organizations to solve practical, real-world data exchange challenges.

We have also worked closely with both the Centers for Medicare & Medicaid Services and the Office for Civil Rights on industry outreach and education.

Workgroup for Electronic Data Interchange (WEDI)

WEDI Comments on the
Trusted Exchange Framework and Common Agreement Draft 2

As approved by the
Executive Committee of the WEDI Board on June XX, 2019

This document contains comments developed by WEDI in response to the recent Trusted Exchange Framework and Common Agreement Draft 2.

General Comments

Comment Solicitation Process:

> **WEDI Comment: WEDI supports** the intent of the Trusted Exchange Framework and Common Agreement (TEFCA), however we encourage ONC to ensure adequate industry notification of comment opportunities related to TEFCA. Formal regulatory comment periods are announced through the Federal Register and we suggest a similar approach to ensure that all materially affected parties are aware of the opportunity to comment.

Implementation Impacts:

> **WEDI Comment: WEDI encourages** ONC to ensure there is adequate time for the health care industry to modify contracts and business associate agreements as well as notices of privacy practices. Ensuring the industry has the ability to implement all of these pieces, as well as any new agreements and documents needed, is critical to the overall goals of interoperability.

Comments on the Introduction to the TEFCA

P. 12 Qualified Health Information Networks (QHIN): QHIN Designation Process:
In order to apply for QHIN Designation, Health Information Networks (HINs) must meet certain prerequisites, including already operating a network that provides the ability to electronically locate and transmit electronic health information (EHI) between multiple persons or entities. The Responsible Coordinating Entity (RCE) receives and processes QHIN applications. HINs, if approved, are first granted provisional status and are granted the QHIN Designation upon confirmation they have satisfied the requirements of the Common Agreement. The RCE will also be responsible for monitoring QHINs on an ongoing basis and adjudicating noncompliance with the Common Agreement up to and including removal of the QHIN from ONC's public directory on HealthIT.gov, when necessary.

WEDI Comment: WEDI supports the general process as outlined in the TEFCA Draft 2. The RCE, as a separate entity, will create the right balance and allows the separation of the agency as the policy maker from the entity that will oversee and enforce the polices. We request ONC provide further clarity around the timeframes of this process to ensure it runs as smoothly, efficiently and as quickly as possible.

WEDI encourages ONC to provide clarity on the capabilities of QHINs while designated as a Provisional QHIN vs. capabilities once designated as a (full) QHIN. Understanding what transactions Provisional QHINS are allowed to conduct within the Trusted Exchange Framework (TEF) is critical to moving forward under TEFCA.

WEDI also encourages ONC to provide clarity on the intent of creating cohorts of Provisional QHINs along with the expectations of entities within the cohort completing the activities to become full QHINs in the same or similar timeframe. It is unclear whether Appendix 2.1.5 is intended to address the potential for one or more Provisional QHINs to require significantly more time to achieve full QHIN status that others within the cohort, i.e. what dependency there is, if any, upon all the Provisional QHINs within a cohort achieving full QHIN status as part of any of the Provisional QHINs completing the process to achieve full QHIN status.

PP. 13-14 Exchange Modalities: Draft 2 proposes to require QHINs support three types of exchange modalities: Targeted Query, Broadcast Query and Message Delivery. Draft 2 removed the Population-Level Health Data Exchange modality and added the Message Delivery modality. This draft allows QHINs to use these exchange modalities for different situations, i.e. allows for flexibility so that QHIN Participants can support broad interoperability for multiple use cases.

WEDI Comment: WEDI supports the proposed exchange modalities; however, these do not include all of the payment use cases allowable under HIPAA. It is possible that such a restriction might be construed as information blocking, which potentially puts stakeholders at risk, dependent upon the content of a final rule on information blocking. We encourage ONC to allow all HIPAA data uses under TEFCA. QHINs, Participants and Participant Members that are also HIPAA covered entities must continue to be able to meet their obligations under HIPAA for health care treatment, payment and operations.

The QHIN Message Delivery modality is a valuable use case, however it will require correct patient matching and implementation of (electronic) provider directories in order to be successful. WEDI membership has key constituents with provider information expertise that can be leveraged and we are well positioned to gather industry feedback and provide education on requirements and best practices for provider directories to meet the industry's needs.

WEDI supports allowing QHINs the flexibility to meet the needs of the Participants within their community, however it appears this would require separate agreements. This would create additional burden and complexity rather than simplifying processes and agreements between entities within the QHIN community.

P. 17 Meaningful Choice and Written Privacy Summary: The draft requires that QHINs, Participants and Participant Members provide individuals the opportunity to exercise Meaningful Choice to request that their EHI not be used or disclosed by the Common Agreement, except as required by any applicable law.

> **WEDI Comment: WEDI encourages** ONC to clarify that Meaningful Choice does not compromise or otherwise overrule other federal or state laws or regulations, e.g. HIPAA, Public Health syndromic surveillance. Meaningful Choice is important for individuals, but the requirements to send notification that an individual has chosen not to participate in exchange still exposes that individuals demographic data across the exchange. The individual's choice to not participate should only be shared if the QHIN is queried.

PP. 19-20 Security Labeling: Draft 2 limits the proposed requirement for security labeling of four of the most commonly requested sensitive data categories.

> **WEDI Comment: WEDI has not determined** whether to support the concept of "privacy tagging" as it is unclear how using a variety of tagging functions will benefit interoperability and make patient information available at the point of service/care. Additionally the standards for privacy tagging are not currently mature enough to implement in the near-term. For example, tagging information could be suppressed or removed within an EHR, thereby resulting in incomplete information. WEDI encourages further exploration of use test cases and operational implementation issues related to this important topic, as well as coordination with other industry initiatives, such as Substance Abuse and Mental Health Services Administration's (SAMHSA) Consent2Share project.
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> We offer our assistance in convening industry stakeholders to further explore best practices for privacy tagging. Any requirement of QHINs to administer security labeling must be done in concert with final provisions of ONC's Health IT Certification Program.

Comment on Appendix 2: Minimum Required Terms & Conditions (MRTCs)

P. 34 Definitions: Health Information Network (HIN): Draft 2 defines an HIN as
"an individual or an entity that satisfies one or both of the following-
1) Determines, oversees, administers, controls, or substantially influences policies or agreements that define business, operational, technical, or other conditions or requirements for enabling or facilitating access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities; or
2) Provides, manages, controls, or substantially influences any technology or service that enables or facilitates the access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities."

> **WEDI Comment: WEDI encourages** ONC to align the definition of HIN from the ONC proposed rule, and the final rule once promulgated, to TEFCA. The definition of a HIN in this version of TEFCA is inconsistent with the definition of a HIN in the recent ONC interoperability proposed rule. ONC should adopt a common definition that originates from their own TEFCA language. WEDI believes

the definition of HIN should be narrowed to include only entities that are an actual network (or formalized component of an actual network) and have an actual operational role and responsibility for the network. For example, to be a HIN, the network itself provides the ability to locate and transmit EHI between multiple persons and/or entities electronically, on demand, or pursuant to one or more automated processes. Moreover, to be a HIN, the entity should also be exchanging EHI in a live clinical environment using the network in some capacity. Thus, health care providers and organizations with limited exchange capabilities, such as interfaces for Admission, Discharge, and Transfer messages or lab results, should not be considered a HIN.

HINs typically operate as Business Associates and currently have Business Associate agreements in place with their participants who are Covered Entities. These agreements facilitate the exchange of EHI since they perform functions or activities on behalf of or provide certain services for Covered Entities, such as determining and administering policies or agreements that define business, operational, technical, or other conditions or requirements for enabling or facilitating access, exchange, or use of health information between or among two or more Covered Entities. Therefore, for example, organizations that develop voluntary standards and policies that may be used by a HIN should not be considered a HIN.

Comments on Appendix 3: Qualified Health Information Network (QHIN) Technical Framework

P. 76 Functions and Technology to Support Exchange: Draft 2 outlines the functions, specifies standards and implementation approaches, as applicable, for the QHIN Technical Framework, which must be supported by QHINs.

WEDI Comment: WEDI encourages ONC to establish use cases, based on the desired outcome, by which the Common Agreement will measure semantic interoperability as part of QHIN requirements. Limiting the base technical standards without greater industry input, even potentially through the establishment of a technical review panel, may enable a set of standards that are not the most appropriate for the trusted exchange framework. A technical review panel would be able to propose standards for public comment adjudicate public comments and work with the applicable standards organization(s) to address any issues identified. This activity should be predatory to their required use under the Common Agreement.

P. 80 ONC Request for Comment #3: Should QHINs be required to transmit other authorization information (e.g., user roles, security labels) in addition to Exchange Purpose and any information required by IHE XUA? What specific elements should a SAML assertion include?

WEDI Comment: WEDI encourages ONC to seek feedback from QHINs and the industry for best practices and approaches to what additional authorization information is transmitted. WEDI membership has key constituents with technical expertise that can be leveraged and we are well positioned to gather industry feedback and provide education on requirements and best practices for data sharing to meet the industry's needs.

P. 82 ONC Request for Comment #6: The IHE XCA profile is content-agnostic; it enables queries for documents based on metadata about the document but not the contents of the document itself. Therefore, the XCA profile does not necessarily support more granular queries for discrete data (e.g., a request for all clinical documents about a patient that contain a specific medication or laboratory result). 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.

> **WEDI Comment: WEDI supports** the use of emerging standards and encourages testing and use of such standards as an alternative, not a requirement. Establishing use cases by which the RCE can seek public comment on applicable and appropriate standards is key to successful implementation and forward movement towards interoperability. WEDI membership has key constituents with technical expertise that can be leveraged and we are well positioned to gather industry feedback on applicable standards.

P. 85 ONC Request for Comment #7: The IHE XCPD profile only requires a minimal set of demographic information (i.e., 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?

> **WEDI Comment: WEDI acknowledges** the adoption of the USCDI as a critical step in establishing interoperability across the U.S. health care system. WEDI believes the success of this model can provide a blueprint for how USCDI can be implemented. By naming the USCDI v.1.0 as a baseline standard that defines the minimum data set that must be captured, tracked and exchanged through specified methodologies, ONC has established a defined and achievable goal for the industry.
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> WEDI supports developing a mechanism to regularly review and update the rules governing the use of the USDCI, any subsequent versions and uses, including subsets of USCDI. This is similar to the maintenance and modifications processes of transactions and code sets under HIPAA. While it is always important to plan for implementation, including appropriate timeframes, it is especially important when preparing to implement new standards and process, to ensure all stakeholders have adequate time to prepare.
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> WEDI has extensive experience providing outreach and education of the HIPAA transactions

P. 85 ONC Request for Comment #8: There are many possible approaches to Patient Identity Resolution, each with its own benefits and risks. For example, a centralized index of patient identity information may be more efficient for resolving patient identities across disparate communities, but also poses a greater risk to privacy if the system is compromised. Federated approaches may be less susceptible to external threats like cyberattacks, but harder to scale across many communities. Recognizing that new technologies and business entities with robust identity matching solutions may disrupt traditional approaches, should the QTF specify a single standardized approach to Patient Identity Resolution across QHINs?

WEDI Comment: WEDI supports pursuing an industry-wide solution or solutions to the issue of patient matching as a critical component of interoperability. Accurately identifying patients and their data to designated record sets is a critical challenge the industry continues to face. Finding solutions that allow identifying patients correctly is essential for health care providers, health plans and others exchanging data for both clinical and administrative purposes. Most importantly, patient care is improved and patient safety enhanced when health information is accurately transmitted between health care entities, especially in emergencies. While numerous patient matching and identity management initiatives have been undertaken (e.g., ONC, National Institute of Standards and Technology, College of Healthcare Information Management Executives, etc.), there currently is no common patient matching strategy that has been adopted by the health care industry. Governmental and commercial market collaboration can foster the adoption of such technology solutions and allow them to improve and adapt as technology advances and new techniques are identified. If these solutions are to be effective, they must be easily implementable and broadly adopted by the industry.

WEDI encourages ONC to pilot test any patient matching methodology prior to requiring that methodology in the national trusted exchange framework. We offer our assistance in convening industry stakeholders to explore patient matching methodologies.

PP. 86-87 ONC Request for Comment #12: Future drafts of the QTF will specify a format for Meaningful Choice notices communicated between QHINs. Which standard/format should the QTF specify? What information should be included in a Meaningful Choice notice (e.g., should a notice include patient demographic information to enable QHINs to resolve the identity of the Individual that exercised Meaningful Choice)?

WEDI Comment: WEDI supports the intent of TEFCA and understands that one of the key components of the TEFCA processes is based on "meaningful choice" of consumers. Currently, different interpretations exist related to whether the interoperability mechanisms require an "opt-out," how security labeling and proofing will be implemented by various entities, and the ultimate effects for consumers. As the "information superhighway" is launched, ONC and all involved entities must take care to ensure that no consumer experiences an unintended consequence or misunderstanding related to data use. As the most sensitive information begins to flow between and among entities, as metadata requirements are being adopted, and as security protocols continue to evolve, ONC should begin with "pilot tests" in a few select areas or markets so that test cases and experiences can begin that will help inform "lessons learned" and ways for improving data exchange for the future.

P. 87 ONC Request for Comment #13: In addition to enabling Meaningful Choice, the Common Agreement requires QHINs to collect other information about an Individual's privacy preferences such as consent, approval, or other documentation when required by Applicable Law. Should the QTF specify a function to support the exchange of such information through the QHIN Exchange Network? Which standards and/or approaches should the QTF specify for this function?

WEDI Comment: WEDI encourages ONC to clarify that Meaningful Choice does not compromise or otherwise overrule other federal or state laws or regulations, e.g. HIPAA, Public Health syndromic surveillance. Meaningful Choice is important for individuals, but the requirements to send notification that an individual has chosen not to participate in exchange still exposes that individuals demographic data across the exchange. The individual's choice to not participate should only be shared if the QHIN is queried.

P. 88 ONC Request for Comment #15: QHINs may participate in a variety of activities and transactions involving First Degree Entities and/or internal operations, including receiving and processing Query and Message Delivery Solicitations, performing Patient Identity Resolution, performing Record Location, sending EHI, receiving EHI, performing queries, granting/revoking access credentials, etc. Future versions of the QTF may specify a list of events a QHIN must record involving First Degree Entities and/or internal operations. Which activities and transactions should the QTF specify as auditable events? What information should the QHIN record about each event?

WEDI Comment: WEDI supports specifying error message reporting standards but the technical details would be best left for an industry Technical Review Panel to identify and subsequently issue for public comment WEDI membership has stakeholders with the expertise needed to identify and evaluate such standards.