



June 17, 2019

Dr. Donald Rucker
National Coordinator
Office of the National Coordinator for Health Information Technology
330 C Street, SW
Floor 7, Switzer Building
Washington, DC 20024

Dear Dr. Rucker:

Thank you for the opportunity to provide comments on the Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2.

As you know, the American Health Information Management Association (AHIMA) is the national non-profit association of health information management (HIM) professionals. Serving 52 affiliated component state associations including the District of Columbia and Puerto Rico, AHIMA represents over 103,000 health information management professionals with the mission of empowering people to impact health. AHIMA's credentialed and certified HIM members can be found in more than 40 different employer settings in 120 different job functions—consistently ensuring that health information is accurate, timely, complete, and available to patients and clinicians.

Our comments and recommendations on certain sections of the Trusted Exchange Framework (TEF Draft 2) and the Minimum Required Terms and Conditions Draft 2 (MRTCs Draft 2) can be found below.

Appendix 1: Trusted Exchange Framework Draft 2

Principle 1 – Standardization

AHIMA supports the Framework's continued call for adherence to applicable standards for electronic health information (EHI) and interoperability that have been adopted by HHS, approved for use by ONC, or identified by ONC in the Interoperability Standards Advisory (ISA). We agree that consistent adherence to standards that are sufficiently mature and piloted will improve usability and access to EHI.

We also agree with ONC's recommendation that HINs should ensure that data exchange within their own network and with other HINs meet minimum quality standards by using testing and onboarding programs to verify minimum quality levels including ONC's Patient Demographic Data Quality (PDDQ) Framework to evaluate the quality of patient demographic data. AHIMA believes improving the quality of data is of paramount importance as we seek to enhance interoperability nationwide. Adverse events in healthcare can often occur as a result of poor data and information. Beyond jeopardizing patient safety, poor data quality also increases healthcare costs and inhibits electronic health information exchange. Requiring HINs to ensure that data exchanged within their own network and beyond meets minimum quality standards will help foster data governance policies and practices that enhance data accuracy and integrity.

Principle 2 – Transparency

AHIMA supports the requirement under Draft 2 of the Framework that a HIN and their Participants should ascribe to certain privacy practices set forth in the Framework including the provision of a written privacy notice in plain language similar to ONC’s Model Privacy Notice. We believe this is critical because some HINs may operate as business associates and are not required to provide a notice of privacy practices under HIPAA. Furthermore, because certain Participants may operate as non-HIPAA entities, they are under no obligation to provide a privacy notice similar to what is required under HIPAA even though the entity accesses, exchanges, uses or discloses ePHI. Such privacy requirements will help enhance transparency to HINs and their Participants’ privacy practices.

Principle 4 – Privacy, Security, and Safety

AHIMA agrees with ONC that HINs should agree upon and consistently share a core set of demographic data each time that EHI is requested. We also agree that Participants of HINs should ensure that the core set of demographic data is consistently captured for all individuals so that it can be exchanged in a standard format and used to match data accurately. Even the most advanced technologies cannot eliminate the risk of human error that often leads to data quality issues. For that reason, AHIMA supports data governance and data quality improvement policies and procedures that are fundamental to improving overall patient matching rates, data integrity and enhancing patient safety including the consistent capture of a core set of demographic data and the use and exchange of standard nomenclatures in a data format that is consumable by a receiving system.

Principle 5 – Access

AHIMA supports the principle in the Framework that unnecessary barriers should not impede the ability of individuals to access and direct their EHI to designated third parties and that individuals should be able to learn how information about them has been accessed, used or disclosed. AHIMA has long advocated that consumer access to their health information is essential to improving health and healthcare. We continue to support efforts that enhance the ability of consumers to access their health information while improving the workflow of health information professionals that are tasked with fulfilling such requests.

Appendix 2: Minimum Required Terms & Conditions (MRTCs)

1. Definitions

AHIMA recognizes that requiring the full Payment and Health Care Operations Exchange Purposes are burdensome to implement immediately. We also appreciate that ONC intends over time to phase in new Exchange Purposes as to allow the industry and potential signatories time to incorporate the necessary standards into their architectures and resolve variation in standards and policies that exist today. Along these lines, we believe sufficient and appropriate pilot testing is a necessary first step prior to the phasing in of additional Exchange Purposes.

3. Data Quality and Minimum Necessary

AHIMA agrees with the requirements of “Section 3.1 Patient Demographic Data for Matching” that each QHIN must send and receive all of the “patient matching data” so labeled and specified in the QHIN Technical Framework (QTF) when and to the extent that all the requirements of Section 3.3 are satisfied.

AHIMA also supports the requirement at Section 3.2 that QHINs must annually evaluate their patient demographic data management practices using the PDDQ Framework. As noted in our [comments](#) to ONC regarding the 21st Century Cures Act proposed rule, we recommend requiring QHINs to submit (in a non-punitive manner) their scores on the five PDDQ process areas to the Recognized Coordinating Entity (RCE) to evaluate data management practices. Such a requirement could establish a benchmark to help measure the breadth and depth of patient matching challenges and whether data quality improvements have been made on a year-to-year basis. Finally, AHIMA believes the 18-month timeline by which a QHIN must conduct a review of its patient demographic data management practices is consistent with other proposed timelines set forth in the MRTCs.

6. Privacy, Security and Patient Safety

AHIMA agrees with the requirement at “Section 6.1.1 Breach Notification Requirements and Security Incidents” that QHINs must comply with HIPAA Rules as if they apply to EHI, including the breach notification requirements applicable to business associates regardless of whether a QHIN is a business associate (and provided the QHIN is not a covered entity). However, for clarity, we recommend that the language in Sections 6.1.1, 7.12 and 8.12 stipulate that notice of the breach should be provided “. . . without unreasonable delay and *in no case later than 60 calendar days after discovery of the breach* in accordance with this Section and Applicable Law.” Inclusion of this technical change will further clarify the timeline by which QHINs must report a breach to the RCE, other QHINs, Participants, Participant Members, and Individual Users with whom the QHIN has a Direct Relationship as well as align with the HIPAA breach notification requirements.

AHIMA is also pleased that “Section 6.1.4 Other Legal Requirements” requires that “to the extent that Applicable Law requires that an Individual either consent to or approve the Use or Disclosure of his or her EHI to the QHIN, then each QHIN that has a Direct Relationship with the Individual shall not Use or Disclose such EHI in connection with the Common Agreement unless the QHIN has obtained the Individual’s consent, approval or other documentation with respect to such Uses or Disclosures consistent with the requirements of Applicable Law.” Operationally, we believe this revision, as well as similar revisions at Section 7.4 and Section 8.4, are more manageable in situations where EHI includes substance use disorder and treatment information covered by 42 CFR Part 2. We remain concerned that some health IT systems are currently unable to segment such sensitive data and that it is often the case that to protect such sensitive information, HIM professionals must create a second electronic record that contains only Part 2 information. Because health information covered by 42 CFR Part 2 must be kept separate unless patient consent is given, providers are often unaware of the risks to their patient from multiple drug interactions and co-existing medical problems, even though substance use disorders can have a cascading effect on an individual’s health and must be carefully managed and coordinated. Requiring QHINs to not Use or Disclose such EHI unless it has obtained an individual’s consent will help ensure such sensitive data is not inadvertently shared. That said, as integrated care delivery models continue to be adopted, we encourage ONC to continue its critical work in enabling meaningful, granular consent in the exchange of EHI including the use of the FHIR Consent Resource to record an individual’s choices in a computationally traceable manner.

AHIMA also supports the requirements “Section 6.2.2 Data Integrity” as well as similar requirements in Sections 7.16 and 8.16 that require the reporting of known instances of inaccurate or incomplete EHI to the Participant (and Participant Member) and that the Participant (and Participant Member) remediate such data integrity issues in a timely manner to the extent reasonably possible. Requiring Participants and Participant Members to safeguard against inaccurate or incomplete EHI will help ensure the access, exchange, use, and disclosure of accurate, timely, and complete data, which is crucial to improving care, enhancing interoperability, and system transformation across the healthcare continuum.

7. Participant Minimum Obligations

AHIMA supports ONC’s intent in Section 7 to require non-HIPAA entities acting as Participants that elect to participate in exchange to be bound by certain provisions that align with the safeguards of the HIPAA Rules. AHIMA is concerned that the existing regulatory landscape lacks sufficient guardrails around non-HIPAA entities to protect the privacy and security of a patient’s electronic health information. Patients may be largely unaware that once they authorize a covered entity and/or business associate to push their health information to a third-party app and such an entity is a non-HIPAA entity, the rights afforded under HIPAA no longer apply. Failure to provide appropriate, transparent privacy and security safeguards could invite opportunities for “bad actors” to enter the market and potentially use such sensitive data for nefarious activities. We are pleased to see that the ONC intends as part of the MRTCs to hold non-HIPAA entities accountable to certain HIPAA safeguards including but not limited to Minimum Necessary requirements, Minimum Security Requirements and Breach Notification requirements. We believe this will not only improve data integrity, confidentiality and security but help foster confidence and trust in the data among Participants and Individual Users.

We also suggest greater clarification is needed in “Section 7.14(ii) Processing of Individual Access Services Request.” The MRTCs states that each Participant that receives an Individual Access Services request with whom it has a Direct Relationship “shall provide such Individual with respect to his or her EHI regardless of whether the Participant is a Covered Entity or Business Associate. . .” However, under HIPAA, if the Participant is a covered entity or the PHI is maintained by a business associate on behalf of a covered entity, an individual has the right to access their PHI in one or more designated record sets maintained by or for the covered entity.¹ Under such circumstances, it is unclear whether HIPAA or Section 7.14 (ii) would prevail. Furthermore, 45 CFR §164.524 excludes two categories of information from the HIPAA right of access: psychotherapy notes and information compiled in reasonable anticipation of or for use in, a civil, criminal or administrative action or proceeding.² Given the broad definition of EHI, it would appear that under Section 7.14 such information would not be excluded, contrary to HIPAA. Therefore, we recommend that Section 7.14(ii) be amended to state:

Each Participant that receives a request for Individual Access Services from an Individual with whom it has a Direct Relationship shall provide such Individual with Individual Access Services with respect to his or her EHI *in accordance with this section and Applicable law. If the Individual wants the EHI to go to a third party, the Individual shall satisfy the conditions at 45 CFR §164.524(c)(3)(ii) as if it applies to EHI.*

We believe this language, taken together with the definitions of “Participant Member Agreement” and “Participant-QHIN Agreement” in Section 1 as well as the requirements in Section 7.18 will clarify any

¹ Available at: <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html>.

² 45 CFR §164.524(a)(1)(i-ii) and 45 CFR §164.501.

confusion as to what information must be provided in response to an Individual Access Services request when a Participant is a covered entity or business associate. We also believe similar clarifications should be provided in Sections 2.2.4(ii) and 8.14(ii) to ensure consistency.

9. Individual Rights and Obligations

AHIMA supports the recommendation in “Section 9.5.1 Right to Request Summary and Applicable Period” that to meet this obligation, covered entities may comply with the requirements of 45 CFR § 164.528. However, as you know, at the end of 2018, the HHS Office for Civil Rights (OCR) issued a Request for Information (RFI) seeking input from the public as to how the HIPAA Rules could be modified, including accounting of disclosures, to further HHS’ goal of promoting coordinated, value-based healthcare. Should OCR proceed to implement section 13405(c) of the HITECH Act and require that an accounting of disclosures include disclosures made for TPO purposes through an EHR during three years before the request, we are concerned that this could diverge from what is required of covered entities under Section 9.5 of the MRTCs. AHIMA recommends that ONC and the RCE work closely with OCR as it moves forward with development of the Common Agreement to ensure alignment with any changes that OCR may make to HIPAA with respect to accounting of disclosures.

AHIMA also recommends that ONC reduce the number of days by which QHINs, Participants, and Participant Members must provide the summary of disclosures from 60 to 30 days. Given the rarity of accounting of disclosures requests, it is difficult today to accurately extrapolate the amount of time it takes to respond to such a request. That said, under current conditions, the time it takes a covered entity to respond to an individual’s request for an accounting of disclosures often depends on the activity or activities of the patient. For example, if the patient’s activities consist of one emergency department visit, a manual abstract can be produced within 1-2 hours. However, if a patient has a long history of activities over six years, it might take at least one business day to perform a manual abstract of the patient’s chart to determine where/when the patient’s information was accessed. In general, HIM professionals try to produce the accounting of disclosures for the requesting individual within the same business day or next business day. Along these lines, we believe that 30 days is sufficient for QHINs, Participants, and Participant Members to provide Individuals with a summary of Disclosures of EHI for Exchange Purposes.

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

Patient Identity Resolution

ONC Request for Comment #9: Different communities tolerate different degrees of risk with respect to accurately matching patient identities. 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.)?

Given the variance in the calculation of patient matching rates across HINs, Participants, and Participant Members, requiring QHINs to meet a minimum performance standard could prove challenging at this time. That said, a minimum performance standard would help ensure that patients are being appropriately matched to their EHI. Therefore, we recommend that ONC and the RCE work with QHINs,

Participants, and Participant members to develop consensus minimum performance standards that could be established prior to implementation of such a requirement in the QTF. We also recommend that the performance standards be phased in over time and become more rigorous as data flows between QHINs become increasingly more sophisticated.

AHIMA also agrees with ONC that QHINs should be required to measure and report on the performance of the algorithm(s) they rely on. Such reporting will help shed further light on the extent of the variation in patient matching algorithms, identify gaps as it relates to certain patient populations (including homeless and pediatrics,) and help drive innovation in improving algorithm performance.

We appreciate the opportunity to provide comments on the Trusted Exchange Framework and Common Agreement Draft 2. We hope that ONC and the RCE will continue to engage extensively with stakeholders on the Framework, and we look forward to working with you to ensure its successful final release and implementation. Should you or your staff have any additional questions or comments, please contact Lauren Riplinger, Vice President, Policy & Government Affairs, at lauren.riplinger@ahima.org and (202) 839-1218.

Sincerely,

A handwritten signature in cursive script that reads "Wylecia Wiggs Harris".

Dr. Wylecia Wiggs Harris, PhD, CAE
Chief Executive Officer
AHIMA