

October 11, 2021

Ms. Mariann Yeager
Chief Executive Officer
The Sequoia Project
1600 Tysons Blvd., 8th Floor
McLean, VA 22102

RE: Elements of the Common Agreement

Dear Ms. Yeager:

On behalf of the American Health Information Management Association (AHIMA), thank you for the opportunity to comment on the draft “Elements of the Common Agreement.”

AHIMA is a global nonprofit association of health information (HI) professionals. AHIMA represents professionals who work with health data for more than one billion patient visits each year. AHIMA’s mission of empowering people to impact health drives our members and credentialed HI professionals to ensure that health information is accurate, complete, and available to patients and providers. Our leaders work at the intersection of healthcare, technology, and business, and are found in data integrity and information privacy job functions worldwide.

AHIMA is strongly supportive of the Common Agreement’s stated goal to “establish a floor of universal interoperability across the country for health care.” AHIMA greatly appreciates the work that the Sequoia Project has done in developing the draft Elements of the Common Agreement. Additionally, AHIMA appreciates the process that was used in developing the draft. Given the significance of this document, AHIMA believes that it has been critical that the Recognized Coordinating Entity (RCE) has sought stakeholder feedback from across the healthcare landscape and ensured that the process remained both transparent and collaborative. Our comments and recommendations on selected sections of the Elements of the Common Agreement are below.

Definitions

AHIMA appreciates that the definitions of defined terms throughout the draft Elements of the Common Agreement are harmonized with pre-existing definitions of terms found in the Health Insurance Portability and Accountability Act (HIPAA) and the 21st Century Cures Act final rule. AHIMA believes that the consistent harmonization of definitions across the Common Agreement and relevant pre-existing policy is critical to ensuring that implementation of the Trusted Exchange Framework and Common Agreement (TEFCA) is done in a manner that minimizes the burden on actors across the healthcare system.

Exchange Purposes

The Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2 states that “many commenters felt that requiring the full Payment and Health Care Operations Exchange Purposes were too burdensome to implement immediately. Therefore, the Common Agreement will initially require 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 the draft Elements of the Common Agreement, it is not apparent to AHIMA that Payment and Operations will be limited initially, as stated above. The draft Elements of the Common Agreement states that “initially, QHINs would support the following Exchange Purposes: payment, health care operations, public health, benefits determination, and individual access services.” The draft states that payment “has the meaning assigned to such term at 45 CFR § 164.501.” and healthcare operations “has the meaning assigned to such term at 45 CFR § 164.501, except that this term shall apply to a healthcare provider regardless of whether the healthcare provider is a Covered Entity.” AHIMA requests clarification on whether the payment and health care operations exchange purposes will be limited as stated in the TEFCA Draft 2.

In addition to the proposed exchange purposes, the RCE plans to work with stakeholders to identify additional exchange purposes over time, as appropriate. AHIMA supports an approach to identifying and implementing additional exchange purposes that would phase in new exchange purposes. This would 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. AHIMA believes that sufficient and appropriate pilot testing is a necessary first step prior to the phasing in of additional Exchange Purposes.

TEFCA Information and Required Information

The draft Elements of the Common agreement states that “A QHIN, Participant, or Subparticipant that receives a request would be obligated to provide all Required Information that is available for the Exchange Purpose asserted, unless providing the Required Information is prohibited by Applicable Law or one of the Framework Agreements. Required Information would generally be the ePHI (as defined by HIPAA) that is created, received, transmitted, or retained by any QHIN, Participant, or Subparticipant prior to or during the term of the applicable Framework Agreement.” AHIMA notes the defined information that will be shared under the Common Agreement is not in exact alignment with the electronic health information (EHI) that is required to be shared according to the prohibitions on information blocking contained in the 21st Century Cures Act final rule. AHIMA encourages the RCE to consider the findings of the joint AHIMA, AMIA, and EHRA coalition report entitled “Defining EHI and the Designated Record Set in an Electronic World.”¹ AHIMA welcomes the opportunity to engage with the RCE in developing a roadmap to refine the definition of TEFCA Information given the findings of the coalition report, with the goal of promoting consistency and improving upon a standardized set of information that is exchanged between QHINs.

¹ “Defining EHI and the Designated Record Set in an Electronic World.” AHIMA.org, AMIA, AHIMA, EHRA Joint Task Force, 20 Sept. 2021, <https://www.ahima.org/media/ztqh1h2q/final-ehi-task-force-report.pdf>.

Individual Access Services (IAS)

In the draft, it is noted that “the Common Agreement’s IAS requirements would specify the elements of a written privacy notice for such IAS Providers, which would include a description of the need to obtain express consent from Individuals regarding the way their information will be accessed, exchanged, Used, or Disclosed by the IAS Provider.” AHIMA strongly supports this provision. We note that some potential IAS providers may not be required to provide a notice of privacy practices under HIPAA, even though the entity accesses, exchanges, uses or discloses ePHI. AHIMA believes this requirement for IAS providers will help enhance transparency to HINs and their Participants’ and Subparticipants’ privacy practices.

Privacy and Security

AHIMA strongly supports that the Common Agreement “will promote strong privacy and security protections.” Specifically, AHIMA supports that the Common Agreement would require “non-HIPAA Entities to protect TEFCA Information that is individually identifiable in substantially the same manner as HIPAA Covered Entities protect PHI, including having to comply with the HIPAA Security Rule and most provisions of the HIPAA Privacy Rule.” AHIMA believes this is necessary because the existing regulatory landscape lacks sufficient guardrails relating to non-HIPAA entities protecting 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 activities that run contrary to the intent of the patient.

The draft notes that “the Common Agreement would also specify expectations for security incident notifications affecting QHIN-to-QHIN exchange that would apply to QHINs and flow down to Participants and Subparticipants.” AHIMA recommends that the Common Agreement should 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. AHIMA believes that inclusion of this language will further clarify the timeline by which QHINs must report a breach to the RCE, other QHINs, Participants, and Subparticipants with whom the QHIN has a Direct Relationship, while also aligning with the HIPAA breach notification requirements.

Special Requirements (including Consent)

AHIMA supports that the Common Agreement “would not require QHINs, Participants, and Subparticipants that are not IAS Providers to obtain Individual consent to Use or Disclose TEFCA Information except to the extent they would be required to do so under Applicable Law.” In cases in which TEFCA Information includes substance use disorder and treatment information covered by 42 CFR Part 2, AHIMA is concerned that some health IT systems are currently unable to segment such sensitive data. 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. AHIMA recommends that as work to improve the granular segmentation of data progresses, such as the work of the Protecting Privacy to Promote Interoperability (PP2PI) work group, either the Common Agreement can be revised, or a new Standard Operating Procedure can be adopted to encourage QHINs to adopt a more granular approach.

Standard Operating Procedure (SOP): QHIN Eligibility Criteria, Onboarding, and Designation

In developing the SOP for QHIN Eligibility Criteria, Onboarding, and Designation, AHIMA urges the RCE to carefully consider challenges associated with patient matching. Specifically, we recommend that the RCE consider the Patient ID Now Framework for a National Strategy on Patient Identity to help drive consensus recommendations relating to addressing patient identification.² The lack of a national strategy around patient identification and matching limits progress in the adoption of digital health information technologies and management and could be a significant barrier to successful implementation of TEFCA.

Given reported variances in the calculation of patient matching rates across a variety of stakeholders in the healthcare system, AHIMA supports implementation of a minimum performance standard. AHIMA believes this would help ensure that patients are being appropriately matched to their TEFCA Information. Therefore, we recommend that the Office of the National Coordinator for Health IT (ONC) and the RCE work with QHINs, Participants, and Subparticipants to develop consensus minimum performance standards that could be established prior to implementation of such a requirement. 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 believes that QHINs should be required to measure and report on the performance of the algorithm(s) they rely on to ensure that they meet minimum standards. 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, and help drive innovation in improving algorithm performance.

Standard Operating Procedure (SOP): Dispute Resolution Process

AHIMA supports the development of an SOP related to the dispute resolution process. There are a number of critical open questions related to how disputes will be resolved under the Common Agreement. Specifically, AHIMA urges the RCE to provide detail regarding how the dispute resolution process will be handled when disputes arise, who will be responsible for enforcing outcomes stemming from the dispute resolution process, as well as further clarification of the RCE's role within the context of the dispute resolution process.

² "Patient ID Now Framework." AHIMA.org, Patient ID Now Coalition, 26 Apr. 2021, <https://catalog.ahima.org/view/251156390/6/>.

Standard Operating Procedure (SOP): Governing Council

AHIMA requests further clarification within the Transitional Council SOP regarding the amendment process to the Common Agreement. AHIMA is concerned that there are several open questions regarding the process by which amendments to the Common Agreement will be adopted. Specifically, will QHIN's need to re-sign the Common Agreement following every amendment? How will amendments flow-down to Participant and Subparticipant agreements and will these agreements need to be amended whenever there is an amendment made to the Common Agreement? Will there be a grace period associated with implementation of amendments to allow for QHINs, Participants, and Subparticipants to come into compliance with the provisions of newly added amendments?

Conclusion

We appreciate the opportunity to provide comments on the Draft Elements of the Common Agreement. We hope that the Office of the National Coordinator for Health Information Technology and the RCE will continue to engage extensively with stakeholders when developing and implementing TEFCA. 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 Matt Kerschner, Director of Regulatory Affairs at matthew.kerschner@ahima.org and (312)-233-1122 or Lauren Riplinger, Vice President, Policy & Government Affairs, at lauren.riplinger@ahima.org and (202) 839-1218.

Sincerely,



Wylecia Wiggs Harris, PhD, CAE
Chief Executive Officer