

June 17, 2019

Donald Rucker, MD
Office of the National Coordinator for Health Information Technology
330 C Street SW
Washington, D.C. 2020

Re: Proposed Trusted Exchange and Common Agreement (TEFCA) 2.0

Submitted Electronically: <https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement>

Dear Dr. Rucker,

On behalf of the 4,000 U.S. hospitals and health systems and more than 165,000 other providers and organizations in the Premier healthcare alliance, we are pleased to submit these comments in response to the Office of the National Coordinator for Health Information Technology (ONC) proposed Trusted Exchange and Common Agreement (TEFCA) 2.0. The Premier healthcare alliance, a 2006 Malcolm Baldrige National Quality Award recipient, maintains the nation's most comprehensive and largest healthcare databases in the industry. Premier works with its members on utilizing informatics, analytics, and data to improve care quality and patient safety, while achieving cost efficiencies. With integrated data and analytics, collaboratives, supply chain solutions, and advisory and other services, Premier enables better care and outcomes at a lower cost. Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. In the comments below, we provide general feedback about ONC's overall approach and strategy and then offer comments and recommendations regarding specific aspects of ONC's proposal.

GENERAL COMMENTS

ONC's proposed TEFCA 2.0 seeks to further advance nationwide interoperability, data access and data exchange. We strongly support the overall intention and direction of the proposed TEFCA 2.0 and believe it will be an important step forward in enabling providers, hospitals and other healthcare stakeholders to participate in nationwide health information exchange. We also support leveraging the considerable progress the industry has made in recent years to electronically exchange patient health information and to adopt open interoperability and data standards. It is essential to address ongoing interoperability challenges so that providers can improve care delivery, patient safety and performance, and to drive operational efficiencies. Premier continues to advocate for, develop and implement innovative solutions to achieve open data access across health IT systems and technologies to support the industry's value-based care transition across the care continuum. Interoperability is essential to enable systems to move beyond simply recording data in electronic health records (EHRs) toward integrating and combining data to streamline analytics on supply chain, financial, public and population health and clinical care for evidence-based decision-making. Without connectivity across the care continuum, data collection remains fragmented and does not provide the total picture necessary for healthcare providers to deliver informed, coordinated, safe and quality care.

Premier's general comments focus on the following:

- Ensuring increased provider data access and availability at the point of care and within workflow
- Reducing provider burdens
- Considering privacy and security

Provider Data Access and Availability at the Point of Care and within Workflow

Data are essential to achieve the vision of a patient/consumer-centered and healthcare provider-driven healthcare system. Providers need robust, scalable, and interoperable health IT systems, EHRs and third-party applications to improve clinical decision making and outcomes. We urge **ONC to focus attention on providers' needs to have real time access to data at the point of care and within workflow**. As we discuss below, we urge ONC to **prioritize the exchange of information for patient care and treatment within TEFCA**.

The inability to access and integrate timely and complete data across the care continuum from multiple sites of service, diverse providers and various data sources threatens quality of care, patient safety and efficiency. The lack of access to complete and timely data adds inefficiencies and costs to the healthcare system and hampers population health efforts, public health surveillance and reporting.

The movement towards value-based care and alternative payment models has created an even greater imperative for health information exchange and interoperability. Advanced payment models such as accountable care organizations (ACOs) and bundled payments involve participation by multiple providers, suppliers and payers who are at risk for coordinating the care of patients, requiring the ability to access and aggregate information from different EHRs, health IT applications and across multiple facilities and care settings.

Reducing Provider Burdens

We are pleased that ONC continues to articulate its commitment to reduce unnecessary regulatory data collection, documentation and reporting burdens and to reduce related costs for providers. Nevertheless, we believe that the proposed TEFCA will result in greater provider burdens and costs. **We again urge ONC to work with its federal partners to further align federal programs to reduce provider burdens and eliminate redundant and unnecessary reporting**. Furthermore, we strongly recommend that agencies more closely coordinate their rulemaking to avoid duplicative, ambiguous or conflicting requirements and timelines.

We believe that ONC underestimates the significant burdens that will impact providers and other stakeholders who are currently using existing, successful exchange networks and solutions. The burdens will include the costs of TEFCA participation, staffing, contractual changes, privacy and security practices modifications, education and training, and other system implementation and administrative costs. For example, drafting new data use agreements, business associate agreements and contracts with qualified health information networks (QHINs) will require not only the legal resources to develop, negotiate and execute them, but also the resources needed to educate stakeholders, including patients and their caregivers. Additionally, providers' compliance with forthcoming ONC and CMS interoperability, information blocking, data access and payment rules, in addition to TEFCA implementation considerations, will present significant challenges for all stakeholders.

Considering Privacy and Security Issues

We are concerned that ONC does not sufficiently address the complexities of patient access to data, especially related to data access that occurs outside or beyond the scope of the Health Insurance Portability and Accountability Act (HIPAA).¹ **We believe that TEFCA policies should be aligned as closely as possible with HIPAA**. Although TEFCA 2.0 proposes to extend HIPAA privacy and security regulations to all TEFCA participants, even those who are not covered entities or business associates, it is unclear how this will be operationalized, and we urge ONC to provide additional details.

Furthermore, ONC needs to clarify how TEFCA will allow for variation in state privacy, security, data access and consent laws and regulations. TEFCA is silent on this variation, other than to note that "all applicable law must be followed." Lacking additional clarity from ONC, stakeholders will continue to struggle to meet TEFCA requirements and all other applicable laws and regulations (including HIPAA, 42 CFR and information blocking). Additionally, as Premier has stated in other comment letters, **ONC should ensure that patients, beneficiaries, enrollees and their caregivers can understand the**

¹ Risky Business? Sharing Data With Entities Not Covered by HIPAA <https://www.manatt.com/Insights/White-Papers/2019/Risky-Business-Sharing-Data-With-Entities-Not>

nuances of privacy and security of their health data, especially when such data is shared as part of TEFCA. We recommend that HHS develop and launch a broad educational and outreach campaign to advise stakeholders, especially patients and their caregivers, about privacy and security of their health information, with a focus on the risks and challenges that are beyond the scope HIPAA.

In the discussion below, we address specific aspects of the TEFCA 2.0 proposal and offer our recommendations.

SPECIFIC COMMENTS

Timeline

ONC's proposed timeline lacks sufficient details and does not include major milestones and work products beyond April 2019. Without such information, it is impossible for stakeholders to understand or anticipate ONC's plans, including the work to be undertaken by the Recognized Coordinating Entity (RCE). Premier **urges ONC to develop and disseminate for public review and further comment, a more comprehensive TEFCA proposal with milestones for all envisioned activities**, including those related to the RCE award and scope of work.

The ONC notice of funding opportunity (NOFO) for the RCE² mentions cohorts of QHINs, although little detail is included (such as the type or number of QHINs within cohorts and in total). Premier urges ONC **to provide additional clarity (in the DRAFT TEFCA) about the onboarding of cohorts of Qualified Health Information Networks (QHINs)**. We recommend that ONC include **additional details and confirm its plans for pilot testing, the formation of QHIN cohorts and the proposed timeline, content, context, processes and key milestones for all stakeholders' onboarding**. Pilot testing should be conducted before nationwide implementation as it is essential to provide opportunities to adjust the proposed approaches, identify and correct major gaps and weakness and help reduce unintended consequences.³

We urge ONC to consider a more focused scope and approach for initial implementation and we caution ONC that the proposed timeline (even the one included in RCE notice of funding opportunity) is overly ambitious. The RCE has not yet been selected, the number and makeup of the QHINs remains unknown and a final Common Agreement won't be released until the RCE is established.

ONC acknowledges that the TEFCA "necessitates modifications to existing participation agreements and trusted frameworks." Again, we note our concerns that ONC is underestimating potential impacts on stakeholders. We believe that the proposed approach, technology, and related processes will require TEFCA participants to make significant investments in their organizations and infrastructure for technology and operational changes. We recommend that ONC further clarify anticipated stakeholder investments in technology and infrastructure as well as ongoing operational changes and enhancements.

TEFCA will impact and potentially disrupt existing stakeholder relationships with various entities, including business associates. We anticipate confusion among stakeholders trying to reconcile their existing relationships with each other and with TEFCA participants. We ask ONC to confirm if/how stakeholders will be able to align TEFCA with their existing relationships, beyond stating that existing agreements will need to be redone. For example, some existing health information exchanges (HIE) and networks have services that exceed the current TEFCA proposed exchange purposes and modalities. Many existing HIEs are exchanging information for treatment, payment, operations, public health activities and quality reporting. Asking stakeholders to move beyond HIPAA-permitted purposes will take considerable resources and time.

Furthermore, the final TEFCA 2.0 timeline should consider and describe **when and how ONC's and CMS' final rulemaking (i.e., interoperability; application programming interfaces (APIs); information blocking) will be implemented and aligned with TEFCA**, since they are interrelated and interdependent. Additionally, as ONC recognizes and adopts new, revised or updated standards (i.e., CDS hooks; read-write; bulk data transport) and as the USCDI expands, we urge ONC to consider and

² <https://www.healthit.gov/topic/onc-funding-opportunities/trusted-exchange-framework-and-common-agreement-recognized>

³ <https://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/match/match4.html>

provide information to stakeholders about how and when such updates and changes will impact TEFCA. Finally, **ONC and CMS need to clarify how and under what circumstances TEFCA participation might be required and/or incentivized by federal programs.**

Pilots and Technical Assistance

As we have cautioned, TEFCA implementation will be a major undertaking for all stakeholders. Congress seems to have anticipated the complexity of TEFCA as the 21st Century Cures Act (Cures) requires that ONC, in collaboration with the National Institute of Standards and Technology (NIST), provide technical assistance. We strongly recommend that ONC provide additional information and clarification (to include the nature and timing of technical assistance). ONC needs to consider the specific and diverse needs of all stakeholders in prioritizing the type, format, timeframe, duration, focus and content of the technical assistance.

Cures also requires that ONC, in consultation with NIST, pilot test TEFCA. However, ONC offers very little information about pilot testing other than stating its intent to conduct pilots. Pilot testing is an appropriate, prudent and essential first step and should be conducted before TEFCA implementation and full-scale national roll out. **ONC should provide information about anticipated pilot testing (to include the approach, methodologies, evaluation, duration, timing and the roles of stakeholders).**

Minimum Required Terms and Conditions (MRTCs)

ONC needs to provide additional clarification about the proposed Minimum Required Terms and Conditions (MRTCs). As we noted in our comments in response to ONC's Interoperability and Information Blocking proposed rule, we have concerns about ONC's definition of electronic health information (EHI) and urge ONC to implement a more narrowly focused definition of EHI within TEFCA.

We request that ONC **provide examples or scenarios to clarify Individual Access Services and the requirement for a direct relationship with an individual.**⁴ We believe that there is ambiguity regarding the provisions for Individual Access Services (ISA) and to what extent entities, such as public health agencies are required to respond to ISA requests. We suggest that ONC develop and publish a "cross-walk" of HIPAA and other applicable laws (such as those for public health) that are cited in the MRTCs. In addition, as part of the description about Permitted and Future Uses of EHI, Premier requests that ONC **further clarify if and provide examples of how data may be stored (maintain/retained), used, re-used and/or aggregated within the TEFCA and by which participants, organizations and/or entities.** Further, ONC needs to provide greater detail about specific methods and processes to ensure ongoing data quality, reliability and usability within TEFCA.

QHIN Technical Framework (QTF)

The QHIN Technical Framework (QTF) specifies functional and technical requirements for data exchange among QHINS, including digital certificate policy; encrypted transmission; user authentication and authorization; query; message delivery; record location; directory services; privacy preferences; auditing; and error handling. We note with concern that the QTF includes numerous (13) specific requests for comment on the proposed approach to technology and standards and we question how ONC and the RCE will successfully assess these. **We urge ONC to provide additional details about how the QTF will be finalized prior to implementation and how the RCE will work with ONC and stakeholders to ensure timely modifications and updates to the QTF after implementation.**

Transparency of Fees

Nationwide exchange of health information needs to be accurate, timely and cost-effective. We remain extremely concerned about the need for and lack of prospective and transparent information on anticipated fees and other costs related to stakeholder participation in TEFCA 2.0. ONC notes that fees will be addressed as part of the "Additional Required Terms and Conditions (ARTCs)" which are to be developed by the RCE. **ONC needs to provide prospective information about all anticipated and proposed fees and costs that stakeholders may incur and confirm that the process for establishing fees will be open to stakeholder feedback and participation.** Additional clarification is

⁴ <https://www.healthit.gov/sites/default/files/page/2019-04/FINALTEFCAQTF41719508version.pdf> Page 4.

needed to address to what extent, with what frequency and under what circumstances fees may be charged. ONC should provide explicit examples of all anticipated fees.

Meaningful Choice

We are concerned that as proposed, “Meaningful Choice” will be challenging and complicated to operationalize. For the last 20 years, the HIPAA privacy standards have engendered consumer trust. Premier believes that TEFCA and all policies, and procedures developed by the RCE should align with HIPAA, including the presumed consent for the exchange of protected health information for treatment and minimum necessary information exchange for payment and healthcare operations. We agree with ONC that individuals should have the opportunity to understand and make informed choices about where, how, and with whom their electronic health information is shared. However, **we suggest that ONC define Meaningful Choice in a way that applies only to the exchange of health information that does not fall under the definitions of treatment, payment and operations (TPO) as established by HIPAA.**

It is unclear if ONC anticipated any discrepancies (and how they would be resolved) between a patient’s Meaningful Choice and other consents/authorizations that the patient may have signed. Establishing a new choice standard for TPO would be inappropriate for HIPAA covered entities and business associates, as the current implied consent model for TPO is an ingrained standard that has served patients well. We ask that ONC clarify that Meaningful Choice applies to data sharing that is not contained within the HIPAA TPO construct. Additionally, ONC should clarify the extent to which the proposed information blocking provisions of their proposed rules will relate to TEFCA.

Exchange Purposes and Exchange Modalities

Achieving interoperability across the care continuum and assuring data availability at the point of care and within the clinical workflow must be a top ONC priority. While there are a broad range of use cases for health information exchange, Premier agrees with ONC in prioritizing information exchange under TEFCA and we urge ONC to first focus on exchange for patient care and treatment. We are supportive of ONC’s plans for initially including a subset of Payment (Utilization) and Health Care Operations (Quality Assessment and Improvement, and Business Planning and Development) as defined in the HIPAA Privacy Rule, rather than the full scope of payment and operations. **We urge ONC to provide additional examples for each of the proposed exchange purposes and modalities to more clearly depict how various exchanges will occur between and among different stakeholders.** Furthermore, **we again urge ONC to pilot test each of the exchange purposes and modalities prior to full TEFCA implementation.**

We support ONC’s intention to phase in new Exchange Purposes in the Common Agreement to support new use cases and recommend that ONC provide additional information about the processes and procedures for adding use cases to the Common Agreement. We urge **ONC to establish and follow a predictable, transparent, and collaborative process to expand the exchange purposes (use cases) and exchange modalities, including providing stakeholders with the opportunity to comment on any anticipated expansions,** similar to ONC’s proposed process for expanding the USCDI. However, the TEFCA proposal lacks clarity about if or how new use cases (exchange purposes) and exchange modalities will be “ready” for potential implementation within TEFCA. We are supportive of the proposal for Individual Access Services; however, we urge ONC to provide examples about how Individual Access Services relate to and interact with Meaningful Choice. Furthermore, we believe that population-level data exchange within the healthcare system is critical for population management and care coordination and recommend that ONC re-prioritize and accelerate standards development and adoption for population-level data exchange.⁵

Security Labeling

Premier is concerned with the way TEFCA proposes to treat sensitive data – requiring security metadata labeling for four types of data without taking into account differing state laws, regulations and approaches. The metadata tagging proposed in TEFCA could result in insufficient information being tagged in some

⁵The Intersection of Technology and Policy: EHR Population Level Data Exports to Support Population Health and Value
https://www.healthit.gov/sites/default/files/page/201803/Population%20Level%20Data%20Export%20Meeting%20Summary%20Report_0.pdf

states, and too much information tagged in other states, thus potentially leading to providers not having access to information required for care and treatment. Premier believes that providers need access to all a patient's information to provide safe and effective care and **we recommend that ONC encourage further discussion among state governors to harmonize state privacy laws concerning health information.**

Summary of Disclosures

ONC has proposed that individuals have "the right to receive a summary of Disclosures of EHI for applicable Exchange Purposes for up to six years immediately prior to the date on which the summary of disclosures is requested." An individual could request such summary from any QHIN, Participant, or Participant Member with which the individual has a direct relationship and the information must be provided within 60 days. Premier believes that such a summary of disclosures is only feasible if the information is electronically tracked and maintained in structure format by a QHIN(s). A Participant or Participant Member would not have access to the information on the various disclosures from the QHIN or other Participants of Participant Members. **We urge ONC to clarify that responding to such requests, including compiling and maintaining the information necessary for such responses, rests solely with the QHINs.**

CONCLUSION

In closing, the Premier healthcare alliance appreciates the opportunity to submit these comments on the proposed TEFCA 2.0. Premier shares the vision of achieving interoperability and the establishment and adoption of open standards to enable an interoperable, learning health ecosystem. Premier hopes our comments are helpful as ONC continues this important work. If you have any questions regarding our comments or need more information, please contact Meryl Bloomrosen at Meryl_bloomrosen@premierinc.com or 202.879.8012.

Sincerely,



Blair Childs
Senior Vice President, Public Affairs
Premier healthcare alliance