



Donald W. Rucker, MD
National Coordinator for Health IT
Office of the National Coordinator
Department of Health and Human Services
Mary E. Switzer Building
330 C Street SW, Office 7009A
Washington, D.C. 20201

Submitted electronically to www.healthit.gov

Re: Draft Two of the Trusted Exchange Framework and Common Agreement

Dear Dr. Rucker,

Thank you for the opportunity to provide athenahealth's perspective on the second draft of the Trusted Exchange Framework and Common Agreement ("TEFCA").

Over the past twenty-one years, athenahealth has built a network of 160,000 clinicians and provides electronic health record ("EHR"), practice management, care coordination, patient engagement, data analytics, and revenue cycle management services to physician practices and hospitals. As a founding member of the CommonWell Health Alliance and implementer of the Carequality collaborative, we pursue innovative solutions with partners across the health IT spectrum to allow the providers on our network to improve the quality of care they deliver through access to real-time information from all care settings. athenahealth has been ranked the #1 rated KLAS Most Interoperable EHR and offers integration with more than 26,000 health plans, 12,000 labs and imaging centers, 95% of U.S. pharmacies, and 1,200 non-athena sites.

While we commend ONC's diligence in advancing interoperability across the healthcare industry as it implements the 21st Century Cures Act, we also urge ONC to be mindful of the significant gains already achieved by health IT companies and to ensure that continuing progress is not stifled. Rather than establishing restrictive frameworks and prescriptive requirements, ONC should leave as light a footprint as possible in shaping innovation and driving private sector investment. We believe that market forces – not government mandates – are the most compelling and effective drivers for change. Therefore, interoperability will become more abundant alongside a strong business incentive to exchange information on a national scale. True private sector leadership must materialize as a cornerstone of TEFCA, and a wide range of business models must be enabled within the guardrails set forth in the framework's principles. Otherwise, TEFCA will likely experience the same fate as the failed and struggling health information exchanges (HIEs), which relied upon unsustainable government and grant funding. If ONC oversteps its role in TEFCA, it risks unintentionally impeding the much-needed organic evolution of technology platforms in healthcare.

ONC's TEFCA proposal contains core principles and characteristics that, if properly implemented, and with a few caveats, will increase the ease of information sharing across the entire healthcare continuum. As ONC develops the final draft, it must make the following changes to ensure that the regulation's intent is effectively realized.

1. ONC Must Make Methodical, Incremental Advances Toward Interoperability

The high-level goals that ONC seeks to achieve through TEFCA – namely, providing a single “on-ramp” to nationwide connectivity, enabling electronic health information to securely follow patients, and supporting nationwide scalability – are laudable intents. The healthcare industry will undoubtedly benefit from more streamlined and prolific connectivity between patients, providers, payers, health IT vendors, and government agencies. However, it is important to note that the health IT industry is already steadily marching toward these three objectives and that ONC risks jeopardizing this inertia by overregulating this sector to manufacture or artificially expedite progress. Instead, ONC should allow the industry time to implement new regulations and adapt to new market forces before proposing additional, substantial regulations.

Within three months, the health IT industry has been tasked with reviewing and responding to a litany of interoperability-related regulations, including ONC’s Interoperability, Information Blocking, and the ONC Health IT Certification Program Notice of Proposed Rulemaking (NPRM), CMS’s Interoperability and Patient Access NPRM, and ONC’s second draft of TEFCA. The introduction of any *one* of these alone would have had a tremendous effect on the health IT industry, as each rule proposes significant changes to the status quo. However, industry stakeholders analyzed these regulations in tandem. Not only has this reduced the quantity and quality of time stakeholders can spend evaluating the details of each proposal, it has triggered industry confusion as health IT companies speculate about the consequences of layering these detailed and dense regulations. The healthcare industry needs innovative disruption, not regulatory disruption.

Concurrent implementation of these rules could be counterproductive to promoting interoperability. Failing to provide the industry with the necessary time to properly implement each regulation and make iterative adjustments could immobilize the industry until the dust has settled – years from now. The multiple layers of regulatory disruption aimed at the same end goal may cause companies to slow, or even halt, the development of innovative functionality and interoperability arrangements until perceiving how these regulations (and subsequent adjustments) operate in tandem. Rather than rushing the progress that is already underway, ONC should allow the industry ample time between effective dates to make incremental steps toward widespread interoperability.

Additionally, ONC should deliberately and transparently share its long-term expectations regarding TEFCA participation with EHR vendors. To best allow vendors to meet the technology needs of physicians, introduce innovative new functionality, and meet updated certification criteria, ONC should clearly detail its long-term vision for TEFCA broadly and EHR vendor participation, specifically.

2. ONC Must Strengthen Eligibility Requirements for Qualified Health Information Networks

Critical to TEFCA’s success is the stability of its “network of networks” structure, which integrates the healthcare industry through point-to-point relationships. Within this structure, Qualified Health Information Networks (QHINs) play an outsized role as they uniquely facilitate information exchange both between *and* within participant networks. In addition, QHINs are responsible to adhere to the Recognized Coordinating Entity’s (RCE’s) Common Agreement, process patient privacy consent, and enforce Participant-QHIN agreements within each

participant network. ONC states that “a QHIN’s ability to operate successfully and efficiently is crucial to ensuring all Individuals and providers have appropriate and real-time access to EHI¹.”

Given the significance of QHINs’ role for *all* TEFCA participants, it is imperative that QHINs sustainably and efficiently perform each function at scale. The current eligibility requirements for Health Information Networks (HINs) seeking QHIN status include: (1) the operation of a network that exchanges electronic health information (EHI) between entities in a live clinical environment; and (2) a written plan of how the HIN will achieve all of the requirements of the Common Agreement. Because HINs are granted QHIN status based - in substantial part - on an unrealized “plan,” there is an alarming likelihood that several QHINs could be approved by the RCE, find the Common Agreement demands too rigorous, exchange information inefficiently, and eventually spin down their QHIN functions.

The result of such instability within TEFCA would be disastrous. The Participants, Participant Members, and Individuals belonging to an unsuccessful QHIN would be forced to scramble and quickly contract with another QHIN. Until the new Participant-QHIN agreements are signed, the entire TEFCA network would experience a gap in access to some EHI. In order to ensure TEFCA’s stability and promote uninterrupted information exchange among QHINs and participants, ONC must strengthen the eligibility standards for HINs seeking QHIN status.

3. ONC Must Ensure Neutrality of the Recognized Coordinating Entity

athenahealth commends ONC for recognizing the importance of private sector leadership in the proliferation of nationwide interoperability. Rather than implementing the Common Agreement itself, ONC astutely chose to partner with an industry-based, non-profit, and trusted RCE to develop, implement, and monitor the framework’s Common Agreement. As ONC selects an RCE, it is imperative that the agency select a truly neutral entity, which represents the interests of all major EHR vendors, to ensure a level playing field for all TEFCA participants.

4. ONC Must Enable a Global Patient Consent Mechanism

Patient consent is crucially important to the exchange of EHI, but it can also impede information flow through inconsistent policies and implementation at the end-user level. For example, a patient may opt-in to record sharing through their primary care office, not realizing that they have been opted-out by default at an unaffiliated specialist. Rather than requiring every entity with a direct patient relationship to process consent data, the RCE should be required to manage a global consent mechanism as a supplement, not a substitute, to the locally managed consent mechanism proposed in TEFCA. This will enable patients to control their consent preferences at a global or local level.

Conclusion

As ONC processes stakeholder feedback and develops the final draft of TEFCA, we encourage the agency to:

- Provide the health IT industry with ample time to properly implement all recent regulation;
- Strengthen eligibility standards for QHINs;

¹ Office of the National Coordinator for Health Information Technology. (2019). *Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2*. Washington, D.C.

- Select a truly neutral entity to serve as RCE; and
- Supplement local patient consent with an additional global option.

Under these conditions, we believe TEFCA can most effectively meet its goals of providing one “on-ramp” to scalable, nationwide connectivity and enabling data to securely follow patients. We look forward to engaging with your office on this important draft framework. Please do not hesitate to reach out directly by phone at (617) 402-8516, or by email at gcarey@athenahealth.com.

Sincerely,

A handwritten signature in black ink, appearing to read "Greg Carey".

Greg Carey
Director, Government & Regulatory Affairs
athenahealth, Inc.