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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 exchangeframework@hhs.gov

Re: Trusted Exchange Framework & Common Agreement

Dear Dr. Rucker,

athenahealth is the most universally-connected healthcare network in the country. Everything we do is to enhance the experience and outcomes of healthcare. Today, we connect 111,000 providers and 106 million patients through clinical and financial services like electronic health records, population health tools, and revenue cycle management. And, because we believe that collaboration and innovation will make healthcare work as it should, we are building the nation's only platform where providers, patients, payers and innovators can partner to transform care, together.

We have spent the past 20 years building a deeply connected network without, and sometimes in spite of, heavy-handed government intervention. Our experience confirms that healthcare information flows best in response to market incentives, not government mandates. For years, we have submitted comments to the Office of the National Coordinator for Health IT (ONC) imploring your colleagues to take a step back and let the private sector continue its marked progress toward not just interoperability but interoperation.

You will no doubt hear similar messages from many stakeholders—that the draft Trusted Exchange Framework and Common Agreement (TEFCA) is overly prescriptive, and ONC has waded too far into areas reserved for the private sector. While in the abstract we agree, we are mindful that ONC had to work within the Congressional mandate set forth in the 21st Century Cures Act. Contractual language developed or supported by a government agency will by its very nature feel like a regulatory overreach. Yet, we believe ONC has struck a reasonable balance between legislative requirements and a commitment to enabling private sector leadership and innovation.

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. True private sector leadership must materialize as a cornerstone of the framework, and a wide range of business models must be enabled within the broad guardrails set forth in the framework's principles. In addition, ONC must assume the role of true coordinator to maintain flexibility for unknown future use cases of health information.

Specifically, ONC should keep the following guiding principles in mind as it finalizes TEFCA:

1. **Identify the correct roles for government and the private sector.**

ONC has likely learned by now that innovation cannot be mandated, nor can it be regulated into existence. The goal of TEFCA is to set the parameters for information to flow so that the private sector—Qualified Health Information Networks (QHINs) in collaboration with participants and end users—can innovate around giving the data utility and helping it to ultimately drive clinician performance. The goal should not be that all QHINs do everything in the same manner or deliver government-defined usability; rather, the goal should be an ecosystem that drives innovation around ever-evolving use cases and allows technology vendors to deliver value and usability based on demand. Perhaps it is feasible to create a single on-ramp for interoperability with respect to sharing longitudinal patient data, but it is neither feasible nor desirable to create a single on-ramp for all types of data exchange.

Technology innovation is driven today by small, iterative steps often rooted in "microtransactions" where data sharing fuels solutions to dozens of small use cases. ONC should define guidelines for information sharing but use caution to not over-regulate. If ONC oversteps its role in TEFCA, it risks unintentionally impeding the much-needed organic evolution of technology platforms in healthcare. If all proprietary technology is discouraged, TEFCA will be interpreted as the only way to exchange healthcare data and prevent future problems and inefficiencies from being tackled in the private sector.

To that end, ONC should ensure that specific standards are set in the Interoperability Standards Advisory (ISA) and not integrated into the principles or common agreement language. As currently written, TEFCA's approach is inconsistent, setting standards in some places but deferring to the ISA in others. Technology needs to be enabled to iterate rapidly, and contractual language does not necessarily lend itself to this swift pace of progress. The ISA's annual public input process will provide an appropriate vehicle to ensure that TEFCA participants are using mature, up-to-date, and accepted standards for information exchange.

2. **Enable business models and a market for QHINs**

If the private sector is to take ownership of driving the implementation and ultimate success of TEFCA, ONC must ensure that it does not regulate market forces out of existence. Congress intended for ONC to knock down remaining barriers to information flow, such as the friction caused by heterogeneous administrative, technical, and legal policies; competitive forces that can run counter to the impetus to share patient information; and fees that are often used as a tool of those competitive forces. We understand and agree with the desire for ONC to ensure that QHINs do not block information through exorbitant fees. However, by prohibiting fees in certain contexts, ONC goes far beyond Congressional intent.

Information exchange is not free. Though there may be requirements outside of TEFCA to provide information at no cost to certain users, such as patients, that does not mean that the exchange of information among QHINs to facilitate individual patient access need to also be at no cost. Furthermore, when combined with the requirement to facilitate population health level bulk data transfers, this policy is ripe for abuse. For example, consumer-facing technology companies could request data on hundreds of thousands of patients for free for the purpose of selling a personal health record service and profiting from what QHINs are required to provide for free. This would greatly distort the market for information flow in healthcare.

QHINs should be able to charge Attributable Costs for all information exchange. If ONC maintains its policy that QHINs may not charge for certain purposes, then ONC must clarify whether Reasonable Allowable Cost for the "free" use cases can be reallocated across the "non-free" use cases. In other words, where a QHIN incurs, but cannot charge, for costs associated with responding to a request for individual access, must it write off that cost? Or can the QHIN cover that cost by amortizing it across other responses to requests for "non-free" use cases?

ONC also cannot and should not limit the types of entities that can become QHINs, as has been suggested in webinars since the release of the draft TEFCA document. The legal, technical, and administrative requirements to become a QHIN are appropriate, significant, and serve as a sufficient barrier to entry. If an EHR vendor or any other type of entity can meet those requirements, ONC's principles of transparency and non-discrimination require that it not arbitrarily limit who can participate.

3. **ONC must act transparently and follow good governing processes.**

ONC should not select the Recognized Coordinating Entity (RCE) before finalizing the framework. Successful implementation of TEFCA depends on the RCE fully understanding the scope of work, which will not be determined until ONC responds to comments received to its draft proposal. It does not make sense to have an entity selected to perform tasks yet to be defined. Furthermore, to select the RCE while ONC is supposed to be reviewing and responding to comments implies that aspects of this proposal are not subject to public input and erodes trust that this process is fair and transparent. We urge ONC to delay the Request for Proposal (RFP) and selection of an RCE until after TEFCA is finalized.

4. **ONC should work with the RCE to enable a global patient consent mechanism.**

Patient consent is a crucially important aspect of TEFCA's success, but it can also impede information flow through inconsistent policies and implementation at the QHIN or 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. The RCE should be required to manage a global consent mechanism as a supplement, not a substitute, to the locally-managed consent mechanism already contemplated by TEFCA. This will enable patients to control their consent preferences at a global or specific level. In addition, it will protect against a potential loophole, as certain participants could create a de facto impediment to information sharing through local consent policies that may not align with patient preferences.

Finally, we note that the draft framework lays out an aggressive timeline for RCE selection, as well as finalizing the framework and implementation. As with countless other programs in the past we anticipate that, particularly given the areas where there are major gaps between today's environment and what TEFCA requires, the timeline as proposed will cause many participants to request delays as the deadline nears. Vendors and QHINs will need to devote significant resources to ensure the requirements around new uses cases for data contemplated in TEFCA can be met. We encourage ONC to heed lessons learned through the EHR certification program and establish a realistic and clear timeline now. Delaying the implementation late in the game is incredibly disruptive. It causes damage and waste in vendor development plans and furthers a pattern of eleventh hour delays on programs not ready for implementation. A clear and predictable regulatory environment and timeline is essential to the success of TEFCA.

Against the backdrop of these principles, we offer the following specific comments.

Specific Comments

Principle 6 - Data-driven Accountability
While athenahealth generally supports TEFCA and acknowledges the importance of data-driven accountability in transforming the healthcare system, we strongly urge ONC to remove principle 6 from the proposal. Congressional intent in the 21st Century Cures Act was to open up connectivity among health information networks; mandating bulk data transport goes far beyond that intent.

More importantly, the industry currently faces legitimate technical and logistical challenges in implementing this principle. As we noted in our comments above regarding the regulation of fees charged for individual access and public health, this is an area ripe for abuse that runs contrary to ONC's policy goals. As companies like Apple and Amazon are just beginning to enter the healthcare space, ONC should let the private sector continue to innovate around bulk data exchanges outside of this framework and consider including it in a later phase should legitimate barriers persist.

Alternatively, if ONC includes data-driven accountability in its final TEFCA, it should include more protections against abuse. While QHINs should not be able to blatantly block requests for bulk data transfers, they should be given wide latitude to de-prioritize such requests, determine what response time is reasonable given other higher-priority requests, and charge fair market value for these responses. These attributes of the information exchange market will ensure it continues to evolve and progress beyond today's status quo.

Part B – Minimum Required Terms and Conditions for Trusted Exchange

3. Standardization
The use of the Fast Healthcare Interoperability Resource (FHIR) standard for population health data mentioned in this section is inconsistent with ONC's approach elsewhere in TEFCA. ONC should align with other sections and not prescribe specific technology standards. The agency should defer to the private sector, through the ISA, to determine standards to fit each use case and continually evolve to remain flexible to ensure TEFCA does not slow or impede private industry progress.

4.3 Disclosures for Patient Safety, Public Health and Quality Improvement Purposes
It is not clear how Section 4.3 fits within the broader scope of TEFCA. More importantly, we believe that this exceeds the scope of what Congress intended ONC to undertake. The language references the requirement to share "information" for the enumerated purposes, but it is unclear what this information is expected to include or what information a QHIN may even possess that would fall into some of the categories. It also is not clear why a Participant would need to consider HIPAA obligations before sharing information for the purposes outlined in this section when the section only requires information sharing from QHINs to Participants.

While the draft TEFCA says that information is to be shared with "Participants and other entities described below," ONC needs to clarify who these other entities are. Is this meant to refer to "government agencies, accrediting bodies, patient safety organizations, or other public or private entities that are specifically engaged in patient quality or safety initiatives"? We encourage ONC to provide clarity and stay within the scope outlined by Congress to focus on the goal to improve and

promote information sharing networks and not attempt to tackle every use case for information sharing in healthcare.

It is appropriate to require QHINs to share information regarding security or patient safety with Participants. It is not appropriate to create a de facto government reporting requirement on QHINs for the information outlined in Section 4.3. We recommend that ONC significantly modify or remove this section of the Common Agreement.

5.2 Non-Discrimination

The private sector interoperability progress over the past few years is attributable to the growth of market forces for healthcare exchange. Additionally, under MACRA, clinicians are now increasingly measured on quality of care for a patient, regardless of where the patient has received care previously. There is a mutual interest in information sharing, and to ensure that these market forces continue to drive healthcare technology forward. Participants in TEFCA and end users must be able to charge for information exchange services to support organic market dynamics. The importance of the market for healthcare information exchange will prevent a situation where a single entity or individual requests all the QHIN data and is able to do so without incurring a fee. As stated in previous section comments, we believe this cost regulation is outside of the scope of TEFCA as Congress intended. It is important to avoid information blocking through excessive pricing models, but the government must exercise caution and avoid eliminating all business cases from existing in this model.

6.2.4 Identity Proofing

Identity proofing should occur at the vendor level and not with the individual user. It is an unnecessary administrative burden to require an end user, such as a clinician or patient, to create and hold individual credentials specific to a QHIN in addition to their credentials with an EHR vendor or other participating system with the QHIN. This is consistent with successful information sharing networks today. For example, a clinician does not have a CommonWell Health Alliance login; the ID proofing occurs between athenahealth and CommonWell to confirm identities.

6.2.5 Authentication

"Each Qualified HIN shall authenticate individuals at a minimum of AAL2, and provide support for at least FAL2 or, alternatively, FAL3."

ONC should clarify that QHINs can authenticate individual end users through the organization in which they participate. As we focus on improving usability and a clinician's experience within their EHR, it would be a step backwards to require multi-factor authentication on the individual user when the network–to-network interaction can more than adequately handle this requirement.

6.2.7 (i) Authorization Server Requirements

"Each Qualified HIN shall ensure that message exchanges are secured using TLS/SSL 1.2 X.509 v3 certificates for authentication, and X.509 certificates are used for authentication of all transactions."

To preserve the availability of future use cases and technology improvements, we suggest ONC make the selection of standards and technology part of the ISA and not prescribe specific technology in the TEFCA, which would limit the potential for future, iterative improvements. The ISA enables flexibility through the annual release and provides a mechanism for the private sector to collaborate to ensure industry-wide best practices are current.

6.2.7 (iii) Authorization Server Requirements

As stated in other sections, we strongly urge ONC to not prescribe technology standards in TEFCA, but rather refer to the ISA as a source of truth and living document that can be updated annually.

6.2.9 Policy Binding and 6.2.10 Auditable Events

To properly scale and implement the agreement, ONC should clarify that QHINs may meet the requirement of having a certificate authority via a third party. QHINs should not be required to create their own infrastructure. Instead, the RCE or other entity can house the certificate authority. As ONC intends for the TEFCA to be a single on-ramp for interoperability, a primary attribute will be to allow a third-party entity to store the certificates to lower the administrative burden on vendors and clinicians, increase the ease of implementation, and decrease barriers to entry to join and participate as a QHIN.

8. Data-driven Choice

As noted above, we strongly urge ONC to remove this section in its entirety. If retained, QHINs should be given much more latitude to limit responses due to lack of bandwidth. The 24-hour restriction is not reasonable for all requests.

9. and 10. Participant and End User Obligations

The breach notification provisions in sections 9.1.6 and 10.1.5 are too broad and do not reflect ordinary practice in existing private sector exchange frameworks. As written, these provisions would not be acceptable to a majority of QHINs and participants. We urge ONC to adopt the terms used by Carequality, which are available on their website.

As written, the breach provisions would require participants to notify QHINs of all breaches, regardless of nexus to the QHIN. Once the PHI is received by the Participant, reporting obligations are governed by relevant regulations, such as HIPAA and state data privacy laws, and by agreements (either business associate agreements or terms of use). Further, once PHI is received, in many instances it will be integrated into the clinical record and indistinguishable from PHI from other sources, making the breach provisions in Sections 9 and 10 impractical. Notification to QHINs should only be required when a breach occurs when information is being transmitted between Participants or QHINs.

We look forward to continuing to work with your office. Please do not hesitate to reach out for further discussion on our comments.

Sincerely,

Stephanie Zaremba
Director, Government Affairs
athenahealth, Inc.