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June 17, 2019

Dr. Don Rucker, MD
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C Street, SW
Washington, DC 20201

Re: Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2

Dear Dr. Rucker,

The American Academy of Ophthalmology, the Academy, is submitting our comments on the Office of the National Coordinator (ONC) Draft 2 of the Trusted Exchange Framework and Common Agreement (TEFCA). The American Academy of Ophthalmology is the largest association of eye physicians and surgeons in the United States. A nationwide community of nearly 20,000 medical doctors, we protect sight and empower lives by setting the standards for ophthalmic education and advocating for our patients and the public. We innovate to advance our profession and to ensure the delivery of the highest-quality eye care.

The Academy generally supports ONC's goals for the Trusted Exchange Framework, particularly the ability to provide physicians access to health information about their patients, regardless of where the patient received care. The Academy recognizes and appreciates ONC's efforts to create a single "on-ramp" for physicians and stakeholders, and the necessity to simplify processes to create nation-wide interoperability.

However, we would like to highlight several important questions that remain, and concerns about the downstream impact of the Framework on clinicians.

Provided below is an outline of the key points, comments and concerns as forwarded by the Academy regarding TEFCA Draft 2. <u>These comments are more fully developed in the body of this comment letter along with other issues and comments not highlighted in our summary</u>.

Executive Summary

We appreciate ONC's work to respond to concerns and develop TEFCA Draft 2. Here is a high-level outline of our thoughts on this draft of TEFCA:

Participation

- The Academy strongly urges ONC to address issues of physician choice and voluntary participation when evaluating the use of Trusted Exchange Networks (TENs) to facilitate payer-provider interoperability.
    - The Academy urges ONC to explicitly discourage Payers and other stakeholders from requiring TEN participation as a term of network contracts and to add language to TEFCA that explicitly protects clinicians from compulsory participation in a QHIN by Payers or other actors.
    - We would caution against requiring TEFCA participation as Sec. 4003 of the 21st Century Cures statue states that TEFCA is meant to be voluntary.

TEFCA Implementation

- The Academy seeks clarification on the pre-implementation testing of TEFCA.

Trusted Exchange Framework

- Cooperation and Non-Discrimination: The Academy applauds ONC's emphasis on eliminating information blocking and encourages ONC to ensure that it be easy for clinicians to switch to a new QHIN or HIN, both financially and functionally.
- Meaningful Choice: Given the constraints of HIPAA and issues with the data segmentation capabilities of many EHRs, we request that ONC specifically incorporate protections for those who cannot share queried data for these reasons.
- Population-Level Data: The Academy encourages ONC to work with QCDRs, such as the IRIS® Registry, as it considers this use case for future availability through TEF.

Minimum Required Terms and Conditions

- Fees: We urge ONC to consider the financial burden this may place on providers in reasonable fees in the MRTCs and other documents.
    - Not doing so may lead to further consolidation and cause small practices to return to paper charts to keep practice solvent and secure patient information.
- EHI Definition and Minimum Necessary Standard: We encourage ONC to narrow the definition of EHI to what is required under HIPAA and to make disclosure of the minimum necessary data as the default under TEFCA to protect patient privacy.
- Restriction on International Exchange: We agree with this restriction and request that ONC require any party receiving data under TEFCA be required to explicitly and clearly inform users when information will be used or analyzed in a foreign country so that a user may give true informed consent for this use case.
- Identification and Authorization: We ask that ONC provide technical assistance to help small practices participating in TEFCA establish inexpensive and reasonable cybersecurity measures to adapt to the breadth of information.
- Timeline to Update to Most Up-to-Date USCDI: We urge ONC to prioritize the USCDI expansion process while also following a transparent and collaborative process.
- Response to Requests for EHI: The Academy asks that ONC remove the requirement that Participant Members transmit a received confirmation of receipt of sent EHI.
- Compliance: The Academy strongly urges ONC to create a standardized compliance form for Participant Members rather than potentially having clinicians fill out multiple forms from each QHIN with which they interact.
    - We suggest that ONC investigate, with the RCE and QHINs, how compliance data can be pulled automatically from Participant clinical flow and EHR.

Detailed Comments of American Academy of Ophthalmology: Contents

I. Participation

The Academy strongly urges ONC to address issues of physician choice and voluntary participation when evaluating the use of Trusted Exchange Networks (TENs) to facilitate payer-provider interoperability. Due to the sensitive nature of electronic health information and the potential disruption to physician practices involved in implementing the required technology, the Academy would like to highlight the importance of ensuring that physicians understand and willingly elect to participate in information sharing via TENs.

We are specifically concerned about the impact this will have on practice viability and, thus, patient access to care. We note that 43 percent of US metropolitan areas have a single health insurer with a market share of at least 50 percent. Clinicians in these situations must either participate with that insurer or face significant financial burdens. This is particularly true in ophthalmology as many of our practices are small practices that operate on small margins and need to participate in most or all of the plans in their area. Without any bargaining power in these markets, the clinician must agree to the dominant insurer's terms of participation in a qualified health information network (QHIN) in TEFCA.

In this use case, it is clear that the clinician participant would join the QHIN unwillingly. Physicians who contract with multiple Payers may need to comply with multiple network requirements and take on costs and administrative burdens associated with each network. This would impose significant financial stress on small practices, and thus increase barriers to care as small practices are unable to afford to operate.

Moreover, by making clinicians mandated consumers of/participants in the TEF, ONC is propagating the same kind of artificial supply-demand relationship between QHINs/HINs and clinicians as was made between EHRs and clinicians under Meaningful Use, and it will likely result in similar unsatisfactory outcomes. By mandating the use of this technology, QHINs and HINs will be able to charge large fees to onboard with them and make it difficult to switch, thus functionally minimizing the ability of the market to drive improvement.

Our concern that Payers would compel participation seems to be well-founded. ONC directly encourages Payers to impose contractual requirements on physicians in their "Highlights for Payers" factsheet. **The Academy urges ONC to explicitly discourage Payers and other stakeholders from requiring TEN participation as a term of network contracts and to add language to TEFCA that explicitly protects clinicians from compulsory participation in a QHIN by Payers or other actors.**

Moreover, while the Academy believes it is important that the rules of the road for security and exchange are addressed and formalized, TEFCA has not been piloted and tested. **We would also caution against requiring TEFCA participation as Sec. 4003 of the 21st Century Cures statute states that TEFCA is meant to be voluntary.**

II. TEFCA Implementation

In the Cures Act, Congress requires ONC to consult with the National Institute for Standards and Technology (NIST) to test TEFCA:

> (iii) PILOT TESTING.—The National Coordinator, in consultation with the National Institute of Standards and Technology, shall provide for the pilot testing of the trusted exchange framework and common agreement established or supported under this subsection (as authorized under section 13201 of the Health Information Technology for Economic and Clinical Health Act). The National Coordinator, in consultation with the National Institute of Standards and Technology, may delegate pilot testing activities under this clause to independent entities with appropriate expertise.

Although ONC noted that it is collaborating with NIST to advance interoperability, no discussion of testing or testing plans was provided. **The Academy seeks clarification on the pre-implementation testing of TEFCA. Given the sheer number of variables and the scope of TEFCA, we strongly encourage ONC to collaborate with NIST to conduct rigorous testing of the Framework prior to implementation.**

III. Trusted Exchange Framework (TEF) Draft 2

A. Cooperation and Non-Discrimination

The Academy applauds ONC's emphasis on eliminating information blocking by prohibiting discriminatory exchange practices, particularly among and between business competitors. We also encourage ONC to ensure that it be easy for clinicians to switch to a new QHIN or HIN, both financially and functionally, in order to partially alleviate some of the issues that arise with solutions that are not market-driven.

B. Meaningful Choice

The Academy strongly agrees with ONC that a patient should be able to prevent or terminate the future exchange of their EHI. We are concerned, however, that, due to the lack of data segmentation capabilities of many EHRs, some clinicians are unable to send data electronically at a granular level. In the event that a clinician has sensitive data subject to a higher privacy standard (e.g., imposed by state law or by 42 CFR Part 2), clinicians may be unable to send electronic health information while still complying with applicable law, even if the data requested is not subject to a higher privacy standard. **TEFCA must specifically incorporate protections for those who cannot share queried data as a result of their EHR design, such that those clinicians are not in violation of the Common Agreement.**

Will reported violations be examined on a case-by-case basis to ensure that clinicians are protected from being required to provide inappropriate disclosures? If a Participant is found to be in violation of the Common Agreement, will there be a mitigation and appeals process?

C. Population-Level Data

The Academy appreciates ONC's recognition of the value to quality and care improvement of qualified clinical data registries (QCDRs). We also appreciate the encouragement ONC provides to QHINs to implement bulk transfer abilities to QCDRs as standards for this use case mature and become available. The Academy encourages ONC

to work with QCDRs, such as the American Academy of Ophthalmology IRIS® Registry (Intelligent Research in Sight), as it considers this use case for future availability through the TEF.

IV. Minimum Required Terms & Conditions (MRTCs) Draft 2

A. Fees

Under the Transparency section of Draft 2 of the MRTCs, ONC indicates that QHINs will have to make fee schedules available to the RCE. In the Cooperation and Non-Discrimination section of Draft 2 of the MRTCs, ONC lays out additional information about permissible fees:

> 5.2.1 Reasonable and Non-Discriminatory Fees. A QHIN must use reasonable and non- discriminatory criteria and methods in creating and applying pricing models if it charges any Fees or imposes any other costs or expenses on another QHIN. Nothing in these terms and conditions requires any QHIN to charge or pay any amounts to another QHIN.
>
> 5.2.2 No Fees for Individual Access Services. Notwithstanding anything to the contrary set forth in the Common Agreement, a QHIN may not charge another QHIN any amount for a QHIN Query or QHIN Message Delivery for the Exchange Purpose of Individual Access Services.
>
> 5.2.3 No Fees for Use or further Disclosure of EHI. A QHIN may not impose any Fee on the Use or further Disclosure of the EHI (including secondary uses) once it is accessed by another QHIN.

There is not a discussion on reasonable fees to charge clinicians. Clinicians acting as Participant Members in the TEFCA will not be able to charge patients for Individual Access Services or for sending information for treatment or payment. We would like to emphasize again that this has the potential to serve as a prohibitive barrier to small, rural, and independent clinician practices. Moreover, clinicians represent the only actor identified that cannot recoup the increased operating costs as physicians are paid on a fee schedule. **We are exceptionally concerned that increased financial burden on providers may lead to further consolidation and cause small practices to return to paper charts in order to keep their practice solvent and secure patient information.** We urge ONC to consider this in their implementation of the MRTCs.

B. Privacy and Security

i. EHI Definition

The Academy is a staunch advocate of interoperability and data portability; however, we are concerned about the implications of the definition of EHI used in this draft of TEFCA. The definition of EHI is exceedingly broad.

The shear breadth of information contained in the definition of EHI will complicate compliance with and enforcement of the TEFCA. We have already seen the consequences of requiring clinicians to exchange data without establishing

minimum necessary standards. Health care organizations will send everything to ensure they comply with the requirement to exchange.[1,2,3] This was the case under the Meaningful Use Program.

Clinicians may find it easier and feel safer (from an enforcement perspective) to simply disclose everything they have. The receiving physician then has to deal with the information overload – sifting through a mountain of information to find the few components that are relevant and important to patient care.

While we appreciate ONC's recognition of the conflict between the broad EHI definition and HIPAA with language reinforcing that HIPAA preempts TEFCA, it is a solution to a problem that does not need to exist and imposes significant burden on the clinician. Attempting to determine how much information to divulge so as not to violate HIPAA and face OCR enforcement or violate the MRTCs amounts to significant cognitive burden. Those who do make such determinations are required to create new policy and procedures. Both scenarios are a result of increased regulatory complexity that contradicts Congress' intent to reduce physician burden.

ii. Minimum Necessary Standard

The Academy is in favor of applying the minimum necessary standard of HIPAA to all Participants and Participant Members of TEFCA. We urge ONC to make disclosure of the minimum necessary data as the default under TEFCA to protect patient privacy. Specifically, the Academy requests that the Minimum Necessary Standard apply to all Participants and Participant Members and any non-contracted third-party applications that use the data on behalf of a patient.

iii. Restriction on International Exchange

The Academy agrees with the ONC decision to not permit QHINs to Use or Disclose EHI outside the United States, except to the extent that an Individual User requests his or her EHI to be Used or Disclosed outside of the United States. We agree that this is necessary to preserve the security and privacy of EHI sent, stored, maintained, or used by Participants and Participant Members while also preserving the rights of each individual with respect to that EHI. We request that ONC require any party receiving data from a trusted exchange under TEFCA be required to explicitly and clearly inform users when information will be used or analyzed in a foreign country so that a user may give true informed consent for this use case.

iv. Identification and Authorization

The Academy agrees with the use of two-factor or multi-factor authentication for requests from patients. We are concerned, however, about the use of vague language in

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[1] Dr. David Barbe, President-elect American Medical Association, *EHR Innovation and Problem-Solving: Physician Perspective*, 2016, available at: https://www.healthit.gov/sites/default/files/David_Barbe-Innovation_&_Problem-Solving.pdf.

[2] Reisman, Miriam, *EHRs: The Challenge of Making Electronic Data Usable and Interoperable*, P & T : a peer-reviewed journal for formulary management vol. 42,9 (2017): 572-575, available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5565131/.

[3] EHR Intelligence, *GAO: Lack of data standards foils EHR interoperability*, *HIE*, 2014, available at: https://ehrintelligence.com/news/gao-lack-of-data-standards-foils-ehr-interoperability-hie.

the MRTCs about the privacy and security requirements for Participant Members. Under the Participant Member Minimum Security Requirements, ONC states:

> To promote the confidentiality, integrity, and availability of EHI and minimize the potential for Breaches of EHI, each Participant Member shall be required to: (i) maintain reasonable and appropriate administrative, technical, and physical safeguards for protecting EHI; (ii) protect against reasonably anticipated impermissible Uses and Disclosures of EHI; (iii) identify and protect against reasonably anticipated threats to the security or integrity of EHI; and (iv) monitor compliance with such safeguards by its workforce. In determining which administrative, technical and physical safeguards to implement, the Participant Member shall consider the following: (i) its size, complexity, and capabilities; (ii) its technical, hardware, and software infrastructure; (iii) the costs of security measures; and (iv) the likelihood and possible impact of potential risks to EHI. Each Participant Member further shall review and modify such safeguards to continue protecting EHI in a changing environment of security threats within a reasonable period of time.

While we appreciate the recognition that the resources, both financial and technical, of practices vary, we urge ONC to ensure that this does not further burden small practices. We ask that ONC provide technical assistance to small practices that participate in TEFCA to help them to put in place inexpensive and reasonable cybersecurity measures to adapt to the new breadth of information exchange under TEFCA.

C. Timeline to Update to Most Up-to-Date United States Core Data for Interoperability (USCDI)

The Academy agrees that 18 months is a reasonable implementation timeline for updates to the USCDI. We ask ONC to allow exceptions for practices if their electronic health record (EHR) vendor is unable to meet this deadline. We are concerned, however, that the USCDI update process is not nimble enough to capture the information needed by all clinicians and public health stakeholders.

In the USCDI Proposed Expansion Process, proposed in January 2018, ONC laid out a data policy with three distinct data class statuses – "emerging," "candidate," and "supported." In the description of the process to move from emerging to supported, it is explicitly clear that it could quite easily take five or more years. While Health IT vendors can provide data beyond the required minimum, they have historically not gone beyond certification requirements. Therefore, the USCDI expansion process will likely delay the availability of crucial data elements for patient care or public health by five or more years.

The AAO urges ONC to prioritize the USCDI expansion process while also following a transparent and collaborative process. The accelerated addition of data classes and elements—along with additional context around these data (i.e., metadata)—is vital to meeting the goals of the Cures Act. **Immediately following the publication of its final rule, ONC should establish a formal USCDI submission, review, and validation process to ensure clinician perspectives are considered.**

D. Response to Requests for EHI

In Section 8.1.iv of the MRTCs, ONC lays out how a Participant Member must respond to requests to send EHI. This section states that a Participant Member must transmit a confirmation of receipt of sent EHI to the Participant that requested the Participant Member send the EHI. It also states that Participant Members must transmit confirmation of receipt messages to senders when they receive requested EHI. While the Academy understands that rationale for these requirements, we are concerned about the amount of additional administrative burden this will put on already over-burdened physicians. Doctors already spend an average of two hours in front of their EHR for every hour spent with patients.[4] This is time taken away from patient care. Because of this, the Academy asks that ONC remove the requirement that Participant Members transmit a received confirmation of receipt of sent EHI.

E. Compliance

Section 7.24 states that Participants shall require that Participant Members provide written documentation evidencing compliance on at least an annual basis for each QHIN. We agree that compliance is vital for this Framework to succeed, however, this requirement has clear potential to add additional administrative burden upon physicians. In addition to taking away from the time spent with patients, this requirement will add unnecessary costs to the health care system. We share the Administration's belief that a clinician's time and energy should be spent on patient care. Reducing administrative burden is an important goal of the Administration and of the Academy. Toward this end, the Academy strongly urges ONC to create a standardized compliance form for Participant Members rather than potentially having clinicians fill out multiple forms from each QHIN with which they interact. We also suggest that ONC should investigate, with the RCE and QHINs, how data for compliance can be pulled automatically from the Participant's clinical flow and EHR.

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We appreciate the opportunity to comment on the ONC Trusted Exchange Framework and Common Agreement Draft 2. If you have questions or need any additional information regarding any portion of these comments, please contact Dr. Jessica Peterson, MD, MPH, AAO Manager of Quality and HIT Policy at jpeterson@aao.org or via phone at 202-737-6662. Again, the Academy would like to thank you for providing us with the opportunity to comment and to work with ONC. We look forward to ongoing engagement and stakeholder input.

Sincerely,

Michael X. Repka, M.D., M.B.A.
AAO Medical Director for Government Affairs

[4] Sinsky C, Colligan L, Li L, Prgomet M, Reynolds S, Goeders L, Westbrook J, Tutty M, Blike G. Allocation of Physician Time in Ambulatory Practice: A Time and Motion Study in 4 Specialties. Ann Intern Med. 2016 Dec 6;165(11):753-760.