



Physicians Caring for Texans

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Posted to Comment Portal on ONC website: www.healthIT.gov

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

Dear Dr. Rucker,

On behalf of our nearly 53,000 physician and medical student members, the Texas Medical Association (TMA) thanks you for the opportunity to comment on the Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2.

TMA recognizes the challenges of exchanging health information and appreciates the work of ONC as it considers the perspectives of various stakeholders.

As usual, our first comments express overriding concerns that we ask ONC to consider as it revises the draft document.

- While we support the Office of the National Coordinator's (ONC's) desire to have only one "on-ramp" for physicians and other clinicians, TMA remains concerned about the interface connection costs and maintenance fees that electronic health record (EHR) vendors charge. ONC must recognize these barriers and work to remove them so the value of exchanging information is a significant positive for physicians rather than a negative or neutral activity.
- While we generally support ONC's desire to create a national interoperability system, we are troubled by the lack of equal support for the individual patient to be able to collect, maintain, and transmit his or her own information outside of this system. By ONC's placing emphasis on the TEFCA, physicians and other clinicians will have difficulty receiving medical information from patients who choose to not to use TEFCA because of trust, cost, or other issues. Indeed, there is a concern among a significant number of patients and physicians that letting third parties be the holder of health information will

create a layer of bureaucracy that will interfere with the patient-physician relationship. Recent massive data breaches at laboratory companies and other entities only encourage this thinking. There are also barriers beyond the technical and legal issues considered in this document. As an example, a hospitalist recently complained to one of our Health Information Technology (HIT) Committee members that he was not permitted to give copies of pertinent inpatient labs and x-ray reports to his patient so the patient could give the reports to his primary care physician and specialist for follow-up visits. Hospital policy was that the patient had to go to the Medical Record Department to get copies of the information, which, of course, would not be the focused information the physician could provide. While we understand the desire of the hospital to control release of information, these policies have a chilling effect on patients' ability to understand and manage their own data.

Keeping these overarching comments in mind, the following comments are matched with the page numbers and sections of the ONC document.

Page 6: Introduction

TMA suggests the following edits to the statement “trusted exchange is an important next step toward advancing the establishment of an interoperable health system that:

- “Empowers individuals to **safely and securely** use their Electronic Health Information to the fullest extent;
- “**Delivers high value to physicians, other clinicians, healthcare organizations, and communities** while enabling the delivery of smarter, safer, efficient, **and more effective care**; and
- “Promotes **high standards for data privacy and security for health information exchange while simultaneously promoting** innovation and competition at all levels.”

TMA believes that the privacy and security of electronic health information should always be considered at least a priority equal with shared exchange, because without privacy and security, shared exchange loses support. Additionally, while we strongly push the need to provide positive value to physicians and other clinicians, ONC must ensure that the value is such that all stakeholders feel motivated to participate.

Page 8: An “On-Ramp” for Data Exchange: Support nationwide scalability

TMA is concerned that the “network of networks” approach, tried without success in Texas, has several potential flaws that must be substantively addressed before it is implemented. These include:

- *Unproven ability to handle network volume:* It should be possible to simulate the traffic of global and targeted queries and the “push” of documents through the TEFCA infrastructure. ONC should commission a feasibility study for this before encouraging its development.

- *Impact of business failures or disconnection from the “network of networks” on information availability:* In Texas over the past decade, significant loss of medical information has occurred as health information exchanges (HIEs) failed. While most of the underlying data still exists in the EHRs of the participants and the information could be recreated, there was never a plan for how to move data from a failed HIE to its successor. ONC needs to develop a process so that information loss does not occur when entities fail in the TEFCA infrastructure. Switching needs to be done overnight and be cost-free for physicians, other clinicians, and healthcare organizations to guarantee that we continue to meet the requirements of the interoperable health care system.
- *Impact of the need to correct misinformation:* The TEFCA structure does not have a standard process for handling incorrect information in a patient’s record. As an example, one of our HIT Committee members had another patient’s record merged into his, with multiple incorrect allergies, medications, procedures, surgical history, and other errors. When this incorrect information is passed across the network, there needs to be a standard process in the TEFCA for completely removing it from all recipients once it is determined to be incorrect.
- *Lack of availability in disaster situations:* It is not clear how the TEFCA infrastructure would function in mass-disasters situations such as the multiple hurricanes that have hit the Gulf Coast in the past 15 years. ONC needs to model what will happen when one or more Qualified Health Information Networks (QHINs) and other parts of the network of networks are unavailable. Simply having a portion of the network go “dark” – i.e., information is not available – is highly risky for those whose information suddenly is inaccessible. Combining the TEFCA approach with a robust emphasis on patient-maintained records would be one way of addressing this issue.
- *Lack of standard data retention times:* While it might seem that each participating organization could offer different data retention periods, this will have the same effect as losing members and presenting partial health information. While some would say that partial information is acceptable, it also can be very unsafe.
- *Impact of potential instability in the Recognized Coordinating Entity (RCE):* Other industries that require RCEs have constructed a funding mechanism to support their RCE. The lack of industry agreement on funding in the health information industry portends either (a) perpetual government funding of the RCE or (b) periods of financial instability as the RCE attempts to secure funding. A similar situation has occurred in Texas with the Texas Health Services Authority, which has struggled to secure permanent funding.
- *Lack of adequate information management tools:* A “network of networks” will provide physicians and other clinicians with duplicate information as well as conflicting information in both broadcast and targeted queries because patients visit multiple physicians, particularly over time. Unless there are extremely sophisticated tools for handling this “data deluge,” physicians and other clinicians will be overloaded and disincentivized from using the TEFCA infrastructure. There needs to be the ability to send a message to a QHIN/Participant such as “don’t ever show me this information

again,” “combine this information with that information when it is sent the next time,” “this information is incorrect,” and “this is the wrong patient.” One of our physician HIT Committee members made the analogy that this process seems to be “like looking for a subject in the index of a book, where you have to read all the individual pages that reference this topic and then summarize the information by yourself.”

- *Lack of mechanisms to handle conflicts in meaningful choice.* Patients will move from QHIN to QHIN over time as they change where they get their health care. The TEFCA approach needs to have a mechanism for addressing changes in the patient’s request to opt out and opt in. Patients cannot be expected to know all of the different QHINs and organizations that have their opt-in/opt-out choices. TMA recommends that the most current meaningful choice decision should be communicated to all other participants so that if a patient opts in after previously opting out in another HIE, the patient’s information will not be blocked by the HIE that has the old choice.
- *Lack of clarity of costs to physicians and patients.* While the TEFCA approach discusses fees and places some limits as summarized in the table on page 20 of the Introduction, ONC provides no insight as to what the costs of the TEFCA approach will be for physicians or patients. TMA believes ONC should model the TEFCA process and develop rough cost estimates for its implementation and maintenance. In this effort, there can be simulations of how to spread the costs so that participants as a class, particularly physicians, know what they are getting into before they spend significant amounts on implementation. TMA wishes to caution ONC that building something before the ongoing costs are known only increases the risks of failure.
- *Impact on patient responsibility:* The continued focus on building networks for health information serves to reduce the need for patients to be responsible for their own information.
- *Ability for physicians and other clinicians to opt out.* ONC should make it clear that physicians and other clinicians are not required to participate in QHINs/HIEs or other parts of the TEFCA infrastructure if they do not find a net positive value in so doing. Similarly, no penalties should be placed on physicians who choose to opt out. That said, TMA believes that providing incentives for participation can shift the value proposition to encourage participation.

While there may be a desire to “just get something done” and to address these issues with future Common Agreement updates, TMA wishes to remind ONC of the numerous failed attempts at interoperability in the past. TMA believes it is extremely important to recognize the above as issues and to start addressing them *before* choosing an RCE and creating the TEFCA infrastructure. Failure of the TEFCA approach, which is possible, will further reduce physician belief that effective interoperability can be achieved.

Page 8: What are the Trusted Exchange Framework (TEF) and the Common Agreement?

In the explanation of the TEFCA, it is stated that “ONC will have final approval of the Common Agreement and all subsequent updates.” TMA believes that the ONC should either be the RCE

or it should cede final approval of Common Agreement updates to the RCE, with processes to ensure that the updates are appropriate. By requiring the RCE to gain ONC approval of updates, ONC is like a parent that refuses to give responsibility to its child. The industry will realize the real power is in the ONC and will fail to respect the activities of the RCE. TMA contends that if ONC insists upon retaining final approval, it is highly likely the RCE will fail.

Pages 10-11: Recognized Coordinating Entity

In our comments on the first draft of TEFCA, TMA expressed concern at the idea of the RCE and that it would add a layer of bureaucracy and potentially stifle progress and innovation. ONC is indicating it will proceed with the RCE, and TMA appreciates that ONC understands the need for an entity that is not for profit, neutral, broadly transparent, free of conflicts of interest, and can ensure a level playing field for all stakeholders.

Page 13: QHIN Message Delivery

TMA strongly supports the addition of QHIN Message Delivery to the Minimum Required Terms and Conditions (MRTC). This has value especially with transitions of care. We anticipate that Direct messaging will be the backbone of this, at least initially. If so, TMA recommends that the TEFCA process include elements listed in the DirectTrust paper, “Feature and Function Recommendations to the HIT Industry to Optimize Clinician Usability of Direct Interoperability to Enhance Patient Care” www.directtrust.org/wp-content/uploads/2017/03/WhitePaper_Final_03.16.2017.pdf.

Page 14: Exchange Purposes

ONC requested comments on the exchange purposes. TMA supports these but recommends that ONC develop a list of, and work plan for addressing, known future exchange purposes prior to choosing the RCE and creating the TEFCA infrastructure. Having a roadmap, albeit imperfect, is far more likely to encourage participation than joining something where it’s not clear how it will evolve.

Page 17: Meaningful Choice and Written Privacy Summary

The MRTC Draft 2 requires that QHINs, Participants, and Participant Members provide Individual Users with the opportunity to exercise meaningful choice to request that their electronic health information (EHI) not be used or disclosed, except as required by applicable law. In general, TMA supports this concept, but TMA recommends that the MRTC have a provision for handling cases where the patient inappropriately chooses to hide information that is critical to the care of the patient or others. While forced disclosure of the health information is not appropriate except where required by law, physicians and other clinicians need to know the patient is not disclosing information that may be needed. An example would be if the patient is pregnant and is about to undergo an imaging study but chooses to hide the pregnancy from the radiologist. Giving physicians and other clinicians a clue that important information is not being disclosed provides an intermediate step that improves safety without a significant impact on patient privacy.

Page 18 – Security Labeling

ONC is considering requirements that special “security” labeling for privacy should be applied at the highest (document or security header) level for:

- Any EHI containing codes from one of the Substance Abuse and Mental Health Services Administration (SAMHSA) Consent2Share sensitivity value sets for mental health, HIV, or substance use in the Value Set Authority Center; and
- Any EHI of patients considered to be minors.

TMA supports the concept of security/privacy labeling, but the recommendation to label information from minors is overly broad and invites discrimination against minors. For example, some health care organizations turn off access to patient portals once a child reaches 12 or 13 years old. If privacy tagging is not at the discrete data level (rather than at the document or security header level), this issue cannot be addressed. Also, note that a sodium value from an infant in the neonatal intensive care unit does not require tagging.

Page 27 – Principle 2 (C) (4) – Publish, keep current, and make publicly available the HIN’s privacy practices.

TMA agrees with ONC that Health Information Networks (HINs) should provide a method by which individuals can exercise meaningful choice regarding the exchange of EHI about them and ensure such choice is honored. However, TMA further recommends that ONC should require that patients have the assurance that all data within the QHIN and other Participants’ databases are removed when patients opt out. Along this same vein, all future requests regarding that patient should state that the patient has opted out of the system. This information notifies physicians and providers of the patient’s status, and provides an opportunity to discuss the benefits of information sharing. TMA believes it is not appropriate for QHINs and other Participants to retain data of patients who have chosen to not participate. ONC correctly notes that exercising meaningful choice should be consistent with applicable law. For example, treating physicians should be able to retain as part of the patient’s medical record salient records received from another physician or a health care provider involved in the care or treatment of the patient.

Principle 5. Page 30 (Deletion from Draft 1)

TMA notes that Draft 1 included section B, “Have policies and procedures in place to allow a patient to withdraw or revoke his or her participation in the qualified HIN.” This section is no longer included in Draft 2. TMA implores ONC to reinstate section B of Principle 5.

Page 49 – Breach Notification

ONC states that “QHINs shall notify, in writing, the RCE and the following to the extent that they are affected by the Breach: other QHINs, Participants, Participant Members, and Individuals with whom the QHIN has a Direct Relationship.” TMA wants to ensure this means that when a QHIN breach occurs that affects patients in a physician practice, the QHIN is not allowed to shift

the responsibility for patient notification onto the physician. The responsibility for notification of those patients needs to be on the QHIN. Today this can and should be addressed in business associate agreements, so perhaps this should be part of the agreement between participating physicians and their QHINs, but this requirement should be made clear in the TEFCA regulations.

Page 49 – Withdraw Consent

Section 6.1.4, Other Legal Requirements, requires QHINs to have procedures in place for patients to withdraw consent, which we certainly want. TMA believes this would be clearer if the right to withdraw consent was also added on page 68 in the Individual Rights and Obligations section.

Page 51 – Identity Proofing

Aligning the process for identity proofing with existing identity proofing processes/entities (i.e., electronic prescribing of controlled substances) would reduce physician burden.

TMA needs more information on how identity proofing of individuals would occur. We understand the concept of “legal photographic identification cards” and “insurance cards,” but we are not clear on the meaning of “comparison to information from an electronic health record (EHR) containing information entered from prior encounters.” ONC needs to provide further explanation of this before TMA can support it as an option.

Page 84-86 – Patient Identity Resolution

ONC Request for Comment #7: The IHE XCPD profile only requires a minimal set of demographic information (i.e., name and birth date/time). Should QHINs use a broader set of specified patient demographic elements to resolve patient identity? What elements should comprise such a set? TMA recommends that ONC investigate allowing patients to require that requests have a voluntary universal identifier known only to the patient and an issuing organization that does not keep demographic information. Essentially this would function as a personal passcode. This will permit patients to control access to their record rather than permitting access through demographic matching, which can result in errors.

ONC Request for Comment #8: There are many possible approaches to Patient Identity Resolution, each with its own benefits and risks. ... should the QTF specify a single standardized approach to Patient Identity Resolution across QHINs? TMA believes the QHIN technical framework (QTF) should not designate a single, standardized approach to patient identity resolution. As the question points out, various levels of privacy risks are associated with any approach, and safer approaches will come through innovation. Robust guidelines would serve better than a single, standardized approach.

Page 85/86 – Directory Services

ONC Request for Comment #11: Should the QTF require QHINs to implement Directory Services? Recognizing there are many possible approaches for implementing Directory Services, should the QTF specify a single standardized approach? If QHINs implement Directory Services, which entities should be included in directories? Should directories be made publicly accessible? TMA has previously stated its support for a private statewide (Texas) physician and other clinician directory. It is difficult to conceive of an effective message delivery system that does not have such a directory. TMA is not supportive of exposing physician directories to the public, as the opportunity for spam and “fake health information” increases with exposure regardless of whether Direct is used or not. It is not important that there be a single approach as long as the directories can talk with each other (much like the ability to place a phone call across carriers).

TMA appreciates the opportunity to provide input on TEFCA Draft 2. Any questions may be directed to Shannon Vogel by emailing shannon.vogel@texmed.org or calling (512) 370-1411.

Sincerely,



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President
Texas Medical Association