

June 17, 2019

Dr. Donald Rucker
National Coordinator for Health Information Technology
Office of the National Coordinator
U.S. Department of Health and Human Services
Mary Switzer Building; Mail Stop: 7033A
330 C ST SW
Washington, D.C. 20201

RE: Draft Trusted Exchange Framework and Common Agreement (TEFCA)

Submitted electronically to exchangeframework@hhs.gov

Dear Dr. Rucker:

The Indiana Health Information Exchange, Inc. (IHIE) is pleased to offer the following comments in response to the Trusted Exchange Framework Draft 2, published on April 19, 2019 by the Office of the National Coordinator for Health Information Technology.

IHIE is a 501(c)(3) corporation founded in 2004 as a health information exchange that enables health service providers to deliver faster, more efficient, higher quality healthcare to patients in Indiana. IHIE operates the Indiana Network for Patient Care (INPC), one of the nation's largest interorganizational clinical data repositories, with more than 12 billion clinical data elements from more than 140 healthcare organizations including Indiana hospitals, physicians, payers, laboratories, long-term care facilities and imaging centers. IHIE is also a founding member of the Strategic Health Information Exchange Collaborative (SHIEC) and participates in SHIEC's Patient Centered Data Home™ (PCDH) Initiative.

Below, please find our comments and recommendations as organized into the following sections:

- I. Overview
- II. General Comments and Recommendations

I. OVERVIEW

IHIE recognizes and commends the efforts of the Department of Health and Human Services (HHS); Office of the National Coordinator for Health Information Technology (ONC); and its partners in developing the Trusted Exchange Framework and Common Agreement (TEFCA) to advance interoperability among health information networks (HINs) and health care providers.

We recognize and appreciate ONC's revisions in TEFCA Draft 2 in response to public feedback and recommendations to TEFCA Draft 1. Some notable examples include:

- Broadening the definition of which stakeholders are eligible to become a Qualified Health Information Network (QHIN).
- Updating the proposed QHIN application process to include a provisional period for testing and surveillance prior to official onboarding.
- Including the QHIN Technical Framework (QTF) to separate specific standards and requirements for incorporation into the Common Agreement.
- Extending the timeframe for QHINs to update agreements and technical requirements from 12 months to 18 months.
- Adding QHIN Message Delivery (Push) and removing the requirement for "Population Level" query.
- Narrowing the Exchange Purposes to include a subset of those defined in TEF 1.

ONC specifically requested comments and recommendations regarding TEFCA Draft 2. IHIE strongly supports leveraging existing health information networks as a policy and technology foundation to advance nationwide scalability, connectivity, and enable electronic health information to securely follow patients without disrupting existing health information networks. IHIE is however deeply concerned that the proposed TEFCA framework will disrupt and setback the last decade of private-public partnerships and create unnecessary regulatory and operational barriers resulting in unfavorable and unfair marketplaces for health information exchanges to compete. In summary we recommend:

- All reasonable efforts should be made to not disrupt existing health information networks, including drafting a sufficiently flexible Common Agreement that accommodates existing health information network participation agreements.

- All entities connecting and exchanging electronic health information through TEFCA should be subject to the same privacy and security requirements, enforcement actions, and penalties.
- Allowing Participants to initially select which Exchange Purposes it can perform in order to accelerate TEFCA participation. Alternatively, allow the RCE to designate required and elective Exchange Purposes.
- Adopting a phased implementation for all current and future Exchange Purposes.
- Permitting exchange services that operate independently of TEFCA and outside the Common Agreement.
- ONC should avoid using TEFCA to duplicate policy objectives of recently proposed information blocking prohibition regulations. This includes both the duty to exchange and determination of reasonable fees. All defined terms under TEFCA should align with complementing and applicable regulations.
- Creating safeguards between QHINs and Participants to assure competitive and fair marketplaces.

We encourage ONC to continue its efforts to engage its stakeholders in the revision process to finalize and implement TEFCA. The Indiana Health Information Exchange respectfully submits the attached TEFCA Draft 2 comments and recommendations for ONC's consideration.

Thank you for the opportunity to provide comments. If you would like any additional information, please contact me directly at jkansky@ihie.org or 317-644-1723.

Sincerely,

A handwritten signature in black ink, appearing to read "John P. Kansky", with a long, sweeping horizontal line extending to the right.

John P. Kansky
President and CEO

Indiana Health Information Exchange

II. GENERAL COMMENTS AND RECOMMENDATIONS

IHIE strongly supports ONC leveraging existing health information networks as a policy and technology foundation to advance nationwide scalability, connectivity, and enable Electronic Health Information (EHI) to securely follow patients and submit the following TEFCA Draft 2 comments and recommendations.

PROMOTE EXISTING HEALTH INFORMATION NETWORKS TO PRESERVE EXISTING VALUE.

We strongly support ONC's commitment and focus to align TEFCA with the 21st Century Cures Act (Cures Act). The Cures Act guides TEFCA to, "*take into account existing trusted exchange frameworks and agreements used by health information networks to avoid the disruption of existing exchanges between participants of health information networks.*" ONC should whenever possible, without materially compromising stated TEFCA principles, avoid disrupting existing health information networks.

ONC can promote existing health information networks, especially in the early stages of TEFCA, by preserving existing health information networks' participation agreement terms and conditions. As TEFCA is voluntary, QHINs, Participants, and Participant Members have limited power to compel revisions and renegotiate existing participation agreements. ONC should authorize practices, like mapping comparable terms and conditions from existing health information network participation agreements to the Common Agreement, to minimize the need to revise and renegotiate all prior agreements.

1. **RECOMMENDATION:** For health information networks seeking to become TEFCA Participants, we recommend ONC expressly allow a QHIN to review a health information network's existing participation agreement for material compliance with the Common Agreement. If the existing participation agreement materially aligns with the Common Agreement, this should be sufficient to satisfy the Common Agreement.

If a Participant disagrees with a QHINs review of an existing participation agreement, a Participant may appeal to the RCE for resolution. By allowing existing participation agreement terms and conditions to be mapped to the Common Agreement ONC is significantly reducing the administrative burden on existing health information networks, incentivizing TEFCA participation, and accelerating TEFCA adoption.

FLEXIBLE AND PHASED IMPLEMENTATION FOR EXCHANGE PURPOSES AND EXCHANGE MODALITIES ENCOURAGES VOLUNTARY TEFCA ADOPTION AND ACCELERATES PARTICIPATION.

We agree with ONC's emphasis on Exchange Purposes and Exchange Modalities to increase EHI use and access between existing health information networks. We also agree with ONC's decision that the full Payment and Health Care Operations Exchange Purposes are initially too burdensome to implement and support ONC's direction to adopt a more limited subset of activities in Payment and Operations. By providing flexibility in selecting and implementing Exchange Purposes, including limited subsets, ONC would incentivize voluntary adoption of TEFCA and minimize disruption to existing health information networks.

2. RECOMMENDATIONS:

- a) We strongly encourage the Common Agreement require QHINs to accommodate all current and future Exchange Purposes and Exchange Modalities.
- b) We also strongly encourage ONC to weigh the benefits of allowing Participants to adopt only those Exchange Purposes a Participant elects. Many existing health information networks already provide some of the Exchange Purposes, but few perform all of the Exchange Purposes.

For example, some private payor health information networks have capabilities to exchange EHI for certain Payment purposes, but not Operations, Treatment, Individual Access, or Public Health. TEFCA should emphasize all reasonable means for inclusivity, not exclusivity, of networks, even if a health information network only performs a limited subset of Exchange Purposes.

- c) Alternatively, if ONC disagrees with permitting Participants to only elect those Exchange Purposes it is best positioned to perform, ONC can designate "Core Exchange Purposes" and "Menu Exchange Purposes." Providing the ability to choose between Core and Menu Set objectives contributed to the wide spread adoption and participation of the Promoting Interoperability (previously Meaningful Use) Program.

We suggest ONC adopt a similar "required" and "elective" approach for Exchange Purposes. ONC can empower the RCE to designate Core Exchange Purposes that all Participants must exchange, and optional Menu Exchange Purposes, which more specialized or advanced health information networks can elect to perform. As health information networks adjust, Menu Exchange Purposes can be reclassified as Core Exchange Purposes.

We support the flexible approach ONC is adopting in adjusting the implementation of anticipated initial Exchange Purposes and encourage ONC to apply it to all Exchange Purposes. ONC emphasizes that it “*intends to phase in new exchange modalities and Exchange Purposes in the Common Agreement to support additional uses cases.*” We encourage a phased implementation, but not for just new uses cases, but also for Exchange Purposes and Exchange Modalities.

3. RECOMMENDATIONS:

- a) **If ONC elects to require that Participants must accommodate all Exchange Purposes or a limited Core Exchange Purpose subset, participation in TEFCA is more practical and achievable to existing health information networks if ONC permits phased Exchange Purpose implementations.**

For example, many existing health information networks can exchange for Treatment purposes, but others such as Public Health and Individual Access Services are more challenging (please see comments below) and will demand increased financial commitments and development resources. ONC both encourages participation in TEFCA and promotes existing health information networks by allowing Participants to implement Exchange Purposes over an agreed upon timeframe.

- b) **The Common Agreement should permit QHINs sufficient authority to work with Participants to prioritize Exchange Purposes implementation over an agreed upon timeframe.**

We understand the need for and support the development of the Individual Access Services as an Exchange Purpose. To date, existing health information networks have focused on exchanging EHI between health care providers and, besides limited patient portals, Individual Access Services are limited. Accordingly, developing and implementing the Individual Access Service Exchange Purpose will be significantly more challenging to QHINs, Participants, and Participants Members and we encourage ONC to explore recommendations to minimize the burden of the adoption of Individual Exchange Services.

4. RECOMMENDATIONS:

- a) **Classify Individual Access Services as an elective “Menu Exchange Purpose” with the intent that within an ONC designated timeframe, Individual Access Services become a “Core Exchange Purpose.”**
- b) **Alternatively, allow QHINs, Participants, and Participant Members to postpone implementation of the Individual Access Service Exchange Purpose until after other more easily implemented Exchange Purposes are widely adopted. This**

enables QHINs, Participants, and Participant members to develop and establish best practices with other organization and learn from prior Exchange Purposes implementations.

TEFCA SHOULD ENCOURAGE THE INNOVATION OF ADDITIONAL SERVICES OUTSIDE THE COMMON AGREEMENT.

ONC indicates its support for exchange modalities and services outside the TEFCA noting *“QHINs, Participants, and Participant Members are in no way limited from voluntarily offering additional exchange modalities and services or from entering into point-to-point or one-off agreements between organizations that are different from the Common Agreement’s MTRC provided that such agreements do not conflict with the policies of the Common Agreement.”*

- 5. RECOMMENDATION:** ONC should clarify whether it intends an exchange modality or service provided by a TEFCA participant outside of TEFCA must comply with the Common Agreement. We strongly encourage that exchange modalities and services outside the TEFCA may, but are not required to, align with the Common Agreement.

For example, some health information networks include data co-operatives for research organizations that operate under a Data Governance Policy. The Data Governance Policy limits use cases, including new use cases, to those which are permitted by members voting. These use cases may be more or less restrictive than TEFCA. If the agreements for the data co-operatives must comply with the Common Agreement, the value of the data co-operatives is significant diminished and TEFCA adoption discouraged.

TEFCA SHOULD NOT DUPLICATE OR CONFLICT WITH PROPOSED INFORMATION BLOCKING PROHIBITION REGULATIONS.

ONC in TEFCA Draft 2 states that *“QHINs, Participants, and Participant Members have a duty to respond to all requests for EHI they receive for any of the Exchange Purposes with the EHI they have available.”* This duty to respond is similar, but not identical, to the objectives of the recently proposed information blocking prohibitions which state that health information networks cannot knowingly, or should not knowingly, engage in a practice that is likely to interfere with prevent, or materially discourage access, exchange or use of EHI. Separate duties under TEFCA and information blocking exceptions to respond to EHI requests, especially as the information blocking prohibitions includes exceptions, create unnecessary regulatory barriers and discourage TEFCA participation.

6. **RECOMMENDATIONS:**

- a) We recommend ONC make the obligation that a QHIN, Participant, or Participant Member must respond to all requests for EHI received through an Exchange Purposes expressly subject to and in alignment with the information blocking prohibitions and exceptions.
- b) QHINs, Participants, and Participant Members will significantly benefit from further discussion and guidance regarding acceptable responses to a TEFCA Exchange Modality if an information blocking exception applies (e.g. privacy and security, patient safety) to the transmission.
- c) We also suggest that ONC not adopt TEFCA participation as a safe harbor from an information blocking enforcement.

ONC also proposed in TEFCA Draft 2 that “*fees and other costs should be reasonable and should not be used to interfere with, prevent, or materially discourage the access, exchange, use or disclosure of EHI within a HIN or between HIN.*” The ONC has also proposed specific requirements regarding permissible and reasonable fees in the information blocking regulations.

7. **RECOMMENDATION:** We recommend ONC provide further guidance regarding the application of any reasonable fee requirements under TEFCA Draft 2 and similar requirements under the information blocking prohibition. TEFCA adoption is discouraged if a fee is unreasonable and impermissible under one set of regulations (e.g. TEFCA), but acceptable under alternatively and equally applicable regulations (e.g. information blocking regulations).

Currently, health information networks face a growing regulatory framework to assure privacy, security, and proper access to EHI. In addition to TEFCA Draft 2, this framework includes HIPAA and the Cures Act as well as newly proposed regulations including the *Interoperability, Information Blocking and the ONC Health IT Certification Program*, and the *Interoperability and Patient Access Proposed Rule*.

8. **RECOMMENDATION:** As commentary for each of these proposed regulations continue to be reviewed, we encourage ONC work in concert with other federal agencies to align common terms and cross reference as necessary. For example, material terms and concepts such as “electronic health information,” “use,” “access,” and “disclosure” as well as “actor” and “health information exchange” should be consistent across common regulations.

REQUIRE AND ALIGN PRIVACY AND SECURITY FOR ALL ENTITIES CONNECTED TO THE TRUST EXCHANGE FRAMEWORK.

The privacy and security of EHI is paramount to TEFCA adoption and patient confidence. TEFCA Draft 2 includes the goal to enable EHI to securely follow the patient when and where it is needed. To meet this goal, we strongly encourage the Common Agreement subject all entities that the exchange EHI to be subject to not just the same privacy and security requirements but also the same penalties and enforcement action as the QHINs, Participants, or Participant Members who are covered entities and business associates under HIPAA.

For example, it is likely that third party application developers may create patient facing applications that enable an Individual Access Services request to QHINs, Participants, or Participant Members. Such third-party application developer should be subject to the same prohibitions on selling or reusing EHI it retrieves on behalf of the individual as the providers who exchange the EHI for permitted purposes.

9. **RECOMMENDATION:** All entities that connect to or exchange EHI as part of TEFCA should be subject to the same minimum privacy and security requirements, enforcement actions, and penalties.

QHIN-PARTICIPANT SAFEGUARDS ENCOURAGE COMPETITIVE MARKETPLACES.

We strongly agree with the safeguards ONC proposed with respect to the RCE selection and operations. Specifically, to avoid conflicts of interest, ONC intends to require the RCE to meet and maintain certain independence criteria through the term of the Cooperative Agreement, such that once an applicant is awarded to be the RCE it may not be affiliated with a QHIN as long as it is the RCE. ONC should establish similar safeguards for QHINs.

Participants are discouraged from participating in TEFCA if it must both contract with a QHIN to exchange EHI, but also compete with the same QHIN on service offerings to Participant Members. For example, a Participant must make available certain intellectual property assets and data to QHINs about service offerings performed for Participant Members in order to obtain QHIN services. If the QHIN can also sell its own competing Exchange Purpose services to the Participant Members, then QHINs have a significant and unreasonable competitive advantage over the Participant.

10. **RECOMMENDATION:** We would encourage that ONC explore similar safeguards for QHINs and Participants that exist for QHINs and the RCE. Specially the need for protections to prevent the QHIN from an unfair competitive advantage in the marketplace.