Comments of
Richard Gibson, MD, PhD
In response to

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Comments on Proposed Trusted Exchange Framework and
Common Agreement Draft 2

Submitted June 17, 2019

Richard Gibson, MD, PhD, President of the Health Record Banking Alliance (HRBA), offers his own comments in response to Draft 2 of the Trusted Exchange Framework and Common Agreement (TEFCA2).[1] These comments are his own and may not reflect the consensus of HRBA, who submitted comments separately.

In general, I believe that ONC has greatly assisted patients in its proposed rule to make an electronic copy of the patient's record available to the patient at no charge. In addition to USCDI for 2019, the C-CDA R2.1 Implementation Guide, and FHIR APIs that correspond to C-CDA document templates, sections, and entries, ONC has called for the new concept of EHI Export accompanied by an Export Format Document to advise the receiver how to make sense of the EHI Export. I believe that while we wait for national standards to extend from C-CDA and FHIR to cover more of the EHI Export, patients and their trusted third-party applications will be able to start to create value from managing the EHI Export. The export will launch an innovative new industry that promises to benefit patients and their families.

The Cures Act calls for putting patients at the center of healthcare and ONC has advanced that cause. I think that TEFCA2 spends too much time trying to support the existing HIE infrastructure when the many-to-many scattered model has not worked. It would be better to center the healthcare record about the patient so that each new provider has exactly one place to go to find out the patient's prior care and the patient's wishes for future care. With relatively small changes to the current EHR Certification requirements, patients could sign up once with each new provider they see and give them their personal health record (PHR) address. The patient establishes their identity with each provider once and makes their request once for ongoing transmissions, and then updates are automatically sent to the patient each time the EHR receives new data on the patient.

The patient is then in control of their record and who sees their record. Without disrupting the certificate of authenticity and integrity of professional records received from providers, a PHR allows the patients to make comments suggesting corrections or additions to their record. The patient's family can have proxy access to the record with the patient's permission, so that the PHR can tell the patient's complete story when the patient is unable to give his or her history himself or herself. The patient can purchase apps that run against their PHR to give them advice

[1] Accessed at https://www.healthit.gov/sites/default/files/page/2019-04/FINALTEFCAQTF41719508version.pdf .

if they choose. The patient can make their records available to research. Further, PHRs are a great place for the patient to store their healthcare and end of life preferences, medical images, genomic information, data from personal devices, and data they enter into apps on their mobile phones. You would never trust a jet liner whose partial service history was kept separately at each airport facility that had worked on it – you expect that all records of service to that airplane are kept in one comprehensive, lifetime, unified record maintained in one place. Why should healthcare records be any different?

Personal Health Records render Broadcast Queries unnecessary. Prior interoperability efforts suggest that Broadcast Queries will be unworkable. Such queries will be a substantial burden on providers and their EHRs. I appreciate ONC exempting Participants that provide Individual Access Services from having to respond to Broadcast Queries. I also think that Broadcast Queries send too much personal data to too many unnecessary recipients.

Detailed comments on parts of the TEFCA2 text follow.

Conclusion

I appreciate all the efforts that ONC has made over the last two years to put patients at the center of healthcare. I look forward to continuing to work with ONC in this important effort.

Respectfully submitted,

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(But reflecting his own comments in this document)

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Text: Individual Users: An Individual User represents an actual person who is the subject of the EHI, such as a patient, health plan member, or a patient representative. Individual Users may have a Direct Relationship with the QHIN, Participant, or Participant Member, depending on the structure of the QHIN to which they belong, but they are not themselves considered Participants or Participant Members.

Gibson Comments: I agree with calling out Individual Users separately from Participants or Participant Members because they are the subject of the electronic health information (EHI) and their needs must be kept front and center. I believe this Exchange Purpose is crucial to patients understanding and being engaged in their care.

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Text: However, commenters expressed concern regarding the relative maturity of Population-Level Data Exchange. While important for modern health care delivery and to the Cures Act's long term goals for quality measurement, risk analysis, research, and public health, the industry is still working to mature this use case in a network exchange context. Therefore, this use case has been removed from the MRTCs.

Gibson Comments: I agree with removing the Population-Level Data Exchange from the requirements as this use case is not yet mature.

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Text: Additionally, ONC received a number of requests from commenters to include a "push-based" exchange modality in the TEF and the Common Agreement. Commenters noted that push transactions play a vital role in supporting transitions of care and public health use cases and would be necessary to fully support required Public Health reporting. Therefore, ONC has included QHIN Message Delivery, which supports instances where a QHIN sends EHI to one or more QHINs for delivery.

Gibson Comments: I applaud ONC for including the push-based QHIN Message Delivery modality in the Trusted Exchange Framework because it covers so many important exchanges of data for patient care, such as an emergency department pushing a summary of care document to the patient's primary care provider.

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Text: The Exchange Purpose described as Individual Access in TEFCA Draft 1 has been modified to Individual Access Services, which includes the HIPAA Privacy Rule right for an individual to view or obtain a copy of his or her Protected Health Information from Covered Entities. The Individual Access Services Exchange Purpose now includes a corresponding requirement for non-HIPAA entities that elect to participate in the Common Agreement.

Gibson Comment: I agree that if a non-HIPAA entity chooses to become part of a QHIN, that it should provide Individuals with access to their data in a manner similar to providers and other HIPAA-covered entities. Such a regulation promotes service consistency when patients and families request their health records.

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Text: The Cures Act emphasizes the need to improve patients' access to their EHI. Many non-HIPAA entities, such as developers of smartphone apps, offer useful and efficient services to individuals who elect to use them as a means to access their EHI. These services allow individuals to play a greater role in managing their own health and shopping for coverage or care. It is essential that individuals have trust in these organizations and the use of these technologies that can ultimately enhance the quality of their care.

Individuals, health care providers, health plans, and networks may not be willing to exchange data through the Common Agreement if smartphone app developers and other non-HIPAA entities present privacy or security risks because they are not obligated to abide by the HIPAA Rules. In order to meet the goals of the Cures Act as well as to help address these concerns and encourage robust data exchange that will ultimately improve the health of patients, the Common Agreement requires non-HIPAA entities, who elect to participate in exchange, to be bound by certain provisions that align with safeguards of the HIPAA Rules. This will bolster data integrity, confidentiality, and security, which is necessary given the evolving cybersecurity threat landscape.

Federal agencies that are not subject to HIPAA may elect to be a Participant or Participant Member. In these instances, such agencies would not be required to comply with the HIPAA Rules referenced in the Common Agreement. However, they must comply with all privacy and security requirements imposed by applicable federal law.

Gibson Comments: If such apps join the Common Agreement, I believe that they should conform to the same regulations as all other parties that join the Common Agreement. Such consistency will promote trust and confidence in the national network of health information exchange.

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Text: Principle 1 — Standardization: Adhere to industry and federally recognized technical standards, policies, best practices, and procedures.

A. Adhere to applicable standards for EHI and interoperability that have been adopted by the U.S. Department of Health & Human Services (HHS), approved for use by ONC, or identified by ONC in the Interoperability Standards Advisory (ISA).

HINs should adhere to federally adopted standards for EHI and interoperability. Specifically, HINs should first look to use standards adopted by HHS, then those approved by ONC through the proposed standards version advancement process as part of the ONC Health IT Certification Program (Certification Program), and finally, those identified in the ISA. In instances where none of the above references include applicable standards, HINs should then consider voluntary consensus or industry standards that are readily available to all stakeholders, thereby supporting robust and widespread adoption. Consistent adherence to these standards will ensure improved usability and access to EHI.

Gibson Comments: I agree with the adherence to federal standards in the hierarchy ONC has proposed.

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Text: Principle 2 — Transparency: Conduct all exchange and operations openly and transparently. C. Publish, keep current, and make publicly available the HIN's privacy practices.

Ensuring that participants of HINs understand the privacy practices of each HIN will help to build trust that EHI will be protected and will not be used in ways that they do not expect. Consequently, HINs and their participants should ascribe to the following privacy practices:

1) HINs should comply with all applicable laws regarding the use and disclosure of EHI.

2) HINs should clearly specify the minimum set of uses and disclosures for exchanging EHI and, for non-treatment purposes, limit the use of EHI to the minimum amount required.

3) HINs should not impede the ability of individuals to access their EHI and direct it to designated third parties, as required by the HIPAA Privacy Rule.

4) HINs should provide a method by which individuals can exercise meaningful choice regarding the exchange of EHI about them and ensure that such individual's choice is honored on a prospective basis, consistent with applicable law.

Gibson Comments: I agree with the practices as stated, especially that HINs should not impede the ability of patients to direct their data to designated third parties.

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Text: Principle 3 — Cooperation and Non-Discrimination: Collaborate with stakeholders across the continuum of care to exchange EHI, even when a stakeholder may be a business competitor. A. Do not seek to gain competitive advantage by limiting access to individuals' EHI.

HINs should not treat individuals' EHI as an asset that can be restricted in order to obtain or maintain a competitive advantage.

Gibson Comments: I agree that EHI cannot be used as a competitive token.

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Text: Principle 5 – Access: Ensure that Individuals and their authorized caregivers have easy access to their EHI. A. Do not impede or put in place any unnecessary barriers to the ability of individuals to access and direct their EHI to designated third parties, and to learn how information about them has been access or disclosed.

HINs who maintain EHI should (1) enable individuals to easily and conveniently access their EHI; (2) enable individuals to direct their EHI to any desired recipient they designate; and (3) ensure that individuals have a way to learn how their information is shared and used. This principle is consistent with the HIPAA Privacy Rule, which requires covered entities to provide PHI to individuals in the form and format in which they request it, if it is readily producible in that form and format. This means that if it is stored electronically, individuals can request it and access it electronically at virtually no cost.

Under the HIPAA Privacy Rule, covered entities are also required to transmit an individual's PHI to a third party when directed by the individual. Covered entities may not impose limitations through internal policies and procedures that unduly burden the individual's right to get a copy or to direct a copy of their health information to a third party of their choosing.

Gibson Comments: I applaud ONC calling out that individuals are entitled to an electronic copy of their EHI at no cost.

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Text: (ii) Each QHIN that receives a request for Individual Access Services from an Individual with whom it has a Direct Relationship shall provide such Individual with Individual Access Services with respect to his or her EHI regardless of whether the QHIN is a Covered Entity or Business Associate; provided, however, that if the Individual wants the EHI to go to a third party, the Individual has satisfied the conditions at 45 CFR § 164.524(c)(3)(ii) as if it applies to EHI.

45 CFR § 164.524(c)(3)(ii): If an individual's request for access directs the covered entity to transmit the copy of protected health information directly to another person designated by the individual, the covered entity must provide the copy to the person designated by the individual. The individual's request must be in writing, signed by the individual, and clearly identify the designated person and where to send the copy of protected health information.

Gibson Comments: If the individual has already designated a third party app to receive their protected health information, then the request should be able to be handled electronically by the third party app and not require the request to be in writing and signed by the individual. This language needs to be updated to reflect the use of a designated third party app by the patient.

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Text: (iv) QHIN is prohibited from requiring the submission of a HIPAA authorization (see 45 CFR 164.508), or a Business Associate Agreement (see 45 CFR 164.504(e)), in order to process a request for Individual Access Services from a Participant who provides Individual Access Services that has been selected by the Individual User who is requesting EHI for Individual Access Services.

(v) With respect to a QHIN Query for Individual Access Services, the response shall be provided as required by these terms and conditions regardless of whether it was prompted by (a) the Individual User; or (b) a QHIN, Participant, or Participant Member who provides Individual Access Services and has been selected by the Individual User who is requesting EHI for Individual Access Services.

Gibson Comments: I agree with prohibiting the use of a HIPAA authorization when a Participant is acting on a request for Individual Access Services. This provision will speed the access by the patient to their data. I further concur with requiring a similar response to a QHIN Query for Individual Access Services, regardless of the entity making the request.

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Text: Notwithstanding the foregoing, a Participant who only provides Individual Access Services shall not be required to respond to requests for EHI except as necessary to respond to an Individual User's request for Individual Access Services, including where such requests utilize a third party.

Gibson Comments: I agree with exempting a personal health record Participant from having to respond to EHI requests.

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Text: 7.3 Individual Exercise of Meaningful Choice. Each Participant shall respect the Individual's exercise of Meaningful Choice by requesting that his or her EHI not be Used or Disclosed by a Participant unless Applicable Law requires the Participant to Use or Disclose the EHI. However, any Individual's EHI that has been Used or Disclosed prior to the Individual's exercise of Meaningful Choice may continue to be Used or Disclosed for an Exchange Purpose. Each Participant shall process each exercise of Meaningful Choice from any Individual, or from Participant Members on behalf of any Individual, and communicate the choice to the QHIN with which it has a signed Participant-QHIN Agreement within five (5) business days after receipt. The Participant shall post instructions on its public website explaining how an Individual can exercise Meaningful Choice. The Participant shall not charge Individuals any amount for their exercise of Meaningful Choice or for communicating it to the applicable QHIN.

Gibson Comments: I agree that this statement makes it clear that the patient's wishes be followed in releasing or not releasing their EHI. I support a Participant posting instructions on their site how Individuals can exercise Meaningful Choice.

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Text: 7.6 Written Privacy Summary. Each Participant agrees to publish and make publicly available a written notice in plain language that describes each Participant's privacy practices regarding the access, exchange, Use and Disclosure of EHI with substantially the same content as described in ONC's Model Privacy Notice. The written privacy summary shall include the following additional information: (i) a description, including at least one (1) example, of each type of Exchange Purpose; (ii) a description that provides an Individual with a reasonable understanding of how to exercise Meaningful Choice; and (iii) whom Individuals can contact for further information about the Participant's privacy policies. This written privacy summary requirement does not supplant the HIPAA Privacy Rule obligations of a Participant that is a Covered Entity to post and distribute a Notice of Privacy Practices that meets the requirements of 45 CFR § 164.520.

Gibson Comments: I agree with ONC's stance that each Participant post a privacy notice similar to the ONC's Model Privacy Notice.

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Text: Such policies and procedures must be commensurate with the risk of incorrect identity proofing (e.g., procedures for applicants receiving credentials to access their medical information may be less rigorous than procedures used for applicants receiving credentials that can be used to access medical information on multiple patients). For example, IAL2 identity proofing for an applicant receiving credentials to access to his or her own medical information can be accomplished by any two of the following:

a) physical comparison to legal photographic identification cards such as driver's licenses or passports, or employee or school identification badges;

b) comparison to information from an insurance card that has been validated with the issuer, (e.g., in an eligibility check within two days of the proofing event); and

c) comparison to information from an electronic health record (EHR) containing information entered from prior encounters.

Gibson Comments: I agree with the less rigorous procedure for identification of individuals wishing to access their own medical information. I think that these methods achieve a reasonable balance between keeping patients' records private and making those records available to those patients.

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Text: Each Participant shall provide Individual Users with the option of using electronic means (e.g., e-mail or secure web portal) to assert their rights for Individual Access Services to EHI.

Gibson Comments: I agree that Individual Access Services be made available via email or secure web portal, avoiding the need for writing and signatures.