Summary of Disclosures
Public Stakeholder Feedback Session
2/12/2020
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*Note:* Today’s presentation is being recorded and will be provided

Problems or Questions? Contact the RCE Team at:

rce@sequoiaproject.org
This project is supported by the Office of the National Coordinator for Health Information Technology (ONC) of the U.S. Department of Health and Human Services (HHS) under 90AX0026/01-00 Trusted Exchange Framework and Common Agreement (TEFCA) Recognized Coordinating Entity (RCE) Cooperative Agreement for $900,000. This information or content and conclusions are those of the author and should not be construed as the official position or policy of, nor should any endorsements be inferred by ONC, HHS or the U.S. Government.
Purpose

- There were a number of public comments suggesting varying approaches to the TEFCA summary of disclosures provision (MRTC 9.5)
- ONC asked the RCE to explore the practical implications of various options
- The RCE is facilitating stakeholder feedback meetings, including a targeted feedback session at the ONC Annual Meeting and a public stakeholder feedback meeting on February 12, to consider these options to inform the RCE’s work
- Feedback will be gathered and shared in future RCE communications to promote transparency
MRTC 9.5—Summary of Disclosures

9.5 Right to Receive Summary of Disclosures of EHI.

9.5.1 Right to Request Summary and Applicable Period.
As described below, Individuals shall have the right to receive a summary of Disclosures of EHI for applicable Exchange Purposes in the context of the Framework Agreements for up to a period of six (6) years immediately prior to the date on which the summary of Disclosures is requested. Individuals submit requests for a summary of Disclosures to any QHIN, Participant, or Participant Member with which the Individual has a Direct Relationship. QHINs, Participants, and Participant Members shall provide the summary within sixty (60) days after receiving the request and shall provide an electronic means for an Individual to submit such requests. For Covered Entities, this obligation may be met by complying with the requirements of 45 CFR § 164.528.

9.5.2 Content of Summary.
The content of the summary of Disclosure(s) shall contain the following information: (i) date of the Disclosure(s); (ii) name of the entity or person who received the EHI and, if known, the address of such entity or person; (iii) brief description of the EHI disclosed; and (iv) brief statement of the purpose of the Disclosure(s) that reasonably informs the Individual of the basis for the Disclosure(s) or, in lieu of such statement, a copy of the written request for the Disclosure(s).

9.5.3 Exceptions.
A summary of Disclosures shall not be required for the following Disclosures: (i) for treatment, payment and health care operations (each as defined in the HIPAA Rules); (ii) to an Individual of his or her own EHI; (iii) pursuant to an Authorization under 45 CFR 164.508 executed by the Individual; (iv) to correctional institutions or law enforcement officials; (v) for national security or intelligence purposes; and (vi) if providing the summary of Disclosures of EHI would be in violation of Applicable Law.
Comparison: HIPAA Accounting of Disclosures (164.528) and TEFCA Summary of Disclosures (9.5)
<table>
<thead>
<tr>
<th>Categories of information</th>
<th>HIPAA Privacy Rule § 164.528</th>
<th>TEFCA 2.0 section 9.5.1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applicable period</td>
<td>The accounting must include disclosures of protected health information that occurred during the six years (or such shorter time period at the request of the individual as provided in paragraph (a)(3) of this section) prior to the date of the request for an accounting.</td>
<td>6 years immediately prior to the date on which summary of disclosures is requested.</td>
</tr>
<tr>
<td>Right to Request</td>
<td>Right to request an accounting of disclosures</td>
<td>Individual right to request a summary of disclosures to any QHIN, Participant, or Participant Member with which patient has a direct relationship</td>
</tr>
<tr>
<td>Patient receiving</td>
<td>1. The covered entity must act on the individual's request for an accounting, no later than 60 days after receipt of such a request, as follows. 2. The covered entity may extend the time to provide the accounting by no more than 30 days...</td>
<td>QHINs, Participants, or Participant members shall provide the summary within sixty (60) days</td>
</tr>
<tr>
<td>Accounting/Summary</td>
<td>Requirement for Covered Entities, but the obligation extends to disclosures to/from business associates of covered entity</td>
<td>For Covered Entities. Obligation may be met by complying with HIPAA requirements (45 CFR § 164.528)</td>
</tr>
</tbody>
</table>

Scope
<table>
<thead>
<tr>
<th>Content of Disclosure</th>
<th>HIPAA Privacy Rule § 164.528 (B)(2)</th>
<th>TEFCA 2.0 section 9.5.2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>Yes. Date of disclosure.</td>
<td>Yes. Date of disclosure(s)</td>
</tr>
<tr>
<td></td>
<td>If a CE has made multiple disclosures under 164.512, the date of the disclosure, and the date of the last such disclosure during the accounting period</td>
<td></td>
</tr>
<tr>
<td>Name</td>
<td>Yes. The name of the entity or persons who received the protected health information.</td>
<td>Yes. Name of entity or persons who received the EHI</td>
</tr>
<tr>
<td>Health Information</td>
<td>Yes. Brief description of the PHI disclosed</td>
<td>Yes. Brief description of EHI disclosed</td>
</tr>
<tr>
<td>Purpose</td>
<td>Yes.</td>
<td>Yes.</td>
</tr>
<tr>
<td></td>
<td>1. A brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure.</td>
<td>1. Brief statement on the purpose of the Disclosure(s) that reasonably informs the individual of the basis of disclosure.</td>
</tr>
<tr>
<td></td>
<td>2. In lieu of such statement, a copy of the written request for disclosure under § 164.502(a)(2)(ii) or § 164.512, if any.</td>
<td>2. In lieu of such statement, a copy of the written request for the disclosure(s) [No reference to any HIPAA provision.]</td>
</tr>
<tr>
<td>Address</td>
<td>Yes. As part of content under name, the address is included in the Accounting of Disclosure.</td>
<td>Yes, if available.</td>
</tr>
<tr>
<td>Number of disclosures</td>
<td>Yes. If a CE has made multiple disclosures under 164.512 the accounting may include the frequency, periodicity, or number of the disclosures during the accounting period.</td>
<td>No. No mention of number, periodicity, or frequency of disclosure with respect to multiple disclosures of EHI.</td>
</tr>
<tr>
<td>Exceptions</td>
<td>HIPAA Privacy Rule § 164.528 (a) (1)</td>
<td>TEFCA 2.0 section 9.5.3</td>
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<tr>
<td>-----------------------------</td>
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<td>---------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>TPO</td>
<td>Yes. As Defined by 164.506</td>
<td>Yes. As Defined in HIPAA Rules. No direct reference to a subsection</td>
</tr>
<tr>
<td>Individual Access</td>
<td>Yes. As provided by 164.502</td>
<td>Yes. To an individual of his/her own EHI. No reference to HIPAA</td>
</tr>
<tr>
<td>Authorization for use and Disclosure</td>
<td>Yes. Pursuant to an authorization as provided in §164.508</td>
<td>Yes. Pursuant to an authorization as provided in §164.508 executed by the individual.</td>
</tr>
<tr>
<td>Correctional, etc.</td>
<td>Yes. Pursuant to an authorization as provided in §164.508</td>
<td>Yes. To correctional institutions or law enforcement officials. No reference to HIPAA</td>
</tr>
<tr>
<td>National Security</td>
<td>Yes. For national security or intelligence purposes as provided in §164.512(k)(2)</td>
<td>Yes. For national security or intelligence purposes. No reference to HIPAA</td>
</tr>
<tr>
<td>Applicable Law</td>
<td>No explicit mention in § 164.528 (a) (1)</td>
<td>Yes. Exempt if providing summary of disclosures violates applicable law</td>
</tr>
<tr>
<td>Facility Directory</td>
<td>Yes. For the facility’s directory or to persons involved in the individuals’ care or other notification purposes as provided in §164.510</td>
<td>No. No explicit mention in MRTC section 9.5.3</td>
</tr>
<tr>
<td>Limited Data Set</td>
<td>Yes. Disclosures as part of a Limited Data Set (LDS) in accordance with §164.514(e) are exempt.</td>
<td>No. No explicit mention of (LDS) in MRTC section 9.5.3</td>
</tr>
<tr>
<td>Compliance</td>
<td>Yes. Disclosures that occurred prior to the compliance date for the Covered Entity are exempt.</td>
<td>No. No explicit mention in the Section 9.5.</td>
</tr>
<tr>
<td>Public Health</td>
<td>No. Disclosures to public health have to be including in an accounting</td>
<td>No. No explicit mention in Section 9.5</td>
</tr>
</tbody>
</table>
Who Can Request a Summary of Disclosures and What Needs to be Tracked under Section 9.5?

**Who:** QHIN, Participants QHIN Participant Member, *with a direct patient relationship*

- **Direct Relationship:** a relationship between (a) an Individual and (b) a QHIN, Participant, or Participant Member, that arises when the QHIN, Participant or Participant Member, as applicable, *offers* services to the Individual in connection with one or more of the Framework Agreements and the Individual agrees to receive such services.

- **Assumption:** It is likely that most TEFCA participants with a direct patient relationship will be CEs (e.g., providers or health plans) or app developers operating pursuant to the HIPAA right of access. Public health agencies may be providers in some cases.

**What:** EHI for applicable Exchange Purposes (not for Treatment, Payment, or Operations) “in the context of the Framework Agreements”

*Notes:*

- EHI is broader than HIPAA PHI, but this could change under future policy.
- EHI would not be PHI if maintained in a PHR that is not a CE.
- Disclosures for Benefits Determination by HIPAA CEs would generally be covered by the HIPAA authorization exclusion (45 CFR 164.508)
What is Excluded and How Frequently is a TEFCA Summary Expected?

Exclusions:

– HIPAA CEs who provide a HIPAA Accounting of Disclosures (AoD). BA actions would generally be covered by the AoD of their CE
– (i) TPO, (ii) to an Individual of his or her own EHI; (iii) pursuant to an Authorization under 45 CFR 164.508; (iv) to correctional institutions or law enforcement officials; (v) for national security or intelligence purposes; and (vi) if providing the summary of Disclosures of EHI would be in violation of Applicable Law

Notes:

– Consumer-facing app developers would generally be exempt under the second exclusion (to individual per HIPAA right of access) and many other users/uses would be excluded as they would be operating under a HIPAA authorization
– Research would often require an authorization under 164.508 and is also not a TEFCA-specified Exchange Purpose
– SSA does not disclose EHI and, therefore, would not have summaries.

Overall: Based on the above, and given that, anecdotal evidence and large healthcare organization data suggesting that relatively few accounting of disclosure requests are made, it is likely that the Summary of Disclosure provision would affect relatively few actors for relatively few transactions, reducing the impact of narrowing scope of the current proposal.
Options
Summary of Options

• Option 1: Eliminate Section 9.5
  – Option 1A: Option 1, with Study of Future Summary of Disclosures Requirement
• Option 2: Apply HIPAA Accounting of Disclosures to Entire TEFCA Ecosystem
• Option 3: Option 2 but Expanded to All EHI
  – Option 3A: Expand Option 3 to Include TPO
• Option 4: Require EHI, Allow More Focused Content Initially, Add Public Health Exception
Option 1—Eliminate Section 9.5

_Do not require a summary of disclosure_ as part of the Common Agreement and _rely on applicable law_ (i.e., HIPAA)

**Pro:** Reduced uncertainty and compliance burden for non-HIPAA CEs (e.g., Business Associates, public health agencies, app developers, etc.). No need for costly and time-consuming policy, workflow, and technology changes. One less required CA term for consideration by prospective participants. Even if a party is participating in TEFCA, not all information disclosed may remain covered by TEFCA or HIPAA. Aligning with HIPAA would limit need to amend the CA should rules changes. App developers and other non-HIPAA entities are already exempt from Accounting of Disclosures so this would not change the status quo. This requirement, of uncertain value, distracts from more strategically important topics.

**Con:** Would not provide patients with desired, needed, and expected protections and information regarding certain TEFCA information disclosures, especially as EHI is broader than PHI and some organizations handling EHI under TEFCA may not be a CE (or even a BA), such as app developers. Would not establish a level playing field for disclosures between CEs and other TEFCA participants.
Option 1A—Eliminate Section 9.5 (Option 1) and Study Future Summary of Disclosures Requirement

Do not require a summary of disclosure as part of the Common Agreement and rely on applicable law (i.e., HIPAA), but initiate a 24-month study and trial period for a possible future Summary of Disclosures requirement.

Pro: Reduced uncertainty and compliance burden for non-HIPAA CEs (e.g., Business Associates, public health agencies, app developers, etc.). No need for costly and time-consuming policy, workflow, and technology changes. One less required CA term for consideration by prospective participants. Provides basis to add Summary of Disclosures requirement after study of need and feasibility.

Con: Would not provide patients with near-term desired, needed, and expected protections and information regarding certain TEFCA information disclosures, especially as EHI is broader than PHI and some organizations handling EHI under TEFCA may not be a CE (or even a BA).
Option 2 —Apply HIPAA Accounting of Disclosures to Entire TEFCA Ecosystem

**HIPAA Accounting of Disclosures provisions apply** to QHINs, QHIN Participant Members, and Participants for PHI (not EHI)

**Pro:** One set of rules for all TEFCA participants. No change for HIPAA CEs. No need for variation in approach from HIPAA.

**Con:** Costly and complex new burdens on non-HIPAA CEs, such as Business Associates, public health agencies, app developers, etc. (Note: Business Associates do not have an independent HIPAA obligation to account but must support the CEs with which they have agreements.) Would not address non-PHI or other disclosures that may not otherwise fall under HIPAA (e.g. redisclosures by app developers). ONC does not enforce HIPAA and HHS OCR does not enforce beyond HIPAA.
Option 3—Option 2 but Expanded to All EHI

**HIPAA Accounting of Disclosures provisions apply** to QHINs, Participant Members, and Participants, but for **all EHI exchanged under Common Agreement**

**Pro:** Ensures all non-excluded EHI exchanged under the TEFCA covered (most such EHI would be in the USCDI). Uniform rules for all TEFCA participants. No change in process for HIPAA CEs. No variation from HIPAA. Expansion to all EHI is largely bounded by the TEFCA focus on USCDI, so not likely to include substantial data in excess of PHI.

**Con:** Introduces new requirements for non-HIPAA CEs, such as Business Associates, public health agencies, app developers, etc. (Note: Business Associates do not have obligation to account but must support their CEs.) Would expand need to provide summaries for current HIPAA CEs and BAs beyond current PHI requirements; EHI could be much broader than ePHI. Would not address disclosures that may not otherwise fall under HIPAA (e.g. redisclosures by app developers).
Option 3A—Expand Option 3 to Include TPO

Have HIPAA Accounting of Disclosures provisions apply to QHINs, QHIN Participant Members, and Participants, for EHI exchanged under the Common Agreement, with no exception for TPO

Pro: Would ensure that all EHI exchanged under the TEFCA covered for all exchange purposes (most EHI is TPO), providing enhanced patient visibility to access of their data, including inappropriate access. One set of rules for all TEFCA participants. No change in process for HIPAA CEs.

Con: Costly and complex new burdens on HIPAA CEs/BAs and non-HIPAA CEs. Would expand greatly expand need to provide summaries for current HIPAA CEs and their B, which As given likely high percentage of TEFCA exchanges that are TPO. Would be major impediment to willingness to sign Common Agreement and spark kinds of concerns with burden and technical capability that have delayed for over a decade implementation of HITECH Act requirement for TPO accounting of disclosures from EHRs. See OCR RFI for background on the topic* Would not address disclosures that may not otherwise fall under HIPAA (e.g. redisclosures by app developers). Adding TPO would greatly increase the size of audit log files and number of reportable disclosures for current HIPAA CEs and their BAs given likely high percentage of TEFCA exchanges that would be TPO.

*HHS/OCR *Request for Information on Modifying HIPAA Rules To Improve Coordinated Care, Federal Register, 12/14/2018, p. 64302
Option 4: Require EHI, Allow More Focused Content
Initially, Add Public Health Exception

Expand current proposal to all EHI exchanged under the Common Agreement, with more focused summary content* for at least first 24 months of the CA and added exclusion for disclosures to public health authorities under 45 CFR 164.512(b)(1). Keep TPO exception, while pilot testing tracking TPO disclosures and consider adding TPO in the future following a pilot.

**Pros:** Ensures all non-excluded EHI exchanged under the TEFCA covered (most such EHI would be in the USCDI). Reduces technical and workflow burden of providing full HIPAA AoD-level summary (and associated contracting hurdles) by focusing on user-friendly and computable presentation of data in audit and transaction logs, SAML queries, etc. while permitting extension to the expanded level of summary content over time. Provides exclusion for access by public health authorities, reducing burdens associated with public health exchange purpose.

**Cons:** Would expand need to provide summaries for current HIPAA CEs and BAs beyond current PHI requirements. Would reduce potential usability and usefulness of the summary for patients. Would go beyond current HIPAA exceptions by excluding public health authorities. Audit logs may not be good basis for useful or useable information. Would not address disclosures that may not otherwise fall under HIPAA (e.g. redisclosures by app developers). Adding TPO after pilot testing would greatly increase the size of audit log files and number of reportable disclosures for current HIPAA CEs and their BAs given likely high percentage of TEFCA exchanges that would be TPO.

*Initially, in a user-friendly and computable format (to be defined), information from audit and transaction logs and technical components of QHIN queries including as available in these source: (i) date of the Disclosure(s); (ii) name of the entity or person who received the EHI and, if known, the address of such entity or person; (iii) brief description of the EHI disclosed; and (iv) the Exchange Purpose of the Disclosure(s) or, in lieu of such information, a copy of the written request for the Disclosure(s).
Comments from 1/28/2020 Targeted Stakeholder Feedback

- General support for Options 1a (remove Section 9.5 and pilot) or 2 (apply HIPAA to all TEFCA participants)
- Overall concern about cost and burden of providing a Summary relative to benefits
- Many questions on content and format of a Summary; consensus that it should be useful to consumers, but concern that defining “usefulness” could be challenging
- Many questions/concerns regarding if an initial request for a Summary would have to go out to Participant/Participant Members and across QHINs or would just cover disclosures by those with a Direct Relationship (and as applicable their BAs).
  - In other words, must the Summary of Disclosures address only disclosures by the party with a Direct Relationship to the query initiator or include intermediate “hops” between requester and data source?
  - **Working assumption**: focus on disclosure to query originator by party with Direct Relationship and not intermediate steps (e.g., other Participant Members, Participants, QHINs) and assume that the entity with the Direct Relationship is only required to account for disclosures that it (or its BAs as applicable) makes.
Comments from 1/28/2020 Targeted Stakeholder Feedback

- Questions and concerns re: what app developers and other non-HIPAA entities could do re: subsequent sharing, especially beyond the TEFCA framework
  - Working assumption: disclosures outside of TEFCA framework (e.g., further disclosure by app developer outside of TEFCA) would not need to be disclosed, even if the app developer has a Direct Relationship with the patient, so long as the app developer meets the provisions of 2.2.2(vi), 7.2(vi), or 8.2(vi) as applicable.
  - Possible refinement is to include app developers in MRTCs/ARTCs (or HIPAA legislation or regulation) for subsequent disclosure
  - Note re: app developers who are part of TEFCA: “All exchanges, retentions, aggregations, Uses and Disclosures of EHI by Participants shall be subject to audit procedures as described in the ARTCs.” 7.2 [similar for QHINs and Participant Members]
  - Concern that limiting desirability of app vendors to access data via IAS/TEFCA would drive app developers to connect with CEs directly, reducing value of the TEFCA and value to patients and consumers
Discussion