

Recognized Coordinating Entity Sessions

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RCE Stakeholder Feedback Session: Common Agreement

Minimum Required Terms and Conditions - MRTCs

RCE Stakeholder Feedback Session: Common Agreement (Minimum Required Terms and Conditions - MRTCs)

- Provide background regarding draft MRTCs as foundational part of Common Agreement
- Highlight public comments and issues for stakeholder understanding
- Inform development of Common Agreement

Draft MRTCs (Published April 2019 for Public Comment)

1. Definitions
2. Initial application, onboarding, designation and operation of QHINs
3. Data quality and minimum necessary
4. Transparency (e.g. agreements, fee schedules, disclosures)
5. Cooperation and non-discrimination
6. Privacy, security and patient safety
7. Participant minimum obligations
8. Participant member minimum obligations
9. Individual rights and obligations

Definitions: Exchange Purposes

- Use or Disclosure Exchange Purposes:
 - Treatment
 - Utilization Review
 - Quality Assessment and Improvement
 - Business Planning and Development
 - Public Health
 - Individual Access Services
 - Benefits Determination
- QHINs, Participants and Participant Members may only request, exchange, retain, aggregate, use or disclose for an Exchange Purpose
 - And only for a Covered Entity or other health care provider
 - N/A to Individual Access Services or Benefits Determination

Public Comment Highlights

- Align with HIPAA, especially for TPO
- Treat as floor vs. ceiling
- Allow core and menu purposes
- Allow phase-in over time to full exchange purposes
- Interaction with existing contractual provisions on data exchange
- QHIN responsibilities vs. Participants and Participant Members
- Agreement with narrowed exchange purposes

QHIN Initial Application, Onboarding, and Designation - 2.1

- 2.1.1 QHIN Application
- 2.1.2 Timing of Review by RCE
- 2.1.3 Requirements for Approval of a QHIN Application
- 2.1.4 Provisional QHIN Status
- 2.1.5 Obligation to Achieve QHIN Designation
- 2.1.6 Requirements for QHIN Designation

Public Comment Highlights

- Move details to SOPs
- Consider centralized vs federated architecture
- Assess QHIN eligibility: Is bar too low?
- Uncertainty re: cohorts & “provisional” status
- Clarify “commercially reasonable efforts”
- Clarify application and onboarding processes

Response to MRTC and Public Comments

Minimum Necessary - 2.2, 3.3, 7.19, 8.19

- Minimum Necessary Requirements shall apply to a QHIN when it Requests, Uses, or Discloses EHI in a Common Agreement context in alignment with HIPAA, as well as HIPAA exceptions:
 - Treatment
 - Disclosure to individual
 - Per authorization
 - Where required by law
- Similar obligations for Participants and Participant Members
- Applies to senders and receivers and to CEs, BAs, and Non-Covered Entities

Public Comment Highlights

- Agreement that minimum necessary should align with HIPAA
- What entities should be responsible for meeting Minimum Necessary (MN)?
 - Requesting system best positioned to determine if request for EHI meets MN
 - Any entity responding to a query should be able to reasonably assume EHI requested satisfies MN

Meaningful Choice - 2.2.3, 7.3, 8.3

- Each QHIN, must respect Individual's exercise of Meaningful Choice (i.e. opt out), unless required by Applicable Law.
- Prior to exercise of Meaningful Choice EHI may continue to be Used or Disclosed for an Exchange Purpose.
- Each QHIN shall process each exercise of Meaningful Choice from any Individual, or from Participants or Participant Members on behalf of any Individual, and communicate the choice to all other QHINs within five (5) business days after receipt in accordance with the requirements of the QHIN Technical Framework.
- Similar provisions for Participants and Participant Members

Public Comment Highlights

- Many serious concerns about feasibility
- Concerns with lack of alignment with HIPAA and other laws, including lack of TPO carve-out as well as HINs existing data sharing requirements.
- Should be more granular than “all or nothing”
- Requiring providers to create new policies beyond HIPAA could create dual track of data management, creating significant burdens
- No current standard supports proposed policy
- Clarify who must obtain and maintain Meaningful Choice, requester or data holder?

Permitted and Future Uses of EHI – 2.2.2

- Recipient QHIN may exchange, retain, aggregate, Use, and Disclose such EHI only in accordance with Applicable Law and only for:
 - one or more of the Exchange Purposes in the CA;
 - proper management and administration of its business and legal responsibilities under the CA or BAA;
 - investigation of a Breach or to comply with the HIPAA or other applicable legal privacy and security obligations;
 - judicial and administrative proceedings, for law enforcement or governmental authorities;
 - as otherwise permitted by Applicable Law
 - where explicitly approved by an Individual after receiving a written privacy summary and Minimum Information for such purpose.
- Information obtained via Individual Access Services may only be exchanged, retained, aggregated, used and disclosed for Individual Access Services.
- All exchanges, retentions, aggregations, Uses and Disclosures of EHI by QHINs shall be subject to audit procedures as described in the ARTCs.

Public Comment Highlights

- Significant number of comments requested clarification
- Alignment with Information Blocking, HIPAA and applicable law
- Implications to future uses of data which would be restrict future use to the Exchange Purpose
- Potential unintended consequences

Consent - 6.1.4, 7.4, 8.4

- QHINs, Participants, and Participant Members with Direct Relationship with Individual shall obtain and maintain copies of Individual's consent, approval or other documentation when required by Applicable Law
- Participating entity may make it available electronically to any other Participant, QHIN, or Participant Member on request to extent permitted by Applicable Law
- Participant, QHIN, or Participant Member shall maintain written policies and procedures to allow an Individual to revoke such consent or approval on a prospective basis

Public Comment Highlights

- Commenters generally supported clarification that consent should be collected from organization with which patient has relationship
- Commenters requested clarification on who consent requirement falls on (e.g., query requester or responder?)
- Need query-able repositories for consent metadata
- Common concern: how consent electronically obtained, exchanged, maintained
- QHINs need consistent electronic method to manage consent; consent disclosure should be standardized across QHIN network(s)
- TEFCA should be comprehensive on consent and clear in its move to electronic consent

Fees - 5.2

- 5.2.1 Reasonable and Non-Discriminatory Fees. 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. A QHIN may not charge another QHIN any amount for Individual Access Services Exchange Purpose.
- 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.

Public Comment Highlights

- Clarify Reasonable and Non-discriminatory (including market pricing of value-add services that go beyond the core required TEFCA services offerings)
- Fee Schedules should be publicly available
- Concern re: fees for public health messages or access.
- Support for prohibition on fees for individual access
- Be explicit on Participants & Participant Members fees
- Clarify: “Nothing in these terms and conditions requires any QHIN to charge or pay any amounts to another QHIN”
- ONC and the RCE should ensure reasonable and consistent fees across QHINS

Summary of Disclosures under TEFCA - 9.5

- Individual Right to Request Summary of Disclosures of EHI under the CA for up to 6 years prior to the request
- Requests may be submitted to any QHIN, Participant, or Participant Member with which Individual has a Direct Relationship.
- Provide summary within sixty (60) days
- For Covered Entities and Business Associates, this obligation may be met by complying with requirements of 45 CFR § 164.528.
- Content of Summary: Disclosure date(s); Recipient name (individual or entity) and address, if known; Brief description of EHI disclosed; Brief statement of disclosure purpose that reasonably informs Individual of basis for Disclosure(s) or, in lieu of such statement, a copy of written request for Disclosure(s).
- Exceptions:
 - Not required for: TPO; Disclosures to an individual of his or her own EHI; pursuant to an Authorization; to correctional institutions or law enforcement officials; national security or intelligence purposes; or if providing summary of Disclosures would be in violation of Applicable Law.

Public Comment Highlights

- Mix of comments
- Some support
- Need to align with HIPAA and OCR guidelines
- Likely to confuse patients
- Only QHINs would be in a position to handle
- Important information be able to be tracked electronically or will require hand data entry, making compliance burdensome
- Exceptions not applicable to consumer-facing apps
- ONC should provide guidance on how to deal with deduplication to reduce variation in how systems handle this complex task

TEFCA Breach Notification - 6.1.1, 7.12, 7.13, 8.12, 8.13

- Requires QHINs to report breaches of EHI to RCE and, to the extent affected, other QHINs, Participant Members and Individuals (if Direct Relationship):
 - If Covered Entity or Business Associate, comply with HIPAA breach notification rule, applicable state breach laws and TEFCA notification
 - If subject to FTC rules, comply with FTC reporting requirement and TEFCA notification
 - If not subject to HIPAA, comply with applicable Business Associate requirements in HIPAA, and applicable state breach laws
 - Early notification is advisable and should be no later than an unreasonable delay under applicable law
 - Law enforcement exception to notification consistent with HIPAA
- Similar provisions for Participants and Participant Members.

Public Comment Highlights

- There are HIPAA and FTC breach notification rules in effect, depending on actor
- Extensive support for uniform breach notification requirements for both HIPAA Covered Entities and non-Covered Entities
- ONC should only apply breach notification requirements to Participant Members not already covered by FTC HITECH breach notification rules
- Are also existing state breach requirements that organization must comply with; these include notice to individuals (even if the QHIN does not have a Direct Relationship), state attorneys general, and others

Thank You!