Standard Operating Procedure (SOP): RCE™ Directory Service (Directory) Requirements Policy

Version 1.0

July 1, 2024

Applicability: QHINs, Participants, and Subparticipants that control a Node

1. COMMON AGREEMENT REFERENCES

The requirements set forth in this Standard Operating Procedure (SOP) are for implementation, in addition to the terms and conditions found in the Common Agreement, the Qualified Health Information Network™ (QHIN™) Technical Framework (QTF), and applicable SOPs. The Trusted Exchange Framework and Common Agreement™ (TEFCA™) Cross Reference Resource identifies which SOPs provide additional detail on specific references from the Common Agreement.

All documents cited in this SOP can be found on the Recognized Coordinating Entity® (RCE™) website.

2 SOP DEFINITIONS

Terms defined in this Section are introduced here and can be found in the TEFCA Glossary. Capitalized terms used in this SOP have the respective meanings assigned to such terms in the TEFCA Glossary.

Delegate: a First Tier Delegate or Downstream Delegate.

Delegated Request: a TEFCA Exchange Request initiated by a Delegate working, directly or indirectly, for a Principal.

Downstream Delegate: a QHIN, Participant, or Subparticipant that (i) is not acting as a Principal when initiating or Responding to a transaction via TEFCA Exchange and (ii) has a direct written agreement with a First Tier Delegate or another Downstream Delegate authorizing the respective Downstream Delegate to initiate or Respond to transactions via TEFCA Exchange for or on behalf of a Principal.

First Tier Delegate: a QHIN, Participant, or Subparticipant that (i) is not acting as a Principal when initiating or Responding to a transaction via TEFCA Exchange and (ii) has a direct written agreement with a Principal authorizing the First Tier Delegate to initiate or Respond to transactions via TEFCA Exchange for or on behalf of the Principal. For purposes of this definition, a "written agreement" shall be deemed to include a documented grant of authority from a government agency.

Initiating Node Only Attestation: an attestation provided by a Participant or Subparticipant to its QHIN attesting that data obtained or created by the Participant's or Subparticipant's Initiating Node that becomes part of a Designated Record Set of a Principal is shared with another Responding Node that is identified in such attestation. For purposes of the Initiating Node Only Attestation, Designated Record Set has the

meaning assigned to that term in 45 CFR § 164.501 but applies to a Principal regardless of whether the Principal is a Covered Entity.

Logical Entity: a Participant or Subparticipant that is represented by one or more Nodes in the RCE Directory Service, all of which share a TEFCAID.

Principal: a QHIN, Participant or Subparticipant that is acting as a Covered Entity, Government Health Care Entity, NHE Health Care Provider, a Public Health Authority, a government agency that makes a Government Benefits Determination, or an IAS Provider (as authorized by an Individual) when engaging in TEFCA Exchange.

Transaction Type(s): any one of a Patient Discovery, Document Query, Document Retrieval, Message Delivery, and/or FHIR.

The following defined terms from the Common Agreement are repeated here for reference.

Directory Entry(ies): listing of each Node controlled by a QHIN, Participant, or Subparticipant, which includes the endpoint resource for such Node(s) and any other organizational or technical information required by the QTF or an applicable SOP.

Initiating Node: a Node through which a QHIN, Participant, or Subparticipant initiates transactions for TEFCA Exchange.

Node: a technical system that is controlled directly or indirectly by a QHIN, Participant, or Subparticipant and that is listed in the RCE Directory Service.

RCE Directory Service: a technical service provided by the RCE that enables QHINs to identify their Nodes to enable TEFCA Exchange. The requirements for use of, inclusion in, and maintenance of the RCE Directory Service are set forth in the Framework Agreements, QTF, and applicable SOPs.

Required Information: the Electronic Health Information, as defined in 45 CFR § 171.102, that is (i) maintained in a Responding Node by any QHIN, Participant, or Subparticipant prior to or during the term of the applicable Framework Agreement and (ii) relevant for a required XP Code, as set forth in the QTF or an applicable SOP(s).

Responding Node: a Node through which the QHIN, Participant, or Subparticipant Responds to a received transaction for TEFCA Exchange.

3 PURPOSE

This SOP describes RCE Directory Services (Directory) policy requirements that QHINs must follow when maintaining Directory Entries, in addition to the specifications set forth in the Framework Agreements, QTF, RCE Directory Service Implementation Guide, and applicable SOPs.

4 PROCEDURE

4.1 Requirements

1. **The Primary Purpose of the Directory is to Represent Technical Relationships.**

   a) The Directory represents exchange Nodes**.** It might not show all Participants and Subparticipants through which a Framework Agreement flows.

   b) The Directory MUST represent the technical path of connectivity, including all Passthrough Nodes.

   c) The Directory also associates multiple Nodes of a Logical Entity across QHINs, Participants, and Subparticipants sharing a TEFCAID, per Section 4.1(14), below.

2. **All Nodes MUST be controlled by a QHIN, Participant, or Subparticipant and listed in the Directory.**

   a) Any Node that handles or transmits data during transport as part of TEFCA Exchange MUST be controlled by a QHIN, Participant, or Subparticipant and subject to a Framework Agreement.

   b) All such Nodes MUST be published in the Directory, representative of each Node's technical path of connectivity.

3. **Directory includes range of Exchange Purposes (XPs) for a QHIN.**

   a) A QHIN MUST publish, at the Organization[1] resource level, all XP Codes that will be initiated from its Designated Network.

   b) A QHIN MUST publish, at the Endpoint[2] resource level, all XP Codes that will be Responded to by the QHIN, Participant, or Subparticipant within its Designated Network.

4. **Directory includes types of Transactions and XPs for each Node.**

   a) Every Initiating Node in the Directory MUST indicate both which Transaction Type(s) and for which XP(s) Codes it will initiate. The XPs published for a Node

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[1] HL7® FHIR® Release 4 available at https://hl7.org/fhir/R4/.
[2] HL7® FHIR® Release 4 available at https://hl7.org/fhir/R4/.

MUST be the set or a subset of the XPs Codes of each Directory Entry above it in the hierarchy, as exemplified by the diagram in Section 4.2 of this SOP.

b) Every Responding Node in the Directory MUST indicate both which Transaction Type(s) and for which XP Codes it will respond. The XPs published for a Node MUST be the set or subset of the XP Codes listed at the endpoints of the Responding Node's QHIN.

5. **Participants and Subparticipants MAY participate in multiple QHINs if they have multiple Nodes with separate HomeCommunityIDs or FHIR Endpoints.**

   a) If multiple Nodes share a HomeCommunityID or FHIR Endpoint, they MUST be represented entirely under the same QHIN.

   b) An organization with multiple Nodes that each have a separate HomeCommunityID or FHIR Endpoint may be a Participant or Subparticipant under multiple QHINs; however, each Responding Node MUST be entirely represented for all Exchange Modalities handled by that Responding Node under one QHIN and that Responding Node MUST NOT be duplicated across multiple QHINs where separate, additional Nodes may be listed.

   c) A Responding Node's source database MUST only be represented by one HomeCommunityID or FHIR Endpoint.

6. **No duplicative Responding Node Directory Entries.**

   a) Before listing any Responding Node in the RCE Directory Service, a QHIN MUST confirm that a Responding Node with the same organization or endpoint identifier for the same capability, including the same HomeCommunityID, does not already exist in the RCE Directory Service under another QHIN.

   b) QHINs MUST NOT list in the RCE Directory Service any such duplicative entry as a Responding Node of a Participant or Subparticipant of such QHIN.

7. **No limit on Initiating Node Directory Entries.**

   a) There is no limit on the number of Initiating Nodes a QHIN may list in the RCE Directory Service for a Participant or Subparticipant.

   b) Each QHIN must ensure that each Initiating Node it enters into the RCE Directory Service meets the requirements set forth in this SOP.

   c) Each Responding Node may be listed by the QHIN that listed the respective Initiating Node or another QHIN. If the Node is an Initiating Node only, then the QHIN must ensure that it is hierarchically below a Responding Node for Document Retrieval or that the Responding Node identified in the Initiating Node Only Attestation is listed in the RCE Directory Service.

8. **A Responding Node MAY be separated by individual Transaction Type.**

   a) A Responding Node may be separated by individual Transaction Type within each Exchange Modality so long as the Responding Node has exactly one Directory

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Entry per Transaction Type at all times. For example, a QHIN that maintains an Enterprise Master Patient Index (eMPI) for all its Participants and Subparticipants may be the Responding Node for Patient Discovery transactions for its entire network, while its Participants and/or Subparticipants, as appropriate, are listed individually as the Responding Nodes for Document Retrieval.

9. **Each Transaction Type MUST be listed no more than once.**

   a) Within a hierarchical chain of Directory Entries, each Transaction Type MUST be listed no more than once (see diagram in Section 4.2 below). For example, a Participant that Responds to Document Retrieval transactions MUST Respond inclusive of all its Subparticipants for which a Response is Required. Any Subparticipants below that Participant's Responding Node cannot also be listed as Responding Nodes for Document Retrieval.

10. **Initiating Node of a Principal MUST also be or have an associated Responding Node.**

   a) A Node that is an Initiating Node of a Principal MUST meet one of the following two requirements unless another exception applies:

      i. Be a Responding Node; or
      ii. Be hierarchically below a Responding Node for Document Retrieval where such Responding Node is sharing all Required Information from a downstream Participant or Subparticipant that would otherwise be provided by the Participant or Subparticipant's Initiating Node, if the Initiating Node were a Responding Node.

   b) Notwithstanding the foregoing, if a QHIN, Participant, or Subparticipant's Responding Node is exempted from required Responses pursuant to the XPs SOP, such QHIN, Participant, or Subparticipant's Initiating Node is not required to be or have an associated Responding Node.

11. **Initiating Node of a Delegate Must Also Be or Have an Associated Responding Node.**

   a) A Node that is an Initiating Node of a Delegate MUST meet one of the following three requirements unless another exception applies:

      i. Be a Responding Node;
      ii. Be hierarchically below a Responding Node for Document Retrieval where such Responding Node is sharing all Required Information from a downstream Participant or Subparticipant that would otherwise be provided by the Participant or Subparticipant's Initiating Node, if the Initiating Node were a Responding Node; or
      iii. Provide an Initiating Node Only Attestation to the QHIN, which is in the Initiating Node Only Attestation form set forth below.

   b) Initiating Node Only Attestation Form:

Participant or Subparticipant Name (the "Attesting Entity"):

The Attesting Entity is a Participant or Subparticipant of [QHIN].

The Attesting Entity is a Delegate of [_____].

For purposes of this Initiating Node Only Attestation, Designated Record Set has the meaning assigned to that term in 45 CFR §164.501 but applies to a Principal regardless of whether the Principal is a Covered Entity.

The Attesting Entity hereby attests that data obtained or created by the Initiating Node following the Initiating Node's use of TEFCA's Connectivity Services that becomes part of a Designated Record Set of [Principal Name] is shared with and maintained in [Name of Principal's Responding Node], which is a Responding Node.

The Attesting Entity MUST notify [QHIN] immediately in the event this Attestation is no longer accurate or complete.

c) Examples:

    i. Southeast Health System has two EHR systems, one of which is connected to TEFCA through QHIN B as both an Initiating Node and a Responding Node ("EHR 1 Node") and one of which is not connected to TEFCA ("EHR 2"). Southeast Health System uses a Delegate that provides a care management system to create care plan for specific diabetic patients (the "Delegate Care Manager"). All data obtained by the Delegate Care Manager and the resulting care plans are maintained in the Delegate Care Manager's system. In addition, the data and resulting care plans are sent back to the respective EHRs in which the Individual's data resides (e.g., either EHR 1 or EHR 2). Because EHR 1 Node is a Responding Node, the Delegate Care Manager can sign an Initiating Node Only Attestation and be an Initiating Node only with respect to Individuals whose records reside in EHR 1. Because EHR 2 is not connected to TEFCA and is not a Responding Node, an Initiating Node Only Attestation is not available for the Delegate Care Manager with respect to Individuals whose records reside solely in EHR 2. As a result, to initiate Queries through TEFCA for Individuals whose records reside in EHR 2, the Delegate Care Manager must be an Initiating Node and Responding Node.

12. All Delegates MUST be represented in the Directory in accordance with the Delegation of Authority SOP and MUST list their Principal for whom the Query is being initiated in the Query itself.

a) If the Delegate's Node is listed as an Initiating Node and the Delegate is initiating Queries as authorized by one or more Principals, then each Delegate must be represented in the RCE Directory Service, as detailed in the Delegation of Authority SOP.

b) Each Query made by a Delegate MUST identify in the transaction the Principal that is providing the underlying authority for such Query, as detailed in an applicable SOP and in the Delegation of Authority SOP.

13. **An Initiating Node MUST publish relevant required identifiers for XPs it initiates, as identified in the QTF, the XPs SOP, or the relevant XP Implementation SOP (e.g., NPI for Treatment).**

14. **A Logical Entity with multiple Nodes MUST have the same TEFCAID shared across each of its Nodes.**

a) QHINs MUST work with their Participants and Subparticipants during onboarding to determine whether any new Directory Entry is affiliated with an existing Logical Entity that has been assigned a TEFCAID.

i. When a new Directory Entry is affiliated with an existing TEFCAID, the publishing QHIN MUST submit its new Directory Entry with that TEFCAID listed. The RCE Directory Service will:

1. Validate the TEFCAID submitted to ensure the TEFCAID already exists.
2. Where it does not exist, an RCE Directory Service validation error will be returned, allowing the QHIN to make a correction.

ii. When a new Directory Entry is not affiliated with an existing TEFCAID, the publishing QHIN MUST NOT submit any value for TEFCAID. The RCE Directory Service will:

1. Assign and populate a new unique TEFCAID.

4.2 Example Diagram

1. **QHIN A is fully federated, passing all transactions to its Participants.**

   o Participant 1 maintains an eMPI/Record Locator Service (RLS) over its Subparticipants but returns individual patient IDs per Subparticipant (Sub) and passes down subsequent Queries for documents.
     ▪ Subs Z and Y only see Document Query and Document Retrieval Queries and Respond independently, since Participant 1 only maintains their patient demographics.
   o Participant 2 maintains a complete clinical data repository and Responds for all transactions for its Subs.

- Sub X never sees or Responds directly to TEFCA transactions.

2. **QHIN B maintains an eMPI/RLS, returns a consolidated patient ID, followed by an aggregated document list. It passes down subsequent Queries for documents.**

   o Participant 3 is a fully federated Passthrough Node, passing all transactions to its Subs.
     - Sub W is a fully federated Passthrough Node, passing all transactions to its Subs.
       - Sub U sees only Document Retrieval Queries and Responds independently, since QHIN B maintains its patient demographics and document list.
     - Sub V only sees Document Retrieval Queries and Responds independently, since QHIN B maintains its patient demographics and document list.

3. **Initiating Nodes: Without leveraging exceptions listed in 4.1(10) of this SOP, only the following may be Initiating Nodes, due to Responding with documents: Sub Z, Y, Participant 2, Sub U, V.**

4. **Participant 3 is a federated gateway, passing through the transactions, and so must be in the Directory. If it were simply flowing down Framework Agreement terms, but not handling transactions, Subs W & V could be directly below QHIN B.**

KEY
- **XCPD:** Cross Community Patient Discovery
- **XCA:** Cross Community Access

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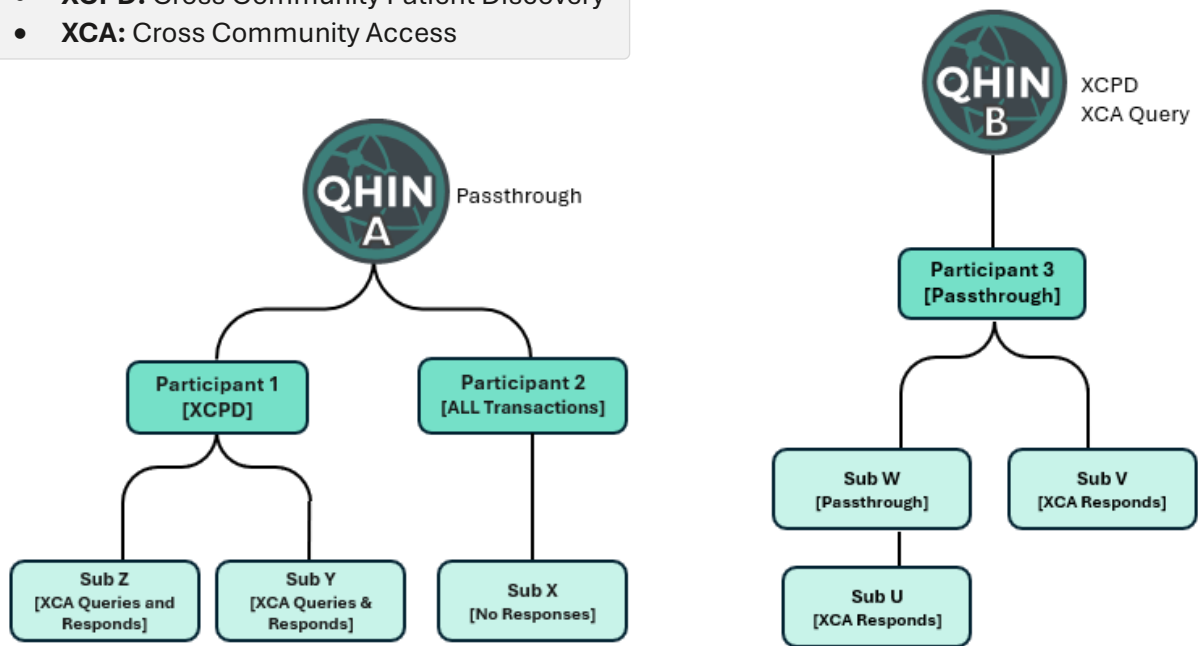
5   VERSION HISTORY

Version	Revision Date	Section #(s) of Update
Draft Version 1.0	January 19, 2024	N/A
Version 1.0	July 1, 2024	All sections