



Elements of the Common Agreement: Draft QHIN Eligibility Criteria

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BACKGROUND

This document provides additional detail to supplement the Elements of the Common Agreement document released previously. The Common Agreement and all related materials are under development, so references in this document reflect current understanding.

The Common Agreement would identify five general eligibility criteria for any organization that seeks to be a QHIN. Below, we have identified the specific requirements for each criterion and identified the type of evidence that the Signatory would be required to provide to the RCE to demonstrate Signatory's compliance.

The objectives are to:

- Establish a baseline set of objective criteria to qualify what organizations may be eligible to serve as a QHIN.
- Clearly define objective requirements that a Signatory must satisfy to be Designated a QHIN.

The final QHIN eligibility requirements in the Common Agreement and related documents may differ from the draft presented here. The Common Agreement is currently under development and will be released in final form in Q1 of 2022. In preparation for release of the finalized Common Agreement, the RCE will share more details and accept input on anticipated elements of the Common Agreement through a set of feedback opportunities announced on the RCE Community Engagement webpage. The RCE is committed to understanding stakeholder perspectives, and the input gathered will inform the drafting of the final Common Agreement. Once ONC approves the final Common Agreement, it will be released publicly.

The RCE further welcomes stakeholder feedback on these draft QHIN eligibility criteria through October 21, 2021. The RCE encourages stakeholders to submit feedback via the RCE's [online form](#), but will also accept feedback sent via email to rce@sequoiaproject.org. All feedback submitted to the RCE will be made publicly available on the RCE's and/or ONC's website, including any personally identifiable or confidential business information that you include in your feedback. Please do not include anything in your feedback submission that you do not wish to share with the general public.

DRAFT QHIN ELIGIBILITY CRITERIA

1. **Signatory must demonstrate that it meets the definition of a U.S. Entity. The specific, required means to demonstrate that a Signatory meets the definition of a U.S. Entity will be set forth in an SOP and would include the following requirements.**
 - a. Signatory must provide a copy of its charter or equivalent document issued by the Secretary of State, or similar government agency, for the jurisdiction in which the Signatory is legally organized or incorporated. Signatory shall provide its principal place of business, which shall be within the United States.
 - b. Signatory must provide a certificate of good standing, or similar document, issued by the relevant governmental authority for the jurisdiction in which Signatory is domiciled and dated within ninety (90) days of the date of Signatory's QHIN application.
 - c. Signatory must provide a current copy of its organizing documents, such as Articles of Incorporation and Bylaws for a corporation or Articles of Organization and Operating agreement for a limited liability company. These documents must be attested to by the Secretary of the organization or another officer of the organization if there is no Secretary.
 - d. Signatory must provide a list of its current officers and members of its governing body/ies, including their full names and business addresses. This list shall identify the officers and their terms of office.
 - (i) Signatory shall also attest that none of the individuals below are listed on the Specially Designated Nationals and Blocked Persons list published by the United States Department of Treasury Office of Foreign Asset Control or the list of Excluded Individuals published by the U.S. Department of Health and Human Services, Office of the Inspector General:
 1. All natural persons who have a 5% or greater ownership interest in the Signatory, if any;
 2. Officers of the legal entity that is the Signatory;
 3. Governing body members of the legal entity that is the Signatory;
 4. Members of the executive management of Signatory.
 - e. Signatory must satisfy all requirements of the Foreign Ownership SOP if Signatory is subject to that SOP.

2. Signatory is able to exchange Required Information, as defined in this Common Agreement. The specific, required means to demonstrate the ability to exchange Required Information will be set forth in an SOP and would include the following requirements.

- a. Signatory must meet the following:
 - (i) Be capable of the exchange of Required Information for all Exchange Purposes. Signatory must describe the exchange purposes that are permitted on its network;
 - (ii) Be capable of conducting exchange with unaffiliated organizations. Signatory must describe entities participating in its network, including their affiliation or non-affiliation with one another;
 - (iii) Signatory must describe how it currently facilitates exchange of health information (e.g. query, push, other exchange modality); and
 - (iv) Signatory shall indicate the length of time that it has experience with (i).
- b. Signatory must submit the number and type of organizations that utilize its exchange services in order to demonstrate that it is engaged in the exchange of Required Information. Signatory shall specify if it limits the types of organizations that can participate in its network or if its network is specialized in any manner (e.g., by geography, exchange purposes, type of information exchanged).
- c. Signatory must submit copies of its data sharing agreements, operating policies and procedures, and other legal agreements and related documents that govern the operation of its health information network.

3. Signatory must demonstrate that it has the ability to perform all of the required functions of a QHIN in the manner required by the Common Agreement, the SOPs, the QTF, and all other applicable guidance from the RCE. Signatory can demonstrate this by having been in operation and supporting the query functionality as outlined in the QTF, or other functionally comparable exchange method, for at least the twelve (12) calendar months immediately preceding its application to be Designated as a QHIN. However, the RCE will consider other evidence that Signatory may offer to demonstrate compliance with this eligibility criterion as more fully set forth in the applicable SOP. Notwithstanding the foregoing, if Signatory does not demonstrate that it has been supporting query functionality as outlined in the QTF, the RCE may deem this requirement to be satisfied on an interim basis and Designate the Signatory as a provisional QHIN as further provided in the QHIN Designation SOP, including additional review during a provisional period and the potential to have the provisional status removed if Signatory

achieves a predetermined level of technical competency. The specific, required means to demonstrate the ability to meet this criterion will be set forth in an SOP and would include the following requirements.

- a. QHINs must demonstrate the ability to successfully process a high number of transactions through a high performing, reliable environment. It is anticipated that QHINs may process tens of millions of transactions each day. The following performance measures must be provided to the RCE as part of Signatory's application:
 - (i) Average monthly transaction volumes
 - (ii) Average annual transaction volumes
- b. Signatory must provide specific information regarding its architecture and an attestation of its ability to expand the volume of data transactions through its network. This information shall include the ability to add technology capacity, staff, and other needed resources. Signatory must provide specific evidence of having been in operation and supporting the query functionality as outlined in the QTF for at least the twelve (12) calendar months immediately preceding its application to be Designated as a QHIN. If Signatory cannot demonstrate twelve (12) calendar months of operating history with query functionality as outlined in the QTF, the RCE can consider other evidence that Signatory is capable of other a functionally comparable exchange method.

The RCE can designate Signatory as a QHIN, assuming Signatory satisfies all other requirements, on a provisional basis if the RCE determines that Signatory can reasonably support the query functionality as outlined in the QTF for a specified period of time in production, exchange with other QHINs and otherwise complies with the requirements of the Common Agreement. The RCE will consider the following when making this determination:

- (i) Evidence to show that Signatory has been engaged in the transmission of Required Information using a different but functionally comparable exchange method to the QTF in a live production environment for at least twelve (12) consecutive months during the twelve (12) months immediately preceding its application to the RCE.
- c. Provisional status for organizations that do not satisfy all eligibility criteria at the time of application:
 - (i) A "Provisional QHIN" is an organization that the RCE Designates as a QHIN on a provisional basis ("Provisional Status") based on a determination that the organization: (1) does not, at the time of its application, satisfy all of the eligibility criteria, but (2) demonstrates the likelihood of being able to satisfy all such criteria during the course of the

Provisional Status. The Provisional Status is a 12-month period in which a Provisional QHIN has the opportunity to demonstrate the ability to perform all of the required functions of a QHIN in the manner required by the Common Agreement, QTF, and applicable SOPs.

- (ii) The RCE may impose such limitations on Signatory during its Provisional Status as the RCE deems reasonably necessary to allow the RCE to monitor Signatory's performance. This may include, but is not limited to, requiring Signatory to provide information about the type and volume of exchange activity, any problems that Signatory or its Participants or Subparticipants experience with exchange activity, participation in meetings with the RCE to discuss Signatory's performance during the Provisional Status, and any other matters that the RCE determines to be necessary. The Provisional Status shall continue for a time period of twelve (12) months following the RCE Designating Signatory as a Provisional QHIN; provided, however, that the RCE has the right to suspend (and toll) or terminate Signatory's Provisional Status at any point if the RCE determines that Signatory is in non-compliance with the requirements and obligations that are applicable to Provisional QHINs, as more fully set forth in the applicable SOP. During its Provisional Status, Signatory may not represent itself as a QHIN. As long as Signatory is under Provisional Status, Signatory may represent itself **only** as a "Provisional QHIN," and must do so clearly and prominently, if/when making any QHIN-related representation(s).
- d. Signatory must identify any gaps between its current technical infrastructure and the requirements of the QTF and identify its plan to address these gaps so that Signatory will be able to fully comply with the QTF once Signatory is Designated as a QHIN.

4. Signatory must demonstrate that it has in place, at the time of its application to be Designated as a QHIN, the organizational infrastructure and legal authority to comply with the obligations of the Common Agreement and a functioning system to govern its health information network. In addition, Signatory must demonstrate it has the resources and infrastructure to support a reliable and trusted network. The specific, required means to demonstrate this will be set forth in an SOP and would include the following requirements.

- a. Signatory must have network governance. This governance must include the following:
 - (i) Network governance must include representatives of entities that participate in Signatory's network. Signatory must describe the eligibility criteria for becoming a representative in its network governance, including any criteria related to ensuring the diversity of

those participating in Signatory's network are represented. Signatory must provide the number (or range) of individuals that participate in the body responsible for its network governance, as well as their affiliations.

- (ii) Network governance must provide for active participation, and representatives must have the authority to inform and make decisions regarding Signatory's network. As an indicum of having representative and participatory network governance, Signatory must state the minimum frequency with which meetings of the governing body are required to take place (e.g., monthly, quarterly, etc.) and attest that these meetings are attended by the number of acting representatives necessary to establish a quorum.
- (iii) Network governance must be codified through written means. Signatory must provide a copy of the document(s) that memorialize the body's authority to govern the network.
- (iv) The rules of network governance must be communicated to members of Signatory's network. Signatory must describe how network governance rules are communicated and enforced (Is this via contract terms, policies, or some other written form? Provide a copy of any such documents).
- (v) Network requirements must be enforced, including for onboarding entities to the network. Signatory must describe how Signatory evaluates organizations to decide that they have the necessary technical, legal, and operational capability to participate in Signatory's network.

b. Signatory's network governance must include the following functions:

- (i) Oversight of the technical framework that enables the exchange of Required Information through its network. If Signatory uses a third-party technology vendor for its network, explain how Signatory conducts oversight of the third party and how Signatory will assure the third party's compliance with the CA and QTF;
- (ii) Signatory must describe and demonstrate the legal means that it uses to enforce the policy, technical, and legal requirements of its network with its participants. If Signatory does not have a network legal agreement, the burden is on Signatory to demonstrate that it does have a legally enforceable approach;
- (iii) A formalized structure, resources, and controls to satisfy the privacy and security requirements of the CA and related SOPs, as well as evidence of compliance as specified in related SOPs;

- (iv) A formalized process to advance cooperation or resolve disputes regarding use of Signatory's network. Signatory shall provide a detailed description of: (1) all disputes that have been processed through the dispute resolution process during the twenty-four (24) months immediately preceding the submission of Signatory's application; (2) any disputes that are pending at the time Signatory submits its application; and (3) any legal claims filed during the twenty-four (24) months immediately preceding the submission of Signatory's application that arose out of a dispute that was first brought to Signatory's dispute resolution process or that was permitted to bypass such process (e.g., a petition for injunctive relief), to the extent Signatory knows of any such legal claims;
 - (v) A formalized process to manage any data breach involving Signatory's network;
 - (vi) A formalized process to impose sanctions on any network participant that violates the rules of Signatory's network, including the suspension or termination of said participant's ability to use the network;
 - (vii) A formalized process to implement changes to any of the above.
- c. The RCE must be confident that Signatories have the requisite financial and personnel resources to support their obligations as QHINs. This includes but is not limited to the following:
- (i) Signatory shall provide an attestation of the organization's financial health to assure continuity of QHIN operations. This includes an attestation that Signatory has available a minimum amount of cash, or cash equivalents, equal to 6 months of operating reserves, as well as copies of its audited financials for the prior two years.
 - (ii) Signatory shall describe the organizational structure and personnel who support the QHIN, including how these individuals work with the network governing body.
 - (iii) Signatory shall provide evidence of one of the following: (1) a certificate of insurance demonstrating that Signatory has current cyber-liability coverage that meets the requirements set forth in the applicable SOP; (2) that Signatory has applied for cyber-liability coverage that meets the requirements set forth in the applicable SOP, including an attestation that Signatory will obtain the coverage prior to Signatory being Designated; or (3) available internal funds, separate from those attested to in 4(c)(i), to self-insure against a cyber-incident up to the amount required by the applicable SOP.

d. Security

- (i) Trusted Network. Signatory must provide evidence that it has been certified under a nationally recognized security framework from a list of pre-approved certifications/certifying bodies developed by the RCE, as required by the *QHIN Security Requirements for the Protection of TI SOP*.
 - (ii) Chief Information Security Officer. Signatory must have a Chief Information Security Officer and provide evidence that the CISO has executive-level responsibility for overseeing the security of Signatory's network.
- e. Detailed information about any HIPAA reportable breaches of ePHI over the past 3 years including the nature of the breach, the number of individuals affected by the breach, the remediation measures undertaken by Signatory and the amount of any fines or penalties.

5. Signatory has the functional and technical ability to comply with the QHIN Technical Framework. The specific, required means to demonstrate this will be set forth in an SOP and would include the following requirement.

- a. Signatory must provide evidence of compliance with the QHIN Technical Framework, including but not limited to any required conformance, interoperability, or partner testing as specified in the *RCE QHIN Testing and Onboarding Process*.