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ONC Program Policy Notice: 2023 – 1

## Trusted Exchange Framework and Common Agreement (TEFCA) Policy Notice: Qualified Health Information Network Designation and Appeals Processes

### I. Purpose

This Program Policy Notice (PPN) documents the processes the Office of the National Coordinator for Health Information Technology (ONC), as well as its contractor performing the responsibilities of the Recognized Coordinating Entity<sup>®</sup> (RCE<sup>™</sup>)<sup>1</sup> will use to evaluate an organization's ability to receive and maintain Designation<sup>2</sup> as a Qualified Health Information Network<sup>™</sup> (QHIN<sup>™</sup>) capable of trusted exchange under the Trusted Exchange Framework and Common Agreement<sup>SM</sup> (TEFCA<sup>SM</sup>).

This PPN expands on Section 16.2 of Common Agreement Version 1.1,<sup>3</sup> which was published in the Federal Register on November 7, 2023, and which is the current version of the Common Agreement. Specifically, Section 16.2 of Common Agreement Version 1.1 states: “ONC anticipates publishing regulations to address the appeals of any of the RCE’s decisions listed in Section 16.1. ONC anticipates issuing sub-regulatory guidance to address those appeals while formulating regulations. Until ONC’s regulations governing those appeals are finalized and effective, the sub-regulatory guidance ONC issues shall be binding under this Common Agreement.” This PPN focuses on those QHIN appeals and provides guidance on the underlying standards and processes that ONC would consider in the case of an appeal, including qualifications for QHIN Designation, suspension, and termination.

ONC has generally derived the standards and processes included in this PPN from Common Agreement Version 1.1 and incorporated standard operating procedures (SOPs)<sup>4</sup> previously disseminated. ONC is leveraging the standards and processes for this PPN to create


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<sup>1</sup> See ONC Recognized Coordinating Entity, <https://rce.sequoiaproject.org/>.

<sup>2</sup> As defined in Common Agreement Version 1.1, *Designation* (including its correlative meanings “Designate,” “Designated,” and “Designating”) means the RCE’s written confirmation to ONC and Signatory that Signatory has satisfied all the requirements of the Common Agreement, the QHIN Technical Framework, and all applicable SOPs, and is now a QHIN.

<sup>3</sup> Trusted Exchange Framework and Common Agreement Version 1.1 (November 7, 2023), 88 FR 76773, available at <https://www.federalregister.gov/documents/2023/11/07/2023-24536/trusted-exchange-framework-and-common-agreement-version-1-1>.

<sup>4</sup> ONC Recognized Coordinating Entity, Standard Operating Procedures, <https://rce.sequoiaproject.org/tefca-and-rce-resources/#StandardOperatingProceduresSOPs>.



transparent and consistent expectations for QHINs and processes for ONC and the RCE to follow should a QHIN appeal an RCE decision related to either: (1) qualifications needed for a health information network (HIN) to be Designated as a QHIN capable of trusted exchange pursuant to the Common Agreement; or (2) procedures governing QHIN Designation, suspension, termination, and administrative appeals to ONC.

Capitalized terms used in this document without definitions have the respective meanings assigned to such terms in Common Agreement Version 1.1, QHIN Technical Framework Version 1.1 (QTF), and associated SOPs<sup>5</sup> including but not limited to the *QHIN Onboarding and Designation SOP Version 2.1*; *Exchange Purposes SOP*; *IAS Exchange Purpose Implementation SOP*; *IAS Provider Privacy and Security Notice and Practices SOP*; *Means to Demonstrate U.S. Ownership and Control of a QHIN SOP*; *ONC Access to and Requests for Confidential Information SOP*; and *QHIN Security Requirements for the Protection of TEFCA Information SOP Version 1.2*.

## II. Background

The 21st Century Cures Act (Pub. L. 114-255, Dec. 13, 2016) (Cures Act) authorizes the National Coordinator to develop or support a trusted exchange framework, including a common agreement among HINs nationally. ONC's overall goal for TEFCA is to establish a universal policy and technical floor for nationwide interoperability. The Common Agreement establishes the infrastructure model and governing approach to enable users in different HINs to securely share information with each other—all under commonly agreed-to expectations and terms, regardless of which network they happen to be in. The Trusted Exchange Framework<sup>6</sup> describes a common set of principles for policies and practices to facilitate data-sharing.

Under TEFCA, the industry-based RCE is an ONC contractor that is charged with developing, operationalizing, and updating the Common Agreement subject to ONC review, as well as stewarding the QTF,<sup>7</sup> which provides the technical specifications for how QHINs connect to one another. The RCE will also oversee QHIN-facilitated network operations and QHIN compliance with the Common Agreement, subject to ONC review.

QHINs play a critical role in advancing the exchange of health information and the standards for securing health information. QHINs are the entities that Participants join for access to TEFCA exchange and have the organizational and technical capabilities to connect Participants nationwide.

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<sup>5</sup> See TEFCA SOPs, RCE Resources, <https://rce.sequoiaproject.org/tefca-and-rce-resources/#StandardOperatingProceduresSOPs>.

<sup>6</sup> The Trusted Exchange Framework: Principles for Trusted Exchange (January 2022), available at [https://www.healthit.gov/sites/default/files/page/2022-01/Trusted\\_Exchange\\_Framework\\_0122.pdf](https://www.healthit.gov/sites/default/files/page/2022-01/Trusted_Exchange_Framework_0122.pdf).

<sup>7</sup> Qualified Health Information Network (QHIN) Technical Framework, Version 1.0 (January 2022), available at [https://rce.sequoiaproject.org/wp-content/uploads/2022/01/QTF\\_0122.pdf](https://rce.sequoiaproject.org/wp-content/uploads/2022/01/QTF_0122.pdf).



### III. Qualifications for Designation

For an entity to become a QHIN, that entity must sign the Common Agreement, thus agreeing to that document's comprehensive Designation requirements—as well as other requirements—for TEFCA exchange. This PPN describes the Designation requirements in three categories: (1) ownership; (2) exchange; and (3) Designated network services.

#### *Ownership Requirements*

An entity seeking QHIN Designation must:

1. Qualify as a U.S. Entity.<sup>8</sup>
2. Not be controlled by any non-U.S. persons or entities.
3. Not pose a national security risk to the United States of America.

#### *Exchange Requirements*

An entity seeking QHIN Designation must:

1. Be capable of exchanging information between more than two unaffiliated organizations;
2. Be capable of exchanging Required Information;
3. Be, at the time of its application, exchanging information for at least one of the authorized Exchange Purposes;
4. Support exchange of all authorized Exchange Purposes;
5. Respond to queries for all authorized Exchange Purposes that ONC or the RCE has identified as required for response; and
6. Not discriminate against any other QHIN in the exchange of information.

Collectively, these exchange requirements help ensure that an entity is capable of TEFCA exchange pursuant to the Common Agreement and is exchanging information at scale to support nationwide interoperability.


#### *Designated Network Services*

An entity seeking QHIN Designation must:

1. Have the organizational infrastructure and legal authority to operate and govern its Designated network.
2. Have policies and procedures in place necessary to support TEFCA exchange and fulfill its responsibilities as a QHIN, which an entity agrees to by signing the Common Agreement.

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<sup>8</sup> Common Agreement Version 1.1 at 13, available at <https://www.healthit.gov/sites/default/files/page/2023-12/Common-Agreement-v1.1.pdf>.

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3. Have a Designated network that is able to support a transaction volume that keeps pace with the demands of network users. Since TEFCA will be a nationwide network, QHINs must be capable of transacting high volumes of data reliably and at scale.
  4. Be able to support secure technical connectivity and data exchange with other QHINs.
  5. Have the ability to enable the exchange of Required Information through the Designated network.
  6. Have a dispute resolution policy governing Participants in the Designated network.
  7. Have a change management policy consistent with its responsibilities as a QHIN.
  8. Have a representative and participatory group or groups with either the authority to approve processes for fulfilling its governance requirements or the ability to review and provide input on processes for fulfilling the governance requirements.
  9. Have privacy and security policies in accordance with the requirements in the Common Agreement.
  10. Have data breach response and management policies that support TEFCA exchange.
  11. Have requisite financial and personnel resources to support its obligations as a QHIN, including sufficient financial reserves and/or insurance-based cybersecurity coverage.

#### **IV. QHINs That Offer Individual Access Services**

One goal of TEFCA is to support patients' access to their health care information. If a QHIN offers Individual Access Services (IAS), in order to maintain its Designation as a QHIN, the QHIN must:

1. Obtain express individual consent from any individual requesting IAS.
2. Make publicly available a privacy and security notice that meets minimum standards in the Common Agreement or relevant SOP(s).
3. Permit any individual to require that all of the individual's individually identifiable information maintained by the QHIN as an IAS provider be deleted, except as prohibited by Applicable Law or where such information is contained in audit logs.
4. Permit any individual to export all of the individual's individually identifiable information maintained by the QHIN as an IAS provider in a computable format.
5. Satisfy the minimum privacy and security requirements in the Common Agreement and relevant SOP(s) (e.g., *IAS Provider Privacy and Security Notices and Practices SOP*; *QHIN Security Requirements for the Protection of TEFCA Information SOP Version 1.2*), including those which apply to all individually identifiable information the QHIN holds.
6. Have an agreement with a qualified, independent third-party credential service provider and must verify, through the credential service provider, the identities of individuals seeking IAS prior to the individuals' first use of such services and upon expiration of their credentials.



## V. QHIN Designation and Onboarding Processes

To establish nationwide exchange of health information, TEFCA calls for the Designation of QHINs—HINs that agree to the common terms and conditions of exchange with each other, as specified in the Common Agreement, and to the functional and technical requirements for exchange, as specified in the QTF.

Under the RCE's contract<sup>9</sup> with ONC, the RCE's role is to support the implementation of TEFCA, including the solicitation and review of applications from HINs seeking QHIN status and administration of the QHIN Onboarding,<sup>10</sup> Designation, and monitoring processes. For entities seeking QHIN Designation, the application provides the RCE with the information needed to determine a prospective QHIN's ability to meet its obligations and responsibilities under the Common Agreement. All work or activities conducted by the RCE under the contract, including work or activities related to Designation, is conducted on behalf of ONC and subject to ONC review.

In this section of the PPN, we describe the application, review, Onboarding, withdrawal, and redetermination processes that Applicant QHINs, ONC, and the RCE will follow for QHIN Designation.

### *Submission of QHIN Application*

In order to be Designated as a QHIN, an Applicant QHIN<sup>11</sup> must submit:

1. A completed QHIN Application<sup>12</sup> to ONC through the RCE; and
2. A copy of the signed Common Agreement, to be countersigned by the RCE upon Designation, to ONC through the RCE.

### *Review of QHIN Application*

Upon receipt of an application for Designation, ONC through its RCE will review the application to determine if the Applicant QHIN has responded to all questions and provided the necessary supporting documentation. If the application is not complete, the RCE will notify the Applicant QHIN within thirty (30) calendar days of receipt of the application of the information that is required to make the application complete. The RCE may extend this period by providing written notice to the Applicant QHIN.

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<sup>9</sup> See USASPENDING.gov, [https://www.usaspending.gov/award/CONT\\_AWD\\_75P00123C00019\\_7570\\_-NONE\\_-NONE-](https://www.usaspending.gov/award/CONT_AWD_75P00123C00019_7570_-NONE_-NONE-).

<sup>10</sup> As defined in Common Agreement Version 1.1, *Onboarding* is the process a QHIN, Participant, or Subparticipant must undergo to become a QHIN, Participant, or Subparticipant and operational in the production environment under the Framework Agreement to which it is a party.

<sup>11</sup> *Applicant QHIN* refers to an entity that submitted an application to be Designated as a QHIN.

<sup>12</sup> QHIN Application, [https://rce.sequoiaproject.org/wp-content/uploads/2023/11/QHIN-Application-for-CA-v1.1\\_508\\_nov3.pdf](https://rce.sequoiaproject.org/wp-content/uploads/2023/11/QHIN-Application-for-CA-v1.1_508_nov3.pdf).



Once the RCE determines that the application is complete, the RCE will review the application to determine whether the Applicant QHIN satisfies the QHIN qualifications set forth in the Common Agreement and applicable SOP(s). The RCE must complete its review within sixty (60) calendar days of notifying the Applicant QHIN that its application is complete. The RCE may extend this period by providing written notice to the Applicant QHIN.

The RCE may contact the Applicant QHIN with questions as the RCE reviews the application consistent with the process described in the *QHIN Onboarding and Designation SOP*.<sup>13</sup> If, following submission of the application, any information submitted becomes untrue or materially changes, the Applicant QHIN must notify the RCE of such changes in writing within five (5) business days.

### *QHIN Approval and Onboarding*

An Applicant QHIN has the burden of proving its compliance with all qualifications for designation, as specified in Sections III and IV above, as applicable. If the RCE determines that an Applicant QHIN meets the QHIN qualifications,<sup>14</sup> then the RCE will notify the Applicant QHIN that the RCE has approved its application for Onboarding.

The RCE may deem an Applicant QHIN to satisfy the QTF requirement to demonstrate experience and ability to operate a high-performing network with query capability requirements on an interim basis and to approve a QHIN's application for Onboarding under a provisional status.<sup>15</sup> "Provisional Status" is a twelve (12) month period in which a QHIN has the opportunity to demonstrate the ability to perform all required functions of a QHIN in the manner required by the Common Agreement, QTF, and applicable SOPs. Once a QHIN with a provisional approval demonstrates that it meets the QHIN network performance requirements, the RCE will notify the Applicant QHIN that the RCE has removed the provisional status.

A QHIN may only maintain provisional approval for twelve (12) months, subject to extension for good cause granted by the RCE. If a QHIN does not have its provisional status removed within this time period, the RCE would provide the QHIN with a written notice denying the application. A QHIN Designated under provisional status would be subject to additional RCE monitoring and review while in that status.


An approved Applicant QHIN is required to submit a signed version of the most current Common Agreement within a time frame set by the RCE. An approved Applicant QHIN is also required to complete the Onboarding process set forth by the RCE, including any tests required by the RCE to ensure the Applicant QHIN's network can connect to those of other QHINs,

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<sup>13</sup> QHIN Onboarding and Designation SOP, [https://rce.sequoiaproject.org/wp-content/uploads/2023/11/SOP-QHIN-Onboarding-and-Designation-v1.1\\_-508\\_nov3.pdf](https://rce.sequoiaproject.org/wp-content/uploads/2023/11/SOP-QHIN-Onboarding-and-Designation-v1.1_-508_nov3.pdf).

<sup>14</sup> QHIN qualifications include the requirements set forth in Section III of this document and, if applicable, Section IV of this document.

<sup>15</sup> QHIN Onboarding and Designation SOP at 4-7, [https://rce.sequoiaproject.org/wp-content/uploads/2023/11/SOP-QHIN-Onboarding-and-Designation-v1.1\\_-508\\_nov3.pdf](https://rce.sequoiaproject.org/wp-content/uploads/2023/11/SOP-QHIN-Onboarding-and-Designation-v1.1_-508_nov3.pdf).



within 12 months of approval of its application by the RCE, unless that time is extended by the RCE by up to 12 months for good cause.

### *QHIN Designation*

An approved Applicant QHIN must notify the RCE upon completion of QHIN approval and Onboarding in a manner determined by the RCE. Once QHIN approval and Onboarding is completed, the RCE will countersign the Common Agreement and provide the Applicant QHIN with the RCE's written determination indicating that the Applicant QHIN has been Designated as a QHIN by the RCE.

Within thirty (30) calendar days of receiving such a written determination, each QHIN must demonstrate that it has completed a successful transaction with all other in-production QHINs according to standards and procedures set forth by the RCE. If a QHIN is unable to complete this requirement within the thirty- (30-) calendar day period provided, the QHIN is required to provide to the RCE an explanation as to why the QHIN is unable to complete the transaction within the allotted time and would be required to include a detailed plan and timeline for completion of a successful transaction in the explanation. The RCE would be required to review and approve or reject the QHIN's plan within five (5) business days of receipt.

### *Withdrawal of QHIN Application*

An application can be withdrawn voluntarily by written notice from the QHIN to the RCE.

### *Denial of a QHIN Application*

If an application is denied, the Applicant QHIN will be notified by the RCE along with the basis for the denial.

### *Re-Application and Renewed Applications*

Applications may be renewed and resubmitted by Applicant QHINs in the event that an application is denied or withdrawn. If an application is withdrawn, then the Applicant QHIN is able to reapply by submitting a new application no sooner than six (6) months after the date on which its previous application was withdrawn. If the reason for withdrawal was failure to respond to an RCE query, then the renewed application must address the question or questions to which the Applicant QHIN previously failed to respond and include an explanation as to why no response was previously provided within the required time frame.

If an application is denied, the Applicant QHIN may reapply by submitting a new application no sooner than six (6) months after the date shown on the written notice of denial. The new application must include all required information and must specifically address the deficiencies noted as the basis for denial of the Applicant QHIN's previous application.



An Applicant QHIN is able to seek redetermination by the RCE of the denial of its application for one or more of the following reasons:

1. The reason or reasons for denial identified by the RCE is or are incorrect due to an inadvertent error or errors by the RCE;
2. The RCE failed to follow the procedures set forth in this document, Common Agreement Version 1.1, or an SOP or SOPs, and this failure materially interfered with the Applicant QHIN's ability to demonstrate that the Applicant QHIN satisfies the QHIN qualifications in this document;
3. The RCE has not applied the QHIN qualifications in this document in a consistent manner across all Applicant QHINs;
4. The RCE discriminated against the Applicant QHIN in the RCE's review of the application;
5. The RCE based its denial on something other than the QHIN qualifications in this document or other requirements imposed on QHINs by Common Agreement Version 1.1, SOP or SOPs, or the QTF.

To request redetermination of the denial of an application, the applicant must file with the RCE a written request for redetermination identifying the basis for the request, to include all supporting documentation for the request, within fifteen (15) calendar days of the date shown on the notice of denial following all procedures set forth by the RCE. An Applicant QHIN bears the burden of showing its entitlement to redetermination.

## VI. Suspension

This section includes RCE and QHIN suspension rights, notice requirements for suspension, and the effect of suspension.


### *Suspension Rights Granted to the RCE to Suspend a QHIN*

The RCE may suspend a QHIN's ability to engage in exchange activities under the Common Agreement if the RCE determines, following completion of an investigation, that a QHIN is responsible for a Threat Condition.<sup>16</sup> To the extent that the RCE determines that one of a QHIN's Participants or Subparticipants has done something or failed to do something that

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<sup>16</sup> As defined in Common Agreement Version 1.1, a Threat Condition occurs under three circumstances: (i) a breach of a material provision of the Common Agreement that has not been cured within fifteen (15) calendar days of receiving notice of the material breach (or such other period of time to which the RCE and QHIN have agreed), which notice shall include such specific information about the breach that the RCE has available at the time of the notice; or (ii) a TEFCA Security Incident; or (iii) an event that a QHIN, its Participant, or their Subparticipant has reason to believe will disrupt normal exchange under the Framework Agreements, either due to actual compromise of or the need to mitigate demonstrated vulnerabilities in systems or data of the QHIN, Participant, or Subparticipant, as applicable, or could be replicated in the systems, networks, applications, or data of another QHIN, Participant, or Subparticipant.





results in a Threat Condition, the RCE may suspend the Participant or Subparticipant or the RCE may direct the QHIN to suspend the Participant or Subparticipant. Such suspension would prevent the Participant or Subparticipant from engaging in exchange activities under the Common Agreement.

The RCE is required to make a reasonable effort to notify a QHIN in advance of the RCE's intent to suspend the QHIN or one of the QHIN's Participants or Subparticipants, including written notice of the Threat Condition giving rise to such suspension. If advance written notice is not reasonably practicable under the circumstances, the RCE will notify the QHIN of the suspension, and the Threat Condition giving rise thereto, as soon as practicable following the suspension. Upon suspension of either the QHIN or one of the QHIN's Participants or Subparticipants, the RCE must work with the QHIN to resolve the issue leading to the suspension.

### *Selective Suspension of Exchange Between QHINs*

A QHIN may, in good faith and to the extent permitted by Applicable Law, determine that it must suspend exchange with another QHIN with which it is otherwise required to exchange because of reasonable concerns related to the privacy and security of information that is being exchanged. If a QHIN makes this determination, it is required to promptly notify the RCE and the QHIN with which it is suspending exchange of its determination and the reason(s) for making the determination.

If a QHIN suspends exchange with another QHIN, it must, within thirty (30) calendar days, initiate the Dispute Resolution Process specified in the Common Agreement to resolve the issues that led to the decision to suspend, or the QHIN may end its suspension and resume exchanging with the other QHIN within thirty (30) calendar days of suspending exchange with the QHIN. Provided that a QHIN selectively suspends exchange with another QHIN in accordance with this section and in accordance with Applicable Law, such selective suspension would not be deemed a violation of the Common Agreement.

### *Additional Suspension Rights of the RCE*

The RCE has the right to suspend any exchange activity under the Common Agreement: (1) upon ten (10) business days' prior written notice to a QHIN if the RCE determines that the QHIN has created a situation in which the RCE may suffer material harm and suspension is the only reasonable step that the RCE can take to protect itself; or (2) immediately if the RCE determines that the safety or security of any person or the privacy or security of TEFCA Information, Confidential Information, or both is threatened. In the case of an immediate suspension under this section, the RCE will provide written notice to the suspended QHIN as soon as practicable following the suspension.



## *Effect of Suspension*

The suspension of a QHIN's ability to participate in any activity under the Common Agreement would have no effect on that QHIN's other TEFCA required obligations, including, without limitation, privacy and security obligations.<sup>17</sup> During any suspension, the QHIN's inability to exchange information under the Common Agreement or comply with those terms of the Common Agreement that require information exchange shall not be deemed a breach of the Common Agreement. Suspension is a temporary status in which a QHIN is allowed time to mitigate any circumstances that give rise to the suspension. While in suspension status, the QHIN is not allowed to exchange information through TEFCA.

In the event of suspension of the QHIN's ability to participate in exchange activities under the Common Agreement, the QHIN would be required to communicate with its Participants that all TEFCA exchange on behalf of the QHIN's Participants will also be suspended during any period of the QHIN's suspension. The QHIN must also require that the QHIN's Participants communicate with their Subparticipants that all TEFCA exchange on behalf of the QHIN's Subparticipants will be suspended during any period of the QHIN's suspension.

## **VII. Termination**

This section describes RCE and QHIN termination rights, notice requirements for termination, and requirements related to the effect of termination.

### *Termination by QHIN*


A QHIN can terminate the Common Agreement it has signed with the RCE at any time without cause by providing ninety- (90-) calendar days prior written notice to the RCE. A QHIN may also terminate the Common Agreement it has signed with the RCE for cause if the RCE commits a material breach of the Common Agreement and the RCE fails to cure its material breach within thirty (30) calendar days of the QHIN providing written notice to the RCE of the material breach; provided, however, if the RCE is diligently working to cure its material breach at the end of this thirty- (30-) calendar day period, then the QHIN would be required to provide the RCE with up to another thirty (30) calendar days to complete its cure.

### *Termination by the RCE*

The RCE may not terminate the Common Agreement it has signed with a QHIN without cause. The RCE is permitted to terminate the QHIN's Common Agreement with immediate effect by giving written notice to the affected QHIN for two reasons: (1) if a QHIN is in material breach of any of the terms and conditions of the Common Agreement and fails to remedy such breach within thirty (30) calendar days after receiving written notice of such breach; provided, however, that if a QHIN is diligently working to cure its material breach at the end of this thirty (30) calendar day period, then the RCE must provide the QHIN with up to another thirty (30)

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<sup>17</sup> Privacy and security obligations expressly include, but are not limited to, requirements in Common Agreement Version 1.1 §§ 7, 10, 11, and 13.



calendar days to complete its cure; or (2) a QHIN breaches a material provision of the Common Agreement it has signed with the RCE where such breach is not capable of a remedy.

### *Termination by the RCE if the RCE Ceases to be Funded*

If federal funding ceases, or if the available funding is not sufficient to provide the necessary funding to support operation of the RCE and there is no successor RCE, then the RCE may terminate the Common Agreement it has signed with a QHIN by providing one hundred and eighty- (180-) calendar days prior written notice to the QHIN.

### *Termination by Mutual Agreement*

The RCE and a QHIN may terminate their Common Agreement at any time and for any reason by mutual, written agreement.

### *Effect of Termination of the Common Agreement*

Upon termination of a Common Agreement, the RCE must promptly remove the terminated QHIN and its Participants and Subparticipants from the RCE Directory Service and any other lists of QHINs that the RCE maintains.

Upon termination of a Common Agreement, a QHIN must, without undue delay, remove all references that identify it as a QHIN from all media and cease all use of any material, including but not limited to, product manuals, marketing literature, and web content that identifies it as a QHIN.

Within twenty (20) business days of termination of the Common Agreement that the QHIN has signed with the RCE, a QHIN shall confirm with the RCE, in writing, that it has complied with the preceding paragraph. To the extent a QHIN stores TEFCA Information, such TEFCA Information may not be distinguishable from other information maintained by the QHIN. When the TEFCA Information is not distinguishable from other information, it is not possible for the QHIN to return or destroy TEFCA Information it maintains upon termination or expiration of the Common Agreement.

Upon termination or expiration of the Common Agreement, if a QHIN is subject to Section 11.1 of the Common Agreement, such section shall continue to apply so long as the information would be ePHI if maintained by a Covered Entity or Business Associate. The protections required under the HIPAA Security Rule shall also continue to apply to all TEFCA Information that is ePHI, regardless of whether a QHIN is a Covered Entity or Business Associate.

In no event shall a QHIN be entitled to any refund of any fees that it has paid the RCE prior to termination.



## VIII. QHIN Appeals to ONC

This section establishes QHIN appeal rights and the process for filing an appeal to ONC. These appeal rights ensure that a QHIN, or Applicant QHIN, that disagrees with certain RCE determinations will have recourse to challenge such determination to ONC.

As previously discussed, the RCE is responsible for operationalizing the Common Agreement, overseeing QHIN-facilitated network operations, and ensuring compliance by participating QHINs. ONC oversees the RCE's work and ONC has the right to review the RCE's conduct, including Designation, corrective action, and/or termination determinations regarding QHINs and the proper execution of nondiscrimination and conflict of interest policies that demonstrate a commitment to transparent, fair, and nondiscriminatory treatment by the RCE of QHINs.<sup>18</sup> ONC may also address complaints made by a QHIN against the RCE as set forth in Section 15.6.1, Escalation of Certain Disputes to ONC, of Common Agreement Version 1.1.

### *Basis for Appeal*

An Applicant QHIN may appeal an RCE denial of its QHIN application. A Designated QHIN may appeal an RCE decision in the following circumstances: (1) an RCE decision to suspend a QHIN or a QHIN's Participant or Subparticipant; and (2) an RCE decision to terminate a QHIN's Common Agreement.

### *Method and Timing for Filing an Appeal*


A statement of intent to appeal followed by a request for appeal must be submitted to ONC electronically and in writing by an authorized representative of the Applicant QHIN or QHIN whose QHIN application was denied or who was suspended or terminated.

In order to file an appeal, an authorized representative of the Applicant QHIN or QHIN must submit electronically and in writing to ONC an initial notice of appeal that includes the date of the notice of appeal, the date of the decision being appealed, the Applicant QHIN or QHIN who is appealing, and what is being appealed (i.e., (1) denial of QHIN application, (2) suspension, or (3) termination) within 10 business days of the Applicant QHIN's or QHIN's receipt of the notice of (1) denial of a QHIN application, (2) suspension, or (3) termination.

An authorized representative of the Applicant QHIN or QHIN must submit electronically and in writing a request for appeal to ONC within 30 calendar days of filing the intent to appeal with ONC. The appeal must include the basis for appeal, a detailed description of the facts supporting the appeal, and any additional documentation necessary to support the appeal. The Applicant QHIN or QHIN filing the appeal may not submit to ONC any additional evidence that was not originally submitted to the RCE.

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<sup>18</sup> See Common Agreement Version 1.1, Section 3.1, <https://www.federalregister.gov/documents/2022/01/19/2022-00948/notice-of-publication-of-the-trusted-exchange-framework-and-common-agreement>.



The statement of intent to appeal and request for appeal must be filed in accordance with the requirements specified in the notice of (1) denial of QHIN application, (2) suspension, or (3) termination.

### *Effect of Appeal on Suspension and Termination.*

An appeal does not stay the suspension or termination.

### *Assignment of a Hearing Officer*

The National Coordinator will arrange for assignment of the appeal to a hearing officer to adjudicate the appeal on his or her behalf. The hearing officer must be an officer properly appointed by the Secretary of Health and Human Services.

### *Adjudication*

The hearing officer will decide issues of law and fact *de novo*. The hearing officer may make a determination based on the written record, which includes (1) the RCE's determination and supporting information and documentation and (2) the appeal submitted by the Applicant QHIN or QHIN (which includes the basis for appeal, a detailed description of the facts supporting the appeal, and any additional documentation necessary to support the appeal). The hearing officer must only consider evidence submitted by the Applicant QHIN or QHIN that was originally submitted to the RCE.

The hearing office may also consider any information from a hearing conducted in-person, via telephone or video-teleconference, or otherwise. The hearing officer will have the discretion to conduct a hearing if he/she: (1) requires clarification by either party regarding the written record; (2) requires either party to answer questions regarding the written record; or (3) otherwise determines a hearing is necessary.

The hearing officer will neither receive witness testimony nor accept any new information beyond what was provided in accordance with the above adjudication requirements.

### *Determination by the Hearing Officer*

The hearing officer will issue a written determination to the RCE and Applicant QHIN or QHIN. The hearing officer's determination on appeal is final unless the Secretary, at the Secretary's sole discretion, chooses to review the determination.