ONC TEFCA RECOGNIZED COORDINATING ENTITY

Public Health Exchange Purpose (XP): Educational Guidance Draft for Stakeholder Feedback

January 19, 2024

This educational resource is being provided for informational purposes only. It does not modify, amend, supersede or interpret any Framework Agreement, Standard Operating Procedure (SOP), or the Qualified Health Information Network Technical Framework (QTF). Please note that while we strive to maintain accuracy in this resource, it is provided for educational purposes only. This resource should not be solely relied upon by QHINs, Participants or Subparticipants. It is ultimately a QHIN's, Participant's, or Subparticipant's contractual responsibility to ensure it is compliant with any applicable Framework Agreement, SOP, or QTF.

Please refer to the official versions of referenced documents available at the RCE website.

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INTRODUCTION

The Covid-19 pandemic underlined the importance of improving public and private sector capabilities to share health information in support of public health purposes. Public health data exchange generally requires a high level of effort, often involving multiple direct interfaces and electronic reporting channels, or use of non-digital means, including fax. Substantial organizational, technical, legal, and financial resources are required to develop and maintain these point-to-point interfaces and legal agreements, which inhibits the use of electronic exchange for public health purposes today.

The Trusted Exchange Framework and Common Agreement SM (TEFCA SM) offers an important vehicle to streamline public health information exchange, support bidirectional exchange between public health entities and health care organizations, and create efficiencies. The Office of the National Coordinator for Health Information Technology (ONC), the Centers for Disease Control (CDC) and The Sequoia Project, acting as the Recognized Coordinating Entity® (RCE™) for TEFCA, are collaborating to specify the policies and technical approaches for TEFCA-based exchange between health care organizations and Public Health Authorities (PHAs). The public health community is also encouraged to participate in defining TEFCA's public health use cases through active engagement and stakeholder feedback to ensure that TEFCA Exchange meets the needs of public health.

This document provides information about the opportunities to use TEFCA in support of public health data exchange and includes a call to action for the public health community to engage in building and participating in public health use cases under TEFCA. This resource includes details that describe:

- How TEFCA-based exchange will work;
- How TEFCA can support the public health community;
- Considerations for PHAs and Health Care Providers to use public health exchange in TEFCA; and
- How the public health community can be actively engaged in TEFCA's development.

We are thankful to the many public and private sector public health experts that helped to inform the development of this document and look forward to continued engagement.

Note that this resource is an educational tool and is not an official statement of policy. Readers are encouraged to also reference the Common Agreement and other technical policy documents on the RCE website as well as the comprehensive User's Guide and descriptions of benefits for various communities, including public health. The RCE website also houses documents that are open for stakeholder feedback. Terms that are capitalized in this document have specific

definitions that can be found in the TEFCA Glossary. The Appendix includes definitions of select terms relevant to public health that fall outside of TEFCA.

WHAT IS TEFCA AND WHY IS IT IMPORTANT TO PUBLIC HEALTH AUTHORITIES?

The 21st Century Cures Act called on the Office of the National Coordinator for Health Information Technology (ONC) to develop or support a Trusted Exchange Framework and Common Agreement that sets a foundation for universal interoperability in the United States. The Common Agreement and the Qualified Health Information Network ™ (QHIN ™) Technical Framework (QTF) establish an infrastructure and governing approach for users in different networks and across different sectors -- including health care providers, payers, and public health -- to securely share electronic health information. The RCE works closely with ONC to develop and maintain the policies, technical approaches, and governance structures to operationalize TEFCA Exchange.

The Common Agreement and related policy and technical documents offer a nationwide approach for the exchange of health information to support a range of Exchange Purposes, enabling a multitude of use cases, including Treatment and Public Health. It simplifies connectivity among networks and creates efficiency by establishing a scalable, standardized approach to exchange policies (such as privacy and security protections, and expectations for cooperation and non-discrimination), as well as to technical frameworks (such as standards for exchange and directory services).

TEFCA Components

- **Trusted Exchange Framework (TEF)** describes a common set of foundational principles for policies and practices to facilitate data sharing.
- **Common Agreement** is the legal contract that the RCE and a QHIN sign. It establishes the infrastructure model and governing approach for users in different health information networks to securely share information with each other.
- **Standard Operating Procedures (SOPs)** provide detailed information or requirements related to the exchange activities under the Common Agreement.
- **QHIN Technical Framework (QTF)** outlines the technical specifications and other technical requirements necessary for QHINs to exchange information.
- **QHIN Application & Onboarding** is the process that applicant QHINs must undergo to become a designated QHIN and to become operational in the production environment.

TEFCA went live in December 2023, when the RCE and an initial set of QHINs signed the Common Agreement Version 1.1 (v1.1). The Common Agreement's set of uniform policies and technical approaches for exchange of health information, reduces the burden health information networks and their participants currently face when they establish connections with entities outside their networks. Consistent policies and technical approaches also increase the overall exchange of health information. When implemented for public health, the use of TEFCA could include electronic case reporting, immunization registry data sharing, vital records data sharing, and case investigations.

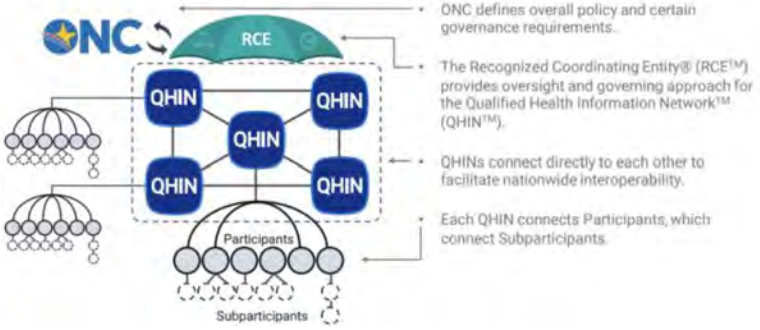
The Common Agreement authorizes six types of Exchange Purposes, of which Public Health is one. This permits entities that participate in TEFCA to appropriately share and request information to and from PHAs through a secure exchange network. Due to the complexities and variations in laws concerning exchange for public health purposes, the Common Agreement states that PHAs are not required to respond to any queries from requesters, although they are encouraged to do so.

TEFCA operates within existing law, including the Health Information Portability and Accountability Act (HIPAA) and any state, territorial, local, and tribal (STLT) laws specific to the sharing of health information. This means that in the event of any inconsistencies, any laws or regulations applicable to PHAs will take precedence over the terms in the Common Agreement. PHAs will want to work with their legal counsel and the QHIN they participate with to determine how to ensure compliance with all Applicable Law.

Public health and health care organizations will need to learn how to use TEFCA effectively for public health purposes and there may be substantial variation in readiness to participate in the near future. Consequently, existing data exchange pathways for public health outside of TEFCA may continue to be used for some time. However, close collaboration between ONC, CDC, the RCE, the public health community, and health care organizations will hasten the ability to use TEFCA Exchange for the benefit of the public's health.

How will TEFCA Exchange work?

Conceptually, TEFCA creates a "network of networks" that allows information to be appropriately shared nationwide. At the core of TEFCA is a set of QHINs that support exchange among other entities. Only the RCE can Designate QHINs through a rigorous application and onboarding process. The first QHINs went live in December 2023.



The Role of QHINs. Imagine a QHIN as a massive Health Information Exchange (HIE) connected to many other HIEs and providers and other entities like laboratories, immunization information systems, and others. It is an interlocking web of Participants and Subparticipants with technical standards, legal agreements, and connections to help the broader health care community and public health share data, among other use cases.

RCE Directory Service: The RCE Directory Service is a key component of TEFCA Exchange, where QHINs publish electronic endpoints and other necessary information about all entities that participate in TEFCA Exchange through the QHIN. All QHINs have access to this information to enable their participants to locate where information can be shared or requested via TEFCA

Exchange. The information in the RCE Directory Service is considered confidential information and is not shared publicly.

Exchange Purpose(s) or XP(s): Every transaction that occurs via TEFCA Exchange must include the XP that represents the reason for why the transaction is being initiated (e.g., Treatment or Public Health). The XP is identified in the transaction header using a specific code, along with other details about the requestor and the information being requested. The detailed requirements for what must be in a transaction for a specific XP are in the QTF and the applicable Sub Exchange Purpose (SubXP) Implementation Standard Operating Procedure (SOP) as discussed below.

Sub Exchange Purpose (SubXP) Implementation SOPs: The SubXP Implementation SOPs specify additional details about a given use case, above and beyond the foundational requirements in the Common Agreement and QTF. This could include details on expected response information and the standard way that data should be formatted for a specific purpose (such as the data elements, standard format and terminology, ontology, taxonomy, or code set). Required information may include certain Health Level Seven (HL7®) Fast Healthcare Interoperability Resources (FHIR®) value sets, data files, or other document types needed to support the Public Health purpose.

A critical component of a SubXP Implementation SOP is that it may assign a unique code to the use case(s) it describes. This code must be represented in each transaction initiated for such SubXP. That said, the adoption of a SubXP Implementation SOP in TEFCA does not impact the ability to use TEFCA Exchange for the broader Exchange Purpose.

Exchange Modalities: Every TEFCA Exchange transaction also adheres to one of the specified exchange modalities. There are two exchange modalities currently used in TEFCA Exchange:

- QHIN Message Delivery (Push transaction)
- QHIN Query (including Patient Discovery, Document Query, and Document Retrieval)

The draft Common Agreement v2 proposes to support Facilitated FHIR-based exchange between endpoints in the RCE Directory Service, including individual and bulk transactions.[1]

A Request for public health data must originate from a QHIN, Participant, or Subparticipant listed in the RCE Directory Service. PHAs could make the Request directly, as a Principal, or by using a Delegate, such as a Health Information Exchange (State, regional, or private) or other intermediary authorized by the PHA. A Delegate to a PHA may include organizations like the Association of Public Health Laboratories (APHL) or a public health data utility that serves as a

[1] FHIR Roadmap for TEFCA Exchange v2 available at https://rce.sequoiaproject.org/wp-content/uploads/2023/12/FHIR-Roadmap-for-TEFCA-Exchange.pdf.

liaison between PHAs and health care providers. The draft Common Agreement v2 includes the following proposed definitions:

Delegate: a QHIN, Participant, or Subparticipant that (i) is not a Principal and (ii) has a written agreement, directly or indirectly, with a Principal authorizing the Delegate to conduct TEFCA Exchange activities 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.

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

All Uses and Disclosures must adhere to the privacy and security requirements in the Common Agreement, any privacy and security notices, and any requirements of Applicable Law.

PHAs are ***encouraged, but not required***, to Respond to queries received from TEFCA Exchange, provided that the Response is authorized by applicable law, is consistent with Privacy and Security Notice when appropriate, and is in accordance with the Common Agreement (CA 9.4.1) and Exchange Purposes (XPs) SOP. If public health elects to participate in TEFCA, it is understood that this may be for data retrieval purposes, to start.

WHAT DOES IT MEAN FOR A PUBLIC HEALTH AUTHORITY TO PARTICIPATE IN TEFCA?

Any PHA or its Delegate that is technically capable of connecting to a QHIN and that signs a Framework Agreement can be a Participant or a Subparticipant of a QHIN. This allows them to have their entity endpoint registered in the RCE Directory Service, which is akin to having a post office on the network. The objective is to allow PHAs to exchange data to meet public health needs, similarly to how other health care organizations are able to do so utilizing TEFCA.

There are a wide variety of PHAs that vary in size, technical capacity, and legal/regulatory environments. Each may need to be handled differently as we think about participation in TEFCA Exchange. For example, some Participants and Subparticipants may be Hybrid Entities under HIPAA. A Participant or Subparticipant that is a Hybrid Entity delivers both clinical services covered by HIPAA and public health services that are not covered by HIPAA.

Likewise, Tribal Health Authorities (e.g., Tribes and Tribal Epidemiology Centers) are PHAs through inherent rights and Federal law, and. as such, are included under the TEFCA Public Health Exchange Purpose. As with other PHAs, Tribal Health Authorities may also provide health care services and may thus be considered Hybrid Entities under HIPAA.

PHAs will need to consult with their own legal counsel before entering into participation agreements for TEFCA Exchange and in defining the types of TEFCA data exchange they will support.

PUBLIC HEALTH SUBXP-1 IMPLEMENTATION STANDARD OPERATING PROCEDURE

The Public Health Exchange Purpose is generally defined in the Common Agreement as:

> "a Request, Use, Disclosure, or Response permitted under the HIPAA Rules and other Applicable Law for public health activities and purposes involving a Public Health Authority, where such public health activities and purposes are permitted by Applicable Law, including a Use or Disclosure permitted under 45 CFR § 164.512(b) and 45 CFR § 164.514(e) [HIPAA Privacy Rule]." (See Appendix for full definition).

This is a broad definition that allows willing data partners to leverage TEFCA for any public health data exchange that is permissible under HIPAA and other Applicable Law as soon as TEFCA Exchange is operational. However, Public Health exchange encompasses a variety of data sharing scenarios (i.e., use cases). Therefore, the RCE is working with ONC, CDC, and the public health community to develop an initial Exchange Purpose (XP) Implementation SOP: Public Health SubXP-1 to further define specific use cases and specifications for those use cases. The RCE will develop additional Exchange Purpose (XP) Implementation SOPs over time to continue to build out use cases that provide value to the public health community.

The adoption of an Exchange Purpose (XP) Implementation SOP: Public Health SubXP-1 ***does not*** modify the terms and conditions related to the broader Public Health XP, as described in the Common Agreement, QTF, and the Exchange Purposes (XPs) SOP.

The RCE encourages robust review of the draft Exchange Purpose (XP) Implementation SOP: Public Health SubXP-1 by STLTs, federal partners, and others to ensure the SOP is as complete and accurate as possible. The draft includes two use cases, using the following definitions.[2,3]

- **Electronic Disease Reporting (e.g., Electronic Case Reporting and Electronic Lab Reporting):** PHAs are generally required by Applicable Law to monitor, investigate, mitigate, and otherwise act to prevent the introduction or spread of diseases and conditions that endanger the public health in their jurisdictions. To facilitate this duty, physicians, clinical laboratories, and other health care organizations are often mandated

[2] A previous version of this document contained different definitions than those above. Please provide feedback on the Electronic Disease Reporting and Electronic Case Investigation definitions as provided here.

[3] Definitions adapted from Use Case Description: Use of CRISP Services for Disease Investigation available at https://www.crisphealth.org/wp-content/uploads/2022/01/Approved_Use-Case-Disease-Investigation-Updated_2021.pdf.

by Applicable Law to report certain diseases and conditions and/or certain indicators thereof. The use of electronic case and lab reporting streamlines this mandated reporting process for health care providers and PHAs alike.

- **Electronic Case Investigation:** is a public health tool that involves a PHA gathering additional information in response to a disease or condition that has already been reported under Applicable Law. This often includes collecting information about the individual's symptoms, their clinical characteristics/history, how/where they may have contracted or acquired the disease/condition, and the overall course of their illness, including clinical interventions received. These investigations help PHAs understand and mitigate the extent to which other people or groups may be at risk. The ability to gather information for case investigation electronically vastly improves the efficacy of these investigations. This includes the ability of a PHA to query health care providers and others for additional information for case investigation in follow-up to a PHA's receipt of an electronic disease report.

Permitted users for purposes of the draft Exchange Purpose (XP) Implementation SOP: Public Health SubXP-1 include QHINs, Participants, and Subparticipants (and their Delegates) that are authorized by Applicable Law, the Common Agreement, and an applicable SOP to assert the Public Health Exchange Purpose.

Push: QHIN Message Delivery & FHIR Push

- The draft SOP supports TEFCA Exchange in the form of a Push, including a Reportable Response, from any QHIN, Participant, or Subparticipant to a PHA, or a PHA's Delegate, in accordance with Applicable Law and the Common Agreement.

Request: QHIN Query & FHIR Request

- The draft SOP supports TEFCA Exchange in the form of a QHIN Query or FHIR Request. Only PHAs or Delegates that are listed in the RCE Directory Service may initiate a Request under the Public Health Exchange Purpose and the proposed Public Health SubXP-1.

All Uses and Disclosures for the Public Health SubXP-1 must adhere to the privacy and security requirements in the Common Agreement, any privacy and security notices, and any requirements of Applicable Law. Additionally, the draft SOP includes a specific requirement that restricts TEFCA Information transacted for purposes of the Public Health SubXP-1 from being persisted or Used or Disclosed for any other purpose aside from which it was intended (aside from required auditing) by any system along the transaction chain that is not the addressed recipient, unless agreed to by the data source or recipient through an specific written agreement.

Over time, additional use cases that may be considered include:

- Vital Statistics Birth Records
- Vital Statistics Death Records
- Cancer Registry Reporting
- Immunization Registry
- Syndromic Surveillance
- Health Care Surveys
- Population Health
- Social Determinants of Health (SDoH)
- Chronic Disease Conditions (e.g., Hypertension; Diabetes)
- Bidirectional Data Exchange for Referrals (BSeR) (e.g., tobacco quitline; other interventions)

Implementation Guides (IGs)

Public health exchange encompasses a variety of data sharing scenarios (e.g., use cases) that support the mission of PHAs. TEFCA Exchange will be done via transactions that conform to widely adopted industry Implementation Guides (IGs) for specific use cases. IGs define the standard way that data should be formatted for a specific purpose.

The draft Exchange Purpose (XP) Implementation SOP: Public Health SubXP-1 references industry IGs (such as the HL7 FHIR Implementation Guide: Electronic Case Reporting (eCR) - US Realm 2.1.0 - STU 2). Each QHIN, Participant, and Subparticipant that participates in Public Health exchange should review the applicable public health IGs and other programmatic documentation for a specific use case.

Each public health IG describes the data elements, standard format and terminology, ontology, taxonomy, or code set. Required information may include certain HFHIR, value sets, data files or other document types needed to support the Public Health purpose.

The publication of an IG or the support of a particular IG does not mean that any PHA is capable of receiving data through TEFCA related to the IG. PHA websites/staff will likely need to communicate directly to share which IG versions are supported and what data elements are required (e.g., they may change a may/shall to must) for a given use case. For example, this may be done to require specific social determinants of health and demographic data. PHAs will also need to describe what methods of transmission they support (including TEFCA), which may differ greatly by jurisdiction as PHAs transition to use of TEFCA Exchange.

Entities that report to PHAs must also validate with the appropriate PHA(s) that submitting data through TEFCA satisfies all reporting requirements for health care and public health exchange nationally.

Considerations for Public Health Authorities and Health Care Organizations

As PHAs and health care organizations that report to public health evaluate how best to engage in TEFCA Exchange, they may want to consider the following:

TEFCA policies. All those considering participation in TEFCA should review the Common Agreement, QTF, SOPs, and other educational resources available on the RCE website.

Public health-specific policies. Each QHIN, Participant, and Subparticipant that is considering participation in public health exchange should review the applicable Public Health SubXP Implementation SOP(s) or other programmatic documentation for a specific use case. Health care organizations reporting to Public Health will also need to communicate with relevant PHAs to determine their timelines for participation.

PHA-specific analysis. PHAs vary greatly in size, technical capacity, and legal/regulatory environments. For example, some Participants and Subparticipants may be Hybrid Entities under HIPAA. A Participant or Subparticipant that is a Hybrid Entity delivers both clinical services covered by HIPAA and public health services that are not covered by HIPAA (see definition in Appendix). As a result, each PHA will need to make its own analysis of how best to participate in TEFCA.

Connecting to TEFCA Exchange. A PHA is most likely to be a Participant or Subparticipant of a QHIN. PHAs will be able to connect to QHINs directly or could use their existing connections to other technical intermediaries (e.g., Association of Public Health Laboratories Informatics Messaging Services [AIMS Platform], HIEs, etc.). In determining how best to join TEFCA, PHAs will want to consider issues such as the support services that are offered, costs, technical requirements, and implementation timelines.

Technical evaluation. PHAs will also need to evaluate their existing data infrastructure and methods of transmission they support and identify any possible needed improvements. This analysis could encompass needed technical infrastructure, staff, and training, among other things.

Policy mapping. Given that TEFCA relies on Applicable Law, PHAs will need to consider how their own policies and requirements may overlay the data standards and other requirements in TEFCA (including in the SOPs). For example, data redaction and retention requirements may need consideration depending on Applicable Law within the STLT's jurisdiction. This type of review will help provide guidance to reporters and other data exchange partners on how to submit data through TEFCA in a way that satisfies all STLT-specific requirements. This may vary greatly by jurisdiction.

Privacy and security. PHAs and health care organizations will need to consider what, if any, gaps exist in their current privacy and security infrastructure and identify any needed enhancements for participation in TEFCA. PHAs may have unique needs or requirements depending on Applicable Law. They should discuss these unique needs, or any other concerns or potential vulnerabilities, with potential QHINs to identify how different QHINs can best support them.

PUBLIC HEALTH EXAMPLES OF TEFCA EXCHANGE

Push – Sender to a Receiver. Health data can be sent from a message source to a data receiver through TEFCA Exchange. The QHIN acts as message broker routing the message to the appropriate responding or receiving source found in the RCE Directory. The message source receives an acknowledgement from the recipient, and an audit log entry is made by the QHIN showing the source and the destination. The specified standard for Push message delivery and message send use case steps can be found in the QTF and draft Exchange Purpose (XP) Implementation SOP: Public Health SubXP-1.

The following pathway examples describe basic scenarios for the exchange of Public Health data using the Common Agreement and QTF specifications for QHIN Message Delivery (or "push"). Additional scenarios may be supported in future Public Health SubXP SOPs.

- Health Care Community to Public Health Authority: The sender is a hospital, health care organization, or laboratory that pushes required information to a PHA or a Delegate to complete a Public Health purpose (e.g., immunization, case report, etc.).
- Health Care Community to Federal Public Health Authority: The sender is a hospital, health care organization, or laboratory that pushes required information to a federal entity (e.g., Centers for Disease Control and Prevention, Food and Drug Administration), as authorized.

Request – Query to a Sender. QHIN Query is defined in the QTF as the act of a QHIN requesting information from one or more other QHINs (i.e., pull). When responding to a query, a QHIN may use a Record Locator Service to find and retrieve required information. That information can be used to satisfy a Public Health purpose in accordance with Applicable Law within the PHA's jurisdiction. TEFCA Request functions and specified standard(s) or profiles are described in the QTF. The QTF also describes the use cases for patient discovery, document query, and document retrieval in detail. PHAs would also need to refer to the draft Exchange Purpose (XP) Implementation SOP: Public Health SubXP-1 and relevant public health IGs, as appropriate.

The following pathway examples describe basic scenarios for the exchange of Public Health data using the Common Agreement and QTF specified QHIN Queries via a QHIN. Please note that a response from a PHA is permitted, but not required. Additional scenarios may be supported in future Public Health SubXP SOPs.

- **Public Health Authority Queries a Provider(s).** A PHA initiates a query to locate required information from a provider(s) or health care organization and receives a response that includes one of the following: 1) the expected required information, 2) an error, or 3) partial results with any errors noted. If there is no information available for response, there is a message received indicating no data available.

- **Public Health Authority Queries a Public Health Authority.** A PHA initiates a query to locate required information from another PHA where that PHA has indicated records exist. The PHA that is initiating the query receives a response that includes one of the following: 1) the expected required information, 2) an error, or 3) partial results with any errors noted.

- **Provider or Health Care Organization (HCO) Queries Public Health Authority.** A provider or health care organization initiates a query to a PHA. The provider may receive a response that includes one of the following: 1) the expected required information, 2) an error or, 3) partial results with any errors noted.

OPPORTUNITIES TO BE ENGAGED AND NEXT STEPS

The ONC and RCE are working on next steps to ensure that PHAs have adequate time to plan for and participate in TEFCA Exchange. Ongoing involvement by PHAs will be important to realize the potential of TEFCA. PHAs are encouraged to:

- Actively participate in TEFCA discussions (internally and externally) and provide feedback on the draft Exchange Purpose (XP) Implementation SOP: Public Health SubXP-1.
- Actively consider how TEFCA can benefit their PHA and build leadership support.
- Consider becoming a Participant or Subparticipant in TEFCA.
- Assess baseline technical readiness (e.g., gain experience exchanging data via interoperability networks (HIE's, AIMS, eHealth Exchange, the Immunization [IZ] Gateway) and internal capacity.

APPENDIX

This Appendix provides select definitions from the draft Common Agreement v2, the draft QTF v2, and associated SOPs. Please refer to the TEFCA Glossary for a compilation of all definitions contained in draft Common Agreement v2, draft QTF v2, and associated SOPs. This Appendix also includes certain terms relevant to public health that are not otherwise defined in TEFCA policies. Sources are included for those terms.

Definitions pursuant to the draft Common Agreement v2 and the draft QTF v2:

Applicable Law: all federal, State, local, or tribal laws and regulations then in effect and applicable to the subject matter herein. For the avoidance of doubt, federal agencies are only subject to federal law.

Designation (including its correlative meanings "Designate," "Designated," and "Designating"): the RCE's written confirmation to ONC and Signatory that Signatory has satisfied all the requirements of the Common Agreement, the QHIN Technical Framework, all applicable SOPs, and is now a QHIN.

Disclosure (including its correlative meanings "Disclose," "Disclosed," and "Disclosing"): the release, transfer, provision of access to, or divulging in any manner of TEFCA Information (TI) outside the entity holding the information.

Exchange Purpose(s) or XP(s): means the reason, as authorized by a Framework Agreement, including the applicable SOPs, for a Transmission, Request, Use, Disclosure, or Response transacted through TEFCA Exchange.

Framework Agreement(s): with respect to QHINs, the Common Agreement; and with respect to a Participant or Subparticipant, the Participant/Subparticipant Terms of Participation (ToP).

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

Participant: to the extent permitted by applicable SOP(s), a U.S. Entity that has entered into the Participant/Subparticipant Terms of Participation (ToP) in a legally binding contract with a QHIN to use the QHIN's Designated Network Services to participate in TEFCA Exchange in compliance with the ToP.

Participant/Subparticipant Terms of Participation (ToP): the requirements set forth in Exhibit 1 to the Common Agreement, to which each Participant and Subparticipant must agree to participate in TEFCA Exchange including the QHIN Technical Framework (QTF), all applicable Standard Operating Procedures (SOPs), and all other attachments, exhibits, and artifacts incorporated therein by reference.

Public Health: with respect to the definition of Exchange Purposes, a Request, Use, Disclosure, or Response permitted under the HIPAA Rules and other Applicable Law for public health activities and purposes involving a Public Health Authority, where such public health activities and purposes are permitted by Applicable Law, including a Use or Disclosure permitted under 45 CFR § 164.512(b) and 45 CFR § 164.514(e). For the avoidance of doubt, a Public Health Authority may Request, Use, and Disclose TEFCA Information (TI) hereunder for Public Health to the extent permitted by Applicable Law and the Framework Agreements.

Public Health Authority (PHA): has the meaning assigned to such term at 45 CFR § 164.501.

Qualified Health Information Network (QHIN): to the extent permitted by applicable SOP(s), a Health Information Network that is a U.S. Entity that has been Designated by the RCE and is a party to the Common Agreement countersigned by the RCE.

QHIN Query: the act of a QHIN requesting information from one or more other QHINs (sometimes referred to as a "pull").

Recognized Coordinating Entity (RCE): the entity selected by ONC that will enter into the Common Agreement with QHINs in order to impose, at a minimum, the requirements of the Common Agreement, including the SOPs and the QTF, on the QHINs and administer such requirements on an ongoing basis. The RCE is a Party to the Common Agreement.

RCE Directory Service: a technical service provided by the RCE that enables QHINs to identify its 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.

Request(s) (including its correlative uses/tenses "Requested" and "Requesting"): the act of asking for information through TEFCA Exchange.

Required Information: any Electronic Health Information, as defined in 45 CFR § 171.102, that is maintained by any QHIN, Participant, or Subparticipant prior to or during the term of the applicable Framework Agreement.

Response(s) (including its correlative uses/tenses "Responded" and "Responding"): the act of providing the information that is the subject of a Request or otherwise transmitting a message in response to a Request through TEFCA Exchange.

Standard Operating Procedure(s) or SOP(s): a written procedure or other provision that is adopted pursuant to the Common Agreement and incorporated by reference into a Framework Agreement to provide detailed information or requirements related to TEFCA Exchange, including all amendments thereto and any new SOPs that are adopted pursuant to the Common Agreement. Each SOP identifies the relevant group(s) to which the SOP applies, including whether Participants and/or Subparticipants are required to comply with a given SOP.

Subparticipant: to the extent permitted by applicable SOP(s), a U.S. Entity that has entered into a ToP in a legally binding contract with a Participant or Subparticipant to use the Participant's or Subparticipant's Connectivity Services to participate in TEFCA Exchange in compliance with the ToP.

TEFCA Exchange: the transaction of information between Nodes using a TEFCA-specific Exchange Purpose code, as defined in the applicable SOP.

TEFCA Information (TI): any information that is transacted through TEFCA Exchange except to the extent that such information is received by a QHIN, Participant, or Subparticipant that is a Covered Entity, Business Associate, or Non-HIPAA Entity (NHE) that is exempt from compliance with the Privacy section of the applicable Framework Agreement and is incorporated into such recipient's system of records, at which point the information is no longer TI with respect to such recipient and is governed by the HIPAA Rules and other Applicable Law.

Treatment: has the meaning assigned to such term at 45 CFR § 164.501.

Use(s) (including correlative uses/tenses, such as "Uses," "Used," and "Using"): with respect to TI, means the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information.

<u>Other definitions used in this document and developed through consensus-building process</u>:
Public Health TEFCA Advocate: those states, localities, tribes, and territories that:

- Are actively participating in TEFCA discussions (internally and externally) and providing feedback.
- Are actively considering how TEFCA can benefit their PHA and have some leadership support.
- Are looking at the Common Agreement and strategizing participation and are considering being an initial participant or sub-participant in TEFCA (understanding that most likely public health will not be a signatory to the Common Agreement).
- Have baseline technical readiness (e.g., have experience exchanging data via interoperability networks (HIE's, AIMS, eHealth Exchange, IZ gateway), have internal capacity, and/or are looking at FHIR opportunities).

Hybrid Entity: any Public Health Authority or Delegate that also meets the official definition of a hybrid entity under HIPAA (45 CFR §164.103), which means a single legal entity:

1) That is a covered entity;
2) Whose business activities include both covered and non-covered functions; and
3) That designates health care components in accordance with paragraph 45 CFR §164.105(a)(2)(iii)(D).

Push: the standards-based transmission of data from a data sender to a data receiver to complete a transaction where there is no specific query provided electronically by the data receiver to begin the transaction. This includes, for example, the transmission of patient-specific data from a health care provider to public health when that patient has a condition that is reportable (e.g., identifiable patient information for a specific condition required by law or regulation to be reported to a STLT Public Health Authority).