Q H I eHealth ExchaNge TEFCA Terms & Conditions Introduction & Background

The Trusted Exchange Framework and Common Agreement (TEFCA)

The 21st Century Cures Act directed the U.S. Department of Health and Human Services (HHS) Office of the National Coordinator (ONC) to, "develop or support a trusted exchange framework, including a common agreement [TEFCA] among health information networks nationally." TEFCA establishes legal, technical, policy, and implementation requirements for participation in this framework. Key source documents for the TEFCA requirements are:

<u>The Common Agreement (Legal Requirements)</u>: ONC and the RCE have developed and published the Common Agreement – the legal contract between each QHIN and the RCE for purposes of TEFCA participation. The Common Agreement includes terms and conditions that a QHIN is **required** to flow down to its Participants that engage in TEFCA-based exchange and to require that those terms be flowed down between QHIN Participants and their Subparticipants that engage in TEFCA-based exchange.

<u>The QTF (Technical Requirements)</u>: The RCE has also published the QHIN Technical Framework (QTF), which focuses primarily on the technical and functional requirements for interoperability between and among QHINs. However, it also specifies certain technical standards that a QHIN must implement and enforce with the Participants and Subparticipants of the QHIN to enable the QHIN-to-QHIN exchange of health information. Per the terms of the Common Agreement, the QTF is a legally binding document.

<u>SOPs (Procedural/Process Requirements)</u>: An initial set of Standard Operating Procedures (SOPs) has been published by the RCE, and additional SOPs are likely to be published over time. SOPs are written procedures that provide further details related to TEFCA Requirements and exchange activities. Each SOP identifies the relevant group or groups to which the SOP applies, including whether a QHIN's Participants and/or their Subparticipants must comply with a given SOP. Per the Common Agreement, SOPs are legally binding documents with respect to those groups to which the SOP states it applies.

<u>Additional TEFCA Requirements</u>: Documents such as implementation guides, written protocols, FAQs, etc. may also be published from time-to-time by the RCE and/or ONC. Such documents may be informational, or they may include

requirements that QHINs must implement and/or require of their QHIN Participants/Subparticipants.

Authority & Intent

Section 4.03(m) of the DURSA grants the Coordinating Committee authority to enter into agreements to broaden access to data through enhanced connectivity across platforms and networks. Pursuant to that authority, the Coordinating Committee authorized eHealth Exchange to sign the *Common Agreement for Nationwide Health Information Interoperability*, the "Common Agreement" that is part of the Trusted Exchange Framework and Common Agreement ("TEFCA"), for purposes of the eHealth Exchange serving as a Qualified Health Information Network (QHIN).

Pursuant to Section 12.05 of the DURSA, an eHealth Exchange Participant may choose to opt-out of participation in TEFCA via the eHealth Exchange, for any reason, by providing written notification of the decision to opt out. Furthermore, a Participant may reverse its decision at any time by providing such decision to the Coordinating Committee in writing.

This process is further described in Operating Policy & Procedure #10 (OPP-10).

The eHealth Exchange QHIN

The eHealth Exchange has been designated by the RCE as a QHIN under TEFCA.

QHINs are **required** to flow certain terms down to their Participants and to require Participants to flow those terms down to their Subparticipants, and so on. The Office of the National Coordinator for Health Information Technology (ONC) and The Sequoia Project, Inc. in its capacity as ONC's Recognized Coordinating Entity (RCE) has developed a standard set of required flow-downs that every Designated QHIN must assure that its TEFCA Participants and their Subparticipants are contractually obligated to follow (the "Terms of Participation" or "TOP"). The ToP expressly allow a QHIN to have additional requirements for its TEFCA Participants and their Subparticipants so long as they do not conflict with the ToP. The ToP are attached and are incorporated by reference as part of this eHealth Exchange TEFCA Terms and Conditions. In addition to the ToP, the eHealth Exchange has a limited number of additional requirements for its TEFCA Participants and their Subparticipants and their Subparticipants and their Subparticipants that are listed below. For the avoidance of doubt, the DURSA shall continue to take precedence over the foregoing for exchange activities that do not utilize the Connectivity Services and over any/all other eHealth Exchange activities that are not subject to these TEFCA Terms and Conditions.

Participation Nomenclature in the eHealth Exchange QHIN

The term "Participant" is used in both the eHealth Exchange network and under TEFCA. In addition, the definition of "Participant" under the DURSA and the definition of "Participant"

under the Common Agreement are different. Complicating matters furthers, some Participants in the eHealth Exchange (under the DURSA's definition) will also be Participants in TEFCA (under the Common Agreement's definition), but others will not. This necessitates a means of distinguishing among the different types of "Participants."

To distinguish among different uses of the term "Participant(s)," the following interpretations apply in the context of the eHealth Exchange QHIN:

eHealth Exchange Participant(s) is used to refer to each/all organizations that participate in the eHealth Exchange pursuant to the DURSA. An eHealth Exchange Participant may or may not also be a TEFCA Participant, as defined below. Whether an eHealth Exchange Participant is also a TEFCA Participant depends upon whether that eHealth Exchange Participant has opted out of participation in the eHealth Exchange QHIN.

TEFCA Participant(s) is used to refer to any/all entities that meet the definition of "Participant" under the Common Agreement. This term includes entities that participate in other QHINs, as well as eHealth Exchange Participants that do not opt out of participation in the eHealth Exchange QHIN.

Participant or You is used herein to refer to Your organization that is already an eHealth Exchange Participant that, by not opting out of the eHealth Exchange QHIN, agrees to participate in TEFCA via the eHealth Exchange QHIN and is bound by the TEFCA Terms & Conditions and TEFCA Materials for purposes of TEFCA-based activities.

The following *TEFCA Terms & Conditions* are not subject to modification and are binding on all eHealth Exchange Participants that do not affirmatively opt out of participation in the eHealth Exchange QHIN.

eHealth Exchange QHIN TEFCA Terms & Conditions

The TEFCA Terms & Conditions ("TEFCA Terms") set forth herein are binding upon eHealth Exchange Participants <u>UNLESS AND UNTIL</u> the eHealth Exchange Participant has affirmatively opted out of participation in the eHealth Exchange QHIN in accordance with Section 12.05 of the DURSA.

By not opting out of participation in the eHealth Exchange QHIN, "Participant" hereby agrees to be bound by the terms and conditions set forth below.

TEFCA TERMS & CONDITIONS

1. Participant Eligibility & Subparticipant Onboarding

- <u>1.1 Participant Eligibility</u>. By not opting out of participation in the eHealth Exchange QHIN, Participant represents and warrants that it meets the definition of a U.S. Entity as set forth in the TEFCA Participant/Subparticipant Terms of Participation (the ToP) that are part of these TEFCA Terms. The RCE may adopt a Standard Operating Procedure (SOP) that further clarifies the U. S. Entity requirement and Participant acknowledges that the eHealth Exchange is required to comply with all SOPs that could affect Participant's/Subparticipant's eligibility to participate in TEFCA Exchange.
- <u>1.2 Subparticipant Eligibility and Onboarding</u>. Participant is responsible for ensuring that each organization that wishes to be a Subparticipant of Participant meets the definition of a U.S. Entity and is one or more of the types of entities that is permitted to participate in TEFCA in accordance with the RCE SOP <u>"Types of Entities that can be a Participant or Subparticipant in TEFCA"</u> which may be amended by the RCE. Participant is responsible for the submission of Subparticipant onboarding information and, by submitting information for purposes of adding an entity to the QHIN Directory, Participant attests that such entity has also agreed to be bound by these TEFCA Terms as a Subparticipant.

2. Scope & Flow-Down Obligations.

- 2.1 Scope of TEFCA Terms. These TEFCA Terms govern Participant's use of the Connectivity Services and overall participation in the eHealth Exchange QHIN. As further set forth below, these TEFCA Terms also govern indirect participation in the eHealth Exchange QHIN by all those that ultimately request and/or receive information via the Connectivity Services vis-à-vis Participant as a Subparticipant (or as their Downstream Subparticipant).
- <u>2.2 Serial Flow-Down Obligations</u>. Participant must flow these TEFCA Terms down to its Subparticipants that connect to the eHealth Exchange QHIN through Participant, if any. In addition, Participant must ensure that its Subparticipants are obligated to flow

down all TEFCA Terms to their Downstream Subparticipants and that these terms are flowed down and enforced between all levels of Upstream and Downstream Subparticipants.

3. TEFCA Compliance

- <u>3.1 Compliance with Applicable Law and the TEFCA Terms</u>. Participant shall comply with all Applicable Law and shall implement and act in accordance with the provisions of these TEFCA Terms, including all TEFCA Materials, which are hereby expressly incorporated into this TEFCA Terms by reference.
- <u>3.2 Compliance with the TEFCA Materials</u>. In addition to these TEFCA Terms & Conditions and the ToP, the following shall comprise the "TEFCA Materials."
 - 3.2.1 <u>TEFCA SOPs</u>. The eHealth Exchange QHIN Governance Committee(QGC) or its designee is responsible for identifying which SOPs are applicable to TEFCA Participants and/or Subparticipants and shall communicate this to Participant in accordance with the process set forth in the TEFCA Protocols. Participant shall comply with all such SOPs and, if applicable to Subparticipants, shall require compliance with the same by its Subparticipants.
 - <u>3.2.2</u> <u>TEFCA Protocols</u>. Participant shall comply with all TEFCA Protocols and shall require that its Subparticipants comply with applicable TEFCA Protocols.
 - 3.2.3 <u>TEFCA Supplements</u>. The TEFCA Supplements specify which of the technical standards and functional requirements from the QTF must be implemented by Participant and its Subparticipants. The TEFCA Supplements also set forth the process for testing and onboarding to the eHealth Exchange QHIN. Participant shall comply with all TEFCA Supplements and, if applicable to Subparticipants, shall require compliance with the same by its Subparticipants.
- <u>3.3 Participant Responsibilities Regarding Subparticipant Compliance with TEFCA Terms</u>. Participant shall be responsible for taking reasonable steps to confirm that all of its Subparticipants are abiding by Applicable Law and by these TEFCA Terms, including all applicable TEFCA Materials. In the event that Participant becomes aware of a material non-compliance by one of its Subparticipants, then Participant shall promptly notify the Subparticipant in writing. Such notice shall inform the Subparticipant that its failure to correct any such deficiencies within the timeframe established by Participant shall constitute a material breach of the Participant-Subparticipant Agreement, which may result in early termination of said agreement.

4. TEFCA Governance, Change Management, & the QHIN Governance Committee

- <u>4.1 TEFCA Governance</u>. The governing approach and governance structure under TEFCA is established by the RCE and ONC and is set forth in the Common Agreement. In accordance with that approach and structure, the process through which the eHealth Exchange will engage those participating in the eHealth Exchange QHIN in TEFCA governance is set forth in the TEFCA Protocols.
- 4.2 <u>TEFCA Change Management</u>. Change management under TEFCA is established by the RCE and ONC and is set forth in the Common Agreement. All QHINs and all TEFCA Participants and Subparticipants are subject to the outcomes of the change management process established under the Common Agreement with respect to the rights and obligations governing participation in TEFCA. For this reason, changes to the TEFCA Terms, including the TEFCA Materials, are <u>not</u> governed by the change management procedure set forth in the DURSA. The procedure for providing notification to Participant of proposed and final changes to the TEFCA Materials is set forth in the TEFCA Protocols.
- <u>4.3 QHIN Governance Committee</u>. To support the distinct governance functions associated with participation in the eHealth Exchange QHIN, and to meet the QHIN governance requirements established by the RCE and ONC, there shall be a "QHIN Governance Committee" or "QGC." The QGC shall include representatives of organizations participating in the eHealth Exchange QHIN, as set forth in the TEFCA Protocols. Participant hereby grants to the QGC the authority to administer certain governance functions pertaining to participation in the eHealth Exchange QHIN and use of the Connectivity Services as set forth in the TEFCA Protocols.

5. Suspension & Termination

5.1 Suspension.

The ToP include detailed rights and requirements that govern the RCE's and the eHealth Exchange's rights as a QHIN to suspend its Participants and/or their Subparticipants and those terms control. For clarity, the eHealth Exchange QHIN is the Upstream QPS to You as described in the ToP, and You are the Upstream QPS to your Subparticipants.

- 5.2 <u>Termination</u>. The provisions of this Section 5.2 are in addition to, and do not amend or replace, the termination provisions set forth in the ToP.
 - 5.2.1 <u>Termination of QHIN Participation by Subsequent Opt-Out</u>. Participant may terminate its participation in the eHealth Exchange QHIN, at any time,

by providing the QHIN Governance Committee or designee at least thirty (30) days' written notice that Participant wishes to opt out of continued participation in the eHealth Exchange QHIN. Opting out of participation in the eHealth Exchange QHIN shall have no effect on Participant's participation in the eHealth Exchange with respect to any non-TEFCA activities, and all other agreements between Participant and the eHealth Exchange, including but not limited to the DURSA, shall remain in full force and effect.

- 5.2.2 <u>Termination of Participation in the eHealth Exchange</u>. Termination of Participant's participation in the eHealth Exchange, for any reason and by either party, shall automatically terminate Participant's participation in the eHealth Exchange QHIN with no further action by either party.
- 5.2.3 <u>Communication of Termination and Effects</u>. Participant shall be solely responsible for communicating any termination under Section 5.2, including any downstream effects thereof, to Participant's Subparticipants.

End of TEFCA Terms & Conditions