



Health IT Advisory
Committee

ASTP HTI-2 Proposed Rule Task Force 2024 Group 3: Information Blocking and TEFCA

Rochelle Prosser, Co-Chair

August 22, 2024



Call to Order/Roll Call

Seth Pazinski, Designated Federal Officer, ASTP

HTI-2 Proposed Rule Task Force 2024 Roster

Group 3 Information Blocking and TEFCA

Name	Organization	Name	Organization
Rochelle Prosser* (Co-Chair)	Orchid Healthcare Solutions	Anna McCollister*	Individual
Shila Blend*	North Dakota Health Information Network	Katrina Miller Parrish*	Patient.com
Hans Buitendijk*	Oracle Health	Kris Mork	Leidos
Sooner Davenport	Southern Plains Tribal Health Board	Eliel Oliveira*	Harvard Medical School & Harvard Pilgrim Health Care Institute
Derek De Young*	Epic	Randa Perkins*	H. Lee Moffitt Cancer Center & Research Institute
Steven Eichner*	Texas Department of State Health Services	Zeynep Sumer-King*	NewYork-Presbyterian
Lee Fleisher*	University of Pennsylvania Perelman School of Medicine	Naresh Sundar Rajan*	CyncHealth
Hannah Galvin*	Cambridge Health Alliance	Sheryl Turney	Elevance Health
Dominic H. Mack	Morehouse School of Medicine	Rachel (Rae) Walker	University of Massachusetts Amherst



Opening Remarks

Rochelle Prosser, Co-Chair

Agenda

- 10:00 AM** **Call to Order/Roll Call**
- Seth Pazinski, Designated Federal Officer, ASTP
- 10:05 AM** **Opening Remarks**
- Rochelle Prosser, Co-Chair
- 10:10 AM** **TEFCA**
- Rachel Nelson, ASTP
- 10:25 AM** **Administrative Updates**
- Sara McGhee, ASTP
 - Ben Dixon, ASTP
- 10:35 AM** **Discussion**
- Rochelle Prosser, Co-Chair
- 10:45 AM** **Task Force Recommendation Worksheet**
- Rochelle Prosser, Co-Chair
- 11:20 AM** **Public Comment**
- Seth Pazinski, Designated Federal Officer, ASTP
- 11:25 AM** **Next Steps**
- Rochelle Prosser, Co-Chair
- 11:30 AM** **Adjourn**

HTI-2 Proposed Rule Task Force 2024: Charge

Overarching Charge: The HTI-2 Proposed Rule Task Force will evaluate and provide draft recommendations to the HITAC on the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule.

Specific Charge:

- Review and provide recommendations on the HTI-2 proposals on public health, standards and certification, and information blocking and TEFCA.
- Recommendations are due prior to the end of the 60-day public comment period.

Subgroup 3: Information Blocking and TEFCA

The Information Blocking and TEFCA Subgroup will review and provide preliminary recommendations for Task Force consideration on the following HTI-2 proposed rule sections.

- **Administrative Updates**
- Information Blocking Enhancements
 - Defined Terms; Exceptions That Involve Practices Related to Actors' Participation in TEFCA
 - Protecting Care Access Exception
 - Requestor Preferences Exception, "Interfere With" or "Interference"
 - Privacy Exception; Infeasibility Exception
- **Trusted Exchange Framework and Common Agreement**



TEFCA

Rachel Nelson, ASTP

TEFCA Proposals in Part 172

PROPOSAL

ASTP proposes to add a new part, part 172, to title 45 of the Code of Federal Regulations to implement certain provisions related to TEFCA that will establish the qualifications necessary for an entity to receive and maintain designation as a QHIN capable of trusted exchange pursuant to TEFCA. More specifically, the proposals in each Subpart cover the following topics:

- **Subpart A:** We propose the statutory basis, purpose, and scope of the TEFCA provisions; the applicability of the TEFCA provisions; and relevant definitions.
- **Subpart B:** We propose requirements related to the qualifications needed to be designated as a QHIN.
- **Subpart C:** We propose QHIN onboarding and designation processes.
- **Subpart D:** We propose RCE and QHIN suspension rights, notice requirements for suspension, and requirements related to the effect of suspension.
- **Subpart E:** We propose RCE and QHIN termination rights, notice requirements for termination, and requirements related to the effect of termination.
- **Subpart F:** We propose to establish QHIN appeal rights and the process for filing an appeal to ASTP.
- **Subpart G:** We propose requirements related to QHIN attestation for the adoption of TEFCA.

BENEFITS

- ASTP believes that certain provisions (Subparts A-F above) related to receiving and maintaining QHIN designation should be implemented through regulation to support QHIN appeals to ASTP and to strengthen TEFCA's viability moving forward.
- Subpart G, which proposes a process for QHINs to attest to the adoption of TEFCA, is required to be established through notice and comment rulemaking per section 3001(c)(9)(D)(ii) of the PHSA.

TEFCA Statutory Basis, Purpose, and Scope

The basis for these provisions would be to implement section 3001(c)(9) of the PHSA (42 U.S.C 300jj-11(c)(9)).

The purpose of this part is to:

- Ensure full network-to-network exchange of health information; and
- Establish a voluntary process for a Qualified Health Information Network™ (QHIN™) to attest to adoption of the Trusted Exchange Framework and Common Agreement™ (TEFCA™).

The scope addresses:

- Minimum qualifications needed for a health information network to be Designated as a QHIN capable of trusted exchange under TEFCA.
- Procedures governing QHIN Onboarding and Designation, suspension, termination, and further administrative review.
- Attestation submission requirements for a QHIN to attest to its adoption of TEFCA.
- ASTP attestation acceptance and removal processes for publication of attesting QHINs in the QHIN Directory.

Qualifications Needed to be Designated as a QHIN

PROPOSAL

In § 172.201, we propose Designation requirements in three categories: (a) ownership; (b) exchange requirements; and foreign ownership

In § 172.202 we propose Individual Access Services (IAS) requirements for a QHIN to obtain and maintain Designation under TEFCA if that QHIN voluntarily offers IAS.

BENEFITS

The proposed requirements would be ongoing and ensure the reliability of TEFCA Exchange and to ensure QHINs could not maintain their status based on technology and standards that have become obsolete.

Promote organizational and operational policies that enable the exchange of health information among networks by minimizing the risk to TEFCA that may be posed by foreign state actors who wish to harm the United States, lessening the risks of subjecting QHINs to potentially conflicting foreign laws, and encouraging trust in the security of exchange under the system.

Reassure individuals that they control access to their data.

IAS providers would meet requirements above and beyond what the HIPAA Rules require of covered entities or business associates, including providing individuals with the right to delete their data and a requirement to encrypt all Individually Identifiable Information.

QHIN™ Onboarding and Designation Processes

PROPOSAL

In § 172.301, we propose to establish the information Applicant QHINs must submit in order to be Designated as a QHIN.

In § 172.302, we propose a thirty (30) calendar day timeframe for notification of missing application information, a sixty (60) calendar day timeframe for completeness review, and a process for application changes and withdrawal.

In § 172.303, we propose the requirements and process for QHIN approval and Onboarding

In § 172.304, we propose a thirty (30) calendar day timeframe of QHIN demonstration of successful transaction with all other in-production QHINs according to standards and procedures for TEFCA exchange. Additionally, we propose that a QHIN Designation will become final sixty (60) days after submitting documentation of completed successful transaction with all other in-production QHINs.

In § 172.305, § 172.306, and § 172.307, we outline the process for withdrawal of a QHIN application, denial of a QHIN application, and process for Re-application, respectively.

BENEFITS

A consistent approach to QHIN Onboarding and Designation that allows for extensions and balances between the need to onboard QHINs promptly and ensure that all QHINs can connect immediately and seamlessly once Designated.

Flexibility to provide updated application information during the review process as needed

- An efficient process to deem applications withdrawn and for an Applicant QHIN to withdraw its application without penalty and re-apply at any time.
- A six-month timeframe for re-application in the case of previous denial which allows the Applicant QHIN to take such time to reconsider and address the deficiencies in its application and which supports efficiency in the review process

Suspension

PROPOSAL

In § 172.401, we propose provisions related to ASTP (or the RCE) suspension of a QHIN or directed suspension of a Participant or Subparticipant.

In § 172.402, we propose provisions related to selective suspension of TEFCA Exchange between QHINs.

BENEFITS

Support the overall security of TEFCA and align with the security requirements for QHINs by enabling ASTP (or an RCE) to suspend a QHIN's authority to engage in TEFCA Exchange if the QHIN is responsible for a Threat Condition

Maintain the integrity of TEFCA and offer a transparent approach to suspension that would communicate the reason for suspension, require timely notification of suspension, and afford QHINs an opportunity to resolve the issue(s).

Enable all parties involved to be aware of the situation in a timely fashion and take action to maintain the privacy and security of TEFCA Exchange activities.

Strengthen the privacy and security protections within TEFCA by extending suspension rights to QHINs to suspend exchange with another QHIN due to reasonable concerns related to the privacy and security of information that is exchanged.

Termination

PROPOSAL

In § 172.501, we propose that a QHIN may terminate its own QHIN Designation at any time without cause by providing ninety (90) calendar days prior written notice.

In § 172.502, we propose that a QHIN's Designation will be terminated with immediate effect by ASTP (or an RCE) giving written notice of termination to the QHIN if the QHIN:

- fails to comply with any regulations of this part and fails to remedy such material breach within thirty (30) calendar days after receiving written notice of such failure; or
- a QHIN breaches a material provision of the Common Agreement where such breach is not capable of remedy

In § 172.503, we propose that QHINs and ASTP (or an RCE) would be able to terminate the QHIN's Designation at any time and for any reason by mutual, written agreement.

BENEFITS

Increase trust by swiftly taking action to remove a non-complaint QHIN and ensure that entities that fail to meet their obligations as QHINs (by failing to comply with the regulations of this Part or by breaching a material provision of the Common Agreement) are no longer able to act as QHINs under the TEFCA framework.

Reasonable and efficient termination at any time where parties are satisfied that a QHIN's termination is in the best interest of all.

Review of RCE® or ASTP Decisions

PROPOSAL

In § 172.601, we propose provisions to establish ASTP's authority to review RCE determinations, policies, and actions, as well as procedures for exercising such review.

In § 172.602, we propose to establish bases for Applicant QHINs and QHINs to appeal decisions to ASTP.

In § 172.603, we propose the method and timing for filing an appeal.

In § 172.604, we propose that an appeal would not stay a suspension or termination, unless otherwise ordered by ASTP or the hearing officer assigned under § 172.605(b).

In § 172.605, we propose provisions related to the assignment of a hearing officer.

In § 172.606, we propose requirements related to adjudication.

In § 172.607, we propose requirements related to a decision by the hearing officer.

BENEFITS

- A QHIN or Applicant QHIN that disagrees with certain RCE or ASTP decisions will have recourse to appeal those decisions through a process that is consistent and fair for all involved
- Ensures effective oversight of the RCE
- A QHIN would only be suspended or terminated for infractions that could, for example, jeopardize the privacy and security of TEFCA Exchange.
- A process for independent decisions through the hearing officer assigned by the National Coordinator
- These proposals align § 172.607 procedures with the ONC Health IT Certification Program appeals procedures in § 170.580(g) as we propose to revise them in this Proposed Rule (see Section III.D.2.b of this preamble)

QHIN™ Attestation for the Adoption of the Trusted Exchange Framework and Common Agreement™

PROPOSAL

In § 172.701, we propose attestation submission requirements for QHINs and review and acceptance processes that ASTP will follow for TEFCA attestations.

In § 172.702, we propose the requirements for a QHIN directory. In § 172.605, we propose provisions related to the assignment of a hearing officer.

BENEFITS

We believe these submission procedures will support a consistent and transparent QHIN attestation process. We welcome comments on these procedures.



Administrative Updates

Sara McGhee, ASTP

Ben Dixon, ASTP

Definition of Serious Risk to Public Health or Safety

PROPOSAL

We propose to revise § 170.102 to include a definition of *serious risk to public health or safety*.

The proposed definition includes fact patterns outlining certain types of conditions, events and phenomena that will always meet the definition of serious risk to health or safety.

BENEFITS

Enhanced understanding among developers and users of certified health IT that certain types of conditions, events, or phenomena constitute egregiously dangerous non-conformities.

ONC-ACB Surveillance of Certain Maintenance of Certification Requirements

PROPOSAL

- Expand ONC-ACBs responsibilities in § 170.556(b) and (d) and require that ONC-ACBs monitor Program-participating developers' satisfaction of specific requirements applicable to the developers under subpart D of 45 CFR part 170, report results of these surveillance activities to ASTP, and engage with developers where applicable to encourage corrective action for identified non-conformities.
 - Would require ONC-ACBs to perform reactive and randomized surveillance based on the specified Maintenance of Certification requirements in §§ 170.402(b)(1) – (4), 170.404(b)(1) and (2), 170.405(b)(1) and (2), 170.406(b), and 170.407(b)
- Revise and add new principles of proper conduct (PoPCs) in § 170.523 to support the proposed expanded surveillance responsibilities, including a new reporting requirement in § 170.523(x).
- Revise and add new minimum required corrective action plan (CAP) elements in § 170.556(d) based on the non-conformities addressed by the CAP.

BENEFITS

- Revised surveillance and PoPC requirements would promote Program efficiency and encourage Program-participating developers to maintain, or when necessary, regain in a more expedited way, conformity with Program requirements for the applicable Maintenance of Certification requirements as required by the Program regulations promulgated under the Cures Act.

Updates to Certification Program Direct Review Procedures

PROPOSAL

- Update the “ONC review of certified health IT” regulatory framework (§ 170.580) to align with proposed enhancements to the ONC-ACBs’ role in surveillance of Program-participating developers’ satisfaction of certain Maintenance of Certification requirements.
- Revise direct review corrective action plan (CAP) regulatory requirements to add flexibility to tailor the minimum elements the developer must address in such a plan for a non-conformity substantiated through “direct review.”
- Revise procedural provisions for health IT developer's suspension from the Program in 45 CFR 170.580, termination of certification procedures in § 170.580(d) and (f), and hearing officer and appeals provisions in § 170.580(g)(5) and (7)(ii).
- Revise wording throughout 45 CFR 170.580 and 45 CFR 170.581 to clarify that certain determinations are made by the National Coordinator (who is appointed by the Secretary) rather than more generally by or within the Office of the National Coordinator (the organizational unit headed by the National Coordinator).

BENEFITS

The proposals would enhance efficiencies for developers and ASTP. It would also explicitly clarify the responsibilities of the National Coordinator and that the Secretary, as a principal officer of the United States, holds appropriate oversight and accountability for the hearing officer’s decisions. The updates also are important to ensure that the National Coordinator can take prompt action, without duplicative data gathering or fact finding.



Discussion

Rochelle Prosser, Co-Chair



Task Force Recommendation Worksheet

Rochelle Prosser, Co-Chair

Discussion Time

Topic	Time
TEFCA	20 min
Administrative Updates	15 min

Public Comment

To make a comment please

Use the Hand Raise Function

If you are on the phone only, press “*9” to raise your hand

*(Once called upon, press “*6” to mute/unmute your line)*

All public comments will be limited to three minutes

You may also email your public comment to onc-hitac@accelsolutionsllc.com

*Written comments will not be read at this time,
but they will be delivered to members of the Task Force and made part of the public record*



Next Steps

Rochelle Prosser, Co-Chair

Upcoming Meetings

Task Force Meeting Date/Time

8/29 11 AM -12:30 PM

9/3 11 AM -12:30 PM (Full Task Force Meeting)

9/4 11 AM -12:30 PM (Full Task Force Meeting)

9/5 11 AM -12:30 PM (Full Task Force Meeting)

HITAC Meeting Date

9/12 TF delivers recommendations to HITAC

Meeting Adjourned