

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 170, 171, and 172

RIN 0955-AA07

Health Data, Technology, and Interoperability: Trusted Exchange Framework and Common Agreement (TEFCA)

AGENCY: Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology, Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule has finalized certain proposals from a proposed rule published in August 2024 and in doing so advances interoperability and supports the access, exchange, and use of electronic health information. Specifically, this final rule amends the information blocking regulations by including definitions related to the Trusted Exchange Framework and Common Agreement (TEFCA) Manner Exception. It also implements provisions related to the TEFCA, which will support the reliability, privacy, security, and trust within TEFCA. Lastly, this final rule includes corrections and updates to current regulatory provisions of the Office of the National Coordinator for Health Information Technology (ONC) Health IT Certification Program.

DATES: This final rule is effective on January 15, 2025.

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I. Executive Summary

A. Purpose of Regulatory Action

The Secretary of Health and Human Services has delegated responsibilities to the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (hereafter ASTP/ONC)¹ for the implementation of certain provisions in Title IV of the 21st Century Cures Act (Pub. L. 114–255, Dec. 13, 2016) (Cures Act) that are designed to: advance interoperability; support the access, exchange, and use of electronic health information (EHI); and identify reasonable and necessary activities that do not constitute information blocking.² ASTP/ONC is

¹ The Office of the National Coordinator for Health Information Technology (ONC) was the previous name of this office. See **Federal Register:** Statement of Organization, Functions, and Delegations of Authority; Office of The National Coordinator for Health Information Technology (89 FR 60903, July 29, 2024).

² Reasonable and necessary activities that do not constitute information blocking, also known as information blocking exceptions, are identified in 45 CFR part 171, subparts B, C and D. ASTP/ONC’s official website, *HealthIT.gov*, offers a variety of resources on the topic of Information Blocking, including fact sheets, recorded webinars, and frequently asked questions. To learn more, please visit: <https://www.healthit.gov/topic/information-blocking/>.

responsible for the implementation of certain provisions of the Health Information Technology for Economic and Clinical Health Act (Pub. L. 111–5, Feb. 17, 2009) (HITECH Act) including: requirements that the National Coordinator perform duties consistent with the development of a nationwide health information technology infrastructure that allows for the electronic use and exchange of information and that promotes a more effective marketplace, greater competition, and increased consumer choice, among other goals. This final rule fulfills statutory requirements; advances equity, innovation, and interoperability; and supports the access to, and exchange and use of, EHI.

B. Summary of Major Provisions

General Comments

We received approximately 270 comment submissions on the broad range of proposals included in the “Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability” proposed rule (HTI–2 Proposed Rule) (89 FR 63498). We thank all commenters for their thoughtful input. For the purposes of this final rule, we have reviewed and responded to comments on a narrowed set of proposals. Specifically, we summarize and respond to comments related to the Trusted Exchange Framework and Common Agreement (TEFCA) information blocking exception and part 172 proposals, and a limited set of the proposed ONC Health IT Certification Program (Program) administrative updates. Comments received in response to other proposals from the HTI–2 Proposed Rule are beyond the scope of this final rule, are still being reviewed and considered, and may be the subject of subsequent final rules related to such proposals in the future.

As discussed above, the name of the office changed from the Office of the National Coordinator for Health Information Technology (ONC) to now be dually titled as the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (ASTP/ONC) per the **Federal Register** notice released on July 29, 2024.³ When the HTI–2 Proposed Rule appeared in the **Federal Register** on August 5, 2024, it referred to the office as “ONC.” It was not until days after the HTI–2 Proposed Rule had been released to the public (on

³ **Federal Register:** Statement of Organization, Functions, and Delegations of Authority; Office of The National Coordinator for Health Information Technology (89 FR 60903).

July 10, 2024)⁴ that the name officially changed. Accordingly, where we referred to “ONC” in the HTI–2 Proposed Rule, we continue to refer to “ONC” when referencing the HTI–2 Proposed Rule in this final rule. However, in the comment summaries, responses, and regulatory text of this final rule, we have revised those references to refer to “ASTP/ONC.” In this final rule, we acknowledge these changes where we have finalized regulatory text as proposed except for the changed reference to “ASTP/ONC.” We note that this change is technical in nature and does not affect any substantive rights or obligations.

1. ONC Health IT Certification Program

a. Administrative Updates

In section III.A.1, we discuss the removal of the “Complete EHR” and “EHR Module” terms from certain sections within subpart E of 45 CFR part 170.

As discussed in section III.A.2, we have removed from 45 CFR part 170, § 170.550(m), “Time-limited certification and certification status for certain ONC Certification Criteria for Health IT,” and removed the certification criteria with time-limited certification and certification status, including § 170.315(a)(10) and (13), (b)(6), (e)(2), and (g)(8). Additionally, as discussed in section III.A.2, we have revised § 170.315(b)(7) and (8) to remove § 170.315(b)(7)(ii) and (b)(8)(i)(B), which were time-limited provisions (now expired) that permitted health IT to demonstrate security tagging of Consolidated–Clinical Document Architecture (C–CDA) documents at the document level. In section III.A.3, we discuss the final revision of § 170.550(h), the Privacy and Security Certification Framework requirements, that adds the certification criterion “decision support interventions” (§ 170.315(b)(11)) to the list of certification criteria in § 170.550(h)(3)(ii).

b. Correction—Privacy and Security Certification Framework

We have finalized a correction to the Privacy and Security Certification Framework in § 170.550(h). As discussed in section III.B, we have added § 170.550(h)(4) that existed prior to the “21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program” final rule (85 FR 25642, May

1, 2020) (ONC Cures Act Final Rule) being finalized but was erroneously deleted.

2. Information Blocking Enhancements

In this final rule, with consideration of public comments, we have finalized the TEFCA Manner Exception in subpart D of part 171 with no revisions. We have also codified definitions of certain terms relevant to the Trusted Exchange Framework and Common Agreement™ (TEFCA™) in § 171.401.

3. Trusted Exchange Framework and Common Agreement™

As discussed in this final rule, we have codified (in new 45 CFR part 172) provisions related to TEFCA to provide greater process transparency and to further implement section 3001(c)(9) of the PHSA, as added by the Cures Act. The finalized 45 CFR part 172 establishes the processes associated with the qualifications necessary for an entity to receive and maintain Designation (as defined in § 172.102) as a Qualified Health Information Network (QHIN) capable of trusted exchange under the Common Agreement. The final provisions codified in part 172 also establish the procedures governing Onboarding (as defined in § 172.102) of QHINs and Designation of QHINs, suspension, termination, and administrative appeals to ASTP/ONC, as described in § 172.100(c)(1) of this final rule. We believe establishing these provisions in regulation support reliability, privacy, security, and trust within TEFCA, which furthers our obligations to “support” TEFCA under sections 3001(c)(9)(A) and (B) of the PHSA and TEFCA’s ultimate success. In addition, in subpart G of part 172, we have codified requirements related to QHIN attestation for the adoption of TEFCA. This subpart implements section 3001(c)(9)(D) of the PHSA. Section 3001(c)(9)(D)(i) requires the publication on ASTP/ONC’s website of a list of the health information networks (HINs) that have adopted the Common Agreement and are capable of trusted exchange pursuant to the Common Agreement. Section 3001(c)(9)(D)(ii) requires HHS to establish, through notice and comment rulemaking, a process for HINs that voluntarily elect to adopt TEFCA to attest to such adoption.

C. Costs and Benefits

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic,

environmental, public health and safety effects, distributive impacts, and equity). Executive Order 14094 (Modernizing Regulatory Review) amends section 3(f) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a “significant regulatory action.” The Office of Management and Budget’s (OMB) Office of Information and Regulatory Affairs (OIRA) has determined that this final rule is not a significant regulatory action under section 3(f) of Executive Order 12866. Accordingly, we have not prepared a detailed Regulatory Impact Analysis (RIA). We did, however, include some quantitative analysis of the costs and benefits of this final rule.

II. Background

A. Statutory Basis

The Health Information Technology for Economic and Clinical Health Act (HITECH Act), Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5), was enacted on February 17, 2009. The HITECH Act amended the Public Health Service Act (PHSA) and created “Title XXX—Health Information Technology and Quality” (Title XXX) to improve healthcare quality, safety, and efficiency through the promotion of health IT and EHI exchange.

The 21st Century Cures Act (Pub. L. 114–255) (Cures Act) was enacted on December 13, 2016, to accelerate the discovery, development, and delivery of 21st century cures, and for other purposes. The Cures Act, through Title IV—Delivery, amended the HITECH Act by modifying or adding certain provisions to the PHSA relating to health IT.

ONC Health IT Certification Program Rules

Section 3001(c)(5) of the PHSA provides the National Coordinator with the authority to establish a certification program or programs for the voluntary certification of health IT. Section 3001(c)(5)(A) specifies that the National Coordinator, in consultation with the Director of the National Institute of Standards and Technology (NIST), shall keep or recognize a program or programs for the voluntary certification of health IT that is in compliance with applicable certification criteria adopted under section 3004 of the PHSA.

⁴ <https://www.hhs.gov/about/news/2024/07/10/hhs-proposes-hti-2-rule-improve-patient-engagement-information-sharing-public-health-interoperability.html>.

Information Blocking Under the 21st Century Cures Act

Section 4004 of the Cures Act added section 3022 of the Public Health Service Act (PHSA) (42 U.S.C. 300jj–52, “the information blocking provision”). Section 3022(a)(1) of the PHSA defines practices that constitute information blocking when engaged in by a health care provider, or a health information technology developer, exchange, or network. Section 3022(a)(3) authorizes the Secretary to identify, through notice and comment rulemaking, reasonable and necessary activities that do not constitute information blocking for purposes of the definition set forth in section 3022(a)(1).

Trusted Exchange Framework and Common Agreement

Section 4003(b) of the Cures Act added section 3001(c)(9)(B)(i) to the PHSA, which requires the National Coordinator “to convene appropriate public and private stakeholders” with the goal of developing or supporting a Trusted Exchange Framework and a Common Agreement (collectively, TEFCA) for the purpose of ensuring full network-to-network exchange of health information. Section 3001(c)(9)(B) outlines provisions related to the establishment of a Trusted Exchange Framework for trust policies and practices and a Common Agreement for exchange between health information networks (HINs)—including provisions for the National Coordinator, in collaboration with the NIST, to provide technical assistance on implementation and pilot testing of TEFCA. Section 3001(c)(9)(C) requires the National Coordinator to publish TEFCA on its website and in the **Federal Register**. Section 3001(c)(9)(D)(i) requires the National Coordinator to publish a list of HINs that have adopted TEFCA. Section 3001(c)(9)(D)(ii) requires the Secretary to establish a process for HINs to attest that they have adopted TEFCA.

B. Regulatory History

The Secretary issued an interim final rule with request for comments on January 13, 2010, “Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology” (75 FR 2014), which adopted an initial set of standards, implementation specifications, and certification criteria. On March 10, 2010, the Secretary issued a proposed rule, “Proposed Establishment of Certification Programs for Health Information Technology” (75 FR 11328), that proposed both

temporary and permanent certification programs for the purposes of testing and certifying health IT. A final rule establishing the temporary certification program was published on June 24, 2010, “Establishment of the Temporary Certification Program for Health Information Technology” (75 FR 36158), and a final rule establishing the permanent certification program was published on January 7, 2011, “Establishment of the Permanent Certification Program for Health Information Technology” (76 FR 1262).

We have engaged in multiple rulemakings to update standards, implementation specifications, certification criteria, and the Program, a history of which can be found in the October 16, 2015, final rule, “2015 Edition Health Information (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications” (80 FR 62602) (2015 Edition Final Rule). The history can be found at 80 FR 62606. A final rule making corrections and clarifications was published for the 2015 Edition Final Rule on December 11, 2015 (80 FR 76868), to correct preamble and regulatory text errors and clarify requirements of the Common Clinical Data Set (CCDS), the 2015 Edition privacy and security certification framework, and the mandatory disclosures for health IT developers.

The 2015 Edition Final Rule established a new edition of certification criteria (“2015 Edition health IT certification criteria” or “2015 Edition”) and a new 2015 Edition Base EHR definition. The 2015 Edition established the minimum capabilities and specified the related minimum standards and implementation specifications that Certified EHR Technology (CEHRT) would need to include to support the achievement of “meaningful use” by eligible clinicians, eligible hospitals, and critical access hospitals under the Medicare and Medicaid EHR Incentive Programs (EHR Incentive Programs) (now referred to as the Promoting Interoperability Programs and the Promoting Interoperability performance category under MIPS) when the 2015 Edition is required for use under these and other programs referencing the CEHRT definition. The final rule also adopted a proposal to change the Program’s name to the “ONC Health IT Certification Program” from the ONC HIT Certification Program, modified the Program to make it more accessible to other types of health IT beyond EHR technology and for health IT that supports care and practice

settings beyond the ambulatory and inpatient settings, and adopted new and revised Principles of Proper Conduct (PoPC) for ONC-ACBs.

After issuing a proposed rule on March 2, 2016, “ONC Health IT Certification Program: Enhanced Oversight and Accountability” (81 FR 11056), we published a final rule by the same title (81 FR 72404) (EOA Final Rule) on October 19, 2016. The EOA Final Rule finalized modifications and new requirements under the Program, including provisions related to our role in the Program. The final rule created a regulatory framework for our direct review of health IT certified under the Program, including, when necessary, requiring the correction of non-conformities found in health IT certified under the Program and suspending and terminating certifications issued to Complete EHRs and Health IT Modules. The final rule also set forth processes for us to authorize and oversee accredited testing laboratories under the Program. In addition, it included provisions for expanded public availability of certified health IT surveillance results.

On March 4, 2019, the Secretary published a proposed rule titled “21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program” (84 FR 7424) (ONC Cures Act Proposed Rule). The proposed rule proposed to implement certain provisions of the Cures Act that would advance interoperability and support the access, exchange, and use of electronic health information. We also requested comment in the ONC Cures Act Proposed Rule (84 FR 7467) as to whether certain health IT developers should be required to participate in TEFCA as a means of providing assurances to their customers and ONC that they are not taking actions that constitute information blocking or any other action that may inhibit the appropriate exchange, access, and use of EHI, with the goal of developing or supporting TEFCA for the purpose of ensuring full network-to-network exchange of health information.

On May 1, 2020, the ONC Cures Act Final Rule was published (85 FR 25642). The final rule implemented certain provisions of the Cures Act, including Conditions and Maintenance of Certification requirements for health IT developers, the voluntary certification of health IT for use by pediatric health providers, and reasonable and necessary activities that do not constitute information blocking. The final rule also implemented certain parts of the Cures Act to support patients’ access to their EHI, and the implementation of

information blocking policies that support patient electronic access. Additionally, the final rule modified the 2015 Edition health IT certification criteria and Program in other ways to advance interoperability, enhance health IT certification, and reduce burden and costs, as well as improving patient and health care provider access to EHI and promoting competition. On November 4, 2020, the Secretary published an interim final rule with comment period titled “Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID–19 Public Health Emergency” (85 FR 70064) (Cures Act Interim Final Rule). The interim final rule extended certain compliance dates and timeframes adopted in the ONC Cures Act Final Rule to offer the healthcare system additional flexibilities in furnishing services to combat the COVID–19 pandemic, including extending the applicability date for information blocking provisions to April 5, 2021.

On April 18, 2023, the Secretary published a proposed rule titled “Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing” (88 FR 23746) (HTI–1 Proposed Rule). The HTI–1 Proposed Rule proposed to implement the Electronic Health Record (EHR) Reporting Program provision of the Cures Act by establishing new Conditions and Maintenance of Certification requirements for health IT developers under the Program. The HTI–1 Proposed Rule also proposed to make several updates to certification criteria and implementation specifications recognized by the Program, including revised certification criterion for: “clinical decision support” (CDS), “patient demographics and observations”, and “electronic case reporting.” The HTI–1 Proposed Rule also proposed to establish a new baseline version of the United States Core Data for Interoperability (USCDI). Additionally, the HTI–1 Proposed Rule proposed enhancements to support information sharing under the information blocking regulations.

On January 9, 2024, the Secretary issued the “Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing” final rule (HTI–1 Final Rule), which implemented the EHR Reporting Program provision of the 21st Century Cures Act and established new Conditions and Maintenance of Certification requirements for health IT

developers under the Program (89 FR 1192). The HTI–1 Final Rule also made several updates to certification criteria and standards recognized by the Program. The Program updates included revised certification criteria for “decision support interventions,” “patient demographics and observations,” and “electronic case reporting,” as well as adopted a new baseline version of the USCDI standard, USCDI Version 3. Additionally, the HTI–1 Final Rule provided enhancements to support information sharing under the information blocking regulations. Through these provisions, we sought to advance interoperability, improve algorithm transparency, and support the access, exchange, and use of EHI. The HTI–1 Final Rule also updated numerous technical standards in the Program in additional ways to advance interoperability, enhance health IT certification, and reduce burden and costs for health IT developers and users of health IT.

On August 5, 2024, the Secretary published a proposed rule titled “Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability” (89 FR 63498) (HTI–2 Proposed Rule). The HTI–2 Proposed Rule sought to advance interoperability, improve transparency, and support the access, exchange, and use of electronic health information through proposals for: standards adoption; adoption of certification criteria to advance public health data exchange; expanded uses of certified application programming interfaces, such as for electronic prior authorization, patient access, care management, and care coordination; and information sharing under the information blocking regulations. Additionally, the HTI–2 Proposed Rule proposed to establish a new baseline version of the USCDI standard and proposed to update the ONC Health IT Certification Program to enhance interoperability and optimize certification processes to reduce burden and costs. The HTI–2 Proposed Rule also proposed to implement certain provisions related to TEFCA, which would support the reliability, privacy, security, and trust within TEFCA. This final rule is the second “Health Data, Technology, and Interoperability” final rule that seeks to advance interoperability, improve transparency, and support the access, exchange, and use of electronic health information.

III. ONC Health IT Certification Program

A. Administrative Updates

1. Updates Pursuant to 2014 Edition Removal

We proposed to remove the “Complete EHR” and “EHR Module” terms from certain sections within subpart E of 45 CFR part 170 because by the time we would finalize any proposal in a final rule, the terms would no longer be relevant (89 FR 63614). As described below, due to the amount of time that has elapsed since the June 30, 2020, effective date of the ONC Cures Act Final Rule’s removal of the 2014 Edition from subparts A, B, and C of part 170, we believe removing obsolete terms as the Program evolves over time maintains clarity of the regulatory text and Program provisions, particularly for regulated entities and interested parties.

a. Removal of “Complete EHR” References

Because the ability to maintain Complete EHR certification was only permitted with health IT certified to the 2014 Edition certification criteria, the “Complete EHR” concept was discontinued for the 2015 Edition (80 FR 62719). In order to finalize removal of the 2014 Edition, the ONC Cures Act Final Rule removed the 2014 Edition certification criteria in § 170.314 from the Program regulations in 45 CFR part 170, § 170.545, and references to “Complete EHR” from the regulation text (85 FR 25655 through 25656). In the HTI–1 Final Rule, we removed the “Complete EHR” language from all reference points in §§ 170.523 and 170.524 (89 FR 1209 through 1210).

However, as explained in the HTI–2 Proposed Rule (89 FR 63614), until now, we have retained references to “Complete EHRs” in certain provisions within subpart E of 45 CFR part 170:

- The definition of “gap certification” (§ 170.502).
- Authorization scope for ONC–ATL status (§ 170.511).
- Requirements for ONC–ACBs to refund fees to developers seeking certification under certain circumstances (§ 170.523(j)(3)).
- Applicability of a newer version of a minimum standard (§ 170.555(b)(2)).

The “Complete EHR” concept remained relevant for supporting continuity through these provisions at that time because the 2014 Edition was not removed from the CFR until the ONC Cures Act Final Rule (85 FR 25655). As explained in the HTI–2 Proposed Rule, the ONC Cures Act Final Rule became effective on June 30, 2020,

and records for the 2014 Edition were required to be retained (including Complete EHRs) until June 30, 2023, under 45 CFR 170.523(g)(1) (89 FR 63614).

However, beginning with the 2015 Edition, Complete EHR certifications could no longer be issued and December 31, 2023, has passed. Thus, we proposed to remove references to “Complete EHRs” from the provisions listed above as of the effective date of this final rule.

b. Removal of “EHR Modules” References

As explained in the 2015 Edition Final Rule (80 FR 62604), in order to better reflect the scope of ONC’s authority under the PHS Act (section 3000(5)) and to make the Program more open and accessible, we replaced the term “EHR Module” with “Health IT Module.”

As noted above, consistent with the three-year records retention requirement for ONC-ACBs (45 CFR 170.523(g)(1)), June 30, 2023, marked the end of a three-year minimum retention period (36 calendar months) since we finalized, in the ONC Cures Act Final Rule, the removal of the 2014 Edition from 45 CFR part 170, subparts A, B, and C (85 FR 25656). Similarly, December 31, 2023, marked the end of the third calendar year following the calendar year in which the ONC Cures Act Final Rule became effective. Because we passed both rules’ three-year retention requirements for ONC-ACBs and the term “EHR Module” is no longer relevant, we proposed to remove from § 170.523(f) reference to “EHR Modules.” In the HTI-2 Proposed Rule (89 FR 63614 through 63615), we included the explanation for removing the term “EHR Modules” from § 170.523(f) in the preamble. However, we erroneously neglected to include the removal of “EHR Modules” in the regulatory text for § 170.523(f). Because we included our intent to remove all of the references to EHR Modules in the HTI-2 Proposed Rule and there were no comments on the removal of the term generally, we have included the revision to the regulatory text for § 170.523(f) in this final rule.

Comments. We did not receive any comments in response to our proposals to remove the terms “Complete EHR” and “EHR Module.”

Response. Because these terms are no longer relevant and retaining them may cause confusion for the public, we have adopted our proposals without revisions.

2. Removal of Time-Limited Criteria

In the ONC Cures Act Final Rule, we finalized § 170.550(m) “time-limited certification and certification status for certain 2015 Edition certification criteria,” which provided that for five specific certification criteria, an ONC-ACB may only issue a certification to a Health IT Module and permit continued certified status for a specified time period (85 FR 25952). The five criteria with time-limited certification and certification status are the “drug-formulary and preferred drug list checks” certification criterion (§ 170.315(a)(10)), “patient-specific education resources” (§ 170.315(a)(13)), “data export” certification criterion (§ 170.315 (b)(6)), “secure messaging” certification criterion (§ 170.315(e)(2)), and “application access—data category request” (§ 170.315(g)(8)). Because the specified time periods for certification to these criteria have elapsed, we proposed to remove all of the certification criteria referenced in § 170.550(m) in one action by removing and reserving § 170.550(m) in its entirety (89 FR 63615 and 63616). We also proposed to remove and reserve these aforementioned certification criteria from the specific CFR locations in which they are adopted. In the ONC Cures Act Final Rule, we also finalized revisions in § 170.315(b)(7)(ii) and (b)(8)(i)(B) to allow security tagging of Consolidated-Clinical Document Architecture (C-CDA) documents at the document level only for the period until 24 months after publication date of the final rule (85 FR 25667). Because that time period has elapsed, we proposed to revise § 170.315(b)(7) and (8) to remove § 170.315(b)(7)(ii) and (b)(8)(i)(B) (89 FR 63616).

Comments. The majority of comments received on this proposal objected in particular to the removal of the “patient-specific education resources” certification criterion in § 170.315(a)(13). They stated that while innovation has progressed, patient-specific educational resources remain essential in supporting clinicians during patient interactions. Another commenter expressed concern over the lack of Fast Healthcare Interoperability Resources (FHIR®)-based standards for patient education resources. The commenter stated that although some patient education resources align with FHIR standards to bolster patient engagement, no specific FHIR standards align with the HL7 Context-Aware Knowledge Retrieval (Infobutton) standard. The same commenter recommended that until clear FHIR standards are established, patient

education resources should be codified in regulations and EHR certification criteria. One commenter stated that while automation and algorithms have advanced, this technology is not universally available or fully developed across all health IT systems and removing this criterion could create a gap in systems where this capability is less robust, particularly in underserved communities. One commenter stated that providing patient-specific educational resources contributes to better long-term outcomes, supporting chronic disease management, treatment adherence, and overall public health. Another commenter suggested that instead of eliminating the certification, updating the criterion to reflect advancements in automation and AI-driven patient education would encourage ongoing innovation.

Response. We thank commenters for providing feedback on the removal of “patient-specific education resources” certification criterion in § 170.315(a)(13). However, we believe commenters expressing specific concerns about maintaining the criterion may have misunderstood the proposal. The discussion of removing the “patient-specific education resources” certification criterion in § 170.315(a)(13) and the decision to end its applicability within the Program as of January 1, 2022, was finalized in the ONC Cures Act Final Rule. In the ONC Cures Act Final Rule, we finalized § 170.550(m), “Time-limited certification and certification status for certain ONC Certification Criteria for Health IT,” which provided that for five specific certification criteria, an ONC-ACB may only issue a certification to a Health IT Module and permit continued certified status for a specified time period (85 FR 25952). One of those criteria included the “patient-specific education resources” certification criterion in § 170.315(a)(13).

Specifically, in the ONC Cures Act Final Rule, we finalized requirements in § 170.550(m)(1) permitting ONC-ACBs to issue certificates for the “patient-specific education resources” certification criterion in § 170.315(a)(13) up until January 1, 2022 (85 FR 25661). We stated that we believed that health IT’s capabilities to identify appropriate patient education materials was widespread among health IT developers and their customers, and noted innovation had occurred for these capabilities, including the use of automation and algorithms to provide appropriate education materials to patients in a timely manner (85 FR 25661). In addition, the “patient-specific education resources”

certification criterion in § 170.315(a)(13) included no means to advance innovations such as FHIR-based educational resources or patient-engagement applications. Therefore, in the ONC Cures Act Final Rule we also stated that we believed this certification criterion was no longer the best way to encourage innovation and advancement in the capabilities of health IT to support clinician-patient interactions and relationships (85 FR 25661).

As the discussion of removing the “patient-specific education resources” certification criterion in § 170.315(a)(13) and the decision to end its applicability within the Program as of January 1, 2022, was finalized in the ONC Cures Act Final Rule seems to have been misunderstood by those commenters, we believe those comments are not applicable to our proposal and out of scope for this rulemaking. We have finalized the proposal to remove and reserve § 170.315(a)(13).

We did not receive comments on the other proposals to remove time-limited certification criteria. Therefore, except as to the modified reference or references to ‘ASTP/ONC,’ we have finalized as proposed and remove and reserve those criteria. We have also finalized the proposal to revise § 170.315(b)(7) and (8) to remove § 170.315(b)(7)(ii) and (b)(8)(i)(B), which were time-limited provisions (now expired) that permitted health IT to demonstrate security tagging of C–CDA documents at the document level.

3. Privacy and Security Framework Incorporation of DSI Criterion

In the ONC HTI–1 Final Rule, we established a revised certification criterion (“decision support interventions” (§ 170.315(b)(11))) to replace the “clinical decision support” certification criterion (§ 170.315(a)(9)) effective January 1, 2025 (89 FR 1196 through 1197). However, we neither proposed nor finalized corresponding privacy and security certification requirements for Health IT Modules certifying to the “decision support interventions” certification criterion. This omission was an oversight. In the HTI–2 Proposed Rule, we proposed to add the “decision support interventions” certification criterion (§ 170.315(b)(11)) to the list of certification criteria in § 170.550(h)(3)(ii) (89 FR 63616).

To provide developers of certified health IT time to comply with these proposed requirements, we specifically proposed to require, in § 170.550(h)(3)(ii), that Health IT Modules certified to the “decision support interventions”

(§ 170.315(b)(11)) must also be certified to the specific privacy and security certification criteria on and after January 1, 2028. We stated that these specific privacy and security certification criteria are: “authentication, access control, and authorization” in § 170.315(d)(1); “auditable events and tamper-resistance” in § 170.315(d)(2); “audit report(s)” in § 170.315(d)(3); “automatic access time-out” in § 170.315(d)(5); “emergency access” in § 170.315(d)(6); “end-user device encryption” in § 170.315(d)(7); “encrypt authentication credentials” in § 170.315(d)(12); and “multi-factor authentication” in § 170.315(d)(13). In the HTI–2 Proposed Rule preamble (89 FR 63616), when listing the specific privacy and security certification criteria that a Health IT Module certified to the “decision support interventions” (§ 170.315(b)(11)) certification criterion must also be certified to, we neglected to include “emergency access” in § 170.315(d)(6). However, because we stated, in the HTI–2 Proposed Rule, that we were proposing to require in § 170.550(h)(3)(ii) that Health IT Modules certified to the “decision support interventions” (§ 170.315(b)(11)) must also be certified to the specific privacy and security certification criteria on and after January 1, 2028, and because § 170.315(d)(6) is one of the specific privacy and security certification criteria referenced in § 170.550(h)(3)(ii), we believe that the public was informed of the requirement to certify to § 170.315(d)(6) as well despite our erroneous omission in the preamble.

Comments. We did not receive any comments specific to this proposal to add the “decision support interventions” certification criterion (§ 170.315(b)(11)) to the list of certification criteria in § 170.550(h)(3)(ii). We did, however, receive comments addressing other provisions related to decision support interventions and timelines that are beyond the scope of this final rule and are still being reviewed and considered for purposes of issuing subsequent final rules for such proposals in the future.

Response. Except as to the modified reference or references to ‘ASTP/ONC,’ we have finalized this provision as proposed.

B. Correction—Privacy and Security Certification Framework

We proposed to make a correction to the Privacy and Security Certification Framework in § 170.550(h) (89 FR 63508). We revised § 170.550(h) in the ONC Cures Act Final Rule but intended for § 170.550(h)(4) to remain unchanged.

However, when we drafted the amendatory instructions, we erroneously included the instruction to revise all of paragraph (h) (85 FR 25952). Due to this error, when the CFR was updated, § 170.550(h)(4) was removed. Therefore, we proposed to add § 170.550(h)(4) back to the CFR [45 CFR 170.550(h)(4) (Jan. 1, 2020)] as it existed prior to the ONC Cures Act Final Rule (89 FR 63508). We included the complete language to be added to § 170.550(h) in the proposed and in the regulatory text of this final rule so that there is sufficient notice of the language that was previously omitted.

Comments. We did not receive any comments on this proposal.

Response. We have corrected this provision in this final rule to add § 170.550(h)(4) back in the CFR.

IV. Information Blocking Enhancements—Part 171, Subpart D (TEFCA™)

In the HTI–2 Proposed Rule, we proposed revisions to defined terms for purposes of the information blocking regulations, which appear in 45 CFR 171.102. Specifically, we proposed to clarify the definition of “health care provider” (89 FR 63616, 63617, and 63802) and adopt definitions for three terms not previously included in § 171.102: “business day” (89 FR 63601, 63602, 63626, and 63802), “health information technology or health IT” (89 FR 63617 and 63802), and “reproductive health care” (89 FR 63633 and 63802). We proposed to revise two existing exceptions in subpart B of 45 CFR part 171 (§§ 171.202 and 171.204). We proposed revisions to paragraphs (a), (d), and (e) of § 171.202 (89 FR 63620 through 63622 and 63803) and to paragraphs (a)(2) and (3) and (b) of § 171.204 (89 FR 63622 through 63628 and 63803). We proposed two new exceptions, one in each in subparts B and C of part 171. The Protecting Care Access Exception was proposed as new § 171.206 (89 FR 63627 through 63639 and 63804) and the Requestor Preferences Exception as new § 171.304 (89 FR 63639 through 63642, 63804 and 63805). We proposed to codify in § 171.401 definitions of certain terms relevant to the Trusted Exchange Framework and Common Agreement™ (TEFCA™) (89 FR 63642, 63804, and 63805) and in § 171.104 descriptions of certain practices that constitute interference with the access, exchange, and use of electronic health information (EHI) (89 FR 63617 through 63620, 63802, and 63803). Lastly, we solicited comment on potential revisions to the TEFCA Manner Exception in subpart D (§ 171.403).

In this final rule, we only address comments on the proposal to codify definitions of certain TEFCA terms in § 171.401 and comments received in response to our potential revisions to the TEFCA Manner Exception. All other information blocking (part 171) proposals from the HTI–2 Proposed Rule and comments received on those proposals are beyond the scope of this final rule but may be a subject of another final rule.

In the HTI–2 Proposed Rule (89 FR 63642 and 63643), we discussed that in the HTI–1 Proposed Rule (88 FR 23872), we proposed to add a *TEFCA manner* condition to the proposed revised and renamed Manner Exception. In the HTI–2 Proposed Rule, we re-stated that this approach “aligns with the Cures Act’s goals for interoperability and the establishment of TEFCA by acknowledging the value of TEFCA in promoting access, exchange, and use of EHI in a secure and interoperable way” (88 FR 23872). In the HTI–1 Final Rule (89 FR 1437), in part 171, we finalized a new subpart D, “Exceptions That Involve Practices Related to Actors’ Participation in The Trusted Exchange Framework and Common Agreement (TEFCA).” We noted that the new subpart consists of three sections, § 171.400, “Availability and effect of exceptions,” which mirrors §§ 171.200 and 171.300, stating that a practice shall not be treated as information blocking if the actor satisfies an exception to the information blocking provision as set forth in subpart D by meeting all applicable requirements and conditions of the exception at all relevant times (89 FR 1388). We reserved § 171.401 for definitions in a future rulemaking, and also reserved § 171.402 for future use. In § 171.403 we finalized a new TEFCA Manner Exception based on the *TEFCA manner* condition we proposed in HTI–1 Proposed Rule.

A. Definitions

While we reserved § 171.401 for possible future use as a “definitions” section in the HTI–1 Final Rule, we declined to finalize any definitions in the HTI–1 Final Rule. Instead, we referred readers to the definitions in the most recent version of the Common Agreement (88 FR 76773) for the terms relevant to the new exception (89 FR 1388). For example, we noted that when we referred to Framework Agreement(s), we meant any one or combination of the Common Agreement, a Participant-QHIN Agreement, a Participant-Subparticipant Agreement, or a Downstream Subparticipant Agreement, as applicable (86 FR 76778). We noted that this approach would allow us to

maintain consistency and harmony between the Common Agreement and the new subpart D regulatory text.

In the HTI–2 Proposed Rule, we proposed to include definitions in § 171.401 by cross-referencing the TEFCA definitions included in the proposed new 45 CFR part 172, “Trusted Exchange Framework and Common Agreement.” We specifically proposed to adopt in § 171.401 the definitions from § 172.102 for the following terms: Common Agreement, Framework Agreement, Participant, Qualified Health Information Network or QHIN™, and Subparticipant. The definitions would apply to all of subpart D.

Comments. We did not receive any comments regarding our proposal to adopt in § 171.401 the definitions from 45 CFR part 172, “Trusted Exchange Framework and Common Agreement,” for the terms: Common Agreement, Framework Agreement, Participant, Qualified Health Information Network or QHIN, and Subparticipant. Comments regarding the substance of those definitions are addressed in section V. of this final rule.

Response. We have finalized the definitions as proposed. The above terms will have the meaning given to them in § 172.102.

B. TEFCA™ Manner Exception

As briefly discussed above, we finalized a new TEFCA Manner Exception in the HTI–1 Final Rule. In the HTI–1 Final Rule, we stated that the TEFCA Manner Exception (§ 171.403) provides that an actor’s practice of limiting the manner in which it fulfills a request to access, exchange, or use EHI to be providing such access, exchange, or use to only via TEFCA will not be considered information blocking when it follows certain conditions (89 FR 1388). Those conditions require that (1) the actor and requestor both be part of TEFCA; (2) that the requestor is capable of such access, exchange, or use of the requested EHI from the actor via TEFCA; and (3) any fees charged by the actor and the terms for any license of interoperability elements granted by the actor in relation to fulfilling the request are required to satisfy, respectively, the Fees Exception (§ 171.302) and the Licensing Exception (§ 171.303). In addition to these three requirements, we noted (89 FR 63643) that we also included a limitation in § 171.403(c), stating that the exception is available only if the request is *not* made via the standards adopted in 45 CFR 170.215, which include the FHIR Application Programming Interface (API) standards.

We noted (89 FR 63643) that our finalized TEFCA Manner Exception differed from the proposed *TEFCA manner* condition in two ways. First, when we proposed the *TEFCA manner* condition, we stated that the Fees Exception and the Licensing Exception would not apply, because “we mistakenly assumed that all actors participating in TEFCA would have *already* reached overarching agreements on fees and licensing such that there would be no need for application of the Fees and Licensing Exceptions” (89 FR 1389). We stated that we believe that by soliciting comments specifically on this point, we provided notice to parties that we either would or would not apply the Fees and Licensing Exceptions. In response to our proposal in the HTI–1 Proposed Rule, some commenters expressed concern that because the Common Agreement prohibits fees between QHINs™ but is otherwise silent on fees between Participants and Subparticipants, the proposal could allow actors to charge fees to access, exchange, or use EHI that did not comply with the Fees or Licensing Exceptions. Some commenters also expressed that this could have the effect of disincentivizing participation in TEFCA and could cause actors to use other options of electronic exchange outside of TEFCA, where the actors believed the Fees and Licensing Exceptions would apply. As such, in the HTI–1 Final Rule, we finalized the TEFCA Manner Exception to include that any fees charged by the actor, and any licensing of interoperability elements, must satisfy the Fees Exception (§ 171.302) and the Licensing Exception (§ 171.303) (89 FR 1389). In the HTI–2 Proposed Rule, we stated that while we continue to believe that it was clear that the alternative would be *to* apply the exceptions, we requested comment on whether there are drawbacks to applying the Fees and Licensing Exceptions, and if we should continue to apply them to the TEFCA Manner Exception as currently required in § 171.403(d).

We noted (89 FR 63643) that the other change made to the proposed *TEFCA manner* condition was the limitation that carves out requests made for access, exchange, or use of EHI via FHIR API standards (89 FR 1389). We finalized this limitation in response to comments noting that a request could be made for access, exchange, or use via FHIR-based API and an actor could respond in a different manner and satisfy the exception (89 FR 1390 and 1391). Commenters on the HTI–1 Proposed Rule further noted that this potential

outcome could undermine our stated purpose in incentivizing TEFCA participation with the new exception (See 89 FR 1390). In the HTI–2 Proposed Rule (89 FR 63643), we solicited comment on this limitation within the TEFCA Manner Exception for requests via FHIR API standards. For example, we solicited comment on whether the limitation should be expanded to include exchange based on versions of the FHIR standards that are more advanced than those adopted in 45 CFR 170.215 or approved through the 45 CFR 170.405(b)(8), “Standards Version Advancement Process—voluntary updates of certified health IT to newer versions of standards and implementation specifications.” We noted that as of the time we issued the HTI–2 Proposed Rule, the limitation would only cover requests made via FHIR API standards codified in § 170.215, including standards that may be updated from time to time through § 170.405(b)(8), which may involve a delay before the version is formally approved under Standards Version Advancement Process (SVAP).

We also sought comment on a different approach (89 FR 63643). We noted that eventually all TEFCA QHINs will be required to support exchange via FHIR API standards. A Participant or Subparticipant who makes a request for access, exchange, or use of EHI via FHIR API will at first make such a request through a QHIN, but in time, a Participant or Subparticipant could directly request access, exchange, or use of EHI via FHIR API standards from another Participant or Subparticipant in a different QHIN. We stated that one option would be to sunset the limitation in § 171.403(c) once all QHINs can support brokered FHIR. Another option would be to sunset the limitation in § 171.403(c) if all QHINs, Participants and Subparticipants support facilitated FHIR exchange. We also stated that as an alternative to these options, we could maintain the exception as is, regardless of FHIR API adoption among TEFCA entities. We requested comment on all of the options, including whether or not the limitation should remain as it is currently.

Comments. The majority of comments we received on whether there are drawbacks to applying the Fees and Licensing Exceptions, and if we should continue to apply them to the TEFCA Manner Exception as currently required in § 171.403(d), were in support of the exception as finalized in the HTI–1 Final Rule. Commenters expressed appreciation that ASTP/ONC listened to their feedback in response to the HTI–1 Proposed Rule and added the Fees and

Licensing Exceptions applicability to the TEFCA Manner Exception. Commenters noted that including the applicability of the Fees and Licensing Exceptions would mitigate risks that some organizations could exploit their TEFCA participation to consolidate market power and stifle competition.

Response. We appreciate the commenters’ support. We are retaining the exception as finalized in HTI–1 Final Rule, such that there will be no changes finalized in this final rule and the Fees and Licensing Exceptions will apply to an actor seeking to use the TEFCA Manner Exception.

Comments. One commenter recommended modifying the TEFCA Manner Exception so that both the requestor and responder must agree on the mechanism (FHIR or other transmission protocol) within TEFCA used to exchange EHI, in order to accommodate TEFCA participants who may not yet have enabled FHIR transactions for TEFCA.

Response. We appreciate the comment and the opportunity to clarify that the exception does not apply to requests made via the standards adopted in 45 CFR 170.215, including version(s) of those standards approved pursuant to 45 CFR 170.405(b)(8) (the Standards Version Advancement Process, or SVAP). The standards adopted in § 170.215 include the FHIR standards the commenter describes. When actors seek to use the TEFCA Manner Exception, as finalized in 45 CFR 171.403, the exception includes a “requestor capability” condition (§ 171.403(b)) that limits the exception to only be available when the requestor is capable of such access, exchange, or use of the requested EHI from the actor via TEFCA. Therefore, if the requestor is unable to receive the EHI from the actor using a FHIR transaction via TEFCA, this exception would not be available to the actor. We believe this provides enough flexibility for actors to use this exception when the requestors are able to access the requested EHI, while ensuring that actors who do not yet have FHIR-based exchange capabilities will not be expected to share via FHIR.

Comments. A few commenters suggested that ASTP/ONC revise the TEFCA Manner exception to state that if an actor charges fees to access data through TEFCA, the TEFCA Manner Exception will not apply, and the requestor would be entitled to EHI through a different manner. One commenter stated that ASTP/ONC should state that charging fees to access data through TEFCA negates the TEFCA Manner Exception and actors that do not provide a secondary method of

exchange would be considered information blockers.

Response. We decline to adopt these suggestions. We have retained the finalized exception from the HTI–1 Final Rule. We reiterate that certain fees are permitted under the Fees Exception, and that an actor participating in TEFCA would still be subject to the restrictions of the Fees Exception if the actor is seeking to make use of the TEFCA Manner Exception (for example, by responding via TEFCA even if the request was not received via TEFCA). We note that, per § 171.403(c), the TEFCA Manner Exception is not available if a requestor requests EHI via the standards adopted in 45 CFR 170.215, including version(s) of those standards approved pursuant to 45 CFR 170.405(b)(8). Under those conditions described in § 171.403(c), a fee could still be considered an interference if it does not meet the requirements of the Fees Exception (or the practice is not covered by another exception).

Comments. Many commenters supported retaining the limitation in the TEFCA Manner Exception to exclude requests made via the standards adopted in § 170.215. Commenters stated that removing the condition in § 171.403(c) could disincentivize joining TEFCA for entities seeking to leverage FHIR-based exchange. Some of those commenters also suggested that the condition should be removed once everyone exchanging data on TEFCA is required to support the more advanced FHIR standard. One commenter recommended removing the condition now, and others recommending ASTP/ONC consider sunseting the condition in the future but stated that it was premature to do so now. Most commenters supported maintaining the condition for now, and recommended ASTP/ONC revisit the exception in the future.

Response. We appreciate the comments and agree that the condition remains useful for advancing interoperability as discussed in the HTI–2 Proposed Rule. We also agree that it is premature to remove the condition at this time. As noted above, we are maintaining the TEFCA Manner Exception as finalized in the HTI–1 Final Rule.

Comments. A few commenters expressed concerns that actors who participate in TEFCA may seek to use this exception to cover practices involving the access, exchange, or use of EHI with entities or requestors who do not participate in TEFCA. The commenters asked for clarification on this point.

Response. We appreciate the opportunity to clarify that this

exception is only available when both the actor and the requestor participate in TEFCA as QHINs, Participants, or Subparticipants (§ 171.403(a)). An actor who participates in TEFCA may not use this exception to cover any practice related to the access, exchange, or use of EHI with an entity who is not a TEFCA QHIN, Participant, or Subparticipant.

Comments. Some commenters expressed concerns related to the “TEFCA SOP XP Implementation: Health Care Operations” because the standard operating procedure (SOP) would allow providers and developers to charge health plans to access data under the health care operations exchange purpose.

Response. Commenters correctly point out that health care providers and developers of certified health IT (“actors” for purposes of the information blocking regulations) are permitted to charge fees under TEFCA for the health care operations exchange purpose as well as other exchange purposes.⁵ However, these fees would need to meet the Fees Exception (§ 171.302) under the information blocking regulations and if charged in conjunction with an actor choosing to voluntarily use and meet the conditions of the TEFCA Manner Exception. We decline, however, to state in this final rule whether any specific fee amount that may be charged as a permitted fee under TEFCA meets the conditions of the Fees Exception.

Comments. We received many comments in response to our question regarding whether the limitation should be expanded to include exchange based on versions of the FHIR standards that are more advanced than those adopted in 45 CFR 170.215 or approved through the 45 CFR 170.405(b)(8), “Standards Version Advancement Process—voluntary updates of certified health IT to newer versions of standards and implementation specifications.” Some commenters suggested that the limitation should only apply to requests made via standards adopted in § 170.215 or through the Standards Version Advancement Process (SVAP). Some suggested that if the actor supports the more advanced FHIR standard that has not yet been adopted, then the actor must respond to a request via that standard. The commenters stated that if the actor does not support the more advanced FHIR standard at the time of the request, then the TEFCA

Manner Exception should still be available.

Response. We appreciate the comments. Until adoption of the FHIR standard is widespread, we think it is sufficient to reserve the carve-out only for versions of the FHIR standard adopted under § 170.215 or approved through the SVAP process. We believe including standards approved through the SVAP process, as well as those adopted under § 170.215, provides the right balance of ensuring newer versions of the FHIR standard can be used without expanding the carve-out to the point that it subsumes the exception itself.

Comments. One commenter encouraged us to clarify that the exception does not mean an organization participating in TEFCA can or will only share data with other organizations participating in TEFCA. Another commenter recommended that the mutuality requirement be phased out so that an actor’s participation in TEFCA allows them to claim the TEFCA Manner Exception regardless of the requestor’s participation.

Response. We appreciate the opportunity to draw attention to § 171.403(a), as finalized in the HTI–1 Final Rule, which states that the actor and requestor *must both be part of TEFCA* for the exception to be available. A request to access, exchange, or use EHI that an actor receives from a requestor who does not participate in TEFCA as a QHIN, Participant, or Subparticipant does not qualify for the TEFCA Manner Exception (89 FR 1388). Nor does anything in this exception, or anything else in the information blocking regulations, permit a TEFCA entity actor to interfere with a non-TEFCA entity’s request to access, exchange, or use EHI, unless required by law or covered by an exception. We decline to adopt the suggestion to remove the mutuality requirement because it would be detrimental to exchange and could force participation in a voluntary exchange framework. We remind all interested parties that participation in TEFCA is voluntary, and no actor is required to join TEFCA.

Comments. Some commenters expressed concerns that the TEFCA Manner Exception could have unintended consequences. For example, one commenter expressed concern that the TEFCA Manner Exception could tip the scales to prioritize TEFCA exchange over all other interoperability pathways and noted that TEFCA does not offer solutions to all needs, including, for example, write-back capabilities and non-EHI data. A few commenters encouraged ASTP/ONC to regularly

review the need for the TEFCA Manner Exception, and to update or sunset the exception in the future.

Response. We appreciate the comments. We agree that retaining multiple pathways to interoperability is important. We will continue to monitor the interaction between TEFCA and the TEFCA Manner Exception.

Comment. One commenter suggested encouraging TEFCA participation by expanding the TEFCA Manner Exception. The commenter noted that the exception states that if both parties (requestor and responder) participate in TEFCA, it is not information blocking to only fulfill requests for EHI via TEFCA. The commenter asserted that this incentivizes a requestor not to become a TEFCA participant, since the exception does not apply against a requestor as long as it is not a TEFCA participant. Instead, the commenter suggested that we incentivize entities to join TEFCA by adjusting the exception to place a burden on any requestor who is not currently a TEFCA QHIN, participant, or sub-participant to explain why joining TEFCA is infeasible or poses an undue burden for their request. The commenter stated this would satisfy the stated goals of the exception and drive adoption within the industry.

Response. We thank the commenter for their suggestions. These suggestions are outside the scope of our solicitation of comments on the TEFCA Manner Exception.

V. Trusted Exchange Framework and Common Agreement™

Section 3001(c)(9)(B)(i) of the PHS Act provides the National Coordinator with the authority to “develop or support a trusted exchange framework for trust policies and practices and for a common agreement for exchange between health information networks.” The components of this Trusted Exchange Framework and Common Agreement™ (TEFCA™) include the Trusted Exchange Framework (a common set of principles designed to facilitate trust between health information networks (HINs)) and the Common Agreement (the agreement Qualified Health Information Networks® (QHINs™) sign), which includes, among other provisions, privacy, compliance, and security requirements). The Common Agreement also references the QHIN Technical Framework (QTF) (which describes technical requirements for exchange among QHINs) as well as, where necessary, SOPs. These documents further the statute’s overall goal of ensuring full network-to-network exchange of health information by

⁵ 4.2 Required Information and Permitted Fees and Table 2 at https://rce.sequoiaproject.org/wp-content/uploads/2024/08/SOP-Exchange-Purposes_CA-v3_508.pdf.

establishing an organizational, operational, and technical floor for nationwide interoperability and securely facilitating the exchange of information across different networks nationwide.

By providing a common and consistent approach for the exchange of health information across many different networks, TEFCA simplifies and significantly reduces the number of separate networks that individuals, health care providers, and other interested parties need to be a part of in order to access the health information they seek. HINs that voluntarily join TEFCA will facilitate exchange in a secure and interoperable manner. TEFCA establishes a method for authenticating trusted HIN participants, potentially lowering the cost and expanding the nationwide availability of secure health information exchange capabilities. The establishment of technical services for HINs that voluntarily join TEFCA, such as an electronic address directory and security services, will help to scale network exchange nationwide. In addition, the organizational and operational policies established through TEFCA enable the exchange of health information among HINs and include minimum conditions required for such exchange to occur.

Updates in Common Agreement Version 2.1 reflect the latest technical specifications, among other changes, including updates to network-based exchange using FHIR APIs, which are a cornerstone of the interoperability initiatives of not only ASTP/ONC but also of other Federal agencies such as the Centers for Medicare & Medicaid Services (CMS), Centers for Disease Control and Prevention (CDC), Health Resources & Services Administration (HRSA), and U.S. Department of Veterans Affairs (VA).

Under TEFCA, QHINs play an important role in advancing secure, standardized health information exchange. QHINs have significant organizational and technical capabilities, facilitate exchange at the highest level of the TEFCA infrastructure, and are the entities with which Participants (and their Subparticipants) connect to engage in TEFCA Exchange. “TEFCA Exchange,” which we proposed to define in § 172.102, means the transaction of electronic protected health information (ePHI) between Nodes⁶ using a TEFCA-

specific purpose of use code, meaning a code that identifies the Exchange Purpose for which exchange is occurring. QHINs voluntarily agree to follow certain organizational and operational policies that allow Participants (entities who have entered into an agreement with the QHIN that includes the Participant/Subparticipant Terms of Participation) and Subparticipants (entities that have entered into an agreement with a Participant or other Subparticipant that includes the Participant/Subparticipant Terms of Participation) to simplify their operations and promote efficiency of scale.

QHINs must meet policy and technical requirements under the Common Agreement. The QTF and SOPs provide additional information on how QHINs meet those requirements. As finalized, QHINs must comply with the provisions in this final rule. QHINs also perform an important role by ensuring that Participants and Subparticipants meet the requirements of TEFCA.

As we discussed in the HTI–2 Proposed Rule (89 FR 63644), we proposed to establish rules in 45 CFR part 172 to implement our obligations under section 3001(c)(9)(D) of the PHS Act to publish a directory of HINs that “have adopted the common agreement and are capable of trusted exchange pursuant to the common agreement” and to establish a process through notice-and-comment rulemaking for HINs to attest to adopting TEFCA.

The provisions also establish the qualifications for HINs to receive and maintain Designation as a QHIN capable of trusted exchange pursuant to TEFCA, as well as establish procedures governing QHIN Onboarding and Designation, suspension, termination, and administrative appeals to ONC as described in the sections below. In the HTI–2 Proposed Rule, we stated that we believe establishing these provisions in regulation would strengthen the trust of interested parties in TEFCA and support its success at scale.

Comments. A majority of commenters supported ONC’s proposal to adopt rules in 45 CFR part 172 regarding TEFCA. A number of commenters encouraged ASTP/ONC to prioritize focusing on high-quality data within data sharing and creating more equal information exchange to advance interoperability.

Many commenters highlighted that strong TEFCA requirements allow organizations who exchange information to avoid national security and fraud risk and have protection against outside bad actors. Several

commenters also expressed support for the implementation of the QTF to support data exchange and noted the importance of TEFCA ensuring the exchange of reliable and high-quality data.

Response. We thank commenters for their support of our proposal to adopt rules in 45 CFR part 172 regarding TEFCA and their support for our implementation of TEFCA. We agree with commenters about the importance of TEFCA in advancing interoperability and high-quality data exchange. We appreciate commenters’ concerns about potential risks of data exchange without TEFCA infrastructure. We are working to fulfill TEFCA’s statutory purpose of ensuring full network-to-network exchange of health information, while also recognizing that appropriate guardrails and protections for information exchange are needed. We agree with commenters who encouraged us to prioritize high-quality data and we are also exploring how TEFCA can help improve data quality for TEFCA Exchange.

Comments. Some commenters recommended that ASTP/ONC should codify all TEFCA requirements so that TEFCA requirements and applicable SOPs not included in the HTI–2 Proposed Rule may be subject to notice and comment rulemaking. These commenters also suggested that ASTP/ONC should become more involved in enforcing TEFCA requirements and providing incentives and removing disincentives for entities to participate in TEFCA. Some of these commenters also expressed that TEFCA should remain in alignment with Health Insurance Portability and Accountability Act of 1996 (HIPAA)⁷ unless there are strong policy reasons for TEFCA to diverge from HIPAA. One commenter requested that ASTP/ONC clarify within TEFCA any HIPAA interactions and protections related to disclosures.

Response. We appreciate the comments. In the Cures Act, Congress directed ONC to convene public-private and public-public partnerships to build consensus and develop or support a trusted exchange framework, including the Common Agreement (42 U.S.C. 300jj–11(c)(9)(A)). The statute provides that the Common Agreement—which must be published in the **Federal Register**, but which is not subject to notice and comment (42 U.S.C. 300jj–11(c)(9)(C))—may include a common method for authenticating trusted health information network participants, a common set of rules for trusted

⁶Node means a technical system that is controlled directly or indirectly by a QHIN, Participant, or Subparticipant and that is listed in the RCE Directory Service.

⁷Public Law 104–191, 110 Stat. 1936.

exchange, organizational and operational policies to enable the exchange of health information among networks, including minimum conditions for such exchange to occur, and a process for filing and adjudicating noncompliance with the terms of the common agreement (42 U.S.C. 300jj–11(c)(9)(B)). ASTP/ONC has convened such partnerships, and we believe the Common Agreement is generally best developed through those channels, as provided for in the Common Agreement to which QHINs agree. We believe the current process strikes the right balance between ASTP/ONC oversight, public engagement, and the use of a public-private partnership to both ensure important input from interested parties and maintain flexibility to adapt to the ever-evolving interoperability landscape. Finally, TEFCA is aligned with the HIPAA Privacy, Security, and Breach Notification Rules in the sense that an entity is able to comply with the HIPAA Rules and TEFCA at the same time. But we do not agree with commenters who suggest that TEFCA should presumptively copy-and-paste definitions or requirements from the HIPAA Rules into TEFCA. The HIPAA Rules and TEFCA are authorized by different statutes that pursue different goals, and while those goals might sometimes overlap, other times they might not. In order to recognize overlap between the two legal frameworks and reduce regulatory burden while balancing other policy interests, including trusted exchange, ASTP/ONC has sometimes aligned TEFCA requirements. However, ASTP/ONC may develop definitions and requirements within TEFCA that are narrower or broader than corresponding definitions and requirements within the HIPAA Rules to satisfy competing policy interests and achieve TEFCA's statutory goal of ensuring full network-to-network exchange of health information.

Comments. One commenter recommended that ASTP/ONC require QHINs to have a privacy official and a chief information security officer to monitor data privacy. Another commenter specifically expressed support for the requirement that any organization aspiring to become a QHIN must adhere to specific privacy and security guidelines, with additional stipulations for those providing Individual Access Services.

Response. We appreciate the commenter's support for TEFCA's existing privacy and security requirements, as well as the additional requirements for QHINs that provide Individual Access Services. Regarding

the comment recommending that each QHIN be required to have a privacy official and a chief information security officer to monitor data privacy, we note that we proposed and have finalized § 172.201(c)(8), which requires QHINs to maintain privacy and security policies that permit the entity to support TEFCA Exchange. The *QHIN Security Requirements for the Protection of TEFCA Information SOP*⁸ provides additional information on how that requirement can be met, including by QHINs having a chief information security officer (CISO). CISOs are responsible for the overall security posture of a QHIN with respect to their participation in TEFCA. This includes technical, administrative, and physical security safeguards and documentation thereof for a QHIN.

Comments. A number of commenters supported ASTP/ONC's approach of proposing to codify TEFCA requirements but expressed concern that it could be adopting TEFCA requirements into a regulatory framework too quickly and requested that ASTP/ONC provide information regarding our intentions to adopt other TEFCA requirements in the future. These commenters recommended that ASTP/ONC take a cautionary approach and potentially delay the adoption of further TEFCA requirements, citing that TEFCA is intended to be fluid and evolve more quickly than regulations. One commenter also urged ASTP/ONC take care with future adoptions of TEFCA requirements that we do not undermine the independence of the Recognized Coordinating Entity[®] (RCE[®]).

Several commenters were concerned that codifying TEFCA hampers the ability of TEFCA to change and adapt as needed, and a few of these commenters suggested that the codification of TEFCA requirements is unnecessary because TEFCA infrastructure is supported by its contractual nature. One commenter specifically recommended that ASTP/ONC incorporate TEFCA and relevant SOPs by reference rather than adopt sections of TEFCA as regulations out of concern that adopting sections of TEFCA as regulations would undermine the sections of TEFCA that are not adopted as a whole and would require future rulemaking actions to modify the sections of TEFCA that have been codified as regulations.

⁸ *QHIN Security Requirements for the Protection of TEFCA Information SOP*, <https://rce.sequoiaproject.org/wp-content/uploads/2024/08/QHIN-Security-for-the-Protection-of-TI-21.pdf>.

Response. We appreciate commenters' support of our proposals and also understand the concerns about the adoption of TEFCA requirements in regulation and the need for TEFCA to evolve as the interoperability landscape changes. The provisions we have finalized in 45 CFR part 172 mainly address QHIN appeals (subpart F) and the underlying requirements regarding which decisions may ultimately be appealed (subparts B through E). We believe establishing QHIN appeal rights in regulation will enhance trust in the TEFCA framework, as QHINs—that have invested significant time and resources into becoming a QHIN—will know that processes exist to appeal decisions that could have a significant impact of their businesses and the exchange of information for their Participants and Subparticipants. That said, we do not believe it would benefit TEFCA to codify all TEFCA requirements in regulation due to the need, as commenters noted, for TEFCA to move quickly and evolve with the ever-changing interoperability landscape. We appreciate commenters' suggestions regarding the future adoption of other TEFCA requirements in regulation and will consider them in the future.

Subpart G in 45 CFR part 172, which addresses QHIN attestation for the adoption of the Trusted Exchange Framework and the Common Agreement, has been adopted in accordance with statutory requirements. Specifically, section 4003(b) of the Cures Act added section 3001(c)(9), "Support for Interoperable Networks Exchange," to the PHSA. Section 3001(c)(9)(D)(ii) requires HHS to establish, through notice and comment rulemaking, a process for HINs that voluntarily elect to adopt TEFCA to attest to such adoption of the trusted exchange framework and common agreement. Section 3001(c)(9)(D)(i) requires the National Coordinator to publish on ONC's website a list of the HINs that have adopted the Common Agreement and are capable of trusted exchange pursuant to the Common Agreement.

For these reasons, we decline to adopt TEFCA solely through incorporation by reference instead of through a regulatory framework.

We also received numerous comments that were out of scope or that recommended that ASTP/ONC adopt new requirements that we did not propose and are not addressed in this rulemaking.

Comments. A number of comments addressed concerns about the role and authority of QHINs in relation to TEFCA Participants. Some commenters urged

ASTP/ONC to take a more direct role in monitoring and enforcing compliance and bolstering Participant confidence as TEFCA participation expands and monitoring by QHINs potentially becomes more difficult. Several commenters were concerned that there was no investigative body for independent oversight within TEFCA and suggested ASTP/ONC should monitor for the possibility of QHINs exercising outsized influence. A few commenters recommended that ASTP/ONC create an oversight board, or a body associated with the Office of the Inspector General (OIG), to provide independent review within TEFCA. These commenters also suggested that ASTP/ONC should include a mechanism for patient-identified issues.

Some commenters suggested that ASTP/ONC require that a QHIN create a continuity plan that includes support for the migration of Participants and Subparticipants if a QHIN is terminated or sanctioned. Additionally, one commenter requested information on how the TEFCA requirements will impact existing SOPs and whether the RCE will continue to have the authority to modify requirements for QHINs through the SOPs.

Response. We thank commenters for their feedback. We appreciate commenters' concerns regarding the role of QHINs in TEFCA governance but have decided not to make any related changes in this final rule. We believe QHINs are best positioned to have primary oversight responsibility over their customers (*i.e.*, Participants) and should have autonomy to make decisions about their networks so long as such decisions do not conflict with the requirements for TEFCA Exchange. We note that there is strong representative and participatory network governance built into the TEFCA infrastructure, including the requirement that QHINs must maintain a representative and participatory group or groups with the authority to approve processes for governing the Designated Network (§ 172.201(c)(7)). Regarding the comments related to including additional oversight within the TEFCA framework, including the suggestion of including HHS OIG in TEFCA governance and oversight, we believe that doing so is not necessary and could limit the flexibility of TEFCA's public-private model of exchange and governance. We believe the oversight provided by ASTP/ONC, including as established in provisions we are finalizing in 45 CFR part 172, meets the needs of the TEFCA community and provides strong support for TEFCA. ASTP/ONC will continue to monitor

TEFCA, and we will consider additional measures should circumstances arise that show that QHINs require additional oversight.

We appreciate the suggestion regarding creation of a mechanism for patient-identified issues and note that there are already mechanisms in place for reporting of patient-identified issues. Patients can report issues to ASTP/ONC through the TEFCA tab in the Health IT Feedback and Inquiry Portal available at <https://inquiry.healthit.gov/support/plugins/servlet/desk/portal/2>. Patients may also report issues to the RCE at <https://rce.sequoiaproject.org/contact/>. We encourage patients to report any issues they are experiencing to ASTP/ONC, the RCE, or both so that we can continue to improve TEFCA Exchange.

We also appreciate the suggestion that we require QHINs to create a continuity plan that includes support for the migration of Participants and Subparticipants if a QHIN is terminated or sanctioned. We did not propose to require a continuity plan in the HTI-2 Proposed Rule and believe it would be appropriate for the public to have an opportunity to submit comments before we could adopt this type of requirement. Therefore, we have decided not to finalize a requirement regarding creation of a continuity plan in this final rule. We may consider including such a requirement in a future rulemaking. In the meantime, we encourage QHINs and their Participants to discuss the details regarding continuity of service and consider addressing such details in the respective Framework Agreement between the two parties.

Regarding the comment concerning how the TEFCA requirements will impact existing SOPs, we note that the SOPs can be updated to align with updated requirements. We expect that the RCE will continue to support the development of SOPs, as they have to this point.

Comments. Multiple commenters raised concerns about the adoption of the Exchange Purposes (XPs) SOP version 3.0 without a public comment period. These commenters highlighted in particular that the recent XPs SOP version 3.0 allows health care providers to charge for data exchanges and requested that ASTP/ONC not allow entities to charge fees for TEFCA-based data exchanges.

Response. We thank commenters for raising this concern to our attention. While we understand the importance of this issue, it falls outside the scope of this final rule. The provisions regarding fees and the XP SOP version 3.0 are not addressed within this final rule. We

encourage further engagement on the topic of fees through public TEFCA meetings, webinars, and other feedback opportunities.

Comments. Several commenters advocated for the inclusion of State, Tribal, Local, and Territorial (STLT) public health agencies in the governance of TEFCA and QHINs to identify priority use cases. A few of these commenters also noted that the exchange of Prescription Drug Monitoring Program (PDMP) information through TEFCA is incompatible with PDMPs' data confidentiality and privacy requirements and suggested that PDMPs be excluded from TEFCA requirements.

A few commenters additionally noted that there is no Common Agreement for advisory boards and suggested that ASTP/ONC recognize advisory boards, including or referencing groups such as patients, providers, payors, and public health. One commenter recommended that TEFCA advisory groups include expanded roles for health plan representatives.

Response. We thank commenters for their input. The involvement of state and local public health agencies, as well as advisory boards, in TEFCA is an important consideration, and we will consider the related suggestions as we implement and refine the TEFCA governance process. We encourage interested communities to continue engaging with us as these aspects of the TEFCA framework are refined. We welcome all feedback from interested parties, which can be submitted via the ASTP/ONC website at <https://inquiry.healthit.gov/support/plugins/servlet/desk/portal/2/create/61>, for consideration and potential inclusion within the TEFCA framework.

We do not understand the comment that there is no Common Agreement for advisory boards. We appreciate the suggestion for enhancing TEFCA's governance. We are currently considering ways to ensure that different groups, such as patients, providers, payors, and public health, are represented within TEFCA's governance, which could include the development of advisory boards or councils. However, we did not make a proposal in this rulemaking regarding advisory boards, and it would be appropriate for the public to have an opportunity to submit comments before we could adopt these types of changes. We may consider addressing this issue in a future rulemaking.

We appreciate the comment that the exchange of PDMP information through TEFCA is incompatible with PDMPs' data confidentiality and privacy

requirements and the suggestion that PDMPs be excluded from TEFCA requirements. We have decided not to make any related changes in this final rule because we did not make any proposals about PDMPs, and it would be appropriate for the public to have an opportunity to submit comments before we could adopt these types of changes. We may consider addressing this issue in a future rulemaking.

Comments. Several commenters were concerned that the TEFCA requirements prioritize TEFCA participation over other mechanisms of interoperability. A few commenters were concerned that the TEFCA requirements allow participants to not respond to queries from entities that are not TEFCA participants when the data exchange is lawful thereby allowing data from certain providers to be siloed. These commenters suggested that ASTP/ONC clarify that the refusal by entities connected to TEFCA to lawfully exchange data with entities that are not licensed health care professionals is information blocking. Commenters also requested that ASTP/ONC publish a request for information (RFI) on the treatment of all federally defined health care providers under TEFCA. One commenter also advocated that TEFCA requirements should focus on treatment and individual access exchange.

Response. We thank commenters for their feedback. The concerns raised regarding TEFCA requirements and their interaction with other interoperability mechanisms are out of scope for this final rule, since the TEFCA requirements do not apply to other mechanisms of interoperability. However, we would like to direct commenters to the TEFCA Manner Exception in 45 CFR 171.403, finalized in the HTI-1 Final Rule (89 FR 1387 through 1388). This exception applies when, among other necessary conditions, both the actor and requestor participate in TEFCA as QHINs, Participants, or Subparticipants (§ 171.403(a); 89 FR 1388). When the necessary conditions under § 171.403 are met, the actor's practice of fulfilling requests for access, exchange, or use of EHI exclusively via TEFCA will not be considered information blocking. We recommend reviewing this exception for further clarity on TEFCA participation and its interplay with information blocking.

Comments. One commenter expressed concern about the perceived lack of intellectual property protections in TEFCA and recommended that ASTP/ONC increase intellectual property protections within TEFCA.

Response. We thank the commenter for their feedback. The issue of intellectual property protections within TEFCA is outside the scope of this final rule, as we did not propose, and this final rule does not address, such provisions. We welcome all feedback from interested parties, which can be submitted via the ASTP/ONC website at <https://inquiry.healthit.gov/support/plugins/servlet/desk/portal/2/create/61>, for consideration and potential inclusion within the TEFCA framework.

Comments. A number of commenters who expressed support for TEFCA were concerned that compliance with TEFCA requirements could be difficult for non-medical specialist entities and entities with limited financial or infrastructure resources. Some of these commenters recommended that ASTP/ONC and the RCE consider providing educational initiatives, incentives, and technical and financial support to providers with limited resources that transition to joining TEFCA. These commenters also expressed concern that participation fees for TEFCA participants should be fair and scaled to the size of and potential use by participants and non-duplicative.

Some commenters requested that ASTP/ONC provide TEFCA Participants more time to prepare when new requirements are adopted as part of updates to the Common Agreement or when SOPs are updated. One commenter also recommended that ASTP/ONC and the RCE establish steps and goals to guide how entities will transition to TEFCA participation. One commenter recommended that ASTP/ONC adopt more specific definitions of Participants and Subparticipants for TEFCA to reduce ambiguity. One commenter particularly requested that ASTP/ONC delay requiring emergency medical services agencies to comply with TEFCA requirements that involve significant technological hurdles or require significant financial and infrastructure resources, and that ASTP/ONC convene a working group to determine how emergency medical services agencies can comply with TEFCA requirements in the future.

Response. We thank commenters for their feedback. We appreciate commenters' concerns about potential financial and technological limitations for some entities regarding TEFCA. We are exploring ways to assist such entities and ensure that the benefits of TEFCA are not disproportionately allocated to larger, for-profit entities. In order to inform such efforts, we are focused on collecting and analyzing exchange metrics as TEFCA matures to

better understand where exchange gaps persist.

We understand that cost is a concern for many organizations, particularly small and rural providers. We continue to engage with providers to understand these concerns and providers' needs better and to develop strategies to assist small and rural providers with TEFCA implementation. We are also developing, along with the RCE, various resources to clarify various questions about TEFCA participation and implementation. We appreciate the request that ASTP/ONC provide TEFCA Participants more time to prepare when new requirements are adopted as part of updates to the Common Agreement or when SOPs are updated and will consider the request as we work to expand TEFCA Exchange and update TEFCA requirements over time.

We also appreciate the recommendation that ASTP/ONC and the RCE establish steps and goals to guide how entities will transition to TEFCA participation and agree that ASTP/ONC and the RCE should provide resources and information to support the transition to TEFCA Exchange. As such, ASTP/ONC and the RCE have recently released a plethora of resources to assist entities considering transitioning to TEFCA Exchange, which are available on the ASTP/ONC⁹ and RCE¹⁰ websites. In addition, we continue to support the transition to TEFCA Exchange through regular webinars and information sessions for the public.

We appreciate the recommendation that ASTP/ONC adopt more specific definitions of Participants and Subparticipants for TEFCA to reduce ambiguity; however, we have not changed the definitions in this final rule because we do not believe the definitions are ambiguous.

Last, we are aware that emergency medical service providers and agencies may face obstacles in joining TEFCA, and we are considering options for addressing such potential obstacles. We plan to conduct additional outreach to the emergency medical service community to better understand their concerns and the issues this community faces and will consider other ways to assess the issue(s) moving forward.

Comments. One commenter suggested that ASTP/ONC should mandate that health information exchanges respond to every QHIN request with sharing data

⁹ <https://www.healthit.gov/topic/interoperability/policy/trusted-exchange-framework-and-common-agreement-tefca>.

¹⁰ <https://rce.sequoiaproject.org/tefca/>.

and participate in TEFCA with at least one QHIN.

Response. We thank the commenter for their feedback. This comment is out of scope for this rulemaking, and therefore, we decline to adopt this suggested change. We also note that we generally believe that participation in TEFCA should remain voluntary and decline to mandate TEFCA participation.

Comments. A number of commenters expressed concern about the interactions of TEFCA requirements with HIPAA requirements, and with other ASTP/ONC and CMS regulations creating an overly complex regulatory framework for interoperability. Commenters urged ASTP/ONC to ensure that TEFCA requirements are compatible with other interoperability and information blocking rulemaking. Another commenter also urged ASTP/ONC to collaborate with CMS to provide endpoint directories and use RESTful FHIR interoperability protocols.

These commenters noted the importance of keeping TEFCA participation voluntary. A few commenters expressed concern that the TEFCA requirements proposed together with other ASTP/ONC and CMS regulations will pressure entities to solely engage with entities connected to TEFCA.

Response. We thank commenters for their feedback and appreciate commenters' concerns about how TEFCA requirements will interact with other regulatory requirements. ASTP/ONC has worked, and will continue to work, with our Federal partners, including CMS, in developing and implementing TEFCA. We are working to align TEFCA requirements with other ASTP/ONC, CMS, and OCR¹¹ requirements when possible, and while we have not required any entity to participate in TEFCA, we are trying to ensure that TEFCA complements other Federal requirements to reduce complexity and encourage more seamless nationwide exchange. For example, as explained in more detail above, entities are able to comply with both HIPAA (HIPAA Privacy, Security, and Breach Notification Rules) and TEFCA. While ASTP/ONC may develop definitions and requirements within TEFCA that are narrower or broader than corresponding definitions and requirements within the HIPAA Rules, ASTP/ONC does try to align TEFCA requirements with the requirements in the HIPAA Rules when possible.

¹¹ The HHS Office for Civil Rights has authority for implementing and enforcing HIPAA.

Comment. One commenter recommended that we refer to, prioritize as a goal, recognize, or focus on high-quality data within data sharing, since one of TEFCA's goals is to create an atmosphere of trust.

Response. We thank the commenter for their feedback. We agree with the importance of data quality within health information exchange. We believe our proposals support data quality by advancing the standardization of health information exchange and helping to improve the completeness and comprehensiveness of data being exchanged. However, additional operational aspects and practical implementations of data quality measures are beyond the scope of this final rule.

Comment. Multiple commenters sought clarification on laboratory involvement with respect to TEFCA proposals. One commenter requested clarification about the participation of laboratories in QHINs and the use of TEFCA as a means for health information exchange in the current environment, where FHIR functionality is not available. Another commenter sought clarification on the value proposition for rerouting laboratory results through TEFCA, given that the existing HL7 v2 messaging framework effectively supports public health reporting. If there is value in rerouting, they questioned what requirements must QHINs meet to facilitate HL7 v2 messaging. The commenter expressed concerns about how the process would introduce additional complexity by requiring QHINs to convert HL7 v2 messages into XCDR, which the receiving QHIN would then need to extract and forward to the connected public health agency. Given these concerns, the commenter suggested that ASTP/ONC and the RCE consider selectively endorsing existing technologies, such as HL7 v2, to operate under the Common Agreement, akin to how eCR reporting is implemented under Carequality.

Response. We appreciate this feedback, but these comments are out of scope for this rule. We did not propose and are not finalizing requirements for laboratories to participate in TEFCA or technical requirements to facilitate HL7 v2 messaging within TEFCA.

Comment. One commenter recommended that TEFCA governance documents be updated to define responsibilities for Participants and QHINs related to disclosures and third-party vetting, as well as how requests are intended to operate within the HIPAA framework and who would monitor/enforce such requirements.

Response. We thank the commenter for the feedback. The HTI-2 Proposed Rule outlines the approach among ONC, the RCE, and QHINs to monitor and enforce proposed requirements under TEFCA.

Comment. One commenter noted that requiring EHRs to demonstrate a connection with an established QHIN or with health information exchanges for health IT to achieve certification will help ensure efficient data sharing and support interoperability goals.

Response. We appreciate the feedback on our proposals. However, this comment is out of scope for this final rule, as we have neither proposed nor are we finalizing a requirement for Health IT Modules to demonstrate a connection with an established QHIN or with a health information exchange for the Health IT Module to obtain certification to any criterion or criteria under the ONC Health IT Certification Program (Program). Nonetheless, we highlight that, as noted in the HTI-2 Proposed Rule (89 FR 63510 and 63511), we intend to accomplish the overall goal of full network-to-network exchange of health information by establishing a floor for interoperability under TEFCA across the country. We believe the suggested EHR requirement might conflict with our intent to encourage innovation, facilitate incremental progress, and promote flexibility.

Comment. One commenter shared multiple suggestions for encouraging TEFCA participation. The commenter noted that TEFCA participation may be encouraged by increasing the utility of TEFCA participation to an entity's patients. They noted that incorporating a mechanism for patients to correct or add to their interoperable records would be beneficial. Rather than limiting TEFCA Individual Access Services (IAS) requests to access and deletion options, they also suggested providing an option for patients to amend or augment their records through a patient portal so that these changes could be automatically incorporated into their records exchanged through TEFCA.

Response. We thank the commenter for their suggestions. We agree with the value of patient engagement. However, the suggestions are beyond the scope of this final rule, as we did not propose and are not finalizing related policies specifically designed to encourage TEFCA participation.

A. Subpart A—General Provisions

For the purposes of subpart A, we proposed (89 FR 63644) in § 172.100 of the HTI-2 Proposed Rule the basis, purpose, and scope for the proposed TEFCA provisions in 45 CFR part 172.

We proposed in § 172.100(a) that the basis for these provisions would be to implement section 3001(c)(9) of the PHSA (42 U.S.C. 300jj–11(c)(9)). We proposed in § 172.100(b) the dual purposes of proposed part 172: (1) to ensure full network-to-network exchange of health information; and (2) to establish a voluntary process for QHINs to attest to adoption of the Trusted Exchange Framework and Common Agreement. We explained that § 172.100(b)(1) supports the statutory basis because the organizational and operational policies covered by part 172 would enable the exchange of health information among health information networks using the common set of rules found in these regulations. We also noted that § 172.100(b)(2) supports the statutory basis because it implements section 3001(c)(9)(D) of the PHSA. We proposed in § 172.100(c) the scope for part 172, which would include: (1) minimum qualifications needed to be Designated as a QHIN capable of trusted exchange under TEFCA; (2) procedures governing QHIN Onboarding and Designation, suspension, termination, and further administrative review; (3) attestation submission requirements for a QHIN to attest to its adoption of TEFCA; and (4) ONC attestation acceptance and removal processes for publication of the list of attesting QHINs in the QHIN Directory.

In proposed § 172.101, we specified the applicability of part 172 by proposing that part 172 would apply only to Applicant QHINs, QHINs, and terminated QHINs. In the HTI–2 Proposed Rule, we noted that our proposed QHIN definition in § 172.102 captures suspended QHINs (since a suspended QHIN is still a QHIN) and so we did not address them separately in proposed § 172.101. In § 172.102, we proposed definitions for certain terms in part 172. In the HTI–2 Proposed Rule, we stated that we intended the definitions provided in the Common Agreement to be consistent with these proposed definitions. We also stated that differences in phrasing would generally be attributable to differences in context, though in the case of any true conflict, we stated that we intend the regulatory definitions to control.

Additionally, ASTP/ONC has hired a contractor to help administer and implement TEFCA Exchange. This contractor, chosen through a competitive solicitation, is known as the RCE. While the RCE is currently one entity, in the future, we noted in the HTI–2 Proposed Rule, ONC may choose to assign some or all of its responsibilities to a different entity or multiple entities. We noted that

assigning responsibilities to a different or multiple entities in the future could, for example, allow for more efficient use of resources or best leverage expertise. In § 172.103, “Responsibilities ONC may delegate to the RCE,” we proposed that ONC may assign certain responsibilities to such an entity or entities for these purposes. We note that we changed the title of this section from the proposed title—“Responsibilities ONC may delegate to the RCE”—to “Responsibilities ASTP/ONC may delegate to the RCE” because of the recent change to the name of our office and to conform with similar changes made throughout this final rule. In addition to changes to the proposed text described below, we have also finalized references to “ONC” in subpart A of the proposed rule to instead refer to “ASTP/ONC.” For further discussion of the use of “ASTP/ONC,” please see the Executive Summary of this final rule.

We proposed in § 172.103(a)(1) through (4) that ONC may assign any of its responsibilities in subparts C (“QHIN Onboarding and Designation Process”) and D (“Suspension”) and §§ 172.501 (“QHIN self-termination”) and 172.503 (“Termination by mutual agreement”). In § 172.103(b), we proposed that any authority exercised by the RCE under this section is subject to review by ONC under subpart F (“Review of RCE Decisions”).

Comments. One commenter argued that any TEFCA expansion to new purposes should be driven by Congressional mandate and conducted transparently with opportunities for public input. The commenter emphasized that an open process ensures that stakeholders’ diverse perspectives are considered fully and that the TEFCA framework evolves to serve all stakeholders’ collective interests. The commenter cautioned against mission creep and recommended establishing clear guardrails for any future expansion of TEFCA’s use cases, including rigorous evaluation, comprehensive needs assessments and industry engagement. Other commenters advised ASTP/ONC to avoid sub-regulatory guidance and instead follow standard rulemaking procedures, including 60-day public comment periods for proposed changes or additions to TEFCA SOPs. One commenter expressed that all substantive issues and core concepts, such as, but not limited to, foundational definitions of the different exchange purposes, should be codified in regulation following the notice and comment rulemaking process, rather than being addressed in TEFCA documents such as SOPs, which do not

undergo the same rigorous review process as do regulations. Another commenter further argued that any future regulatory changes should relate back to the text of the Cures Act.

Response. We thank the commenter for the feedback. We have developed and implemented TEFCA consistent with the 21st Century Cures Act (section 3001(c)(9) of the PHSA, as added by the 21st Century Cures Act (Pub. L. 114–255, Dec. 13, 2016)). That statute sets out at least one broad statutory purpose: ensuring full network-to-network exchange of health information. TEFCA as currently designed furthers that purpose. We do agree that TEFCA should generally be related to that goal or other ones suggested in the statute—for instance, that the exchange should be “trusted”—but we believe that statute envisions that TEFCA will be flexible within that broad goal, consistent with the need for flexibility in rapidly developing spaces like health information technology and health information exchange. For example, section 3001(c)(9)(B) identifies a list of potential topics the Common Agreement “may include,” but does not require the Common Agreement to address those topics or suggest that those topics are the only ones the Common Agreement can address.

We appreciate the commenters’ suggestion to follow standard rulemaking procedures. As noted previously in this rulemaking, we believe the inclusion of TEFCA provisions in this rulemaking will strengthen the trust of interested parties in TEFCA and support its success at scale. We likewise believe that TEFCA must remain flexible and agile, in order to enable nationwide exchange at scale.

Comments. Commenters supported the general definitions related to TEFCA proposed in regulatory text, suggesting that those terms may arise in other regulatory programs and can be later cross-referenced.

Response. We thank commenters for their support and have finalized the definitions related to TEFCA we proposed in § 172.102 with some modifications based on comments we received and as explained hereafter.

Comments. One commenter expressed concern about codifying definitions from the Common Agreement in regulation and specifically identified inconsistencies between the Common Agreement and the proposed regulatory definitions. The commenter noted that some definitions in the HTI–2 Proposed Rule do not fully align with the Common Agreement (e.g., Threat Condition and Recognized Coordinating Entity) and some of the definitions (e.g.,

XP Code) are included in the regulation but not used in the proposed regulatory text. The commenter also noted that certain definitions in the HTI–2 Proposed Rule refer to applicable SOPs (e.g., the definition for Participant/Subparticipant Terms of Participation), while others do not—including when the Common Agreement does refer to the SOP. For example, Exchange Purposes in the proposed regulatory text omits reference to SOPs, though the Common Agreement includes such reference. The commenter states that leaving out references to SOPs could change the meaning of the Common Agreement and render the SOPs inapplicable. The commenter also stated that the term “Responding Node” is used in the definition of Required Information but not defined in the regulation. Further the commenter noted that some definitions refer to “ONC (or an RCE)” (e.g., threat condition), other times there is no mention of an RCE, even though the Common Agreement includes such a reference (e.g., Qualified Health Information). The commenter suggested that differing definitions between the Common Agreement and the regulatory text will lead to confusion and misinterpretation. The commenter also expressed concern that, if such inconsistencies are finalized in the regulatory text, they could necessitate subsequent amendments to the Common Agreement that are inconsistent with the public input used to establish the definitions in the Common Agreement.

Response. We appreciate the comments that opined on the potential for confusion and misinterpretation related to certain proposed definitions. We also appreciate the input related to clear and consistent alignment between the regulatory definitions and the Common Agreement. As noted in the proposed rule, we intend for the definitions in this final rule to be consistent with the definitions in the Common Agreement and the SOPs. We have adopted this approach to maintain consistency between the Common Agreement and the regulatory text (89 FR 63642). However, in some cases we used different verbiage in the HTI–2 Proposed Rule to accommodate discussion of different contexts such as future or past circumstances. In other cases, differences between definitions in the regulation text and the Common Agreement may be the result of inconsistencies in the level of specification between the Common Agreement and definitions in the HTI–2 Proposed Rule. However, we agree with the commenter that these

differences in the definitions between the Common Agreement or SOPs and this rulemaking may lead to confusion and misinterpretation or the need for amendments to the Common Agreement. Therefore, in this final rule we have addressed inconsistencies by revising the final regulatory text wherever feasible to directly align with definitions in the Common Agreement and SOPs. Below we explain how, in response to public comment, we have further aligned definitions in this final rule to the definitions in the Common Agreement and SOPs.

Regarding the comment that leaving out references to SOPs could change the meaning of the Common Agreement and render the SOPs inapplicable, we reiterate our statement in the HTI–2 Proposed Rule that in the case of any true conflict, we intend for the regulatory definitions to control (89 FR 63644). We also note that, as stated, our definitions in the HTI–2 Proposed Rule included references to SOPs (see for example, § 172.102, definitions of “Governance Services” and “Participant/Subparticipant Terms of Participation”). We have further updated definitions in this final rule to incorporate reference to SOPs where necessary to align with the Common Agreement as described below.

Regarding the definition of “Threat Condition,” we agree with the comment that the definition in this final rule should be identical to the definition in the Common Agreement. Given our stated intent for the TEFCA-specific definitions in these regulations to align with the definitions in the Common Agreement and SOPs (89 FR 63642), and public comments that clearly stated a preference for aligning the definitions in this final rule to the definitions in the Common Agreement and SOPs, we have finalized this definition to align with the definition in the Common Agreement. As such, we have modified the proposed definition and finalized the definition of “Threat Condition” as set out in the regulatory text at the end of this document.

Regarding the definition of “Recognized Coordinating Entity,” we agree with the commenter that the definition in this final rule should be identical to the definition in the Common Agreement. Given our intent for the TEFCA-specific definitions in these regulations to align with the definitions in the Common Agreement and SOPs (89 FR 63642), and public comments that clearly stated a preference for aligning the definitions in this final rule to the definitions in the Common Agreement and SOPs, we have finalized this definition to align with

the definition in the Common Agreement. As such, we have modified the proposed definition and finalized the definition of “Recognized Coordinating Entity® (RCE®)” as set out in the regulatory text at the end of this document.

Regarding the comment that “XP Code” is included in the regulation, but not used in the regulatory text, we are not clear on the specific issue the commenter is raising. We note that “Exchange Purpose Code or XP Code” was defined in the regulatory text for the Proposed Rule (89 FR 63806) as a code that identifies the Exchange Purpose being used for TEFCA Exchange. We use only “Exchange Purpose Code” in the discussion in this final rule, but we recognize interested parties may commonly use “XP Code”. Therefore, as noted in the HTI–2 Proposed Rule, we interpret the “or” between “Exchange Purpose Code” and “XP Code” in the definition to indicate that the two terms are interchangeable. Accordingly, we have decided that use of either term is appropriate throughout the regulation (89 FR 63806) and have finalized the definition of “Exchange Purpose Code or XP Code” as proposed.

Regarding the comment that certain definitions refer to applicable SOPs (e.g., the definition for Participant/Subparticipant Terms of Participation) while others do not, we note that this inconsistency was not intentional. Given our intent for the TEFCA-specific definitions in these regulations to align with the definitions in the Common Agreement and SOPs (89 FR 63642), and the public comments that clearly stated a preference for aligning the definitions in this final rule to the definitions in the Common Agreement and SOPs, we have finalized the definition of “Exchange Purpose(s) or XP(s)” to align with the definition in the Common Agreement. As such, we have modified the definition of “Exchange Purpose(s) or XP(s)” to align with the Common Agreement definition, which includes mention of SOP(s).

Regarding the comment that the term “Responding Node” was included in the proposed definition of “Required Information” but not proposed to be defined in § 172.102, we note that this inconsistency was not intentional. In order to address commenters’ reasonable expectation that we would define terms necessary to understand other terms we proposed to define where such definitions are consistent with those in the Common Agreement per our stated intent of alignment (89 FR 63642), we have finalized the definition of “Responding Node” in § 172.102.

Regarding the comment that some definitions refer to “ONC (or an RCE)” (e.g., Threat Condition), and other times there is no mention of an RCE even though the Common Agreement includes such a reference (e.g., Qualified Health Information Network), we intentionally referenced the RCE in certain circumstances and not others in the definitions we proposed in § 172.102. Our goal with the proposed definitions was to afford ourselves flexibility in the event that one day there is no longer an RCE. We emphasize, however, that the current RCE, the Sequoia Project, is now in the second year of a five-year contract with ASTP/ONC.

Comments. One commenter identified what they believed to be two typos in proposed 45 CFR 172.102. The commenter noted that a few definitions, notably the proposed definitions for the HIPAA Privacy Rule and the HIPAA Security Rule, reference the regulations at 45 CFR part 160 and subparts A and E of 45 CFR part 164, as well as to 45 CFR part 160 and subparts A and C of 45 CFR part 164. The commenter asked for clarification on what subparts were meant to be referenced.

Response. The terms HIPAA Privacy Rule and the HIPAA Security Rule are both defined in § 172.102 by referencing their codifications in the CFR. Both rules have slightly different citations. The citation for the HIPAA Privacy Rule is 45 CFR part 160 and subparts A and E of 45 CFR part 164. The HIPAA Security Rule is located at 45 CFR part 160 and subparts A and C of 45 CFR part 164. Because those are the correct citations for the HIPAA Privacy and Security Rules, we have finalized the HIPAA Privacy Rule and the HIPAA Security Rule definitions in § 172.102 as proposed.

Comments. One commenter recommended a revision to the definition of “Framework Agreements” to include only those documents for which a draft was made available to the public and the public has some opportunity to provide input on the draft before a final version is effective. The commenter requested that we require such a process for all Framework Agreements. The commenter noted that the RCE should make SOP drafts available for public feedback or any other transparent process around their establishment and review. The commenter noted further that under the proposed rule, ASTP/ONC can review an RCE decision, but that there is no process for a QHIN or a participant to appeal or require formal review of an SOP. The commenter cited an SOP issued last summer that the

commenter believed significantly narrowed the scope of required response for treatment purposes, which it said cut off access to the networks for hundreds of thousands of patients. The commenter believed that the proposed rule would allow this result to happen again.

Response. We appreciate the comments. However, the definition of “Framework Agreement(s)” we proposed tracks the definition in the Common Agreement, and we believe that deviating from the definition in the Common Agreement for such a foundational concept might be confusing or suggest differences between the meaning of Framework Agreements in the Common Agreement and the regulation that we do not intend. Nor do we agree with the commenters who suggest that we should require more process for SOPs than is laid out in the Common Agreement (at section 5.3 of version 2.0). That process—to which QHINs, Participants, and Subparticipants agree by signing the Framework Agreements—balances the need for input by the public with the need to respond quickly in a fast-developing space. We understand that, as the commenter points out, sometimes individual entities will disagree with particular SOPs, but that is part of the balance struck in the Common Agreement’s procedures, and we decline the invitation to impose a higher regulatory standard on SOPs than set forth in the Common Agreement. We believe that transparency is essential to TEFCA’s success because it is in the best interest of individuals whose health information is exchanged via TEFCA and is central to the efforts of HHS to enhance and protect the health and well-being of all Americans. Since we began developing TEFCA following the passage of the Cures Act in 2016, ASTP/ONC and the RCE have held dozens of webinars, listening sessions, and other feedback opportunities with the public and interested communities to promote transparency and provide the opportunity for public comment. We will continue to offer robust feedback opportunities related to TEFCA in the future. In addition, ASTP/ONC’s processes for gathering feedback on TEFCA documents, processes, and procedures have been transparent and consistent—and the feedback we have received has informed the development of and changes to the Common Agreement and Terms of Participation, both of which are included in the finalized definition of “Framework Agreement(s),” as well as SOPs, which are not.

We do not believe that the appeals process we have finalized in 45 CFR part 172 should be expanded to include appeals of SOPs. Section 5 of the Common Agreement¹² discusses TEFCA’s change management process for updating the Common Agreement and SOPs. This process was developed with significant input from prospective QHINs, interested communities, Federal partners, and the public. It provides opportunities for input from multiple different kinds of entities that participate in TEFCA. ASTP/ONC must approve all changes, additions, or deletions. In addition, section 15 of the Common Agreement¹³ addresses dispute resolution, and section 15.6 addresses the escalation of certain disputes to ASTP/ONC.¹⁴ We note these sections to highlight that the governance in place for TEFCA ensures that changes to TEFCA’s policies and procedures are informed by feedback and driven by a strong, consistent process with ASTP/ONC oversight embedded throughout the processes.

Besides the revisions to the Definitions section discussed above, subpart A was finalized as proposed with a few modifications. Specifically, the name “ONC” used in the title of proposed § 171.103, as well as the proposed text of § 171.103(a), has been finalized as “ASTP/ONC” to reflect the recent change to our office’s name and ensure consistency in the use of ASTP/ONC throughout this final rule. In addition, we have added language requiring an RCE to seek and receive ASTP/ONC’s prior authorization before making certain decisions (e.g., interim or final designation decisions (§ 172.303(b)), setting onboarding requirements and determining a QHIN has complied with those requirements (§ 172.304(b) and (c)), and deeming a QHIN application withdrawn for failure to respond to information requests during the designation process (§ 172.305(c)). We have added language to § 172.103(b) to clarify that ASTP/ONC cannot subdelegate the authority to grant prior authorization to an RCE. These revisions, taken together, help to ensure that an RCE remains subordinate to ASTP/ONC and provides only fact-gathering, ministerial, and administrative support to ASTP/ONC.

B. Subpart B—Qualifications for Designation

In the HTI–2 Proposed Rule (89 FR 63644), we discussed that in subpart B,

¹² Common Agreement for Nationwide Health Information Interoperability ([healthit.gov](https://www.healthit.gov)).

¹³ *Id.*

¹⁴ *Id.*

we proposed qualifications for Designation. In § 172.200, we proposed to tie QHIN status to meeting the requirements specified in § 172.201. We proposed that an Applicant QHIN (as we proposed to define it in § 172.102) would need to meet all requirements in § 172.201 to be *Designated*, and a QHIN would need to continue to meet all requirements in § 172.201 to *maintain its Designation*. We noted that the requirements we proposed in § 172.201 would be ongoing; a QHIN that does not meet those requirements at all times would be subject to suspension or termination, consistent with the regulations we proposed in subparts D and E of part 172. In the HTI–2 Proposed Rule, we stated that the continuing obligation to meet the requirements in § 172.201 would help to ensure the reliability of TEFCA Exchange and that QHINs could not maintain their status based on technology and standards that have become obsolete. Because the obligations would be ongoing, throughout this section we referred to Applicant QHINs as well as Designated QHINs as “QHINs” unless there was a need to differentiate.

As we explained in the HTI–2 Proposed Rule (89 FR 63645), the Designation qualifications proposed in § 172.201 described certain requirements for Designation. For an entity to become a QHIN, that entity must sign the Common Agreement, thus memorializing its agreement to the comprehensive Designation requirements—as well as other requirements—for trusted exchange under TEFCA. The comprehensive Designation requirements in the Common Agreement correspond to the proposed requirements included in this subpart.

In § 172.201, we proposed Designation requirements in three categories: (a) ownership; (b) exchange requirements; and (c) Designated Network Services.

In § 172.201(a), we proposed the ownership requirements. In § 172.201(a)(1), we proposed that a QHIN must be a U.S. Entity, as we proposed to define “U.S. Entity/Entities” in § 172.102. Under that proposed definition, a U.S. Entity must be a corporation, limited liability company, partnership, or other legal entity organized under the laws of a state or commonwealth of the United States or the Federal law of the United States, be subject to the jurisdiction of the United States and the state or commonwealth under which it was formed, and have its principal place of business be in the United States under

Federal law. Additionally, we proposed that none of the entity’s directors, officers, or executives, and none of the owners with a five percent (5%) or greater interest in the entity, may be listed on the *Specially Designated Nationals and Blocked Persons List* published by the United States Department of the Treasury’s Office of Foreign Asset Control or on the Department of Health and Human Services, Office of Inspector General’s List of Excluded Individuals/Entities. We explained that this requirement would help to promote organizational and operational policies that enable the exchange of health information among networks by ensuring that those who actually control the health information exchanged under these provisions are subject to U.S. laws, and it would help to avoid giving access to that information to actors whom the government has previously identified as national security or fraud risks.

We requested comment on whether the above approach, including the specific five percent (5%) threshold, will effectively limit access of bad actors trying to join TEFCA as a QHIN, or whether commenters believe the threshold should be a different percentage.

In § 172.201(a)(2), we proposed that an Applicant QHIN must not be under Foreign Control, which is a term we proposed to define in § 172.102. If, in the course of reviewing a QHIN application, ONC believes or has reason to believe the Applicant QHIN may be under Foreign Control, ONC would refer the case to the HHS Office of National Security (ONS) for review. If information available to ONS supports a determination of Foreign Control, ONS will notify ONC. An application will be denied if ONS notifies ONC that the Applicant is under Foreign Control.

Given the scale of the responsibilities that a Designated QHIN would have with respect to supporting health information exchange and the importance that healthcare data has to the critical infrastructure of our nation’s health care system, we noted in the HTI–2 Proposed Rule that we believe that a QHIN should not be under Foreign Control. We stated we believe the requirements proposed in § 172.201(a)(1) and (2), in conjunction with the proposed definitions that those provisions reference, are necessary to ensure that all QHINs are subject to United States law and that compliance by QHINs is enforceable under United States law. Further, we stated these proposals are designed to strengthen the security of the network. We added in the HTI–2 Proposed Rule that we

believe that the above proposals would 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.

In the HTI–2 Proposed Rule (89 FR 63645), we noted that within the proposed definition of “U.S. Entity/Entities” in § 172.102, we proposed that for an entity seeking to become a QHIN to meet the definition, none of the entity’s directors, officers, or executives, and none of the owners with a five percent (5%) or greater interest in the entity, can be listed on the *Specially Designated Nationals and Blocked Persons List* published by the United States Department of the Treasury’s Office of Foreign Asset Control or on the Department of Health and Human Services, Office of Inspector General’s List of Excluded Individuals/Entities. We also noted that we believe the five percent (5%) threshold strikes the right balance between protecting the security of the network from high-risk or known bad actors and achieving practical administrability of TEFCA. We noted individuals with less than five percent (5%) ownership in an entity would likely have limited means of influencing the actions of an entity connected to TEFCA. In the HTI–2 Proposed Rule, we stated we believe that entities—particularly those with a large number of shareholders—would face undue hardship without this sort of exception for small shareholders. In the HTI–2 Proposed Rule, we noted this regulation only would provide the standard that ONC would apply when evaluating QHINs; it would not supersede any stricter requirements imposed by other applicable laws, including, for example national security laws. It remains the responsibility of QHINs (and any other entity) to comply with all applicable laws.

In § 172.201(b), we proposed exchange requirements for QHINs. In the HTI–2 Proposed Rule, we stated we believe these exchange requirements are necessary to build a data sharing infrastructure that is private and secure and that meets all the requirements of PHS section 3001(c)(9). We believe each of the exchange requirements below is important to the implementation and operationalization of TEFCA Exchange, as described in § 172.201, at scale. We proposed that an entity seeking to become a QHIN must, beginning at the time of application,

either directly or through the experience of its parent entity, meet certain exchange requirements, including: (1) be capable of exchanging information among more than two unaffiliated organizations; (2) be capable of exchanging all Required Information (as that term is defined in § 172.102); (3) be exchanging information for at least one of the Exchange Purposes (as that term is defined in § 172.102) authorized in the Common Agreement or an SOP(s); (4) be capable of receiving and responding to transactions from other QHINs for all Exchange Purposes; and (5) be capable of initiating transactions for the Exchange Purposes that such entity will permit its Participants and Subparticipants to use through TEFCA Exchange.

In the HTI–2 Proposed Rule we stated that, collectively, we believe these requirements are tailored to help ensure that a QHIN is capable of TEFCA Exchange, supports a trusted exchange framework, and maintains consistent practices of exchanging information at scale to support nationwide interoperability. The first requirement, proposed in § 172.201(b)(1), that the entity seeking to become a QHIN be capable of exchanging information among more than two unaffiliated organizations, is a requirement that would ensure a minimum technical ability exists and that exchange would be enabled beyond just the QHIN itself.

We discussed (89 FR 63646) that the second requirement, proposed in § 172.201(b)(2), is also a minimum condition, except it is directed at the minimum quantity of *data* a QHIN must be capable of exchanging. This proposed requirement would ensure that every QHIN can exchange Required Information (as that term is defined in proposed § 171.102) and provides certainty to Participants and Subparticipants who seek to join a QHIN that there is a minimum scope of data that they can reliably expect to be able to exchange via TEFCA Exchange Purposes.

The proposed requirements in § 172.201(b)(3) through (5) are intended to establish basic parameters and expectations for QHINs in order to qualify for Designation. We proposed, in § 172.201(b)(3), that a QHIN or Applicant QHIN must be exchanging information for at least one Exchange Purpose. If a QHIN is not exchanging information for at least one of the Exchange Purposes authorized under TEFCA (for examples, see the “Exchange Purpose” definition proposed in § 172.102) at the time of application, we noted in the HTI–2 Proposed Rule that it is not meeting a

minimum condition necessary for such exchange to occur and cannot be Designated. While exchange for an Exchange Purpose under TEFCA requires an Exchange Purpose Code, Applicant QHINs can demonstrate that they are meeting the requirement to exchange information for at least one of the Exchange Purposes by conducting exchange for an Exchange Purpose without use of an Exchange Purpose Code.

We proposed in § 172.201(b)(4) to require a QHIN to be capable of receiving and responding to transactions from other QHINs for all Exchange Purposes, to ensure that health information can be exchanged among health information networks under TEFCA. For this same reason, we proposed in § 172.201(b)(5) to require a QHIN to be capable of initiating transactions for the Exchange Purposes that such entity will permit its Participants and Subparticipants to use through TEFCA Exchange. We noted that ensuring that QHINs will respond to Participant or Subparticipant requests for information, and that the Participants or Subparticipants are able to receive the information from QHINs, enables health information exchange among the QHINs, Participants and Subparticipants.

We noted in the HTI–2 Proposed Rule that a QHIN’s ability to transact for all Exchange Purposes is a threshold requirement for an entity that seeks Designation and is essential for ensuring that the TEFCA framework facilitates exchange for each Exchange Purpose authorized in the Common Agreement or an SOP(s) for implementation. We also noted that, without this requirement, there would be no certainty that the TEFCA framework would advance exchange beyond the Treatment Exchange Purpose, which is the most prevalent purpose for health information exchange today and the purpose of use that most health care entities seeking Designation would be most familiar with. TEFCA’s network connectivity—including this requirement that QHINs have the ability to exchange for all Exchange Purposes—and scale would help, for example, health care providers gain access to more comprehensive and complete information about their patients, which can support improved care, better outcomes, decreased provider burden, and reduced costs.

Entities performing TEFCA Exchange as described in § 172.201 would have the option to request information for all Exchange Purposes. At the time of publication of this final rule, TEFCA supports exchange for the following

Exchange Purposes: treatment; payment; health care operations; public health; Individual Access Services (IAS), and government benefits determination. Over time, additional Exchange Purposes may be added. Information regarding whether responses are required for a given Exchange Purpose would be included in an SOP.

In § 172.201(c), we proposed that an Applicant QHIN must meet certain Designated Network Services requirements. Based on our experience in the health IT ecosystem, we noted that we believe adequate network performance is important for the success of TEFCA, as those participating in TEFCA Exchange would be most likely to trust the TEFCA infrastructure if it is performing at a high level. We also expressed that unreliable network performance would dilute confidence in the network and discourage participation.

In § 172.201(c)(1), we proposed that a QHIN must maintain the organizational infrastructure and legal authority to operate and govern its Designated Network. For instance, under this proposal, QHINs would be required to have a representative and participatory group or groups that approve the processes for fulfilling the TEFCA governance functions and that participate in governance for the Designated Network. In § 172.201(c)(2), we proposed that a QHIN must maintain adequate written policies and procedures to support meaningful TEFCA Exchange as described in § 172.201 and fulfill all responsibilities of a QHIN in the part (which an entity agrees to by signing the Common Agreement). For instance, under this proposal, QHINs would be required to have a detailed written policy that describes the oversight and control of the technical framework that enable TEFCA Exchange.

In § 172.201(c)(3), we proposed that a QHIN must maintain a Designated Network (as proposed to be defined in § 172.102) that can support a transaction volume that keeps pace with the demands of network users. We noted in the HTI–2 Proposed Rule that since TEFCA is a nationwide network and will be used daily to support various health data needs to inform care delivery, quality assessments, public health, and health care operations, QHINs must be capable of transacting high volumes of data reliably and at scale. In § 172.201(c)(4), we proposed that a QHIN must maintain the capacity to support secure technical connectivity and data exchange with other QHINs. One of the most fundamental aspects of interoperable network exchange is

technical connectivity, which makes network-to-network exchange possible and, therefore, was important to include in this regulation.

In § 172.201(c)(5) through (7), we proposed certain requirements related to governance for TEFCA to ensure all QHINs are aligned and able to manage risk effectively. In § 172.201(c)(5), we proposed that a QHIN must maintain an enforceable dispute resolution policy governing Participants in the Designated Network that permits Participants to reasonably, timely, and fairly adjudicate disputes that arise between each other, the QHIN, or other QHINs. This proposed requirement would afford flexibility to QHINs to establish their own dispute resolution process while ensuring the process is timely and fair. We expressed that disputes may arise for a variety of reasons, so the QHIN, as the entity overseeing its Participants, is best placed to handle such disputes in a way that minimizes disruptions for the rest of the network. Ensuring that a QHIN has such a dispute resolution policy would, therefore, likely minimize such disruptions.

Similarly, in § 172.201(c)(6), we proposed that a QHIN maintain an enforceable change management policy consistent with its responsibilities as a QHIN. A change management policy establishes the standard procedures to approve different types of changes to TEFCA documents (e.g., standard operating procedures) and policies and will help to avoid changes that are disruptive or in conflict across entities.

In § 172.201(c)(7), we proposed that a QHIN must maintain a representative and participatory group or groups with the authority to approve processes for governing the Designated Network. We explained (89 FR 63647) that the participatory network governance built into the TEFCA infrastructure is important to ensure that the requisite engagement exists between QHINs, Participants, and Subparticipants engaged in TEFCA Exchange. In the HTI–2 Proposed Rule, we stated that we believe the above requirements are fundamental aspects of a network-of-networks focused on participatory governance and the ability to adapt to an ever-changing health information exchange landscape.

In the HTI–2 Proposed Rule, regarding the proposed requirement in § 172.201(c)(7) specifically, we emphasized that TEFCA uses a representative and participatory governance structure. Representative and participatory governance gives those participating in the network a role in informing the policies and decisions that ultimately would affect them. We

explained that such a governance structure helps to motivate health care entities and their networks to voluntarily join TEFCA. We also noted that we believe that requiring a QHIN to have a representative and participatory group or groups that has the ability to review and provide input on the governance requirements of the QHIN's Designated Network is an optimal approach for this requirement.

In § 172.201(c)(8), we proposed that an entity seeking to become a QHIN must maintain privacy and security policies that permit the QHIN to support TEFCA Exchange. We identified certain policies that fell within this requirement (89 FR 63647), which we have slightly modified here for clarity and technical accuracy, and which included the following:

- Maintaining certification under a nationally recognized security framework by a qualified, independent third party that ensures its assessments are consistent with the NIST Cybersecurity Framework (CSF) (using both NIST 800–171 (Rev. 2) and NIST 800–53 (Rev. 5) as a reference), ensuring the QHIN performs HIPAA Security Rule risk analyses (as required by § 164.308(a)(1)(ii)(A)) and verifies all requirements for technical audits and assessments are met.

- Having a qualified, independent third party complete an annual security assessment consistent with the NIST Cybersecurity Framework (CSF) (using both NIST 800–171 (Rev. 2) and NIST 800–53 (Rev. 5) as a reference). The third party would review the QHIN for consistency with HIPAA Security Rule risk analysis requirements at § 164.308(a)(1)(ii)(A). Additionally, the annual security assessment must include comprehensive internet-facing penetration testing, must include an internal network vulnerability assessment, and must use methodologies and security controls consistent with Recognized Security Practices, as defined by Public Law 116–321 (42 U.S.C. 17931 and 300jj–52).

- Employing a Chief Information Security Officer with executive-level responsibility.

- Disclosing any breaches of electronic protected health information (including disclosure of any such breaches within the three (3) years preceding applying to become a QHIN) to the RCE and to all QHINs that are likely impacted.

- Complying with 45 CFR part 164, subparts A, C, and E, as applicable, as if the QHIN were a covered entity as described in that regulation.

- Maintaining and complying with a written privacy policy.

We noted in the HTI–2 Proposed Rule that these policies and requirements would provide privacy and security protections for the health information that will be exchanged through TEFCA. All entities that elect to participate in TEFCA, including entities that are not regulated under HIPAA, would be expected to meet a high bar for privacy and security given the nature of the data being exchanged. We stated that it is unlikely that an entity would wish to participate in a network without privacy and security standards, thereby inhibiting TEFCA exchange.

To further support the security of TEFCA, we proposed in § 172.201(c)(9) that a QHIN must maintain data breach response and management policies that support secure TEFCA Exchange. For instance, given the number of electronic connections TEFCA will support, a data breach response and management policy would support a transparent process and timely awareness of a data breach or other security events (e.g., ransomware attacks) which could enable the QHIN to manage secure connectivity services without disrupting patient care.

In § 172.201(c)(10), we proposed that a QHIN must maintain adequate financial and personnel resources to support all its responsibilities as a QHIN, including, at a minimum, sufficient financial reserves or insurance-based cybersecurity coverage, or a combination of both. We noted in the HTI–2 Proposed Rule that this requirement would help to provide stability to TEFCA in the event of unexpected financial or economic occurrences—whether system-wide or specific to individual QHINs. For instance, we stated that this requirement could be met if the QHIN has available a minimum amount of cash, cash equivalents, borrowing arrangements (e.g., a line of credit), or a mix of the three that is equal to six (6) calendar months of operating reserves. Regarding insurance requirements, a QHIN's general liability coverage and the cyber risk/technology coverage should each have limits of at least \$2,000,000 per incident and \$5,000,000 in the aggregate, which limits can be met through primary coverage, excess coverage, available internal funds, or a combination thereof. We noted that the requirements proposed herein may be insufficient for larger QHINs and recognized that certain QHINs will meet and exceed these minimums.

QHINs will be the central connection points for TEFCA Exchange, responsible for routing queries, responses, and messages among many participating entities and individuals. We proposed,

in § 172.201(c)(10), that QHINs must have sufficient financial resources and personnel capacity to perform such functions successfully. We also noted we believe that QHINs must be prepared to address incidents should they arise and must have the ability to fulfill potential liability obligations, either through insurance, sufficient financial reserves, or some combination of the two.

We stated that one goal of TEFCA is to support patients gathering their healthcare information. In § 172.202, “QHINS that offer individual access services,” we proposed IAS requirements for a QHIN to obtain and maintain Designation under TEFCA if that QHIN voluntarily offers IAS. In § 172.202(a), we proposed that a QHIN would be required to obtain express consent from any individual before providing IAS, as defined in § 172.102. We noted that we believe this is an important requirement so that individuals who use IAS that a QHIN offers are informed of the privacy and security practices that are being employed to protect their data. In § 172.202(b), we proposed that a QHIN would be required to make publicly available a privacy and security notice that meets minimum TEFCA privacy and security standards to support transparent exchange practices. We stated that we believe this requirement would provide transparency to all individuals who are considering using IAS regarding how their data is protected and secured by a QHIN providing IAS.

In § 172.202(c), we proposed a QHIN that is the IAS provider for an individual would be required to delete the individual’s Individually Identifiable Information (as defined in § 172.102) maintained by the QHIN upon request by the individual except as prohibited by Applicable Law or where such information is contained in audit logs. We noted (89 FR 63648) that we believe this requirement would provide individuals with reassurance that they control access to their data. We also expressed that we believe the carve out for audit logs is appropriate because audit logs are generally used to provide chronological records of system activities and should not be deleted. In § 172.202(d), we proposed that a QHIN would be required to permit any individual to export in a computable format all of the individual’s Individually Identifiable Information maintained by the QHIN as an IAS provider. We stated that we believe this requirement would ensure that individuals may access, control, and use their own data held by an IAS provider.

In § 172.202(e), we proposed that all Individually Identifiable Information the QHIN maintains must satisfy certain criteria, including: (1) all Individually Identifiable Information must be encrypted; (2) without unreasonable delay and in no case later than sixty (60) calendar days following discovery of the unauthorized acquisition, access, Disclosure, or Use of Individually Identifiable Information, the QHIN must notify, in plain language, each individual whose Individually Identifiable Information has been or is reasonably believed to have been affected by unauthorized acquisition, access, Disclosure, or Use involving the QHIN; and (3) a QHIN must 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. We noted that to the extent the QHIN is already required by Applicable Law to notify an individual as described in proposed § 172.202(e)(2), we did not propose that it be required to duplicate such a notification. Lastly, the proposed requirement in § 172.202(e)(3) would set a baseline for proving the identity of IAS users that are requesting data via TEFCA Exchange.

Comments. Multiple commenters expressed support for the provisions of this subpart that will establish the qualifications for HINs to receive and maintain Designation as a QHIN, including as an IAS provider. Multiple commenters also expressed support for the proposed qualification requirements. Other commenters cautioned that additional requirements of QHINs could limit entities from participating in TEFCA or deter them from considering becoming a QHIN.

Response. We appreciate commenters’ support for the proposed qualifications for QHIN Designation. We also understand commenters’ caution to ASTP/ONC regarding additional requirements and appreciate the need within TEFCA to establish strong guardrails for QHIN participation while not unduly burdening Applicant QHINs and QHINs. We agree with commenters that additional requirements for QHINs are not, at this time, appropriate as we work to balance flexibility, participation, and our commitment to strong guardrails for QHIN participation. The current requirements were developed based on ASTP/ONC’s and the RCE’s collective experience with health information exchange and were informed by a wide range of interested communities and the public.

As TEFCA evolves, we will continue to consider ways to strengthen it and ensure that QHINs are held to a high but reasonable standard. In this final rule, we have finalized all subpart B proposals without revision.

Comments. One commenter asked whether any changes to the proposed QHIN designation process would be retroactively applicable to entities currently undergoing that process. Another commenter expressed support for the previous “sub-regulatory” approach for establishing criteria and requirements for QHIN Designation that allowed for flexibility. Some commenters also recommended new requirements. Commenters recommended aligning qualifications with existing Department of Homeland Security standards and/or FedRAMP certification standards for cybersecurity. Another commenter recommended background checks, validation of National Provider Identifiers (NPIs), and a rigorous review of organizational credentials. A separate commenter encouraged ASTP/ONC’s continued emphasis on and improvement of security and privacy requirements. Another commenter recommended that we leverage QHIN qualification criteria to require that pharmacists, with an established treatment relationship with patients, have access to clinical data.

Response. Regarding the question whether any changes to the proposed QHIN Designation process would be retroactively applicable to entities currently undergoing that process, we note that we are finalizing the QHIN Designation requirements and process within the HTI–2 Proposed Rule, and as discussed above, without revision in this final rule. The provisions will be effective upon the effective date specified for this final rule in the “effective date” section. The qualification requirements we have finalized in 45 CFR part 172, subpart B, align with and have no substantive differences from the requirements for and process followed by all Designated QHINs and Applicant QHINs.

We appreciate the comment in support of the previous sub-regulatory approach that we have utilized in TEFCA to this point to establish the processes within the TEFCA framework.

We appreciate the suggestions for updating the existing QHIN Designation requirements within the TEFCA framework (e.g., aligning qualifications with existing Department of Homeland Security standards and/or FedRAMP certification standards for cybersecurity, improving privacy and security requirements, emphasis on background checks, validation of NPIs, and a

rigorous review of organizational credentials). We emphasize our confidence in the strength of the existing requirements. We may consider some of these suggested changes for future rulemaking. While we cannot adopt the various new QHIN Designation requirements recommended by commenters because we did not propose them, we do note that we consulted with various Federal agencies and industry partners in developing the QHIN Designation requirements around privacy and security that align with Federal agency participation requirements.

We appreciate the recommendation that we leverage QHIN qualification criteria to require that pharmacists, with an established treatment relationship with patients, have access to clinical data; however, we do not understand how the QHIN qualification criteria directly relate to the suggested requirement. We encourage the commenter to review the *Exchange Purpose Vetting Process SOP*, which provides helpful information for entities that seek to exchange information for treatment via TEFCA.

As noted in our response to comments above, we proposed to adopt in regulation certain provisions related to TEFCA in order to provide greater process transparency and further implement section 3001(c)(9) of the PHSA, as added by the Cures Act. We believe codifying TEFCA through regulation facilitates alignment with the broader legislative goals around nationwide health information exchange, interoperability, privacy, and security.

Comments. One commenter suggested that the qualification related to transaction volume establish specific performance metrics for the speed of data transfer. In particular, the commenter argued that 48-hour turnarounds for use cases such as prior authorization would be untenable.

Response. We appreciate commenter's suggestion related to transaction volume. The RCE and ASTP/ONC plan to develop performance metrics and service level agreements for TEFCA as we develop more experience and a better understanding about the needs of the TEFCA community. We will consider this comment as we develop the performance metrics and service level agreements for TEFCA.

Comments. One commenter suggested that the 5% ownership requirement for "bad" actors should not be increased and that lowering the threshold could be appropriate for good cause. Another commenter suggested that ASTP/ONC clarify that the 5% threshold is for an

individual and that collusion between multiple individuals would have a threshold of over 25%. The commenter was supportive of the proposal that QHINs would be ineligible if they are found to be under Foreign Control.

Response. We thank the commenters for the suggestion and the support of our proposal regarding Foreign Control. We continue to believe, based on significant feedback from interested communities, cybersecurity and security experts, and the public, that the five percent (5%) threshold is appropriate and strikes the right balance between protecting the security of the network from high-risk and known bad actors and achieving practical administrability of TEFCA. Individuals with less than 5% ownership in an entity would likely have limited means of influencing the actions of an entity connected to TEFCA. We appreciate the reasoning for the proposal of an aggregate threshold but have decided not to implement that suggested change because it would be extremely difficult and burdensome to determine whether a group of actors is "colluding" as suggested by commenter, as determining whether "collusion" is present could require information that may not be readily available.

Comments. One commenter suggested that we publish all "Designation" documentation on our website for public review.

Response. While ASTP/ONC supports and promotes transparency where possible and appropriate, we decline to adopt the commenter's recommendation in this instance. Foremost, we did not propose such an approach and thus all potentially affected entities have not had an opportunity to comment on the matter. In addition, some of the information received from Applicant QHINs may include confidential information.

C. Subpart C—QHIN™ Onboarding and Designation Processes

In the HTI-2 Proposed Rule, we stated that (89 FR 63648) TEFCA establishes a universal floor for interoperability across the country through a network of networks. In 2019, ONC issued a Notice of Funding Opportunity and subsequently awarded a cooperative agreement to The Sequoia Project to serve as the RCE to support the implementation of TEFCA. In August 2023, ONC awarded The Sequoia Project a five-year contract to continue serving as the RCE.

To establish nationwide health information exchange, TEFCA calls for the Designation of QHINs—HINs that agree to the common policy, functional, and technical requirements for TEFCA

Exchange. The QHIN Designation Requirements as described in § 172.201 define the baseline legal and technical requirements for secure information sharing on a nationwide scale—all under commonly agreed-to rules. Exchange through TEFCA simplifies connectivity and creates efficiency by establishing a standardized approach to exchange policies and technical frameworks.

Under the 2019 to 2023 cooperative agreement¹⁵ and the current RCE contract,¹⁶ the RCE's role has been to support the implementation of TEFCA, including the solicitation and review of applications from HINs seeking QHIN status and administration of the Designation and monitoring processes. For entities seeking Designation, the application provides the RCE with the information needed to determine a prospective QHIN's ability to meet its obligations and responsibilities for TEFCA Exchange. All work or activities conducted by the Sequoia Project in their capacity as the RCE under the RCE contract, including work or activities related to Designation, is conducted on behalf of ONC.

In subpart C of part 172, we described the proposed QHIN Onboarding and Designation processes. *Onboarding*, as we proposed to define it in § 172.102, is the process a prospective QHIN must undergo to become a QHIN and become operational in the production environment.¹⁷ *Designation*, as we proposed to define it in § 172.102, is the written determination that an Applicant QHIN has satisfied all regulatory requirements and is now a QHIN.¹⁸

In § 172.300, we explained that subpart C of part 172 would establish for QHINs the application, review, Onboarding, withdrawal, and redetermination processes that ONC will follow for Designation. We noted that establishing these processes will ensure that ONC (or an RCE) takes a consistent approach to QHIN Onboarding and Designation.

We stated that the first step in becoming a QHIN under TEFCA is submission of an application. In § 172.301, we proposed to establish the information Applicant QHINs must submit in order to be Designated as a

¹⁵ Notice of Funding Opportunity (NOFO)—Trusted Exchange Framework and Common Agreement—Recognized Coordination Entity (RCE) Cooperative Agreement, https://www.healthit.gov/sites/default/files/facas/TEFCA%20NOFO_FINAL_508.pdf.

¹⁶ See *USASPENDING.gov*, https://www.usaspending.gov/award/CONT_AWD_75P00123C00019_7570_-NONE_-NONE-

¹⁷ 87 FR 2822.

¹⁸ 87 FR 2818.

QHIN. We proposed that an Applicant QHIN must submit: (1) a completed QHIN application; and (2) a signed copy of the Common Agreement. Regarding the first proposed requirement, in § 172.301(a), we noted that we may update the application over time and the most recent version will be available on ONC's and the RCE's website. The application will specify what supporting documentation an Applicant QHIN must submit. We proposed the second requirement in § 172.301(b) because the Applicant QHIN would sign the Common Agreement upon application, but the RCE would only countersign and create a binding agreement with the Applicant QHIN once the Applicant QHIN completes Onboarding and is Designated.

We stated that the next step to becoming a QHIN is application review. In § 172.302, we proposed a process, with required timelines and allowable extensions, for ONC (or an RCE) to review applications. We proposed in § 172.302(a) that, on receipt of an application, ONC (or an RCE) will review the application to determine if the Applicant QHIN has completed all parts of the application and provided the necessary supporting documentation. Further, we proposed that, if the QHIN Application is not complete, ONC (or an RCE) will notify the applicant in writing of the missing information within thirty (30) calendar days of receipt of the application. Last, we proposed (89 FR 63649) that ONC (or an RCE) may extend this period by providing written notice to the Applicant QHIN. We noted that "written notice" throughout part 172 would include notice provided by email to the points of contact the Applicant QHIN listed in their application.

In the HTI-2 Proposed Rule we stated that we believe the above timeframe and allowable extensions would allow ONC (or an RCE) enough time to perform a thorough review of each application and ensure that ONC (or an RCE) is provided with the responses and supporting documentation needed to assess the merits of an application. We also noted that we believe the 30-day review timeframe—along with the ability of ONC (or an RCE) to extend this period by providing written notice to the Applicant QHIN—strikes the right balance between moving an application forward as quickly as possible while still providing ONC (or an RCE) with enough time to conduct a review of the application to ensure it is complete and contains all the required material.

We proposed in § 172.302(b) that once the QHIN application is complete, ONC (or an RCE) will review the application

to determine whether the Applicant QHIN satisfies the requirements for Designation set forth in § 172.201, and, if the Applicant QHIN proposes to provide IAS, the requirements set forth in § 172.202. We proposed this step to make clear that ONC (or an RCE) will review an application not only for completeness but also to determine if the qualifications are met. We also proposed ONC (or an RCE) would complete its review within sixty (60) calendar days of providing the Applicant QHIN with written notice that its application is complete. We further proposed that ONC (or an RCE) may extend this period by providing written notice to the Applicant QHIN. We noted in the HTI-2 Proposed Rule that we believe that sixty (60) calendar days will *generally* be an adequate amount of time to conduct a thorough, comprehensive review of the substance of the application. However, we also noted that we are cognizant that there may be complex applications that require additional time for review and, therefore, proposed that ONC (or an RCE) may extend this period by providing written notice to the Applicant QHIN.

We proposed in § 172.302(c) that ONC (or an RCE) may contact the Applicant while the application is being reviewed to request additional information. ONC (or an RCE) will provide the timeframe for responding to its request and the manner to submit additional information, which may be extended on written notice to the Applicant QHIN. We noted we believe this provision would be beneficial because the Applicant QHIN will need to provide detailed responses that may be complex and will vary among Applicant QHINs. We also stated we anticipate there will often need to be a discussion between ONC (or an RCE) and the Applicant QHIN to reach a resolution and shared understanding. This provision would provide for this vital communication between ONC (or an RCE) and the Applicant QHINs. We proposed that an Applicant QHIN must respond to ONC (or an RCE) within the timeframe ONC (or an RCE) identifies because ONC (or an RCE) will be in the best position to understand the complexity of the question and estimate a reasonable amount of time for the Applicant QHIN to respond. That said, we noted that we understand that each application, as well as the questions associated with each application, will vary significantly on a case-by-case basis and, therefore, proposed that ONC (or an RCE) may extend the timeframe by providing written notice to the Applicant QHIN.

We stated that we believe this approach creates appropriate flexibility regarding timing of Applicant QHIN responses, while still leaving the discretion to decide the need for and length of such extensions.

We proposed in § 172.302(d) that failure to respond to a request within the proposed timeframe, or in the manner specified, is a basis for a QHIN Application to be deemed withdrawn, as set forth in § 172.305(c). In such situations, we proposed that ONC (or an RCE) would provide the Applicant QHIN with written notice that the application has been deemed withdrawn. We stated that we believe this requirement is important to support an efficient application process and to ensure that Applicant QHINs respond to requests in a timely manner. We reiterated that under proposed § 172.302(c), as discussed above, ONC (or an RCE) can extend the timeframe for responding to a request for information. We noted that an Applicant QHIN should request an extension if it does not believe it can meet the proposed response timeframe.

We proposed in § 172.302(e) that if, following submission of the application, any information submitted by the Applicant QHIN becomes untrue or materially changes, the Applicant QHIN must notify ONC (or an RCE), in the manner specified by ONC (or an RCE), of such changes in writing within five (5) business days of the submitted material becoming untrue or materially changing. This proposed requirement takes into consideration the possibility that, over the course of ONC's (or an RCE's) review of an application, an Applicant QHIN's circumstances or information provided with the Applicant QHIN's application may change. This provision would ensure that if such changes occur, the Applicant QHIN would promptly notify ONC (or an RCE) of such changes. We stated that we believe, based on ONC's experience with health IT implementation and coordination efforts, that five (5) business days is enough time for the Applicant QHIN to notify ONC (or an RCE) of the change(s).

In § 172.303, we proposed requirements related to QHIN approval and Onboarding. We proposed in § 172.303(a) that an Applicant QHIN would have the burden of demonstrating its compliance with all qualifications for Designation in § 172.201, and, if the Applicant QHIN proposes to provide IAS, the qualifications in § 172.202. We proposed in § 172.303(b) that if ONC (or an RCE) determines an Applicant QHIN meets the requirements for Designation

set forth in § 172.201, and, if the Applicant QHIN proposes to provide IAS, the qualifications set forth in § 172.202, then ONC (or an RCE) will notify the Applicant QHIN in writing that it has approved its application, and the Applicant QHIN can proceed with Onboarding. These proposed requirements are important for ensuring that the Applicant QHIN is notified of its status and support the transparency and efficiency of the Onboarding process.

We proposed in § 172.303(c) that an approved Applicant QHIN would be required to submit a signed version of the Common Agreement within a timeframe set by ONC (or an RCE). This proposed provision is important in addition to § 172.301(b) (which would require an Applicant QHIN to submit a signed version of the Common Agreement when applying) to ensure that, if the Common Agreement changes between the time the QHIN applies and when it is approved, the QHIN will have signed the most recent version. We did not propose a specific timeframe for submission, and instead proposed to allow ONC (or an RCE) to set the timeframe for each Applicant QHIN, since we believe each timeframe should be tailored to the needs of the Applicant QHIN and the complexity of each application.

We proposed in § 172.303(d) that an approved Applicant QHIN must complete the Onboarding process set forth by ONC (or an RCE), including any tests required by ONC (or an RCE) to ensure the Applicant QHIN's network can connect to those of other QHINs, within twelve (12) months of approval of the QHIN application, unless that time is extended in ONC's (or an RCE's) sole discretion by up to twelve (12) months. Based on our experience with health IT implementation and discussions with the current RCE, we stated that we believe the proposed twelve (12) month timeframe is sufficient time for approved Applicant QHINs to complete the Onboarding process including any tests with QHINs and other Applicant QHINs. We expressed that we believe this timeframe strikes an appropriate balance between the need to onboard QHINs promptly and the need to ensure that all QHINs can connect immediately and seamlessly once Designated. We noted that during the Onboarding process, the Applicant QHIN would have regular check-ins with ONC (or an RCE) to monitor the progress on any outstanding requirements, to coordinate technical testing, and to address any issues that could put the Applicant QHIN in jeopardy of failing to meet the

proposed Onboarding timeframe detailed above.

In § 172.304, we proposed the specific procedural requirements for the Designation of QHINs. In § 172.304(a), we proposed the process that would follow an Applicant QHIN's satisfaction of the Onboarding process requirements. We proposed that once the Onboarding process requirements are satisfied, the Common Agreement would be countersigned and the Applicant QHIN would receive a written determination indicating that it had been Designated as a QHIN, along with a copy of the countersigned Common Agreement.

In § 172.304(b), we proposed that within thirty (30) calendar days of receiving its written determination of Designation, each QHIN would be required to demonstrate in a manner specified by ONC (or an RCE) that it has completed a successful transaction with all other in-production QHINs according to standards and procedures for TEFCA Exchange. This proposed provision is important because it would ensure that a Designated QHIN is able to exchange information with other QHINs, which is a core function of QHINs. We stated we believe that the thirty (30)-day timeframe will afford a Designated QHIN ample time to move from testing to production. We also stated we believe that the standards and procedures for such exchanges should remain flexible such that ONC (or an RCE) may update the requirements from time to time as appropriate. QHINs which are unable to complete a successful transaction within the finalized time period would have their Designation revoked.

We proposed in § 172.304(c) that if a QHIN is unable to complete the requirement in § 172.304(b), described above, within the thirty (30)-day period provided, the QHIN would be required to provide to ONC (or an RCE) a written explanation as to why the QHIN is unable to complete the requirement within the allotted time and include a detailed plan and timeline for completion of the requirement. We proposed that ONC (or an RCE) will then review and approve or reject the QHIN's plan, basing its decision on the reasonableness of the explanation based on the specific facts and circumstances, within five (5) business days of receipt. We proposed that if the QHIN fails to provide ONC (or an RCE) its plan or ONC (or an RCE) rejects the QHIN's plan, ONC (or an RCE) will rescind its approval of the application, rescind the QHIN Designation, and deny the application. We stated that we believe these proposals would provide QHINs with the appropriate flexibility to request an extension if the

circumstances do not allow the QHIN to meet the timeline. We also expressed that we believe the proposed five (5)-business day timeframe would provide ONC (or an RCE) with enough time to review the request and reach a decision regarding the request based on the information provided. We proposed that within thirty (30) calendar days of the end of the term of the plan, each QHIN must demonstrate in a manner specified by ONC (or an RCE) that it has completed a successful transaction with all other in-production QHINs according to standards and procedures for TEFCA Exchange. We noted that we believe that the thirty (30)-day timeframe will afford a Designated QHIN ample time to move from testing to production.

In § 172.304(d), we proposed that a QHIN Designation will become final sixty (60) days after a Designated QHIN has submitted its documentation, in a manner specified by ONC (or an RCE), that it has completed a successful transaction with all other in-production QHINs. This proposal will allow ONC (or an RCE) to exercise its ability to review a Designation.

In § 172.305, we proposed requirements related to withdrawal of an application. In § 172.305(a), we proposed that an Applicant QHIN may withdraw its application by providing ONC (or an RCE) with written notice in a manner specified by ONC (or an RCE). In § 172.305(b), we proposed that an Applicant QHIN may withdraw its application at any point prior to Designation. In § 172.305(c), we proposed that on written notice to the Applicant QHIN, an application may be deemed as withdrawn as a result of the Applicant QHIN's failure to respond to requests for information from ONC (or an RCE). We stated that we believe the approach in proposed § 172.305 would create an efficient process for ONC (or an RCE) to deem applications withdrawn if an Applicant QHIN fails to respond to requests for information, and also supports a flexible process by allowing an Applicant QHIN, for whatever reason, to decide to withdraw its application without penalty. Given the requirements placed on Applicant QHINs seeking to be Designated, we stated we think it is reasonable to believe that some Applicant QHINs will need to withdraw their applications to address any number of issues that could arise during the application process.

In § 172.306, we proposed that if an Applicant QHIN's application is denied, the Applicant QHIN will be provided with written notice that includes the basis for the denial. We did not propose a specific template that would be used to explain the basis of a denial, as such

explanation would likely vary based on the specific facts and circumstances.

In § 172.307, we proposed requirements for re-application. In § 172.307(a), we proposed that Applicant QHINs may resubmit their applications by complying with the provisions of § 172.301 in the event that an application was denied or withdrawn. We noted that re-application pursuant to § 172.307(a) would also be conditioned on meeting the requirements of proposed paragraphs (b) through (d) of § 172.307, as applicable. We proposed in § 172.307(b) that an Applicant QHIN may reapply at any time after it has voluntarily withdrawn its application as specified in § 172.305(a). We wanted to create flexibility for Applicant QHINs to reassess their applications and, if desired, resubmit the application. We also stated we believe that providing an Applicant QHIN that withdraws its application with discretion to choose when to re-apply would result in better applications and create administrative efficiency. This is because Applicant QHINs would be motivated to self-identify issues and correct them in a subsequent application. Also, Applicant QHINs that withdraw applications early would allow ONC (or an RCE) to avoid expending resources to review and identify such issues.

In § 172.307(c), we proposed that if ONC (or an RCE) deems an application to be withdrawn as a result of the Applicant QHIN's failure to respond to requests for information from ONC (or an RCE), then the Applicant QHIN may reapply by submitting a new application no sooner than six (6) months after the date on which its previous application was submitted. We proposed that the Applicant QHIN must respond to the prior request for information and must include an explanation as to why no response was previously provided within the required timeframe. We proposed in § 172.307(d) that if ONC (or an RCE) denies an application, the Applicant QHIN may reapply by submitting a new application consistent with the requirements in § 172.301, no sooner than six (6) months after the date shown on the written notice of denial. The application must specifically address the deficiencies that constituted the basis for denying the Applicant QHIN's previous application.

We noted in the HTI-2 Proposed Rule that we believe the proposed six (6)-month minimum time period before re-application, in § 172.307(c) and (d), would support efficiency in the review process, as ONC (or an RCE) could shift its attention to other Applicant QHINs or issues while the Applicant QHIN

whose application was withdrawn as a result of the Applicant QHIN's failure to respond to requests for information or was denied reconsiders its application and addresses the previously identified deficiency or deficiencies. Because the Applicant QHIN that withdraws its application has not had its application denied or deemed withdrawn for failure to respond to ONC (or an RCE) requests for information, the Applicant QHIN may be prepared to reapply much sooner than is the case for Applicant QHINs that have had their application denied or deemed withdrawn. We welcomed comments on the proposed processes and requirements in this subpart. Specifically, we requested comment on whether the six-month timeframe for re-application after an application has been deemed to be withdrawn as a result of the Applicant QHIN's failure to respond to requests for information or has been denied is appropriate, as well as other timeframes we proposed.

In addition to changes to the proposed regulatory text explained below, and as explained elsewhere in this final rule, we have finalized references to "ONC" in subpart B of the proposed rule as "ASTP/ONC." In some instances (for example, in § 172.303(d)), we also modified proposed regulatory text to ensure that the proper possessive is used and finalized text reading "ASTP/ONC's" instead of "ONC's." For further discussion of the use of "ASTP/ONC," please see the Executive Summary of this final rule.

Comments. One commenter stated that it was a seamless process to connect to the TEFCA network through the QHIN, but recommended there not be a means where users are opted into the exchange via a QHIN by default.

Response. While we appreciate the feedback, this comment is beyond the scope of the proposed regulations because we did not make any proposals related to a QHIN's policies and procedures related to opting-in (or not opting-in). Since the comment is out of scope it would not be appropriate to respond to such policy concerns here. However, we welcome all feedback from interested parties, which can be submitted via the ASTP/ONC website at <https://inquiry.healthit.gov/support/plugins/servlet/desk/portal/2/create/61>, for consideration and potential inclusion within the TEFCA framework.

Comments. Overall, commenters were supportive of our proposal to codify requirements related to QHIN Designation, Onboarding and dispute resolution at this time. However, a couple of commenters expressed concern that the codification could slow

down the onboarding process and eliminate the adaptability for future QHINs. One commenter stated that the proposed regulation could hinder the RCE's and ASTP/ONC's ability to make quick, necessary adjustments based on real-world implementation feedback from future QHIN applicants. This commenter said that codifying the requirements could limit the number of QHINs in the network by potentially discouraging or disqualifying future QHINs due to a less forgiving application process. The commenter opined that this might hinder the emergence of innovative solutions and potentially lead to less favorable terms for Participants and Subparticipants.

Response. We appreciate the feedback and the commenters' concerns. By codifying the QHIN Designation, Onboarding, and dispute resolution requirements, we establish a baseline for expectations for QHINs. We believe this is supported by Congress' instruction that the Common Agreement may include "a common method for authenticating trusted health information network participants" (42 U.S.C. 300jj-11(c)(9)(B)(i)(I)). For commenters concerned about potential future requirements, while we appreciate the feedback, this comment is beyond the scope of the proposed regulations. However, we welcome all feedback from interested parties, which can be submitted via the ASTP/ONC website at <https://inquiry.healthit.gov/support/plugins/servlet/desk/portal/2/create/61>, for consideration and potential inclusion within the TEFCA framework.

Comments. One commenter requested that the Onboarding process be clarified to give more information regarding the redetermination process for QHIN application.

Response. We appreciate the comment but decline to make any changes to the Onboarding process. We believe the current Onboarding process, as well as the redetermination process, are sufficiently detailed so that QHINs will know what to expect while ensuring flexibility remains in place to allow for reconsideration based on a variety of circumstances.

Comments. Commenters requested that ASTP/ONC make TEFCA's onboarding process become more stringent to keep the system free of bad actors. In addition to a stricter onboarding process, the commenters also recommended active monitoring and swift enforcement, and the creation of a mandatory notification system to alert legitimate practices when their NPIs and credentials are used in data exchanges, ensuring they are aware of

all activities tied to their identities. Another commenter emphasized that this has become a serious issue under TEFCA, particularly as the HITECH Act's requirement to share patient information with a third party at the patient's direction at minimal cost encourages some entities to misrepresent that they are acting on behalf of the patient.

Response. We appreciate the comments and concern. We believe that Onboarding and Designation provisions we are finalizing, including the substantive requirements at §§ 172.201 and 172.202, establish a rigorous testing and onboarding process that will prevent bad actors from misusing the TEFCA framework. Specifically, since we proposed substantive requirements for QHIN approval and Onboarding, and QHIN designation, in §§ 172.303 and 172.304 in the HTI-2 Proposed Rule, we have developed a robust vetting process for ensuring that Participants and Subparticipants that want to query for treatment exchange through TEFCA using the code that requires a response are in fact providers that require the information for treatment of a patient. In addition, the Treatment XP Implementation SOP¹⁹ establishes a definition for TEFCA required treatment that includes the requirement that the TEFCA required treatment XP code can only be asserted by a QHIN, Participant, or Subparticipant if the Query is in connection with or intended to inform health care services that an entity identified in the SOP is providing or intends to provide to a patient through synchronous or asynchronous interaction (either in-person or virtual) with a Licensed Individual Provider. This definition is narrower than the HIPAA Rules' definition of treatment and we believe necessary to build trust within the TEFCA community. We will consider expanding the scope of disclosures that are required under TEFCA's treatment Exchange Purpose over time.

We have decided not to implement a mandatory notification system as suggested because we believe the approach we are taking to address the possibility of misuse of the TEFCA network, as discussed above, is more appropriate, and that a mandatory notification system could be overly burdensome, particularly given the extremely large number of transactions we anticipate occurring through TEFCA once fully implemented.

Comments. One commenter questioned why § 172.304 references provisional designation when the RCE is currently revising the Onboarding and Designation SOP to remove references to provisional status.

Response. We agree that the references to "provisional" designation are confusing and unnecessary. We have revised the regulatory language in § 172.304 to remove reference to provisional Designation and reiterate that a QHIN is Designated when the Common Agreement is countersigned. As we proposed and have finalized, the Designation is rescindable if the requirements for exchange are not met within the 60-day limit described in § 172.304(d), otherwise, the Designation is final.

Comments. One commenter offered support of the six-month timeframe for re-application after an application has been withdrawn or denied. The commenter stated that it is important for ASTP/ONC to take the time it needs and assure security and appropriateness.

Response. We appreciate this comment in support of a six-month timeframe and have finalized the provision in § 172.307(c) as proposed.

Comment. One commenter emphasized the need for strict enforcement of deadlines and application criteria. The commenter also recommended that if the requirements were not met, the application should not only be withdrawn but also prompt an audit of the applicant's activities and a review of any data exchanges that took place during the application process. The commenter also suggested expanding the criteria for withdrawing an application to include not just failures to respond but also the discovery of fraudulent activities or the use of illegitimate credentials at any point during the application process.

Response. We appreciate the feedback. We decline to adopt stricter deadlines and application criteria. We believe the current structure accounts for these concerns, for instance, by requiring a QHIN to specifically address any unresolved issues upon reapplication. Regarding the suggestions to require an audit of the applicant's activities and a review of any data exchange that took place during the application process and expanding the criteria for withdrawing an application, we have decided not to implement the changes in this rulemaking because we believe such potential changes should be reviewed and considered by the public. We may consider the changes in future rulemaking.

We have finalized all of subpart C as proposed, except that we removed

language referring to provisional Designation in § 172.304 for the reasons explained above. In addition, we have added language requiring an RCE to seek and receive ASTP/ONC's prior authorization before making interim or final designation decisions (§ 172.303(b)), setting onboarding requirements and determining a QHIN has complied with those requirements (§ 172.304(b) and (c)), and deeming a QHIN application withdrawn for failure to respond to information requests during the Designation process (§ 172.305(c)). Under § 172.103(b), ASTP/ONC cannot subdelegate to the RCE those requirements for prior agency authorization. Combined with the review provisions that apply to all RCE actions in subpart F of part 172, this language helps to ensure that an RCE remains subordinate to ASTP/ONC and provides only fact-gathering, ministerial, and administrative support to ASTP/ONC.

D. Subpart D—Suspension

Within this subpart, in the HTI-2 Proposed Rule, we proposed provisions associated with suspension, notice requirements for suspension, and the effect of suspension. In § 172.401, we proposed provisions related to ONC (or the RCE) suspension of a QHIN or directed suspension of a Participant or Subparticipant. In § 172.401(a), we proposed that ONC (or an RCE) may suspend a QHIN's authority to engage in TEFCA Exchange if the ONC (or an RCE) determines that a QHIN is responsible for a Threat Condition. Within the TEFCA infrastructure, QHINs are expected to meet a high bar for security, including, but not limited to, third-party certification to industry-recognized cybersecurity standards; compliance with the HIPAA Security Rule or the standards required by QHIN participation that mirror the HIPAA Security Rule requirements; annual security assessments; designation of a Chief Information Security Officer; and having cyber risk coverage.

This proposed provision would support the overall security of TEFCA and align with the security requirements for QHINs by enabling ONC (or an RCE) to suspend a QHIN's authority to engage in TEFCA Exchange if the QHIN is responsible for a Threat Condition. According to the definition proposed in § 172.102, a Threat Condition may occur in three circumstances: (i) a breach of a material provision of a Framework 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 contracting parties have agreed), which

¹⁹ XP Implementation: Treatment, https://rce.sequoiaproject.org/wp-content/uploads/2024/07/SOP-Treatment-XP-Implementation_508.pdf.

notice shall include such specific information about the breach that is available at the time of the notice; or (ii) a TEFCA Security Incident, as that term is defined in § 172.102; or (iii) an event that ONC (or an RCE), a QHIN, its Participant, or their Subparticipant has reason to believe will disrupt normal TEFCA Exchange, 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 through replication in the systems, networks, applications, or data of another QHIN, Participant, or Subparticipant; or (iv) any event that could pose a risk to the interests of national security as directed by an agency of the United States government. We proposed this policy because we believe that in each of these situations, in order to protect the security of TEFCA Exchange, ONC (or an RCE) must be able to take immediate action to suspend a QHIN's authority to engage in TEFCA exchange and limit the potential effects of the Threat Condition.

In § 172.401(b), we proposed if ONC (or an RCE) determines that one of a QHIN's Participants or Subparticipants has done something or failed to do something that results in a Threat Condition, ONC (or an RCE) may direct the QHIN to suspend that Participant's or Subparticipant's authority to engage in TEFCA Exchange. This provision proposed to extend the ONC (or an RCE's) authority to suspend a QHIN's authority to engage in TEFCA Exchange to also include the authority to order a QHIN to suspend a Participant's or Subparticipant's authority to engage in TEFCA Exchange. We stated that we believe this provision would help protect the security of TEFCA Exchange because any Threat Condition—whether due to the action or inaction by a QHIN, Participant, or Subparticipant—could jeopardize the security of TEFCA and must be addressed once identified. We also noted we believe that in order to protect the security of TEFCA Exchange, ONC (or an RCE) must be able to take immediate action to order a QHIN to suspend a Participant's or Subparticipant's authority to engage in TEFCA Exchange and limit the potential effects of a Threat Condition resulting from something a Participant or Subparticipant has done or failed to do.

In § 172.401(c), we proposed that ONC (or an RCE) will make a reasonable effort to notify a QHIN in writing, in advance, of ONC's (or an RCE's) intent to suspend the QHIN or to direct the QHIN to suspend one of the QHIN's Participants or Subparticipants, and give the QHIN an opportunity to

respond. Such notice would identify the Threat Condition giving rise to such suspension. We acknowledged that a suspension would significantly disrupt the activities of a QHIN, Participant, or Subparticipant and therefore § 172.401(c) proposed to require ONC (or an RCE) to make a reasonable effort to notify affected parties in advance of the ONC's (or an RCE's) intent to suspend. We proposed to only require ONC (or an RCE) to make a reasonable effort to notify the entity because the circumstances surrounding a Threat Condition may limit ONC's (or an RCE's) ability to provide advance written notice to the QHIN or the QHIN's Participants or Subparticipants, despite ONC's (or an RCE's) best efforts. In § 172.401(d), we proposed ONC (or an RCE) shall lift a suspension once the Threat Condition is resolved. We stated we believe that it would no longer be necessary to continue a suspension once a Threat Condition is resolved.

We stated in the HTI–2 Proposed Rule that we believe the provisions outlined in § 172.401 would help 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)—including in concert with their Participants or Subparticipants—that led to the suspension and to resume TEFCA Exchange.

In § 172.402, we proposed provisions related to selective suspension of TEFCA Exchange between QHINs. In § 172.402(a), we proposed that a QHIN may, in good faith and to the extent permitted by Applicable Law, suspend TEFCA Exchange with another QHIN because of reasonable concerns related to the privacy and security of information that is exchanged. In § 172.402(b), we proposed that if a QHIN decides to suspend TEFCA exchange with another QHIN, it is required to promptly notify, in writing, ONC (or an RCE) and the QHIN with which it is suspending exchange of its determination and the reason(s) for making the decision.

These proposed provisions are intended to further 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. We emphasize that we proposed the concerns must be “reasonable” and must be related to the “privacy and security of information that is exchanged” in order to ensure

that suspension of TEFCA Exchange between QHINs is not based on other factors, such as competitive advantage. We solicited comments on examples of reasonable concerns related to the privacy and security of information that is exchanged. These proposed requirements would support trust between QHINs, which is a foundational element of TEFCA and would help TEFCA establish a universal floor for interoperability across the country. We stated that we believe prompt notification of the selective suspension to ONC (or an RCE) and the suspended QHIN would 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.

In § 172.402(c), we proposed that if a QHIN suspends TEFCA Exchange with another QHIN under § 172.402(a), it must, within thirty (30) calendar days, initiate the TEFCA dispute resolution process in order to resolve the issues that led to the decision to suspend, or the QHIN may end its suspension and resume TEFCA Exchange with the other QHIN within thirty (30) calendar days of suspending TEFCA Exchange with the QHIN. We proposed this provision to provide the parties with an opportunity to resolve concerns related to privacy and security and potentially continue exchange once the issues have been resolved. We stated we believe the thirty (30)-day timeframe would provide sufficient time to resolve issues that led to the suspension, end the suspension, and resume TEFCA Exchange activities in a timely manner. Ultimately, TEFCA will be most impactful and successful if QHINs trust each other and are able to confidently exchange information with each other, so it is in the best interests of the QHINs involved, as well as TEFCA overall, to address and resolve a selective suspension quickly, and by the least disruptive means possible.

In § 172.402(d), we proposed that, provided that a QHIN suspends TEFCA exchange with another QHIN in accordance with other provisions in § 172.402 and in accordance with Applicable Law, such selective suspension would not be deemed a violation of the Common Agreement. This provision would promote the integrity of TEFCA by ensuring that a QHIN with reasonable and legitimate concerns related to the privacy and security of information that is exchanged would not be deterred from suspending exchange activities with another QHIN for fear of being in violation of the Common Agreement.

As described elsewhere in this final rule, we have finalized references to

“ONC” in subpart D of the proposed rule as “ASTP/ONC.” For further discussion of the use of “ASTP/ONC,” please see the Executive Summary of this final rule.

Comments. One commenter was supportive of the criteria and process we proposed for the suspension. However, the commenter also highlighted the need to ensure that when a QHIN is suspended, Participants and Subparticipants utilizing that QHIN are protected from actions taken by HHS, ASTP/ONC or the OIG including but not limited to information blocking requirements.

Another commenter was concerned about the lack of clarity regarding the suspension of a QHIN and requested that ASTP/ONC clarify the obligations of hospitals and health systems in such cases to ensure compliance with interoperability rules.

Response. We appreciate the concerns the commenter raised regarding protecting Participants and Subparticipants from actions taken by HHS, ASTP/ONC or the OIG including but not limited to actions related to information blocking requirements. We note that, in the event of suspension of a QHIN’s ability to participate in exchange activities under the Common Agreement, the Common Agreement requires the QHIN 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 (*see* section 17.4.4 of Common Agreement Version 2.1). The Common Agreement also requires the QHIN to require its Participants to 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 (*see* section 17.4.4 of Common Agreement Version 2.1). We believe these provisions provide appropriate transparency to entities affected by a suspension.

With regard to the comments related to protection from actions taken by HHS, ASTP/ONC or the OIG including but not limited to actions related to information blocking requirements, we note that Participants and Subparticipants remain subject to all applicable laws (*e.g.*, HIPAA Privacy, Security, and Breach Notification Rules, and information blocking regulations). We encourage Participants and Subparticipants to review the information blocking regulations, including the exceptions, to determine their applicability to an actor’s facts and circumstances. We also refer readers to section 17.4.4 of the Common

Agreement (which discusses the effect of suspension).

We also encourage organizations that connect to a QHIN to discuss transition plans in the event of a suspension with the QHIN and review any appropriate material or requirements.

Comments. One commenter requested additional information from ASTP/ONC on the consequence for repeated Threat Conditions coming from any one QHIN after a Threat Condition has been cured.

Response. We thank the commenter for the suggestion. We did not make any proposals related to consequences for repeated Threat Conditions coming from any one QHIN after a Threat Condition has been cured; nonetheless, we agree with the commenter that we should consider how to address such situations and whether they warrant additional scrutiny. Because we did not make any proposals related to such consequences, we believe it would be appropriate to solicit public comment before adopting consequences of this nature, so we have finalized this rule without addressing that specific issue. We may consider this suggestion in a future rulemaking.

In § 172.401(d), we modified the final regulatory text to better align with § 172.401(b). Specifically, in § 172.401(b), we state that ASTP/ONC would provide direction to the QHIN to suspend one of the QHIN’s Participants or Subparticipants. In § 172.401(d), we proposed that ONC (or, with ONC’s prior authorization, an RCE) shall lift a suspension of either the QHIN or one of the QHIN’s Participants or Subparticipants once the Threat Condition is resolved. We have changed the final regulatory text in § 172.401(d) to state that ASTP/ONC (or, with ASTP/ONC’s prior authorization, an RCE) shall provide direction to the QHIN to lift the suspension of one of the QHIN’s Participants or Subparticipants once the Threat Condition is resolved. We believe this finalized text better aligns with the text in § 172.401(b), which states that ASTP/ONC (or, with ASTP/ONC’s prior authorization, an RCE) will provide direction to the QHIN regarding the suspension of one of its Participants or Subparticipants.

Comments. A few commenters suggested updates to § 172.401 to clarify the requirements for selective suspension. One commenter suggested that a QHIN should be permitted to selectively suspend exchange with another QHIN’s Participant(s) or Subparticipant(s). The commenter noted that a more targeted suspension is reasonable and practical to implement while any specific issues are addressed. Another commenter requested that ASTP/ONC specify that a QHIN may

implement a selective suspension due to concerns about patient safety and data integrity.

Response. We appreciate the commenters’ support for selective suspension for QHINs. Section 172.402(a), which we have finalized as proposed, states that a QHIN may, in good faith and to the extent permitted by Applicable Law, suspend TEFCA Exchange with another QHIN because of reasonable concerns related to the privacy and security of information that is exchanged. We decline to modify § 172.402 to permit a QHIN to selectively suspend exchange with another QHIN’s Participant(s) or Subparticipant(s). We appreciate the request for a more targeted selective suspension in certain circumstances, but we believe each QHIN should be responsible for ensuring that its Participants and Subparticipants are meeting applicable requirements. We believe the finalized language in § 172.402(a) that states that a QHIN may suspend exchange between another QHIN if there is reasonable concern about the privacy and security of the data, as well as the finalized language in § 172.402(b) that states that the QHIN must notify the other QHIN of the suspension in writing, creates appropriate guardrails for selective suspension.

We have finalized the provisions in subpart D as proposed, except as follows. We have added to § 172.401(a) language requiring an RCE to seek and receive ASTP/ONC’s prior authorization before suspending a QHIN. We have added to § 172.401(b) language requiring an RCE to seek and receive ASTP/ONC’s prior authorization before directing the QHIN to suspend a Participant’s or Subparticipant’s TEFCA Exchange. We have added to § 172.401(d) language requiring an RCE to seek and receive ASTP/ONC’s prior authorization before lifting a suspension of either a QHIN or one of a QHIN’s Participants or Subparticipants once the Threat Condition is resolved. We have modified § 172.103(b) to clarify that ASTP/ONC cannot subdelegate to the RCE those requirements for prior agency authorization. Combined with the review provisions that apply to all RCE actions in subpart F of part 172, this language helps to ensure that an RCE remains subordinate to ASTP/ONC and provides only fact-gathering, ministerial, and administrative support to ASTP/ONC. We have also revised the text of § 172.401 for added clarity.

We also would like to clarify one point regarding the proposed security requirements for QHINs. Earlier in this section we stated that within the TEFCA

infrastructure, QHINs are expected to meet a high bar for security, including compliance with the HIPAA Security Rule or the standards required by the HIPAA Security Rule. We make the distinction between “compliance with the HIPAA Security Rule” and compliance with the standards required by QHIN participation that mirror the HIPAA Security Rule requirements because some entities may not be a covered entity or business associate (*i.e.*, a Non-HIPAA Entity) that are regulated by the HIPAA Security Rule. In order for TEFCA to have consistent security standards, we proposed that even though Non-HIPAA Entities cannot be covered by HIPAA, we can still apply comparable security standards to such entities. To be clear, the HHS Office for Civil Rights (OCR) is the only entity that may determine a HIPAA covered entity’s compliance with the HIPAA Security Rule. Any determination by a third party or by the RCE that a QHIN meets the QHIN requirements does not constitute a determination by HHS of the QHIN’s compliance with the requirements of the HIPAA Security Rule.

E. Subpart E—Termination

In this subpart, we proposed provisions related to a QHIN’s right to terminate its own Designation, ONC’s (or an RCE’s) obligation to terminate a QHIN’s Designation and related notice requirements, and requirements related to the effect of termination. In § 172.501, we proposed that a QHIN may terminate its own QHIN Designation at any time without cause by providing ninety (90) calendar days prior written notice. This provision supports the voluntary nature of TEFCA by allowing a QHIN that, for whatever reason, no longer wants to serve as a QHIN, to terminate its own QHIN Designation with ninety (90) calendar days prior written notice. We stated we believe a QHIN should be able to terminate its Designation, regardless of the circumstances or reason and that ninety (90) calendar days would provide enough time for ONC, the RCE and the departing QHIN to analyze and address the impacts of the QHIN’s departure.

In § 172.502, we proposed that a QHIN’s Designation will be terminated with immediate effect by ONC (or an RCE) giving written notice of termination to the QHIN if the QHIN: (a) fails to comply with any regulations of the part and fails to remedy such material breach within thirty (30) calendar days after receiving written notice of such failure; provided, however, that if a QHIN is diligently working to remedy its breach at the end of this thirty (30) day period, then ONC

(or an RCE) must provide the QHIN with up to another thirty (30) calendar days to remedy its material breach; or (b) a QHIN breaches a material provision of the Common Agreement where such breach is not capable of remedy. We requested comments on examples of material provisions of the Common Agreement where a breach is not capable of remedy.

We stated in the HTI–2 Proposed Rule that we believe these proposals would promote transparency in TEFCA and strengthen the underlying trust among and between entities connected to TEFCA. These termination provisions would enable ONC (or an RCE) to take swift action to remove a non-compliant QHIN and ensure that entities that fail to meet their obligations as QHINs (by failing to comply with the regulations of the part or by breaching a material provision of the Common Agreement) are no longer able to act as QHINs under the TEFCA framework. Without the ability for ONC (or an RCE) to terminate non-compliant QHINs, this trust—which is foundational to TEFCA and necessary for the ultimate success of TEFCA—could quickly erode and undermine TEFCA’s progress.

In § 172.503, we proposed that QHINs and ONC (or an RCE) would be able to terminate the QHIN’s Designation at any time and for any reason by mutual, written agreement. Allowing two parties to terminate an agreement by mutual, written agreement ensures that two parties are not forced to follow an agreement that neither wants to follow. In the HTI–2 Proposed Rule, ONC stated we believe it is reasonable and efficient to allow termination at any time where both ONC (or an RCE) and the QHIN are satisfied that a QHIN’s termination is in the best interest of all.

During the comment period we noticed discrepancies between the use of business days and calendar days when discussing termination in preamble and regulation text. Accordingly, we updated the use of business days (and adopted the full proposed definition of business days in regulation text) and calendar days in the preamble discussion in this subpart to match the use of business days and calendar days in the regulation text we proposed in this subpart.

As described elsewhere in this final rule, we have finalized references to “ONC” in subpart E of the proposed rule as “ASTP/ONC.” For further discussion of the use of “ASTP/ONC,” please see the Executive Summary of this final rule.

Comments. Several commenters noted strong support for the termination process of QHINs when necessary,

particularly in cases of financial instability, violations of guidelines, or failure to meet established qualifications and regulations. Commenters emphasized the importance of having the ability to decertify non-compliant QHINs as needed to uphold the integrity of the system.

Some commenters raised concerns regarding the implications of the termination of a QHIN’s Designation, particularly for Participants and Subparticipants, as well as hospitals and health systems that rely on these networks. Commenters highlighted the lack of a migration plan and support system for these groups, which raises questions about their options during a transition. Additionally, commenters expressed concerns about compliance reporting and potential information blocking claims affecting Participants and Subparticipants if a QHIN is terminated.

Response. We thank these commenters for these comments. We appreciate commenters’ concerns related to termination of QHINs generally, and more specifically related to the effects of a termination on Participants and Subparticipants and the lack of a migration plan, but we believe these comments are out of scope for this final rule because we did not include any proposals in the HTI–2 Proposed Rule to address the effects of a termination.

We also believe the comments related to protection from compliance reporting requirements and the information blocking regulations are out of scope for this final rule because such comments relate to information blocking enforcement. Nonetheless, it is important to emphasize that when a QHIN is terminated, its Participants and Subparticipants will be unable to exchange or respond to queries through that QHIN—meaning TEFCA Exchange would not be possible through that QHIN. We invite Participants and Subparticipants to review the exceptions to the information blocking regulations to determine if the facts of their specific scenarios would fit under an information blocking exception. We also refer readers to section 17.3.5 of the Common Agreement (section 10.3 of the Terms of Participation) which discusses the effect of termination.

We encourage organizations that connect to a QHIN to discuss transition plans with the QHIN as they are discussing connecting to that QHIN and establishing the parameters of their relationship with the QHIN. We also note that, based on the requirements for Designation we have finalized, QHINs should be high-functioning entities that

can support nationwide exchange at scale, and such organizations will have strong incentives to ensure their ongoing participation as QHINs.

Comments. One commenter sought clarification on the rationale behind ASTP/ONC's decision to include all termination provisions of the Common Agreement in the regulation except for section 17.3.5, "Effect of Termination of the Common Agreement." The commenter further stated that its request for clarification underscores the need for transparency and understanding of the regulatory framework affecting QHINs and their stakeholders.

Response. We appreciate this comment. We did not propose to include provisions related to the effect of termination of the Common Agreement because we do not believe that provisions focused on the effect of a termination are necessary in this rulemaking. The termination provisions we included in this rulemaking explain the requirements and processes for termination. If a QHIN is terminated and decides to appeal the decision, the requirements and processes in this rulemaking would be integral in deciding whether the appeal would be successful. On the other hand, provisions related to the effect of termination would have little bearing on the ultimate success of an appeal and thus we do not think it is necessary to include such provisions in this rulemaking. As the commenter noted, there is a provision in the Common Agreement that addresses the effect of termination.

We have finalized all provisions in subpart E as proposed. In addition, we have added to § 172.502 language requiring an RCE to seek and receive ASTP/ONC's prior authorization before terminating a QHIN. Under § 172.103(b), ASTP/ONC cannot subdelegate to the RCE this requirement for prior agency authorization. Combined with the review provisions that apply to all RCE actions in subpart F of part 172, this language helps to ensure that an RCE remains subordinate to ASTP/ONC and provides only fact-gathering, ministerial, and administrative support to ASTP/ONC.

F. Subpart F—Review of RCE[®] or ASTP/ONC Decisions

ASTP/ONC oversees the RCE's work and has the right to review the RCE's conduct and its execution of nondiscrimination and conflict of interest policies that demonstrate the RCE's commitment to treating QHINs in a transparent, fair, and

nondiscriminatory way.²⁰ In subpart F, we proposed to establish processes for review of RCE or ONC actions, including QHIN appeal rights and the process for filing an appeal. These appeal rights would ensure that a QHIN or Applicant QHIN that disagrees with certain RCE or ONC decisions will have recourse to appeal those decisions. Our proposed § 172.600 reflects this overall scope as an applicability section for this subpart.

In § 172.601, we proposed provisions to establish ONC's authority to review RCE determinations, policies, and actions, as well as procedures for exercising such review. We proposed in § 172.601(a) that ONC may, in its sole discretion, review all or any part of any RCE determination, policy, or action. In § 172.601(b) we proposed ONC may, in its sole discretion and on notice to affected QHINs or Applicant QHINs, stay any RCE determination, policy, or other action. In § 172.601(c), we proposed ONC may, in its sole discretion and on written notice, request that a QHIN, Applicant QHIN, or the RCE provide ONC additional information regarding any RCE determination, policy, or other action. In § 172.601(d), we proposed that on completion of its review, ONC may affirm, modify, or reverse the RCE determination, policy, or other action under review. Additionally, we proposed to provide notice to affected QHINs or Applicant QHINs that includes the basis for ONC's decision. In § 172.601(e), we proposed ONC will provide written notice under this section to affected QHINs or Applicant QHINs in the same manner as the original RCE determination, policy, or other action under review. We stated we believe these proposals provide transparency into the level of oversight ONC has in reviewing RCE determinations, policies, or actions and firmly establish ONC's authority to affirm, modify, or reverse such determinations, policies, and actions. We also noted we believe these provisions are important to assure QHINs and Applicant QHINs that we have the ability to effectively exercise oversight of the RCE, as well as provide all parties with an interest in the administration of TEFCA with confidence that we can and will take necessary action to ensure that QHINs and Applicant QHINs comply with the regulations we proposed in part 172.

²⁰ See Common Agreement section 3.1, 89 FR 35107 (May 1, 2024), <https://www.federalregister.gov/documents/2024/05/01/2024-09476/notice-of-publication-of-common-agreement-for-nationwide-health-information-interoperability-common>.

In § 172.602, we proposed to establish bases for Applicant QHINs and QHINs to appeal decisions to ONC. We proposed that an Applicant QHIN or QHIN may appeal certain decisions to ONC or a hearing officer, as appropriate. In § 172.602(a)(1), we proposed that an Applicant QHIN would be able to appeal the denial of its application. In § 172.602(a)(2), we proposed that a QHIN would be able to appeal a decision to (1) suspend a QHIN or instruct a QHIN to suspend its Participant or Subparticipant; or (2) terminate a QHIN's Common Agreement. We requested comment on the proposed bases for appeal.

In § 172.603, we proposed the method and timing for filing an appeal. In § 172.603(a), we proposed that to initiate an appeal, an authorized representative of the Applicant QHIN or QHIN must submit electronically, in writing to ONC, a 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 the decision being appealed within fifteen (15) calendar days of the Applicant QHIN's or QHIN's receipt of the notice of denial of an application, suspension or instruction to suspend its Participant or Subparticipant, or) termination. With regard to an appeal of a termination, the fifteen (15) calendar day timeframe may be extended by ONC up to another fifteen (15) calendar days if the QHIN has been granted an extension for completing its remedy under § 172.502(a). The notice of appeal would serve to notify ONC that the Applicant QHIN or QHIN is planning to file an appeal and would require inclusion of only the minimum amount of information necessary to provide such notice (*i.e.*, 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). As such, we stated we believe fifteen (15) business days would be an adequate amount of time for deciding whether to initiate an appeal and submitting such information.

In § 172.603(b), we proposed that an authorized representative of an Applicant QHIN or QHIN must submit electronically, to ONC, within thirty (30) calendar days of filing the intent to appeal: (1) A statement of the basis for appeal, including a description of the facts supporting the appeal with citations to documentation submitted by the QHIN or Applicant QHIN; and (2) Any documentation the QHIN would like considered during the appeal.

We stated we expect that it would take an Applicant QHIN or QHIN some

time to collect all of the relevant information and documentation to support its appeal, and accordingly proposed a timeframe for requesting an appeal of thirty (30) calendar days from the filing of the intent to appeal with ONC. We welcomed comments on whether this timeframe, as well as the timeframe for submitting an intent to appeal, are adequate and appropriate.

In § 172.603(c), we proposed that an Applicant QHIN or QHIN filing the appeal may not submit on appeal any evidence it did not submit prior to the appeal, except by permission of the hearing officer. We stated we believe this provision balances a QHIN or Applicant QHIN's right to introduce evidence with the need for orderly proceedings. We are aware that under our proposed regulations, QHINs facing suspension or termination do not have an express right to introduce evidence. We solicited comments on whether and when a QHIN facing suspension or termination should have a right to introduce that evidence—for example as part of demonstrating that a material breach has been remedied or is capable of remedy under § 172.502, at the hearing officer stage, or some combination of the two based on circumstances of the suspension or termination.

In § 172.604, we proposed that an appeal would not stay a suspension or termination, unless otherwise ordered by ONC or the hearing officer assigned under § 172.605(b). This means that in the event of an appeal of a suspension or termination, the appeal would not stop the suspension or termination from being effective. We stated we believe this proposed approach is important because a QHIN would only be suspended or terminated for infractions that could, for example, jeopardize the privacy and security of TEFCA Exchange.

Before a QHIN is terminated under § 172.502(a), we noted the QHIN would have already been given an opportunity to remedy the breach unless the breach is not capable of remedy. The move by ONC or an RCE to terminate a QHIN would mean either the QHIN tried and failed to remedy the issue, or a remedy is not possible. In either case, we stated we believe it would be appropriate not to stay the termination. In the case of a suspension, the QHIN would have been found to be responsible for a Threat Condition, and we stated we believe the risk to the privacy and security of the TEFCA ecosystem would far outweigh any perceived benefit of staying the suspension.

In § 172.605, we proposed provisions related to the assignment of a hearing

officer. In § 172.605(a), we proposed that, in the event of an appeal, the National Coordinator may exercise authority under § 172.601 to review the RCE determination being appealed. We further proposed an appealing QHIN or Applicant QHIN that is not satisfied with ONC's subsequent determination may appeal that determination to a hearing officer by filing a new notice of appeal and other appeal documents that comply with § 172.603. In § 172.605(b), we proposed if ONC declines review under paragraph (a), or if ONC made the determination under review, ONC would arrange for assignment of the case to a hearing officer to adjudicate the appeal.

We specified in proposed § 172.605(c) that the hearing officer must be an officer appointed by the Secretary of Health and Human Services (for more information about officers and appointments, see section III.D.5.c of the HTI–2 Proposed Rule, 89 FR 63612 through 63615). In § 172.605(d), we proposed, the hearing officer may not be responsible to, or subject to the supervision or direction of, personnel engaged in the performance of investigative or prosecutorial functions for ONC, nor may any officer, employee, or agent of ONC engaged in investigative or prosecutorial functions in connection with any adjudication, in that adjudication or one that is factually related, participate or advise in the decision of the hearing officer, except as a counsel to ONC or as a witness.

In § 172.606, we proposed requirements related to adjudication. In § 172.606(a), we proposed that the hearing officer would decide issues of law and fact *de novo* and would apply a preponderance of the evidence standard when deciding appeals. *De novo* review means that the hearing officer would decide the issue on appeal without deference to a previous decision (*i.e.*, ONC's or the RCE's decision to (1) deny an application, (2) suspend a QHIN or to instruct a QHIN to suspend its Participant or Subparticipant, or (3) terminate a QHIN's Common Agreement). We stated we believe *de novo* review is appropriate for appeals by Applicant QHINs or QHINs because ONC ultimately has responsibility for TEFCA operations and implementation, even though the RCE is a contractor acting on ONC's behalf. Given the gravity and potentially significant implications (financial, effect on existing contracts, etc.) of a denied application, suspension, or termination, we noted we believe the hearing officer the National Coordinator arranges to be assigned should make an independent

decision, taking all of the facts and evidence the parties present into consideration.

As described in the HTI–2 Proposed Rule, the “preponderance of the evidence” standard means the burden of proof is met when the party with the burden (the appealing Applicant QHIN or QHIN) convinces the fact finder (hearing officer) that there is a greater than 50% chance that the claim is true. This standard is used in most civil cases and would only require the appealing party to show that a particular fact or event was more likely than not to have occurred. We stated we believe this threshold creates the right balance for requiring an appealing Applicant QHIN or QHIN to make a strong case to succeed on appeal, while not imposing a standard that would be extremely difficult for the appeal Applicant QHIN or QHIN to meet. We requested comment on whether the “preponderance of the evidence” is the appropriate standard, or if another standard (*e.g.*, clear and convincing evidence, beyond a reasonable doubt, etc.) would be more suitable.

In § 172.606(b), we proposed that a hearing officer would make a determination based on the written record or any information from a hearing conducted in-person, via telephone, or otherwise (for example, via video teleconference). We proposed that the written record would include ONC's or the RCE's determination and supporting information, as well as all appeal materials submitted by the Applicant QHIN or QHIN pursuant to § 172.603. We proposed these requirements for the written record because it is important that the written record reflect both the position of ONC or the RCE and the Applicant QHIN or QHIN. We proposed that the hearing officer would have sole discretion to conduct a hearing in certain situations. We proposed that the hearing officer could conduct a hearing to require either party to clarify the written record under § 172.606(b)(1). Last, we proposed that the hearing officer could conduct a hearing if they otherwise determine a hearing is necessary. We stated we believe the last provision is necessary because it gives the hearing officer discretion to conduct a hearing based on the specific circumstances surrounding the appeal, even if the need for the hearing does not fit under the first or second criteria detailed above.

In § 172.606(c), we proposed that a hearing officer would neither receive witness testimony nor accept any new information beyond what was provided in accordance with paragraph (b) of this section, except for good cause shown by

the party seeking to submit new information. We noted we believe this provision will help ensure that the appeals process is consistent and fair for all involved.

In § 172.607, we proposed requirements related to a decision by the hearing officer. In § 172.607(a), we proposed that the hearing officer would issue a written determination. We requested comment on whether we should include a specific timeframe for issuing the written determination, or whether abstaining from including a specific timeframe is a better approach given the varying complexity and circumstances of each appeal.

To ensure accountability, and to ensure that the hearing officer's decisions would be subject to the discretionary review of a principal officer of the United States, we proposed in § 172.607(b) that a hearing officer's decision on an appeal is the final decision of HHS unless within 10 business days, the Secretary, at the Secretary's sole discretion, chooses to review the determination. We also proposed that ONC would notify the appealing party if the Secretary chooses to review the determination and once the Secretary makes his or her determination. We did not propose a specific timeframe for the Secretary to complete their review (if the Secretary chooses to review) because we believe that if the Secretary makes the decision to review a hearing officer's determination, the Secretary would be informed enough on the issues of the case to determine an appropriate review timeframe.

As described elsewhere in this final rule, we have finalized references to "ONC" in subpart F of the proposed rule as "ASTP/ONC." For further discussion of the use of "ASTP/ONC," please see the Executive Summary of this final rule.

Comments. Commenters were generally supportive of ASTP/ONC's proposal for a review process of RCE or ASTP/ONC decisions but expressed concerns regarding the scope and standard of ASTP/ONC's review of RCE and prior ASTP/ONC decisions. In particular, some commenters stated that ASTP/ONC's discretion for review of RCE or prior ASTP/ONC decisions would be too broad and suggested that ASTP/ONC include narrower requirements for when a Hearing Officer can review RCE or prior ASTP/ONC decisions *de novo*, such as limiting use of the *de novo* standard to only when it was a denial of QHIN designation. A few commenters also suggested that ASTP/ONC specify a timeframe for ASTP/ONC review and decision and

similarly for review and written decisions by a hearing officer. One commenter recommended that a hearing officer have 30 days to issue a written decision on an appeal.

Response. We appreciate commenters' concerns about the scope of ASTP/ONC's ability to review decisions and the timeframe for when a hearing officer must issue a decision. In this final rule, we finalize all subpart F proposals as proposed, except for revisions made in response to comments as discussed here. As TEFCA participation grows, it is important for ASTP/ONC and a hearing officer to be able to review decisions that are impactful to TEFCA participation, and in a manner that gives all TEFCA participants confidence in TEFCA. A *de novo* standard supports such confidence because the hearing officer can exercise independent judgment and review of all relevant facts and law. As for the timeframe for reviews, a 30-day timeframe for issuing a decision by either ASTP/ONC or a hearing officer under subpart F could be too limiting in complex cases. However, we do believe that providing clarity on timeframes for decisions would be helpful to parties subject to ASTP/ONC and/or hearing officer decisions. Accordingly, we have revised subpart F in two ways. We have specified in § 172.601(f) that ASTP/ONC will issue a decision within a timeframe agreed to by the affected Applicant QHIN or QHIN, as applicable, the RCE, and ASTP/ONC. ASTP/ONC may, however, at its sole discretion, extend the timeframe for a decision as circumstances necessitate. This remains consistent with our proposal in that we did not place a time limit on issuing a decision. ASTP/ONC will issue a decision by mailing or sending electronically written notice of such decision as specified in § 172.601(e). Similarly to ASTP/ONC timeframe revision, we have revised § 172.607(a) to specify that the hearing officer will issue a written determination within a timeframe agreed to by the affected Applicant QHIN or QHIN, as applicable, and ASTP/ONC and approved by the hearing officer. The hearing officer may, at their sole discretion, extend the timeframe for a written determination as circumstances necessitate. Again, this is consistent with our proposal in that we did not place a time limit on issuing a decision.

We have also revised the format of § 172.603(a) to provide clarity regarding the method and timing for an applicant QHIN or QHIN to file an appeal. The addition of the numerated list in § 172.603(a) is a formatting change made for clarity.

In addition, we have added to §§ 172.601(a) and (b) and 172.605(a) language that if ASTP/ONC reviews (under § 172.601(a)) or stays (under § 172.601(b)) an RCE determination for which regulations in part 172 required ASTP/ONC's prior authorization, no agent, official, or employee of ASTP/ONC who helped to evaluate or decide the prior authorization, or a prior authorization involving the same party(s) or underlying facts, may participate in deciding or advising ASTP/ONC on its review of (including whether it should stay) that determination. This language will help protect any review by ASTP/ONC of the RCE from influence by someone who previously authorized the RCE action under review, protect the fairness and integrity of ASTP/ONC's review process, and preserve the separation of functions within ONC.

Comments. A commenter raised concerns that the scope of subpart F was too limiting. The commenter recommended that disputes between QHINs, and between a QHIN and a Participant, should be afforded review and appeal under the regulations. The commenter argued that a QHIN's dispute resolution policy, which it is required to maintain per subpart B, would be ineffective in resolving disputes between QHINs or with a Participant of another QHIN. The commenter further asserted that a QHIN's decision to take action against a Participant significantly affects that Participant, their patients, and other Participants (including from other QHINs) that rely on the Participant's data to make care decisions. As such, the commenter specifically recommended that we include a process for appeal and ASTP/ONC review of QHIN decisions to suspend Participants or Subparticipants, including providing a Participant the opportunity to appeal such decisions. The commenter also recommended that a QHIN be afforded the right to appeal an instruction (presumably by the RCE or ASTP/ONC) to suspend a Participant or Subparticipant.

Response. We did not propose the scope of review and appeals that the commenter recommends, and the public was not put on notice that such a policy might be finalized and given an opportunity to comment. Thus, we decline to adopt such an approach in this final rule.

We note that we considered proposing to extend the appeal process to Participants and Subparticipants but decided against proposing that approach for a couple reasons. First, we believe that QHINs should have the autonomy

to make decisions within their respective networks. Second, we note that Participants and Subparticipants are able to join different QHINs if they cannot resolve a dispute with an existing QHIN.

For similar reasons, we believe the Dispute Resolution Process should be limited to disputes filed by the RCE or a QHIN. A QHIN could elevate a dispute on behalf of its Participant or Subparticipant to the Dispute Resolution Process, but we believe that is a decision that should be left to the respective QHIN.

G. Subpart G—QHIN™ Attestation for the Adoption of the Trusted Exchange Framework and Common Agreement™

Section 4003(b) of the Cures Act added section 3001(c)(9), “Support for Interoperable Networks Exchange,” to the PHSA. Section 3001(c)(9)(D)(ii) requires HHS to establish, through notice and comment rulemaking, a process for HINs that voluntarily elect to adopt TEFCA to attest to such adoption of the framework and agreement. Section 3001(c)(9)(D)(i) also requires the National Coordinator to publish on ONC’s website a list of the HINs that have adopted the Common Agreement and are capable of trusted exchange pursuant to the Common Agreement.

QHINs are the only entities permitted to “adopt” the Common Agreement, which is accomplished by becoming a signatory to the Common Agreement. As such, we proposed that only QHINs would be able to attest to the adoption of the Common Agreement and the Trusted Exchange Framework. While the Trusted Exchange Framework was foundational for creating the provisions of the Common Agreement, it is, as noted above, a separate set of principles. Therefore, we proposed that for purposes of attesting to the adoption of the Trusted Exchange Framework, QHINs would be required to expressly attest to their agreement and adherence to the Trusted Exchange Framework.²¹

We described that once attestation is complete and deemed valid, QHINs would be publicly listed on ONC’s website. This regulatory provision would implement the HIN attestation provision from the Cures Act and would provide benefits to the public, Federal partners, and interested parties. For example, a Federal website listing of attesting QHINs would make it easy for the public to identify whether an entity is or is not a QHIN and provide a

resource for Federal partners to help determine whether participants in some of their programs also belong to a network that is recognized as a QHIN. Section 3001(c)(9)(E) provides the option for Federal agencies to require, under certain circumstances, adoption of TEFCA for health information exchange networks that they contract with or enter into agreements with.

To implement sections 3001(c)(9)(D)(i) and (ii) of the PHSA, we proposed to establish subpart G in part 172, titled “QHIN Attestation for the Adoption of the Trusted Exchange Framework and Common Agreement.”

We proposed in § 172.700 that subpart G would establish the attestation submission requirements applicable to QHINs. In § 172.701, we proposed attestation submission requirements for QHINs and review and acceptance processes that ONC will follow for TEFCA attestations. In § 172.701(b), we proposed that in order to be listed in the QHIN Directory described in proposed § 172.702, a QHIN would be required to submit to ONC an attestation affirming agreement with and adherence to the Trusted Exchange Framework and its adoption of the Common Agreement. We further proposed in § 172.701(b) that a QHIN would be required to submit to ONC identifying information consisting of its name, address, city, state, zip code, and a hyperlink to its website. We also proposed that the QHIN would be required to submit to ONC identifying information about its authorized representative including the representative’s name, title, phone number, and email address. We proposed that a QHIN would also be required to provide documentation confirming its Designation as a QHIN. We also proposed that a QHIN would be required to provide ONC with written notice of any changes to its identifying information provided in accordance with § 172.701 within 30 calendar days of the change(s) to its identifying information. We noted we believe the above provisions provide clear instructions for submitting a QHIN attestation that will support a consistent and transparent QHIN attestation process and provides ONC with the information needed to identify the entity and contact the authorized representative.

We proposed in § 172.701(c) that a QHIN must electronically submit its attestation and documentation specified in § 172.701(b) either via an email address identified by ONC or via a submission on the ONC website, if available. We proposed in § 172.701(d) that once a QHIN has submitted its attestation and documentation, ONC

would either accept or reject the submission within 30 calendar days. We proposed that ONC would accept the submission if it determines that the QHIN has satisfied the requirements of § 172.701(b) and (c). In such instances, we proposed that ONC would provide written notice to the applicable QHIN’s authorized representative that the submission has been accepted. In § 172.701(d), we also proposed that ONC would reject a submission if it determines that the requirements of § 172.701(b) or (c), or both, have not been satisfied. In such instances, we proposed that ONC would provide written notice to the QHIN’s authorized representative of the determination along with the basis for the determination. We proposed that an ONC determination would be a final agency action and not subject to administrative review, except the Secretary may choose to review the determination as provided in § 172.607(b). However, we proposed that a QHIN may, at any time, resubmit an attestation and documentation in accordance with §§ 172.701(b) and (c). We stated we believe these submission procedures will support a consistent and transparent QHIN attestation process. We welcomed comments on these procedures.

In § 172.702, we proposed the requirements for a QHIN directory. We proposed in § 172.702(a) that this subpart would establish processes for publishing a directory of QHINs on the ONC website. We proposed in § 172.702(b)(1) that, within fifteen (15) calendar days of notifying a QHIN that its submission has been accepted, ONC would publish, at a minimum, the QHIN’s name in the QHIN directory.

We proposed § 172.702(b)(2) to identify within the QHIN directory those QHINs that have been suspended under the Common Agreement. A QHIN directory that includes QHINs that have adopted the Common Agreement and are capable of TEFCA Exchange and those QHINs suspended under the Common Agreement offers a transparent list of QHINs participating in TEFCA. As noted above, the QHIN directory may serve as a useful tool for the public, Federal partners, and other interested parties seeking information about QHINs. Therefore, we welcomed comments regarding the information we proposed to include in the QHIN directory.

We proposed in § 172.702(c) to establish requirements for removal of a QHIN from the QHIN directory. We proposed in § 172.702(c)(1) that ONC will remove a QHIN that is no longer eligible for QHIN status from the QHIN

²¹ The Trusted Exchange Framework (TEF): Principles for Trusted Exchange (January 2022), https://www.healthit.gov/sites/default/files/page/2022-01/Trusted_Exchange_Framework_0122.pdf.

directory. We proposed that a QHIN whose Common Agreement has been terminated would no longer be considered a QHIN and so would be removed from the QHIN directory. We noted the removal of a QHIN whose Common Agreement has been terminated from the QHIN Directory would be a ministerial action by ONC.

We proposed in § 172.702(c)(2) that upon termination of a QHIN's Common Agreement, ONC (or an RCE) will send a written statement of intent to remove the QHIN from the QHIN Directory to the authorized representative of the QHIN. Under § 172.702(c)(3), we proposed that the written statement would include, as appropriate, (i) the name of the terminated QHIN and the name and contact information of the authorized representative of the QHIN; (ii) a short statement setting forth findings of fact with respect to any violation of the Common Agreement or other basis for the QHIN's termination; (iii) other materials as the RCE may deem relevant. In § 172.702(d), we proposed that a QHIN that is removed from the QHIN Directory would remain removed until a new attestation is accepted by ONC in accordance with the processes specified in subpart G of the part. In § 172.702(e), we proposed that an ONC determination under § 172.702 is final agency action and not subject to further administrative review, except the Secretary may choose to review the determination as provided in § 172.607(b). We stated we believe this proposal was appropriate because a QHIN would have had ample opportunity to appeal its termination under the provisions in proposed subpart F (89 FR 63654).

We sought comments on alternative ways to structure the requirements to remove a QHIN from the QHIN directory.

Comments. Multiple commenters agreed with our proposal to require QHINs to attest, with one commenter noting the potential burden attestation could cause for all other Participants and Subparticipants. Another commenter, while not suggesting we impose attestation requirements, recommended that we include all TEFCA Participants, Subparticipants and delegates along with their entity type (e.g., health plan, provider, delegate of provider) and relationship(s) in a publicly accessible directory on ASTP/ONC's website. The commenter asserted that this would provide greater transparency and help health care organizations understand the networks that other entities participate in to determine whether a connection already

exists or if a new exchange needs to be set-up.

Response. We appreciate commenters' agreement with our proposal and one commenter's suggestions. In this final rule, we have finalized a requirement, in order to be listed in the QHIN Attestation Directory, that applies only to QHINs that attest. We have also finalized all subpart G proposals as proposed, except for revisions made in response to comments discussed here and below. We generally strive to improve transparency where appropriate and permissible. Congress authorized, in PHSA section 3001(c)(9)(D), a directory of health information networks, which is a directory narrower in scope than the commenter suggested and that we proposed. Therefore, we decline to adopt the commenter's suggested changes to the scope of information included in the QHIN Attestation Directory. We will consider ways in which TEFCA can improve such transparency for QHINs, Participants, Subparticipants, and the public at large.

Comments. One commenter did not support the QHIN attestation proposal, arguing that it was unnecessary and duplicative of a QHIN signing the Common Agreement. The commenter further questioned the requirement to "adhere to" the Trusted Exchange Framework (TEF), noting that, by its own terms, it is a compilation of non-binding principles. Another commenter similarly argued that the TEF was broad and could not be practically "adhered to." Both of these commenters inquired as to what "adhere to" meant in terms of the TEF, with one suggesting that "adhere to" be replaced with "agreement with." One commenter suggested that we clarify that any rejection of an attestation by ASTP/ONC will not affect the QHIN's designation status or ability to participate in TEFCA.

Response. Establishing a process for attesting to the adoption of TEFCA by QHINs that voluntarily elect to adopt TEFCA fulfills a statutory obligation by ASTP/ONC. Such a process is paired with the public posting on our website of a directory of these QHINs, which may provide easy recognition and validation for the public of those entities that have been deemed QHINs under TEFCA. We agree with commenters that our proposed wording in § 172.701(b)(1)(i)(A) of ". . . [a]greement with and adherence to the [TEF] . . ." may cause confusion and perceived contradiction with what are characterized as broad, non-binding principles. The statute uses the term "adoption" with regard to both the Common Agreement and TEF. As such,

we are reverting to use of this term under our regulatory process for attesting to adoption of the Common Agreement and the TEF by revising § 172.701(b)(1)(i) to read as follows: "[a]ttestation affirming its adoption of the Common Agreement and Trusted Exchange Framework." For clarity, by attesting to "adopt" the TEF, we mean a QHIN would practice and use the TEF principles. We also clarify that the regulatory process for QHIN attestation is separate and distinct from the regulatory criteria we are finalizing for obtaining and maintaining QHIN status, as well as any requirements in the Common Agreement.

Comments. Multiple commenters expressed a need for a definitive attestation schedule for QHINs. One commenter suggested that we incorporate the required attestation into the RCE's onboarding and designation process.

Response. Attestation would be expected each time a QHIN signs the Common Agreement, including new versions, and/or the TEF is updated. To be listed on the ASTP/ONC website, QHINs would need to comply with the attestation submission and acceptance requirements of § 172.701. As proposed and finalized in § 172.701 a QHIN will be able to electronically submit its attestation via email or via the ASTP/ONC website, if available. The exact timing (beyond when signing the Common Agreement and/or when the TEF is updated) and specifics of the submission method, such as by use of a voluntary standard form, will not be codified in regulation through this final rule, but will be determined in a manner that best aligns with statutory obligations and overall efficiencies.

Comments. Multiple commenters expressed concern that use of "QHIN Directory" will confuse stakeholders, as the Common Agreement refers to an "RCE Directory Service" and the QHIN Technical Framework (QTF) refers to a "QHIN Directory." One commenter suggested that we establish a hyperlink from our website to the RCE website because the RCE maintains a list of QHINs.

Response. Our approach, finalized in this final rule, fulfills a specific statutory requirement to post the names on our website. We agree with the commenters that "QHIN Directory" may cause some confusion. Therefore, in alignment with the statutory instruction, we are renaming the directory "QHIN Attestation Directory" and have revised references throughout §§ 172.701 and 172.702 accordingly to refer to the "QHIN Attestation Directory" rather than the QHIN Directory. We have also

revised § 172.702(a) (“Applicability”) to more clearly align with statutory instruction by stating “[t]his subpart establishes processes for publishing a directory on the ASTP/ONC website of QHINs that voluntarily elect to adopt TEFCA and attest to such adoption.” We also note, in response to comment, that we currently provide a hyperlink to the RCE website from our website.

As described elsewhere in this final rule, we have finalized references to “ONC” in subpart G of the proposed rule as “ASTP/ONC.” For further discussion of the use of “ASTP/ONC,” please see the Executive Summary of this final rule. We also made a minor change to § 172.702(c)(3)(iii) by removing the word “the” before ASTP/ONC, to align with other references to ASTP/ONC. This change is for clarity and is non-substantive.

VI. Severability

As we explained in the HTI–2 Proposed Rule (89 FR 63511), it was our intent that if any provision of the proposed rule were, if or when finalized, held to be invalid or unenforceable—facially or as applied to any person, plaintiff, or circumstance—or stayed pending further judicial or agency action, such provision shall be severable from other provisions finalized, and from rules and regulations otherwise in effect, and not affect the remainder of provisions finalized. It was and continues to be our intent that, unless such provision shall be held to be utterly invalid or unenforceable, it be construed to give the provision maximum effect permitted by law including in the application of the provision to other persons not similarly situated or to other, dissimilar circumstances from those where the provision may be held to be invalid or unenforceable.

This final rule establishes part 172 and finalizes revisions to certain sections within 45 CFR parts 170 and 171. The provisions finalized in this final rule, whether codified in 45 CFR part 170, 171, or 172, are intended to and will operate independently of each other and of provisions finalized in previous rules, even if multiple of them may serve the same or similar general purpose(s) or policy goal(s). Where any section or paragraph in part 170, 171, or 172 is necessarily dependent on another, the context generally makes that clear (such as by cross-reference to a particular standard, requirement, condition, or pre-requisite, or other regulatory provision). Where any section or paragraph within 45 CFR part 170, 171, or 172 includes a dependency on any provision of any section or

paragraph of any part in title 45 of the CFR, or in any other title of the CFR, that is stayed or held invalid or unenforceable (as described in the preceding paragraph), we intend that other provisions of such paragraph(s) or section(s) in 45 CFR part 170, 171, or 172 that operate independently of said provision would remain in effect.

For example, if the regulation at § 171.403 TEFCA Manner Exception were stayed or held facially invalid or unenforceable in whole or in part, we would intend for the other information blocking exceptions in part 171 to remain available to actors, and for all sections and paragraphs within parts 170 and 172 to also continue to be in effect. To provide another example, if any provision of any section or paragraph of part 172 were stayed or held utterly invalid or unenforceable, we would intend for all other sections in part 172 that do not depend upon the stayed or invalidated provisions to remain in full effect. Similarly, if any provision of part 172 were stayed or held to be invalid or unenforceable as applied to any person, plaintiff, or circumstance, it is our intent that such provision—and any section or paragraph of part 172, 171, or 170 that may reference such provision—be construed to give the provision maximum effect permitted by law including in the application of the provision to other persons not similarly situated or to other, dissimilar circumstances from those where the provision may be held to be invalid or unenforceable.

To ensure our intent for severability of provisions is clear in the CFR, we proposed (as explained at 89 FR 63511) the addition to §§ 170.101 (89 FR 63766) and 171.101 (89 FR 63802), and inclusion in the newly codified § 172.101 (89 FR 63805), of a paragraph stating our intent that if any provision is held to be invalid or unenforceable it shall be construed to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which case the provision shall be severable from the part and shall not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other dissimilar circumstances.

We did not receive any comments specific to our proposal to codify paragraphs stating our intent for severability in part 170, 171, or 172 or regarding our explanation that the provisions finalized in this rule are intended to and will operate independently of each other. We have finalized as proposed, the addition to

§§ 170.101 and 171.101, and inclusion in the newly codified § 172.101, a paragraph stating our intent for severability of provisions in each of these parts. We affirm and emphasize our intent that if any provision of this final rule were held to be invalid or unenforceable—facially or as applied to any person, plaintiff, or circumstance—or stayed pending further judicial or agency action, such provision shall be severable from other provisions of this rule, and from rules and regulations currently in effect, and not affect the remainder of this rule. We further affirm and emphasize our intent that if any provision codified in part 170, 171, or 172, whether finalized in this or a prior rule, were to be held to be invalid or unenforceable—facially or as applied to any person, plaintiff, or circumstance—or stayed pending further judicial or agency action, such provision shall be severable from other provisions of this rule, and from rules and regulations currently in effect, and not affect the remainder of this final rule. It is also our intent that, unless such provision shall be held to be utterly invalid or unenforceable, it be construed to give the provision maximum effect permitted by law including in the application of the provision to other persons not similarly situated or to other, dissimilar circumstances from those where the provision may be held to be invalid or unenforceable.

VII. Collection of Information Requirements—Qualified Health Information Networks™

Under the Paperwork Reduction Act of 1995 (PRA), codified as amended at 44 U.S.C. 3501 *et seq.*, agencies are required to provide a 60-day notice in the **Federal Register** and solicit public comment on a proposed collection of information before it is submitted to OMB for review and approval. In order to fairly evaluate whether an information collection should be approved by the OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

1. Whether the information collection is necessary and useful to carry out the proper functions of the agency.
2. The accuracy of the agency’s estimate of the information collection burden;
3. The quality, utility, and clarity of the information to be collected; and
4. Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Under the PRA, the time, effort, and financial resources necessary to meet

the information collection requirements referenced in this section are to be considered. We solicited comment on our assumptions as they relate to the PRA requirements summarized in this section.

Qualified Health Information Networks™

As stated in the HTI–2 Proposed Rule (89 FR 63661), we proposed in § 172.301 to establish the information Applicant QHINs must submit in order to be Designated as a QHIN. We proposed that an Applicant QHIN must submit: (1) a completed QHIN application; and (2) a signed copy of the Common Agreement. We noted that we may update the application over time and the most recent version will be available on ASTP/ONC’s and the RCE’s website.

In § 172.701, we proposed attestation submission requirements for QHINs and review and acceptance processes that ONC would follow for TEFCA attestations. In § 172.701(b), we proposed that in order to be listed in the

QHIN Directory described in proposed § 172.702, a QHIN would be required to submit to ONC an attestation affirming agreement with and adherence to the Trusted Exchange Framework and its adoption of the Common Agreement. We further proposed in § 172.701(b) that a QHIN would be required to submit to ONC identifying information consisting of its name, address, city, state, zip code, and a hyperlink to its website. We also proposed that the QHIN would be required to submit to ONC identifying information about its authorized representative including the representative’s name, title, phone number, and email address.

We proposed that a QHIN would also be required to provide documentation confirming its Designation as a QHIN. We also proposed that a QHIN would be required to provide ONC with written notice of any changes to its identifying information provided in accordance with § 172.701 within 30 calendar days of the change(s) to its identifying information.

We stated our belief that QHINs would face minimal burden in complying with the proposed application, attestation, and supporting documentation requirements. For the purposes of estimating the potential burden, we estimated that 15 Applicant QHINs would apply and subsequently submit an attestation to ONC. We stated that it would take approximately one hour on average for an applicant QHIN to submit a completed QHIN application. We also stated that it would also take approximately one hour on average for a QHIN to complete and submit to ONC their attestation and required documentation. We stated that we expect a general office clerk could complete these required responsibilities.²² We welcomed comments on whether more or fewer QHINs should be included in our estimate. We also welcomed comments on whether more or less time should be included in our estimate.

TABLE 2—ESTIMATED ANNUALIZED TOTAL BURDEN HOURS FOR QHINs TO COMPLY WITH APPLICATION AND ATTESTATION REQUIREMENTS

Code of Federal Regulations section	Number of applicant QHIN or QHINs	Average burden hours	Total
45 CFR 172.301	15	1	15
45 CFR 172.701	15	1	15
Total Burden Hours			30

Comments. We did not receive any comments related to information collection activities for QHINs.

Response. We have finalized our regulatory collection of information requirements as proposed, but with unrelated revisions to subparts B, C, and G.

VIII. Regulatory Impact Analysis

A. Statement of Need

This final rule is necessary to meet our statutory responsibilities under the Cures Act and to advance HHS policy goals to promote interoperability and information sharing.

B. Alternatives Considered

We have been unable to identify alternatives that would appropriately implement our responsibilities under the Cures Act and support interoperability and information sharing consistent with our policy goals. We believe our policies take the necessary

steps to fulfill the mandates specified in the PHSA, as amended by the HITECH Act and the Cures Act, in the least burdensome way. We welcomed comments on our assessment and any alternatives we should have considered.

Comments. We did not receive any comments on alternatives that we should have considered related to the provisions included in this final rule.

Response. We have finalized our assessments on the proposals finalized in this final rule.

C. Overall Impact—Executive Orders 12866 and 13563—Regulatory Planning and Review Analysis

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094, entitled “Modernizing

Regulatory Review” (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96354), section 202 of the Unfunded Mandates reform Act of 1995 (March 22, 1995; Pub. L. 104–4), the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act, 5 U.S.C. 801 *et seq.*), and the Executive Order 13132 on Federalism (August 4, 1999).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The Executive Order 14094 amends section 3(f) of Executive Order 12866. The amended section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an

²² According to the May 2022 Bureau of Labor Statistics occupational employment statistics, the

mean hourly wage for Office Clerks, General (43–9061) is \$19.78.

action that is likely to result in a rule: (1) having an annual effect on the economy of \$200 million or more in any 1 year (adjusted every 3 years by the Administrator of OMB's OIRA for changes in gross domestic product), or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in the Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

An RIA must be prepared for rules with significant regulatory action(s) and/or with significant effects as per section 3(f)(1) (\$200 million or more in any 1 year). OIRA has determined that this final rule is not a significant regulatory action under 3(f) of Executive Order 12866, as amended by E.O. 14094. Accordingly, we have not prepared a detailed RIA. We did, however, include some quantitative analysis of the costs and benefits of this final rule.

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act, 5 U.S.C. 801 *et seq.*), OIRA has determined that this final rule does not meet the criteria set forth in 5 U.S.C. 804(2).

Trusted Exchange Framework and Common AgreementSM

The regulations in 45 CFR part 172 outline the application requirements an Applicant Qualified Health Information Network[®] (QHINTM) must submit in order to be Designated as a QHIN, ongoing Designation requirements, and the requirements that an entity would attest to meeting as a QHIN under the TEFCA framework. We estimate that an Applicant QHIN will spend on average an hour to complete the application process. We estimate that an average QHIN will spend at most one hour to complete the attestation process. As we stated in the regulatory impact analysis in the HTI-2 Proposed Rule, we consider these efforts to be de minimis.

We do not assess the burden of a QHIN to appeal a Recognized Coordinating Entity[®] (RCETM) decision as part of their participation in the

TEFCA framework, as this rulemaking creates the appeals process for QHINs but does not require it. Further, we expect that appeals will most often follow RCE decisions related to QHIN participation in the TEFCA framework, rather than ASTP/ONC decisions. We, therefore, do not assess the burden of the appeals process as part of this rulemaking's impact analysis.

Comments. We did not receive any comments on the costs and benefits related to the provisions included in this final rule.

Response. We have finalized our regulatory impact analyses on the matters finalized in this final rule as discussed above and in the HTI-2 Proposed Rule.

D. Regulatory Flexibility Act

The RFA requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. The Small Business Administration (SBA) establishes the size of small businesses for Federal Government programs based on average annual receipts or the average employment of a firm.²³

Although we did not include an analysis of the proposed TEFCA regulations in the HTI-2 Proposed Rule, we have included an analysis of the finalized TEFCA regulations in this final rule. We estimate that up to 15 Applicant QHINs would apply and subsequently submit an attestation to ASTP/ONC to be listed in the QHIN Attestation Directory. Section 3001(c)(9)(B)(i) of the PHSA provides the National Coordinator with the authority to "develop or support a trusted exchange framework for trust policies and practices and for a common agreement for exchange between health information networks." The components of this Trusted Exchange Framework and Common AgreementTM (TEFCATM) include the Trusted Exchange Framework (a common set of principles designed to facilitate trust between health information networks (HINs)) and the Common Agreement (the agreement Qualified Health Information Networks[®] (QHINsTM) sign), which includes, among other provisions, privacy, compliance, and security requirements). The Common Agreement also references the QHIN Technical Framework (QTF) (which describes technical requirements for

exchange among QHINs) as well as, where necessary, SOPs.

By providing a common and consistent approach for the exchange of health information across many different networks, TEFCA simplifies and significantly reduces the number of separate networks that individuals, health care providers, and other interested parties need to be a part of in order to access the health information they seek. Health information networks that voluntarily join TEFCA will facilitate exchange in a secure and interoperable manner. TEFCA establishes a method for authenticating trusted health information network participants, potentially lowering the cost, and expanding the nationwide availability of secure health information exchange capabilities. The establishment of technical services for health information networks that voluntarily join TEFCA, such as an electronic address directory and security services, will be critical to scale network exchange nationwide. In addition, the organizational and operational policies established through TEFCA enable the exchange of health information among health information networks and include minimum conditions required for such exchange to occur. We believe our qualification criteria is structured in a way that it encourages participation from small entities.

We believe that many health information networks impacted by this final rule most likely fall under the North American Industry Classification System (NAICS) code 541511 "Custom Computer Programming Services."²⁴ OMB advised that the Federal statistical establishment data published for reference years beginning on or after January 1, 2022, should be published using the 2022 NAICS United States codes.²⁵ The SBA size standard associated with this NAICS code is set at \$34 million annual receipts or less. There is enough data generally available to establish that between 75% and 90% of entities that are categorized under the NAICS code 541511 are under the SBA size standard.

We estimate that this final rule would have effects on health information networks, some of which may be small entities. We believe, however, that we have adopted the minimum number of requirements necessary to accomplish our primary policy goal of enhancing

²³ The SBA references that annual receipts mean "total income" (or in the case of a sole proprietorship, "gross income") plus "cost of goods sold" as these terms are defined and reported on Internal Revenue Service tax return forms.

²⁴ <https://www.sba.gov/sites/sbagov/files/2023-06/Table%20of%20Size%20Standards%20Effective%20March%2017%2C%202023%20%282%29.pdf>.

²⁵ <https://www.sba.gov/article/2022/feb/01/guidance-using-naics-2022-procurement>.

interoperability. Further, as discussed in this RIA above, there are very few appropriate regulatory or non-regulatory alternatives that could be developed to lessen the compliance burden associated with this final rule because the policies are derived directly from legislative mandates in the Cures Act.

Comments. We received no comments on our approach.

Response. We have finalized our approach and analysis as discussed above. We do not believe that this final rule would create a significant impact on a substantial number of small entities, and the Secretary certifies that this final rule would not have a significant impact on a substantial number of small entities.

E. Executive Order 13132—Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications.

Comments. We received no comments.

Response. Nothing in this final rule imposes substantial direct compliance costs on state and local governments, preempts state law, or otherwise has federalism implications.

F. Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule that imposes unfunded mandates on state, local, and tribal governments or the private sector requiring spending in any one year of \$100 million in 1995 dollars, updated annually for inflation. The current inflation-adjusted statutory threshold is approximately \$183 million in 2024.

Comments. We received no comments on the application of this law to our proposals finalized in this final rule.

Response. The estimated potential cost effects of this final rule do not reach the statutory threshold; therefore, this final rule does not impose unfunded mandates on state, local, and tribal governments, or the private sector.

List of Subjects

45 CFR Part 170

Computer technology, Electronic health record, Electronic information system, Electronic transactions, Health, Healthcare, Health information technology, Health insurance, Health records, Hospitals, Laboratories, Medicaid, Medicare, Privacy, Public

health, Reporting and recordkeeping requirements, Security.

45 CFR Part 171

Computer technology, Electronic health record, Electronic information system, Electronic transactions, Health, Healthcare, Health care provider, Health information exchange, Health information technology, Health information network, Health insurance, Health records, Hospitals, Privacy, Public health, Reporting and recordkeeping requirements, Security.

45 CFR Part 172

Computer technology, Electronic health record, Electronic information system, Electronic transactions, Health, Healthcare, Health information technology, Health insurance, Health records, Hospitals, Laboratories, Medicaid, Medicare, Privacy, Public health, Security.

For the reasons set forth in the preamble, 45 CFR subtitle A, subchapter D, is amended as follows:

PART 170—HEALTH INFORMATION TECHNOLOGY STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA AND CERTIFICATION PROGRAMS FOR HEALTH INFORMATION TECHNOLOGY

■ 1. The authority citation for part 170 continues to read as follows:

Authority: 42 U.S.C. 300jj–11; 42 U.S.C. 300jj–14; 5 U.S.C. 552.

■ 2. Revise § 170.101 to read as follows:

§ 170.101 Applicability.

(a) The standards, implementation specifications, and certification criteria adopted in this part apply to health information technology and the testing and certification of Health IT Modules.

(b) If any provision of this part is held to be invalid or unenforceable facially, or as applied to any person, plaintiff, or circumstance, it shall be construed to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which case the provision shall be severable from this part and shall not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other dissimilar circumstances.

■ 3. Amend § 170.315 by:

■ a. Removing and reserving paragraphs (a)(10) and (13) and (b)(6);

■ b. Revising paragraphs (b)(7) and (8); and

■ c. Removing and reserving paragraphs (e)(2) and (g)(2).

The revisions read as follows:

§ 170.315 ONC certification criteria for Health IT.

* * * * *

(b) * * *

(7) *Security tags—summary of care—send.* Enable a user to create a summary record formatted in accordance with the standard adopted in § 170.205(a)(4) that is tagged as restricted and subject to restrictions on re-disclosure according to the standard adopted in § 170.205(o)(1) at the document, section, and entry (data element) level.

(8) *Security tags—summary of care—receive.* (i) Enable a user to receive a summary record that is formatted in accordance with the standard adopted in § 170.205(a)(4) that is tagged as restricted and subject to restrictions on re-disclosure according to the standard adopted in § 170.205(o)(1) at the document, section, and entry (data element) level; and

(ii) Preserve privacy markings to ensure fidelity to the tagging based on consent and with respect to sharing and re-disclosure restrictions.

* * * * *

■ 4. Amend § 170.502 by revising the definition of “Gap certification” to read as follows:

§ 170.502 Definitions.

* * * * *

Gap certification means the certification of a previously certified Health IT Module(s) to:

(1) All applicable new and/or revised certification criteria adopted by the Secretary at subpart C of this part based on test results issued by a NVLAP-accredited testing laboratory under the ONC Health IT Certification Program or an ONC-ATL; and

(2) All other applicable certification criteria adopted by the Secretary at subpart C of this part based on the test results used to previously certify the Health IT Module(s) under the ONC Health IT Certification Program.

* * * * *

■ 5. Revise § 170.511 to read as follows:

§ 170.511 Authorization scope for ONC-ATL status.

Applicants may seek authorization from the National Coordinator to perform the testing of Health IT Modules to a portion of a certification criterion, one certification criterion, or many or all certification criteria adopted by the Secretary under subpart C of this part.

■ 6. Amend § 170.523 by revising paragraphs (f) introductory text and (j)(3) to read as follows:

§ 170.523 Principles of proper conduct for ONC-ACBs.

* * * * *

(f) *Certified product listing.* Provide the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC), no less frequently than weekly, a current list of Health IT Modules that have been certified that includes, at a minimum:

* * * * *

(j) * * *

(3) Previous certifications that it performed if its conduct necessitates the recertification of Health IT Module(s).

* * * * *

■ 7. Amend § 170.550 by revising paragraph (h)(3)(ii) and adding paragraph (h)(4) to read as follows:

§ 170.550 Health IT Module certification.

* * * * *

(h) * * *

(3) * * *

(ii) Section 170.315(a)(4), (10), and (13) and, on and after January 1, 2028, (b)(11), are also certified to the certification criteria specified in § 170.315(d)(1) through (3), (5) through (7), and (12), and, for the time period up to and including December 31, 2027, (d)(13).

* * * * *

(4) *Methods to demonstrate compliance with each privacy and security criterion.* One of the following methods must be used to meet each applicable privacy and security criterion listed in paragraph (h)(3) of this section:

(i) Directly, by demonstrating a technical capability to satisfy the applicable certification criterion or certification criteria; or

(ii) Demonstrate, through system documentation sufficiently detailed to enable integration, that the Health IT Module has implemented service interfaces for each applicable privacy and security certification criterion that enable the Health IT Module to access external services necessary to meet the privacy and security certification criterion.

* * * * *

PART 171—INFORMATION BLOCKING

■ 8. The authority citation for part 171 continues to read as follows:

Authority: 42 U.S.C. 300jj–52; 5 U.S.C. 552.

■ 9. Amend § 171.101 by adding paragraph (c) to read as follows:

§ 171.101 Applicability.

* * * * *

(c) If any provision of this part is held to be invalid or unenforceable facially,

or as applied to any person, plaintiff, or circumstance, it shall be construed to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which case the provision shall be severable from this part and shall not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other dissimilar circumstances.

■ 10. Add § 171.401 to read as follows:

§ 171.401 Definitions.

Common Agreement has the meaning given to it in 45 CFR 172.102.

Framework Agreement has the meaning given to it in 45 CFR 172.102.

Participant has the meaning given to it in 45 CFR 172.102.

Qualified Health Information Network or *QHIN* has the meaning given to it in 45 CFR 172.102.

Subparticipant has the meaning given to it in 45 CFR 172.102.

■ 11. Add part 172 to read as follows:

PART 172—TRUSTED EXCHANGE FRAMEWORK AND COMMON AGREEMENT

Subpart A—General Provisions

Sec.

- 172.100 Basis, purpose, and scope.
- 172.101 Applicability.
- 172.102 Definitions.
- 172.103 Responsibilities ASTP/ONC may delegate to the RCE.

Subpart B—Qualifications for Designation

- 172.200 Applicability.
- 172.201 QHIN Designation requirements.
- 172.202 QHINS that offer Individual Access Services.

Subpart C—QHIN Onboarding and Designation Processes

- 172.300 Applicability.
- 172.301 Submission of QHIN application.
- 172.302 Review of QHIN application.
- 172.303 QHIN approval and Onboarding.
- 172.304 QHIN Designation.
- 172.305 Withdrawal of QHIN application.
- 172.306 Denial of QHIN application.
- 172.307 Re-application.

Subpart D—Suspension

- 172.400 Applicability.
- 172.401 QHIN suspensions.
- 172.402 Selective suspension of exchange between QHINS.

Subpart E—Termination

- 172.500 Applicability.
- 172.501 QHIN self-termination.
- 172.502 QHIN termination.
- 172.503 Termination by mutual agreement.

Subpart F—Review of RCE or ASTP/ONC Decisions

- 172.600 Applicability.
- 172.601 ASTP/ONC review.

- 172.602 Basis for appeal by QHIN or Applicant QHIN.
- 172.603 Method and timing for filing an appeal.
- 172.604 Effect of appeal on suspension and termination.
- 172.605 Assignment of a hearing officer.
- 172.606 Adjudication.
- 172.607 Determination by the hearing officer.

Subpart G—QHIN Attestation for the Adoption of the Trusted Exchange Framework and Common Agreement

- 172.700 Applicability.
- 172.701 Attestation submission and acceptance.
- 172.702 QHIN Attestation Directory.

Authority: 42 U.S.C. 300jj–11; 5 U.S.C. 552.

Subpart A—General Provisions

§ 172.100 Basis, purpose, and scope.

(a) *Basis and authority.* The provisions of this part implement section 3001(c)(9) of the Public Health Service Act.

(b) *Purpose.* The purpose of this part is to:

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

(c) *Scope.* This part addresses:

- (1) Minimum qualifications needed for a health information network to be Designated as a QHIN capable of trusted exchange under TEFCA.
- (2) Procedures governing QHIN Onboarding and Designation, suspension, termination, and further administrative review.
- (3) Attestation submission requirements for a QHIN to attest to its adoption of TEFCA.

(4) ASTP/ONC attestation acceptance and removal processes for publication of attesting QHINS in the QHIN Attestation Directory.

§ 172.101 Applicability.

(a) This part applies to Applicant QHINS, QHINS, terminated QHINS, and the Recognized Coordinating Entity.

(b) If any provision of this part is held to be invalid or unenforceable facially, or as applied to any person, plaintiff, or circumstance, it shall be construed to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which case the provision shall be severable from this part and shall not affect the remainder thereof or the application of the provision to other persons not similarly

situated or to other dissimilar circumstances.

§ 172.102 Definitions.

For purposes of this part, the following definitions apply:

Applicable Law. All Federal, State, local, or Tribal laws and regulations then in effect and applicable to the subject matter in this part. For the avoidance of doubt, Federal agencies are subject only to Federal law.

Applicant QHIN. Any organization with a pending QHIN application before the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC).

Business Associate Agreement (BAA). A contract, agreement, or other arrangement that satisfies the implementation specifications described within 45 CFR parts 160 and subparts A, C, and E of 45 CFR part 164, as applicable.

Business day or business days. Monday through Friday, except the legal public holidays specified in 5 U.S.C. 6103 and any day declared to be a holiday by Federal statute or Executive order.

Common Agreement. The most recent version of the agreement referenced in section 3001(c)(9) of the Public Service Health Act as published in the **Federal Register**.

Confidential Information. Any information that is designated as Confidential Information by the person or entity that discloses it, or that a reasonable person would understand to be of a confidential nature and is disclosed to another person or entity pursuant to TEFCA Exchange. For the avoidance of doubt, “Confidential Information” does not include electronic protected health information (ePHI). Notwithstanding any label to the contrary, “Confidential Information” does not include any information that:

- (1) Is or becomes known publicly through no fault of the recipient; or
- (2) Is learned by the recipient from a third party that the recipient reasonably believes is entitled to disclose it without restriction; or
- (3) Is already known to the recipient before receipt from the discloser, as shown by the recipient’s written records; or
- (4) Is independently developed by recipient without the use of or reference to the discloser’s Confidential Information, as shown by the recipient’s written records, and was not subject to confidentiality restrictions prior to receipt of such information from the discloser; or

(5) Must be disclosed under operation of law, provided that, to the extent permitted by Applicable Law, the recipient gives the discloser reasonable notice to allow the discloser to object to such redisclosure, and such redisclosure is made to the minimum extent necessary to comply with Applicable Law.

Connectivity Services. The technical services provided by a QHIN, Participant, or Subparticipant to its Participants and Subparticipants that facilitate TEFCA Exchange and are consistent with the technical requirements of the TEFCA framework.

Covered Entity. Has the meaning assigned to such term at 45 CFR 160.103.

Designated Network. The health information network that a QHIN uses to offer and provide Designated Network Services.

Designated Network Services. The Connectivity Services and/or Governance Services.

Designation (including its correlative meanings “Designate,” “Designated,” and “Designating”). The written determination that an Applicant QHIN has satisfied all requirements 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.

Electronic Protected Health Information (ePHI). Has the meaning assigned to such term at 45 CFR 160.103.

Exchange Purpose(s) or XP(s). The reason, as authorized by a Framework Agreement, including the applicable standard operating procedure(s) (SOP(s)), for a transmission, Query, Use, Disclosure, or Response transacted through TEFCA Exchange.

Exchange Purpose Code or XP Code. A code that identifies the Exchange Purpose being used for TEFCA Exchange.

Foreign Control. A non-U.S. Person(s) or non-U.S. Entity(ies) having the direct or indirect power, whether or not exercised, to direct or decide matters materially affecting the Applicant’s ability to function as a QHIN in a manner that presents a national security risk.

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).

Governance Services. The governance functions described in applicable SOP(s), which are performed by a QHIN’s Designated Network Governance Body for its Participants and Subparticipants to facilitate TEFCA Exchange in compliance with the then-applicable requirements of the Framework Agreements.

Health information network or HIN. The meaning assigned to it in 45 CFR 171.102.

Individual has the meaning assigned to such term at 45 CFR 171.202(a)(2).

HIPAA. The Health Insurance Portability and Accountability Act of 1996.

HIPAA Privacy Rule. The regulations set forth in 45 CFR part 160 and subparts A and E of 45 CFR part 164.

HIPAA Rules. The regulations set forth at 45 CFR parts 160, 162, and 164.

HIPAA Security Rule. The regulations set forth in 45 CFR part 160 and subparts A and C of 45 CFR part 164.

Individual. Has the meaning assigned to such term at 45 CFR 171.202(a)(2).

Individual Access Services (IAS). The services provided to an Individual by a QHIN, Participant, or Subparticipant that has a direct contractual relationship with such Individual in which the QHIN, Participant or Subparticipant, as applicable, agrees to satisfy that Individual’s ability to access, inspect, or obtain a copy of that Individual’s Required Information using TEFCA Exchange.

Individually Identifiable Information. Refers to information that identifies an Individual or with respect to which there is a reasonable basis to believe that the information could be used to identify an Individual.

Node. A technical system that is controlled directly or indirectly by a QHIN, Participant, or Subparticipant and that is listed in the RCE Directory Service.

Non-U.S. Entity. Any entity that is not a U.S. Entity.

Non-U.S. Person. Any Individual who is not a U.S. Qualified Person.

Onboarding. The process a prospective QHIN must undergo to become a QHIN and become operational in the production environment.

Organized Health Care Arrangement. Has the meaning assigned to such term at 45 CFR 160.103.

Participant. A U.S. Entity that has entered into the Participant/Subparticipant Terms of Participation 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 Participant/Subparticipant Terms of Participation.

Participant/Subparticipant Terms of Participation (ToP). The requirements to which QHINs must contractually obligate their Participants to agree; to which QHINs must contractually obligate their Participants to contractually obligate their Subparticipants and Subparticipants of the Subparticipants to agree, in order to participate in TEFCA Exchange including the QHIN Technical Framework (QTF), all applicable SOPs, and all other attachments, exhibits, and artifacts incorporated therein by reference.

Qualified Health Information Network® or QHIN™. A Health Information Network that has been so Designated.

Query(s) (including its correlative uses/tenses “Queried” and “Querying”). The act of asking for information through TEFCA Exchange.

Recognized Coordinating Entity® (RCE®). The entity selected by ASTP/ONC that enters 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.

Required Information. The Electronic Health Information, as defined in 45 CFR 171.102, that is:

(1) Maintained in a Responding Node by any QHIN, Participant, or Subparticipant prior to or during the term of the applicable Framework Agreement; and

(2) Relevant for a required XP Code.

Responding Node. A Node through which the QHIN, Participant, or Subparticipant Responds to a received transaction for TEFCA Exchange.

Response(s) (including its correlative uses/tenses “Responds,” “Responded” and “Responding”). The act of providing the information that is the subject of a Query or otherwise transmitting a message in response to a Query through TEFCA Exchange.

Subparticipant: a U.S. Entity that has entered into the Participant/Subparticipant Terms of Participation in a legally binding contract with a Participant or another Subparticipant to use the Participant's or Subparticipant's Connectivity Services to participate in TEFCA Exchange in compliance with the Participant/Subparticipant Terms of Participation.

TEFCA Dispute Resolution Process. An informal, non-binding process under TEFCA through which QHINs can meet, confer, and seek to amicably resolve disputes.

TEFCA Exchange. The transaction of information between Nodes using an XP Code.

TEFCA Information or 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 that is exempt from compliance with the Privacy section of the applicable Framework Agreement and is incorporated into such recipient's system of record, at which point the information is no longer TEFCA Information with respect to such recipient and is governed by the HIPAA Rules and other Applicable Law.

TEFCA Security Incident. (1) An unauthorized acquisition, access, Disclosure, or Use of unencrypted TEFCA Information using TEFCA Exchange, except any of the following:

(i) Any unintentional acquisition, access, Use, or Disclosure of TEFCA Information by a Workforce Member or person acting under the authority of a QHIN, Participant, or Subparticipant, if such acquisition, access, Use, or Disclosure:

(A) Was made in good faith;

(B) Was made by a person acting within their scope of authority;

(C) Was made to another Workforce Member or person acting under the authority of any QHIN, Participant, or Subparticipant; and

(D) Does not result in further acquisition, access, Use, or Disclosure in a manner not permitted under Applicable Law and the Framework Agreements.

(ii) A Disclosure of TI where a QHIN, Participant, or Subparticipant has a good faith belief that an unauthorized person to whom the Disclosure was made would not reasonably have been able to retain such information.

(iii) A Disclosure of TI that has been de-identified in accordance with the standard at 45 CFR 164.514.

(2) Other security events that adversely affect a QHIN's, Participant's, or Subparticipant's participation in TEFCA Exchange.

Threat Condition. (1) A breach of a material provision of a Framework 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 Parties have agreed), which notice shall include such specific information about the breach that the RCE has available at the time of the notice; or

(2) A TEFCA Security Incident; or

(3) An event that the RCE, a QHIN, its Participant, or their Subparticipant has

reason to believe will disrupt normal TEFCA Exchange, 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; or

(4) Any event that could pose a risk to the interests of national security as directed by an agency of the United States government.

Trusted Exchange Framework. The most recent version of the framework referenced in section 3001(c)(9) of the Public Service Health Act published in the **Federal Register**.

U.S. Entity/Entities. Any corporation, limited liability company, partnership, or other legal entity that meets all of the following requirements:

(1) The entity is organized under the laws of a state or commonwealth of the United States or the Federal law of the United States and is subject to the jurisdiction of the United States and the state or commonwealth under which it was formed;

(2) The entity's principal place of business, as determined under Federal common law, is in the United States; and

(3) None of the entity's directors, officers, or executives, and none of the owners with a five percent (5%) or greater interest in the entity, are listed on the *Specially Designated Nationals and Blocked Persons List* published by the United States Department of the Treasury's Office of Foreign Asset Control or on the United States Department of Health and Human Services, Office of Inspector General's List of Excluded Individuals/Entities.

U.S. Qualified Person. Those individuals who are U.S. nationals and citizens at birth as defined in 8 U.S.C. 1401, U.S. nationals but not citizens of the United States at birth as defined in 8 U.S.C. 1408, lawful permanent residents of the United States as defined in Immigration and Nationality Act, and non-immigrant aliens who are hired by a U.S. Entity as an employee in a specialty occupation pursuant to an H-1B Visa.

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.

§ 172.103 Responsibilities ASTP/ONC may delegate to the RCE.

(a) ASTP/ONC may delegate to the RCE the TEFCA implementation

responsibilities specified in the following sections:

- (1) Any section(s) of subpart C of this part;
 - (2) Any section(s) of subpart D of this part;
 - (3) Section 172.501; and
 - (4) Section 172.503.
- (b) Notwithstanding any delegation, any authority exercised by the RCE under this section is subject to review under subpart F of this part and to any requirement in this part that the RCE receive ASTP/ONC's prior authorization before taking a specific action.

Subpart B—Qualifications for Designation

§ 172.200 Applicability.

This subpart establishes Designation qualifications.

(a) *Applicant QHIN.* An Applicant QHIN must meet all requirements in § 172.201 to be Designated. An Applicant QHIN that proposes to offer Individual Access Services must also meet all requirements in § 172.202 to be Designated.

(b) *QHIN.* A QHIN must continue to meet all requirements in § 172.201 to maintain its Designation. A QHIN that offers Individual Access Services must also continue to meet all requirements in § 172.202 to maintain its Designation.

(c) *Performance of TEFCA Exchange.* The Designation qualifications in §§ 172.201 and 172.202 describe certain requirements for Designation.

§ 172.201 QHIN Designation requirements.

(a) *Ownership requirements.* An entity must:

- (1) Be a U.S. Entity;
- (2) Not be under Foreign Control.

(b) *Exchange requirements.* An entity must, beginning at the time of application, either directly or through the experience of its parent entity:

- (1) Be capable of exchanging information among more than two unaffiliated organizations;
- (2) Be capable of exchanging all Required Information;
- (3) Be exchanging information for at least one Exchange Purpose authorized under TEFCA;
- (4) Be capable of receiving and responding to transactions from other QHINs for all Exchange Purposes authorized under TEFCA; and
- (5) Be capable of initiating transactions for the Exchange Purposes authorized under TEFCA that such entity will permit its Participants and Subparticipants to use through TEFCA Exchange.

(c) *Designated Network Services requirements.* An entity must:

(1) Maintain the organizational infrastructure and legal authority to operate and govern its Designated Network;

(2) Maintain adequate written policies and procedures to support meaningful TEFCA Exchange and fulfill all responsibilities of a QHIN in this part;

(3) Maintain a Designated Network that can support a transaction volume that keeps pace with the demands of network users;

(4) Maintain the capacity to support secure technical connectivity and data exchange with other QHINs;

(5) Maintain an enforceable dispute resolution policy governing Participants in the Designated Network that permits Participants to reasonably, timely, and fairly adjudicate disputes that arise between each other, the QHIN, or other QHINs;

(6) Maintain an enforceable change management policy consistent with the responsibilities of a QHIN;

(7) Maintain a representative and participatory group or groups with the authority to approve processes for governing the Designated Network;

(8) Maintain privacy and security policies that permit the entity to support TEFCA Exchange;

(9) Maintain data breach response and management policies that support meaningful TEFCA Exchange; and

(10) Maintain adequate financial and personnel resources to support all its responsibilities as a QHIN, including sufficient financial reserves or insurance-based cybersecurity coverage, or a combination of both.

§ 172.202 QHINs that offer Individual Access Services.

The following requirements apply to QHINs that offer Individual Access Services:

(a) A QHIN must obtain express consent from any individual before providing Individual Access Services.

(b) A QHIN must make publicly available a privacy and security notice that meets minimum TEFCA standards.

(c) A QHIN, that is the IAS provider for an Individual, must delete the individual's Individually Identifiable Information maintained by the QHIN upon request by the individual except as prohibited by Applicable Law or where such information is contained in audit logs.

(d) A QHIN must permit any Individual to export in a computable format all of the Individual's Individually Identifiable Information maintained by the QHIN as an Individual Access Services provider.

(e) All Individually Identifiable Information the QHIN maintains must satisfy the following criteria:

(1) All Individually Identifiable Information must be encrypted.

(2) Without unreasonable delay and in no case later than sixty (60) calendar days following discovery of the unauthorized acquisition, access, Disclosure, or Use of Individually Identifiable Information, the QHIN must notify in plain language each Individual whose Individually Identifiable Information has been or is reasonably believed to have been affected by unauthorized acquisition, access, Disclosure, or Use involving the QHIN.

(3) A QHIN must 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 Individual Access Services prior to the Individuals' first use of such services and upon expiration of their credentials.

Subpart C—QHIN Onboarding and Designation Processes

§ 172.300 Applicability.

This subpart establishes, as to QHINs, the application, review, Onboarding, withdrawal, and redetermination processes for Designation.

§ 172.301 Submission of QHIN application.

An entity seeking to be Designated as a QHIN must submit all of the following information in a manner specified by ASTP/ONC:

(a) Completed QHIN application, with supporting documentation, in a form specified by ASTP/ONC; and

(b) A signed copy of the Common Agreement.

§ 172.302 Review of QHIN application.

(a) ASTP/ONC (or an RCE) will review a QHIN application to determine if the Applicant QHIN has completed all parts of the application and provided the necessary supporting documentation. If the QHIN application is not complete, the applicant will be notified in writing of the missing information within thirty (30) calendar days of receipt of the application. This timeframe may be extended by providing written notice to the Applicant QHIN.

(b) Once the QHIN application is complete, ASTP/ONC (or an RCE) will review the application to determine whether the Applicant QHIN satisfies the requirements for Designation set forth in § 172.201 and, if the Applicant QHIN proposes to provide IAS, the requirements set forth in § 172.202. ASTP/ONC (or an RCE) will complete its review within sixty (60) calendar days of the Applicant QHIN being

provided with written notice that its application is complete. This timeframe may be extended by providing written notice to the Applicant QHIN.

(c) Additional information may be requested from the Applicant QHIN while ASTP/ONC (or an RCE) is reviewing the application. The timeframe for responding to the request and the manner to submit additional information will be provided to the applicant and may be extended on written notice to the Applicant QHIN.

(d) Failure to respond to a request within the proposed timeframe or in the manner specified is a basis for a QHIN Application to be deemed withdrawn, as set forth in § 172.305(c). In such situations, the Applicant QHIN will be provided with written notice that the application has been deemed withdrawn.

(e) If, following submission of the application, any information submitted by the Applicant QHIN becomes untrue or materially changes, the Applicant QHIN must notify ASTP/ONC (or an RCE) in the manner specified by ASTP/ONC (or an RCE) of such changes in writing within five (5) business days of the submitted material becoming untrue or materially changing.

§ 172.303 QHIN approval and Onboarding.

(a) An Applicant QHIN has the burden of demonstrating its compliance with all qualifications for Designation in § 172.201 and, if the Applicant QHIN proposes to provide IAS, the qualifications in § 172.202.

(b) If ASTP/ONC (or, with ASTP/ONC's prior authorization, an RCE) determines that an Applicant QHIN meets the requirements for Designation set forth in § 172.201, and if the Applicant QHIN proposes to provide IAS, the qualifications set forth in § 172.202, then ASTP/ONC (or, with ASTP/ONC's prior authorization, an RCE) will notify the applicant in writing that its application has been approved, and the Applicant QHIN may proceed with Onboarding.

(c) An approved Applicant QHIN must submit a signed version of the Common Agreement within a timeframe set by ASTP/ONC (or an RCE).

(d) An approved Applicant QHIN must complete the Onboarding process, including any tests required to ensure the Applicant QHIN's network can connect to those of other QHINs and other Applicant QHINs, within twelve (12) months of approval of its QHIN application, unless that timeframe is extended in ASTP/ONC's (or an RCE's) sole discretion by up to twelve (12) months.

§ 172.304 QHIN Designation.

(a) If all requirements of the Onboarding process specified in § 172.303 have been satisfied:

(1) The Common Agreement will be countersigned; and

(2) The Applicant QHIN will be provided with a written determination indicating that the applicant has been Designated as a QHIN, along with a copy of the countersigned Common Agreement.

(b) Within thirty (30) calendar days of receiving its Designation, each QHIN must demonstrate in a manner specified by ASTP/ONC (or, with ASTP/ONC's prior authorization, an RCE) that it has completed a successful transaction with all other in-production QHINs according to standards and procedures for TEFCA Exchange.

(c) If a QHIN is unable to complete the requirement in paragraph (b) of this section within the thirty (30)-day period provided, the QHIN must provide ASTP/ONC (or an RCE) with a written explanation of why the QHIN has been unable to complete a successful transaction with all other in-production QHINs within the allotted time and include a detailed plan and timeline for completion of a successful transaction with all other in-production QHINs. ASTP/ONC (or, with ASTP/ONC's prior authorization, an RCE) will review and either approve or reject the QHIN's plan based on the reasonableness of the explanation and the specific facts and circumstances, within five (5) business days of receipt. If the QHIN fails to provide its plan or the plan is rejected, ASTP/ONC (or, with ASTP/ONC's prior authorization, an RCE) will rescind its approval of the application, rescind the QHIN Designation, and deny the application. Within thirty (30) calendar days of end of the term of the plan, each QHIN must demonstrate in a manner specified by ASTP/ONC (or, with ASTP/ONC's prior authorization, an RCE) that it has completed a successful transaction with all other in-production QHINs according to standards and procedures for TEFCA Exchange.

(d) A QHIN Designation will become final sixty (60) days after a Designated QHIN has submitted its documentation that it has completed a successful transaction with all other in-production QHINs.

§ 172.305 Withdrawal of QHIN application.

(a) An Applicant QHIN may voluntarily withdraw its QHIN application by providing written notice in a manner specified by ASTP/ONC (or an RCE).

(b) An Applicant QHIN may withdraw its QHIN application at any point prior to Designation.

(c) Upon written notice to the Applicant QHIN, a QHIN application may be deemed withdrawn by ASTP/ONC (or, with ASTP/ONC's prior authorization, an RCE) as a result of the Applicant QHIN's failure to respond to requests for information from ASTP/ONC (or an RCE).

§ 172.306 Denial of QHIN application.

If an Applicant QHIN's application is denied, the Applicant QHIN will be provided with written notice that includes the basis for the denial.

§ 172.307 Re-application.

(a) Subject to paragraphs (b) through (d) of this section, applications may be resubmitted by Applicant QHINs by complying with the provisions of § 172.301 in the event that an application is denied or withdrawn.

(b) The Applicant QHIN may reapply at any time after it has voluntarily withdrawn its application as specified in § 172.305(a).

(c) If ASTP/ONC (or an RCE) deems a QHIN application to be withdrawn as a result of the Applicant QHIN's failure to respond to requests for information, then the Applicant QHIN may reapply by submitting a new QHIN application no sooner than six (6) months after the date on which its previous application was submitted. The Applicant QHIN must respond to the prior request for information and must include an explanation as to why no response was previously provided within the required timeframe.

(d) If ASTP/ONC (or an RCE) denies a QHIN application, the Applicant QHIN may reapply by submitting a new application consistent with the requirements in § 172.301 no sooner than six (6) months after the date shown on the written notice of denial. The application must specifically address the deficiencies that constituted the basis for denying the Applicant QHIN's previous application.

Subpart D—Suspension

§ 172.400 Applicability.

This subpart describes suspension responsibilities, notice requirements for suspension, and the effect of suspension.

§ 172.401 QHIN suspensions.

(a) ASTP/ONC (or, with ASTP/ONC's prior authorization, an RCE) may suspend a QHIN after determining that the QHIN is responsible for a Threat Condition.

(b) ASTP/ONC (or, with ASTP/ONC's prior authorization, an RCE) may direct the QHIN to suspend that Participant's or Subparticipant's authority to engage in TEFCA Exchange on determining that one of a QHIN's Participants or Subparticipants has done something or failed to do something that resulted in a Threat Condition.

(c) ASTP/ONC (or an RCE) will make a reasonable effort to notify a QHIN in writing in advance of an intent to suspend the QHIN or to provide direction to the QHIN to suspend one of the QHIN's Participants or Subparticipants, and to give the QHIN an opportunity to respond. Such notice will identify the Threat Condition giving rise to such suspension.

(d) ASTP/ONC (or, with ASTP/ONC's prior authorization, an RCE) shall lift a suspension of the QHIN, or provide direction to the QHIN to lift the suspension of one of the QHIN's Participants or Subparticipants, once the Threat Condition is resolved.

§ 172.402 Selective suspension of exchange between QHINs.

(a) A QHIN may, in good faith and to the extent permitted by Applicable Law, suspend TEFCA Exchange with another QHIN because of reasonable concerns related to the privacy and security of information that is exchanged.

(b) If a QHIN decides to suspend TEFCA Exchange with another QHIN, it is required to promptly notify, in writing, ASTP/ONC (or an RCE) and the QHIN with which it is suspending exchange of its decision and the reason(s) for making the decision.

(c) If a QHIN suspends TEFCA Exchange with another QHIN under paragraph (a) of this section, it must, within thirty (30) calendar days, initiate the TEFCA Dispute Resolution Process in order to resolve the issues that led to the decision to suspend, or the QHIN may end its suspension and resume TEFCA Exchange with the other QHIN within thirty (30) calendar days of suspending TEFCA Exchange with the QHIN.

(d) Provided that a QHIN suspends TEFCA Exchange with another QHIN in accordance with this section and in accordance with Applicable Law, such suspension will not be deemed a violation of the Common Agreement.

Subpart E—Termination

§ 172.500 Applicability.

This subpart establishes QHIN termination responsibilities, notice requirements for termination, and the effect of termination.

§ 172.501 QHIN self-termination.

A QHIN may terminate its own Designation at any time without cause by providing ninety (90) calendar days prior written notice.

§ 172.502 QHIN termination.

A QHIN's Designation will be terminated with immediate effect by ASTP/ONC (or, with ASTP/ONC's prior authorization, an RCE) giving written notice of termination to the QHIN if the QHIN:

(a) Fails to comply with any of the regulations of this part and fails to remedy such material breach within thirty (30) calendar days after receiving written notice of such failure; provided, however, that if a QHIN is diligently working to remedy its material breach at the end of this thirty- (30-) day period, then ASTP/ONC (or an RCE) must provide the QHIN with up to another thirty (30) calendar days to remedy its material breach; or

(b) A QHIN breaches a material provision of the Common Agreement where such breach is not capable of remedy.

§ 172.503 Termination by mutual agreement.

A QHIN's Designation may be terminated at any time and for any reason by mutual, written agreement between the QHIN and ASTP/ONC (or an RCE).

Subpart F—Review of RCE or ASTP/ONC Decisions

§ 172.600 Applicability.

This subpart establishes processes for review of RCE or ASTP/ONC actions, including QHIN appeal rights and the process for filing an appeal.

§ 172.601 ASTP/ONC review.

(a) ASTP/ONC may, in its sole discretion, review all or any part of any RCE determination, policy, or action. If ASTP/ONC reviews an RCE determination that required ASTP/ONC's prior authorization under this part, no ASTP/ONC officer, employee, or agent who was engaged with helping to evaluate or decide the prior authorization, or a prior authorization involving the same party(s) or underlying facts, may participate in deciding or advising ASTP/ONC on its review of that determination.

(b) ASTP/ONC may, in its sole discretion and on notice to affected QHINs or Applicant QHINs, stay any RCE determination, policy, or other action pending ASTP/ONC review. If ASTP/ONC stays an RCE determination that required ASTP/ONC's prior authorization under this part, no ASTP/

ONC officer, employee, or agent who was engaged with helping to evaluate or decide the prior authorization, or a prior authorization involving the same party(s) or underlying facts, may participate in deciding or advising ASTP/ONC on whether it should stay that determination.

(c) ASTP/ONC may, in its sole discretion and on written notice, request that a QHIN, Applicant QHIN, or the RCE provide ASTP/ONC additional information regarding any RCE determination, policy, or other action.

(d) On completion of its review, ASTP/ONC may affirm, modify, or reverse the determination, policy, or other action under review. ASTP/ONC will provide notice to affected QHINs or Applicant QHINs that includes the basis for ASTP/ONC's decision.

(e) ASTP/ONC will provide written notice under this section to affected QHINs or Applicant QHINs in the same manner as the original RCE determination, policy, or other action under review.

(f) ASTP/ONC will issue a decision under this section within a timeframe agreed to by the affected Applicant QHIN or QHIN, as applicable, the RCE, and ASTP/ONC. ASTP/ONC may, at its sole discretion, extend the timeframe for a decision as circumstances necessitate.

§ 172.602 Basis for appeal by QHIN or Applicant QHIN.

(a) An Applicant QHIN or QHIN may appeal the following decisions to ASTP/ONC or a hearing officer, as appropriate:

(1) *Applicant QHIN.* An Applicant QHIN may appeal a denial of its QHIN application.

(2) *QHIN.* A QHIN may appeal:

(i) A decision to suspend the QHIN or to instruct the QHIN to suspend its Participant or Subparticipant.

(ii) A decision to terminate the QHIN's Common Agreement.

(b) [Reserved]

§ 172.603 Method and timing for filing an appeal.

(a) To initiate an appeal, an authorized representative of the Applicant QHIN or QHIN must submit electronically, in writing to ASTP/ONC, a notice of appeal that includes the date of the notice of appeal, the date of the decision being appealed, the Applicant QHIN or QHIN that is appealing, and the decision being appealed within fifteen (15) calendar days of the Applicant QHIN's or QHIN's receipt of the notice of:

(1) Denial of a QHIN application;

(2) Suspension or instruction to suspend its Participant or Subparticipant; or

(3) Termination. With regard to an appeal of a termination, the 15-calendar day timeframe may be extended by ASTP/ONC up to another fifteen (15) calendar days if the QHIN has been granted an extension for completing its remedy under § 172.502(a).

(b) An authorized representative of an Applicant QHIN or QHIN must submit electronically to ASTP/ONC, within thirty (30) calendar days of filing the intent to appeal, the following:

(1) A statement of the basis for appeal, including a description of the facts supporting the appeal with citations to documentation submitted by the QHIN or Applicant QHIN; and

(2) Any documentation the QHIN would like considered during the appeal.

(c) The Applicant QHIN or QHIN filing the appeal may not submit on appeal any evidence that it did not submit prior to the appeal except evidence permitted by the hearing officer under § 172.606.

§ 172.604 Effect of appeal on suspension and termination.

An appeal does not stay the suspension or termination, unless otherwise ordered by ASTP/ONC or the hearing officer assigned under § 172.605(b).

§ 172.605 Assignment of a hearing officer.

(a) On receipt of an appeal under § 172.603, ASTP/ONC may exercise its authority under § 172.601 to review an RCE determination being appealed. If ASTP/ONC exercises its authority under § 172.601 to review an RCE determination that required ONC's prior authorization under this part, no ASTP/ONC officer, employee, or agent who was engaged with helping to evaluate or decide the prior authorization, or a prior authorization involving the same party(s) or underlying facts, may participate in deciding or advising ASTP/ONC on its review of that determination. An appealing QHIN or Applicant QHIN that is not satisfied with ASTP/ONC's subsequent determination may appeal that determination to a hearing officer by filing a new notice of appeal and other appeal documents that comply with § 172.603.

(b) If ASTP/ONC declines review under paragraph (a) of this section, or if ASTP/ONC made the determination under review, ASTP/ONC will arrange for assignment of the case to a hearing officer to adjudicate the appeal.

(c) The hearing officer must be an officer appointed by the Secretary of Health and Human Services.

(d) The hearing officer may not be responsible to, or subject to the

supervision or direction of, personnel engaged in the performance of investigative or prosecutorial functions for ASTP/ONC, nor may any officer, employee, or agent of ASTP/ONC engaged in investigative or prosecutorial functions in connection with any adjudication, in that adjudication or one that is factually related, participate or advise in the decision of the hearing officer, except as a counsel to ASTP/ONC or as a witness.

§ 172.606 Adjudication.

(a) The hearing officer will decide issues of law and fact *de novo* and will apply a preponderance of the evidence standard when deciding appeals.

(b) In making a determination, the hearing officer may consider:

(1) The written record, which includes:

(i) The RCE's or ASTP/ONC's determination and supporting information; and

(ii) Appeal materials submitted by the Applicant QHIN or QHIN under § 172.603.

(2) Any information from a hearing conducted in-person, via telephone, or otherwise. The hearing officer has sole discretion to conduct a hearing:

(i) To require either party to clarify the written record under paragraph (b)(1) of this section; or

(ii) If the hearing officer otherwise determines a hearing is necessary.

(c) The hearing officer will neither receive witness testimony nor accept any new information beyond what was provided in accordance with paragraph (b) of this section, except for good cause shown by the party seeking to submit new information.

§ 172.607 Determination by the hearing officer.

(a) The hearing officer will issue a written determination within a timeframe agreed to by the affected Applicant QHIN or QHIN, as applicable, and ASTP/ONC and approved by the hearing officer. The hearing officer may, at their sole discretion, extend the timeframe for a written determination as circumstances necessitate.

(b) The hearing officer's determination on appeal is the final decision of HHS unless within ten (10) business days, the Secretary, in the Secretary's sole discretion, chooses to review the determination. ASTP/ONC will notify the appealing party if the Secretary chooses to review the determination and will provide notice of the Secretary's final determination.

Subpart G—QHIN Attestation for the Adoption of the Trusted Exchange Framework and Common Agreement

§ 172.700 Applicability.

This subpart applies to QHINs.

§ 172.701 Attestation submission and acceptance.

(a) *Applicability.* This subpart establishes:

(1) The attestation submission requirements for QHINs.

(2) The review and acceptance processes that ASTP/ONC will follow for TEFCA attestations.

(b) *Submission of QHIN attestation.*

(1) In order to be listed in the QHIN Attestation Directory described in § 172.702, a QHIN must submit all of the following information to ASTP/ONC:

(i) Attestation affirming its adoption of the Common Agreement and Trusted Exchange Framework.

(ii) General identifying information, including:

(A) Name, address, city, state, zip code, and a hyperlink to its website.

(B) Designation of an authorized representative, including the representative's name, title, phone number, and email address.

(iii) Documentation confirming its Designation as a QHIN.

(2) A QHIN must provide ASTP/ONC with written notice of any changes to its identifying information provided in accordance with this paragraph (b) within thirty (30) business days of the change(s) to its identifying information.

(c) *Submission method.* A QHIN must electronically submit its attestation and documentation either via an email address identified by ASTP/ONC or via a submission on the ASTP/ONC website, if available.

(d) *Review and acceptance.* (1) Within thirty (30) business days, ASTP/ONC will either accept or reject an attestation submission.

(2) ASTP/ONC will accept an attestation if it determines that the QHIN has satisfied the requirements of paragraphs (b) and (c) of this section. ASTP/ONC will provide written notice to the applicable QHIN's authorized representative that the attestation has been accepted.

(3) ASTP/ONC will reject an attestation if it determines that the requirements of paragraph (b) or (c) of this section, or both, have not been satisfied.

(4) ASTP/ONC will provide written notice to the QHIN's authorized representative of the determination along with the basis for the determination.

(5) An ASTP/ONC determination under this section is final agency action

and not subject to further administrative review, except the Secretary may choose to review the determination as provided in § 172.607(b). However, a QHIN may, at any time, resubmit an attestation in accordance with paragraphs (b) and (c) of this section.

§ 172.702 QHIN Attestation Directory.

(a) *Applicability.* This subpart establishes processes for publishing a directory on the ASTP/ONC website of QHINs that voluntarily elect to adopt the Common Agreement and Trusted Exchange Framework and attest to such adoption.

(b) *Publication.* (1) Within fifteen (15) calendar days of notifying a QHIN that its QHIN submission has been accepted, ASTP/ONC will publish, at a minimum, the QHIN's name in the QHIN Attestation Directory on the ASTP/ONC website.

(2) ASTP/ONC will identify within the QHIN Attestation Directory those

QHINs that are suspended under the Common Agreement.

(c) *Removal from the QHIN Attestation Directory.* (1) A QHIN whose Common Agreement has been terminated no longer qualifies to be included in the QHIN Attestation Directory as it is no longer considered a QHIN and will be removed from the QHIN Attestation Directory.

(2) Upon termination of a QHIN's Common Agreement, ASTP/ONC (or an RCE) will send a written statement of intent to remove the QHIN from the QHIN Attestation Directory to the authorized representative of the QHIN.

(3) Any written statement given under paragraph (c)(2) of this section shall consist of the following, as appropriate:

(i) The name of the terminated QHIN and the name and contact information of the authorized representative of the QHIN.

(ii) A short statement setting forth findings of fact with respect to any violation of the Common Agreement or

other basis for the QHIN's termination under the Common Agreement and justifying the termination on the basis of those findings of facts.

(iii) Other materials as ASTP/ONC (or the RCE) may deem relevant.

(d) *Duration.* A QHIN that is removed from the QHIN Attestation Directory will remain removed until a new attestation is accepted by ASTP/ONC in accordance with the processes specified in this subpart.

(e) *Final agency action.* An ASTP/ONC determination under this section is final agency action and not subject to further administrative review, except the Secretary may choose to review the determination as provided in § 172.607(b).

Xavier Becerra,

Secretary, Department of Health and Human Services.

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