Summary: Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Blocking (RIN: 0955-AA03)

On July 10, 2024, HHS Office of the National Coordinator for Health IT (ONC) issued the *Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2)* proposed rule. This proposed rule includes 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. It proposes to establish a new baseline version of the United States Core Data for Interoperability, and makes other updates to the ONC Health IT Certification Program. Finally, the proposed rule also includes provisions related to Trusted Exchange Framework and Common Agreement (TEFCA).

Key links include:

- Proposed Rule
- Press Release
- HTI-2 Overview Fact Sheet
    - HTI-2 Proposed Key Dates Fact Sheet
    - HTI-2 Electronic Prescribing & Real-Time Prescription Benefit Fact Sheet
    - HTI-2 Information Blocking Definition Enhancements Fact Sheet
    - HTI-2 Information Blocking Exceptions Fact Sheet
    - HTI-2 Public Health Fact Sheet
    - HTI-2 TEFCA Fact Sheet
    - HTI-2 USCDI Version 4 Fact Sheet
    - HTI-2 Modular API Capabilities Fact Sheet
    - HTI-2 Patient, Provider, Payer API Fact Sheet

Below is a summary of the key provisions of the final rule.

ONC Certification Program ("Program")

New and Revised Standards and Certification Criteria

i. The United States Core Data for Interoperability Version 4 (USCDI v4)

ONC proposes to update the USCDI standard in § 170.213 by adding USCDI v4 and by establishing an expiration date of January 1, 2028, for USCDI v3.

ii. SMART App Launch 2.2

ONC proposes to adopt release 2.2.0 (SMART v2.2 Guide) in § 170.215(c)(3). ONC proposes that the adoption of the SMART v2 Guide in § 170.215(c)(2) expires on January 1, 2028. ONC also clarifies the existing Program requirements to support patient authorization using SMART App Launch capabilities. Specifically, we clarify that if both the "permission-patient" and "permission-v2" capabilities are required in support of patient authorization for certification to a criterion in the Program, then a Health IT Module must support the following:

- Support for the ability for patients to authorize an application to receive their EHI based on individual FHIR resource-level and individual sub-resource-level scopes.

- Support for the ability for patients to authorize an application to receive their EHI based on individual sub-resource-level scopes when corresponding resource-level scopes are requested.

iii. User-Access Brands and Endpoints

ONC proposes to adopt the User-access Brands and Endpoints (Brands) specification for its service base URL publication requirements. Specifically, ONC proposes in its updated § 170.404(b)(2)(iii) to require that, by January 1, 2028, service base URLs and related API Information Source details, including each organization's name, location, and facility identifier, must be published in an aggregate vendor consolidated "FHIR Bundle" according to the Brands specification.

Additionally, in the proposal to revise § 170.404(b)(3) where ONC proposes new requirements for the publication of API discovery details for payer network information, including service base URLs and API Information Source details, ONC proposes to adopt Brands specification.

iv. Standards for Encryption and Decryption of Electronic Health Information

ONC proposes to adopt the updated version of Annex A of the Federal Information Processing Standards (FIPS) 140-2 (Draft, October 12, 2021) in § 170.210(a)(3) and incorporate it by reference in § 170.299. ONC proposes to add an expiration date of January 1, 2026, to the FIPS 140-2 (October 8, 2014) version of the standard presently adopted in § 170.210(a)(2). ONC also proposes to remove the standard found in § 170.210(f), which is no longer referenced in any active certification criteria. Revising § 170.210(a) by adding an expiration date in § 170.210(a)(2) and a new version of the FIPS standard in § 170.210(a)(3) would impact three certification criteria that currently reference the standard in § 170.210(a)(2), including § 170.315(d)(7) "end-user device encryption;" (d)(9) "trusted connection;" and (d)(12) "encrypt authentication credentials."

v. Minimum Standards Code Sets Updates

ONC proposes to adopt newer versions of the following minimum standards code sets:

- § 170.207(a) – Problems
- § 170.207(c) – Laboratory tests
- § 170.207(d) – Medications
- § 170.207(e) – Immunizations
- § 170.207(f) – Race and Ethnicity
- § 170.207(n) – Sex
- § 170.207(o) – Sexual orientation and gender information
- § 170.207(p) – Social, psychological, and behavioral data

vi. New Imaging Requirements for Health IT Modules

ONC proposes to revise the certification criteria adopted in § 170.315(b)(1), (e)(1), (g)(9), and (g)(10) to include new certification requirements to support access, exchange, and use of diagnostic images via imaging links. ONC did not propose a specific standard associated with the support of this functionality. ONC proposes that by January 1, 2028, a health IT developer of a Health IT Module certified to the certification criteria related to "transitions of care" in § 170.315(b)(1), "view, download, and transmit" in § 170.315(e)(1), "application access—all data request," in § 170.315(g)(9), and "standardized API for patient and population services," in § 170.315(g)(10) must update their Health IT Module and provide the updated version to their customers to maintain certification of that Health IT Module.

vii. Revised Clinical Information Reconciliation and Incorporation Criterion

ONC proposes a primary proposal and an alternative proposal for revising the "clinical information reconciliation and incorporation" certification criterion in § 170.315(b)(2) to expand the number and types of data elements that Health IT Modules certified to this criterion would be required to reconcile and incorporate. The primary proposal would require Health IT Modules certified to § 170.315(b)(2) to be capable of reconciling and incorporating all USCDI data elements according to at least one of the versions of the USCDI standard specified in § 170.213. The alternative proposal would require Health IT Modules to reconcile and incorporate data elements from six additional USCDI data classes beyond the existing three data classes required as part of the current certification criterion's functionality.

ONC also proposes new functional requirements to enable user-driven automatic reconciliation and incorporation. ONC proposes that by January 1, 2028, a health IT developer of a Health IT Module certified to the criterion in § 170.315(b)(2) must update their Health IT Module and provide the updated version to their customers in order to maintain certification of that Health IT Module.

viii. Revised Electronic Prescribing Certification Criterion

ONC proposes to incorporate the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard version 2023011 in an updated version of the electronic prescribing certification criterion in § 170.315(b)(3)(ii). Under this proposal, health IT developers may maintain health IT certification conformance with the current version of the criterion using NCPDP SCRIPT standard version 2017071 for the time period up to and including December 31, 2027. By January 1, 2028, a health IT developer of a Health IT Module certified to the criterion in § 170.315(b)(3) must update the Health IT Module to use the NCPDP SCRIPT standard version 2023011 and provide that update to their customers in order to maintain certification of the Health IT Module. ONC also proposes a series of updates to the transactions included in § 170.315(b)(3)(ii) including removing transactions currently identified as optional for the certification criterion.

ix. New Real-Time Prescription Benefit Criterion

ONC proposes to establish a real-time prescription benefit certification criterion in § 170.315(b)(4) based on the National Council for Prescription Drug Programs (NCPDP) Real-Time Prescription Benefit (RTPB) standard version 13. ONC proposes to include this certification criterion in the Base EHR definition.

x. Electronic Health Information (EHI) Export – Single Patient EHI Export Exemption

ONC proposes to exempt Health IT Modules that act primarily as intermediaries between systems and, through integration, function without any direct human interaction from the requirement in § 170.315(b)(10)(i)(B) to provide functionality without subsequent developer assistance to operate. This exemption would be available if the developer of such a Health IT Module receives fewer than ten requests in the immediately preceding calendar year for a single patient EHI export. Developers of certified health IT with Health IT Modules certified to § 170.315(b)(10) that claim the exemption would need to report the number of requests for single patient EHI export on an annual basis to their ONC-Authorized Certification Bodies (ACBs) by March 1 of each calendar year beginning in 2028.

xi. Revised End-User Device Encryption Criterion

ONC proposes to revise § 170.315(d)(7) to include a new requirement that Health IT Modules certified to this criterion encrypt EHI stored server-side on and after January 1, 2026.

xii. Revised Criterion for Encrypt Authentication Credentials

ONC proposes to revise the "encrypt authentication credentials" certification criterion in § 170.315(d)(12) by expiring the current "yes" or "no" attestation requirement and replacing it with a new requirement that Health IT Modules that store authentication credentials protect the confidentiality and integrity of its stored authentication credentials according to the Federal Information Processing Standards (FIPS) 140-2 (October 12, 2021) industry standard.

xiii. Health IT Modules Supporting Public Health Data Exchange

ONC proposes:

- to revise the Program's current certification criteria related to public health in § 170.315(f), including referencing newer versions of respective exchange and vocabulary standards in the current § 170.315(f) certification criteria (§ 170.315(f)(1) – (f)(7));
- two additional certification criteria for birth reporting (§ 170.315(f)(8)) and bi-directional exchange with a prescription drug monitoring program (PDMP) (§ 170.315(f)(9));
- new certification criteria for Health IT Modules supporting public health data exchange in § 170.315(f)(21) – (25), (28) and (29); and,
- a new certification criterion for a standardized FHIR®-based API for public health data exchange in § 170.315(g)(20).

xiv. Bulk Data Enhancements

ONC proposes to adopt the HL7® FHIR® Bulk Data Access v2.0 implementation specification (Bulk v2 IG) in § 170.215(d)(2). ONC also proposes to require server support for the "group export" operation and a "_type" query parameter for performance improvement. ONC intends for this proposal to raise the floor from its current Bulk v1 IG requirements for certification, where it requires support for the group export operation but does not require support for any of the optional query parameters in the IG.

xv. New Requirements to Support Dynamic Client Registration Protocol in the Program

ONC proposes to add requirements in the Program to support dynamic client registration and subsequent authentication and authorization for dynamically registered apps for patient-facing, user-facing, and system confidential applications. This includes adding requirements to the following in the Program:

- § 170.315(g)(10) certification criterion
- § 170.315(g)(20), (30), and (32) – (35) proposed certification criteria
- § 170.315(j)(2), (5), (8), (11) proposed certification criteria
- API Conditions and Maintenance of Certification requirements in § 170.404

ONC also proposes to adopt the HL7® Unified Data Access Profiles (UDAP™) Security for Scalable Registration, Authentication, and Authorization Implementation Guide Release 1.0.0 implementation guide (UDAP Security IG v1).

xvi. New Certification Criteria for Modular API Capabilities

ONC proposes to add a new category of certification criteria to § 170.315 titled "modular API capabilities" in § 170.315(j). ONC proposes that the certification criteria in § 170.315(j) would represent API capabilities that are standards-based, including through new standards, such as HL7® Clinical Decision Support (CDS) Hooks, SMART Health Cards, and HL7 FHIR® Subscriptions, as well as standards and functionalities historically referenced in § 170.315(g)(10). These modular API capabilities would be referenced and

incorporated into Health IT Modules to support standardized APIs for clinical use cases in § 170.315(g)(10), public health use cases in § 170.315(g)(20), and health insurance and coverage use cases in § 170.315(g)(30)-(36), as well as other future use cases across the health IT landscape.

xvii. Multi-factor Authentication Criterion

ONC proposes to revise the "multi-factor authentication" (MFA) certification criterion in § 170.315(d)(13) and accordingly update the privacy and security (P&S) certification framework in § 170.550(h). The proposed update would revise the MFA certification criterion by replacing the current "yes" or "no" attestation requirement with a specific requirement to support multi-factor authentication and configuration for three certification criteria on and after January 1, 2028.

xviii. Revised Computerized Provider Order Entry – Laboratory Criterion

ONC proposes to update the "computerized provider order entry – laboratory" certification criterion in § 170.315(a)(2) to require enabling a user to create and transmit laboratory orders electronically according to the standard proposed in § 170.205(g)(2), the HL7® Laboratory Order Interface (LOI) Implementation Guide (IG). ONC further proposes to update § 170.315(a)(2) to require technology to receive and validate laboratory results according to the standard proposed in § 170.205(g)(3), the HL7® Laboratory Results Interface (LRI) IG. ONC proposes that by January 1, 2028, a health IT developer of a Health IT Module certified to the criterion in § 170.315(a)(2) must update its Health IT Module and provide the updated version to its customers in order to maintain certification of that Health IT Module.

xix. Revised Standardized API for Patient and Population Services Criterion to Align with Modular API Capabilities

ONC proposes to revise the certification criterion in § 170.315(g)(10) to reorganize requirements to improve clarity and align with new proposals in this rule, including proposed:

- Restructuring of existing requirements to reference the "modular API capabilities" certification criteria proposed in § 170.315(j)
- Support for dynamic registration and subsequent authentication and authorization of patient-facing, user-facing, and system confidential apps
- Support for multi-factor authentication for patient-facing authentication according to requirements proposed in § 170.315(d)(13)(ii) support for imaging links in data response requirements
- Support for a read and search API for system apps
- Support for "_type" query parameter for Bulk FHIR API
- Support for the issuance of verifiable health records as specified by the requirements proposed in § 170.315(j)(22)
- Support for subscriptions as a server according to the requirements specified in proposed § 170.315(j)(23)
- Support for workflow triggers for decision support interventions according to the requirements specified in proposed § 170.315(j)(20)
- Support for authorization revocation for users (e.g., clinicians)
- Moving of the API documentation requirements in § 170.315(g)(10) to the API Conditions and Maintenance of Certification requirements in § 170.404

ONC proposes that by January 1, 2028, a health IT developer of a Health IT Module certified to the criterion in § 170.315(g)(10) must update its Health IT Module and provide the updated version to its customers in order to maintain certification of that Health IT Module.

xx. Patient, Provider, and Payer APIs

ONC proposes a set of certification criteria in § 170.315(g)(30) through (36) that aim to complement and advance the policies that CMS has developed to increase patient, provider, and payer access to information. Health IT developers, including those that support payers, would be able to ensure that Health IT Modules certified to these proposed criteria, when used to satisfy the CMS requirements, have been tested for conformance with widely available industry standards designed to support interoperability for each use case. ONC proposes to adopt a set of HL7® FHIR® IGs in § 170.215 to support these certification criteria, and to incorporate these specifications by reference in § 170.299.

Conditions and Maintenance of Certification Requirements – Insights and Attestations

a. Insights Condition and Maintenance of Certification Requirements

ONC proposes to update the Insights Condition by requiring health IT developers to include health care provider identifiers, for providers included in the data submitted in response for the measures specified in § 170.407. ONC also proposes updates to the overall process for reporting and newer versions of certified health IT for responses submitted under the Insights Condition in § 170.407(b).

ONC proposes to update two measures under the Insights Condition. First, ONC proposes to revise the "individuals' access to electronic health information through certified health IT" measure in § 170.407(a)(3)(i) to include both individuals and individuals' authorized representatives accessing their EHI. Second, ONC proposes to require developers to submit responses on specific data classes and elements from C-CDA documents reconciled and incorporated both through manual and automated processes in § 170.407(a)(3)(ii)(E). ONC also intends to make various technical updates to the measure specification sheets accompanying the Insights Condition, including the clarification of certain definitions and terms, as well as adding new metrics.

b. Attestations Condition and Maintenance of Certification Requirements

ONC proposes to revise the Attestations Condition and Maintenance of Certification requirements by adding the requirement in § 170.406(a)(2) that a health IT developer, as a Condition of Certification, attest to compliance with § 170.402(b)(4), if the health IT developer certified a Health IT Module(s) to the "decision support interventions" certification criteria in § 170.315(b)(11).

Information Blocking Enhancements

ONC proposes revisions to definitions used in the information blocking regulations.

ONC proposes to amend the definition of "health care provider" so that it is explicitly clear that the terms "laboratory" and "pharmacist" have the meanings established for these terms in 42 U.S.C. 300jj(10) and (12), respectively.

ONC proposes to add a section (§ 171.104) to the information blocking regulations that would codify certain practices (acts and omissions) that constitute interferences for purposes of the information blocking definition (codified in § 171.103). The proposed codified practices are not an exhaustive list; additional practices not described in the proposed § 171.104 that are likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI may also be considered to rise to the level of an interference.

For purposes of the information blocking Privacy Exception, the term "individual" is defined in § 171.202(a)(2). ONC proposes technical corrections to cross-referenced citations.

To clearly establish coverage of the § 171.202(d) sub-exception for all actors' practices under the same requirements, ONC proposes to change the name of the sub-exception to: "interfering with individual access based on unreviewable grounds." This proposed change to the header text is intended to express the expansion of its availability to actors who are not Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entities or business associates.

ONC proposes to slightly modify the header of § 171.202(e) for ease of reference to "Individual's request not to share EHI." ONC also proposes to revise the § 171.202(e) sub-exception to remove the existing limitation that allows the exception to be used only for individual-requested restrictions on EHI sharing that are permitted by other applicable law. The proposal would extend the availability of the § 171.202(e) sub-exception to an actor's practice of applying restrictions the individual has requested on the access, exchange, or use of an individual's EHI even when the actor may have concern that another law applicable to some or all of the actor's operations could compel the actor to provide access, exchange, or use of EHI contrary to the individual's expressed wishes.

ONC proposes revisions to three conditions of the Infeasibility Exception. Specifically, ONC proposes to modify the § 171.204(a)(2) segmentation condition to specifically cross-reference additional information blocking exceptions under which an actor may choose to withhold EHI that the actor could, under applicable law, make available.

ONC proposes to modify the § 171.204(a)(3) third party seeking modification use condition by changing the words "health care provider" to "covered entity as defined in 45 CFR 160.103" in the exclusion from applicability of this condition. ONC also proposes in § 171.204(a)(3)(ii) to extend the exclusion from applicability of the third party seeking modification use condition requests for modification use from health care providers, as defined in § 171.102 and who are not covered entities, requesting such use from actors whose activities would make them a business associate of that same health care provider if the healthcare provider (actor) was covered by HIPAA.

ONC proposes to modify the § 171.204(b) responding to requests condition by establishing different timeframes for sending written responses to the requestor based on the § 171.204(a) condition under which fulfilling the requested access, exchange, or use of EHI is infeasible. The proposed revision would retain the requirement that actors communicate to requestors "in writing the reason(s) why the request is infeasible" that was finalized in the ONC Cures Act Final Rule.

ONC proposes a new Protecting Care Access Exception that would, under specified conditions, apply to acts or omissions likely to interfere with access, exchange, or use of particular EHI that an actor believes could create a risk of exposing patients, care providers, and other persons who assist in access or delivery of health care to potential administrative, civil, or criminal investigations or other actions on certain bases.

The practices that the proposed Protecting Care Access Exception (§ 171.206) would except from the information blocking definition would be those implemented based on the actor's good faith belief that sharing EHI indicating that any person(s) sought, received, provided, or facilitated the provision or receipt of reproductive health care that was lawful under the circumstances in which it was provided could result in a risk of potential exposure to legal action for those persons and that the risk could be reduced by practices likely to interfere with particular access, exchange, or use of specific EHI. For purposes of the Protecting Care Access Exception, ONC proposes to rely on the same definition of "reproductive health care" (which can be found in 45 CFR 160.103) that is used for purposes of the HIPAA regulations.

To satisfy the proposed new Protecting Care Access (§ 171.206) Exception, an actor's practice would need to satisfy the threshold condition (§ 171.206(a)), and at least one of the other two conditions in the exception: the patient protection condition (§ 171.206(b)) or the care access condition (§ 171.206(c)). The

combination of conditions required to satisfy the proposed new Protecting Care Access Exception and the definition of "legal action" (in § 171.206(d)) for purposes of the exception would, together, seek to ensure that the exception would not apply to an actor's attempts to shield any person from legal action based on allegations that health care items or services the person provided are substandard.

The Protecting Care Access Exception's threshold condition (§ 171.206(a)) includes requirements that the practice be: undertaken based on the actor's belief as specified in § 171.206(a)(1), no broader than necessary as specified in § 171.206(a)(2) and be implemented consistent with a written organizational policy or case-by-case determination contemporaneously documented in writing as specified in § 171.206(a)(3). Meeting the threshold condition would be necessary, but not alone sufficient, for an actor's practice to be covered by the proposed Protecting Care Access (§ 171.206) exception. To satisfy the exception, any actor's practice likely to interfere with access, exchange, or use of EHI would also need to satisfy at least one of the other two conditions (in paragraphs (b) and (c)) of the proposed exception.

ONC also propose a patient protection condition (§ 171.206(b)), that can be met by practices implemented by the actor for the purpose of reducing a risk of potential legal action that the actor believes a patient could otherwise face because the EHI shows or invites a reasonable inference that the patient has or has done any of the following (see proposed § 171.206(b)(1)): (i) obtained reproductive health care that was lawful under the circumstances in which it was provided; (ii) Inquired about or expressed an interest in seeking reproductive health care; or (iii) Particular demographic characteristics or any health condition(s) or history for which reproductive health care is often sought, obtained, or medically indicated.

The proposed patient protection condition would specify (§ 171.206(b)(2)) that to meet the condition the actor's practice must be subject to nullification by explicit request or directive from the patient. ONC clarifies (in proposed § 171.206(b)(3)) that for purposes of the patient protection condition's other paragraphs that "patient" means the natural person who is the subject of the EHI, or another natural person referenced in, or identifiable from, the EHI as having sought or received reproductive health care.

ONC proposes a care access condition (§ 171.206(c)) that can be met by practices an actor might choose to implement for the purpose of reducing a risk of potential exposure to legal action for licensed health care professionals, other health care providers, or persons involved in providing or in facilitating the provision or receipt of reproductive health care that is lawful under the circumstances in which such health care is provided. ONC requests comment on multiple, potentially non-exclusive, alternative proposals for additional requirements under the care access condition that would function to restrict the exception's coverage of practices that interfere with access, exchange, or use in scenarios that also implicate the HIPAA Privacy Rule's individual right of access provisions (45 CFR 164.524).

ONC proposes clarifying provisions in § 171.206(d) and § 171.206(e). Proposed § 171.206(d) would clarify when reproductive health care sought, obtained, provided, or facilitated by someone other than the actor will be presumed to have been lawful for purposes of assessing whether an actor's practice meets the exception's patient protection or care access condition.

ONC also proposes a new information blocking exception: "Requestor Preferences" in 45 CFR 171.304. This exception stands separate from and independent of other exceptions and would apply where an actor honors or adheres to a requestor's preference(s) expressed or confirmed in writing for: (1) limitations on the amount of EHI made available to the requestor; (2) the conditions under which EHI is made available to the requestor; and (3) when EHI is made available to the requestor for access, exchange, or use. The exception would offer an actor certainty that, so long as the actor's practices meet the conditions of the exception, the actor can honor or adhere to a requestor's preferences related to these specific

preferences without concern that the actor may be engaging in "information blocking" as defined in 45 CFR 171.103.

ONC seeks comment on some aspects of the TEFCA Manner Exception in 45 CFR 171.403, including the limitation on its use for requests made via a FHIR API and the application of the Fees and Licensing Exceptions to practices that satisfy the exception.

Trusted Exchange Framework and Common Agreement™

ONC proposes to add a new part, part 172, to subchapter D of title 45 of the Code of Federal Regulations to implement certain provisions related to the TEFCA. These proposed provisions would establish 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 proposals would also establish the procedures governing Onboarding (as defined in § 172.102) of QHINs and Designation of QHINs, suspension, termination, and administrative appeals to ONC, as described in the sections below. These policies already exist today, but until now, have been included in sub-regulatory guidance.

In subpart A, ONC proposes the statutory basis, purpose, and scope of the TEFCA provisions in part 172; the applicability of the TEFCA provisions in part 172; and relevant definitions.

In subpart B, ONC proposes requirements related to the qualifications needed to be Designated, as proposed to be defined in § 172.102.

In subpart C, ONC describes the proposed QHIN Onboarding and Designation processes.

In subpart D, ONC proposes RCE and QHIN suspension rights, notice requirements for suspension, and the requirements related to the effect of suspension.

In subpart E, ONC proposes RCE and QHIN termination rights, notice requirements for termination, and requirements related to the effect of termination.

In subpart F, ONC proposes to establish QHIN appeal rights and the process for filing an appeal to ONC. These appeal rights would ensure that a QHIN, or Applicant QHIN, that (1) disagrees with certain RCE determinations or (2) believes an action or inaction by a QHIN or the RCE could threaten TEFCA's integrity will have recourse to appeal such determination, action, or inaction to ONC.

In subpart G, ONC proposes 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 ONC's website of those 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.