



Health Data, Technology, and Interoperability (HTI-2) Proposed Rule

Patient Engagement, Information Sharing, and Public Health Interoperability Proposed Rule

OVERVIEW WEBINAR

JULY 17, 2024

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AGENDA

- Purpose
- Certification Standards and Functionality Updates
- Condition and Maintenance of Certification Requirements
- Information Blocking Proposals
- TEFCA

Purpose of HTI-2 Proposed Rule



Implementing the 21st Century Cures Act

- APIs that allow EHI to be accessed, exchanged, and used without special effort
- Reasonable and necessary activities that do not constitute information blocking
- Establish the qualifications necessary for an entity to receive and maintain designation as a QHIN capable of trusted exchange pursuant to TEFCA



Achieving the Goals of the Biden-Harris Administration Executive Orders

- E.O. 13994 “Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats”
- E.O. 13985 “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government” and E.O. 14091 “Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government”
- E.O. 14036 “Promoting Competition in the American Economy”
- E.O. 14058 “Transforming Federal Customer Experience and Service Delivery to Rebuild Trust in Government”



Leveraging Health IT and Advancing Interoperability

- HITECH Act
- Interoperability Advancement
- ONC Health IT Certification Program

What Are We Proposing to Do?

- ▶ Advance health IT infrastructure nationwide;
- ▶ Minimize data silos so health IT users can access information from various settings;
- ▶ Emphasize technology solutions that are easier to adopt, particularly in settings with limited resources;
- ▶ Enhance interoperability across health care and public health;
- ▶ Advance equity;
- ▶ Support patients' access to lawful reproductive health care; and
- ▶ Strengthen support for actors honoring patients' individual privacy preferences



New and Revised

Standards and Certification Criteria

New and Revised Standards and Certification Criteria

Standards

- The United States Core Data for Interoperability Version 4 (USCDI v4)
- SMART App Launch 2.2
- User-Access Brands and Endpoints
- Standards for Encryption and Decryption of Electronic Health Information
- Minimum Standards Code Sets Updates
- Bulk Data Enhancements

New Criteria

- New Real-Time Prescription Benefit Criterion
- New Health IT Modules Supporting Public Health Data Exchange
- New Requirements to Support Dynamic Client Registration Protocol in the Program
- New Certification Criteria for Modular API Capabilities
- New Patient, Provider, and Payer APIs

Revised Criteria

- Revised Interoperability Criteria with New Imaging Requirements
- Revised Clinical Information Reconciliation and Incorporation Criterion
- Revised Electronic Prescribing Certification Criterion
- Revised Electronic Health Information (EHI) Export – Single Patient EHI Export Exemption
- Revised End-User Device Encryption Criterion
- Revised Criterion for Encrypt Authentication Credentials
- Revised Computerized Provider Order Entry – Laboratory Criterion
- Revised Multi-factor Authentication Criterion
- Revised Standardized API for Patient and Population Services

Diagnostic Imaging Hyperlink

PROPOSAL

ONC proposes to revise the certification criteria found at § 170.315(b)(1), § 170.315(e)(1), § 170.315(g)(9), and § 170.315(g)(10) to include certification requirements to support capturing and documenting hyperlinks to diagnostic imaging. ONC is not, however, proposing a specific standard associated with the support of this functionality, and ONC notes that this requirement can be met with a context-sensitive link to an external application which provides access to images and their associated narrative.

BENEFITS

Diagnostic images are often stored in systems external to the EHR, such as picture archiving and communication systems (PACS) or vendor neutral archives (VNA). Promoting access to images via EHR hyperlink functionality may encourage more widespread adoption and integration of these already existing pathways and reduce inefficient CD-ROM-dependent exchange.

Revised Clinical Information Reconciliation and Incorporation Criterion

PROPOSAL

- ONC proposes two options for revising the “clinical information reconciliation and incorporation” (CIRI) 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:
 - Primary proposal: Require CIRI of all USCDI data elements.
 - Alternative proposal: Require CIRI of a limited set of additional USCDI data elements.
- ONC additionally proposes adding a new functional requirement to enable user-driven automatic CIRI

BENEFITS

- Support for longitudinal patient record.
- New capabilities that would benefit providers by reducing the burden of reconciliation and incorporation in clinical workflows.

USCDI Version 4

PROPOSAL

ONC proposes to adopt USCDI v4 as part of the Certification Program and require that Health IT Modules certified to criteria that reference the USCDI (at § 170.213) update and provide their customers with such technology by January 1, 2028.

BENEFITS

- The adoption of USCDI v4 would add 20 new data elements, some of which are specifically relevant to behavioral health and marginalized and underserved communities, including:
 - Goals and preferences
 - Treatment intervention preference, care experience preference data elements
 - Health Status Assessments
 - Alcohol use, substance use, and physical activity data elements
- USCDI v4 would also support data users' abilities to identify, assess, and analyze gaps in care, which could in turn be used to inform and address the quality of healthcare through interventions and strategies.

USCDI Related Certification Criteria

- Transitions of care at § 170.315(b)(1)
- Clinical information reconciliation and incorporation at § 170.315(b)(2)
- Decision support interventions at § 170.315(b)(11)
- View, download, and transmit to 3rd party at § 170.315(e)(1)
- Electronic case reporting at § 170.315(f)(5)
- Consolidated CDA creation performance at § 170.315(g)(6)
- Application access – all data request at § 170.315(g)(9)
- Standardized API for patient and population services at § 170.315(g)(10)

Revised Electronic Prescribing Certification Criterion

PROPOSAL

ONC proposes to incorporate National Council for Prescription Drug Programs (NCPDP) SCRIPT standard version 2023011 in an updated version of the electronic prescribing criterion in § 170.315(b)(3)(ii).

ONC proposes that health IT developers must update to the proposed version of the criterion incorporating NCPDP SCRIPT standard version 2023011 by January 1, 2028.

ONC proposes a series of updates to the transactions included in § 170.315(b)(3)(ii) including removing transactions currently identified as optional for the criterion.

BENEFITS

- With electronic prescribing, or “e-Prescribing,” health care providers can enter prescription information into a computer device – like a tablet, laptop, or desktop computer – and securely transmit the prescription to pharmacies.
- When a pharmacy receives a request, it can begin filling the medication right away.

Real-Time Prescription Benefit

PROPOSAL

ONC proposes a “Real-Time Prescription Benefit” certification criterion at 45 CFR 170.315(b)(4) to enable the exchange of patient eligibility, product coverage, and benefit financials for a chosen product and pharmacy, and to identify coverage restrictions and alternatives when they exist.

Proposes to incorporate National Council for Prescription Drug Programs (NCPDP) Real-Time Prescription Benefit (RTPB) standard version 13 in partnership with CMS.

BENEFITS

- Health IT certified to the proposed criterion would enable prescribers to assist patients with understanding the financial impacts associated with different prescriptions.
- Ability to understand this information at the point of care can ensure that patients receive the right medication and address affordability issues when a medication is prescribed.



Security Criteria Revisions

Revised End-User Device Encryption Criterion + Related Standards Proposals

PROPOSAL

- We propose to revise § 170.315(d)(7) to include a new requirements that Health IT Modules certified to this criterion encrypt personally identifiable information (PII) stored on end-user devices and server-side.
- Additionally, we propose to adopt the latest FIPS Annex A standard in § 170.210(a), updating from the October 8, 2014, version to the October 12, 2021, version.

BENEFITS

- Improved security by updating ONC requirements to align the latest NIST approved encryption algorithms.

Multi-Factor Authentication

PROPOSAL

ONC proposes to revise the “multi-factor authentication” (MFA) certification criterion in § 170.315(d)(13) and accordingly update the privacy and security certification framework in § 170.550(h). The proposed update would revise the MFA 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:

- “view, download, transmit” (§ 170.315(e)(1));
- “standardized API for patient and population services” (§ 170.315(g)(10)) (for “patient-facing” access);
- and “electronic prescribing” (§ 170.315(b)(3)).

BENEFITS

- Updates match industry best practices for information security, particularly for important authentication use cases in health IT.

Revised Criterion for Encrypt Authentication Credentials

PROPOSAL

ONC proposes to revise the “encrypt authentication credentials” certification criterion in § 170.315(d)(12).

ONC proposes to replace the current “yes” or “no” attestation requirement with a requirement for Health IT Modules that store authentication credentials to protect the confidentiality and integrity of its stored authentication credentials according to the Federal Information Processing Standards (FIPS) 140-2 (Draft, October 12, 2021) industry standard. ONC also proposes to change the name of this criterion to “protect stored authentication credentials,” which would more appropriately describe the revised criterion.

BENEFITS

- Promotes protection of stored authentication credentials according to industry standards
- Critical defensive step to help ensure that stolen or leaked authentication credentials are useless to an attacker



New and Revised

Public Health Data Exchange Certification Criteria

Public Health Data Exchange- Revisions and New Criteria

PROPOSAL

- ONC propose to update existing certification criteria for reporting public health data to include new and updated standards
- ONC also proposes to establish new certification criteria for reported public health data including the ability to receive, validate, parse and filter data according to standards
- ONC proposes a new, standards-based APIs for public health data exchange

BENEFITS

- The capabilities we propose are intended to advance tools which can be used in a variety of ways across multiple programmatic and organizational use cases and processes.
- Modernization efforts across health IT and health IT for public health will progress and upgrade on the same timeline, using the same standards across the ecosystem.
- Establishing minimum functional capabilities and exchange standards for health IT to send and health IT for public health to receive public health data, we expect to enhance interoperability across health care and public health and provide a long-term mechanism for alignment as data exchange matures over time.

Public Health Data Exchange- Revisions and New Criteria

Immunizations (f)(1)	By January 1, 2027	Update to HL7 Version 2.5.1 IG for Immunization Messaging, Release 1.5 2018 Update and support new functionality to respond to incoming patient-level queries
Syndromic surveillance (f)(2)	By January 1, 2027	Update to 2019 version of HL7 Version 2.5.1 Implementation Guide: Syndromic Surveillance, Release 1 – US Realm Standard for Trial Use, July 2019
Electronic lab reporting (f)(3)	By January 1, 2028	Update to HL7 Version 2.5.1 LOI from EHR, Release 1 & LRI, Release 1, specifically the Public Health Profile within the IG and support new functionality for receipt of reportable lab orders and transmission of reportable lab results according to the IGs
Cancer registry reporting (f)(4)	By January 1, 2028	Update to require the HL7 FHIR Central Cancer Registry Reporting Content IG 1.0.0 - STU1 and require support for Cancer pathology reporting according to the HL7 FHIR Cancer Pathology Data Sharing, 1.0.0
Case reporting (f)(5)	By January 1, 2028	Update to use the eICR profile of the HL7 FHIR eCR IG only
AU / AR (f)(6)	By January 1, 2027	Update to HL7 CDA® R2 Implementation Guide: Healthcare Associated Infection (HAI) Reports, Release 3 - U.S. Realm
Health care surveys (f)(7)	By January 1, 2027	Update HL7 CDA® R2 Implementation Guide: National Health Care Surveys (NHCS), R1 STU Release 3.1 – US Realm
Birth reporting (f)(8)	New Criterion	HL7 FHIR Vital Records Birth and Fetal Death Reporting 1.1.0 – STU 1.1
Prescription Drug Monitoring Program (f)(9)	New Criterion	Functional requirement to enable query of a PDMP, including bi-directional interstate exchange and to receive PDMP data in an interoperable manner

Public Health Data Exchange- Revisions and New Criteria

Immunizations (f)(21)

Receive, validate, parse, and filter immunization information to advance bi-directional interoperability between health care and public health agencies
Standard: HL7 Version 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5 2018 Update

Syndromic Surveillance (f)(22)

Receive, validate, parse, and filter incoming syndromic surveillance information
Standard: HL7 Version 2.5.1 Implementation Guide: Syndromic Surveillance, Release 1 – US Realm Standard for Trial Use, July 2019

Electronic lab reporting (f)(23)

Receive, validate, parse, and filter incoming reportable laboratory test results/values
Standard: HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface, Release 1 STU Release 4 - US Realm (LRI), specifically the Public Health Profile within the Implementation Guide

Cancer Pathology Reporting (f)(24)

Receive, validate, parse, and filter incoming cancer pathology reports
HL7 FHIR Cancer Pathology Data Sharing, 1.0.0 - STU1

Electronic Case Reporting (f)(25)

Receive, validate, parse, and filter of electronic case reports and reportability response
HL7 CDA® R2 Implementation Guide: Public Health Case Report—the Electronic Initial Case Report (eICR) Release 2, STU Release 3.1—US Realm (HL7 CDA eICR IG) to the HL7 eCR FHIR IG

Birth Reporting (f)(28)

Receive, validate, parse, and filter incoming birth reports
HL7 FHIR Vital Records Birth and Fetal Death Reporting—1.1.0 - STU 1.1

Prescription Drug Monitoring Program (f)(29)

Receive, validate, parse, filter prescription data, support query and exchange electronic controlled substance medication prescription information through a FHIR-based API, Bulk FHIR, or SMTP-based edge protocol; or, optionally through TEFCAs

Standardized API for Public Health Data Exchange Proposal

PROPOSAL

We propose a standardized HL7 FHIR-based API for public health data exchange at § 170.315(g)(20) that would extend the capabilities included in the standardized API for patient and population services in § 170.315(g)(10). This new certification criterion would support ongoing and future development of public health FHIR IGs leveraging a core set of existing, modular, and extensible capabilities and standards.

BENEFITS

- A necessary first step towards furthering a FHIR-based ecosystem that would support a wide array of public health data exchange use cases
- Better streamline and reduce reporting burden for healthcare organizations and developers, while expanding PHA's access to critical data for action
- Extend the capabilities included in the standardized API for patient and population services in § 170.315(g)(10) by requiring support for FHIR Resources Profiled in the United States Public Health Profiles Library Implementation Guide (USPHPL IG)
- Ensure that PHAs will have consistent access of discrete functionalities, defined capabilities, and standardized data from providers using certified health IT systems for a range of public health use cases
- Support ongoing and future development of public health FHIR IGs leveraging a core set of existing, modular, and extensible capabilities and standards



Patient, Provider, and Payer API

Patient, Provider, and Payer API Capabilities

PROPOSAL

ONC proposes a set of certification criteria in § 170.315(g)(30) through (36). These proposed certification criteria reference a set of FHIR implementation specifications that ONC proposes to adopt, on behalf of the Secretary, in § 170.215.

BENEFITS

- The proposed certification criteria align with CMS-established API requirements and would enable implementers to ensure that APIs developed to meet CMS regulations adhere to required and recommended interoperability standards and support other features important to effective information sharing.
- Reduce burden associated with certain administrative processes.
- Increase patient and provider access to important health care data held by payers.

Patient Access API

PROPOSAL

ONC proposes to adopt the “Patient access API” certification criterion in § 170.315(g)(30) to specify requirements for health IT that can be used by payers to enable patients to access health and administrative information using a health application of their choice, including payer drug formulary information, and patient clinical, coverage, and claims information.

Proposes to reference standards including CARIN Blue Button IG, Da Vinci PDex IG, Da Vinci US Drug Formulary IG, and the US Core IG.

BENEFITS

- Access to data held by payers can increase patient understanding of their health and health care, helping patients to be more informed when making decisions about their care.
- Aligns with CMS requirements for payers to establish Patient Access APIs originally finalized in CMS’ Interoperability and Patient Access final rule.

Provider Access API

PROPOSAL

ONC proposes to adopt the “Provider access API – client” and “Provider access API – server” certification criteria at § 170.315(g)(31) and (g)(32) to specify requirements for provider and payer systems to support provider access to payer information. This information can include patient clinical, coverage, and claims information.

Proposes to reference standards including CARIN Blue Button IG, Da Vinci PDex IG, and US Core IG.

BENEFITS

- Provider access to data held by payers about their patients can help inform better care coordination as well as higher quality care and can support provider participation in value-based care.
- Aligns with CMS requirements for payers to establish a Provider Access API finalized in CMS’ Interoperability and Prior Authorization final rule.

Payer-to-Payer API

PROPOSAL

ONC proposes to adopt a “Payer-to-payer API” certification criterion in § 170.315(g)(33) to specify requirements for health IT that can be used by payers to support electronic exchange between payer systems.

Proposes to reference standards including CARIN Blue Button IG, Da Vinci PDex IG, and US Core IG.

BENEFITS

- The exchange of patient information between payers can allow health information to follow a patient when they switch insurance plans and can enable improved coordination of care, increased patient empowerment, and reduced administrative burden.
- Aligns with CMS requirements for payers to establish Payer-to-Payer Access APIs originally finalized in CMS’ Interoperability and Patient Access final rule and updated in the Interoperability and Prior Authorization final rule.

Prior Authorization API – Provider and Payer

PROPOSAL

ONC proposes to adopt “Prior authorization API – provider” and “Prior authorization API – payer” certification criteria in § 170.315(g)(34) and (g)(35).

The proposed provider certification criterion specifies requirements for providers to request coverage requirements and assemble and submit documentation for prior authorization, while the payer criterion supports payers’ ability to provide information about coverage and documentation requirements and receive prior authorization requests from providers.

Proposes to reference standards including Da Vinci Coverage Requirements Discovery IG, Da Vinci Documentation Templates and Rules IG, and Da Vinci Prior Authorization Support IG.

BENEFITS

- These criteria have the potential to reduce administrative burden associated with the largely manual prior authorization process which exists today.
- By streamlining the electronic prior authorization process, patients can receive rapid information about whether treatments are approved.
- Criteria align with CMS requirements for payers to establish Prior Authorization APIs, and with requirements for participants in the Promoting Interoperability programs to report on new Prior Authorization measures, both finalized in CMS’ Interoperability and Prior Authorization final rule.

Provider Directory API – Health Plan Coverage

PROPOSAL

ONC proposes to adopt a “Provider directory API – health plan coverage” certification criterion in § 170.315(g)(36), which specifies technical requirements for health IT that can be used by payers to publish information regarding the providers that participate in their networks.

Proposes to reference standards including Da Vinci PDex Plan Net IG.

BENEFITS

- Ability for patients to understand which providers, facilities, and pharmacies are covered by their current or future plan can improve patients’ ability to find the right provider and health care plan.
- Aligns with CMS requirement for payers to establish Provider Directory APIs finalized in CMS’ Interoperability and Patient Access final rule.



Standardized API for Patient and Population Services & Modular API Capabilities

Revised Certification Criterion for Standardized API for Patient and Population Services

PROPOSAL

ONC proposes to revise the “standard API for patient and population services” certification criterion at § 170.315(g)(10) by requiring support of several updated standards, including USCDI v4 and SMART App Launch 2.2, by requiring support for dynamic client registration, and by requiring support for several new standard API workflow capabilities, such as workflow triggers, verifiable health cards, and subscriptions.

Additionally, ONC proposes that such Health IT Modules support multi-factor authentication for patient-facing authentication, imaging links in data response requirements, support for read and search API for system applications and support for “_type” query parameter for Bulk FHIR API.

BENEFITS

- These enhancements and updates would ensure that patients have access to more information, such as diagnostic images via imaging links, more granular control of their data through US Core Scopes, and more modern experiences connecting apps of their choice to their health information via dynamic client registration.
- Clinicians would benefit from an expanded use of standard APIs, required by USCDI v4, including access, exchange, and use of data elements salient to behavioral health and underserved communities. Clinicians would also have a range of tools, including CDS Hooks and Subscriptions with which to support decision-making and manage patient information. Public health, researchers, and others would benefit from improved access to bulk data through required support for the Bulk FHIR IG version 2.

Overview of proposed revisions to (g)(10) API certification criterion



Updating existing standards for information access and authentication / authorization

- USCDI v3 → v4
- US Core IG v6.1.0 → v7.0.0
- Bulk Data Access IG v1.0 → v2.0
- SMART App Launch IG v2.0 → v2.2



Adding new standard for dynamic registration

- Dynamic client registration using HL7 FHIR® Unified Data Access Profiles (UDAP™) Security IG v1.0.0



Adding new standards-based API workflow capabilities

- API-based workflow triggers using HL7® CDS Hooks Release 2.0
- Verifiable health records using SMART Health Cards Framework v1.4.0 and HL7® SMART Health Cards: Vaccination and Testing IG v1.0.0
- API-based event notifications using HL7® FHIR® Subscriptions R5 Backport IG v1.1.0

New Certification Criteria to Support Modular API Capabilities § 170.315(j)

PROPOSAL

ONC proposes to add 14 new certification criteria in § 170.315(j) titled “modular API capabilities.” ONC proposes to include 8 new certification criteria that are substantially similar to capabilities currently referenced in the § 170.315(g)(10) API criterion, such as functional registration and SMART app launch user authorization. Five additional criteria in § 170.315(j) reflect more advanced capabilities enabled by the HL7® FHIR® standard, such as HL7® CDS Hooks, SMART Health Cards, and FHIR® Subscriptions.

BENEFITS

- Promotes the ONC Health IT Certification Program’s modular certification approach and enables different combinations of capabilities across Health IT Modules depending on use case needs.
- Enables more modularity and flexibility for health IT developers that wish to certify to more discrete functions, rather than large, multi-functionality, and all-encompassing certification criteria.
- Supports a growing number of clinical, public health, and administrative use cases, and foster innovation and competition in these spaces by providing flexibility for modular development approaches among developers of certified health IT.



Conditions and Maintenance of Certification Requirements

API Condition and Maintenance of Certification Requirements

PROPOSAL

ONC proposes to update the § 170.404 API Condition and Maintenance of Certification requirements with requirements for the new proposed criteria at § 170.315(g)(20), § 170.315(g)(30) through (36), and § 170.315(j), as well as update and revise existing requirements for § 170.315(g)(7) through (10). New and updated requirements include requirements for documentation publication, authenticity verification, registration for production use, and publication of API discovery details for patient access and payer information.

BENEFITS

- Facilitates API access without special effort by proposing new and revised API Condition and Maintenance of Certification requirements for existing and proposed Certification Program criteria.
- Applies existing API Condition and Maintenance of Certification requirements to new proposed API criteria, reduces app developer burden by standardizing existing requirements, and increases clarity in the Certification Program criteria regulation text.

Attestations Condition and Maintenance of Certification Requirements

PROPOSAL

ONC proposes to revise the Attestations Condition and Maintenance of Certification requirements and add a requirement in § 170.406(a)(2) that a health IT developer attest to compliance with the Assurance Maintenance of Certification requirement in § 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).

BENEFITS

Supports and enhances transparency and accountability in the Program and supports a health IT developers’ ongoing compliance with Program requirements.



Information Blocking Proposals

Overview of Information Blocking Proposals



Definitions

- Health Care Provider, Health IT, Business Day
- Certain practices meeting “interference” definition



Existing Exceptions Updates

- Infeasibility – revise 2 conditions
- Privacy – expand 2 sub-exceptions
- TEFCA Manner – Request for Comment



Proposed New Exceptions

- Protecting Care Access
- Requestor Preferences

New Protecting Care Access Exception

PROPOSAL

Under its specified conditions, the exception would apply to practices likely to interfere with EHI access, exchange, or use an actor believes in good faith could create or increase a risk of potential exposure to legal action, including investigation, that the actor believes could potentially be brought:

- under law in effect at the time the actor engages in the practice;
- against patients, health care providers, or those who help make providing or receiving care possible;
- for the mere fact that
 - a person sought, obtained, provided, or facilitated reproductive care that was lawful under the conditions in which it was provided; or
 - (where the patient protection condition applies) a patient has health conditions or history for which reproductive health care is often sought, obtained, or medically indicated.

BENEFITS

- Offers actors certainty that practices satisfying the exception will not be considered “information blocking”
- Assures patients that the information blocking regulations support actors limiting EHI sharing in response to risks that arise over time, while also continuing to support patients’ own access to their EHI and other sharing of EHI consistent with applicable law and patient preferences that fosters better patient care.
- Supports continued advances in digitization, interoperability, and public confidence in the nationwide health information technology infrastructure.

New Protecting Care Access Exception

OVERVIEW

An actor's practice implemented to reduce the risk of potential exposure to legal action would not be information blocking when the actor's practice satisfies at least 2 conditions:

Threshold



Patient Protection

< OR >

Care Access



- **Threshold Condition Requirements:**
 - 1) Belief (an actor holds in good faith)
 - 2) Tailoring (of practice)
 - 3) Implementation (of practice) based on actor's
 - organizational policy – or –
 - case-by-case determination
- **Patient Protection Condition** – applicable to practices actor believes could reduce the patient's risk of potential exposure to legal action based on mere fact reproductive health care sought/received or a health history or condition for which reproductive health care often sought, received, or medically indicated
- **Care Access Condition** – applicable to practices actor believes could reduce potential exposure to legal action of health care providers or other persons who provide care or are otherwise involved in facilitating reproductive health care that is lawful under circumstances provided

New Requestor Preferences Exception

PROPOSAL

A proposed Requestor Preferences Exception (to be codified in 45 CFR 171). This exception would apply where an actor honors 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;
3. When EHI is made available to the requestor for access, exchange, or use.

BENEFITS

- The exception would offer actors certainty that, under the exception's specified conditions, an actor's honoring these requestor preferences would not constitute information blocking.
- Would apply to honoring preferences of any requestor, including individuals, health care providers, and any other requestor of access, exchange, or use (for permissible purposes) of EHI the actor has.
- Flexible to accommodate, to the extent the actor may be able and willing to do so, the considerable variety of unique preferences it is possible for a requestor to have in comparison even to similarly situated requestors.



TEFCA PROPOSALS

TEFCA Proposals in Part 172

PROPOSAL

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

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

BENEFITS

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

Resources Available on HealthIT.gov!

RESOURCES AVAILABLE

Visit <https://healthIT.gov/proposedrule> for additional information. More updates will be added over time.

- General Overview
- USCDI v4
- Electronic Prescription
- Information Blocking (Exceptions)
- Information Blocking (Definitions)
- Public Health Reporting
- TEFCA
- Modular API
- Patient, Provider, and Payer API
- Key Compliance Dates



Don't Miss Our Upcoming Webinars!

UPCOMING WEBINARS

Visit <https://healthIT.gov/proposedrule> for additional information. More updates will be added over time.



Public Health

July 30, 2:00 PM ET



Information Blocking

August 08, 2:00 PM ET



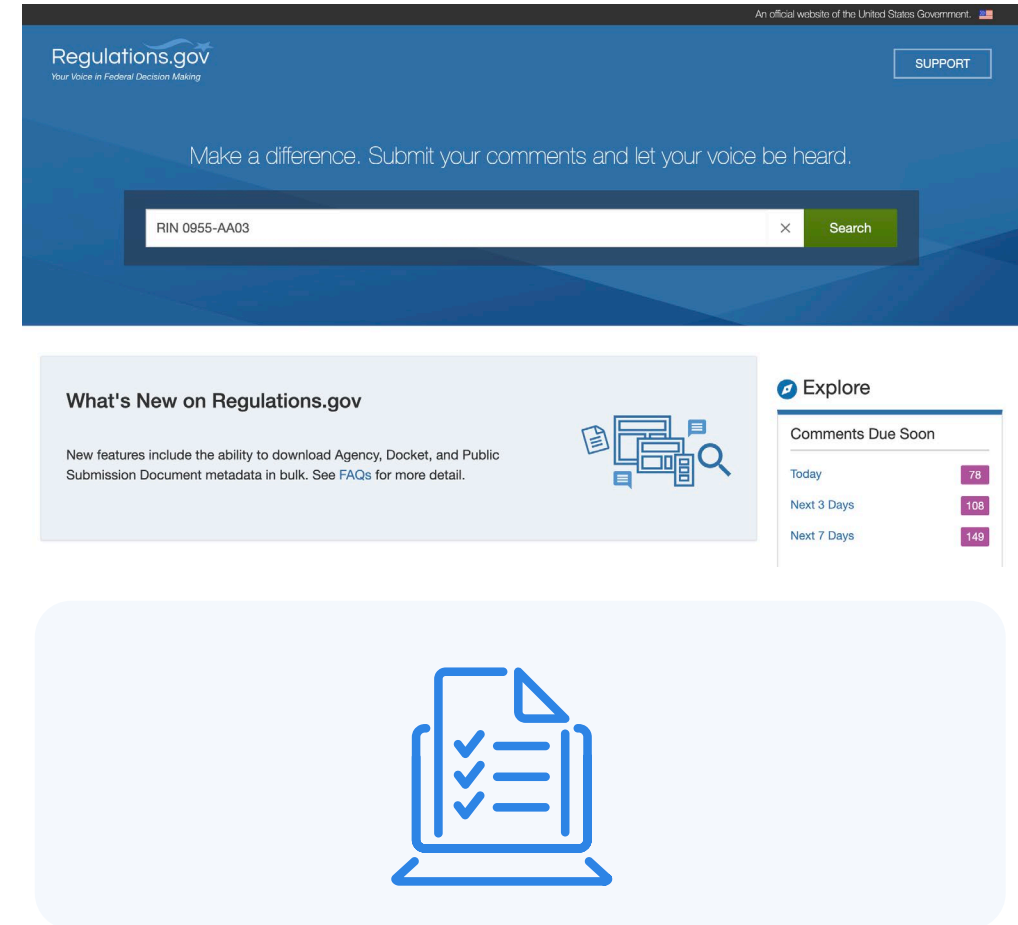
Patient, Payer, Provider API

August 15, 2:00 PM ET

How to Submit a Comment

Federal eRulemaking Portal

You may submit comments, identified by RIN 0955-AA06, through <http://www.regulations.gov>. Attachments should be in Microsoft Word, Microsoft Excel, or Adobe PDF; however, we prefer Microsoft Word.



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