Office of the National Coordinator for Health Information Technology

Public Health Webinar: HTI-1 Proposed Rule

Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing

May 24, 2023

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The **What**

… answering the three **“whats”** you want to know

What's In a Name?

Health Data, Technology, and Interoperability:

Certification Program Updates, Algorithm Transparency, and Information Sharing

- **Prefix:** Health Data, Technology, and Interoperability
- **Suffix:** Certification Program Updates, Algorithm Transparency, and Information Sharing
- **Acronym:** HTI
- **Numbering:** One (1)
- **Shorthand:** "HTI-1 Proposed Rule"

What's In the Rule?

1. New Regulatory Approach for Certification Criteria ("edition-less")
2. Certification Standards and Functionality Updates
3. Decision Support Interventions (DSI) and Algorithmic Transparency
4. Insights Condition and Maintenance of Certification Requirements (EHR Reporting Program)
5. Information Blocking
6. Opportunities for Comment

Today's Webinar

- Immunization, eLR and Cancer standards updates
- USCDI move from V1 to V3 for ONC certification
- eCR proposed standards for certification
- Insights Condition—Public Health Exchange Measures—Exchange with IIS
- Information Blocking Enhancements—Manner Exception for TEFCA
- Laboratory Data Interoperability Request for Information
- How to provide public comment

What's the Why?

Implementing the 21st Century Cures Act

- EHR Reporting Program
- APIs that allow EHI to be accessed, exchanged, and used without special effort
- Reasonable and necessary activities that do not constitute information blocking

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"

Leveraging Health IT and Advancing Interoperability

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

New Regulatory Approach for Certification Criteria (“Edition-less”)

Discontinuing Year-Themed "Editions"

Proposal

Discontinue year-themed editions and establish a single set of certification criteria, "ONC Certification Criteria for Health IT."

Benefits

- Allows the Certification Program and health IT developers to more effectively utilize new and updated standards and functionality in a timely manner
- Allows users of health IT to work in partnership with health IT developers to update their systems for new standards or functionality in the manner that works best for their unique needs
- Assists health care industry participants in other HHS programs that reference Certification Program standards and criteria, such as CMS's Promoting Interoperability Program, by ensuring developers provide timely updates for any new or updated certification criteria
- Supports users of health IT by reducing potential confusion of tracking use of different editions of certified health IT

Establishing Applicability and Expiration Timelines for Certification Criteria and Standards

Proposal

- Establish the dates by which a prior version of a criterion is no longer applicable when a new, revised, or updated version of that criterion is adopted
- Establish applicable timelines, including expiration dates, for the adoption of standards when a new, revised, or updated version of the standard is adopted for the same purpose

Benefits

- Support establishment of clear timelines associated with the specific criterion or standard
- Facilitate ease of reference for federal, state, local or tribal programs seeking to align their program requirements to the standards and implementation specifications available in certified health IT
- Ensure that customers are provided with timely technology updates

Two Forms of Compliance

Certification Criteria

Health IT developers with a Health IT Module certified to any revised certification criterion must *update* their certified Health IT Modules and *provide* such updated health IT to their customers in accordance with the timelines defined for a specific criterion and/or standard included in § 170.315.

Assurances Condition and Maintenance of Certification Requirements

Condition: A health IT developer must provide an assurance that it will not interfere with a customer's timely access to interoperable health IT certified under the Program.

Maintenance of Certification:

- *Update:* ONC proposes that a health IT developer must update a Health IT Module, once certified to a certification criterion adopted in § 170.315, to all applicable revised certification criteria, including the most recently adopted capabilities and standards included in the revised certification criterion;
- *Provide:* ONC proposes that a health IT developer must provide all Health IT Modules certified to a revised certification criterion to its customers; and
- *Timeliness:* ***A health IT developer must follow the timeliness requirements identified in the rule.***

Certification Standards and Functionality Updates

Select New and Revised Standards and Certification Criteria

- **Standards**
  - United States Core Data for Interoperability Standard Version 3
  - C-CDA Companion Guide Release 3*
  - US Core Implementation Guide 5.0.1*
  - “Minimum Standards” Code Sets Updates
    - SNOMED, RxNorm, LOINC, NDC, etc.

- **New and Revised Certification Criteria**
  - Electronic Case Reporting § 170.315(f)(5)
  - Clinical Decision Support § 170.315(a)(9)
  - Standardized API for Patient and Population Services § 170.315(g)(10)
  - ***New*** Patient Requested Restrictions Criteria in § 170.315(d)(14)
  - Patient Demographics and Observations Certification Criterion in § 170.315(a)(5)
  - Updates to Transitions of Care Criterion in § 170.315(b)(1)

USCDI

*Based on the annual US Core and C-CDA release cycles, we believe US Core IG v6.0.0 and C-CDA Companion Guide Release 4 will be published before ONC issues a final rule. It is our intent to consider adopting the updated IGs that supports the data elements in USCDI v3 since we propose to adopt USCDI v3 in this rule.

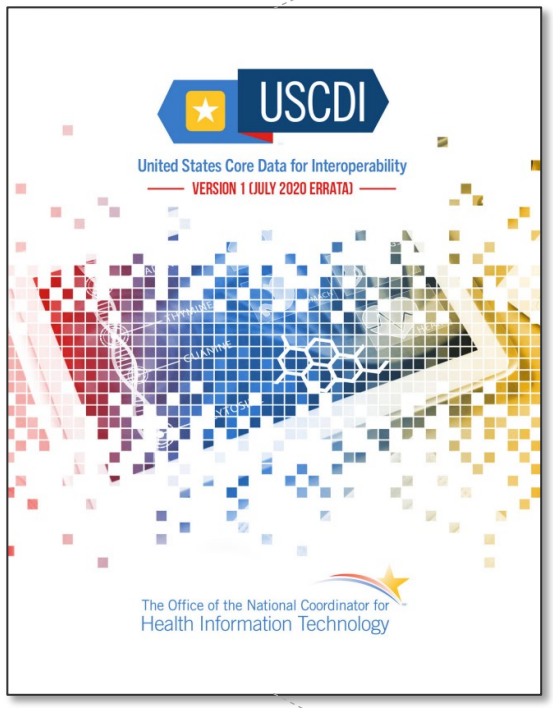
Vocabulary Standards Updates for Immunization, eLR, and Cancer criteria

Criteria Updates	Corresponding Standard(s) Update
• § 170.315(f)(1) Public Health – Transmission to immunization registries • § 170.315(f)(3) Public Health – Transmission to public health agencies – reportable laboratory tests and values/results • § 170.315(f)(4) Public Health – Transmission to cancer registries	• CVX – Vaccines Administered, June 15, 2022 • NDC – Vaccine NDC Linker, updates through July 19, 2022 • LOINC Database version 2.72, February 16, 2022 • SNOMED CT US Edition March 2022

These vocabulary standards are considered “minimum standard code sets” because they update several times per year. Developers may use newer versions of these standards without needing to notify their ACBs or re-certify

USCDI Background

- **Standard established by ONC in the 2020 21st Century Cures Act Final Rule**
- **Minimum dataset required for interoperability**
  - Defines required data elements and vocabulary standards
  - Focuses on patient access/care coordination use cases
- **Updated on an annual cycle with federal agency and industry input**
  - Updates based on multiple criteria including standards maturity and public/industry priority



USCDI v1 Summary of Data Classes and Data Elements

Allergies and Intolerances
- Substance (Medication)
- Substance (Drug Class)
- Reaction

Assessment and Plan of Treatment
- Assessment and Plan of Treatment

Care Team Members
- Care Team Members

Clinical Notes
- Consultation Note
- Discharge Summary Note
- History & Physical
- Imaging Narrative
- Laboratory Report Narrative
- Pathology Report Narrative
- Procedure Note
- Progress Note

Goals
- Patient Goals

Health Concerns
- Health Concerns

Immunizations
- Immunizations

Laboratory
- Tests
- Values/Results

Medications
- Medications

Patient Demographics
- First Name
- Last Name
- Previous Name
- Middle Name (incl Middle Initial)
- Suffix
- Birth Sex
- Date of Birth
- Race
- Ethnicity
- Preferred Language
- Current Address
- Previous Address
- Phone Number
- Phone Number Type
- Email Address

Problems
- Problems

Procedures
- Procedures

Provenance
- Author Time Stamp
- Author Organization

Smoking Status
- Smoking Status

Unique Device Identifier(s) for a Patient's Implantable Device(s)
- Unique Device Identifier(s) for a Patient's Implantable Device(s)

Vital Signs
- Diastolic Blood Pressure
- Systolic Blood Pressure
- Body Height
- Body Weight
- Heart Rate
- Respiratory Rate
- Body Temperature
- Pulse Oximetry
- Inhaled Oxygen Concentration
- BMI Percentile (2 - 20 Years)
- Weight-for-length Percentile (Birth - 36 Months)
- Head Occipital-frontal Circumference Percentile (Birth - 36 Months)

USCDI v3

Allergies and Intolerances
- Substance (Medication)
- Substance (Drug Class)
- Reaction

Assessment and Plan of Treatment
- Assessment and Plan of Treatment
- SDOH Assessment

Care Team Member(s)
- Care Team Member Name
- Care Team Member Identifier
- Care Team Member Role
- Care Team Member Location
- Care Team Member Telecom

Clinical Notes
- Consultation Note
- Discharge Summary Note
- History & Physical
- Procedure Note
- Progress Note

Clinical Tests
- Clinical Test
- Clinical Test Result/Report

Diagnostic Imaging
- Diagnostic Imaging Test
- Diagnostic Imaging Report

Encounter Information
- Encounter Type
- Encounter Diagnosis
- Encounter Time
- Encounter Location
- Encounter Disposition

Goals
- Patient Goals
- SDOH Goals

Health Insurance Information ★
- Coverage Status ★
- Coverage Type ★
- Relationship to Subscriber ★
- Member Identifier
- Subscriber Identifier ★
- Group Number ★
- Payer Identifier ★

Health Status/ Assessments ★★
- Health Concerns ➔
- Functional Status ★
- Disability Status ★
- Mental Function ★
- Pregnancy Status ★
- Smoking Status ➔

Immunizations
- Immunizations

Laboratory
- Test
- Values/Results
- Specimen Type ★
- Result Status ★

Medications
- Medications
- Dose ★
- Dose Units of ★Measure
- Indication ★
- Fill Status ★

Patient Demographics/ Information ★★
- First Name
- Last Name
- Middle Name (Including middle initial)
- Name Suffix ★★
- Previous Name
- Date of Birth
- Date of Death ★
- Race
- Ethnicity
- Tribal Affiliation ★
- Sex ★★
- Sexual Orientation
- Gender Identity
- Preferred Language
- Current Address
- Previous Address
- Phone Number
- Phone Number Type
- Email Address
- Related Person's Name
- Related Person's Relationship ★
- Occupation
- Occupation Industry ★

Problems
- Problems
- SDOH Problems/Health ★Concerns
- Date of Diagnosis
- Date of Resolution

Procedures
- Procedures
- SDOH Interventions
- Reason for Referral ★

Provenance
- Author Organization
- Author Time Stamp

Unique Device Identifier(s) for a Patient's Implantable Device(s)
- Unique Device Identifier(s) for a patient's implantable device(s)

Vital Signs
- Systolic blood pressure
- ★Diastolic blood pressure
- ★Heart Rate
- Respiratory rate
- Body temperature
- Body height
- Body weight
- Pulse oximetry
- Inhaled oxygen concentration
- BMI Percentile (2 - 20 years)
- Weight-for-length Percentile (Birth - 24★ ★ Months)
- Head Occipital-frontal Circumference Percentile (Birth - 36 Months)

★ New Data Classes and Elements ➔ Data Element Reclassified ★★ Name and Other Changes to Existing Data Classes/Elements

United States Core Data for Interoperability (USCDI) v3

- **Proposal:** Adopt USCDI v3 as the new baseline for certification.
  - USCDI v3 would be codified in § 170.213(a).
  - Both v1 and v3 would be referenced as applicable in § 170.213 up to and including December 31, 2024. However, only v3 could be used after December 31, 2024.
- **Benefits:** Expanding the data elements and data classes included in USCDI increases the amount of data available to be used and exchanged for patient care.
- **Specifics:** Health IT Modules certified to criteria that reference USCDI would need to update to USCDI v3 by the end of 2024 using the applicable US Core IG and C-CDA Companion Guide:
  - § 170.315(b)(1): Transitions of Care
  - § 170.315(b)(2): Clinical Information Reconciliation and Incorporation
  - § 170.315(b)(9): Care Plan
  - § 170.315(e)(1): View, Download, and Transmit 3rd Party
  - § 170.315(g)(6): Consolidated CDA Creation Performance
  - § 170.315(g)(9): Application Access-All Data Request
  - § 170.315(g)(10): Standardized API for Patient and Population Services
  - § 170.315(d)(14): Patient Requested Restrictions (by January 1, 2026)

“Minimum Standards” Code Sets Updates

Proposal

ONC proposes to update minimum code set versions for vocabulary standards used in several certification criteria

Code sets with updated versions in this NPRM:

- SNOMED CT US Edition March 2022
- LOINC Database version 2.7.2, February 16, 2022
- NDC – Vaccine NDC Linker, updates through July 19, 2022
- CDC Race and Ethnicity Code Set Version 1.2 (July 2021)
- RxNorm July 5, 2022 Full Monthly Release

Benefits

This proposal would promote semantic interoperability, accurate quality measure and public health reporting, and support research by:

- Establishing a new, more recent baseline version developers of certified health IT must use for several vocabulary code sets and certification criteria
- Enabling developers of certified health IT to use newer versions of these adopted standards on a voluntary basis as these vocabulary code sets update, which may be several times per year

Revised Criterion: § 170.315(f)(5) - Electronic Case Reporting

Electronic Case Reporting

Proposal

- ONC is proposing to require that Health IT Modules support eCR using consensus-based, industry-developed HL7® CDA and FHIR® standards
- Health IT Modules would need to support either:
  - HL7 CDA Implementation Guides for Electronic Initial Case Reports (eICR) and Reportability Response (RR) **or**
  - HL7 FHIR Implementation Guides to provide similar functionality and the Electronic Reporting **and**
  - Surveillance Distribution (eRSD) FHIR profile
- Developers of certified health IT may certify to revised standards and functionality 60-days after the effectiveness of a final rule; however, the must certify to revised criterion by January 1, 2025

Electronic Case Reporting

Benefits

- Facilitate transmission of electronic case reports to public health authorities
- Improve interoperability and implementation consistency
- Empower public health authorities to have an improved picture of where and when disease outbreaks occur
- Promote bi-directional exchange of health data between health care providers and public health authorities
- Promote the sharing of standardized knowledge artifacts related to electronic case reporting
- Enable the use of SVAP as newer standards emerge

FHIR-Based Approach Would Reference Specific Profiles within the eCR FHIR IG

- HL7 FHIR® Implementation Guide: Electronic Case Reporting (eCR) - US Realm 2.1.0 – STU 2 US
  - Electronic Initial Case Report (eICR) profile – Used to report a suspected case from healthcare to public health following the match of clinical data against a trigger code
  - Reportability Response (RR) profile – Used to communicate from public health to healthcare whether the initial case contained in the eICR is reportable and any related follow-up
  - Electronic Reporting and Surveillance Distribution (eRSD) profiles – Supports the distribution of reporting guidance and parameters, trigger code value sets, and more complex reporting rules
  - Data Element support would be required for
    - “Mandatory” and “must support” data elements across these profiles
    - eRSD Specification Library
    - eRSD Supplemental Library
    - Reportable Conditions Trigger Codes (RCTC) Value Set for Electronic Case Reporting
      - Regulatory baseline: RCTC OID: 2.16.840.1.114222.4.11.7508, Release March 29, 2022

CDA-Based Approach Would Reference Specific CDA IGs & the eRSD profile of the eCR FHIR IG

- HL7 CDA R2 Implementation Guides
  - 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 R2 Implementation Guide: Reportability Response, Release 1, STU Release 1.1 - US Realm
  - Support for data elements with minimum cardinality requirements equal to or greater than “1” and data elements with minimum cardinality requirements equal to or greater than "0" and a conformance verb of "SHOULD" or a "SHALL"

- HL7 FHIR IG, eRSD profiles – Supports the distribution of reporting guidance and parameters, trigger code value sets, and more complex reporting rules
  - “Mandatory” and “must support” data elements across these profiles would be required, in addition to those included as part of the eRSD Specification Library, the eRSD Supplemental Library, and Reportable Conditions Trigger Codes (RCTC) Value Set for Electronic Case Reporting
    - Regulatory baseline: RCTC OID: 2.16.840.1.114222.4.11.7508, Release March 29, 2022

Regulatory baseline: RCTC

- The RCTC value set currently includes
  - ICD-10 CM, SNOMED CT, LOINC, RxNorm, CVX, and CPT codes
  - Representing condition-specific diagnoses, resulted lab tests names, lab results, lab orders for conditions reportable upon suspicion, and medications for select conditions

- Given that the contents of the RCTC value set update frequently, we propose to recognize the RCTC value set as a minimum standard code set. This enables
  - ONC to reference a persistent version of the RCTC value set as a baseline for use in the Program
  - Developers of certified health IT to support newer or updated versions of RCTC value sets for their customers as soon as new releases are available

- Health IT Modules may voluntarily support an updated version (e.g., a subsequent release) of the RCTC value set
  - We anticipate that health IT developers would be incentivized by their customers to take advantage of this opportunity to voluntarily support updated versions of the RCTC value set because it will include new codes reflecting new or emerging infectious diseases.

Specifically, in § 170.315(f)(5)(ii) we propose that a Health IT Module enable a user to:

- Consume and process electronic case reporting trigger codes and parameters and identify a reportable patient visit or encounter based on a match from the Reportable Conditions Trigger Code value set in § 170.205(t)(4) received from the eRSD profiles as specified in the HL7 FHIR eCR IG in § 170.205(t)(1)
- Create a case report consistent with at least one of the following standards:
  - The eICR profile of the HL7 FHIR eCR IG in § 170.205(t)(1), or
  - The HL7 CDA eICR IG § 170.205(t)(2)
- Receive, consume, and process a case report response that is formatted to either the RR profile of the HL7 FHIR IG in § 170.205(t)(1) or the HL7 CDA RR IG in § 170.205(t)(3)
- Transmit a case report electronically to a system capable of receiving an electronic case report.

Proposal for Reporting and Requests for Comment

- ONC is proposing that the functional requirements for Health IT Modules certifying to (f)(5) remain agnostic as to which reporting platform the electronic case is transmitted
  - Rather, ONC proposes to require that the Health IT Module be capable of transmitting electronic case reports consistent with the reporting requirement(s) established by a PHA

- A Health IT Module certifying to (f)(5) may meet the reporting requirement by supporting electronic reporting to any system designated by the PHA and capable of receiving an electronic case report, such as:
  - State-based registry
  - Health Information Exchange
  - Other intermediary or proprietary platform (e.g., APHL AIMS)

- ONC seeks feedback on:
  - The option to use either CDA or FHIR or both IGs for certification;
  - Whether the eRSD profile is appropriate for Health IT Modules that use the CDA IG, as the CDA IG states;
  - Whether the eRSD profile is adequately defined to establish baseline functionality

Deadline for Transitioning to Revised (f)(5)

- Developers of certified health IT would have until December 31, 2024, to update and provide Health IT Modules certified to the proposed revised standards and functionality for (f)(5)
  - In proposed § 170.315(f)(5)(i) Enable a user to create an electronic case report for transmission meeting the requirements described in paragraphs § 170.315(f)(5)(i)(A) through (C) of this section for the time period up to and including December 31, 2024; or meet the requirements described in paragraph (f)(5)(ii) of this section

- Implications of this construct are
  - Developers who are ready to certify using CDA and/or FHIR approaches may do so as soon as a final rule is
  - Developers will have until January 1, 2025, to update and provide Modules certified to § 170.315(f)(5)(ii) to their clients

Insights Condition and Maintenance of Certification Requirements (EHR Reporting Program)

Insights Condition and Maintenance of Certification

- **The Cures Act laid the foundation for transparent reporting**
  - Required establishing the Electronic Health Record (EHR) Reporting Program to provide transparent reporting to measure the performance of certified health IT
  - Specified its implementation as part of a Condition and Maintenance of Certification for certified health IT developers.

- **Insights Condition shall provide transparent reporting that aims to:**
  - Address information gaps in the health IT marketplace
  - Provide insights on the use of specific certified health IT functionalities
  - Provide information about consumers' experience with certified health IT

How Were the Measures Developed?

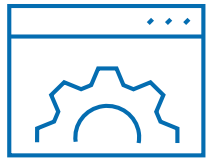
- ONC's contractor, The Urban Institute, developed a set of draft measures based on:
  - Research, including market research;
  - Input from stakeholders and health IT measurement experts; and
  - Input from feasibility and validity testing
- Public feedback was obtained on the draft measures, including from the 2021 EHR Reporting Program Task Force of the HITAC.
- The draft measures were revised based on HITAC and public feedback, along with additional research, to create the current list of measures.

Insights Condition: Measures and Related Criteria

AREA	MEASURE	RELATED CRITERION/CRITERIA
Individual Access to EHI	Individuals' Access to Electronic Health Information Supported by Certified API Technology	§§ 170.315(e)(1); 170.315(g)(10)
Clinical Care Information Exchange	C-CDA Documents Obtained Using Certified Health IT by Exchange Mechanism	§ 170.315(b)(2)
Clinical Care Information Exchange	C-CDA Medications, Allergies, and Problems Reconciliation and Incorporation Using Certified Health IT	§ 170.315(b)(2)
Standards Adoption & Conformance	Applications Supported Through Certified Health IT	§ 170.315(g)(10)
Standards Adoption & Conformance	Use of FHIR in Apps Supported by Certified API Technology	§ 170.315(g)(10)
Standards Adoption & Conformance	Use of FHIR Bulk Data Access Through Certified Health IT	§ 170.315(g)(10)
Standards Adoption & Conformance	Electronic Health Information Export Through Certified Health IT	§ 170.315(b)(10)
Public Health Information Exchange	Immunization Administrations Electronically Submitted to Immunization Information System Registries Through Certified Health IT	§ 170.315(f)(1)
Public Health Information Exchange	Immunization History and Forecasts	§ 170.315(f)(1)

Who Will Be Reporting on These Measures and How?

- Developers of certified health IT would be expected to report (as required by each measure) if they meet the following criteria:
  - They have at least 50 hospital users or 500 clinician users across their certified health IT products;
  - Their product(s) are certified to the criterion/criteria associated with the measure; and
  - The developer has any users of the applicable criterion/criteria associated with the measure.
- Otherwise the health IT developer would report it does not meet the minimum reporting qualifications.
- Submissions for the Insights Condition shall occur via web-based form and method, consistent with the requirement in § 3009A(c) of the PHSA, and shall be made publicly available via an ONC website



What Is the Reporting Frequency and Timeline?

- Developers of certified health IT shall submit measures every six months
  - Reporting aligned with the “Attestations” Condition and Maintenance of Certification
    - Submission windows: April 1 – 30; October 1 – 31

- Reporting of measures will be phased in over two years

Year 1 Measures

- **Individual Access to EHI**
  - Individuals’ Access to Electronic Health Information Supported by Certified API Technology
- **Public Health Information Exchange**
  - Immunization Administrations Electronically Submitted to Immunization Information System Registries Through Certified Health IT
  - Immunization History and Forecasts
- **Standards Adoption & Conformance**
  - Applications supported through certified health IT measure

Year 2 Measures

- **Clinical Care Information Exchange**
  - C-CDA Documents Obtained Using Certified Health IT by Exchange Mechanism
  - C-CDA Medications, Allergies, and Problems Reconciliation and Incorporation Using Certified Health IT
- **Standards Adoption & Conformance**
  - Use of FHIR in Apps Supported by Certified API Technology
  - Use of FHIR Bulk Data Access Through Certified Health IT
  - Electronic Health Information Export Through Certified Health IT

Information Blocking

Overview of Information Blocking Enhancements

Definitions

- Offer Health IT
- Health IT Developer of Certified Health IT

Exceptions

- Infeasibility Exception – 1 revised and 2 new conditions
- Manner Exception – TEFCA condition

Requests for Information

- Additional exclusions from “offer” Health IT
- Practices required under the Common Agreement
- Data tagging and filtering capabilities of Health IT

Defining "Offer Health IT"

Proposal

ONC is proposing to define what it means to *offer health IT* for purposes of the information blocking regulations.

- Generally includes providing, supplying, or otherwise making available certified health IT under any arrangement or terms except for certain beneficial and necessary activities that would be explicitly excluded.

- Would explicitly codify that we do not interpret individuals or other entities to offer health IT when they engage in activities such as certain donation and subsidized supply arrangements, specific implementation and use activities, and certain legal services arrangements.

Benefits

- Give clarity about the implications for an individual or entity's status under information blocking regulations of them making available funding subsidies for, or certain features or uses of, certified health IT.

- Encourage beneficial arrangements under which health care providers in need can receive subsidies for the cost of obtaining, maintaining, or upgrading certified health IT.

- Give health care providers (and others) who use certified health IT certainty that implementing certain health IT features and functionalities, as well as engaging in certain practices that are common and beneficial in an EHR-enabled health care environment, will *not* be considered an offering of certified health IT (regardless of who developed that health IT).

Infeasibility Exception – Uncontrollable Events Condition

Proposal

Revise the condition by replacing the words “due to” with “because of” to make clear that a causal connection is needed to use this exception

- The fact that an uncontrollable event occurred is not a sufficient basis alone for an actor to meet the uncontrollable events condition of the Infeasibility Exception.
- The use of the words “due to” in the condition conveys that the actor must demonstrate a causal connection between not providing access, exchange, or use of EHI and the uncontrollable event.

Benefits

- Makes clear that the actor must demonstrate a causal connection between not providing access, exchange, or use of EHI and the uncontrollable event.
- Makes clear that the fact that an uncontrollable event specified in § 171.204(a)(1) occurred is not a sufficient basis alone for an actor to meet the uncontrollable events condition of the Infeasibility Exception.

Infeasibility Exception – Third Party Modification Use Condition

Proposal

A request to enable one or more third parties to modify EHI (including but not limited to creation and deletion functionality) could be considered infeasible unless the request is from a health care provider requesting such use from an actor that is its business associate.

Benefits

Reduces actor burden and uncertainty.

- Less documentation requirements compared under the “infeasible under the circumstances” condition
- No need to determine if another exception applies to the request, such as the Security Exception.

Note: Other exceptions may still apply.

Infeasibility Exception – Manner Exception Exhausted Condition

Proposal – Three Part Test

1. The actor could not reach agreement with a requestor in accordance with § 171.301(a) or was technically unable to fulfill a request for electronic health information in the manner requested;
2. The actor offered all alternative manners in accordance with § 171.301(b) for the electronic health information requested but could not reach agreement with the requestor; and
   - Alternative Proposal for # 2 discussed in preamble: "as few as two alternative manners"
3. **The actor does not provide the same access, exchange, or use of the requested electronic health information to a substantial number of individuals or entities that are similarly situated to the requester.**

- *Currently provides*
- *Same*
- *Substantial number*
- *Similarly Situated*

Benefits

- Provides certainty (do not have to demonstrate infeasibility under the circumstances)
- Reduces inappropriate or unnecessary diversion of actor resources
- Ensures actors reasonably allocate resources toward interoperable, standards-based manners

Manner Exception – TEFCA Condition

Proposal

ONC proposes to add a TEFCA condition to the proposed revised and renamed Manner exception. The TEFCA condition would offer Qualified Health Information Networks (QHINs), participants, and subparticipants in TEFCA the ability to fulfill EHI requests from any QHIN, participant, or subparticipant in TEFCA using TEFCA means, even if the requestor would have preferred to use another means.

Benefits

- 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.
- Facilitates a responding actor reaching agreeable terms with a requestor to fulfill an EHI request and acknowledges that certain agreements have been reached for the access, exchange, and use of EHI.
- Provides a clear, efficient process for actors participating in TEFCA to prioritize the use of TEFCA means for fulfilling requests for access, exchange, and use of EHI from other TEFCA entities.

RFI-Laboratory Data Interoperability

- Which implementation guides or other standards should ONC adopt in certification criteria for health IT supporting transmittal and receipt of laboratory orders, laboratory results and directory of services?
- Would developers of laboratory information systems or in vitro diagnostics systems that have not traditionally submitted products for certification under the Program seek out and benefit from certification to criteria relevant to such developers' products?
- Are there any other steps that ONC and HHS should consider taking to advance laboratory interoperability?

Opportunities to Comment and to Learn More

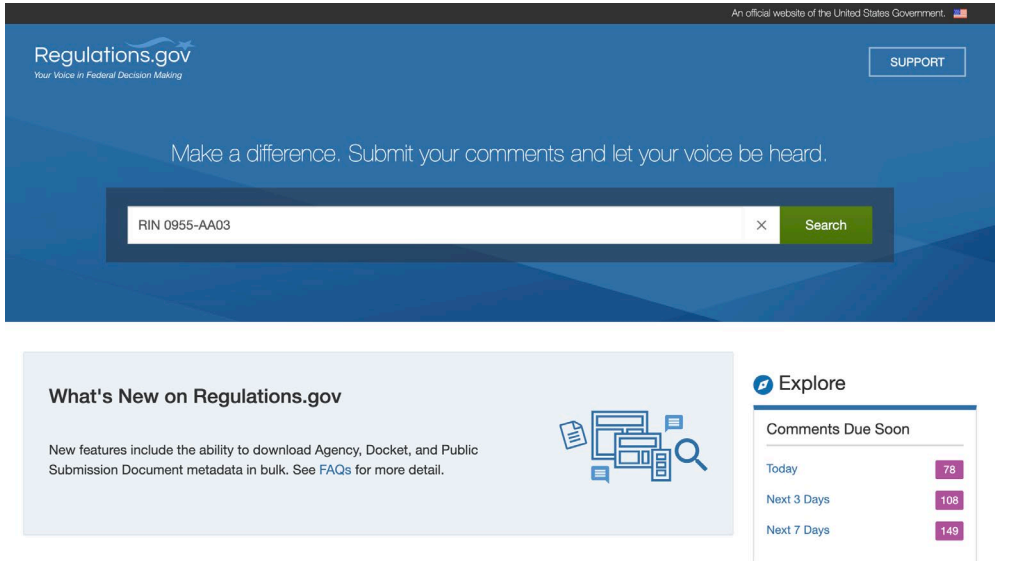
Requests for Information

- Laboratory Data Interoperability
- Pharmacy Interoperability Functionality within the ONC Health IT Certification Program including Real-Time Prescription Benefit Capabilities
- FHIR Standard
  - FHIR Subscriptions
  - Clinical Decision Support Hooks
  - FHIR Standard for Scheduling
  - SMART Health Links

How to Submit a Comment

Federal eRulemaking Portal

You may submit comments, identified by RIN 0955-AA03, through http://www.regulations.gov. Attachments should be in Microsoft Word, Microsoft Excel, or Adobe PDF; however, we prefer Microsoft Word.

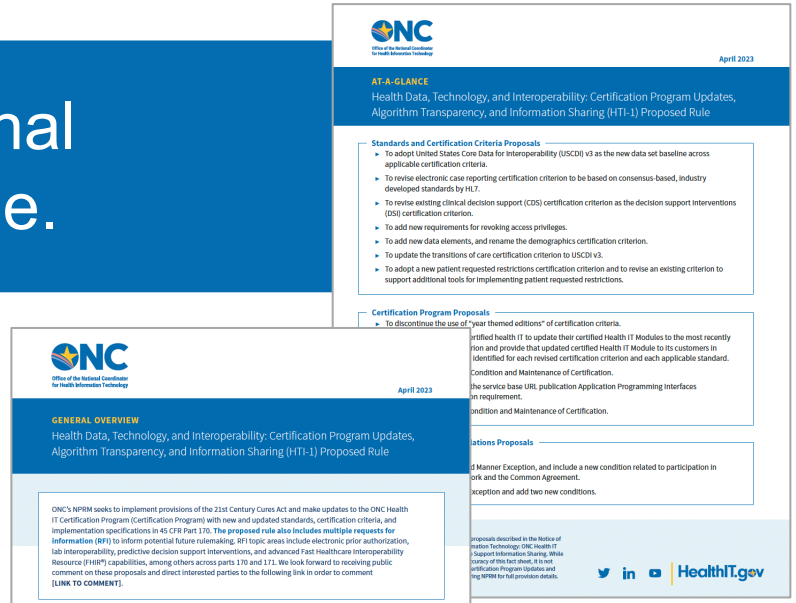


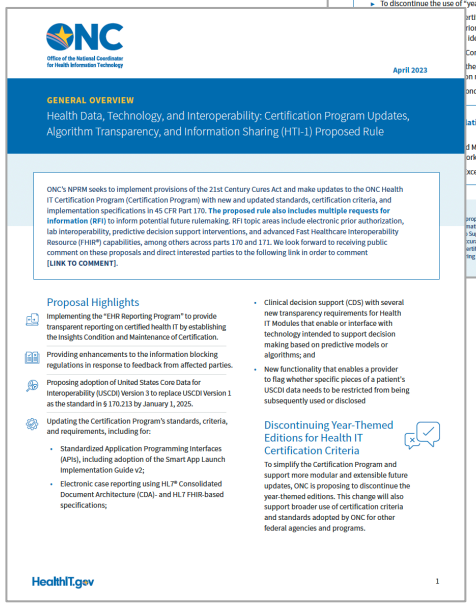
Public Comment Template

We will provide a template following publication of the proposed rule in the Federal Register for the public to use, if they so choose, when submitting their comments.

Resources Available on HealthIT.gov!

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





Fact Sheets

- General Overview
- At-a-Glance
- Decision Support Interventions and Predictive Models
- Information Blocking (upcoming release)
- Insights Condition (upcoming release)

Measurement Spec Sheets

- One for each of the 9 proposed Insights Condition measures.

HITAC HTI-1 Proposed Rule Task Force

Overarching Charge:
The HTI-1 Proposed Rule Task Force 2023 will evaluate and provide draft recommendations to the HITAC on the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule.

- All Task Force meetings are open to the public
- Registration and meeting materials can be found at: https://www.healthit.gov/topic/federal-advisory-committees/hitac-calendar

Don’t Miss Our Upcoming Webinars!

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

Upcoming Webinars

DSI and Algorithmic Transparency Proposals

May 4, 1:00 PM ET

Insights Condition Proposals

May 11, 1:00 PM ET

Information Blocking Proposals

May 18, 1:00 PM ET

Office of the National Coordinator for Health Information Technology

Contact ONC

Phone: 202-690-7151

Health IT Feedback Form: https://www.healthit.gov/form/healthit-feedback-form

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