



Office of the National Coordinator
for Health Information Technology

ONC HTI-1 Proposed Rule Information Session

AMIA

May 30, 2023



Health Data, Technology, and Interoperability (HTI-1)

Certification Program Updates, Algorithm Transparency, and Information Sharing

+ 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”
- E.O. 14091 “Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government”

+ Leveraging Health IT and Advancing Interoperability

- HITECH Act authorities to
 - Enhance Certification Program criteria
 - Advance interoperability through standards and implementation specifications
 - Modify ONC Health IT Certification Program structure



Decision Support Interventions

Proposed Revised Criterion: § 170.315(a)(9) - Clinical Decision Support (CDS)

Proposal:

Revise and rename existing CDS criterion to Decision Support Intervention (DSI) criterion.

This new description reflects an array of contemporary and emerging decision support functionalities, including predictive functionalities.

This revision includes:

A definition for “predictive decision support intervention”

Requirements for Health IT Modules that enable or interface with predictive decision support interventions

Requirements for developers of health IT that certify such Health IT Modules

Additional requirements for regardless of whether the DSI is predictive or not

Proposal Objective and Intended Benefits

Objective: Enable improved information transparency on the trustworthiness of predictive DSIs to support their widespread use in health care.

Improve Transparency



Regarding how a predictive DSI is designed, developed, trained, evaluated, and should be used

Enhance Trustworthiness



Through transparency on how certified health IT developers manage potential risks and govern predictive DSIs that their certified Health IT Modules enable or interface with

Support Consistency



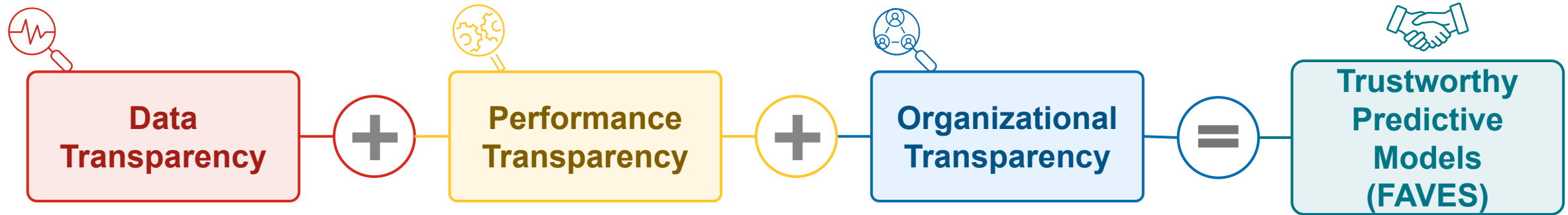
In the availability of predictive DSI information to users, so that users may determine the DSI's quality and whether its recommendations are fair, appropriate, valid, effective, and safe (FAVES)

Advance Health Equity by Design



By addressing bias and health disparities, potentially propagated by predictive DSIs, to expand the use of these technologies in safer, more appropriate, and more equitable ways

Transparency Is a Prerequisite for Trustworthy AI



Data Transparency

Proposed requirements would enable users to know when a DSI uses specific data elements relevant to health equity, including:

- Social Determinants of Health
- Race, Ethnicity, & Language
- Gender Identity
- Sexual Orientation

Performance Transparency

Proposed source attributes would enable users to have consistent and routine electronic access to technical and performance information on predictive DSIs

- Spanning intended use, training data descriptions, measures of fairness, and ongoing maintenance
- Information provided in plain language and available to users via “direct display,” “drill down” or “link out” functionality

Organizational Transparency

Proposed requirement for certified health IT developers to employ or engage in risk management of predictive DSIs

- Analyze risks; mitigate risks; and establish governance for predictive DSIs spanning 8 socio-technical characteristics including Validity, Reliability, Robustness, Fairness, Intelligibility, Safety, Security, & Privacy
- Report summary information publicly

Proposed Definition: “Predictive Decision Support Intervention”

Predictive Decision Support Intervention Means:

“Technology intended to support decision-making based on algorithms or models that derive relationships from training or example data and then are used to produce an output or outputs related to, but not limited to, prediction, classification, recommendation, evaluation, or analysis.”

- Technology estimates a value based on relationships ‘learned’ in prior data
 - Contrast with evidence-based DSI which supports decision-making by relying on pre-defined rules based on expert consensus or from expert recommendation (e.g., computable clinical guidelines).
- Predictive DSIs include those based on:
 - Simple statistics or regression model → risk calculator
 - Machine learning models (e.g., predicting healthcare costs; sepsis onset; no-show)
 - From widely used ASCVD and APACHE IV models, to bespoke machine learning models used to predict opioid overdose, hospital bed capacity, and other emerging use cases^{11,12}
 - Natural language processing (NLP) and large language models (LLMs) (sometimes referred to as generative AI)
- DSI may be presented in a broad array of forms (e.g., alerts, order sets, flowsheets)
- Proposed definition is
 - **Not** tied to a specific purpose or intended use.
 - **Not** dependent on who developed the algorithm or model (can be someone other than a developer of certified health IT)
 - **Not** based on a level of risk associated with the technology’s purpose.

Proposed Requirements for § 170.315(b)(11) – Decision Support Interventions

Health IT Modules would be required to enable a user to review “source attributes” information



Bibliographic citation of the intervention

Developer of the intervention

Funding source of the intervention

Release, and if applicable, revision date(s) of the intervention



NEW: Use in the intervention of specific demographic data

NEW: Use of social determinants of health data

NEW: Use of health status/assessment data

Predictive Decision Support Intervention – Source Attributes

Intervention Details (3)

- Output
- Intended use
- Cautioned out of scope use(s)

Intervention Development (3)

- Input features including description of training and test data
- Process used to ensure fairness in development
- External validation process, if available

Quantitative Performance Measures (5)

- Validity and Fairness of prediction in test data
- Validity and Fairness of prediction in external data, if available
- References to evaluation of use of the model on outcomes, if available

Ongoing Maintenance & Intervention Use (3)

- Update and continued validation or fairness schedule
- Validity of prediction in local data, if available
- Fairness of prediction in local data, if available



Proposed New Requirements for All Health IT Modules Certified to the DSI Criterion



Source attributes information must be available as a “plain language description” to users “via direct display, drill down, or link out from a Health IT Module”

- This would make a historic expectation explicitly required



If a DSI is developed by a developer of certified health IT, information for all attributes are required, unless otherwise noted in proposed regulation as “if available”



For DSIs that are developed by other parties, health IT modules must clearly indicate when any attribute is not available for the user to review

- Other parties include health systems, third-party software developers, medical education publishers, etc.

Proposed New Requirements for All Health IT Modules Certified to the DSI Criterion



Health IT Modules must enable users to “author and revise source attributes and information” beyond those listed

- This would provide flexibility for users to design DSI information unique to their circumstances



Enable end users to provide feedback based on information displayed through the intervention and

- Make available such feedback data for export, in a computable format,
- Data includes but not limited to the intervention, action taken, user feedback provided (if applicable), user, date, and location
- This would support quality improvement for all DSIs

Pillars of IRM Practices

Risk Analysis

- Analyze potential risk(s) and adverse impact(s) associated with the predictive DSI

Risk Mitigation

- Implement practices to minimize or mitigate risk(s) identified in the Risk Analysis associated with the predictive DSI

Governance

- Establish policies and implement controls for predictive DSI, including how data are acquired, managed, and used in the predictive DSI

Note: Generally, many of the proposed terms and concepts in the IRM proposal rely on the National Institute of Standards and Technology (NIST) [AI Risk Management Framework](#) and U.S. Department of the Treasury's Office of the Comptroller of the Currency (OCC) [Model Risk Management Guidance & Handbook](#).

Characteristics for Risk Analysis & Mitigation for Predictive DSIs

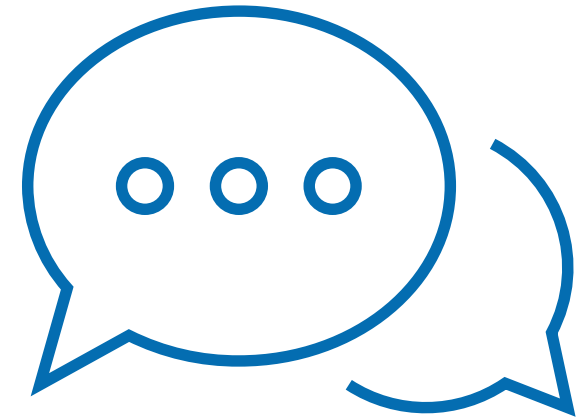


Propose to require certified health IT developers employ or engage in risk analysis and mitigation practices for 8 characteristics:

1. Validity
 2. Reliability
 3. Robustness
 4. Fairness
 5. Intelligibility
 6. Safety
 7. Security
 8. Privacy
- Proposal includes definitions and descriptions of each characteristic and approaches that should be taken to assess and mitigate risks.
 - Request comment on whether these proposed requirements should include more specificity, including on approaches to assess and mitigate risks.
 - Request comment on best practices or other items contained within the risk analysis proposal that should be explicitly required.

Questions in the HTI-1 NPRM

- Source attributes
 - Should patients have electronic access to source attributes?
 - Should the public have access to source attributes?
 - Any source attributes related to predictive DSIs left off the list that should be there?
- Feedback loops include intervention, action taken, user feedback provided (if applicable), user, date, and location
 - Are these data sufficient to evaluate and improve DSI performance, facilitate research, and associate patient health outcomes?





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, they 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





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

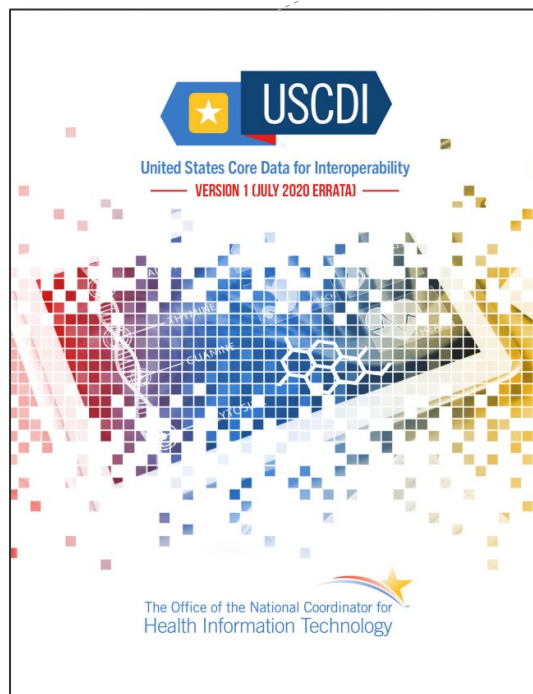
- Consume and process electronic case reporting trigger codes and parameters and identify a reportable patient visit or encounter based on a match from the Reportable Conditions Trigger Code value set in § 170.205(t)(4) received from the eRSD profiles as specified in the HL7 FHIR eCR IG in § 170.205(t)(1)
- 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.



US Core Data for Interoperability

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 <ul style="list-style-type: none"> • Substance (Medication) • Substance (Drug Class) • Reaction 	Clinical Tests <ul style="list-style-type: none"> • Clinical Test • Clinical Test Result/Report 	Health Status/ Assessments ★ ★ <ul style="list-style-type: none"> • Health Concerns → • Functional Status ★ • Disability Status ★ • Mental Function ★ • Pregnancy Status ★ • Smoking Status → 	Patient Demographics/ Information ★ ★ <ul style="list-style-type: none"> • 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 ★ 	Procedures <ul style="list-style-type: none"> • Procedures • SDOH Interventions • Reason for Referral ★
Assessment and Plan of Treatment <ul style="list-style-type: none"> • Assessment and Plan of Treatment • SDOH Assessment 	Diagnostic Imaging <ul style="list-style-type: none"> • Diagnostic Imaging Test • Diagnostic Imaging Report 			Provenance <ul style="list-style-type: none"> • Author Organization • Author Time Stamp
Care Team Member(s) <ul style="list-style-type: none"> • Care Team Member Name • Care Team Member Identifier • Care Team Member Role • Care Team Member Location • Care Team Member Telecom 	Encounter Information <ul style="list-style-type: none"> • Encounter Type • Encounter Diagnosis • Encounter Time • Encounter Location • Encounter Disposition 	Immunizations <ul style="list-style-type: none"> • Immunizations 		Unique Device Identifier(s) for a Patient's Implantable Device(s) <ul style="list-style-type: none"> • Unique Device Identifier(s) for a patient's implantable device(s)
Clinical Notes <ul style="list-style-type: none"> • Consultation Note • Discharge Summary Note • History & Physical • Procedure Note • Progress Note 	Goals <ul style="list-style-type: none"> • Patient Goals • SDOH Goals 	Laboratory <ul style="list-style-type: none"> • Test • Values/Results • Specimen Type ★ • Result Status ★ 		Vital Signs <ul style="list-style-type: none"> • 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)
	Health Insurance Information ★ <ul style="list-style-type: none"> • Coverage Status ★ • Coverage Type ★ • Relationship to Subscriber ★ • Member Identifier ★ • Subscriber Identifier ★ • Group Number ★ • Payer Identifier ★ 	Medications <ul style="list-style-type: none"> • Medications • Dose ★ • Dose Units of Measure ★ • Indication ★ • Fill Status ★ 	Problems <ul style="list-style-type: none"> • Problems • SDOH Problems/Health Concerns • Date of Diagnosis • Date of Resolution 	

★ 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)



Standardized API

Standardized API Revisions and Related API Conditions Updates

Proposal

ONC is proposing several revisions to § 170.315(g)(10) including:

- Adoption of new standard baselines for USCDI v3, US Core, and SMART App Launch Framework
- Adoption of standards-based requirements for authentication, authorization, and token introspection, leveraging SMART v2
- Clarification for patient authorization revocation to occur within 1 hour of a request
- Revise and standardize the service base URL publication API Maintenance of Certification requirement



Benefits

- Enabling increased capabilities and functionality for individuals to share information with apps of their choice
- Addressing privacy and security concerns by empowering patients to limit an app's access at a granular level, as they determine
- Improve security through adoption of enhanced authentication and authorization requirements
- Align industry approaches to publishing service base URLs based on familiar standards
- Improve the availability of service base URLs for patient access to their information without special effort



API Conditions & Maintenance of Certification Requirements: Enhancing FHIR Endpoint Requirement

- **Proposal(s):** ONC proposes to reference specific standards for publicly publishing service base URLs in § 170.404(b)(2) using HL7 FHIR and US Core IGs. Additionally, developers with Health IT Modules certified to § 170.315(g)(10) would be required to review these URLs quarterly and, as necessary, update.
- **Benefits:** In conjunction with existing requirements that service base URLs for all customers be published at no charge for use, regardless of whether the Health IT Modules certified to § 170.315(g)(10) are centrally managed by the Certified API Developer or locally deployed by an API Information Source, these proposals would:
 - Align industry approaches to publishing service base URLs based on familiar standards
 - Improve the availability of service base URLs for patient access to their information without special effort
 - Ensure that service base URLs are actively monitored for errors or defects and updated, as needed, quarterly
 - Support scalable endpoint directories for Trusted Exchange Framework and Common Agreement (TEFCA)



Patient Requested Restrictions

New Patient Requested Restrictions Criterion in § 170.315(d)(14)

Proposal

- ONC proposes that for any data expressed in the standard in § 170.213, a health IT developer must **enable a user to flag** whether such data needs to be restricted from being subsequently used or disclosed and prevent any data flagged from being included in a use or disclosure
- ONC proposes to modify the Privacy and Security Framework in § 170.550(h) to add the proposed new “patient requested restrictions” criterion and to require it by January 1, 2026 (or 24 months after the effective date of a final rule)
- ONC also proposes to modify § 170.315(e)(1) to add a paragraph (iii) stating patients (and their authorized representatives) must be able to use an internet-based method to request a restriction to be applied for any data expressed in § 170.213

Benefits

As ONC pursues policies intended to improve the interoperability and sharing of data through adoption of standards-based certification criteria and implementation specifications, we are aware of the imperative to protect health data privacy. This proposal would:

- Enable a user of certified health IT to implement a process to restrict data from use or disclosure in response to a patient request
- Support the HIPAA Privacy Rule’s “right to request a restriction” on uses and disclosures (See 45 CFR 164.522(a))
- Advance health IT tools to support patient-directed privacy requests for data the patient deems sensitive (e.g., through a patient portal)



Why this proposal is important for patients and caregivers

- We believe the need to protect sensitive health information is foundational to a health equity by design principle not only to protect patient privacy, but also to mitigate the risk of any unintended negative impact on an individual resulting from the disclosure of sensitive health information
- The concept of "sensitive data" is dynamic and specific to the individual
 - Patient populations that have historically been subject to discrimination may identify a wide range of demographic information as sensitive, including race, ethnicity, preferred language, sex, sexual orientation, gender identity, and disability status
- We believe that certified health IT should—to the extent feasible—support covered entities so they can execute these processes to protect individuals' privacy and to provide patients an opportunity to exercise this right
- We propose several standards-based and standards-agnostic approaches to flag data as sensitive and restrict the (re)sharing of data deemed as such



Standards-Agnostic Primary Proposal, Standards-Specific Alternative Proposals

- Health IT Module would have flexibility to implement the right to restriction dependent on their specific development and implementation constraints
 - “Flags” may leverage use of security labels like those included in the HL7 data segmentation for privacy (DS4P) implementation guides (IGs), or other data standards such as provenance or digital signature specifications.
 - The use of such standards or specifications would be at the discretion of the health IT developer.
- Alternate Proposals would:
 - Require the use of the use HL7 CDA DS4P and the HL7 FHIR DS4P IGs in whole or with varying degrees of specificity
 - Healthcare Privacy & Security Classification System (HCS) Security Label Vocabulary only
 - HCS Security Label Vocabulary with constraints based on certain use cases
 - Constraints on USCDI data elements that would be required to tag with security labels



Comment Early, Comment Often

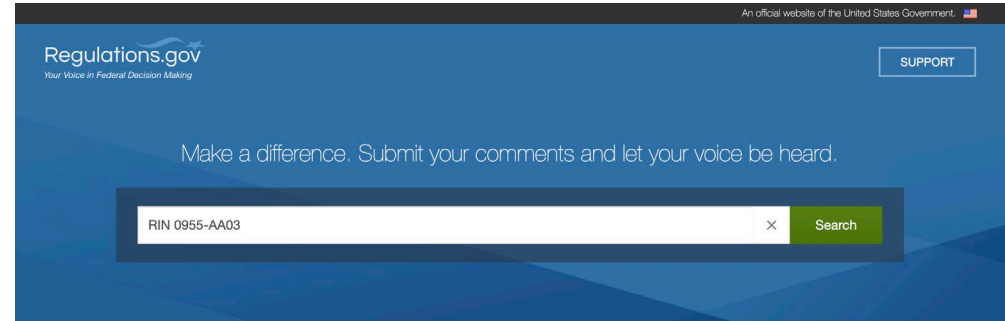
Submit Comments by June 20, 2023!

Federal eRulemaking Portal

You may submit comments through the [Federal Register](#). 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.



What's New on Regulations.gov

New features include the ability to download Agency, Docket, and Public Submission Document metadata in bulk. See [FAQs](#) for more detail.

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Comments Due Soon

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Next 7 Days	149



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 (upcoming release)
- Information Blocking (upcoming release)
- Insights Condition (upcoming release)

AT-A-GLANCE
Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule
April 2023

Standards and Certification Criteria Proposals

- To adopt United States Core Data for Interoperability (USCDI) v3 as the new data set baseline across applicable certification criteria.
- To revise electronic case reporting certification criterion to be based on consensus-based, industry developed standards by HL7.
- To revise existing clinical decision support (CDS) certification criterion as the decision support interventions (DSI) certification criterion.
- To add new requirements for revoking access privileges.
- To add new data elements, and rename the demographics certification criterion.
- To update the transitions of care certification criterion to USCDI v2.
- To adopt a new patient requested restrictions certification criterion and to revise an existing criterion to support additional tools for implementing patient requested restrictions.

Certification Program Proposals

- To discontinue the use of "year themed editions" of certification criteria.

GENERAL OVERVIEW
Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule
April 2023

ONC's NPSM seeks to implement provisions of the 21st Century Cures Act and make updates to the ONC Health IT Certification Program (Certification Program) with new and updated standards, certification criteria, and implementation specifications in 45 CFR Part 170. The proposed rule also includes multiple requests for information (RFI) to inform potential future rulemaking. RFI topics areas include electronic prior authorization, lab interoperability, predictive decision support interventions, and advanced Fast Healthcare Interoperability Resource (FHIR) capabilities, among others across parts 170 and 171. We look forward to receiving public comment on these proposals and direct interested parties to the following link in order to comment. [\[LINK TO COMMENT\]](#).

Proposal Highlights

- Implementing the "FHIR Reporting Program" to provide transparent reporting on certified health IT by establishing the Insights Condition and Maintenance of Certification.
- Providing enhancements to the information blocking regulations in response to feedback from affected parties.
- Proposing adoption of United States Core Data for Interoperability (USCDI) Version 3 to replace USCDI Version 1 as the standard in § 170.213 by January 1, 2025.
- Updating the Certification Program's standards, criteria, and requirements, including:
 - Standardized Application Programming Interfaces (APIs), including adoption of the Smart App Launch Implementation Guide v2;
 - Electronic case reporting using HL7 Consolidated Document architecture (CDA), and HL7 FHIR based specifications;
- Clinical decision support (CDS) with several new transparency requirements for Health IT Modules that enable or interface with technology intended to support decision making based on predictive models or algorithms; and
- New functionality that enables a provider to flag whether specific pieces of a patient's USCDI data needs to be restricted from being subsequently used or disclosed.

Discontinuing Year-Themed Editions for Health IT Certification Criteria

To simplify the Certification Program and support more modular and extensible future updates, ONC is proposing to discontinue the year-themed editions. This change will also support broader use of certification criteria and standards adopted by ONC for other federal agencies and programs.

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Office of the National Coordinator
for Health Information Technology

Contact ONC

Jeffery Smith, M.P.P.
Deputy Division Director,
Certification & Testing Division
Office of Technology
Office of the National Coordinator for Health IT
Jeffery.Smith@hhs.gov



Phone: 202-690-7151



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