ONC Proposed Rule

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

Overview

Disclaimers and Public Comment Guidance

- The materials contained in this presentation are based on the proposals in the "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing" proposed rule. While every effort has been made to ensure the accuracy of this restatement of those proposals, this presentation is not a legal document. The official proposals are contained in the proposed rule.

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

4. Information Blocking

5. Decision Support Interventions (DSI) and Algorithmic Transparency

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.

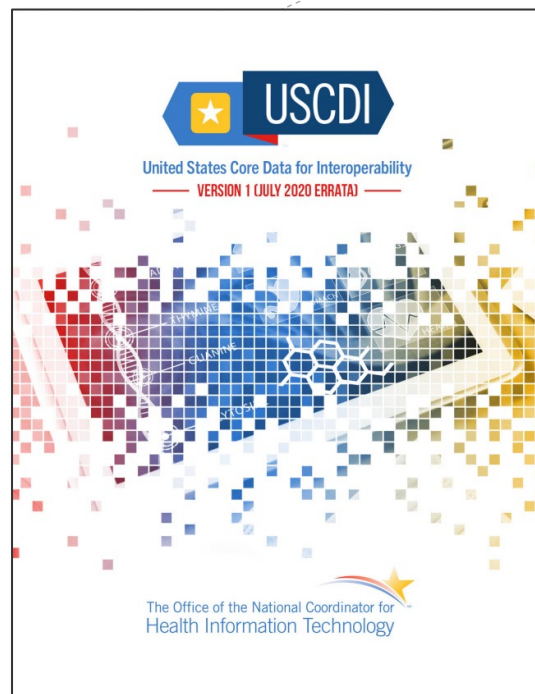- **New and Revised Certification Criteria**
  - Electronic Case Reporting § 170.315(f)(5)
  - Clinical Decision Support § 170.315(a)(9)
  - Standardized API for Patient and Population Services § 170.315(g)(10)
  - ***New*** Patient Requested Restrictions Criteria in § 170.315(d)(14)
  - Patient Demographics 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.

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
United States Core Data for Interoperability
VERSION 1 (JULY 2020 ERRATA)

The Office of the National Coordinator for Health Information Technology

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

# 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
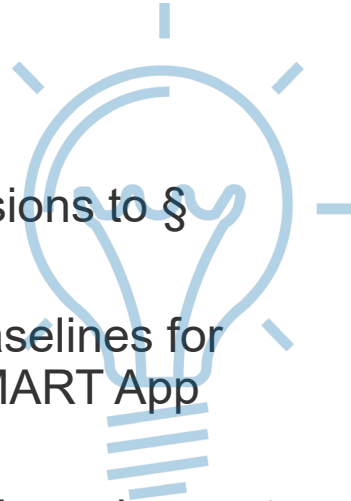
Electronic Case Reporting

Proposal

- ONC is proposing to require that Health IT Modules support eCR using consensus-based, industry-developed HL7® CDA and FHIR® standards

- Developers of certified health IT would have until the end of 2024, to adopt HL7 CDA or HL7 FHIR implementation guides to provide functionality

Benefits

- 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

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. We are also cognizant that the concept of "sensitive data" is dynamic and specific to the individual. 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)

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

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

Insights Condition and Maintenance of Certification

EHR Reporting Program	Insights Condition

- **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 <u>across</u> their certified health IT products;
    - Their product(s) are certified to the criterion/criteria associated with the measure; and
    - The developer has <u>any users of the applicable criterion/criteria</u> associated with the measure.

- Otherwise the health IT developer would report it does <u>not</u> meet the minimum reporting qualifications.

- Submissions for the Insights Condition shall occur <u>via web-based form</u> and method, consistent with the requirement in § 3009A(c) of the PHSA, and <u>shall be made publicly available</u> via an ONC website

What is the reporting frequency and timeline?

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

- Reporting of measures will be <u>phased in over two years</u>
  - Year 1 will start with measures related to individual access, public health exchange and the applications supported through certified health IT measure
  - Year 2 will follow with the rest of the measures

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.

DSI and Algorithmic Transparency

Decision Support Interventions (DSI) Proposals

ONC proposes to revise the existing CDS criterion § 170.315(a)(9) to reflect an array of contemporary and emerging software functionalities that aid user decision-making in health care, including artificial intelligence (AI) and machine learning (ML).

This revision includes:

- A definition for "predictive decision support intervention"

- Updating the Base EHR definition to include the proposed revised DSI criterion in § 170.315(b)(11)

- Requirements for Health IT Modules that enable or interface with predictive DSIs to provide relevant technical and performance information to users

- Requirements for certified health IT developers to employ or engage in risk management practices related to predictive DSIs

- Requirements for certified health IT developers with Health IT Modules certified to DSI criterion to participate in Real World Testing
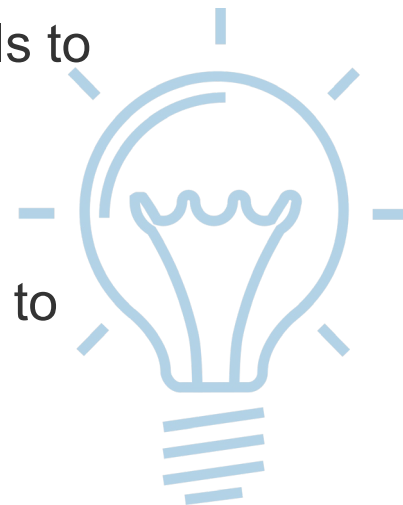
DSI Proposals – Benefits

ONC proposes these revisions to optimize the use of predictive and other DSIs types in health care. These baseline requirements for transparency aim to improve the trustworthiness of predictive algorithms and support their widespread use in health care.

Other intended outcomes include:

- **Improving transparency** regarding how a predictive DSI is designed, developed, trained, evaluated, and should be used

- **Enhancing 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

- **Supporting 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)

- **Advancing 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

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 training data.

- Agnostic to specific purposes or intended uses.

- Does not convey or consider a level of risk associated with its use.

- Not dependent on who developed the algorithm or model (can be someone other than a health IT developer).

- Examples include:

  - Simple statistics and regression models used in a risk calculator (e.g., such as the widely used ASCVD model, which predicts heart events, and APACHE IV model, which predicts in-hospital death for ICU patients)

  - Machine learning models of various complexity, including neural networks and gradient boosted machines (used, for example, to predict hospital readmission, sepsis onset, and patient no-shows) and large language models including generative pre-trained transformers (e.g., ChatGPT)

- Outputs of predictive model may be presented in a broad array of forms that DSIs can take (e.g., alerts, order sets, flowsheets, etc.).

Transparency Is A Prerequisite for Trustworthy AI

Data Transparency

Proposed source attributes requirement 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

Predictive DSI Transparency

Proposed source attributes would enable 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
- Report summary information publicly

Snapshot of Proposals to Promote Transparent & Trustworthy DSIs through the ONC Health IT Certification Program

Increase Transparency of Predictive Models

Technical & Performance

- Information about how the predictive DSI "works" made available to users, in plain language and via direct display, drill down, or link out:
  - Output and intended use, out of scope use(s), description of training data, external validation, update schedule, etc.
  - Like a "nutrition label"; leverage existing "source attributes" certification requirement
- Supportive of health equity by design:
  - Identification of REL, SOGI, SDOH, & Health Status data elements used
  - Information on validity and fairness of prediction in test and local data (if available)
- Additional enhancements that enable:
  - Authoring and revision capability for users
  - User feedback capabilities and feedback exports for quality improvement of DSIs

Governance

- Public disclosure regarding how certified health IT developer manages risks and govern predictive DSIs:
  - Risk analysis (8 risk types): validity, reliability, robustness, fairness, intelligibility, safety, security, and privacy
  - Risk mitigation of those risks
  - Governance processes, including data management
- Summary documentation must be:
  - Publicly accessible through hyperlink without precondition
  - Reviewed annually for updates
- Detailed documentation must be:
  - Available to ONC upon request from ONC for each predictive DSI the certified health IT enables or interfaces with
  - Reviewed annually for updates

Oversight

- Conformance to proposed new requirements through Real World Testing (RWT) Program:
  - RWT for all DSI types (predictive, evidence-based, and linked referential) beginning for 2024 plans
  - Annual cycle of RWT plans and results publicly available via the Certified Health IT Product List (CHPL)
  - Measures demonstrating conformance to requirements, self-identified by developer
- Summary of intervention risk management practices made publicly available
- Detailed risk management practices made available to ONC upon request from ONC

What would the DSI proposals mean for…

Patients
- Enables patients to benefit from health care provider's use of trustworthy predictive models for decisions related to their care
- Addresses potential, preventable harms (model risks) resulting from the use of predictive models
- Supports patient access to underlying information about use of a predictive DSI as part of the patient's care

Providers
- Enables consistent availability of and access to information necessary to determine whether to trust predictive DSIs for patient care
- Enables clinicians to use predictive DSIs in more appropriate, equitable, and safer ways for patients and populations

Developers
- Supports consensus on how to communicate technical and performance details of predictive DSIs consistently for users
- Creates market conditions for developers with high-quality predictive DSIs to have an advantage over those with poor-quality predictive DSIs

Industry
- Creates flexible guardrails for industry to assess and demonstrate that predictive DSIs are fair, appropriate, valid, effective, and safe
- Establishes an information ecosystem to enable prospective, proactive, and ongoing assessment of predictive models in health care

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)

Don't Miss Our Upcoming Webinars!

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

Upcoming Webinars

NPRM Overview

April 27, 1:00 PM ET

DSI and Algorithmic Transparency Proposals

May 4, 1:00 PM ET

**Insights Condition Proposals**

May 11, 1:00 PM ET

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.
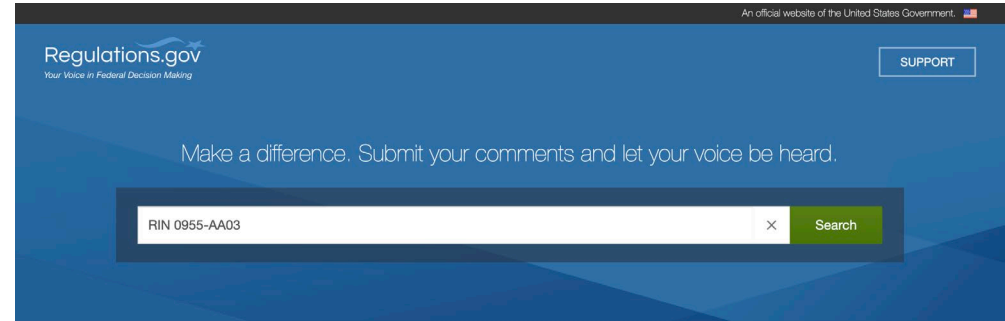
HTI-1 Proposed Rule Task Force 2023

HTI-1 Proposed Rule Task Force 2023

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.

Specific Charge: Provide recommendations on ONC's proposals that would:

- Rename all certification criteria within the ONC Health IT Certification Program (Program) as "ONC Certification Criteria for Health IT" and discontinue year themed "Editions"

- Establish a new baseline version of the United States Core Data for Interoperability (USCDI) from Version 1 to Version 3

- Implement the Electronic Health Record (EHR) Reporting Program as a new Insights Condition and Maintenance of Certification for health information technology (health IT) developers under the Program

- Enhance information sharing under the information blocking regulations

HTI-1 Proposed Rule Task Force 2023 (continued)

Specific Charge: Provide recommendations on ONC's proposals that would:

- Adopt new and revised standards and certification criteria, including:
    - Electronic case reporting certification criterion;
    - Clinical decision support (CDS) and decision support interventions (DSI) certification criteria;
    - Application programming interfaces (APIs) for patient and population services;
    - FHIR US Core Implementation Guide STU version 5.0.
    - HL7 CDA® R2 IG: C–CDA Templates for Clinical Notes STUR2.1 Companion Guide, Release 3 US Realm;
    - A new patient requested restrictions certification criterion; and
    - Requirements for health IT developers to update their previously certified health IT.

- Establish additional Assurances Condition and Maintenance of Certification requirements

- Solicit requests for information (RFIs) on Program standards, certification criteria, and information blocking to inform potential future rulemaking

Recommendations are due to the HITAC by the end of the 60 day public comment period.

HTI-1 Proposed Rule Task Force 2023 – Topics by Group

Group 1: Information Blocking (IB)
- Information Blocking Defined Terms – Proposals
- IB Request for Information (RFI): Additional Exclusions for Offer Health IT
- IB Manner Exception - TEFCA Manner Proposal
- IB RFI 2 – Possible Additional TEFCA Reasonable and Necessary Activities
- IB Infeasibility Exception Proposals
- Revise Existing Condition: Uncontrollable Events
- New Condition: Third Party Seeking Modification Use
- New Condition: Manner Exception Exhausted
- IB RFI 3 – Health IT Capabilities for Data Segmentation and User/Patient Access

HTI-1 Proposed Rule Task Force 2023 – Topics by Group (continued)

Group 2: ONC Health IT Certification Updates – New and Revised Certification Criteria
- Decision Support Interventions (DSI) and Predictive Models
- Electronic Case Reporting
- "The ONC Certification Criteria for Health IT" and Discontinuing Year Themed "Editions"
- Assurances Condition and Maintenance of Certification Requirements
- Requirement for Health IT Developers to Update their Previously Certified Health IT
- Patient Requested Restrictions Certification Criterion

Group 3: ONC Health IT Certification Program Updates – Insights Condition, Standards Updates, and RFIs
- Insights Condition and Maintenance of Certification
- The United States Core Data for Interoperability Standard (USCDI) v3
- C-CDA Companion Guide Updates
- Standardized API for Patient and Population Services
- FHIR US Core Implementation Guide STU version 5.0.1
- Requests for Information

HTI-1 Proposed Rule Task Force 2023 – Roster

Name	Organization	Name	Organization
Steven Eichner* (Co-Chair)	Texas Department of State Health Services	Hung Luu*	Children's Health
Steven Lane*(Co-Chair)	Health Gorilla	Meg Marshall**	Department of Veterans Affairs (VA)
Hans Buitendijk*	Oracle Health	Clem McDonald*	National Library of Medicine
Rajesh Godavarthi*	MCG Health, part of the Hearst Health network	Eliel Oliveira*	Dell Medical School, University of Texas at Austin
Adi Gundlapalli**	CDC	Fillipe Southerland*	Yardi Systems, Inc.
Jim Jirjis*	HCA Healthcare	Sheryl Turney*	Carelon Digital Platforms (an Elevance Health company)
Elaine Johanson**	FDA	Deven McGraw*	Invitae Corporation
Hannah Galvin*	Cambridge Health Alliance	Anna McCollister*	Individual
Naresh Sundar Rajan*	CyncHealth		

*HITAC Member
**HITAC Federal Representative

HTI-1 Proposed Rule Task Force 2023 – Proposed Meeting Schedule

GROUP 1	GROUP 2	GROUP 3
Tuesdays 10:30 – Noon ET	Wednesdays, 10:30 – Noon ET	Thursdays, 10:30 – Noon ET

- The first task force meeting is planned for April 25, 2023, from 10:30 – Noon ET and will include all task force members

- 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

Contact ONC

☎ **Phone:** 202-690-7151

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

🐦 **Twitter:** @onc_healthIT

in **LinkedIn:** Office of the National Coordinator for Health Information Technology

▶ **Youtube:** https://www.youtube.com/user/HHSONC

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