Office of the National Coordinator for Health Information Technology

Brief Overview and Q&A Session HTI-1 Proposed Rule

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

6/12/2023

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.

- ONC must protect the rulemaking process and comply with the Administrative Procedure Act. During the rulemaking process, ONC can only present the information that is in the proposed rule as it is contained in the proposed rule. ONC cannot interpret that information, nor clarify or provide any further guidance.

- ONC cannot address any comments made by anyone attending the presentation or consider any such comments in the rulemaking process, unless submitted through the formal comment submission process as specified in the Federal Register.

- This communication is produced and disseminated at U.S. taxpayer expense.

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"

Why the Rule?

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

What's in the Rule?

ONC Health IT Certification Program

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

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

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

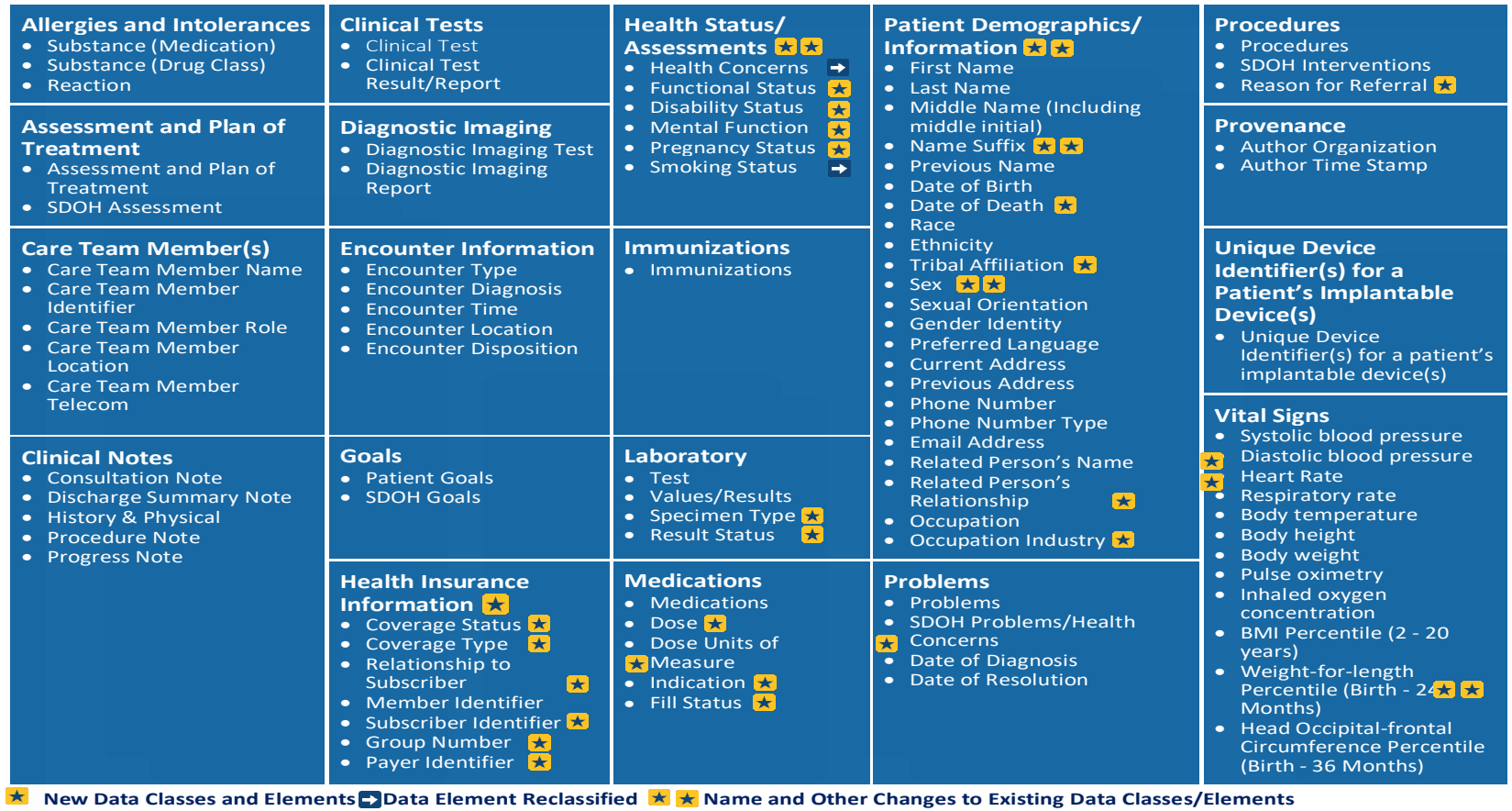
- **Standards**
  - United States Core Data for Interoperability Standard Version 3
  - C-CDA Companion Guide Release 3*
  - US Core Implementation Guide 5.0.1*
  - “Minimum Standards” Code Sets Updates
    - SNOMED, RxNorm, LOINC, NDC, etc.

- **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 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

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

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

DSI and Algorithm Transparency

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

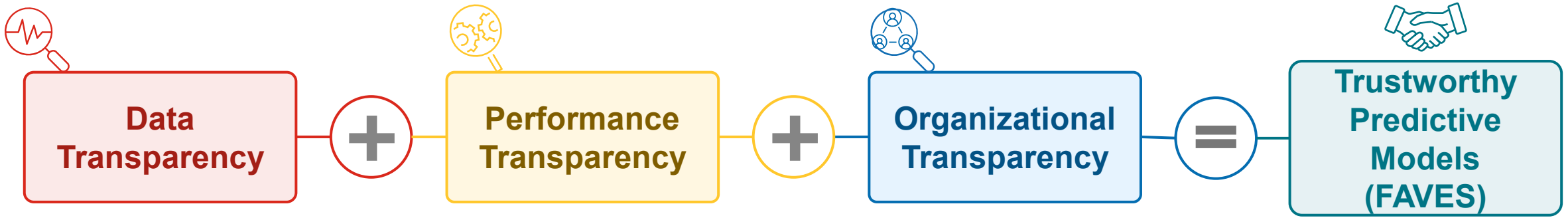
Support Consistency

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

Overview of Proposed Source Attribute Requirements

If a Health IT Module enables or interfaces with predictive DSIs, we are proposing that the module must make information about additional Source Attributes available to provide users transparency on how the predictive DSI was designed, developed, trained, evaluated, and should be employed.

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

Benefits for Patients, Providers, and Industry

Patients

- Enables patients to benefit from the use of FAVES predictive models related to their care
- Avoids preventable harms, such as errors in decision making, health inequities, bias, and discrimination
- Clarifies patient access to underlying information

Providers

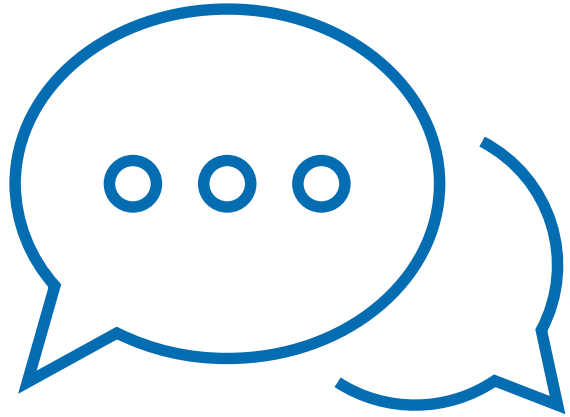
- Enables access to information necessary to trust predictive DSIs for patient care
- Provides better assurances that PDSIs work as intended and anticipated
- Enables clinicians to use PDSIs in more appropriate, equitable, and safer ways for patients and populations

Developers/Industry

- Helps drive consensus on how to communicate the “ingredients” of predictive DSIs consistently
- Helps developers with high quality models thrive
- Helps establish an information ecosystem that enables an actionable and widely accepted approach for transparency and trustworthiness of algorithms in health care

Questions in the HTI-1 Proposed Rule

- 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?



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.

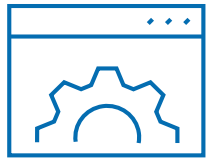
- **Insights Condition shall provide transparent reporting that aims to:**
  - Address information gaps in the health IT marketplace
  - Provide insights on the use of specific certified health IT functionalities
  - Provide information about consumers' experience with certified health IT

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



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

Opportunities to Learn More

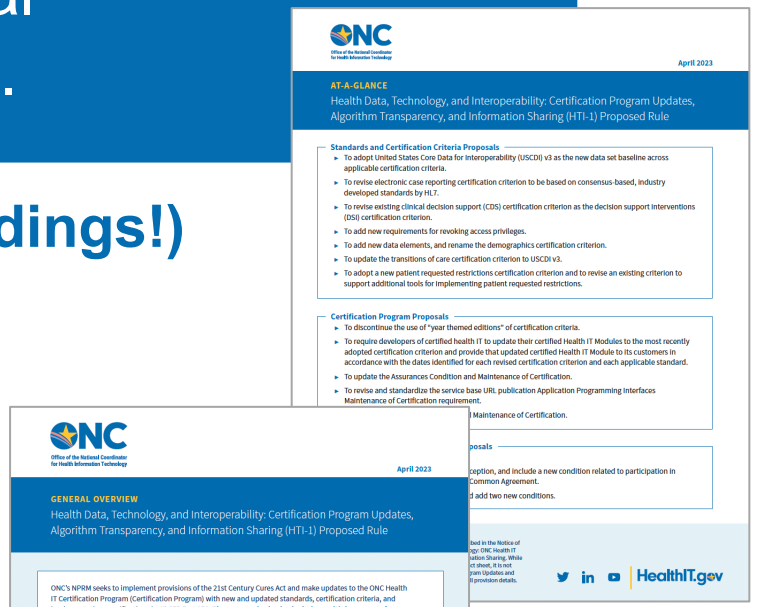
Resources Available on HealthIT.gov!

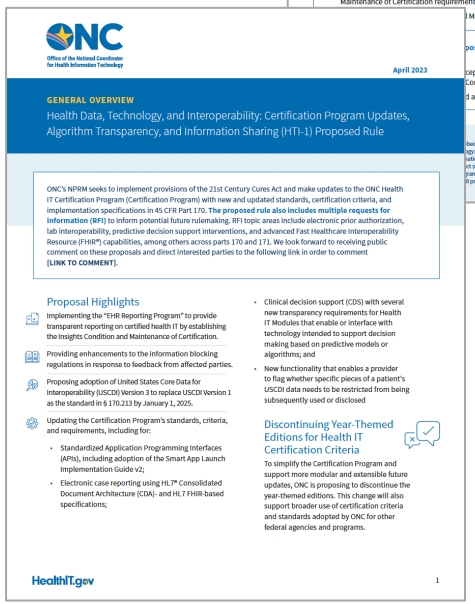
Visit https://healthIT.gov/proposedrule for additional information. More updates will be added over time.

Blog Posts (2) and Webinars (7 with slides and recordings!)

Fact Sheets

- General Overview
- At-a-Glance
- Decision Support Interventions and Predictive Models
- Insights Condition
- Update and Provide Certified Health IT
- Information Blocking





Measurement Spec Sheets

One for each of the 9 proposed Insights Condition measures

Health Information Technology Advisory Committee (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

The Importance of Public Comments and How to Comment on the HTI-1 Proposed Rule

Public Comments Form the Basis of Final Rules

- During the 21st Century Cures Act Rulemaking, ONC received approximately 2,000 comments from the public
- These comments formed the basis of the 21st Century Cures Act Final Rule
- For example, in the 21st Century Cures Act Proposed Rule, we proposed definitions for Health Information Network (HIN) and Health Information Exchange (HIE) that we revised based on public comment
  - The terms “network” and “exchange” are not defined in the information blocking provision of the 21st Cures Act or in any other relevant statutory provisions.
  - We proposed a definition for HIN and a definition for HIE
  - Based on public comment, we adopted a modified definition to address the feedback, consistent our statements in the Proposed Rule

Example of Public Comment Informing Final Rules: HIN/HIE

21st Century Cures Act Proposed Rule definition

- *Health Information Exchange* or *HIE* means an individual or entity that enables access, exchange, or use of electronic health information primarily between or among a particular class of individuals or entities or for a limited set of purposes.
- *Health Information Network* or *HIN* means an individual or entity that satisfies one or both of the following—
- (1) Determines, oversees, administers, controls, or substantially influences policies or agreements that define business, operational, technical, or other conditions or requirements for enabling or facilitating access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities. (2) Provides, manages, controls, or substantially influences any technology or service that enables or facilitates the access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities.

21st Century Cures Act Final Rule definition:

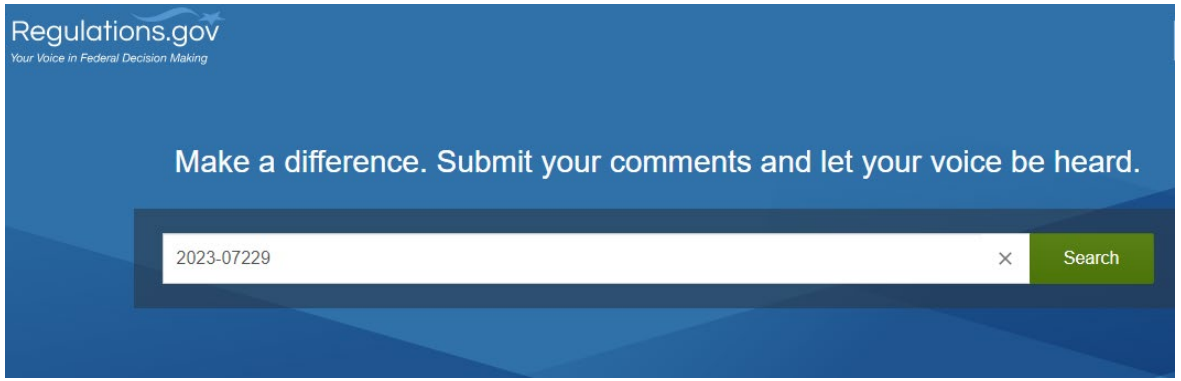
- *Health information network* or *health information exchange* means an individual or entity that determines, controls, or has the discretion to administer any requirement, policy, or agreement that permits, enables, or requires the use of any technology or services for access, exchange, or use of electronic health information:
- (1) Among more than two unaffiliated individuals or entities (other than the individual or entity to which this definition might apply) that are enabled to exchange with each other; and
- (2) That is for a treatment, payment, or health care operations purpose, as such terms are defined in 45 CFR 164.501 regardless of whether such individuals or entities are subject to the requirements of 45 CFR parts 160 and 164.

How to Submit a Comment Online

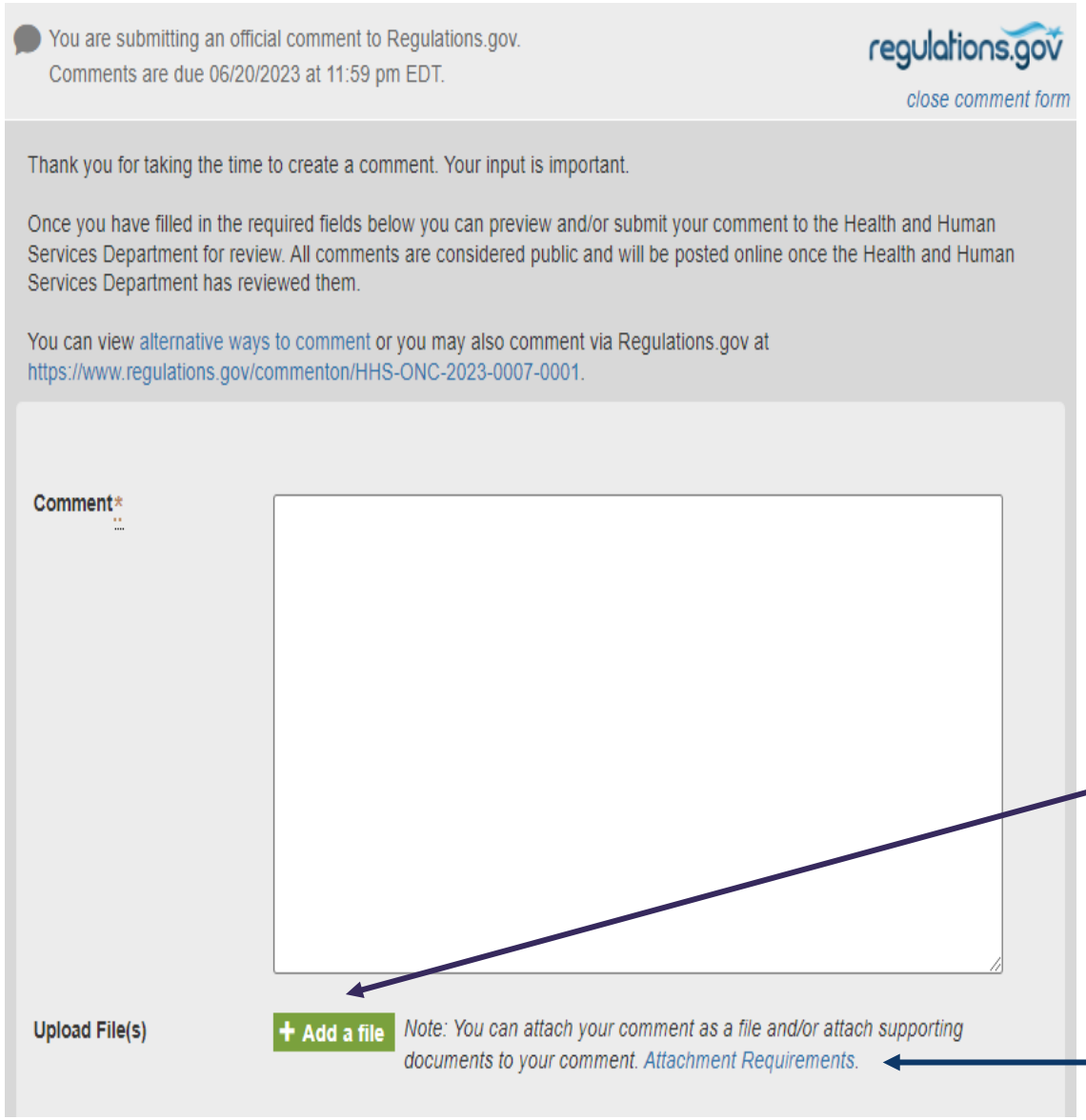
From the HTI-1 Proposed Rule on FederalRegister.gov, just click the

Submit a Formal Comment button

Or, at http://www.regulations.gov search by Federal Register docket number 2023-07229



Enter Your Comment



You may submit text in the comment field, upload a comment document, or both.

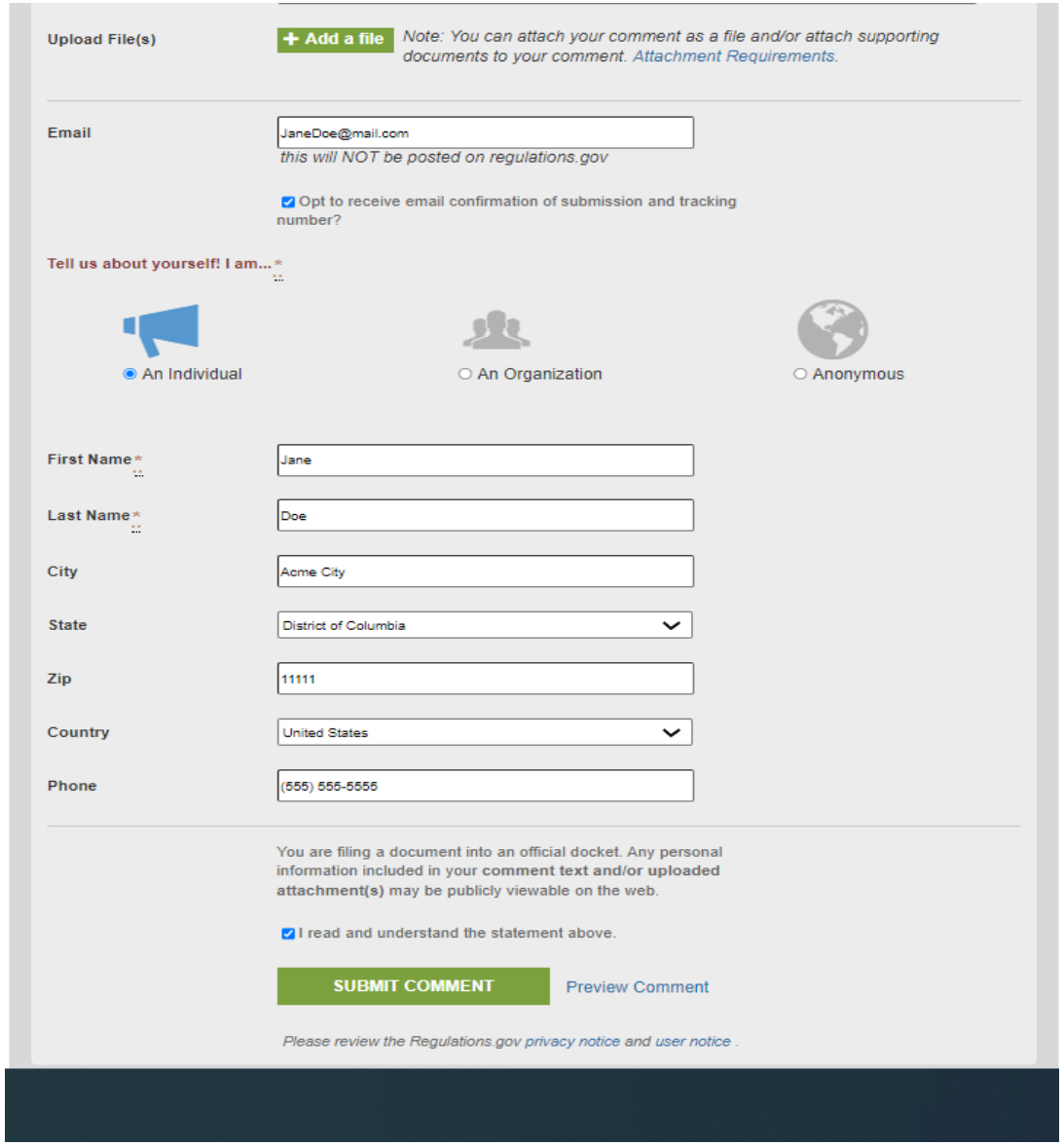
Public Comment Template

We provide on HealthIT.gov a template for the public to use, if they so choose, when submitting their comments.

To upload a completed comment template or other file, click **Add a file** button

To view regulations.gov supported file formats and size per comment submission, click "*Attachment Requirements*" link below the comment field

Submit Your Comment



Enter your information

Select the “I read and understand the statement above” box.

Select the “Submit Comment” button.

Office of the National Coordinator for Health Information Technology

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