Office of the National Coordinator for Health Information Technology

HTI-1 Proposed Rule

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

A Focus on How Patients and Caregivers Can Contribute to the Rulemaking

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6/2/2023

ONC Overview

Office of the National Coordinator for Health IT

- Founded in 2004 by executive order, established in statute in 2009
- ONC is charged with formulating the federal government's health IT strategy to advance national goals for better and safer health care through an interoperable nationwide health IT infrastructure

Laying the foundation of EHRs across the industry

- $40B CMS investment to subsidize EHRs for hospitals and ambulatory providers
- ONC "certification" for health IT systems

Leveraging EHRs to drive value

- Defines "information blocking" (practices that prevent, discourage, or interfere with access, exchange, or use of electronic health information)
- Requires access to information through APIs "without special effort"
- Requires nationwide governance for health information exchange networks – Trusted Exchange Framework and Common Agreement

ONC Activities & Objectives

ONC Activities

- Standards
- Certification
- Exchange

Coordination

- Federal
- State & Public

ONC Objectives

- Advance the development and use of health IT capabilities
- Establish expectations for data sharing

ONC's Current Areas of Focus

Build the digital foundation

- Data standards
- Health IT gaps
- HHS Health IT Alignment policy

Make interoperability easy

- TEFCA
- APIs

Promote information sharing

- Enforce information-blocking rules
- Partner with HHS agencies (e.g., CMS payment programs, CDC public health reporting, etc.)

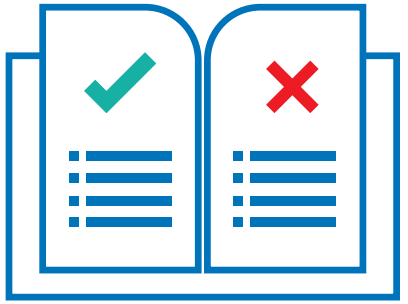
Ensure proper use of digital information and tools

- Health-equity-by-design principles for data capture and use
- Transparency in areas such as algorithm use and safety

Rulemaking Process

Brief Overview of the Rulemaking Process

The rulemaking process is a set of procedures that federal agencies follow to meet legal requirements for developing regulations.



- This includes statutory rulemaking requirements applicable to a wide range of agencies including the:
  - Administrative Procedure Act
  - Regulatory Flexibility Act
  - Paperwork Reduction Act
  - Unfunded Mandates Reform Act
  - Information Quality Act

- This includes Presidential rulemaking requirements such as:
  - Executive Order 12866 – requires covered agencies to submit significant rules to the Office of Management and Budget's (OMB's) Office of Information and Regulatory Affairs (OIRA) for review.
  - Executive Order 13563: Retrospective Analysis of Existing Rules
  - Executive Order "Modernizing Regulatory Review" April 6, 2023

Unified Agenda

- Unified Agenda of Federal Regulatory and Deregulatory Actions is a semiannual compilation of information about regulations under development by federal agencies, published in the spring and fall.
- Each edition of the Unified Agenda includes regulatory agendas from all Federal entities that currently have regulations under development or review.
- The Unified Agenda provides information about Federal regulatory and deregulatory activities to the President and his Executive Office, the Congress, agency managers, and the public.

ONC HTI-1 Proposed Rule

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View Rule

View EO 12866 Meetings | Printer-Friendly Version | Download RIN Data in XML

HHS/ONC **RIN:** 0955-AA03 **Publication ID:** Fall 2022

Title: ONC Health IT Certification Program Updates, Health Information Network Attestation Process for the Trusted Exchange Framework and Common Agreement, and Enhancements to Support Information Sharing

Abstract:

The rulemaking implements certain provisions of the 21st Century Cures Act, including: the Electronic Health Record Reporting Program condition and maintenance of certification requirements under the ONC Health IT Certification Program; a process for health information networks that voluntarily adopt the Trusted Exchange Framework and Common Agreement to attest to such adoption of the framework and agreement; and enhancements to support information sharing under the information blocking regulations. The rulemaking would also include proposals for new standards and certification criteria under the Certification Program related to the United States Core Data for Interoperability, real-time benefit tools, electronic prior authorization, and potentially other revisions to the Certification Program.

Agency: Department of Health and Human Services(HHS)
Priority: Other Significant
RIN Status: Previously published in the Unified Agenda
Agenda Stage of Rulemaking: Proposed Rule Stage
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 45 CFR 170 45 CFR 171 45 CFR 172
Legal Authority: 42 U.S.C. 300jj–11 42 U.S.C. 300jj–14 42 U.S.C. 300jj–19a 42 U.S.C. 300jj-52 5 U.S.C. 552 Pub. L.114-255 Pub. L. 116-260

Legal Deadline:

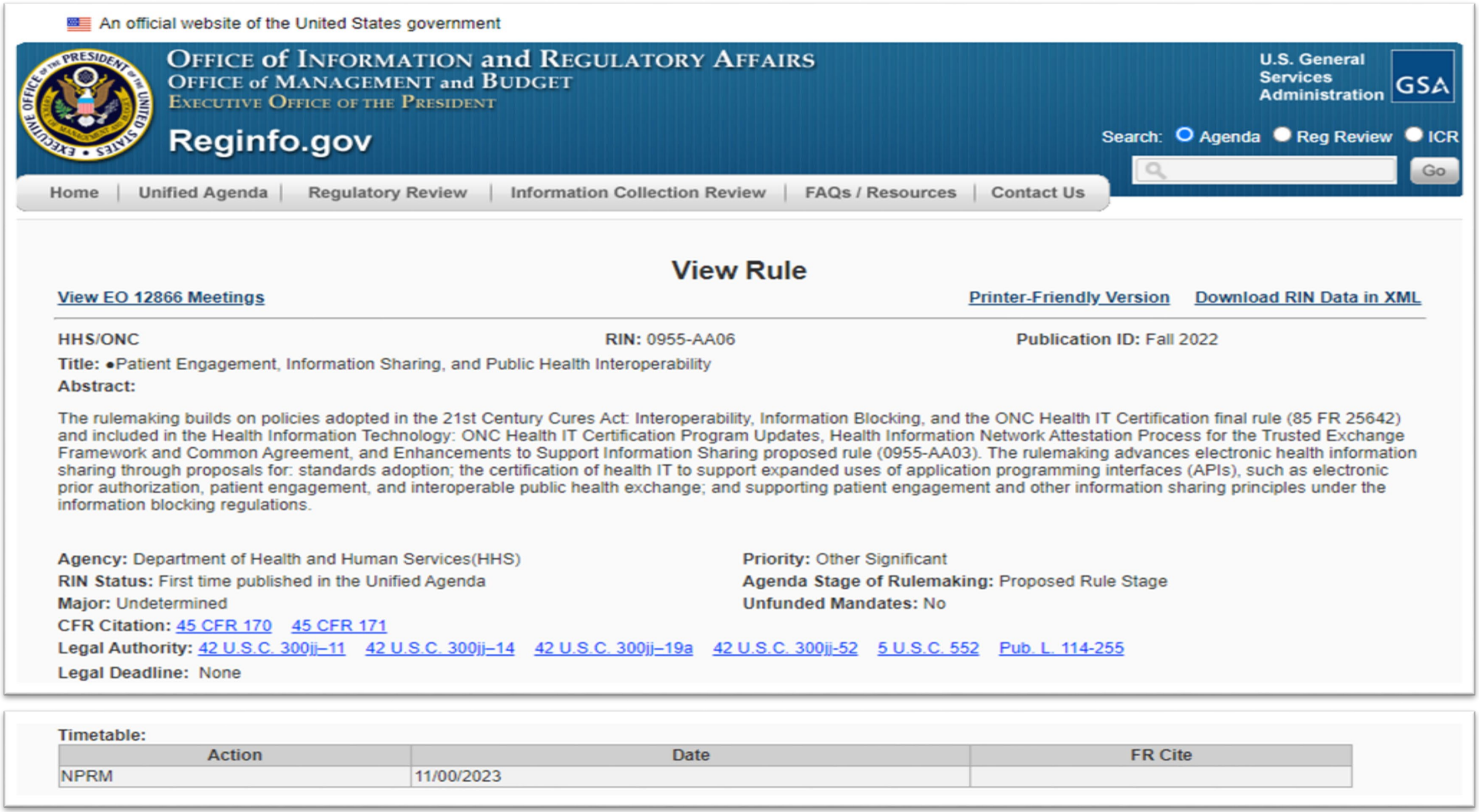
Action	Source	Description	Date
Final	Statutory	Conditions of certification and maintenance of certification	12/13/2017
Final	Statutory	Publish a list of the health information networks that have adopted the common agreement and are capable of trusted exchange pursuant to the common agreement.	07/24/2019

Timetable:

Action	Date	FR Cite
NPRM	12/00/2022	

https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202210&RIN=0955-AA03

ONC HTI-2 Proposed Rule



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View Rule

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HHS/ONC **RIN:** 0955-AA06 **Publication ID:** Fall 2022

Title: •Patient Engagement, Information Sharing, and Public Health Interoperability

Abstract:

The rulemaking builds on policies adopted in the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification final rule (85 FR 25642) and included in the Health Information Technology: ONC Health IT Certification Program Updates, Health Information Network Attestation Process for the Trusted Exchange Framework and Common Agreement, and Enhancements to Support Information Sharing proposed rule (0955-AA03). The rulemaking advances electronic health information sharing through proposals for: standards adoption; the certification of health IT to support expanded uses of application programming interfaces (APIs), such as electronic prior authorization, patient engagement, and interoperable public health exchange; and supporting patient engagement and other information sharing principles under the information blocking regulations.

Agency: Department of Health and Human Services(HHS)
RIN Status: First time published in the Unified Agenda
Major: Undetermined
CFR Citation: 45 CFR 170 45 CFR 171
Legal Authority: 42 U.S.C. 300jj–11 42 U.S.C. 300jj–14 42 U.S.C. 300jj–19a 42 U.S.C. 300jj-52 5 U.S.C. 552 Pub. L. 114-255
Legal Deadline: None

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule Stage
Unfunded Mandates: No

Timetable:

Action	Date	FR Cite
NPRM	11/00/2023	

https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202210&RIN=0955-AA06

How Public Comments Inform a Final Rule

- The notice-and-comment process enables anyone to submit a comment on any part of the proposed rule
- The agency must base its reasoning and conclusions on the rulemaking record, consisting of comments, scientific data, expert opinions, and facts accumulated during the pre-rule and proposed rule stages
- To move forward with a final rule, the agency must conclude that its proposed solution will help accomplish the goals or solve problems identified, and also consider whether alternative solutions would be more costs effective or cost less
- Depending on the rulemaking record, an agency may:
  - Terminate the rulemaking
  - Continue the rulemaking with changes to aspects of the rule to reflect new issues
  - Publish a supplemental proposed rule if there are major changes
  - Proceed with a final rule if changes are minor, or are a logical outgrowth of the issues and solutions discussed in the proposal

Source: https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf

Requests for Information

- Agencies issue Requests for Information (RFI) to gather input from the public on important topics that are not yet ripe for rulemaking
- RFIs are not the same as Proposed Rules because they inform potential future rulemaking
- Agencies consider these comments to inform potential future rulemaking proposals that could lead to a final regulation
- HTI-1 Proposed Rule has RFIs, a few which we will cover today:
  - SMART Health Links
  - Health IT Capabilities for Data Segmentation and User/Patient Access

HTI-1 Proposed Rule – General 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.

- 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.

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

HTI-1 Proposed 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.

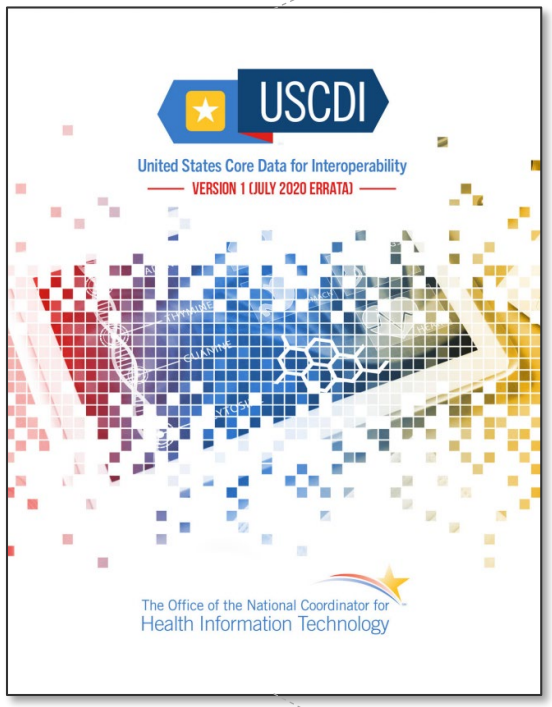
- **New and Revised Certification Criteria**
  - Electronic Case Reporting § 170.315(f)(5)
  - Clinical Decision Support § 170.315(a)(9)
  - Standardized API for Patient and Population Services § 170.315(g)(10)
  - ***New*** Patient Requested Restrictions Criteria in § 170.315(d)(14)
  - Patient Demographics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

Why this proposal is important for patients and caregivers

- **More accurate and complete data**
  - USCDI v3 expands the amount and type of data available to be used and exchanged through certified health IT
  - Supports consistent capture of more accurate and complete patient characteristics
    - Help address disparities in health outcomes for all patients, including those who may be marginalized and underrepresented
- **Better care, experiences and outcomes**
  - USCDI v3 supports providers' ability to identify, assess, and analyze gaps in care, which could in turn be used to inform and address the quality of healthcare through interventions and strategies
- **Supports “health equity by design”**
  - USCDI v3 supports the concept of “health equity by design,” where health equity considerations are identified and incorporated from the beginning and throughout the technology design, build, and implementation process, and health equity strategies, tactics, and patterns are guiding principles for developers, enforced by technical architecture, and built into the technology at every layer

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

Why this proposal is important for patients and caregivers

- **Supports Public Health Initiatives**
  - The proposed updates would continue ONC's efforts to develop and standardize APIs and would help individuals and other authorized health care providers, including those engaged in public health, to securely access EHI through the broader adoption of standardized APIs

- **Foster competition and improves electronic access to EHI**
  - This proposed rule would foster competition by advancing foundational standards for certified API technology
    - Help individuals connect to their information and can help authorized health care providers involved in the patient's care to securely access information
    - Foster an ecosystem of new applications that can connect through the API technology to provide patients with improved electronic access to EHI and more choices in their health care providers
    - Similar to how APIs have impacted other sectors of the economy, such as travel, banking, and commerce

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

SMART Health Links

- Builds on the concept of SMART Health Cards - aggregate data in meaningful sets, signed by an issuer, and stored/presented by a consumer as needed
  - For example: Managing an immunization record that can be shared with schools or employer
  - Designed to only include the minimum information necessary for a given use case
  - A non-forgeable digital artifact analogous to a paper record on official letterhead
- SMART Health Links use cases:
  - Share a link to any collection of FHIR data, including signed data
  - Share a link to a Smart Health Card that is too large for a QR code
  - Share link to a "dynamic" SMART Health Card (i.e. data changes over time)

SMART Health Links RFI

- SMART Health Links:
  - Uses similar approach to SMART Health Cards for sharing data
  - Intended to allow individuals explicit control over with whom they share their health information
  - Aims to overcome some of the known limitations of the SMART Health Cards technology
- We request feedback on:
  - Value and feasibility of the SMART Health Links Protocol
  - Concerns regarding its implementation
  - Approaches ONC could take to encourage rapid advancement of SMART Health Links
  - Any other promising industry-led innovative activities that we should consider that are aligned with the FHIR standard, and which would help improve interoperability using health IT

HTI-1 Proposed Rule – 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

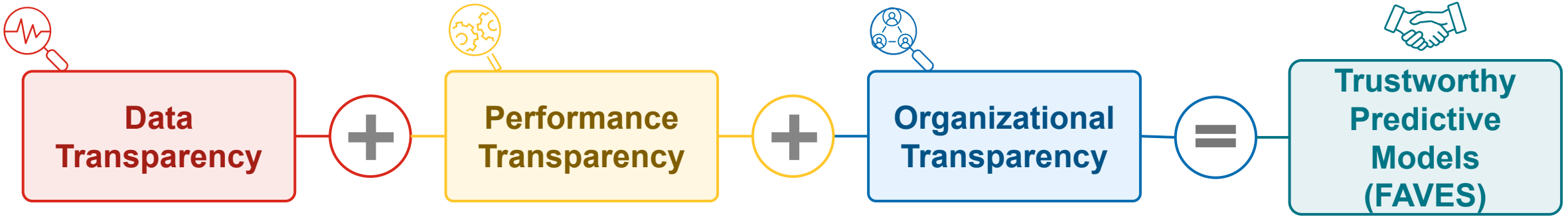
Support Consistency

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

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

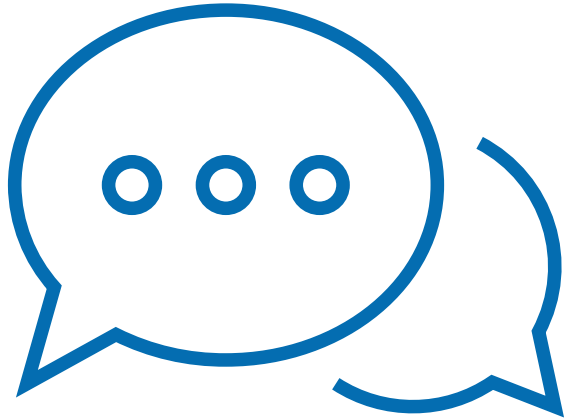
Propose to require certified health IT developers employ or engage in risk analysis and mitigation practices for 8 characteristics:

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?



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

Information Blocking

Definition of Information Blocking

45 CFR 171.103:

(a) Information blocking means **a practice** that—

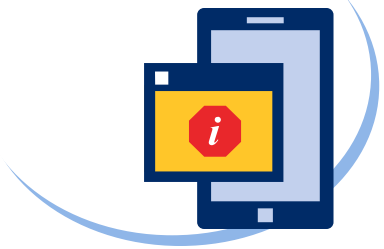
(1) **Except as required by law** or covered by an exception, is likely to **interfere with** access, exchange, or use of **electronic health information** (EHI); and

(2) If conducted **by a health information technology developer, health information network or health information exchange**, such developer, network or exchange **knows, or should know**, that such practice is likely to interfere with access, exchange, or use of EHI; or

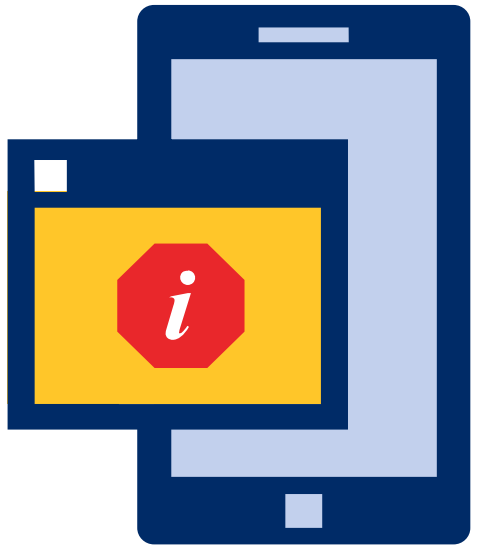
(3) If conducted by a **health care provider**, such provider **knows** that such practice is unreasonable and is likely to interfere with the access, exchange, or use of EHI.

~~(b) Until date specified in 45 CFR 171.103(b), EHI for purposes of § 171.103(a) is limited to the EHI identified by the data elements represented in the USCDI standard adopted in § 170.213.~~

This is proposed to be removed in the Proposed Rule



Overview of Information Blocking Elements



What Makes an Individual or Entity an Information Blocker?

- ❑ Actor regulated by the information blocking provision
- ❑ Involves electronic health information (EHI)
- ❑ Practice is likely to interfere with access, exchange, or use of EHI
- ❑ Requisite knowledge by the actor
- ❑ Not required by law
- ❑ Not covered by an exception

Information Blocking – Definition of Electronic Health Information (EHI)

- EHI means **electronic protected health information (ePHI)** to the extent that the ePHI would be included in a **designated record set** as these terms are defined for HIPAA.
  - *Except for* psychotherapy notes (45 CFR 164.501) and information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding.
- This is applicable whether or not the information is held by or for a HIPAA covered entity.

Information Blocking Exceptions

Exceptions that involve not fulfilling requests to access, exchange, or use EHI

1. Preventing Harm Exception

2. Privacy Exception

3. Security Exception

4. Infeasibility Exception

5. Health IT Performance Exception

Exceptions that involve procedures for fulfilling requests to access, exchange, or use EHI

6. Content and Manner Exception

7. Fees Exception

8. Licensing Exception

HTI-1 Proposed Rule – 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

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

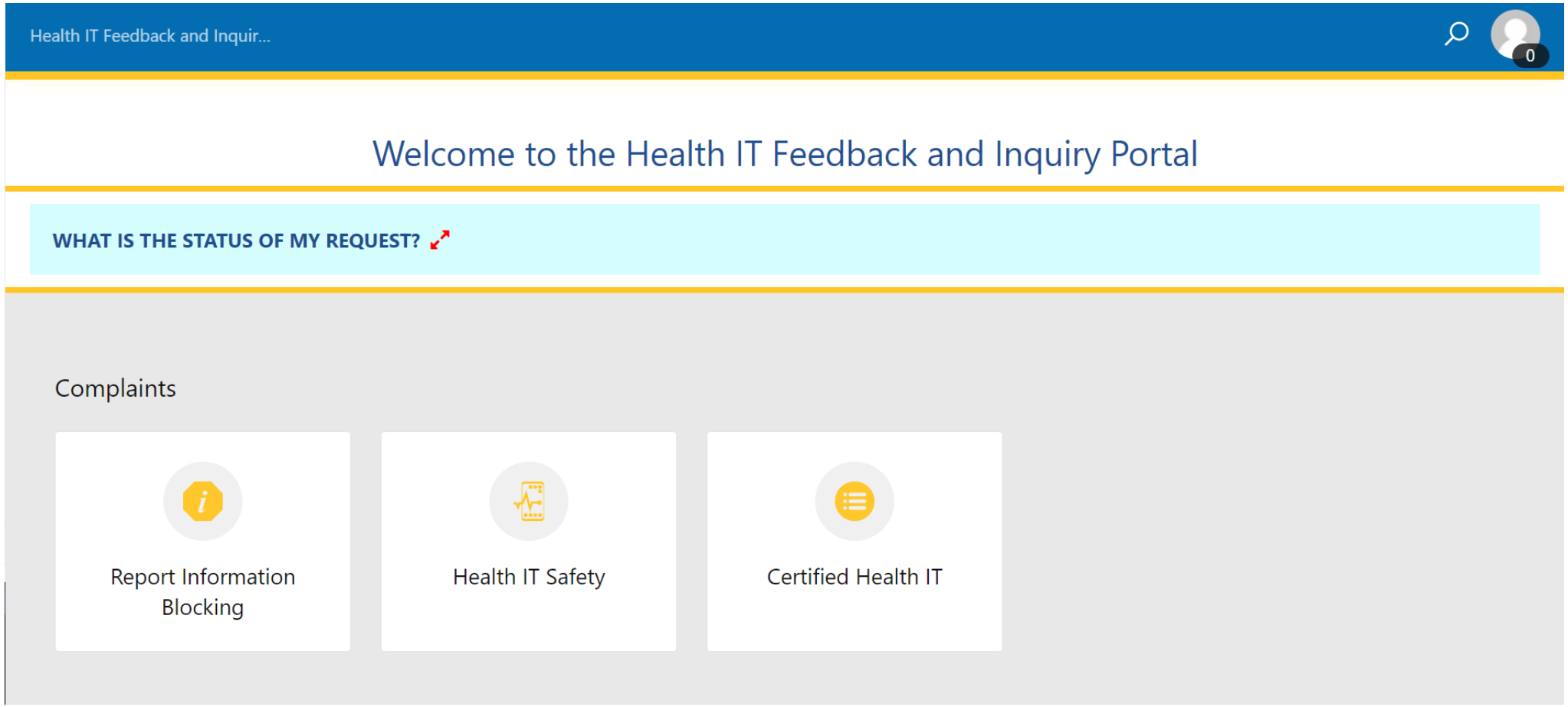
- Aligns with the Cures Act's goals for interoperability and the establishment of TEFCA by acknowledging the value of TEFCA in promoting access, exchange, and use of EHI in a secure and interoperable way.
- Facilitates a responding actor reaching agreeable terms with a requestor to fulfill an EHI request 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.

Information Blocking Data Segmentation RFI

- ONC believes that data segmentation is an integral capability for enabling the access, exchange, and use of electronic health information
- Today, even certified health IT products' capabilities to segment and filter the same information differently for different users and reasons for access or use seems to vary widely throughout the market
- Interested parties have also indicated that their certified health IT may have little or no ability to restrict a patient's personal representative's access to only some of the patient's EHI using electronic means such as a portal or API or to hold back only some pieces of the patient's EHI, in response to or at the patient's request, while honoring the patient's simultaneous preference for the rest of their EHI to be shared with another of their health care providers.
  - For example, patients may express a preference for a delay in the availability of information to them (such as in a health care provider's patient portal).
  - Or, for another example, an actor could choose to honor a patient request that the actor withhold certain information from particular access, exchange, or use consistent with the individual right to request restrictions under the HIPAA Privacy Rule and the information blocking Privacy Exception.[418]
- We seek comment to inform steps we might consider taking to improve the availability and accessibility of solutions supporting health care providers' and other information blocking actors' efforts to honor patients' expressed preferences regarding their EHI

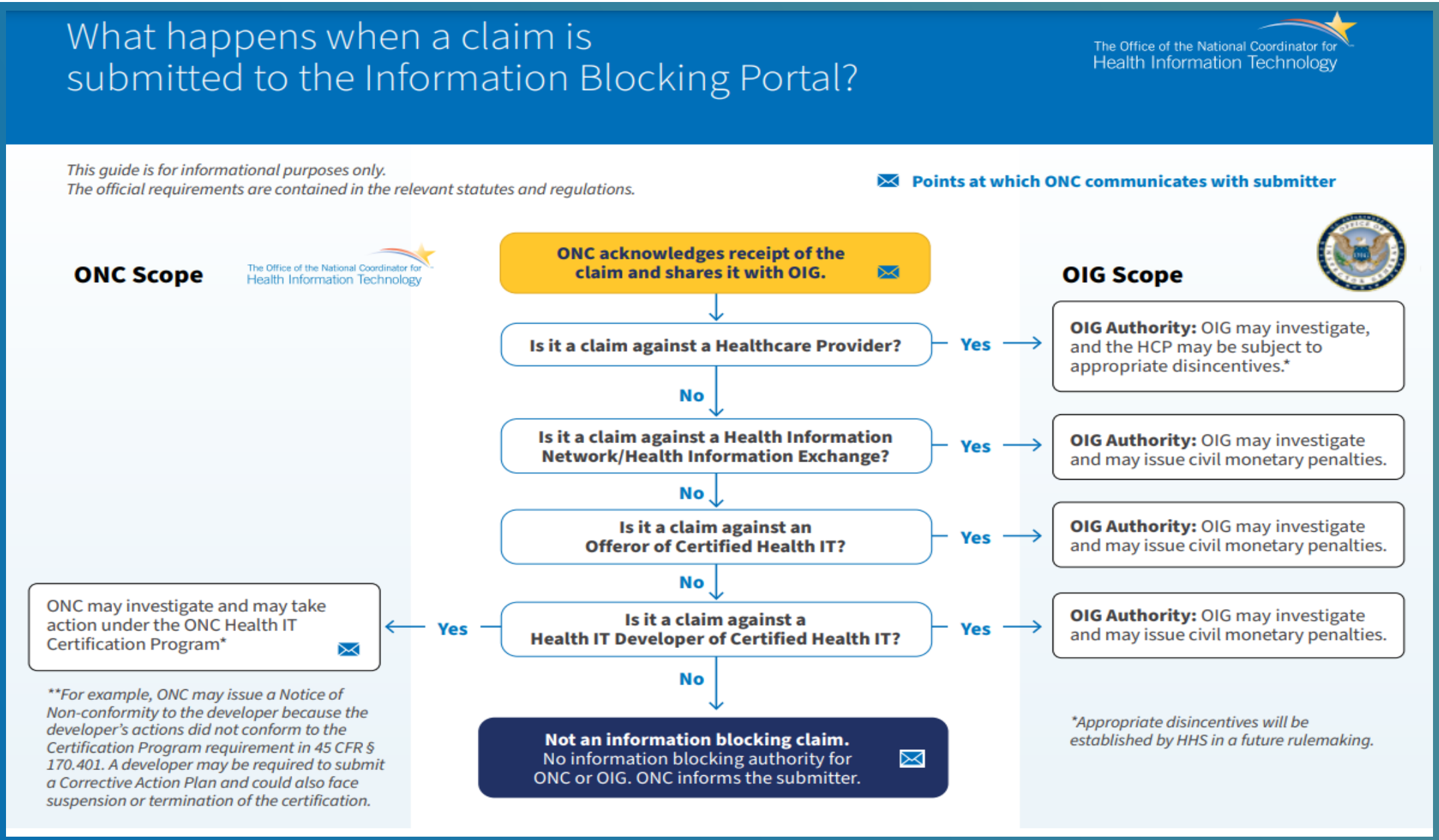
Information Blocking – Complaints and Enforcement

Report Information Blocking Portal



HealthIT.gov/feedback

Information Blocking Claims



https://www.healthit.gov/sites/default/files/page2/2021-11/Information-Blocking-Portal-Process.pdf

What Are the Consequences for Information Blocking?

"Actor"	Consequence
Health care providers	• Appropriate disincentives
Health information networks and Health information exchanges	• Civil monetary penalties (CMPs) up to $1 million per violation
Health IT developers of certified health IT	• Civil monetary penalties (CMPs) up to $1 million per violation • Certification action which could include a termination or ban

Notes on Enforcement:

- Civil monetary penalties (CMPs): enforcement dates will be established by current OIG rulemaking.
- Appropriate disincentives: to be established by future HHS rulemaking.

Request for Advisory Opinion Authority

HHS Office of the National Coordinator for Health IT
FY 2024 President's Budget: Justification of Estimates to the Appropriations Committee

Proposed Law

1. Advisory Opinions for Information Blocking

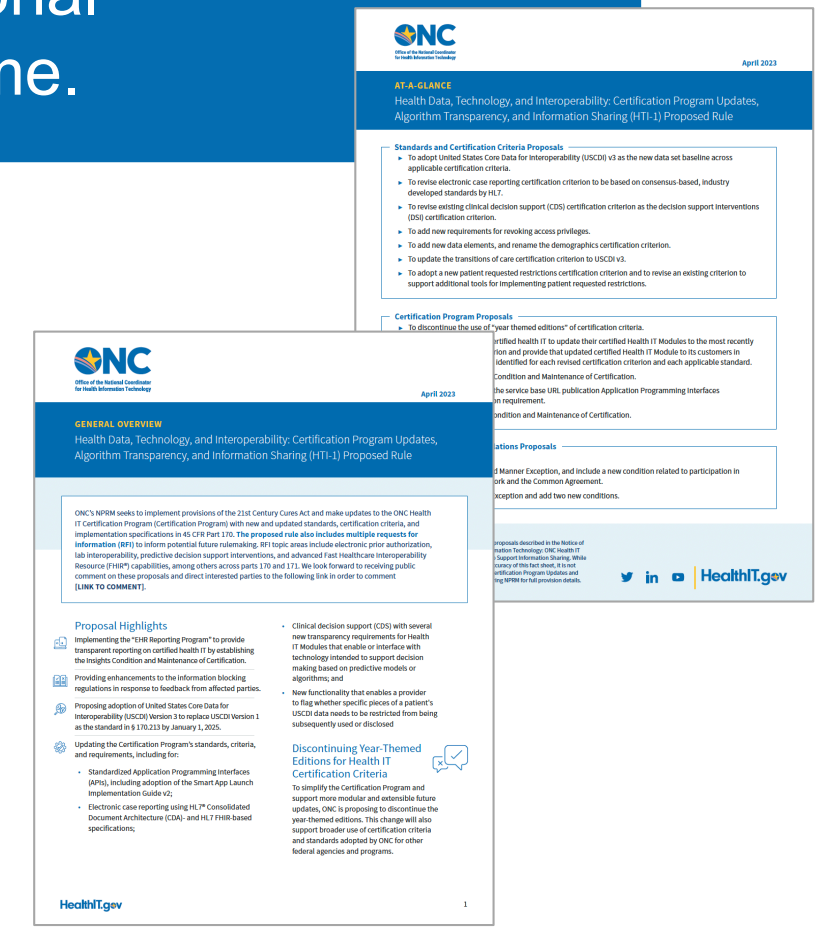
   Provide HHS the authority to create an advisory opinion process and issue advisory opinions for information blocking practices governed by section 3022 of the Public Health Service Act (PHSA), 42 USC 300jj-52. The opinion would advise the requester whether, in the Department's view, a specific practice would violate the information blocking statutory and regulatory provisions; it would be binding on the Department, such that the Department would be barred from taking enforcement action against the practice. In addition, provide ONC with the authority to collect and retain fees charged for issuance of such opinions, and to use such fees to offset the costs of the opinion process.

https://www.healthit.gov/sites/default/files/page/2023-03/FY%202024%20ONC%20508%20%28002%29.pdf

HTI-1 Proposed Rule – Opportunities to Learn More

Resources Available on HealthIT.gov!

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



Fact Sheets

- General Overview
- At-a-Glance
- Decision Support Interventions and Predictive Models
- 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

Don’t Miss Our Upcoming (and Past) Webinars on the HTI-1 Proposed Rule!

Visit https://healthIT.gov/proposedrule for additional information.

Upcoming Webinars

Brief Overview/ Questions and Answers

June 8, 1:00 PM ET

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:

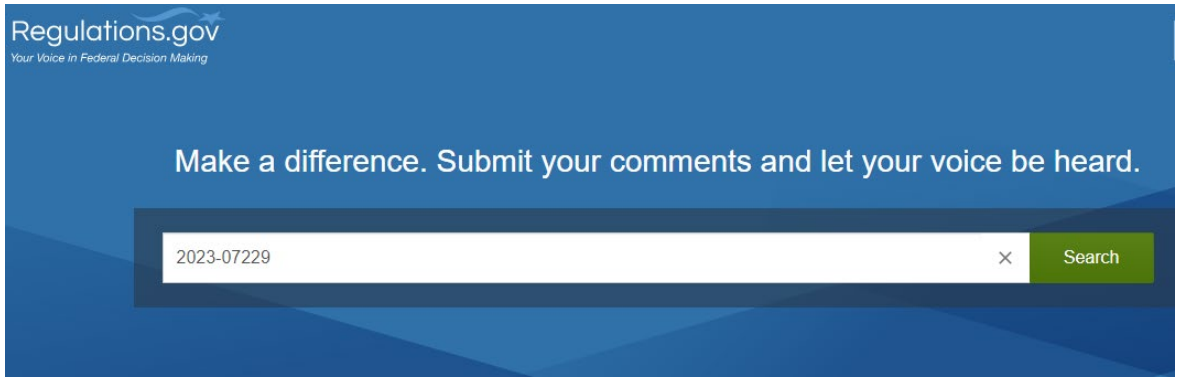
- *Health information network* or *health information exchange* means an individual or entity that determines, controls, or has the discretion to administer any requirement, policy, or agreement that permits, enables, or requires the use of any technology or services for access, exchange, or use of electronic 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

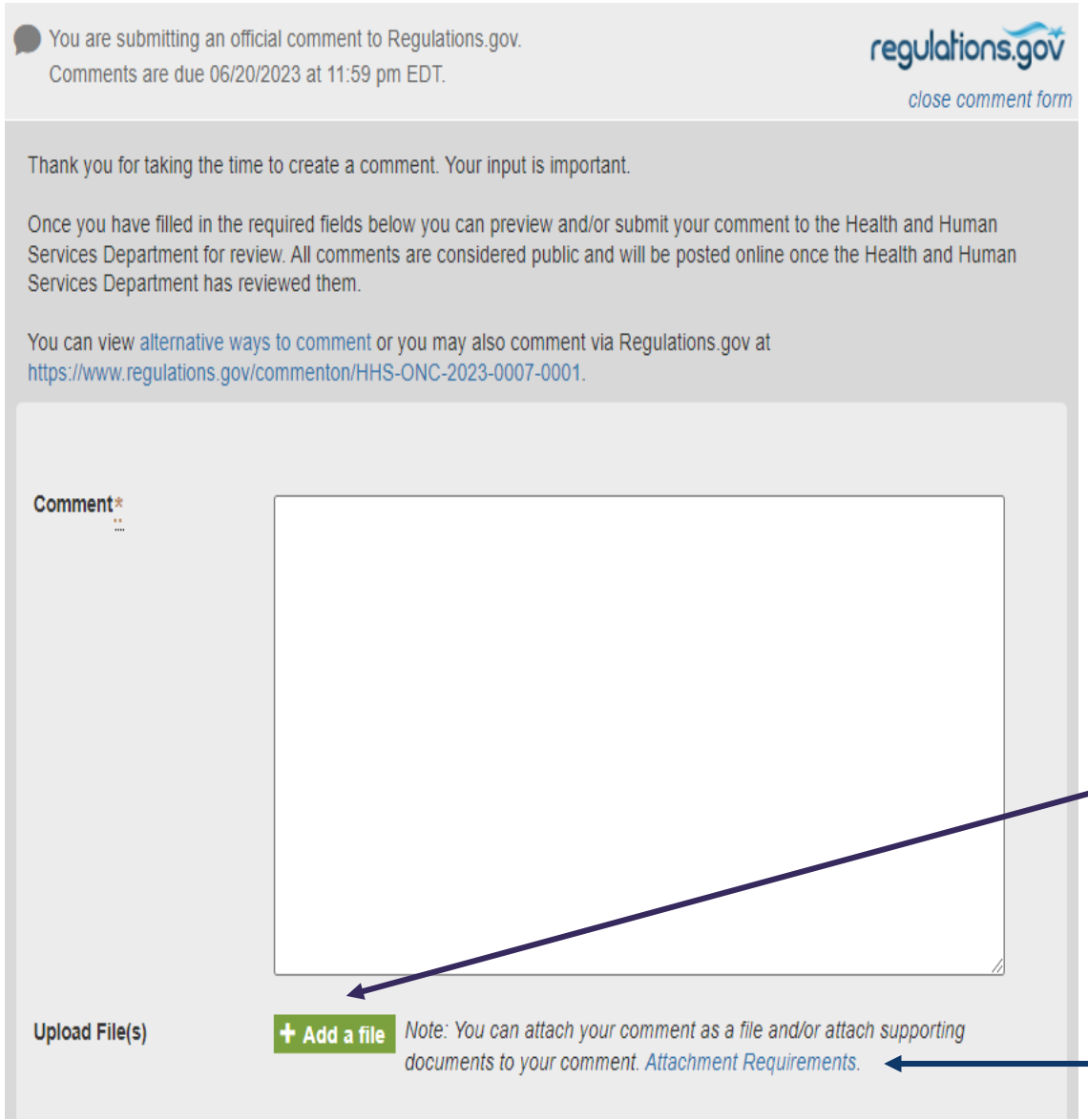
From the HTI-1 Proposed Rule on FederalRegister.gov, just click the

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.

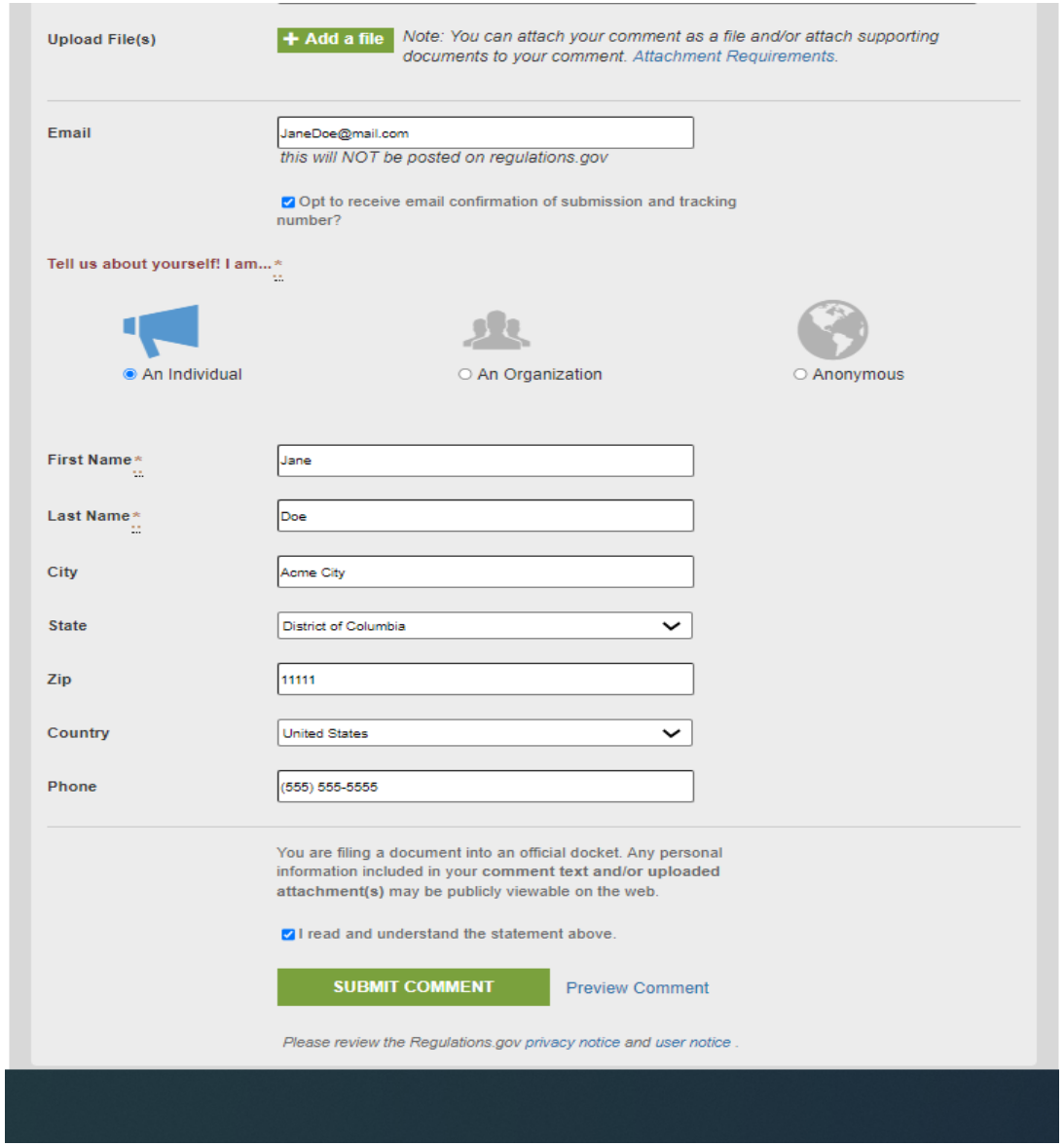
Public Comment Template

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.

General Information and Resources

ONC's Guide to Getting and Using Your Health Records

https://www.healthit.gov/how-to-get-your-health-record/

Don’t Miss Our Upcoming Webinar on Supporting Ready Patient Access to Test Results!

Visit https://www.healthit.gov/newsroom/events for additional information.

Policy in Practice: Supporting Ready Patient Access to Test Results

June 5, 2:00 PM ET

ONC and HHS Resources

- **Learn how to get, check, and use your records.** If the health information you need is not available through a patient portal, you can request it from the doctor's office. Visit the Guide to Getting & Using Your Health Records for practical tips to help you access, review, and make the most of your health records.
- Patient Access Information for Individuals: Get it, Check it, Use it!
- ONC Patient Engagement Playbook
- Guide to Privacy and Security of Electronic Health Information
- "Your Health Information, Your Rights" Infographic
- OCR Access Sub-Regulatory Guidance
- Patient Access Videos
- API Training Module
- Access Frequently Asked Questions (FAQs)
- Improving the Health Records Request Process for Patients Insights from User Experience Research [PDF- 2.7MB]
- ONC's Cures Act Final Rule
- Information Blocking
- Trusted Exchange Framework and Common Agreement (TEFCA)

Office of the National Coordinator for Health Information Technology

Contact ONC

Phone: 202-690-7151

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

Twitter: @onc_healthIT

LinkedIn: Office of the National Coordinator for Health Information Technology

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

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