

21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule

Overview

Presented to the Health Information
Technology Advisory Committee

March 18, 2020

The Office of the National Coordinator for
Health Information Technology



Please Note:

- The materials contained in this presentation are based on the provisions contained in 45 C.F.R. Parts 170 and 171. While every effort has been made to ensure the accuracy of this restatement of those provisions, this presentation is not a legal document. The official program requirements are contained in the relevant laws and regulations. Please note that other Federal, state and local laws may also apply.
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Overview & 2015 Edition Cures Updates

Elise Sweeney Anthony,
Executive Director,
Office of Policy, ONC

Beth Myers,
Deputy Director,
Office of Policy, ONC

Purpose of the Final Rule

- ✓ **Patients:** Right of Access to their Chart, Supporting Patient Privacy and Security, the Ability to Shop for Care and Avoid Bankruptcy
- ✓ **Doctors and Hospitals:** Making Patient's Chart Data Requests Easy and Inexpensive, Allowing Choice of Software, Implementation
- ✓ **Patients, Doctors, and Hospitals:** Improving Patient Safety
- ✓ **Health IT Developers:** Minimizing API Development and Maintenance Costs, Protecting Intellectual Property
- ✓ **American Public:** Maximizing Innovation, Transparency in Health Care

Information Blocking – Path to the 21st Century Cures Act



In a 2015 report to Congress, ONC provided a definition of information blocking, an analysis of the extent to which the practice exists in the industry, and recommendations to address the issue.



ONC continued to engage with stakeholders and provided ongoing technical assistance to Congress.



In December 2016, the 21st Century Cures Act was signed into law. It included a definition of information blocking and provisions for addressing information blocking.

Information Blocking – Path to the Final Rule



Following the enactment of the Cures Act, ONC continuously met with stakeholders.



ONC listened to and reviewed complaints of information blocking.



ONC consulted with federal agencies, including the HHS OIG, HHS OCR, and the Federal Trade Commission.



After release of the ONC proposed rule on March 4, 2019, ONC received **over 2,000 comment submissions**. ONC met with stakeholders and consulted with federal agencies.



ONC's final rule released on March 9, 2020.

Updates to the 2015 Edition Certification Criteria

Time-Limited and Removed Criteria

- Drug formulary/Drug List Checks
- Patient-Specific Education
- Secure Messaging
- Problem List, Medication List, Med Allergy List
- Smoking Status
- Common Clinical Data Set summary record – create & receive criteria (replaced with USCDI)
- API (replaced with Standardized API criterion)
- Data Export (replaced with EHI export criterion)

Revised Criteria

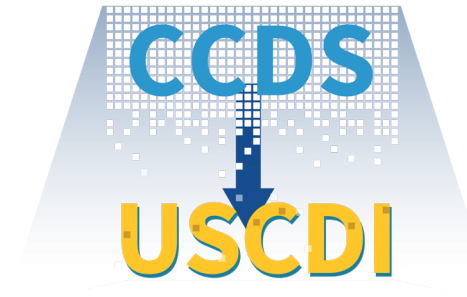
- Interoperability criteria (C-CDA, VDT, etc.)
 - Updated with USCDI
 - Updated with C-CDA Companion Guide
- ASTM criteria
- Security tags send & receive criteria
- Electronic Prescribing (aligned with CMS)
- CQM – report criterion (aligned with CMS)

New Criteria

- Electronic Health Information (EHI) export
- Standardized API for patient and population services
- Privacy and Security Attestation Criteria

Revised: United States Core Data for Interoperability Standard

The United States Core Data for Interoperability (USCDI) standard will replace the Common Clinical Data Set (CCDS) definition 24 months after publication of this final rule.



USCDI includes the following new required data classes and data elements:



Provenance



Clinical Notes



Pediatric Vital Signs



Address, Email & Phone Number

Health IT developers need to update their certified health IT to support the USCDI for all certification criteria affected by this change within 24 months after the publication of the final rule.

USCDI Standard Annual Update Schedule

ONC will establish and follow a predictable, transparent, and collaborative process to expand the USCDI, including providing stakeholders with the opportunity to comment on the USCDI's expansion.





Conditions and Maintenance of Certification

Avinash Shanbhag,
Acting Executive Director,
Office of Technology, ONC

Robert Anthony,
Director Certification &
Testing ONC

Michael Lipinski,
Director Division of
Federal Policy &
Regulatory Affairs, ONC

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Health Information Technology



Agenda

Conditions and Maintenance of Certification

- Information Blocking
 - Assurances
 - Communications
 - Application Programming Interfaces (APIs)
 - Real World Testing
 - Attestations
 - *(Future) EHR Reporting Criteria Submission*
-

Conditions and Maintenance of Certification

The 21st Century Cures Act (Section 4002) requires the Secretary of HHS to establish Conditions and Maintenance of Certification requirements for the ONC Health IT Certification Program

The Conditions and Maintenance of Certification express initial requirements and ongoing requirements for health IT developers and their certified Health IT Module(s).

Any noncompliance with the proposed Conditions and Maintenance of Certification requirements would be subject to ONC direct review, corrective action, and enforcement procedures under the ONC Health IT Certification Program.

There are seven Conditions of Certification with accompanying Maintenance of Certification Requirements. They are:

1. **Information Blocking**
2. **Assurances**
3. **Communications**
4. **Application Programming Interfaces (APIs)**
5. **Real World Testing**
6. **Attestations**
7. ***(Future) Electronic Health Record (EHR) Reporting Criteria Submission***

Information Blocking - § 170.401

CONDITIONS OF CERTIFICATION

A health IT developer may not take any actions that constitutes “information blocking” as defined in section 3022(a) of the Public Health Service Act (PHSA) and § 171.103

MAINTENANCE OF CERTIFICATION

No accompanying Maintenance of Certification requirements beyond ongoing compliance with the Condition

INFORMATION BLOCKING

vs. "Actors" regulated by the information blocking provision:



- Health Care Providers



- Health IT Developers of Certified Health IT



- Health Information Exchanges

- Health Information Networks

Assurances - § 170.402

CONDITIONS OF CERTIFICATION

A health IT developer must:

1. Provide assurances that it will not take any action that constitutes information blocking, or any other action that may inhibit the appropriate exchange, access, and use of electronic health information
2. Ensure full compliance and unrestricted implementation of certification criteria capabilities
3. Not take any action to interfere with a user's ability to access or use certified capabilities
4. Disclose and attest whether a health IT product presented for certification stores clinical information
5. Certify a health IT product which electronically stores clinical information to the § 170.315(b)(10) criteria

MAINTENANCE OF CERTIFICATION

- For a period of 10 years beginning from the date of certification, retain all records and information necessary that demonstrate initial and ongoing compliance with the requirements of the ONC Health IT Certification Program
- Certify to the criterion in § 170.315(b)(10) within 36 months of the final rule's publication date, if a health IT product electronically stores information

Electronic Health Information (EHI) Export Criterion

In response to comments on this criterion and for the proposed information blocking policies, we have adopted a focused definition of EHI.

We also defined the scope of data that needs to be exported to EHI, as defined, that can be stored at the time of certification by the product, of which the Health IT Module is a part.

General Requirements

A certified Health IT Module must include export capabilities for:

- a) a single patient EHI export to support patient access and
- b) patient population EHI export to support transitions between health IT systems

The export file(s) created must:

- a) be electronic and in a computable format, and
- b) the publicly accessible hyperlink of the export's format must be included with the exported file(s).



Note: Health IT developers have the flexibility to determine their products' standard format for the purpose of representing the exported EHI

Communications - § 170.403

CONDITIONS OF CERTIFICATION

A health IT developer may not prohibit or restrict communication regarding the following subjects for certified Health IT Modules:

1. The usability of its health IT
2. The interoperability of its health IT
3. The security of the health IT
4. Relevant information regarding user's experiences when using its health IT
5. The business practices of developers of health IT related to exchanging EHI;
6. The manner in which a user of the health IT has used such technology



Conditions and Maintenance of Certification

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Regulatory Affairs, ONC

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Communications - § 170.403

UNQUALIFIED PROTECTION FOR CERTAIN COMMUNICATIONS

- Making a disclosure required by law;
- Communicating information about adverse events, hazards, and other unsafe conditions to government agencies, health care accreditation organizations, and patient safety organizations;
- Communicating information about cybersecurity threats and incidents to government agencies;
- Communicating information about information blocking and other unlawful practices to government agencies; or
- Communicating information about a health IT developer's failure to comply with a Condition of Certification requirement, or with any other requirement of this part, to ONC or an ONC-ACB.

Communications - § 170.403



PERMITTED PROHIBITIONS AND RESTRICTIONS

- Developer employees and contractors
- Non-user-facing aspects of health IT
- Intellectual property, provided that—
 - ✓ No broader than necessary to protect the developer's legitimate intellectual property interests consistent with the permitted prohibitions and restrictions.
 - ✓ It does not restrict or preclude a public display of a portion of a work subject to copyright protection (without regard to whether the copyright is registered) that would reasonably constitute a "fair use" of that work.

Communications - § 170.403

PERMITTED PROHIBITIONS AND RESTRICTIONS (cont.)

- Screenshots and video

A health IT developer may require persons who communicate screenshots or video to —

- ✓ Not alter the screenshots or video, except to annotate the screenshots or video or resize the screenshots or video;
- ✓ Limit the sharing of screenshots to the relevant number of screenshots needed to communicate about the health IT
- ✓ Limit the sharing of video to:
 - The relevant amount of video needed to communicate about the health IT; and
 - Only videos that address temporal matters that cannot be communicated through screenshots or other forms of communication

- Pre-market testing and development.

Communications - § 170.403

MAINTENANCE OF CERTIFICATION

- Notify all customers annually starting in 2020 that any communication or contract/agreement provision that violates the Communication Condition of Certification will not be enforced by the health IT developer
- Notify all customers annually up to and until the health IT developer amends the contract or agreement to remove or void any contractual provisions that violate the Condition of Certification

Application Programming Interfaces (APIs)

- § 170.404

ONC has established API Conditions of Certification to address the use of certified API technology and the healthcare ecosystem in which certified API technology will be deployed, including health IT developers' business practice.

SCOPE OF ELECTRONIC HEALTH INFORMATION

The scope of patients' electronic health information that must be accessible via certified API technology is limited to the data specified in the United States Core Data for Interoperability standard (USCDI).

CERTIFICATION

Key Definitions



Certified API Technology

Capabilities of health IT that fulfill any of the API-focused certification criteria adopted in the rule



Certified API Developer

Health IT developer that creates the “certified API technology”



API Information Source

Organization that deploys certified API technology



API User

Persons and entities that create or use software applications that interact with “certified API technology”

Application Programming Interfaces - § 170.404

API Conditions of Certification

API Conditions of Certification

Applies to actions and behaviors of certified health IT developers related to the use of their Certified API Technology

API Certification Criteria

API Certification Criteria

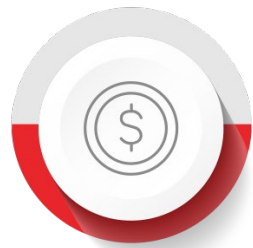
- Certified API criteria (§ 170.315(g)(7) through (10))
- Scope of EHI limited to United States Core Data for Interoperability (USCDI)
- Includes new 2015 Edition Secure, Standards Based API criteria ((§ 170.315(g)(10))
 - “read-only” focus
 - HL7® FHIR® Release 4.0.1 as base standard
 - Support for single patient and population services

API Conditions of Certification – High Level Overview



Transparency

This condition clarifies the publication requirements on certified API developers for their business and technical documentation necessary to interact with their certified API technology.



Fees

This condition sets criteria for allowable fees, and boundaries for the fees certified API developers would be permitted to charge for the use of the certified API technology, and to whom those fees could be charged.



Openness and Pro-Competitive

These conditions set business requirements that certified API developers will have to comply with for their certified API technology to promote an open and competitive marketplace.

API Maintenance of Certification

The API maintenance of certification requirements address ongoing requirements that must be met by certified API developers and their certified API technology

Requirements for Certified API developer related to use of certified API technology adopted in **§ 170.315(g)(10)**

Authenticity Verification

A Certified API Developer is permitted to institute a process to verify the authenticity of API Users so long as such process is objective and the same for all API Users and completed within **ten** business days.

Application Registration

A Certified API Developer must register and enable all applications for production use within **five** business days of completing its verification of an API User's authenticity.

Service Base URL Publication

Certified API developers are required to publish service base URLs for all its customers of certified API technology that can be used by patients to access their electronic health information.

Real World Testing - § 170.405

CONDITIONS OF CERTIFICATION

A health IT developer with Health IT Module(s) certified to § 170.315(b), (c)(1) through (3), (e)(1), (f), (g)(7) through (10), and (h) must successfully test the real-world use of the technology for interoperability in the type of setting in which such technology would be marketed.

MAINTENANCE OF CERTIFICATION

- Submit real world testing **PLAN** to the ONC-ACB by a date that enables the ONC-ACB to publish the plan on the CHPL no later than December 15 of each calendar year.
- Submit real world testing **RESULTS** to the ONC-ACB by a date that enables the ONC-ACB to publish the results on the CHPL no later than March 15 of each calendar year.

Real World Testing - § 170.405

RWT Plans should also include:

- **USCDI Updates for C-CDA.**
Health IT certified to § 170.315(b)(1), (b)(2), (e)(1), (g)(6), (f)(5), and/or (g)(9)
- **C-CDA Companion Guide Updates.** *Health IT certified to § 170.315(b)(1), (b)(2), (b)(9), (e)(1), (g)(6), and/or (g)(9)*
- **Electronic Prescribing.** *Health IT certified to § 170.315(b)(3)*



24 months

Standards Version Advancement Process

- The Standards Version Advancement Process allows developers to choose among the versions of standards and implementation specifications listed in regulation or National Coordinator (NC)-approved newer version updates for any or all standards applicable to criteria subject to real world testing requirements.
- This flexibility to choose among NC-approved versions of standards and implementation specifications will be available both when developers seek initial certification or to maintain certification of a Health IT Module.

How Will It Work?

To take advantage of the flexibility to update to NC-approved versions, a developer will need to:

- Provide advance notice to all affected customers and its ONC-ACB
 - ✓ expressing intent to update to the more advanced version of the standard;
 - ✓ expectations for how the update will affect interoperability of each affected Health IT Module;
 - ✓ whether intend to continue to support the certificate(s) for the existing certified Health IT Module(s) version
- Successfully demonstrate conformance with approved more recent versions of the standard(s) or implementation specification(s) included in each updated certification criterion.
- Maintain the updated certified Health IT Module(s) in full conformance with all applicable Program requirements.

Attestations - § 170.406

CONDITIONS OF CERTIFICATION

A health IT developer attest, as applicable, to compliance with the Conditions and Maintenance of Certification

MAINTENANCE OF CERTIFICATION

- Health IT developers must submit their attestations every six months
- 30-day window for open submissions

April 1, 2021

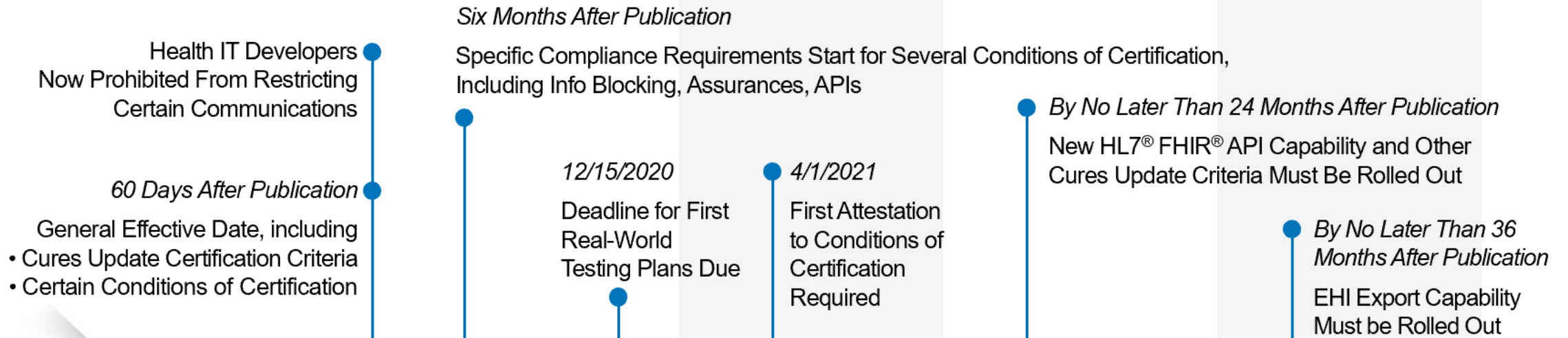
First window opens

ONC Direct Review of The Conditions And Maintenance Of Certification

ONC will utilize the processes established for ONC direct review of certified health IT.



Certification



Publication Date
[MM/DD/20]

2020

2021

2022

2023

Six Month Preparation Period, Compliance Encouraged

Compliance with Exceptions Required, EHI Definition Limited to USCDI

Compliance with Exceptions Required, Full EHI Definition in Effect

6 Months After Publication
Compliance Starts for Information Blocking Rules Part 171

24 Months After Publication

Information Blocking



21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule

Information Blocking

Michael Lipinski, JD

Director, Regulatory Affairs Division, Office of Policy, ONC

The Office of the National Coordinator for
Health Information Technology



Information Blocking in the 21st Century Cures Act

21st Century Cures Act, Section 4004:

- Defines “information blocking”
- Authorizes the Secretary to identify, through rulemaking, reasonable and necessary activities that do **not** constitute information blocking
- Identifies the HHS Office of Inspector General (OIG) as the HHS office to investigate claims of information blocking and provides referral processes to facilitate coordination with the HHS Office for Civil Rights (OCR)
- Prescribes penalties for information blocking
- Charges ONC with implementing a complaint process for reporting information blocking, and provides confidentiality protections for complaints





What Makes an Individual or Entity an Information Blocker?

Elements of information blocking

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

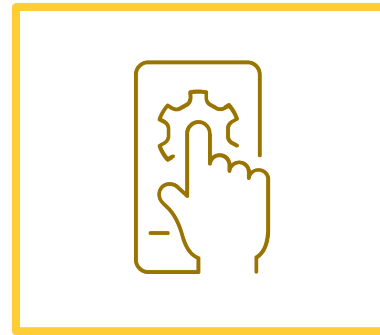
Compliance Timeline

- Actors do **not** have to comply with the information blocking provision until **six months after publication** of the final rule.
- Enforcement of information blocking civil monetary penalties (CMPs) will not begin until established by future rulemaking by OIG. As a result, actors will not be subject to penalties until the CMP rule is final.
 - *At a minimum*, the timeframe for enforcement will **not** begin sooner than the compliance date of the ONC final rule and will depend on when the CMP rules are final.
 - Discretion will be exercised such that conduct that occurs before the CMP rule is final will not be subject to information blocking CMPs.

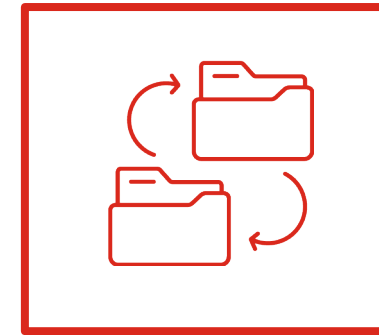
“Actors” Regulated in the Final Rule



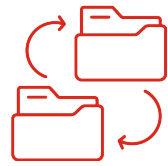
**Health Care
Providers**



**Health IT
Developers of
Certified Health IT**



**Health Information
Networks (HIN)/
Health Information
Exchanges (HIE)**



Health Information Networks & Exchanges

Who are they?

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 EHI:

1. Among **more than two unaffiliated individuals or entities** (other than the individual or entity to which this definition might apply) **that are able 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.

Changed in Four Ways

Electronic Health Information

What does it mean?

Electronic protected health information (ePHI) as the term is defined for HIPAA in 45 CFR 160.103 **to the extent that the ePHI would be included in a designated record set (DRS)** as defined in 45 CFR 164.501 (other than psychotherapy notes as defined in 45 CFR 164.501 or information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding), regardless of whether the actor is a covered entity as defined in 45 CFR 160.103.



Changes and Clarifications from the Proposed Rule

- Focused definition on ePHI included in a DRS.
- This definition does not expressly include or exclude price information. To the extent that ePHI includes price information and is included in a DRS, it would be considered EHI.

“Interfere with” or “Interference” What is it?

Interfere with or interference means to prevent, materially discourage, or otherwise inhibit.

- **Publication of “FHIR service base URLs” (sometimes also referred to as “FHIR endpoints”)** - A FHIR service base URL cannot be withheld by an actor as it (just like many other technical interfaces) is necessary to enable the access, exchange, and use of EHI.
- **Delays** – An actor’s practice of slowing or delaying access, exchange, or use of EHI could constitute an interference and implicate the information blocking provision.
- **Costs for Electronic Access by Patients/Individuals** - An actor’s practice of charging an individual, their personal representative, or another person or entity designated by the individual for electronic access to the individual’s EHI would be inherently suspect under an information blocking review.

“Interfere with” or “Interference” What is it not?

Interfere with or interference means to prevent, materially discourage, or otherwise inhibit.

- ***Business Associate Agreements (BAAs)*** – Actors are **not** required to violate BAAs or associated service level agreements. *However*, a BAA or its associated service level agreements must not be used in a discriminatory manner by an actor to forbid or limit disclosures that otherwise would be permitted by the Privacy Rule.
- ***Educate Patients about Privacy and Security Risks of Apps and 3rd Parties*** – Actors may provide patients with information that:
 - Focuses on any current privacy and/or security risks posed by the technology or the third-party developer of the technology;
 - Is factually accurate, unbiased, objective, and not unfair or deceptive; and
 - Is provided in a non-discriminatory manner.

Overview of the Exceptions

The **eight exceptions** are divided into **two categories**:

Exceptions for *not fulfilling* requests to
access, exchange, or use EHI



1. Preventing Harm



2. Privacy



3. Security



4. Infeasibility



5. Health IT Performance

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



6. Content and Manner



7. Fees



8. Licensing



Content and Manner Exception

Overview

It will not be information blocking for an actor to limit the content of its response to a request to access, exchange, or use EHI or the manner in which it fulfills a request, provided certain conditions are met.

To satisfy this exception,
an actor must meet both of these conditions:

Content condition

+

Manner condition



Objective

This exception provides clarity and flexibility to actors concerning the required content of an actor's response to a request to access, exchange, or use EHI and the manner in which the actor may fulfill the request. It supports innovation and competition by allowing actors to first attempt to reach and maintain market negotiated terms for the access, exchange, and use of EHI.



Content and Manner Exception

Content Condition

- 1. Up to 24 months** after the publication date of the final rule, an actor must respond to a request to access, exchange, or use EHI with, *at a minimum*, the EHI identified by the **data elements represented in the USCDI standard**.
- 2. On and after 24 months** after the publication date of the final rule, an actor must respond to a request to access, exchange, or use EHI with **EHI as defined in § 171.102**.



Content and Manner Exception

Manner Condition – Any Manner Requested

- An actor must fulfill a request **in any manner** requested *unless* the actor is:
 1. Technically unable to fulfill the request in a manner requested; **or**
 2. Cannot reach agreeable terms with the requestor to fulfill the request.
- If an actor fulfills a request in **any manner requested**, the actor is **not** required to comply with the Fees or Licensing Exception.



Content and Manner Exception

Manner Condition – Alternative Manner

- If an actor responds in an **alternative manner**, the actor must fulfill the request **without unnecessary delay** in the **following order of priority**, only proceeding to the next consecutive paragraph if **technically unable** to fulfill the request in that manner:
 1. Using technology certified to standard(s) adopted in Part 170 that is specified by the requestor.
 2. Using content and transport standards specified by the requestor and published by:
 - Federal Government; or
 - Standards developing organization accredited by the American National Standards Institute.
 3. Using an alternative machine-readable format, including the means to interpret the EHI, agreed upon with the requestor.



Health IT for Pediatric Care and Practice Settings

Beth Myers,
Deputy Director,
Office of Policy, ONC

The Office of the National Coordinator for
Health Information Technology

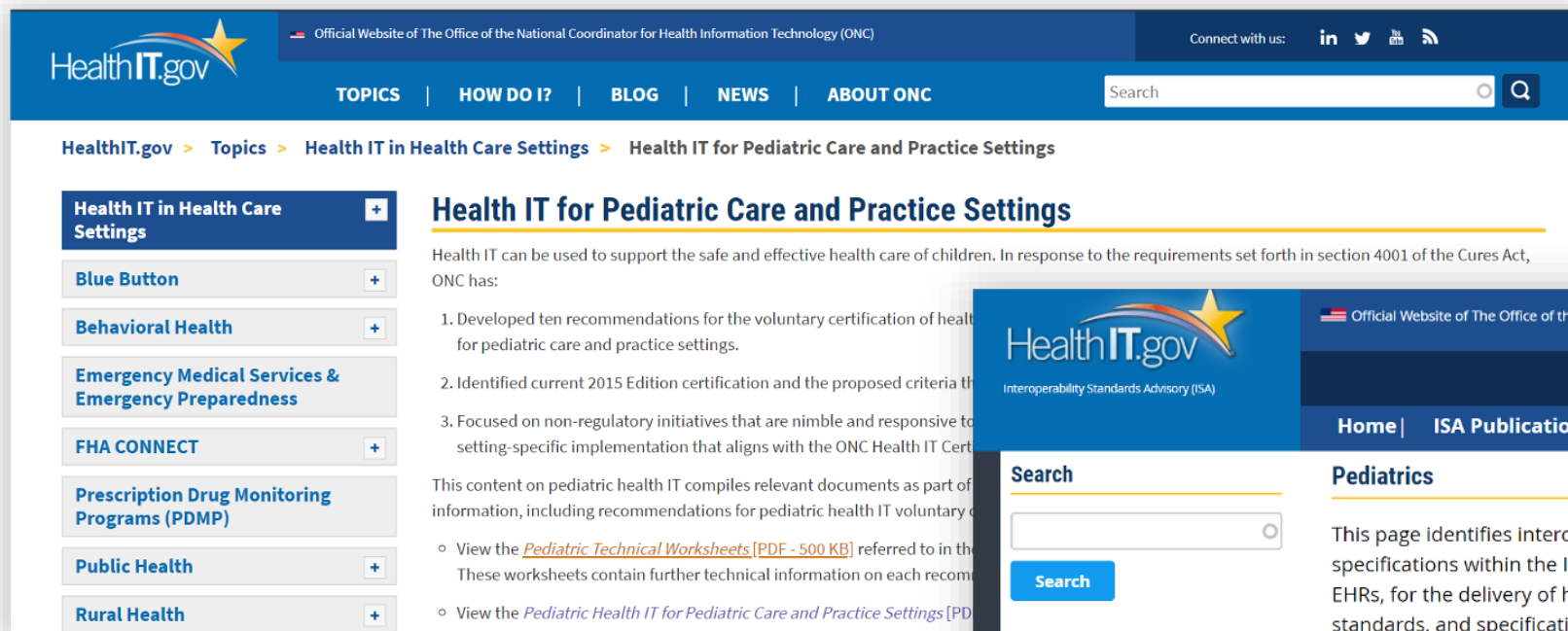


Health IT for Pediatric Care and Practice Settings

In response to the requirements set forth in section 4001 of the Cures Act, ONC:

- 1** Developed ten recommendations for the voluntary certification of health IT for pediatric care under the Program, not as a separate certification program.
- 2** Identified current and new 2015 Edition certification criteria that support pediatric care and practice settings based on clinical priorities.
- 3** Focused on non-regulatory initiatives that are nimble and responsive to stakeholders, including development of informational resources to support setting-specific implementation that aligns with the ONC Health IT Certification Program.

Health IT for Pediatric Care and Practice Settings



HealthIT.gov > Topics > Health IT in Health Care Settings > Health IT for Pediatric Care and Practice Settings

Health IT in Health Care Settings

- Blue Button
- Behavioral Health
- Emergency Medical Services & Emergency Preparedness
- FHA CONNECT
- Prescription Drug Monitoring Programs (PDMP)
- Public Health
- Rural Health

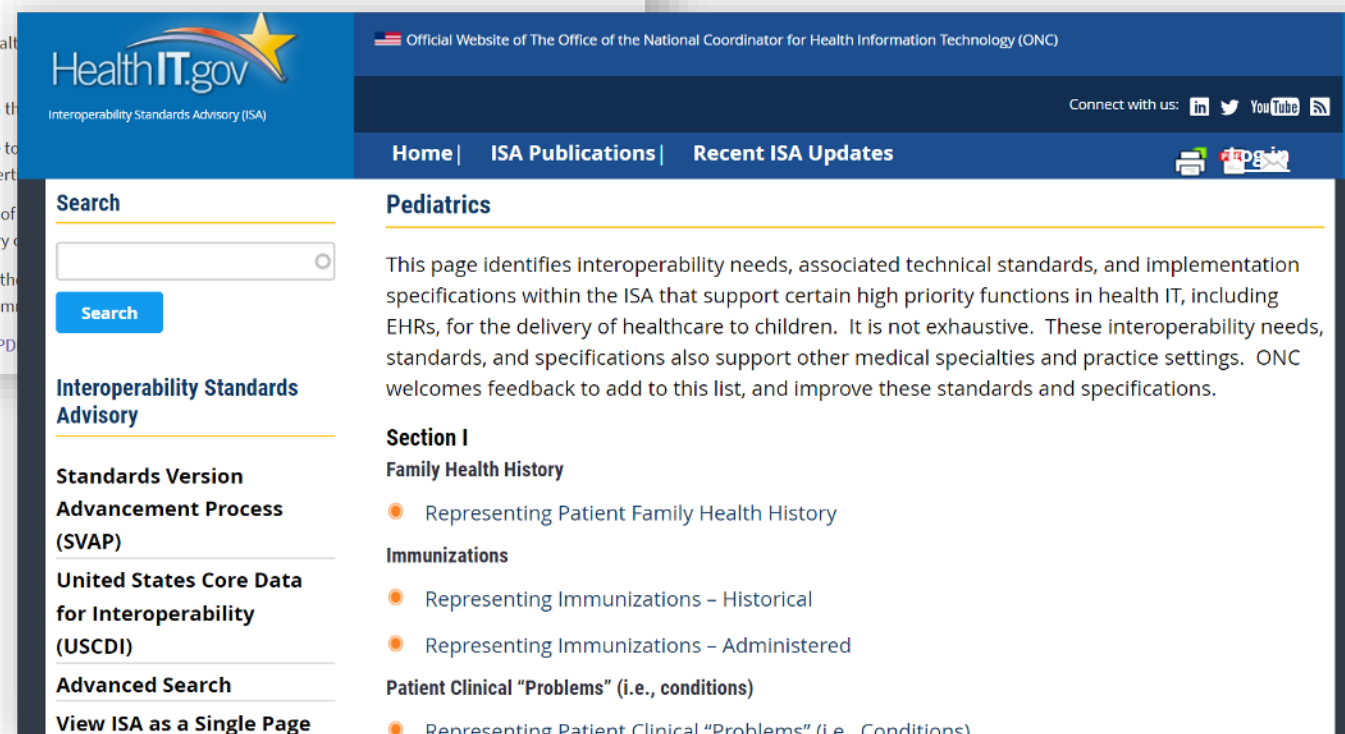
Health IT for Pediatric Care and Practice Settings

Health IT can be used to support the safe and effective health care of children. In response to the requirements set forth in section 4001 of the Cures Act, ONC has:

1. Developed ten recommendations for the voluntary certification of health IT for pediatric care and practice settings.
2. Identified current 2015 Edition certification and the proposed criteria for pediatric care and practice settings.
3. Focused on non-regulatory initiatives that are nimble and responsive to setting-specific implementation that aligns with the ONC Health IT Certification Program.

This content on pediatric health IT compiles relevant documents as part of information, including recommendations for pediatric health IT voluntary certification.

- View the [Pediatric Technical Worksheets \[PDF - 500 KB\]](#) referred to in the recommendations. These worksheets contain further technical information on each recommendation.
- View the [Pediatric Health IT for Pediatric Care and Practice Settings \[PDF - 1.2 MB\]](#).



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Interoperability Standards Advisory (ISA)

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Pediatrics

This page identifies interoperability needs, associated technical standards, and implementation specifications within the ISA that support certain high priority functions in health IT, including EHRs, for the delivery of healthcare to children. It is not exhaustive. These interoperability needs, standards, and specifications also support other medical specialties and practice settings. ONC welcomes feedback to add to this list, and improve these standards and specifications.

Section I

Family Health History

- Representing Patient Family Health History

Immunizations

- Representing Immunizations – Historical
- Representing Immunizations – Administered

Patient Clinical “Problems” (i.e., conditions)

- Representing Patient Clinical “Problems” (i.e., Conditions)

Search

Interoperability Standards Advisory

- Standards Version
- Advancement Process (SVAP)
- United States Core Data for Interoperability (USCDI)
- Advanced Search
- View ISA as a Single Page

Please visit www.healthit.gov/curesrule

- View the Final Rule
- Fact Sheets
- Upcoming Webinar Schedule
- Previously Recorded Webinars
- Additional Resources





The 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](https://www.healthit.gov/form/healthit-feedback-form)



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