



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

Overview

Presented by ONC Leadership

The Office of the National Coordinator for
Health Information Technology



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

Agenda

- Logistics
- Updates to the 2015 Edition Certification Criteria
- Conditions and Maintenance of Certification Requirements
- Information Blocking
- Health IT for Pediatric Care and Practice Settings



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

A large, abstract graphic on the left side of the slide, composed of numerous overlapping triangles and polygons in various shades of blue, green, yellow, and orange. The shapes are arranged in a way that creates a sense of depth and movement, resembling a stylized map or a complex network.

Updates to the 2015 Edition Certification Criteria

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.



Revised: Electronic Prescribing and Clinical Quality Measures



Electronic Prescribing (e-Rx) Standard And Certification Criterion

- Finalized an update to the electronic prescribing certification criterion to reference the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard version 2017071.



Clinical Quality Measures (CQMs) – Report Criterion

- Removed the Health Level 7 (HL7®) Quality Reporting Document Architecture (QRDA) standard requirements in the 2015 Edition “CQM – report” criterion, AND
- In their place, required Health IT Modules to support the CMS QRDA Implementation Guide (IGs).
 - This will help reduce the burden for health IT developers and remove certification requirements that do not support quality reporting for CMS programs.
 - <https://ecqi.healthit.gov/qrda-quality-reporting-document-architecture>

Revised: Security Tags

Final rule supports a more granular approach to security tagging data

- Changed the names of the two current 2015 Edition DS4P criteria:
 - Security tags – Summary of Care (send)
 - Security tags – Summary of Care (receive)
- Updated the requirements for these **voluntary** criteria to support security tagging at the document, section, and entry (individual data element) levels.
- Preserved granular privacy marking capabilities to support multiple care and specialty settings including behavioral health and pediatric health care settings to reduce provider reliance on manual redaction.



New: Electronic Health Information (EHI) Export Criterion

Adopted a focused definition of EHI to **ePHI** to the extent that it would be included in a **designated record set**.

For certification, Developers are required to ensure health IT products are capable of exporting the EHI that can be stored by the product at the time of certification.

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

New: Application Programming Interface (API) Criterion

- Established a new application programming interface (API) certification criterion that requires health IT developers to support standardized APIs for single patient and population services.
- Certification criterion is limited to API-enabled “read” services using the HL7® Fast Healthcare Interoperability Resources (FHIR) Release 4 standard.
- The use of the FHIR standard and a set of implementation specifications provides known technical requirements against which third-party apps can be developed.

Supports two types of API-enabled services:

- » Services for which a **single patient’s data** is the focus
- » Services for which **multiple patients’ data** are the focus



New: Privacy & Security Transparency Attestations

Adopted two new privacy and security certification criteria requiring transparency attestations as part of the updated 2015 Edition privacy and security certification framework.

Privacy and Security Certification Criteria

1. **Encrypt Authentication Credentials**
2. **Multi-factor Authentication**





Conditions and Maintenance of Certification Requirements

Conditions and Maintenance of Certification Requirements

The 21st Century Cures Act requires HHS to establish Conditions and Maintenance of Certification requirements for the ONC Health IT Certification Program.

Seven (7) Conditions of Certification with Maintenance of Certification Requirements

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

1. Information Blocking

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



The condition of certification for information blocking applies to certified health IT developers only

MAINTENANCE OF CERTIFICATION

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

2. Assurances

CONDITION OF CERTIFICATION

A health IT developer **must** provide assurances to the Secretary 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 (EHI) unless for reasonable and necessary activities identified by the Secretary.

a. **Full Compliance and Unrestricted Implementation of Certification Criteria Capabilities**

b. **Certification to the “Electronic Health Information (EHI) Export” Criterion**

c. **Records and Information Retention**

MAINTENANCE OF CERTIFICATION

By and after 36 months after the publication date, any developer of a certified product which electronically stores EHI **must** certify to and provide customers with the EHI export functionality.

Health IT developers have to retain records and information necessary to demonstrate ongoing compliance.

3. Communications

CONDITIONS OF CERTIFICATION

A health IT developer **may not** prohibit or restrict communication of the following:

- (1) Usability
- (2) Interoperability
- (3) Security
- (4) User's experiences when using the health IT
- (5) Business practices of developers related to exchanging EHI
- (6) Manner in which a user of the health IT has used such technology

MAINTENANCE OF CERTIFICATION

A health IT developer **must** notify all customers that any communication or contract/agreement provision that violates the Communication Condition of Certification will not be enforced.

Note: A health IT developer is required to amend contracts/agreements to remove or void such provisions when the contracts/agreements are modified for other purposes.

4. Application Programming Interfaces (APIs)

ONC has established API Conditions of Certification to address the use of certified API technology (Section 170.315 g7-10) 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

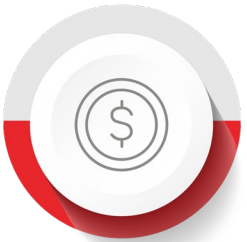
Persons and entities that create or use software applications that interact with "certified API technology"

4. API Conditions of Certification



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.

4. 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 and the Standardized API criterion **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.

5. Real World Testing

CONDITION OF CERTIFICATION

A health IT developer of certified* Health IT Module(s) **must** successfully test the real-world use of the technology for interoperability in the type of setting in which such technology is marketed.

*Certified to the interoperability-focused certification criteria.

MAINTENANCE OF CERTIFICATION

ACB - Authorized Certification Body
CHPL - Certified Health IT Product List

A health IT developer of certified Health IT Module(s) **must**:

- (1) Submit its real world testing plan to its 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.
- (2) Submit its real world testing results to its 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.
- (3) Notify the responsible ONC-ACB of any non-conformity with Program requirements.

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.

How Will It Work?

To update to NC-approved versions, a developer will need to:

- Notify its ONC-Authorized Certification Body (ONC-ACB) and its customers of its intent to move to newer NC-approved standards version updates as well as whether, and for how long, they might plan to continue supporting prior versions of the standards.
- Ensure that the standards version updates are effectively implemented.
- Address standards version updates in annual real-world testing plans and results.
- Demonstrate conformance of its health IT to all applicable criteria including any NC-approved standards versions it has chosen to incorporate.



<https://www.healthit.gov/SVAP>

6. Attestations

CONDITIONS OF CERTIFICATION

- A health IT developer **must** provide an attestation, as applicable, to compliance with the Conditions and Maintenance of Certification.
- This excludes the "EHR reporting criteria submission" Condition of Certification which does not require attestation.

MAINTENANCE OF CERTIFICATION

- Health IT developers **must** submit their attestations every six months
- Attestation window open for 30 days

First attestation period opens:

April 1, 2021

ONC Direct Review of The Conditions And Maintenance Of Certification

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

**STEP
1**

Review and Health IT
Developer Notice

**STEP
2**

Records
Access

**STEP
3**

Corrective
Action Plan

**STEP
4**

Certification
Ban and/or Termination

**STEP
5**

Appeal

**STEP
6**

Public Listing
of Certification Ban
and/or Termination

Information Blocking

Information Blocking

What is information blocking?

A practice by a health care provider, health IT developer, health information exchange, or health information network that, except as required by law or specified by the **Secretary as a reasonable and necessary activity**, is likely to interfere with access, exchange, or use of electronic health information.

What are the exceptions?

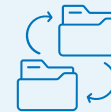
- Section 4004 of the Cures Act authorizes the Secretary to identify reasonable and necessary activities that do not constitute information blocking.
- In consultation with stakeholders, we have identified eight exceptions for practices that are reasonable and necessary, provided certain conditions are met.

INFORMATION BLOCKING

Three categories of "Actors":



- Health Care Providers



- Health IT Developers
of Certified Health IT



- Health Information Exchanges
and/or Health Information Networks

Definition of Electronic Health Information (EHI)

- Focused the scope of EHI to mean **electronic protected health information (ePHI)** to the extent that the ePHI is included in a **designated record set** as these terms are defined for HIPAA.
- This is applicable whether the actor is a covered entity or not.



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



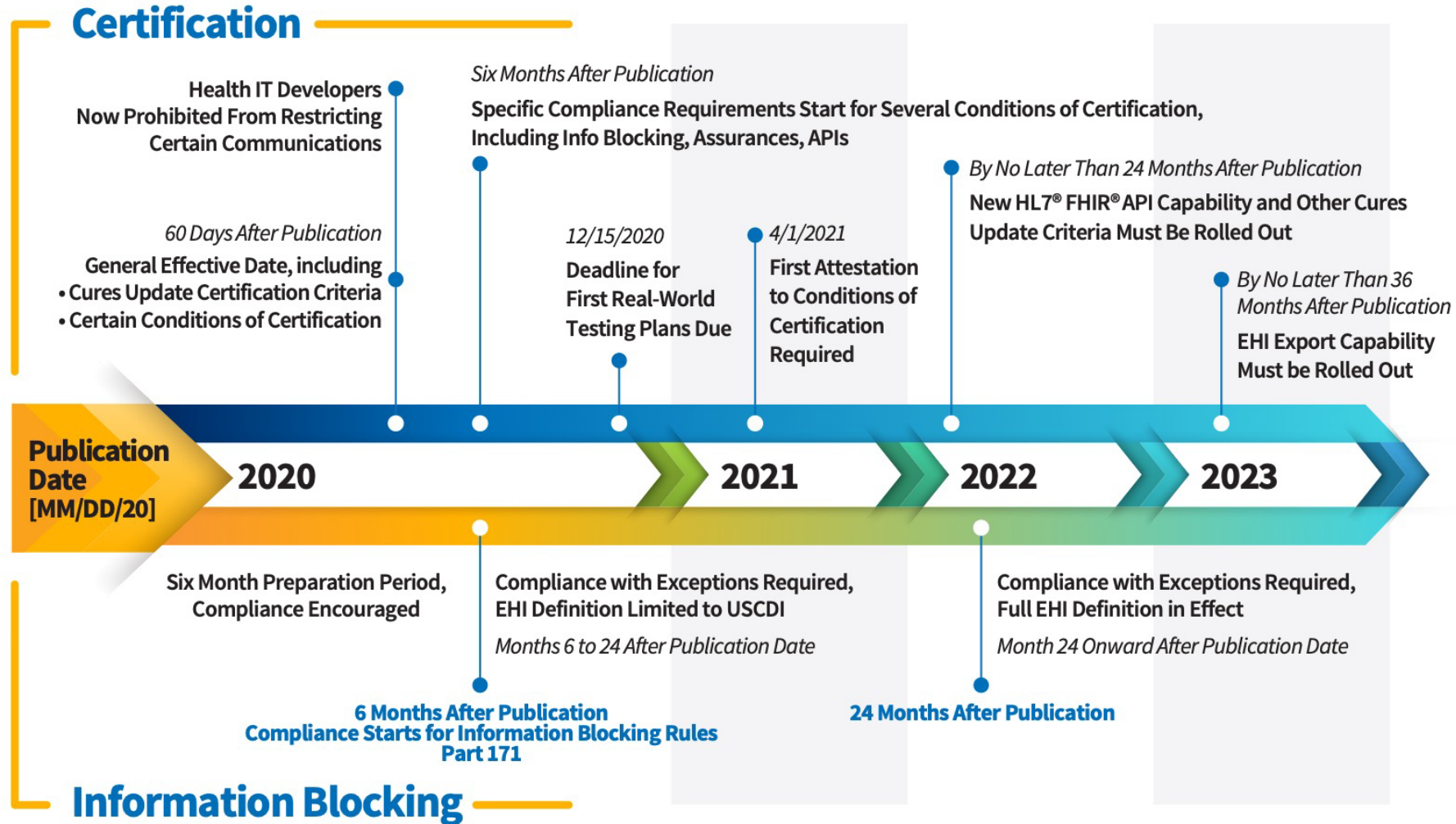
Health IT for Pediatric Care and Practice Settings

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.

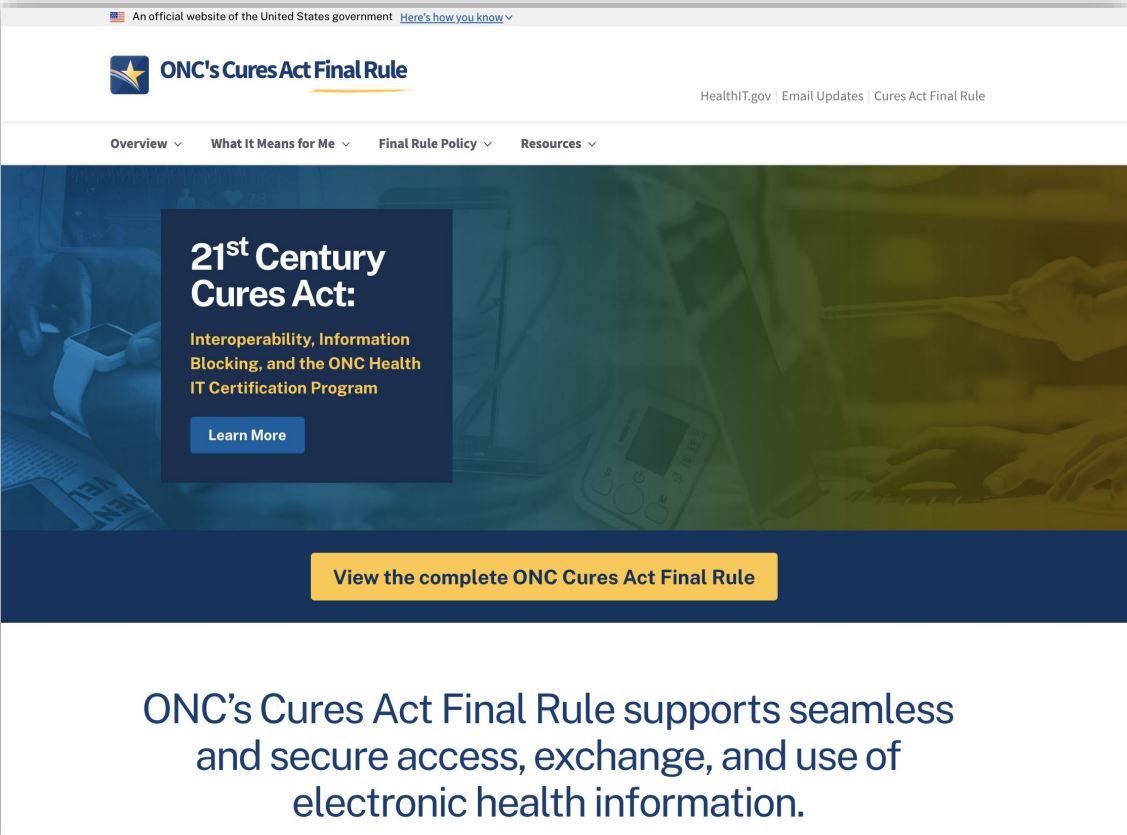
Compliance Timeline



EHI = Electronic Health Information USCDI = United States Core Data for Interoperability

Please visit www.healthit.gov/curesrule

- View the Final Rule
- Fact Sheets
- Upcoming Webinar Schedule
- Previously recorded webinars
- Additional resources



An official website of the United States government [Here's how you know](#) ▼

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

[Learn More](#)

[View the complete ONC Cures Act Final Rule](#)

ONC's Cures Act Final Rule supports seamless and secure access, exchange, and use of electronic health information.



The Office of the National Coordinator for
Health Information Technology

Contact ONC



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<https://www.healthit.gov/form/healthit-feedback-form>



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