# Conditions and Maintenance of Certification

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# 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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# Agenda

## Conditions and Maintenance of Certification

- Information Blocking

- Assurances

- Communications

- Application Programming Interfaces (APIs)

- Real World Testing

- Attestations

- *(Future) EHR Reporting Criteria Submission*

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# 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*

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# 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

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**ℹ 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

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# 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

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# 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

# 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 an 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"

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# 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

- 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 Certification Criteria

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# 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.
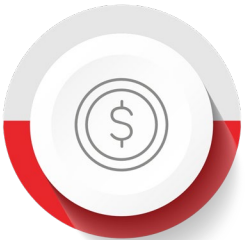
**Fees**

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.

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# 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.

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# 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.

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# 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

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# ONC Direct Review of The Conditions And Maintenance Of Certification

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

**STEP 1** Initiating Review and Health IT Developer Notice
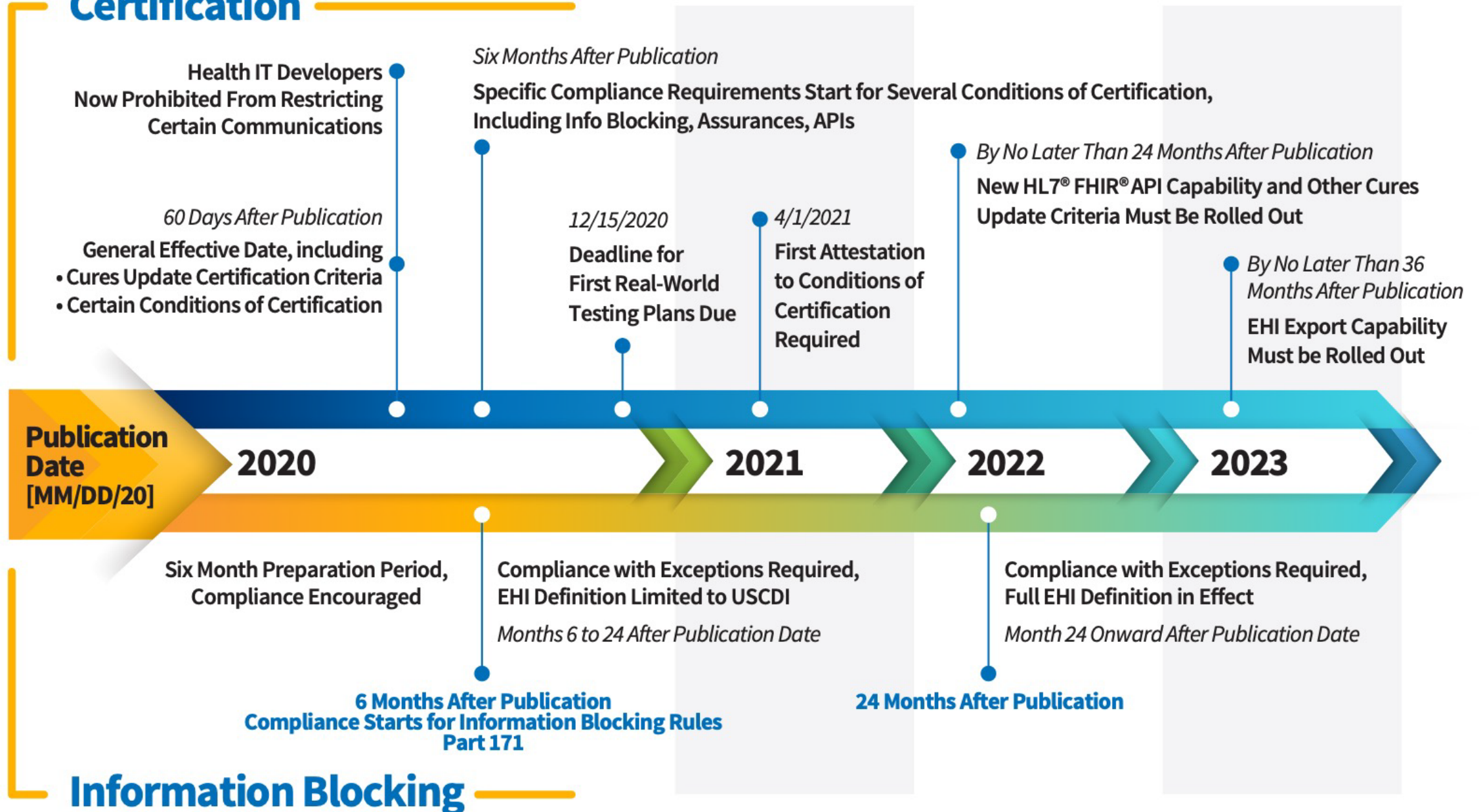
**STEP 2** Records Access

**STEP 3** Corrective Action Plan

**STEP 4** Certification Ban and/or Termination

**STEP 5** Appeal

**STEP 6** Public Listing of Certification Ban and/or Terminations

# Certification

**Health IT Developers Now Prohibited From Restricting Certain Communications**

*Six Months After Publication*

**Specific Compliance Requirements Start for Several Conditions of Certification, Including Info Blocking, Assurances, APIs**

*By No Later Than 24 Months After Publication*

**New HL7® FHIR® API Capability and Other Cures Update Criteria Must Be Rolled Out**

*60 Days After Publication*

**General Effective Date, including**
- **Cures Update Certification Criteria**
- **Certain Conditions of Certification**

*12/15/2020*

**Deadline for First Real-World Testing Plans Due**

*4/1/2021*

**First Attestation to Conditions of Certification Required**

*By No Later Than 36 Months After Publication*

**EHI Export Capability Must be Rolled Out**

**Publication Date [MM/DD/20]**

**2020** → **2021** → **2022** → **2023**

**Six Month Preparation Period, Compliance Encouraged**

**Compliance with Exceptions Required, EHI Definition Limited to USCDI**

*Months 6 to 24 After Publication Date*

**Compliance with Exceptions Required, Full EHI Definition in Effect**

*Month 24 Onward After Publication Date*

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

**24 Months After Publication**

# Information Blocking

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

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# Contact ONC

📞 **Phone:** 202-690-7151

💬 **Health IT Feedback Form:**
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