ONC Cures Rule: 2015 Edition Updates
Conditions & Maintenance of Certification

Office of the National Coordinator for Health IT
April 22, 2020
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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Compliance Timeline – Enforcement Discretion

In light of COVID-19, ONC will exercise its discretion in enforcing all new requirements under 45 CFR Part 170 that have compliance dates and timeframes until 3 months after each initial compliance date or timeline identified in the ONC Cures Act Final Rule.
## Enforcement Discretion Dates and Timeframes

<table>
<thead>
<tr>
<th>Provision</th>
<th>Compliance Date/Timeframe</th>
<th>Enforcement Discretion Date/Timeframe</th>
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<tbody>
<tr>
<td><strong>Condition of Certification (CoC) – Information Blocking</strong></td>
<td>6 months after final rule publication</td>
<td>3 months after the compliance timeframe</td>
</tr>
<tr>
<td><strong>CoC – Assurances</strong> – Will not take any action that constitutes information blocking or actions that inhibit access, exchange, and use of electronic health information (EHI)</td>
<td>6 months after final rule publication</td>
<td>3 months after the compliance timeframe</td>
</tr>
<tr>
<td><strong>CoC – Assurances</strong> – EHI Export Rollout</td>
<td>36 months after final rule publication</td>
<td>3 months after the compliance timeframe</td>
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<tr>
<td><strong>CoC – Assurances</strong> – Other</td>
<td>Effective date of final rule</td>
<td>3 months after the compliance date</td>
</tr>
<tr>
<td><strong>CoC – Communications</strong> – Notice to all customers with which developer has contracts or agreements containing provisions that contravene Communications CoC</td>
<td>Annually beginning in calendar year 2020</td>
<td>Notice can be made until March 31, 2021 for the 2020 calendar year</td>
</tr>
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<td><strong>CoC – Application Programming Interface (API)</strong> – Compliance by Certified API Developers with health IT certified to current API criteria</td>
<td>6 months after final rule publication</td>
<td>3 months after the compliance timeframe</td>
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<tr>
<td><strong>CoC – API</strong> – Rollout of new standardized API functionality</td>
<td>24 months after final rule publication</td>
<td>3 months after the compliance timeframe</td>
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</table>
| **CoC – Real World Testing (RWT)** – Submit initial plan and initial results submission | Plan: December 15, 2020  
Results: March 15, 2022                                              | Generally remains the same, except for initial cycle for the annual submissions  
**Initial Plan**: Initial RWT plans (i.e., 2021 RWT plans) may be submitted through March 15, 2021  
**Initial Results**: Initial RWT results from the 2021 performance year may be submitted up through June 2022 |
| **CoC – RWT** – Updates to United States Core Data for Interoperability (USCDI) | 24 months after final rule publication                              | 3 months after the compliance timeframe                         |
| **CoC – Initial Attestations**                                           | April 1-30, 2021 attestation window for attestation period running from the effective date of final rule through March 31, 2021 | Generally remains the same except for the initial attestation, which will now be accepted through July 30, 2021 |
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<td><strong>ONC-Authorized Certification Bodies (ONC-ACBs): Initial RWT plan and initial results submission</strong></td>
<td>Plan: December 15, 2020 Results: March 15, 2022</td>
<td>Same as CoC RWT enforcement discretion for initial plan and initial results</td>
</tr>
<tr>
<td><strong>ONC-ACBs: Certification to Common Clinical Data Set (CCDS)/USCDI Criteria</strong></td>
<td>Only certify to CCDS for 24 months after final rule publication</td>
<td>3 months after the compliance timeframe</td>
</tr>
<tr>
<td><strong>ONC-ACBs: Certification to Application Access - Data Category Request Criterion</strong></td>
<td>Only certify for 24 months after final rule publication</td>
<td>3 months after the compliance timeframe</td>
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<tr>
<td><strong>ONC-ACBs: Certification to Data Export Criterion</strong></td>
<td>Only certify for 36 months after final rule publication</td>
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Updates to the 2015 Edition Certification Criteria
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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.
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

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

   **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.

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

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

c. Records and Information Retention
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.*
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).

**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

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.
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**
Contact ONC

Add additional call to action or relevant speaker information and contact details.

Phone: 202-690-7151

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

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