The Office of the National Coordinator for Health Information Technology

Health IT Advisory Committee

Conditions and Maintenance of Certification Requirements Task Force

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Agenda

- Call to Order/Roll Call
- Review of Charge
- Discussion of Updates to 2015 Edition Certification Criteria
  - Electronic health information export
  - Electronic prescribing
  - Clinical quality measures – export
  - Privacy and security-related *attestation* criteria
- Review Schedule of Topics
- Public Comment
- Next Steps and Adjourn

Conditions of Certification Task Force Charge

- **Overarching Charge**: Provide recommendations on the API," "real world testing," and "attestations" conditions and maintenance of certification requirements; updates to most 2015 Edition health IT certification criteria; changes to the ONC Health IT Certification Program; and deregulatory actions.

- **Specific Charge:** Provide recommendations on the following:

  - "API," "real world testing," and "attestations" conditions and maintenance of certification requirements
  - Updates to the 2015 Edition certification criteria: "Standardized API for patient and population services," "electronic health information export," "electronic prescribing," "clinical quality measures – export," and privacy and security-related *attestation* criteria ("encrypt authentication credentials" and "multi-factor authentication")
  - Modifications to the ONC Health IT Certification Program (Program)
  - Deregulatory actions related to certification criteria and Program requirements

Proposed Changes to the 2015 Edition Certification Criteria

Removed Criteria

2015 Base EHR Definition Criteria

- x Problem list (§ 170.315(a)(6))
- x Medication list (§ 170.315(a)(7))
- x Medication allergy list (§ 170.315(a)(8))
- x Smoking status (§ 170.315(a)(11))

Other Criteria

- x Drug formulary and preferred drug list checks (§ 170.315(a)(10)
- x Patient-specific education resource (§ 170.315(a)(13))
- x Common Clinical Data Set summary record – create (§ 170.315(b)(4))
- x Common Clinical Data Set summary record – receive (§ 170.315(b)(5))
- x Secure messaging (§ 170.315(e)(2))

Updated Criteria

Remove	Update with
x Electronic prescribing (§ 170.315(b)(3))	✓ Electronic prescribing (§ 170.315(b)(11))
x Data export (§ 170.315(b)(6))	✓ Electronic health information (EHI) export (§ 170.315(b)(10))
x Data segmentation for privacy – send (§ 170.315(b)(7))	✓ Data segmentation for privacy – send (§ 170.315(b)(12))
x Data segmentation for privacy – receive (§ 170.315(b)(8))	✓ Data segmentation for privacy – receive (§ 170.315(b)(13))
x Application access – data category request (§ 170.315(g)(8))	✓ Standardized API for patient and population services (§ 170.315(g)(10))

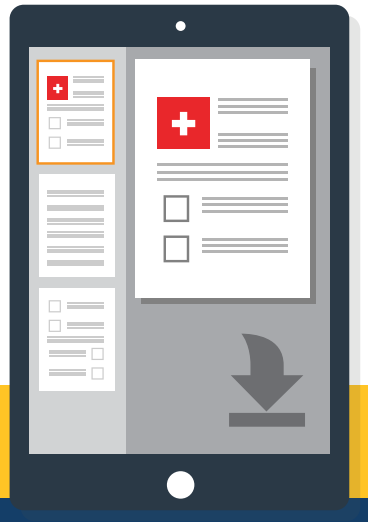
Revised Criteria

- ✓ Clinical Quality Measures (CQMs) – report criterion (§ 170.315(c)(3))
- ✓ Common Clinical Data Set/ United States Core Data for Interoperability criteria (§ 170.315(b)(1), (e)(1), (f)(5), (g)(6), and (g)(9))
- ✓ C-CDA Companion Guide criteria (The above listed criteria and § 170.315(b)(2) and (b)(9))
- ✓ Minimum Standards Code Sets criteria

New Criteria

- + Encrypt authentication credentials (§ 170.315(d)(12))
- + Multi-factor authentication (MFA) (§ 170.315(d)(13))
- + Consent management for application programming interfaces (§ 170.315(g)(11))

Electronic Health Information (EHI) Export Criterion



- Our new proposal would require health IT developers to provide the capability to electronically export all EHI that they produce and electronically manage in a computable format.
- We propose to make this criterion part of the 2015 Edition Base EHR definition, and for providers and developers to implement this within 24 months of the final rule's effective date.

HOW WILL IT WORK?

The proposed EHI Export certification requirement requires that:

1

All EHI produced and electronically managed by a developer's health IT must be readily available to export for:

A. a single patient upon request for their health data, and

B. all patients when a provider seeks to change Health IT systems.

2

The export file must:

A. be computable, and

B. include documentation to allow for interpretation and use of EHI. The documentation must be made publicly available via a hyperlink.

Note: Health IT developers would have the flexibility to determine their products' export standards.

https://www.healthit.gov/NPRM

Electronic Prescribing and Clinical Quality Measures

ELECTRONIC PRESCRIBING (e-Rx) STANDARD AND CERTIFICATION CRITERION

- We propose to update the e-Rx SCRIPT standard in 45 CFR 170.205(b) to NCPDP SCRIPT 2017071, which would result in a new e-Rx standard eventually becoming the baseline for certification. We also propose to adopt a new certification criterion in § 170.315(b)(11) for e-Rx to reflect these updated proposals.

CLINICAL QUALITY MEASURES (CQMs) – REPORT CRITERION

- We propose to remove the HL7 Quality Reporting Document Architecture (QRDA) base standard conformance requirements from the 2015 Edition "CQMs – report" criterion in § 170.315(c)(3) and, in their place, require Health IT Modules to support the CMS QRDA Implementation Guide (IGs).
  - This would reduce the burden for health IT developers by only having to support one implementation of the QRDA standard rather than two (i.e., the HL7 and CMS IGs).
  - https://ecqi.healthit.gov/qrda-quality-reporting-document-architecture

Privacy and Security Transparency Attestation Criteria

- We propose to add two new criteria to the 2015 Edition privacy and security certification framework:
  - » **Encrypt Authentication Credentials**
    - Must be in accordance with FIPS Publication 140-2
  - » **Multi-factor Authentication**
    - Must be in accordance with industry recognized standards (e.g. NIST Special Publication 800-63B Digital Authentication Guidelines, ISO 27001)

- Developers choose whether to have these functionalities for their certified health IT.
- These criteria are attestation based and developers would not be tested to these criteria.
- Developer must attest **YES or NO** to having the functionality; however developers' attestations would be listed on the Certified Health IT Product List
- Already certified health IT would need to be **"re-certified" to these criteria within 6 months** of the final rule effective date*

**For health IT certified for the first time after the final rule effective date, they would need to meet the criteria at the time of certification*

Schedule of Topics

Meeting Dates	Topics
Week 1: Feb 18-22	• **Overview and HITAC Charge** • Overall process and timing for providing recommendations
Week 2: Feb 25 – Mar 1	• **Kick-off Meeting**

Week 3: Mar 4-8	• **Meeting 1 – Conditions and Maintenance of Certification**
	  • Real World Testing
	  • Attestations
	• **Meeting 2 – Conditions and Maintenance of Certification/Updates to 2015 Edition Criteria**
	  • Application Programming Interfaces
	• **Meeting 3 – Updates to the 2015 Edition Certification Criteria**
	  • Electronic health information export
	  • Electronic prescribing
	  • Clinical quality measures – export
	  • Privacy and security-related *attestation* criteria

	• **Meeting 1 – Modifications to the ONC Health IT Certification Program**
	  • Corrections
	  • Principles of Proper Conduct
	• **Meeting 2 – Deregulatory Actions**
	  • Removal of Randomized Surveillance Requirements
	  • Removal of the 2014 Edition from the Code of Federal Regulations
	  • Removal of the ONC-Approved Accreditor from the Program
	  • Removal of Certain 2015 Edition Certification Criteria and Standards
	  • Removal of Certain ONC Health IT Certification Program Requirements
	  • Recognition of Food and Drug Administration Processes

	• **HITAC Committee Meeting (3/19-20) – Present draft recommendations to HITAC**

Public Comment

To make a comment please call:

Dial: 1-877-407-7192

*(once connected, press "*1" to speak)*

All public comments will be limited to three minutes.

You may enter a comment in the
"Public Comment" field below this presentation.

Or, email your public comment to onc-hitac@accelsolutionsllc.com.

Written comments will not be read at this time, but they will be delivered to members of the Workgroup and made part of the Public Record.

Meeting Adjourned