

Conditions and Maintenance of Certification Requirements Task Force

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Agenda

- Call to Order/Roll Call
- Review of Charge
- Attestations
- Application Programming Interfaces
- 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

Attestations - § 170.406



CONDITION OF CERTIFICATION

 A health IT developer must provide an attestation, as applicable, to compliance with the Conditions and Maintenance of Certification, except for the "EHR reporting criteria submission" Condition of Certification



Application Programming Interface (API) Criterion

• We propose to adopt a new API criterion in § 170.315(g)(10), which would replace the "application access – data category request" certification criterion (§ 170.315(g)(8)) and become part of the 2015 Edition Base EHR definition. This new certification criterion would require the use of Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standards and several implementation specifications.



» https://www.hl7.org/fhir/overview.html



- 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



Application Programming Interfaces - § 170.404

API TECHNOLOGY ROLES



API Technology Supplier

Health IT developer that creates API technology presented for certification in the ONC Health IT Certification Program



API Data Provider

Health care organization that deploys the API technology



API User

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

ONC has designed API Conditions of Certification that will complement the technical capabilities described in our other proposals, while addressing the broader technology and business landscape in which these API capabilities will be deployed and used.

Note: The API Conditions of Certification only apply to API Technology Suppliers with health IT certified to any API-focused certification criteria

TRANSPARENCY

ONC has proposed that API Technology Suppliers make business and technical documentation necessary to interact with their APIs in production freely and publicly accessible.

PERMITTED FEES

ONC has proposed to adopt specific conditions that would set boundaries for the fees API Technology Suppliers would be permitted to charge and to whom those permitted fees could be charged.

PRO-COMPETITIVENESS

ONC has proposed that API Technology Suppliers would have to comply with certain requirements to promote an open and competitive marketplace.

https://www.healthit.gov/NPRM

Application Programming Interfaces (APIs) - § 170.404



CONDITIONS OF CERTIFICATION

- Requires health IT developers to publish APIs that allow health information from such technology to be
 accessed, exchanged, and used without special effort through the use of APIs or successor technology or
 standards, as provided for under applicable law
 - Through the APIs, a developer must also provide access to all data elements (i.e., the USCDI) of a patient's EHR to the extent permissible under applicable privacy laws
- An API Technology Supplier must make business and technical documentation necessary to interact with their APIs in production freely and publicly accessible
- All fees related to API technology, not otherwise permitted by this section, are prohibited from being imposed by an API technology Supplier
- API Technology Suppliers must grant API Data Providers (i.e., health care providers who purchase or license API technology) the sole authority and autonomy to permit API Users to interact with the API technology

MAINTENANCE OF CERTIFICATION

- An API Technology Supplier must register and enable all applications for production use within one business day of completing its verification of an applications developer's authenticity
- An API Technology Supplier must Support the publication of "Service Base URLs" (i.e., FHIR® server endpoints) for all of its customers, regardless of those that are centrally managed by the API Technology Supplier or locally deployed by an API Data Provider, and make such information publicly available at no charge
- An API Technology Supplier with API technology certified to § 170.315(g)(8) must provide all API Data Providers with a (g)(10)-certified API within 24 months of this final rule's effective date

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 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.







Health IT Advisory Committee







