



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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March 11, 2019



Agenda

- Call to Order/Roll Call
- Review of Charge
- API Discussion (continued)
- Modifications to the ONC Health IT Certification Program
 - » Corrections
 - » Principles of Proper Conduct
- 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

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



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

Modifications to the ONC Health IT Certification Program – Updates to the Principles of Proper Conduct

ONC-ACBs MUST NOW:

1. Accept test results from any ONC-ATL in good standing.
2. Review and confirm health IT developer submission of real world testing plans and results and make plans and results publicly available.
3. Collect health IT developers' quarterly attestations and note in Certified Health IT Product List (CHPL) when Health IT Modules are updated under the Standards Version Advancement Process (VAP) flexibility.
4. Ensure that health IT developers seeking to take advantage of the Standards VAP flexibility comply with the applicable requirements, retain records of the timing and content of developers' § 170.405(b)(5) notices, and timely post each notice's content publicly on the CHPL.
5. Review and submit health IT developer Conditions and Maintenance of Certification attestations to ONC for public availability.
6. Report to ONC any information that could lead ONC to perform direct review, including potential noncompliance with a Condition of Certification.



NEW FLEXIBILITIES FOR ONC-ACBs:

1. The role of the ONC AA would be eliminated, permitting ONC ACBs to select the ISO/IEC 17065 accreditation body of their choice.
2. Certain randomized surveillance requirements would be eliminated.
3. ONC ACBs would be able to certify Health IT Modules that they have evaluated for conformance with certification criteria without first passing through an ONC ATL as long as conformity methods were approved by the National Coordinator.



NO LONGER REQUIRED:

1. Certain disclosure requirements regarding certified health IT limitations.
2. Transparency attestations by health IT developer regarding the sharing of information in its mandatory disclosures.



Schedule of Topics

Meeting Dates	Topics
	<ul style="list-style-type: none"> • Overview and HITAC Charge • Overall process and timing for providing recommendations
Week 2: Feb 25 – Mar 1	<ul style="list-style-type: none"> • Kick-off Meeting
Week 3: Mar 4-8	<ul style="list-style-type: none"> • Meeting 1 – Conditions and Maintenance of Certification <ul style="list-style-type: none"> • Real World Testing • Attestations • Meeting 2 – Conditions and Maintenance of Certification/Updates to 2015 Edition Criteria <ul style="list-style-type: none"> • Application Programming Interfaces • Meeting 3 – Updates to the 2015 Edition Certification Criteria <ul style="list-style-type: none"> • Electronic health information export • Electronic prescribing • Clinical quality measures – export • Privacy and security-related <i>attestation</i> criteria
Week 4: Mar 11-15	<ul style="list-style-type: none"> • Meeting 1 – Modifications to the ONC Health IT Certification Program <ul style="list-style-type: none"> • Application Programming Interfaces (continued) • Corrections • Principles of Proper Conduct • Meeting 2 – Deregulatory Actions <ul style="list-style-type: none"> • 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
	<ul style="list-style-type: none"> • HITAC Committee Meeting (3/19-20) – Present draft recommendations to HITAC

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.



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Meeting Adjourned



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