



The Office of the National Coordinator for
Health Information Technology
Health IT Advisory Committee

Conditions and Maintenance of Certification Requirements Task Force

Denise Webb, co-chair
Raj Ratwani, co-chair

March 6, 2019



Agenda

- Call to Order/Roll Call
- Review of Roster and Charge
- Real World Testing
- Attestations
- Review Schedule of Topics
- Public Comment
- Next Steps and Adjourn

Task Force Roster

Name	Organization	Role
Denise Webb	Individual	Chair
Raj Ratwani	MedStar Health	Chair
Carolyn Petersen	Individual	Member
Ken Kawamoto	University of Utah Health	Member
Sasha Termaat	Epic	Member
Leslie Lenert	Medical University of South Carolina	Member
John Travis	Cerner	SME

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

Real World Testing - § 170.405



CONDITIONS OF CERTIFICATION

- Requires that health IT developers have successfully tested the real-world use of the technology for interoperability in the type of setting in which such technology would be marketed
- This Condition of Certification applies to health IT developers with Health IT Module(s) certified to certain certification criteria focused on interoperability and data exchange (i.e., §§ 170.315(b), (c)(1) through (c)(3), (e)(1), (f), (g)(7) through (g)(11), and (h))

MAINTENANCE OF CERTIFICATION

- Health IT developers must submit publicly available prospective annual real world testing plans and retrospective annual real world testing results for certified health IT products focused on interoperability
- Standards Version Advancement Process: permits health IT developers to voluntarily use newer versions of adopted standards. Please also see the Standards Version Advancement Process fact sheet for more details.

Standards Version Advancement Process

- The Standards Version Advancement Process would allow 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 would 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:

- Notify its ONC-Authorized Certification Body (ONC-ACB) and its customers of its intent to move to newer NC-approved standards version updates as well as whether, and for how long, they might plan to continue supporting prior versions of the standards.
- Ensure that the standards version updates are effectively implemented.
- Address standards version updates in the required annual real world testing plans and results.
- Demonstrate conformance of its health IT to all applicable criteria including, but not limited to, any NC-approved standards versions it has chosen to incorporate into its certified Health IT Module.

How Versions Get Approved



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



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



Schedule of Topics

Meeting Dates	Topics
Week 1: Feb 18-22	<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 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
	<ul style="list-style-type: none"> • Meeting 1 – Modifications to the ONC Health IT Certification Program <ul style="list-style-type: none"> • 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

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.



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Meeting Adjourned



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