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

Conditions and Maintenance of Certification Task Force: Recommendations to the HITAC

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

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Agenda

- Task Force Members

- Task Force Charge

- Recommendations

  » Summary of Approved Recommendations (31)

  » Real World Testing (3; one withdrawn)

  » Application Programming Interfaces (1)

  » Applicability of Conditions and Maintenance of Certification Requirements for Self-Developers (1)

- Questions and Feedback

- Vote on Recommendations

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 "application programming interfaces (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

Summary of Approved Recommendations

- **Overarching Recommendation**

  - **Recommendation 1:** Clarity on rationale for maintaining a "2015" Edition – approved by HITAC on 4/10/2019

- **Real World Testing –** all approved by HITAC on 4/25/2019

  - **Recommendation 2:** Timing of submission of real world testing plan/results

  - **Recommendations 3-5:** Certification criteria the plan must address

  - **Recommendations 6-7:** Scenario and use case focused testing

  - **Recommendation 9:** Expected involvement of providers and third parties to support real world testing

  - **Recommendation 10:** Methodology

  - **Recommendation 11:** Measurement/metrics

  - **Recommendation 14:** Review and revise the Regulatory Impact Analysis

Summary of Approved Recommendations

- **Attestations -** approved by HITAC on 4/25/2019

  - **Recommendation 15:** Include a specific deadline at the middle of the year and the end of year/ beginning of year for attestations

- **Application Programming Interfaces (APIs) –** all approved by HITAC on 4/25/2019

  - **Recommendation 16:** Key terms

  - **Recommendations 17-19:** Proposed API standards, implementation specifications, and certification criterion

  - **Recommendations 20-21:** Proposed adoption of standards and implementation specifications to support persistent user authentication and app authorization

  - **Recommendation 23:** Transparency conditions

  - **Recommendation 24:** App registration/ Condition of Certification requirements

Summary of Approved Recommendations

- **Electronic Health Information Export** – approved by HITAC on 4/25/2019
  - **Recommendations 26-29:** Request for clarifications around: scope, compliance with other laws, audit logs, timeframes

- **Electronic Prescribing** – approved by HITAC on 4/25/2019
  - **Recommendation 30:** Certain e-Rx transactions should be optional

- **Clinical Quality Measure – Export** – approved by HITAC on 4/25/2019
  - **Recommendations 31-32:** QRDA updates

Summary of Approved Recommendations

- **Privacy and Security Attestations Criteria (Encrypt Authentication Credentials and Multi-factor Authentication)** – approved by HITAC on 4/25/2019
  - **Recommendations 33-34:** Apply privacy and security attestations only to new certifications/new products and add a text box for developers to describe their yes/no attestations

- **Deregulatory Actions** – all approved by HITAC on 4/25/2019
  - **Recommendation 35:** Removal of randomized surveillance requirements
  - **Recommendation 36:** Removal of certain 2015 Edition certification criteria

Real World Testing

Recommendation 8 [REVISED]: ONC states that successful real world testing means: "Electronic health information is received by and used in the certified health IT." The CMC TF recommends ONC provide clarification in the final rule preamble in section VII.B.5 around testing the "receipt and use" of information received through exchange versus testing the exchange of information (sending and receiving). When the health IT being tested does not receive data in the criterion being tested ~~When there are no end users of the health IT product being tested~~, use-based testing would not be pertinent.

The TF recommends ONC expect that if health IT developers are testing the use of data received through exchange, the health IT vendors should have intended users involved in usability testing.

Users (providers) were not considered in the cost estimates for real world testing in the proposed rule preamble. Therefore, the TF recommends ONC revise real world testing cost estimates in the final rule preamble section XIV.C.2.a.3.6 to incorporate this.

To reduce cost, the TF further recommends ONC prioritize real world testing criteria based on risk.

Real World Testing

Recommendation 12 [WITHDRAWN]: ~~The CMC TF recommends ONC elaborate and provide more clarity in the final rule preamble section VII.B.5 on the standards version advancement process when a version of standards is available under this process but does not yet have testing tools available to determine conformance. It is fairly clear vendors must factor all claimed versions of standards into their real world testing, but the final rule preamble should clarify how the health IT developers are to address new versions for which tooling does not exist yet that they have attested to support and how the health IT developer and ONC-ACBs will judge or determine conformance. The TF further recommends ONC clarify whether testing will be required in a subsequent year's real world testing plan once tooling is available or whether the health IT developer's previous attestation is sufficient.~~

Real World Testing

Recommendation 13 [REVISED]: The CMC TF recommends ONC clarify in the final rule preamble the role and expectations of testing partners ~~third parties~~ over which the health IT developers have no control or authority over. For example, some testing partners ~~third parties~~ (for example: immunization registries,~~)~~ ~~and~~ other EHR developers and providers) are likely to receive many requests to participate in other parties' real world testing. While these testing partners ~~entities~~ can try to be helpful, they will have limited resources to assist other groups.

The TF further recommends ONC clarify whether declining to participate as a testing partner in real world testing is considered to be information blocking. The TF recommends ONC consider and clarify in the final rule preamble how reasonable protections can be provided for testing partners ~~those~~ who have limited resources and, therefore, are unable to participate in an unlimited set of tests. The final rule preamble should provide reasonable assurances for health IT developers who have tried to engage testing partners ~~third parties~~ in testing yet were not successful in getting their commitment to participate.

Application Programming Interfaces

Recommendation 22 [REVISED]: ~~The CMC TF has concerns over ONC not proposing a standard way for a request for multiple patients' data and recommends ONC specify a standard approach that will be available in FHIR R4. Otherwise, each developer could implement this differently and invest time in non-standard ways and then likely have to spend time/money transitioning to the standard way. The CMC TF also recognized that there is an immediate need now to satisfy this type of request. If ONC identifies FHIR R4 for implementation in the final rule, the FHIR R4 standard could be used for bulk queries but on a different timeline than implementation of more established R4 implementation guides that support a search for a single patient's data. The TF would like to see successful implementations of products that search for multiple patients using the FHIR R4 standard prior to requiring adoption across the industry of this 2015 Edition certification criterion for multiple patients.~~ The CMC TF recognizes additional standards and piloting work of bulk API queries is important, and to allow for that work, the TF recommends ONC require this functionality 12 months after other API updates are expected.

Applicability of Conditions and Maintenance of Certification Requirements for Self-Developers

Recommendation 25 [NEW]: The CMC TF recommends ONC evaluate the appropriateness of requiring self-developers seeking and maintaining certification to meet all the requirements as proposed in the rule for the real world testing, APIs, and attestations to conditions of maintenance and certification for certified health IT modules that are not offered for commercial resale but must be certified in order for the providers using the modules to participate in certain federal programs. The TF recommends ONC specifically address the following in its evaluation and update the final rule preamble Section VII and regulatory text where appropriate:

Real world testing: Permitting self-developers seeking and maintaining certification to use their production experience for the venues where they have deployed their software and their actual trading partner experience to meet the real world testing requirements assuming the certified capabilities otherwise meet the other criteria required for certification. Additionally, allowing self-developers of certified Health IT Modules to meet the requirements for Maintenance of Certification in subsequent years with results of the initial real world testing if nothing has changed in the way their self-developed certified product functions and operates.

APIs: CMC requirements applicable to fees as these requirements may not apply to self-developers seeking and maintaining certification. If the self-developer is selling its API technology or charging for its use, the self-developer seeking and maintaining certification of its API technology would be subject to the CMC requirements related to *API fees* and *permitted fee conditions* in § 170.404.
Attestations: None