

Conditions and Maintenance of Certification
Task Force
Recommendations
May 13, 2019

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Carolyn Petersen, co-chair
Robert Wah, co-chair
Health Information Technology Advisory Committee
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Carolyn and Robert:

The Health Information Technology Advisory Committee (HITAC) asked the Conditions and Maintenance of Certification Task Force (CMC TF or TF) to provide recommendations on certain Conditions and Maintenance of Certification Requirements, updates to most 2015 Edition certification criteria, changes to the ONC Health IT Certification Program, and deregulatory actions.

In our April 25 transmittal, we advanced 35 of our 36 recommendations to the HITAC. At the April 10 HITAC meeting, the Committee had previously approved Recommendation #1. At the April 25 HITAC meeting, the Committee considered the other 34 recommendations and voted affirmatively on 30 of those recommendations. The HITAC asked us to take recommendations #8, #12, #13, and #22 back to the TF to address concerns raised at the meeting. This transmittal supplements the April 25 transmittal and advances recommendations #8, #13, and #22 for reconsideration and a vote. After further TF discussion on #22, we decided the proposed rule sufficiently address the Standards Advancement Process and are withdrawing #22. We are also advancing #25 (previously deferred) for consideration and a vote.

1. Background

1.1. Overarching charge:

The Conditions and Maintenance of Certification Task Force will develop and advance 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.

1.2. Detailed charge:

Make specific recommendations on:

1.2.1. Conditions and Maintenance of Certification Requirements

Recommendations on the following Conditions and Maintenance of Certification requirements: “API,” “real world testing,” and “attestations.”

1.2.2. Updates to 2015 Edition Certification Criteria

Recommendations on most proposed updates to the 2015 Edition certification criteria including: “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”).

1.2.3. Modifications to the ONC Health IT Certification Program

Recommendations on proposed modifications to the ONC Health IT Certification Program (Program).

1.2.4. Deregulatory Actions

Recommendations on proposed deregulatory actions related to certification criteria and Program requirements including: (1) removal of a threshold requirement related to randomized surveillance which allows ONC- Authorized Certification Bodies (ONC-ACBs) more flexibility to identify the right approach for surveillance actions, (2) removal of the 2014 Edition from the Code of Federal Regulations (CFR), (3) removal of the ONC-Approved Accreditor (ONC-AA) from the Program, (4) removal of certain 2015 Edition certification criteria, (5) removal of certain Program requirements, and (6) recognition of relevant Food and Drug Administration certification processes with a request for comment on the potential development of new processes for the Program.

2. Recommendations

2.1. Overarching Recommendations

2.1.1. Clarity on Rationale for Maintaining a “2015” Edition

Recommendation 1: Approved by HITAC, 4/10/2019

2.2 Conditions and Maintenance of Certification Requirements

2.2.1 Real World Testing

2.2.1.1 Timing of submission of real world testing plan

Recommendation 2: Approved by HITAC, 4/25/2019

2.2.1.2 Certification Criteria Plan Must Address

Recommendations 3 - 5: Approved by HITAC, 4/25/2019

2.2.1.3 Scenario and Use Case Focused Testing

Recommendations 6 - 7: Approved by HITAC, 4/25/2019

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, use-based testing would not be pertinent. 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.

Discussion

The CMC TF thinks testing the use of information is important to usability of interoperability. Testing the use of information received through exchange requires consideration of human factors and usability to understand whether the intended users can efficiently and effectively use the presented information.

Use of data testing would be pertinent to the receipt of data in the EHR. If health IT developers are testing the use of data received through exchange, the health IT vendors should have users involved in the testing to validate that users can process and use that information. When certified health IT products receive “foreign” data, we have heard user feedback desiring it be viewable, actionable, and reportable alongside the user’s “native” data to be useful and reduce burden on providers using the technology. The intent of this TF is not to prescribe certain design approaches but to encourage user-centered design.

The TF recognizes that the expense of use-based testing is significant for both health IT developers and users of HIT. The TF significantly discussed the costs of this proposal for multiple players: vendors, the other interoperability partners who would be involved, provider organizations and users. The concern was how to prioritize where testing is helpful without unnecessarily increasing cost or burden.

Recommendation 9: Approved by HITAC, 4/25/2019

2.2.1.4 Methodology

Recommendation 10: Approved by HITAC, 4/25/2019

2.2.1.5 Measurement/metrics

Recommendation 11: Approved by HITAC, 4/25/2019

2.2.1.6 Standards Version Advancement Process

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.~~

Given the following text in the proposed rule preamble, the CMC TF decided Recommendation 22 was not needed and are withdrawing it from consideration:

“On the other hand, the Program’s testing infrastructure (which is now inclusive of government-developed and non-government-developed tools) may experience certain lag times in terms of when updated test tools to support the approved version advancements would be available to test Health IT Modules for certification purposes. As a result, we propose to provide the ability for ONC-ACBs to accept a developer self-declaration of conformity as to the use, implementation, and conformance to a newer version of a standard (including but not limited to implementation specifications) as sufficient demonstration of conformance in circumstances where the National Coordinator has approved a version update of a standard for use in certification through the Standards Version Advancement Process but an associated testing tool is not yet updated to test to the newer version. Again, we clarify that a health IT developer would be able to choose which National Coordinator-approved standard version(s) it seeks to include in a new or updated certified Health IT Module and would be able to do so on an itemized basis.”

2.2.1.7 Other Considerations

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.

Recommendation 14: Approved by HITAC, 4/25/2019

2.2.2 Attestations

Recommendation 15: Approved by HITAC, 4/25/2019

2.2.3 Application Programming Interfaces

2.2.3.1 Key Terms

Recommendation 16: Approved by HITAC, 4/25/2019

2.2.3.2 Proposed API Standards, Implementation Specifications, and Certification Criterion

Recommendations 17 - 19: Approved by HITAC, 4/25/2019

2.2.3.3 Proposed Adoption of Standards and Implementation Specifications to Support Persistent User Authentication and App Authorization

Recommendations 20-21: Approved by HITAC, 4/25/2019

2.2.3.4 Search Support

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.**

2.2.3.5 Transparency Conditions

Recommendation 23: Approved by HITAC, 4/25/2019

2.2.3.6 App Registration/ Condition of Certification Requirements

Recommendation 24: Approved by HITAC, 4/25/2019

2.2.4 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

Discussion:

A health system or provider may choose to self-develop and use innovative health IT software and may participate in federal programs that require the software be certified. The TF generally agreed the requirements for the real world testing and API CMC would apply to self-developers seeking and maintaining certification of Health IT Modules to one or more of the 2015 Edition criteria focused on interoperability and data exchange (criteria listed in the preamble Section VII.5). However, the TF is concerned that universally applying all aspects of the requirements for the real world testing CMC to self-developers seeking certification and maintaining certification of their certified Health IT Modules may place an undue burden on these self-developers, particularly for self-developers seeking and maintaining certification of products with a low volume of users. The TF agreed that while the requirements related to API fees may not apply to self-developers, the other requirements of the API CMC would apply to self-developers seeking and maintaining certification of API technology (i.e., technology certified to criteria in § 170.315(g)(7) through (11)), regardless of fees.

2.3 Updates to the 2015 Edition Certification Criteria

2.3.1 Electronic Health Information Export

Recommendations 26 - 29: Approved by HITAC, 4/25/2019

2.3.2 Electronic Prescribing

Recommendation 30: Approved by HITAC, 4/25/2019

2.3.3 Clinical Quality Measures – Export

Recommendations 31-32: Approved by HITAC, 4/25/2019

2.3.4 Privacy and Security Transparency Attestations Criteria (Encrypt Authentication Credentials and Multi-factor Authentication)

Recommendations 33 - 34: Approved by HITAC, 4/25/2019

2.4. Modifications to the ONC Health IT Certification Program (No Recommendations)

2.4.1 Corrections

2.4.2 Principles of Proper Conduct

2.5 Deregulatory Actions for Previous Rulemakings

2.5.1. Removal of Randomized Surveillance Requirements

Recommendation 35: Approved by HITAC, 4/25/2019

2.5.2 Removal of Certain 2015 Edition Certification Criteria

Recommendation 36: Approved by HITAC, 4/25/2019

Respectfully submitted,

Denise Webb and Raj Ratwani
CMC TF Co-Chairs