



Meeting Notes

Health Information Technology Advisory Committee Conditions and Maintenance of Certification Requirements Task Force March 14, 2019, 2:30 p.m. – 3:45 p.m. ET Virtual

The March 14, 2019, meeting of the Conditions and Maintenance of Certification Requirements Task Force (CMCTF) of the Health IT Advisory Committee (HITAC) was called to order at 2:30 p.m. ET by Lauren Richie, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC).

Lauren Richie conducted roll call.

Roll Call

MEMBERS IN ATTENDANCE

Raj Ratwani, Co-Chair, MedStar Health
Denise Webb, Co-Chair, Individual
Carolyn Petersen, Member, Individual
Sasha TerMaat, Member, Epic
John Travis, Member, Cerner

MEMBERS NOT IN ATTENDANCE

Kensaku Kawamoto, Member, University of Utah Health
Leslie Lenert, Member, Medical University of South Carolina

ONC STAFF

Lauren Richie, Branch Chief, Coordination, Designated Federal Officer
Kate Tipping, ONC Conditions of Maintenance of Certification Requirements Task Force Lead
Lauren Wu, ONC SME

Review of Charge

Kate Tipping reviewed the charge.

- **Overarching Charge:** Provide recommendations on the “application programming interface (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

Discussion of Draft Recommendations

The CMCTF reviewed a draft recommendations document discussing any refinements to the recommendations. The recommendations were shared in a collaborative Google document where the group was able to modify and update language easily. Items the CMCTF members changed are identified below with red text denoting the updates or added text.

2.2.1.2 Certification Criteria Plan Must Address

- **Recommendation 3:** ONC should provide more clarity or put guardrails around care settings/venue to what the test plan must cover. **The goal is to make minimum expectations clear in regards to applicable care setting as venues (which setting, sufficient number of settings) for the health IT product.**
 - **John Travis** noted that the intention was around efficiency and applicability.

2.2.1.3 Scenario and Use Case Focused Testing

- **Recommendation 6:** ONC should clarify and define the terms, “scenario” and “use case” if these terms mean the same thing, choose and use just one of these terms in the rule.
 - **Sasha TerMaat** recalled the group discussing something around workflow.
 - This discussion resulted in the addition of the following: **ONC should also clarify the term “workflow” as it’s used in real world testing.**
 - The workgroup also added and additional recommendations as follows: **We recommend vendors be given discretion to incorporate permissible testing approaches, including, for example, automated testing and regression testing (also possibly automated).**
- **Recommendation 7:** ONC should provide clarification around testing the exchange of information, or about the use of the information. Testing the use of that information requires consideration of human factors and usability to understand whether the intended users efficiently and effectively use the presented information.
 - Through the discussion, the CMCTF added the following: **When there are no end users of the product being tested, use-based testing would not be pertinent.**
 - The CMCTF also worked on editing the second part of the recommendation, resulting in the following: **Use of data testing, if expected, would be pertinent to the receipt of data in the HER. If we are testing the use, we need to have the providers involved in the testing. Being able to determine if the providers can process and use that information when there is an exchange. The providers were not considered in the cost estimates for real world testing in the proposed rule preamble.**
- **Recommendation 8:** ONC should clarify the expected involvement of providers **and third parties** to support the “real world” nature of the testing.
 - The discussion resulted in the addition of third parties, noted in red above.



2.2.1.5 Measurement/metrics

- Together the CMCTF updated the following recommendation, as detailed in red.
- **Recommendation 10:** ONC should include a description of “measurement.” ONC should provide clarity about the role of measurement **and specify for** what kinds and for what purposes or proof points. After the pilot year, consider updating metric expectations: **where the real world testing is of both interoperability and use of received data, consider there be at least one metric of interoperability and one metric of use which might correspond with metrics of use used in safety enhanced design testing.**

2.2.1.7 Other Considerations

- The language was refined as follows in red.
- **Recommendation 13:** ONC should review and revise **regulatory impact** time estimates that would be required to ensure they are accurate **and align** to the clarified understanding of the **real world testing** proposal.

2.2.3.1 Key Terms

- **Recommendation 15**
 - The CMC TF decided to add the following to this recommendation: **Relationships prior to the involvement of an API Data provider are particularly of interest.**

2.2.3.2 Proposed API Standards, Implementation Specifications, and Certification Criterion

- **Recommendation 16:** ONC should adopt solely FHIR Release 4 in the final rule for reference in proposed § 170.315(g)(10) (Option 4). **This was recommended as the first normative version, supporting enhanced capabilities (such as bulk data), and not divide the focus of the industry with multiple standards.**
 - The addition was made to clarify why the CMCTF chose option 4.

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

- **Recommendation 18:** ONC should address the legitimate and expected activity for SMART Guide to protect patient data **with respect to providing persistent tokens to applications and their ability to keep the token confidential.** The CMC TF recommends ONC provides further clarity. **Someone will need to ascertain that API users provided a persistent token are creating products that secure the token appropriately, but it is not clear who plays that role. ONC will need to clarify who it is and how the determination is made.**

2.2.3.5 Transparency through the Publication of API Documentation

- **Recommendation 20:** ONC should clarify what happens at six months and what happens at 24 months. **The CMCTF was puzzled by requirements to update API documentation (6 months) prior to the requirement to update API capabilities (24 months).**

2.3.3 Clinical Quality Measures – Export

- **Recommendation 27:** ONC should update the quality measurement proposal per the table below. ONC proposes that all products adopt both the CMS ambulatory IG for QRDA III and CMS inpatient IG



for QRDA I. **The CMCTF identified this as an important technical correction for quality reporting use cases.**

Denise Webb noted that there will be a renumbering of the recommendations, as an additional recommendation was added. The co-chairs will be presenting at the next HITAC meeting on March 19, 2019. The co-chairs will have 45 minutes to present; this includes time for questions.

Public Comment

There was no public comment.

Next Steps and Adjourn

The CMCTF members were asked to review the recommendations within the shared Google document to prepare for sharing with the HITAC, making sure everything is captured correctly.

The next CMCTF meeting will be held on Thursday, March 21 at 9:30 a.m. ET.

Lauren Richie adjourned the meeting at 3:45 p.m. ET.