



Meeting Notes

Health Information Technology Advisory Committee Conditions and Maintenance of Certification Requirements Task Force March 28, 2019, 12:00 p.m. – 1:00 p.m. ET Virtual

The March 28, 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 12:00 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
Leslie Lenert, Member, Medical University of South Carolina
John Travis, Member, Cerner

MEMBERS NOT IN ATTENDANCE

Kensaku Kawamoto, Member, University of Utah Health
Carolyn Petersen, Member, Individual
Sasha TerMaat, Member, Epic

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

Lauren Richie turned the meeting over to Kate Tipping to review the charge.

Review of Charge

Kate Tipping reviewed the charge for the CMCTF.

- **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

Recommendation Review

Denise Webb reviewed the recommendations from the group, sharing feedback from the March 19 HITAC meeting.

Denise Webb commented that she still believes that there should be a new version of certification.

- **John Travis** agreed with Denise Webb.

Recommendation 8: 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. When there are no end users of the product being tested, use-based testing would not be pertinent.

- **Denise Webb** noted that real world testing should be a part where applicable.
- **Raj Ratwani** agreed that the recommendation needs to be strengthened.

Recommendation 17: 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 dividing the focus of the industry with multiple standards.

- The workgroup asked ONC to verify timelines with CMS requirement for 2015 Edition update.
- Les Lenert said that FHIR has evolved, it was intended as a work in progress. Need to encourage that Release 4 is really the intended release product.
- Denise Webb noted that there seems to be a general consensus to moving forward with Release 4, but thought there should be a vote as a group.

Ken Kawamoto added the following recommendation but was not on the call to discuss the details.

Recommendation XX: ONC should require compliance with HL7 US Core FHIR Implementation Guides derived from the Argonaut implementation guides, rather than the Argonaut implementation guides themselves. Where HL7 Implementation Guides are not available for the corresponding and required Argonaut functionality, ONC should facilitate their inclusion as HL7 standards. This is because Argonaut is a closed membership group with no opportunity for the vast majority of stakeholders such as EHR vendors and healthcare systems to provide input, whereas HL7 is an open-member, ANSI-accredited standards development organization which enables such stakeholder input.

The workgroup agreed with these recommendations and will add them.

Recommendation 21: ONC should clarify what happens at 6 months and what happens at 24 months. The



CMC TF was puzzled by requirements to update API documentation (6 months) prior to the requirement to update API capabilities (24 months).

- **Denise Webb** initiated a discussion around this that resulted in the addition of “for these criteria” as noted below.
- For the purposes of the specific transparency conditions proposed in § 170.404(a)(2) and their relationship and applicability to API Technology Suppliers with products already certified to § 170.315(g)(7), (8), or (9), we propose to establish a compliance date of six months from the final rule’s effective date (which would give developers approximately eight months from the final rule’s publication date) to revise their existing API documentation to come into compliance with the final rule **for these criteria**.

Recommendation 22: ONC should further clarify the requirements and expectations around the app registration condition of certification based on a number of issues the CMC TF identified regarding app registration. The CMC TF recommends clarification in the rule that would address the following:

- What the practice of “registration” consists of and does not consist of and who is the party responsible for keeping a list of registered apps.
- What “verifying the identity” of an API user consists of and does not consist of and who is the party responsible for performing this. If this is optional, specify that those who haven’t performed it are clearly excused from possible cases where API users misrepresent themselves.
- What “vetting” an app (in contrast to verifying identity of a user) consists of and what falls outside the definition of vetting and who is the party responsible for vetting and who is prohibited from vetting. If vetting is optional and not performed, specify that those who haven’t performed it are clearly excused from any possible consequences attributable to poorly designed or malicious apps.
- Identifying any tasks (such as an API Data Provider whitelisting a particular app for the first time or an API Data Provider endorsing particular apps) that fall outside of “registration,” “identity verification,” and “vetting.” Describe the tasks, and identify the parties that can and cannot perform them. If they aren’t performed, provide clarity that the party is not liable.

Denise Webb shared a concern around not vetting apps and suggested there might be more needed around security.

The workgroup will continue this discussion during the next meeting.

Lauren Richie opened the lines for public comment.

Public Comment

There was no public comment.

Next Steps and Adjourn

The next meeting will be on Friday, March 29th at 4:00 p.m. ET.

Lauren Richie adjourned the meeting at 1:00 p.m. ET.