



## Meeting Notes

### Health Information Technology Advisory Committee Conditions and Maintenance of Certification Requirements Task Force April 03, 2019, 9:00 a.m. – 10:00 a.m. ET Virtual

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The April 03, 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 9:00 a.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

Kensaku Kawamoto, Member, University of Utah Health

Leslie Lenert, Member, Medical University of South Carolina

Carolyn Petersen, Member, Individual

Sasha TerMaat, Member, Epic

John Travis, Member, Cerner

#### ONC STAFF

Lauren Richie, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC)

Kate Tipping, ONC Conditions of Maintenance of Certification Requirements Task Force Lead

Lauren Wu, ONC SME

### Call to Order/Roll Call

**Lauren Richie** called the meeting to order and turned it over to Kate Tipping to review the charge.

### Discussion of Recommendations

**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

**Denise Webb** reviewed the recommendations that had open discussion items working to finalize and present at the April 10 HITAC meeting.

**Recommendation 8:** ONC should provide clarification around testing the exchange of information, or about the use of the information. **The task force thinks testing of the use of information is important to usability of interoperability.** 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.

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 providers can process and use that information. When certified health IT products receive “foreign” data, we have heard user feedback desiring it be presented in the same view as the “native” data to be useful and reduce burden on providers using the technology. The intent of this task force is not to prescribe certain design approaches but to encourage user-centered design. The CMC TF recommends use of data testing validate the data a user receives in the certified health IT be viewable, actionable, and reportable along side the user’s native data.

**The task force recognizes that the expense of this testing is significant, for both health IT developers and users of HIT.** Users (providers) were not considered in the cost estimates for real world testing in the proposed rule preamble.

- CMCTF added the language in red to further refine this recommendation.

**Recommendation 17:** ONC should adopt solely FHIR Release 4 **(or a subsequent 4.x version if one is created with errata)** 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.

- **Denise Webb** summarized the discussion around this recommendation. The CMCTF supports version 4 or the subsequent version to fix errata in that version. This language change is noted above in red and was initialed by Ken Kawamoto

**Recommendation XX:** ONC should require compliance with HL7 US Core FHIR Implementation Guides (which are) derived from the Argonaut implementation guides, rather than require use of 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.

- **Denise Webb** noted that the group wanted to confirm that Sasha TerMaat was okay with adding this, as the other members had an opportunity to provide feedback already.
  - **Sasha TerMaat** agreed to this recommendation and it will be added to the recommendations.

The CMCTF had concerns around timing of implementation for fast healthcare interoperability resource (FHIR) updates which resulted in the addition of the recommendation below.

**Recommendation XX:** The task force is concerned that the timeline proposed for implementing FHIR updates as well as other 2015 Edition updates (and similar changes introduced through CMS regulation) may place an unreasonable burden on health IT developers and health IT users, particularly small developers and healthcare providers. The task force considered providing a waiver for those unable to adopt in time, but was concerned about the complexity and expense of a waiver process and also the challenges introduced by having varying interoperability standards in use past the deadline. Instead, the task force recommends a timeline that accommodates development and implementation without the unintended consequence of increasing healthcare costs.

**Ken Kawamoto** suggested the following recommendation be added.

**Recommendation XX:** ONC should provide formal guidance on compliance with relevant privacy and security regulations such as HIPAA of current uses of FHIR APIs, such as in SMART on FHIR applications or CDS Hooks services (e.g., sending of full patient demographic details in all cases, the use of broadly-scoped data access tokens).

- The CMCTF members agreed to adding this recommendation.

**Recommendation 20:** The CMCTF has concerns over ONC not proposing a standard way for a request for multiple patients' data and recommends ONC specify a standard approach that is available in FHIR R4. There are concerns because each developer could implement this differently and invest time in non-standard ways and then likely have to spend time/money transitioning to a standard way. The CMCTF also recognized there is an immediate need now to satisfy this type of request.

- The group expressed concern about the current maturity of bulk queries using FHIR. The maturity is lower than for other use cases and concerned with recommending something that hasn't been tested.
- The CMCTF will finish the discussion on this during the next call.

**Lauren Richie** opened the lines for public comment.

## Public Comment

There was no public comment.

## Comments in The Public Chat



**Leslie Lenert:** Nice language Sasha!

**Leslie Lenert:** Until there is an operational demonstration of FHIR 4 bulk data loading, it's premature to require its implementation for maintenance of certification. Don't you think this could easily bring an EHR to its knees performance wise without optimization?

## Next Steps and Adjourn

During the next meeting, the CMCTF will discuss:

- Finish the discussion on recommendation 20
- Recommendation 22 – app registration
- Recommendation 27 – eprescribing
- Recommendation regarding self-developers
- There are four additional items related to all developers that could clarify what is expected of them.

Raj Ratwani will lead the next meeting. The goal by the end of the meeting is to be able to advance the letter with all of the recommendations to the HITAC during the meeting on April 10.

The next meeting of the CMCTF is on Friday, April 5 at 3:00 p.m. ET.

**Lauren Richie** adjourned the meeting at 10:00 a.m. ET.