



## Meeting Notes

### Health Information Technology Advisory Committee Conditions and Maintenance of Certification Requirements Task Force May 1, 2019, 9:00 a.m. – 10:00 a.m. ET Virtual

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The May 1, 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

**Denise Webb, Co-Chair**, Individual  
**Raj Ratwani, Co-Chair**, MedStar Health  
Kensaku Kawamoto, Member, University of Utah Health  
Leslie Lenert, Member, Medical University of South Carolina  
Sasha TerMaat, Member, Epic  
John Travis, Member, Cerner

#### MEMBERS IN ATTENDANCE

Carolyn Petersen, Member, Individual

#### ONC STAFF

Cassandra Hadley, ONC  
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

**Lauren Richie** turned the meeting over to Raj Ratwani, co-chair.

### Discussion of Recommendations

**Raj Ratwani** opened the discussion regarding recommendation 22.

#### RECOMMENDATION 22

- **Sasha TerMaat** provided a summary of the previous discussions regarding this recommendation.



- **Denise Webb** suggested that there be a consideration to suggest that the timeline be changed; she suggested that this be an overall recommendation from the HITAC. She questioned if the implementation timeline should be delayed 36 months?
- **Sasha TerMaat** suggested a few options:
  - Acknowledge Arien's feedback provided at the April 25 HITAC meeting.
  - Acknowledge the complexity of standards work in this area and extend the timeframe.
  - Not set a specific timeframe, but instead suggested some amount of time after piloting.
- **Sasha TerMaat** suggested that ONC should set the expectation that they are moving too fast healthcare interoperability resource (FHIR) Release 4 (R4) which would set functional requirements for development.
  - With ONC 2015 Edition, ONC encouraged the use of FHIR even though it wasn't required. Sasha asked if something similar should be done here.
- **Denise Webb** suggested changing the timeline for this requirement.
- **Sasha TerMaat** felt that this solution would aggregate Arien's feedback and the CMC TF's initial recommendation.
- **Ken Kawamoto** agreed with the suggestion for ONC to identify the goal and provide an idea of the timeline.
- **Denise Webb** expressed concern for the timeline, especially because of everything else going on in healthcare.
- **John Travis** also expressed concern for the timeline.

The task force discussion resulted in the following as drafted by Sasha TerMaat.

**Updated Recommendation 22:** The CMC TF recognizes additional standards and piloting work of bulk application programming interface (API) queries is important, and to allow for that work, we recommend ONC require this functionality 12 months after other API updates are expected.

#### Discussion points:

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. We support ONC's approach of recommending but not requiring this approach.

The task force recognizes further standards work and piloting in this area is important. We encourage ONC to play a role in ensuring that work happens. 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.

## RECOMMENDATION 25

The CMC TF made real-time edits to this recommendation resulting in the following recommendation.

**Updated Recommendation 25:** The CMC TF recommends ONC evaluate the appropriateness of requiring self-developers of health IT to meet the following aspects of conditions of maintenance and certification for real world testing, APIs, and attestations 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 in the final rule preamble Section VII:

**Real world testing:** Making specific mention of a permitting self-developer to use their production experience for the venues where they have actually deployed their software and for the trading partner experience, they actually have to meet the real world testing requirements assuming the certified capabilities otherwise meet the other criteria required for certification. Additionally, allowing the self-developers to meet the maintenance of certification in subsequent years with results of the initial real world testing if nothing has changed in the way their self-developed product functions and operates.

**APIs:** Provisions applicable to fees as these provisions would likely not apply to self-developers. If the self-developer has contracts or commercial arrangements with respect to the health IT modules certified to the API criteria, they would be subject to these conditions of certification.

**Attestations:** None

**Discussion:** A health system or provider may choose to develop innovative software modules. A health system or provider using the self-developed software may participate in federal programs that require that self-developed health IT modules be certified. The TF is concerned that universally apply all aspects of the CMC for real world testing to self-developers and their certified health IT products.

The task force approved all changes discussed.

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

## Public Comment

There was no public comment.

## Next Steps and Adjourn

**Denise Webb** thanked the task force members for their input. The task force made it through all of the recommendations; therefore, they decided to cancel the meeting scheduled for Friday, May 3.

**Denise Webb** noted that she would review the changes made with Carolyn Petersen who was not in attendance. She also asked the task force to conduct a final review and send an email approval.

**Lauren Richie** adjourned the meeting at 9:44 a.m. ET.