



## Meeting Notes

### Health Information Technology Advisory Committee Conditions and Maintenance of Certification Requirements Task Force April 24, 2019, 9:00 a.m. – 10:00 a.m. ET Virtual

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The April 24, 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  
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)  
Stephanie Fiore, ONC SME  
Lauren Wu, ONC SME

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

### Discussion of Recommendations

**Raj Ratwani** welcomed the task force and noted that there is one recommendation remaining, recommendation 25, for the task force to review.

**Denise Webb** noted that Les Lenert and John Travis worked to revise and edit the recommendation over email.

**John Travis** commented that certified health information technology needs to enable the participant to meet program requirements. Those things should apply to any certified product. Les had raised the point that there shouldn't be an undue burden on self-developers.



**Denise Webb** provided language to combine both John Travis and Les Lenert’s language. Denise felt that from a patient safety perspective, a self-developer should mostly be held to the same criteria. It is important to not stifle innovation, but that shouldn’t differ for a commercial developer versus a self-developer.

**Carolyn Petersen** noted that it is important to know that the system met some type of criteria from a patient perspective.

**Ken Kawamoto** commented that it is important to think about the patient experience. In terms of things already done, a lot is completed through local configuration. His main question is: where are the places within the system used for federal programs?

**Les Lenert** noted that application programming interfaces (APIs) and SMART on fast healthcare interoperability resources (FHIR) are adding to diversity, but it is important to maintain certification for federal programs. The focus should be on maintenance and certification issues which will require attention from the institutions involved and is the focus of the task force. He emphasized the importance of identifying and sharing the risk of unintended consequences.

**Raj Ratwani** emphasized the importance of there being a base-level of safety regardless of whether it is a self-developer or not.

**Carolyn Petersen** asked for clarity on what was being proposed.

- **Les Lenert** commented that there are requirements that self-developers shouldn’t have imposed upon them compared to commercial developers. His greatest concern is in regards to maintenance of certification. He suggested certifying once and then having the ability to maintain certification for an extended period of time which would be different than with commercial developers.
- **Raj Ratwani** expressed that whether it is a commercial or self-developer, safety is the priority. If it isn’t touching safety, he agrees with Les.
- **Ken Kawamoto** suggested advising ONC on the types of items to be considered, as he wasn’t sure that a complete recommendation written by the task force would be possible.
- **Sasha TerMaat** suggested that this might be more about the number of users. If there are only 20 users and the requirement is ten users need to be tested, this would be incredibly burdensome. In contrast, if a self-developed product has the same number of users as a commercial product, the reliability is much more significant. She suggested that there be something added to the recommendations about the types of testing and considering testing considerations when there is a small number of users.

**John Travis** shared a strawman to help the discussion.

**Sasha TerMaat** noted that this should be a floor, not a ceiling.

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

## Public Comment

There was no public comment.



## Next Steps and Adjourn

**Denise Webb** asked the task force to make their changes in the shared document so that during the next meeting the group can review and finalize.

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