Meeting Notes

Health Information Technology Advisory Committee
Conditions and Maintenance of Certification Requirements Task Force
March 21, 2019, 9:30 a.m. – 10:30 a.m. ET
Virtual

The March 21, 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 9:30 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

MEMBERS NOT IN ATTENDANCE

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:

- o "API," "real world testing," and "attestations" conditions and maintenance of certification requirements
- o 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")
- o Modifications to the ONC Health IT Certification Program (Program)
- o Deregulatory actions related to certification criteria and Program requirements

HITAC Debrief

Denise Webb reviewed the preamble section of the notice of proposed rulemaking (NPRM) that discusses self-developers.

The final rule establishing ONC's Permanent Certification Program, "Establishment of the Permanent Certification for Health Information" (76 FR 1261), addresses self-developers. The language in the final rule describes the concept of "self-developed" as referring to a Complete EHR or EHR Module designed, created, or modified by an entity that assumed the total costs for testing and certification and that will be the primary user of the health IT (76 FR 1300). Therefore, self-developers differ from other health IT developers in that their products are not made commercially available and they do not have customers. While we propose that all general Conditions and Maintenance of Certification requirements apply to such developers, we also seek comment on which aspects of the Conditions and Maintenance of Certification requirements may not be applicable to self-developers. For example, when considering the Communications Condition of Certification, a self-developer of health IT may not have customer contracts, but could have other agreements in place, such as NDAs, that would be subject to the Condition of Certification.

Denise Webb shared that the information blocking task force covered this for self-developers, but have asked this group to discuss the remaining items that might not be applicable for self-developers. An example of the self-developers is a health system.

Les Lenert commented that this is a heavy lift to start with and is anti-competitive.
- Denise Webb agreed but noted that this is not what this group is being asked to do.

John Travis commented that there is an accountability point beyond that they are just trying to do it for themselves. It isn't without consequence, as some health systems may do this to meet requirements for alternative payment models, for example. There needs to be accountability for information blocking.
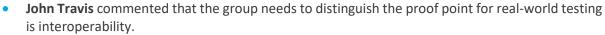- **Les Lenert** mentioned limiting to patient-facing requirements.
- **Denise Webb** noted that this goes beyond the modules that are certified for information blocking.
- **John Travis** commented that if they are a provider, they are already subject to information blocking as a provider. Real world testing is underscoring the certified capability. It may be important to retain if the goal is to ensure that the module is up to the claims of being certified.

Denise Webb asked if the group believed that self-developers should be subject to real-world testing?
- **Les Lenert** agreed that it applies to the degree it is deployed in the organization.

- **John Travis** commented that the group needs to distinguish the proof point for real-world testing is interoperability.
- **Les Lenert** expressed concern that this is an opportunity to squash innovation.
- **Raj Ratwani** commented that aspects of this may apply, but additional information may be needed. There needs to be work done to talk to people to understand concerns more deeply than what might be submitted via comment.

Carolyn Petersen noted that groups who do specialized things might be the groups who are interested in self-developing. Concerned about limiting specific needs that are not well served by a commercial vendor.

- **Les Lenert** agreed with this comment. The question is when does the certification criteria become an undue barrier for innovation? He questioned how to streamline the process so that innovation is not stifled.
- **Sasha TerMaat** noted there is flexibility in the current program that those with specific needs would only certify to specific modules. This scenario is accommodated in the current certification program. If one of these products is used for interoperability, it needs to be tested in the real world the same way a consumer product would be.

John Travis commented that the same path needs to be followed for both self-developers and commercial developers.

- **Les Lenert** noted that he would agree to disagree, as a representative of educational institutions.

John Travis commented that this rule was designed to regulate against bad behavior of commercial behaviors. There is potential for unintended consequences for self-developers if applied the same way. ONC needs to address a provider organization that plays both the provider and self-developer role. A self-developer does not get into this to be regulated this heavily. ONC will need to figure out if there should be different applicability for self-developers.

Les Lenert suggested a world where innovative products are used alongside a commercial product. This is an area where innovation cannot be lost.

- **John Travis** commented that this is an important point to register.

Denise Webb suggested that the group recommends that the conditions of certification and maintenance apply to self-developers; however, the other Task Force members suggested the following should be kept in mind:

1. Par level real world testing for interoperability. Reinforce the ability to point to use and participation of health information exchange as an option.
2. Maintain or provide for moderation of burden to self-developers seeking certification when applying conditions of certification to them.
3. ONC should evaluate the application of conditions of certification to self-developed products seeking certification.

Sasha TerMaat started to draft the comments that were shared during the discussion in the Google document (and are noted in 1-3 above).

- **Denise Webb** asked the members to go into the shared document to help refine the language prior to the next meeting.

Lauren Richie opened the lines for public comment.

Public Comment

There was no public comment.

Comments in the public chat

Sasha TerMaat: Which document are we working on today, is it DRAFT CMC TF Recommendations_3-12-2019?

Kate Tipping: yes

Sasha TerMaat: Thanks Kate.

Sasha TerMaat: I am taking discussion notes in that document.

Next Steps and Adjourn

The next CMCTF meeting is on Thursday, March 28 at 12:00 p.m. ET.

Lauren Richie adjourned the meeting at 10:30 a.m. ET.