Meeting Notes
Health Information Technology Advisory Committee
Conditions and Maintenance of Certification Requirements Task Force
March 6, 2019, 3:00 p.m. – 4:00 p.m. ET
Virtual

The March 6, 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 3:00 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

Denise Webb, Co-Chair, Individual
Raj Ratwani, Co-Chair, MedStar Health
John Travis, Member, Cerner

MEMBERS NOT IN ATTENDANCE

Kensaku Kawamoto, Member, University of Utah Health
Leslie Lenert, Member, Medical University of South Carolina
Carolyn Petersen, Member, Individual
Sasha TerMaat, Member, Epic

ONC STAFF

Stephanie Fiore, ONC
Cassandra Hadley, HITAC Back Up/Support
Christopher Monk, ONC SME
Lauren Richie, Branch Chief, Coordination, Designated Federal Officer
Kate Tipping, ONC Conditions of Maintenance of Certification Requirements Task Force Lead

Call to Order

Lauren Richie turned the meeting over to the co-chairs.

Review of Roster and Charge

Kate Tipping, ONC 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

Raj Ratwani, co-chair, noted that during today's discussion real-world testing will be discussed following up from the discussion on March 5, 2019.

Real World Testing Discussion

CONDITIONS OF CERTIFICATION

- Requires that health IT developers have successfully tested the real-world use of the technology for interoperability in the type of setting in which such technology would be marketed
- This Condition of Certification applies to health IT developers with Health IT Module(s) certified to certain certification criteria focused on interoperability and data exchange (i.e., §§ 170.315(b), (c)(1) through (c)(3), (e)(1), (f), (g)(7) through (g)(11), and (h))

MAINTENANCE OF CERTIFICATION

- Health IT developers must submit publicly available prospective annual real-world testing plans and retrospective annual real world testing results for certified health IT products focused on interoperability
- Standards Version Advancement Process: permits health IT developers to voluntarily use newer versions of adopted standards. Please also see the Standards Version Advancement Process fact sheet for more details.

Discussion

ONC asked for comment on whether to include patient health information capture.

- **John Travis** commented that he wasn't sure if it fits well, but there isn't anything wrong with it. Perhaps this is an option item.
- **Denise Webb** shared a concern for testing in the real world with public health agencies and all the states in the nation. It points out a concern mentioned yesterday about the broadness. There are no guardrails around what the testing has to cover. There is a concern around the broadness of this. It would help vendors if there was some type of guardrail around settings.
  - **Raj Ratwani** noted it is deliberately broad. He suggested that there be a templated test plan for vendors to follow. A suggested template could help this process and is a nonregulatory way of handling some of this.
  - **Raj Ratwani** commented that is the goal of testing will determine a lot of these items.

(b) Maintenance of Certification

(1) Real world testing plan submission. A health IT developer must submit an annual real-world testing plan to its ONC-ACB via a publicly accessible hyperlink no later than December 15 of each calendar year for each of its certified 2015 Edition Health IT Modules that include certification criteria referenced in paragraph (a) of this section.

- **Raj Ratwani** noted that Sasha TerMaat shared yesterday that she had concerns about a year-end date due to the holidays.
- **John Travis** commented that the anniversary date for certification could be a potential alternative, rather than certifying at the end of the year.
- In general, the CMCTF decided that the date should be revisited.

(ii) The plan must include all health IT certified to the 2015 Edition through August 31st of the preceding year.
(ii) The plan must address the following for each of the certification criteria identified in paragraph (a) of this section that is included in the Health IT Module's scope of certification:

- (A) The testing method(s)/methodology(ies) that will be used to demonstrate real-world interoperability and conformance to the certification criteria's requirements, including scenario- and use case-focused testing;
    - o **Raj Ratwani** noted there is a lot of confusion around this. Clarification around scenario, use case, and workflow is needed. Is this about testing the exchange of information or about testing the exchange and use of the information? Testing the use requires a human element. If testing use, providers would need to be involved because they would need to digest the information being exchanged.
        - **John Travis** commented that it is dealing with recording and use. He believes ONC wants it distinguished from what certification would have accomplished; the goal is that it is grounded in real-world use.
        - **Raj Ratwani** shared that clarification is needed on whether the information is usable and useful to the provider and patient it is being sent to. It seems that the point of real-world testing is to get to information that is usable and useful.
        - **Denise Webb** commented that based on yesterday's conversation, there need to be better estimates for the level of effort if the provider is engaged.
    - o **John Travis** if the requirements don't change, he suggested the following alternatives:
        - A regression approach
        - An attestation to things not having changed
        - Actual production performance that would allow leverage from the fact that the capability is already implemented
        - A menu of flexibility that could be deemed acceptable, rather than insisting that it has to be use case testing every year.

- (B) The care setting(s) that will be tested for real-world interoperability and an explanation for the health IT developer's choice of care setting(s) to test;

- o **John Travis** commented that in the past there were sources that could be examples (e.g., hospital and ambulatory). Vendors should be testing on a consistent level. Higher levels of provider taxonomy should be considered. There will need to be conditions that govern that nothing changed. If it isn't a new capability and was part of a prior year testing, there needs to be an ability to allow for efficient regression testing (e.g., test again, but don't need to be as formalized because already went through the process).
  - o **Raj Ratwani** noted that if it is about the exchange of information, there might be other ways this could be done. If the goal is to get to usability, provider participation will be needed. **Denise Webb** shared that vendors don't want the government to be overly prescriptive. She recommends that there be a pilot year because it would serve the entire community well.

- (C) The timeline and plans for any voluntary updates to standards and implementation specifications that the National Coordinator has approved through the Standards Version Advancement Process.
- (D) A schedule of key real-world testing milestones;
- (E) A description of the expected outcomes of real-world testing;
- (F) At least one measurement/metric associated with the real world testing; and
- (G) A justification for the health IT developer's real-world testing approach.
  - o **Raj Ratwani** commented that these items need a template or guidelines related to what this might look like.
  - o **John Travis**, in regards to measurement, need to define what it is.

Public Comment

There was no public comment.

Comments in the public chat

Next Steps and Adjourn

The meeting was adjourned at 3:58 p.m. ET. The next meeting will be on March 7, 2019 at 10:00 a.m. ET