Meeting Notes
Health Information Technology Advisory Committee
Conditions and Maintenance of Certification Requirements Task Force
March 5, 2019, 4:00 p.m. – 5:00 p.m. ET
Virtual

The March 5, 2019, meeting of the Conditions of Maintenance of Certification Requirements Task Force of the Health IT Advisory Committee (HITAC) was called to order at 4:00 p.m. ET by Lauren Richie, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC).

Lauren Richie welcomed everyone to the Conditions of Maintenance of Certification Requirements Task Force (CMCTF). The CMCTF will be commenting on the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program notice of proposed rulemaking (NPRM).

Lauren Richie conducted roll call.

Roll Call

Denise Webb, Co-Chair, Individual
Raj Ratwani, Co-Chair, MedStar Health
Carolyn Petersen, Member, Individual
Sasha TerMaat, Member, Epic
John Travis, Member, Cerner

MEMBERS NOT IN ATTENDANCE

Kensaku Kawamoto, Member, University of Utah Health
Leslie Lenert, Member, Medical University of South Carolina

ONC STAFF

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

Call to Order

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

Welcome and Introductions

Denise Webb, co-chair introduced herself to the CMCTF noting that she would be working with Raj Ratwani as co-chair.

Raj Ratwani, co-chair introduced himself and then asked the members of the CMCTF also to introduce themselves. The ONC staff providing support introduced themselves as well.

Overview of Charge

Kate Tipping, ONC reviewed the charge with 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

Workplan

Kate Tipping reviewed the workplan. Noting that by week five, draft recommendations will be finalized and presented to the HITAC on March 19-20. During week eight, recommendations will be presented to the HITAC on April 10. There will be time to refine and finalize recommendations, but the week of April 29, a final transmittal letter will be submitted to the National Coordinator on behalf of the HITAC.

Review Schedule of Topics

Raj Ratwani reviewed the workplan for the CMCTF.

- March 6 – Conditions and Maintenance of Certification
    - o Real World Testing
    - o Attestations
- March 7 – Conditions and Maintenance of Certification/Updates to 2015 Edition Criteria
    - o Application Programming Interfaces
- March 8 – Updates to the 2015 Edition Certification Criteria
    - o Electronic health information export
    - o Electronic prescribing
    - o Clinical quality measures – export
    - o Privacy and security-related attestation criteria

- Week of March 11 – Modifications to the ONC Health IT Certification Program
  - Corrections
  - Principles of Proper Conduct
- Week of March 11 – Deregulatory Actions
  - Removal of Randomized Surveillance Requirements
  - Removal of the 2014 Edition from the Code of Federal Regulations
  - Removal of the ONC-Approved Accreditor from the Program
  - Removal of Certain 2015 Edition Certification Criteria and Standards
  - Removal of Certain ONC Health IT Certification Program Requirements
  - Recognition of Food and Drug Administration Processes

Raj Ratwani shared that he and Denise would alternate roles leading each meeting.

Denise Webb noted that it was structured this way based on priority. She noted a template would be provided to assist with capturing the feedback from the CMCTF.

Sasha TerMaat shared that she was hoping to provide written comment and questioned the best way to do that.
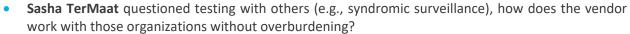- **Lauren Richie** noted that a shared Google document might be helpful.
- **Kate Tipping** has started to draft a template that can then be shared as a Google document for the group to provide feedback.

Real World Testing
- As noted in the NPRM, successful real-world testing has three things:
  1. Continued compliance with certification
  2. Exchange in intended use settings
  3. Receive and use of electronic health information in the certified electronic health record (EHR)

- **Sasha TerMaat** noted that there might be a need to adjust the success criteria to ensure alignment of what is expected.
- **John Travis** agreed with Sasha and suggested extending to include test case boundaries and additional specificity.
- **Sasha TerMaat** commented that everyone needs to understand the expected scope of testing.
- **John Travis** commented that the definition of care and practice setting is unclear in the NPRM.
- **Raj Ratwani** shared that he has a concern about the level of rigor of the cases, key criteria that should be embedded in the cases. While they don't want to be too specific, there does need to be some guidance.
- **John Travis** noted that the format for certain items would not vary based on care setting.
- **Sasha TerMaat** shared that she was struggling to find the balance with production like settings, to not overburden providers, but to also have realistic data in production like settings.
  - **Raj Ratwani** questioned if there are human actions that come into play as well? Does that get in the way of what is being tested and is that a potential challenge?
  - **Sasha TerMaat** noted that if providers are involved, ONC needs to adjust the impact estimates.

- **Sasha TerMaat** questioned testing with others (e.g., syndromic surveillance), how does the vendor work with those organizations without overburdening?
  - o **John Travis** noted that someone needs to stand in the role of recipient. Are third-party trading parties going to need to be engaged? There are a lot of questions about who is playing this role.
- **John Travis** suggested a pilot year for 2020, given the timing of the final rule to get people used to a rhythm.
- **Sasha TerMaat** mentioned scenario and use case testing. What are the advantages of scenario based-test versus using other types of testing methods that might apply to what is being tested?
  - o **Raj Ratwani** questioned if these were defined in the NPRM. He noted confusion by the use of scenario and use case testing because these are typically used interchangeably.
- **John Travis** noted that better elaboration on test case design is needed. How much discretion is being given to the vendor?
- **John Travis** noted that there is an annual testing, but if something doesn't change there should be recognition granted because nothing has changed since prior testing. He suggested a regression requirement. Perhaps the vendor has to attest that the capability has been maintained?
  - o **Sasha TerMaat** agreed with John Travis. She did express concern for deadlines at the end of the year which causes problems due to the holidays. Perhaps there is something that could be done to alter to a different time of year.
- **Sasha TerMaat** didn't understand how participation metrics were relevant to use case-based testing.
- **Raj Ratwani** noted that if the provider is interacting with the technology, it makes sense for it to be use case based. If not focused on human interaction, not sure how much the variability in use cases matters.

Raj Ratwani recapped the items discussed during the discussion:

- Greater clarity is needed overall
- What does real world testing mean?
- Working with a provider organization? Or is the vendor driving the testing?
- How is care in practice setting defined?
- How are the test cases defined?
- Who would the testing partner be?
- How much can the testing be leveraged if the requirement doesn't depend on care and practice setting?
- Greater clarity is needed related to what the type of testing should look like (e.g., scenario-based, workflow)

Sasha TerMaat and **John Travis** committed to sharing notes related to the items discussed during today's meeting.

Denise Webb noted that related to care settings, the NPRM notes that it is up to the developer.
- **John Travis** noted that guidance is needed regarding that choice.

Lauren Richie transitioned to public comment.

Public Comment

There were no public comments.

Next Steps and Adjourn

The meeting was adjourned at 5:00 p.m. ET