Meeting Notes
Health Information Technology Advisory Committee
Conditions and Maintenance of Certification Requirements Task Force
March 7, 2019, 10:00 a.m. – 12:00 p.m. ET
Virtual

The March 7, 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 10:00 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

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

MEMBERS NOT IN ATTENDANCE

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

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 called the meeting to order and turned the meeting over to the co-chairs.

Review of 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

Attestation

Denise Webb reviewed what was in the notice of proposed rulemaking (NPRM) for attestation.

CONDITIONS OF CERTIFICATION

- A health IT developer must provide an attestation, as applicable, to compliance with the Conditions and Maintenance of Certification, except for the "EHR reporting criteria submission" Condition of Certification.

MAINTENANCE OF CERTIFICATION

- Health IT developers must submit their attestations every six months

Discussion

- **Sasha TerMaat** questioned the 14-day submission period, confused that there wasn't just a deadline identified. She suggested that ONC sets a deadline, saying it has to happen within 14 days is prescriptive and unnecessary.
  - o **Carolyn Petersen** noted that a 14-day period can create more hassle due to unforeseen events.
  - o **Denise Webb** agreed with Carolyn and Sasha's comments. She asked Kate Tipping to follow-up with any additional information regarding the choice to set the 14-day period.

Denise Webb transitioned to the discussion of APIs.

Application Programming Interfaces

- ONC proposes to adopt a new API criterion in § 170.315(g) (10), which would replace the "application access – data category request" certification criterion (§ 170.315(g)(8)) and become part of the 2015 Edition Base EHR definition. This new certification criterion would require the use of Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standards and several implementation specifications.

- Supports two types of API-enabled services:
  - o Services for which a single patient's data is the focus
  - o Services for which multiple patients' data are the focus

Discussion

- **Sasha TerMaat** noted that there is not a standard way to share multiple patients' data. She questioned whether there is a better investment of industry time to work on standardizing and then implement at a later date.
  - o **Carolyn Petersen** expressed concern about the timing of standardization.
  - o **Sasha TerMaat** shared her concern that with no standard, each developer will implement differently. This could introduce waste because at some point in the future there will be a need to move to a standard way, for it to be more effective. If already invested in different ways, the transition could be harder.
  - o **Carolyn Petersen** still expressed concern that this will not move forward.
  - o **Raj Ratwani** commented that he understands the point Sasha is making, but is also concerned about how to move this forward.

Which FHIR Release?

  - o **John Travis** commented that he knows there is a lot of support for FHIR release 4, but will need to follow-up for more details regarding the merits of the different options.
  - o **Sasha TerMaat** agreed to follow-up with her team for more information too.
  - o This topic will be revisited during Monday's meeting, March 11 at 9:00 a.m.

Application Programming Interfaces - § 170.404

API Technology Roles Discussion

- The CMC TF recommends a more explicit statement of the acceptable relationship between an API technology supplier and user.

Discussion – "National Coordinator could leave the FHIR standard version the same and approve a new version of the ARCH to include more FHIR resources"

- **John Travis** shared there is a lot of redundancy with the United States Core Data for Interoperability (USCDI) required data classes. There is no value add with adopting ARCH.
- **Sasha TerMaat** noted that there is value in everyone adopting the same service, it is useful to specify the resource expected and the implementation guides that need to be followed.
- **Denise Webb** commented that implementation guides help ensure everyone is on the same page. She recommends that this goes forth with specified guidance for implementation.

Specific Proposals

Discussion - Adoption of standards for app authorization

- **Sasha TerMaat** commented that there needs to be a provision to ensure that the app can keep a secret, but that is not provided for in the current process. She recommends addressing the legitimate and expected activity for SMART Guide - protect patient's data. Need clarity that the technology

provider knows that the app can keep a secret (e.g. attestation from API user). Alternatively, if the API technology supplier doesn't play the role, will the API data provider play that role and how will they make the determination?

Discussion - Data response

- While there was a discussion about this topic from the CMCTF, most of the concern would fall under the USCDI Task Force.

Search Support Discussion

- **Sasha TerMaat** noted this brings up the same issue (identified above) related to no standards for multiple patients.

Application (App) Registration Discussion

- There was a lot of discussion about this item.
- **Denise Webb** suggested that John Travis and Sasha TerMaat provide a recommendation for how to best move forward.
- **Carolyn Petersen** suggested that ONC help provide a more consistent registration experience.

Secure connection, authentication and authorization

- There were no concerns from the CMCTF.

TRANSPARENCY

- ONC has proposed that API Technology Suppliers make business and technical documentation necessary to interact with their APIs in production freely and publicly accessible.

Discussion
- **Denise Webb** commented that six months might conflict with the 24 months.

ONC asked for comment and recommendations on factors that would enable registration with minimal barriers.
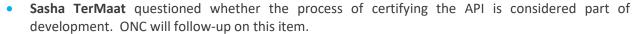
- **Sasha TerMaat** expressed a number of concerns around liability.
- **Sasha TerMaat** suggested that ONC provide additional clarity if it exists. If it doesn't exist, the CMCTF should comment that additional clarity is needed.

PERMITTED FEES

- ONC has proposed to adopt specific conditions that would set boundaries for the fees API Technology Suppliers would be permitted to charge and to whom those permitted fees could be charged.

Discussion

- **Sasha TerMaat** questioned whether the process of certifying the API is considered part of development. ONC will follow-up on this item.
- **Sasha TerMaat** questioned what is expected on page 262 of the NPRM.
  - **Denise Webb** asked John Travis and Sasha TerMaat to provide additional information if more clarity is needed.

PRO-COMPETITIVENESS (pages 264-270)

- ONC has proposed that API Technology Suppliers would have to comply with certain requirements to promote an open and competitive marketplace.

Discussion

- **Denise Webb** noted there is an incorrect reference on page 264, Openness and Pro-competitive Conditions should be v. not iv.
  - This reference is also incorrect, VIII.C.4.b within this section.

Lauren Richie opened the lines for public comment.

Public Comment

There was no public comment.

Next Steps and Adjourn

The meeting was adjourned at 11:46 a.m. ET. The next meeting will be on March 8, 2019 at 3:00 p.m. ET. During this meeting, there will be a discussion on the updates to the 2015 Certification Criteria.