Meeting Notes

Health Information Technology Advisory Committee
Conditions and Maintenance of Certification Requirements Task Force
April 05, 2019, 3:00 p.m. – 4:00 p.m. ET
Virtual

The April 05, 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

MEMBERS IN ATTENDANCE

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

MEMBERS NOT IN ATTENDANCE

Denise Webb, Co-Chair, Individual

ONC STAFF

Lauren Richie, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC)
Avinash Shanbhag, ONC SME
Kate Tipping, ONC Conditions of Maintenance of Certification Requirements Task Force Lead
Lauren Wu, ONC SME

Call to Order/Roll Call

Lauren Richie turned the meeting over to Kate Tipping.

Discussion of Recommendations

Kate Tipping noted that Avinash Shanbhag was on the call to answer any questions that members might have. She turned the meeting over to Raj Ratwani, co-chair.

Raj Ratwani noted that the group left off on Recommendation 22.

Ken Kawamoto asked about the state of the bulk data specification and its maturity. He questioned if it was ready to be included as a requirement.

- **Avinash Shanbhag** Health Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR) bulk application programming interface (API) was developed about a year and a half ago. It is currently balloted in Release 4. The security component (back-end guide) will be balloted at the May HL7 meeting.
- **Ken Kawamoto** suggested that if ONC goes with FHIR Release 4, he questioned if it is mature enough to incorporate in the rule.
- **Avinash Shanbhag** noted that it has been in development for over a year, so it has reached maturity, (at least in his mind) but it is up to the group to decide.
- **Sasha TerMaat** asked if it was just tested in a connect-a-thon or has it been implemented in the real world.
- **Avinash Shanbhag** noted that it will be implemented in the coming months.
- **Sasha TerMaat** commented that it is undesirables to implement bulk data queries in nonstandard ways which is one of the advantages of FHIR Release 4. May need to think about a timeline for things that may already be implemented.
  - ○ **Ken Kawamoto** agreed and noted that production implementation experience is necessary.

Based on the discussion, Recommendation 20 was updated with the language that follows in red.

Recommendation 20: The CMC TF has concerns over ONC not proposing a standard way for a request for multiple patients' data and recommends ONC specify a standard approach that is available in FHIR R4. There are concerns because each developer could implement this differently and invest time in non-standard ways and then likely have to spend time/money transitioning to standard way. The CMC TF also recognized there is an immediate need now to satisfy this type of request. If ONC identifies R4 FHIR for implementation, the standard method could be used for bulk queries but on a different timeline than implementation of more established R4 implementation guides. The Task Force would like to see successful implementations prior to requiring adoption across the industry.

Raj Ratwani transitioned the conversation to Recommendation 22.

Recommendation 22: ONC should further clarify the requirements and expectations around the app registration condition of certification based on a number of issues the CMC TF identified regarding app registration. The CMC TF recommends clarification in the rule that would address the following:

- What the practice of "registration" consists of and does not consist of and who is the party responsible for keeping a list of registered apps.
- What "verifying the identity" of an API user consists of and does not consist of and who is the party responsible for performing this. If this is optional, specify that those who haven't performed it are clearly excused from possible cases where API users misrepresent themselves.
- What "vetting" an app (in contrast to verifying identity of a user) consists of and what falls outside the definition of vetting and who is the party responsible for vetting and who is prohibited from vetting. If vetting is optional and not performed, specify that those who haven't performed it are clearly excused from any possible consequences attributable to poorly designed or malicious apps.
- Identifying any tasks (such as an API Data Provider whitelisting a particular app for the first time or an API Data Provider endorsing particular apps) that fall outside of "registration," "identity

verification," and "vetting." Describe the tasks, and identify the parties that can and cannot perform them. If they aren't performed, provide clarity that the party is not liable.

Sasha TerMaat noted that based on the discussion the group decided that existing security protections should mitigate the risks. Overall, there is a general concern about application (app) vetting which is addressed above in the recommendation.

John Travis expressed concern about Recommendation 23. Based on this discussion, the items in red were added to the recommendation below.

Recommendation 23: ONC should provide clarity around the scope of the EHI export. The CMC TF recommends it be limited to EHI collected and retained by the certified EHR technology and apply only to the EHI that is part of the legal medical record. Narrowing to the legal medical record was important in particular for research data stored in an EHR.

The Task Force additionally discussed the concerns of product scope and certification scope in cases where the legal medical record might not be applicable or might remain broader than a particular product's scope.

An alternative proposal is to have developers provide a plain language definition of EHI held by their certified HIT module and to use that as part of their export documentation. This plain language definition could also exclude information typically excluded from a legal medical record that concerned the task force, such as exporting incomplete information (a half-finished note for example) or research information (where exporting might invalidate a clinical trial in process). This alternative might address concerns raised about a legal medical record not being an existing definition under HIPAA in the original proposed recommendation.

Raj Ratwani transitioned to Recommendation 27.

John Travis had a number of concerns. As an example, as proposed the criteria are too broad and unwieldy. These appeal to different audiences (i.e., pharmacy only, prescriber, long-term care).
- **Sasha TerMaat** agreed with John Travis' concerns. Based on these concerns the recommendation was updated as follows.

Recommendation 27: ONC should make e-Rx transactions that are not applicable to all settings and/or need piloting optional. If all transactions are required, this could jeopardize the timeline specified for availability/production use.

Prescriber applicable:
- NewRxRequest
- NewRxResponseDenied
- RxFillIndicatorChange
- RxChangeRequest, RxChangeResponse
- RxRenewalRequest, RxRenewalResponse (note this is also new, and could be implemented after 1/1/2020 without loss of current functionality)

Optional prescriber applicable:
- REMSInitiationRequest
- REMSInitiationResponse
- REMSRequest
- REMSResponse

LTC only:
- Resupply
- DrugAdministration
- Recertification

Pharmacy only:
- RxTransferRequest
- RxTransferResponse
- RxTransferConfirm

Not applicable:
- GetMessage. Get Message is an obsolete method of message retrieval that essentially is unused since intermediated electronic transacting came into being through RxHub and SureScripts back about 2007 or 2008.

Sasha TerMaat was asked to add additional language to Recommendation 28; the additional language is in red below.

Recommendation 28: ONC should update the quality measurement proposal per the table below.
ONC proposes that all products adopt both the CMS ambulatory IG for QRDA III and CMS inpatient IG for QRDA I. If this change is not made, developers will not know how to comply to irrelevant requirements for QRDA in domains where they don't make sense. Inpatient Implementation Guides include hospital information (for example, hospital identifiers) that would not be relevant to an ambulatory context and vice versa. We see this as an important technical correction for quality reporting use cases.

Raj Ratwani reviewed the last item in regard to self-developers. Denise Webb proposed the following recommendation and the group agreed to move forward with this language as an official recommendation.

Proposal: Conditions and maintenance of certification apply to all developers of certified health IT, including self-developers. In particular:
1. Par level real-world testing for interoperability. Reinforce 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.
4. ONC should carefully weigh the benefits and costs of regulating self-developed products beyond certification purposes, as the referenced FDA Pre-Certification process is being considered for such purposes. Excessive regulation may lead to net harms to patients by stifling innovation.

Raj Ratwani asked the group for their approval on the recommendations to move forward with presenting these recommendations to the HITAC on April 10. The CMCTF approved the recommendations.

Kate Tipping volunteered to update the recommendations in the letter to the committee and distribute for final review.

Lauren Richie opened the lines for public comment.

Public Comment

There was no public comment.

Comments in The Public Chat

Sasha TerMaat: Apologies, I just joined. This is Sasha.

Lauren Richie: tx

John Travis: I have joined as of about 5 minutes ago

Lauren Richie: tx

Next Steps and Adjourn

Lauren Richie adjourned the meeting at 4:00 p.m. ET.