Meeting Notes

Health Information Technology Advisory Committee
Conditions and Maintenance of Certification Requirements Task Force
March 8, 2019, 3:00 p.m. – 4:30 p.m. ET
Virtual

The March 8, 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
Leslie Lenert, Member, Medical University of South Carolina
Carolyn Petersen, Member, Individual
Sasha TerMaat, Member, Epic
John Travis, Member, Cerner

MEMBERS NOT IN ATTENDANCE

Raj Ratwani, Co-Chair, MedStar Health
Kensaku Kawamoto, Member, University of Utah Health

ONC STAFF

Stephanie Fiore, ONC
Christopher Monk, ONC SME
Lauren Richie, Branch Chief, Coordination, Designated Federal Officer
Kate Tipping, ONC Conditions of Maintenance of Certification Requirements Task Force Lead

Review of Charge

Kate Tipping shared that Steve Posnack will be doing a presentation on application programming interfaces (API) on March 13. More details can be found on the ONC website.

She then 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:

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

Discussion of Updates to the 2015 Edition Certification Criteria

Kate Tipping provided an overview of the changes and updates to the 2015 Certification Criteria.

Proposed Changes to the 2015 Edition Certification Criteria

- Removed certain criteria because they are sufficiently widespread among health care providers since they have been part of certification and the Certified EHR Technology definition since the 2011 Edition and have not substantively changed and it is unlikely that developers will remove them.
- Items removed include:
  - Problem list (§ 170.315(a)(6))
  - Medication list (§ 170.315(a)(7))
  - Medication allergy list (§ 170.315(a)(8))
  - Smoking status (§ 170.315(a) (11))
  - Drug formulary and preferred drug list checks (§ 170.315(a) (10)
  - Patient-specific education resource (§ 170.315(a) (13))
  - Common Clinical Data Set summary record – create (§ 170.315(b)(4))
  - Common Clinical Data Set summary record – receive (§ 170.315(b)(5))
  - Secure messaging (§ 170.315(e)(2))
- Updated items include the criteria below:

Remove	Update with
Electronic prescribing (§ 170.315(b)(3))	Electronic prescribing (§ 170.315(b)(11))
Data export (§ 170.315(b)(6))	Electronic health information (EHI) export (§ 170.315(b)(10))
Data segmentation for privacy – send (§ 170.315(b)(7))	Data segmentation for privacy – receive (§ 170.315(b)(13))
Application access – data category request (§ 170.315(g)(8))	Standardized API for patient and population services (§ 170.315(g)(10))

- Revised Criteria
  - Clinical Quality Measures (CQMs) – report criterion (§ 170.315(c)(3))
  - Common Clinical Data Set/ USCDI criteria

  - C-CDA Companion Guide criteria
  - Certification criteria that reference the minimum standards code sets
- New Criteria
  - Consent management for application programming interfaces § 170.315(g)(11)
  - Encrypt authentication credentials certification criterion § 170.315(d)(12)
  - Multi-factor authentication (MFA) criterion § 170.315(d)(13)

170.315 2015 EDITION HEALTH IT CERTIFICATION CRITERIA

Electronic health information export, Electronic prescribing, Clinical quality measures – export, and Privacy and security-related attestation criteria.

Electronic Health Information Export Discussion

- **Sasha TerMaat** suggested buckets to consider for this proposal.
  - This implies that open notes have been implemented. Any of the patients' historical notes would be part of the content that is exported which is something clinicians would want to think about.
  - As a health system implements this, how would they be sure that they were not implementing something that was not supposed to released electronically per their state laws? How does this jive with other regulations and legislation? There are particular categories of information that could be tricky.
  - As a vendor, one way to do this would be to have a query that could be edited by a health system to filter out psychiatric notes or usage restrictions on data that is stored (e.g. claims set that has a redisclosure restriction), if there is a teenage restriction.
  - She suggested a recommendation that there needs to be further elaboration due to state laws. As proposed health systems could release too much, puts them at risk for sharing too much or information blocking because they don't share enough.
- **John Travis** noted that the export needs to provide for the ability to export all of the data within the EHR Module presented for certification. He is not sure it extends to everything, but it does seem clear that it is for everything certified.
  - There is still a practical definition of what is held by certification.
  - **Sasha TerMaat** confirmed that this distinction is critical.
- There was agreement that the language needs to be clarified to understand the boundaries. Is the scope of certification or all integrated products?
- **Carolyn Petersen** noted that the context of this is patient requests for information; the trend is for patients to be able to have access to their information.
- **Sasha TerMaat** noted the importance of harmonizing state laws. It is likely that patients would feel that state laws are not in compliance with what they would necessarily want. If consumers are demanding the data, the difficulty is the concern of violating state laws; the export is easy.
- **Denise Webb** noted that it has to be designed in a way that the information can be released.
- **Sasha TerMaat** shared that manual review is how health information departments handle this today, but this doesn't jive with some of the other proposals.

We seek comment on whether this portion of the criterion should be made more prescriptive to only allow the patient and his or her authorized representative to be the requestor of their EHI, similar to how we have previously scoped such criteria as "view, download, and transmit to 3rd party" (§ 170.315(e)(1))

- Proposing the legal medical record
- **John Travis** noted that they are trying to make it broad enough to deal with different policies.
- **Sasha TerMaat** noted that no state would be able to run a query to accommodate all the variants for local state laws.

We seek comment on these exclusion categories and request feedback on what metadata elements should remain included for export, or be added to the list of data that would be allowed to be excluded in a subsequent final rule.

- **Sasha TerMaat** noted that audit logs could have issues related to the privacy of all the other party's working at the health system.
- **Denise Webb** noted that the health systems would need the audit log.
- **Sasha TerMaat** suggested it should be for the transition systems use case, but not the patient use case.

Enable a user to create an export file(s) with all of a single patient's electronic health information the health IT produces and electronically manages on that patient.

- **Sasha TerMaat** noted that health IT developers might want to offer other options for the patient because it will be delivered faster.
- **Sasha TerMaat** suggested that specific time ranges shouldn't be required because it introduces more complexity than is anticipated.

Comments regarding the two years from the effective date of the final rule

- **Denise Webb** noted that this may be better addressed by specific vendors providing comment.

Electronic prescribing

- **Denise Webb** noted that these dates won't align with the 24-month dates.
  - Narrowing the scope, it would be reasonable to do by 2020. Adding the other items would jeopardize that ability to meet these timelines.
- **John Travis** suggested scaling back what is required and making items optional.
- **Sasha TerMaat** suggested making the following changes noted in red:
  (11) *Electronic prescribing.* (i) Enable a user to perform whichever subset of the following prescription-related electronic transactions are relevant to their domain and system design and have been piloted and are ready for widespread use in accordance with the standard specified in § 170.205(b)(1) and, at a minimum, the version of the standard specified in § 170.207(d)(3) as follows:
  (A) *Optional.* Ask mailbox (GetMessage).
  (B) Relay acceptance of transaction (Status).
  (C) Error response (Error).
  (D) Create new prescriptions (NewRx, Optional: NewRxRequest, Optional: NewRxResponseDenied).
  (E) Change prescriptions (RxChangeRequest, RxChangeResponse).
  (F) Renew prescriptions (RxRenewalRequest, RxRenewalResponse).
  (G) *Optional.* Resupply (Resupply).
  (H) Return receipt (Verify)
  (I) Cancel prescriptions (CancelRx, CancelRxResponse).
  (J) Receive fill status notifications (RxFill, Optional: RxFillIndicatorChange).
  (K) *Optional.* Drug administration (DrugAdministration).

(L) *Optional.* Transfer (RxTransferRequest, RxTransferResponse, RxTransferConfirm).
(M) *Optional.* Recertify (Recertification).
(N) Request and receive medication history (RxHistoryRequest, RxHistoryResponse).
(O) *Optional.* Complete risk evaluation and mitigation strategy transactions (REMSInitiationRequest, REMSInitiationResponse, REMSRequest, and REMSResponse).
(ii) For each transaction listed in paragraph (b)(11)(i) of this section, the technology must be able to receive and transmit the reason for the prescription using the diagnosis elements in DRU Segment if that segment is supported by the standard for that transaction.
(iii) *Optional.* For each transaction listed in paragraph (b)(11)(i) of this section, the technology must be able to receive and transmit the reason for the prescription using the indication elements in the SIG Segment if that segment is supported by the standard for that transaction.
(iv) Limit a user's ability to prescribe all oral liquid medications in only metric standard units of mL (*i.e.*, not cc).
(v) Always insert leading zeroes before the decimal point for amounts less than one and must not allow trailing zeroes after a decimal point when a user prescribes medications.

Clinical Quality Measurement - report

- **Sasha TerMaat** questioned the timing of when this would take effect.
- **John Travis and Sasha TerMaat** expressed concern with ONC's proposal that all products adopt both the CMS ambulatory implementation guide (IG) for Quality Reporting Document Architecture (QRDA) III and CMS inpatient IG for QRDA I.
    - **Sasha TerMaat** noted that this is not going to work technically because the implementation guide needs to match the setting.
        - **Sasha TerMaat** provided tables to the CMCTF for how this should be updated.
- **Sasha TerMaat** noted that quality reporting in FHIR is a good future recommendation, but is not currently ready.

Encrypt authentication credentials

- **Sasha TerMaat** wondered if it publicizes something that providers don't want to have out there and can make it a vulnerability, perhaps it would make sense to only apply this for future products not retrospectively for products already in use.
- **Sasha TerMaat** suggested adding a text box for developers to describe their yes/no attestations in certification. This would also help with clarity for use cases (e.g. login, signing).

Lauren Richie opened the lines for public comment.

Public Comment

There was no public comment.

Next Steps and Adjourn

The next CMCTF will be held on Monday, March 11, 2019 at 9:00 a.m. and will be a review of modifications to the ONC Health IT Certification Program.

Lauren Richie adjourned the meeting at 4:30 p.m. ET.