Conditions and Maintenance of Certification Task Force Recommendations

April 25, 2019

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Robert Wah, co-chair
Health Information Technology Advisory Committee
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Carolyn and Robert:

The Health Information Technology Advisory Committee (HITAC) asked the Conditions and Maintenance of Certification Task Force (CMC TF or TF) to provide recommendations on certain Conditions and Maintenance of Certification Requirements, updates to most 2015 Edition certification criteria, changes to the ONC Health IT Certification Program, and deregulatory actions. This transmittal offers 35 of the 36 recommendations the TF wishes to advance to the HITAC for consideration, which are informed by the deliberations among the Task Force subject matter experts. The TF also took into consideration feedback provided by the HITAC members at the March 18 and April 10 HITAC meetings. Since the April 10 meeting, we made revisions to provide clarity on whether each recommendation is seeking changes to the final rule preamble, the regulatory text or both; and to respond to feedback provided.

1. Background

1.1. Overarching charge:

The Conditions and Maintenance of Certification Task Force will develop and advance recommendations on the "application programming interfaces (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.

1.2. Detailed charge:

Make specific recommendations on:

1.2.1. Conditions and Maintenance of Certification Requirements

Recommendations on the following Conditions and Maintenance of Certification requirements: "API," "real world testing," and "attestations."

1.2.2. Updates to 2015 Edition Certification Criteria

Recommendations on most proposed updates to the 2015 Edition certification criteria including: "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").

1.2.3. Modifications to the ONC Health IT Certification Program

Recommendations on proposed modifications to the ONC Health IT Certification Program (Program).

1.2.4. Deregulatory Actions

Recommendations on proposed deregulatory actions related to certification criteria and Program requirements including: (1) removal of a threshold requirement related to randomized surveillance which allows ONC- Authorized Certification Bodies (ONC-ACBs) more flexibility to identify the right approach for surveillance actions, (2) removal of the 2014 Edition from the Code of Federal Regulations (CFR), (3) removal of the ONC-Approved Accreditor (ONC-AA) from the Program, (4) removal of certain 2015 Edition certification criteria, (5) removal of certain Program requirements, and (6) recognition of relevant Food and Drug Administration certification processes with a request for comment on the potential development of new processes for the Program.

2. Recommendations

2.1. Overarching Recommendations

As part of our deliberations, the CMC TF discussed a number of topics relating to the proposed rule. Given the overarching nature of these topics, we felt it helpful to provide a set of general recommendations to ONC.

2.1.1. Clarity on Rationale for Maintaining a "2015" Edition

In review of the records retention requirements for ONC-ACBs, but applicable to many sections of the proposed rule, the CMC TF questioned *why* ONC proposed to modify the 2015 Edition as opposed to creating a *new* Edition. There are broad-sweeping changes to the 2015 Edition as a result of this proposed rule. By not updating to a new Edition, users of the CHPL would be confused about which version of 2015 Edition is being referenced. Also, there are records retention implications for ONC-ACBs and Health IT developers when an Edition is continually modified rather than retired and replaced by a new Edition that may require retention for an inordinate amount of time that would not otherwise be required if a new Edition is established instead when there are significant modifications to an Edition by rulemaking.

Recommendation 1: The Committee recommends ONC introduce a new Edition of certification rather than propose changes to the 2015 Edition.

HITAC vote held on 4/10/2019: Majority of HITAC Members – aye; 1 – nay; 1 – abstain

2.2 Conditions and Maintenance of Certification Requirements

2.2.1 Real World Testing

2.2.1.1 Timing of submission of real world testing plan

ONC proposes that 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 specified for this Condition of Certification. Prior to submission to the ONC-ACB, the plan would need to be approved by a health IT developer authorized representative capable of binding the health IT developer for execution of the plan and include the representative's contact information. The plan would need to include all health IT certified to the 2015 Edition through August 31 of the preceding year.

Recommendation 2: The CMC TF recommends ONC reconsider the due date for real world testing plans and provide more flexibility for the deadline to avoid holidays and avoid overloading the ONC-ACBs/federal government. The CMC TF recommends an alternative for 170.405(b)(1): instead of requiring submission of an annual real world testing plan to the ONC-ACB via a publicly accessible hyperlink no later December 15 of each year, require submission no later than the latest certification anniversary date each year for the health IT developers' applicable certified 2015 Edition Health IT Modules.

2.2.1.2 Certification Criteria Plan Must Address

Recommendation 3: The CMC TF recommends ONC provide more clarity in the final rule preamble in section VII.B.5 around the care settings/venues the test plan must cover with the goal of making minimum expectations clear and establishing which settings and the number of settings for the applicable certified Health IT Modules.

Recommendation 4: The CMC TF recommends ONC provide guidelines in the final rule preamble for a test plan. The TF supports the proposed pilot year and recommends including the pilot year in the final rule. After the pilot year, the TF suggests creation of a standardized template incorporating the elements of an acceptable test plan.

Recommendation 5: The CMC TF recommends ONC provide clarity in the final rule preamble on how successful real world testing is met for the following: (1) continued compliance with certification criteria (including standards and code sets), (2) exchange in intended use settings, and (3) receipt and use of electronic health information in the certified EHR. The TF reviewed and determined not all three elements are possible for *all* certification criteria proposed for real world testing.

2.2.1.3 Scenario and Use Case Focused Testing

The CMC TF had significant discussion on the definition of scenario testing versus use case testing and whether or not they were essentially the same.

Recommendation 6: The CMC TF recommends ONC clarify and define the terms, "scenario" and "use case" (§ 170.405(b)(1)(iii)(A)). If these terms mean the same thing, choose and use just one of these terms in the final rule regulatory text and in the preamble. In the final rule preamble, the TF also recommends ONC clarify the term "workflow" as it is used in section VII.B.5 of the proposed rule preamble regarding real world testing. The TF acknowledges the variability that exists in provider workflows and is concerned this could require an infinite number of test cases for a health IT developer's customer base. The TF recommends the final rule preamble be clear and reasonable with what is intended where the preamble states "...developers can and should design scenario-based test cases that incorporate multiple functionalities as appropriate for the real world workflow and setting."

The TF recommends ONC clarify in the final rule preamble where existing interoperability testing (such as that performed by The Sequoia Project or other existing networks) can satisfy expectations for real world testing.

Recommendation 7: The CMC TF recommends modifying § 170.405(b)(1)(iii)(A) to also include as permissible testing approaches automated testing and regression testing:

(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, use case-focused, automated, or regression testing;

Recommendation 8:

The CMC TF recommends ONC provide clarification in the final rule preamble in section VII.B.5 around testing the use of information received through exchange versus testing the exchange of information (sending and receiving). When there are no end users of the health IT product being tested, use-based testing would not be pertinent.

The TF recommends ONC expect that if health IT developers are testing the use of data received through exchange, the health IT vendors should have intended users involved in usability testing.

Users (providers) were not considered in the cost estimates for real world testing in the proposed rule preamble. Therefore, the TF recommends ONC revise real world testing cost estimates in the final rule preamble section XIV.C.2.a.3.6 to incorporate this.

To reduce cost, the TF further recommends ONC prioritize real world testing criteria based on risk.

Discussion

The CMC TF thinks testing the use of information is important to usability of interoperability. Testing the use of information received through exchange requires consideration of human factors and usability to understand whether the intended users can efficiently and effectively use the presented information.

Use of data testing would be pertinent to the receipt of data in the EHR. If health IT developers are testing the use of data received through exchange, the health IT vendors should have users involved in the testing to validate that users can process and use that information. When certified health IT products receive "foreign" data, we have heard user feedback desiring it be viewable, actionable, and reportable alongside the user's "native" data to be useful and reduce burden on providers using the technology. The intent of this TF is not to prescribe certain design approaches but to encourage user-centered design.

The TF recognizes that the expense of use-based testing is significant for both health IT developers and users of HIT. The TF significantly discussed the costs of this proposal for multiple players: vendors, the other interoperability partners who would be involved, provider organizations and users. The concern was how to prioritize where testing is helpful without unnecessarily increasing cost or burden.

Recommendation 9: The CMC TF recommends ONC clarify in the final rule preamble the expected involvement of providers and third parties to support the "real world" nature of the testing.

The TF recommends ONC provide guidance in the final rule preamble on testing options that address the use of simulated data and address requirements for unidirectional versus bidirectional test cases. For example, the final rule should clarify whether the health IT developer is required to provide testing for both endpoints/sides in a bi-directional testing scenario.

2.2.1.4 Methodology

Recommendation 10: The CMC TF recommends ONC allow in the final rule preamble for flexibility for vendors with regard to real world testing where there is no difference in the testing approach, result or capability. The TF suggests the preamble address the following:

- Common capability – test once across all settings and test cases if truly the same capability for the same requirement
- Unchanged capability – allow the vendor to attest to capabilities that remain unchanged from prior year
- Common requirement – test once if the requirement does not vary across all settings and test cases for requirements such as secure communication
- Production experience – clarify whether real world testing is required for what already has long-standing evidence and history of operating in real world production environments
- Clarify applicability of requirement for various practice and care settings. For example, clarify whether all of the named CDA/document types apply to every venue
- Attestation – allow for attestation instead of retesting

2.2.1.5 Measurement/metrics

Recommendation 11: The CMC TF recommends ONC include in the final rule preamble section VII.B.5 a description of "measurement" and provide clarity on the role of measurement and specificity for what kinds and for what purposes or proof points. The TF recommends ONC consider including updated metric expectations after the pilot year. Where the real world testing is for both interoperability and use of received data, the TF recommends ONC consider specifying in the final rule preamble section that there be at least one metric for interoperability and one metric for use, which might correspond with metrics of use used in safety enhanced design testing.

2.2.1.6 Standards Version Advancement Process

Recommendation 12: The CMC TF recommends ONC elaborate and provide more clarity in the final rule preamble section VII.B.5 on the standards version advancement process when a version of standards is available under this process but does not yet have testing tools available to determine conformance. It is fairly clear vendors must factor all claimed versions of standards into their real world testing, but the final rule preamble should clarify how the health IT developers are to address new versions for which tooling does not exist yet that they have attested to support and how the health IT developer and ONC-ACBs will judge or determine conformance. The TF further recommends ONC clarify whether testing will be required in a subsequent year's real world testing plan once tooling is available or whether the health IT developer's previous attestation is sufficient.

2.2.1.7 Other Considerations

Recommendation 13: The CMC TF recommends ONC clarify in the final rule preamble the role and expectations of third parties over which the health IT developers have no control or authority over. For example, some third parties (immunization registries) and EHR developers are likely to receive many requests to participate in other parties' real world testing. While these entities can try to be helpful, they will have limited resources to assist other groups. The TF further recommends ONC clarify whether declining to participate in real world testing is considered to be information blocking. The TF

recommends ONC consider and clarify in the final rule preamble how reasonable protections can be provided for those who have limited resources and, therefore, are unable to participate in an unlimited set of tests. The final rule preamble should provide reasonable assurances for health IT developers who have tried to engage third parties in testing yet were not successful in getting their commitment to participate.

Recommendation 14: The CMC TF recommends ONC review and revise the Regulatory Impact Analysis time estimates that would be required to ensure they accurately reflect and align with the clarified understanding of the real world testing expectations in the final rule.

2.2.2 Attestations

Recommendation 15: The CMC TF recommends ONC include a specific deadline at the middle of the year and the end of year/ beginning of year for attestations in the final rule preamble section VII.B.6. This would provide flexibility for the ONC-ACBs to work with developers to get the attestations in rather than specifying a predefined 14-day window of time which seems too prescriptive and subject to problems should the period of time fall during a holiday or government closures, etc. The TF recommends ONC consider, for example, setting the deadline for the health IT developers to submit their semi-annual attestations to the ONC-ACB to the last Friday of January and July (this avoids holidays).

2.2.3 Application Programming Interfaces

2.2.3.1 Key Terms

Recommendation 16: The CMC TF recommends ONC clarify in the final rule preamble section VII.B.4.b what is considered an acceptable relationship between the API Technology Supplier and the API User, or clarify what activities are expected or permitted to occur between the API Technology Suppliers and API Users. There are multiple relationships supported in this environment and this particular relationship is not sufficiently addressed in the proposed rule preamble. Relationships prior to the involvement of an API Data Provider are of particular interest.

2.2.3.2 Proposed API Standards, Implementation Specifications, and Certification Criterion

Recommendation 17: The CMC TF recommends ONC solely adopt FHIR Release 4 (or a subsequent 4.x version if one is created with errata) in the final rule for reference in proposed § 170.315(g)(10) (Option 4) and in the preamble section VII.B.4.c and VII.B.4.c.i. The TF is making this recommendation because FHIR Release 4 provides the first normative version, will support enhanced capabilities (such as bulk data), and will focus and unify the industry on a single release of the standard versus multiple releases of the standard.

Recommendation 18: The CMC TF recommends ONC move forward in the final rule with implementation specifications and implementation guides to ensure everyone is working from the same set of specifications as this would enhance interoperability and reduce implementation complexity and potentially cost. The TF sees value in health IT developers harmonizing to a specified version/release.

Recommendation 19: The CMC TF recommends ONC require compliance with HL7 US Core FHIR Implementation Guides (IGs) rather than specifying the Argonaut implementation guides in the final rule regulatory text § 170.215(a)(3) and (4) and preamble section VII.B.4.c.ii. Where HL7 IGs are not available for the corresponding and required Argonaut functionality, the TF recommends ONC assist in facilitating their inclusion in the HL7 US Core FHIR IGs.

2.2.3.3 Proposed Adoption of Standards and Implementation Specifications to Support Persistent User Authentication and App Authorization

Recommendation 20: The CMC TF recommends ONC address the legitimate and expected activity for SMART Guide to protect patient data with respect to providing persistent tokens to applications and the applications' ability to keep the token confidential. Someone will need to ascertain that API Users provided a persistent token are developing products that secure the token appropriately, but it is not clear who plays that role. The TF recommends the ONC clarify who it is and how the determination is made in the final rule preamble section VII.4.c.iii.

Recommendation 21: The CMC TF recommends ONC work with OCR and other responsible agencies to provide formal guidance on current uses of FHIR APIs, such as in SMART on FHIR applications or CDS Hooks services, with respect to compliance with relevant privacy and security regulations, such as HIPAA (e.g., the inappropriate sending of full patient demographic details, the inappropriate use of broadly-scoped data access tokens). This deliberation can leverage the work and recommendations of the prior HIT Policy Committee and HIT Standards Committee Joint API Task Force as a starting point (https://www.healthit.gov/sites/default/files/facas/APITF_Links_to_API_comments_and_recommendations_from_HITSC_and_HITPC_2015-11-30.docx).

2.2.3.4 Search Support

Recommendation 22: 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 will be available in FHIR R4. Otherwise, each developer could implement this differently and invest time in non-standard ways and then likely have to spend time/money transitioning to the standard way. The CMC TF also recognized that there is an immediate need now to satisfy this type of request. If ONC identifies FHIR R4 for implementation in the final rule, the FHIR R4 standard could be used for bulk queries but on a different timeline than implementation of more established R4 implementation guides that support a search for a single patient's data. The TF would like to see successful implementations of products that search for multiple patients using the FHIR R4 standard prior to requiring adoption across the industry of this 2015 Edition certification criterion for multiple patients.

2.2.3.5 Transparency Conditions

Recommendation 23: The CMC TF recommends ONC clarify what happens at 6 months and what happens at 24 months concerning publication of API documentation by revising the preamble text as specified below. The CMC TF was puzzled by requirements to update API documentation (6 months) prior to the requirement to update API capabilities (24 months).

Revise preamble text in section VII.B.4.d.iii to read: "For the purposes of the specific transparency conditions proposed in § 170.404(a)(2) and their relationship and applicability to API Technology Suppliers with products already certified to § 170.315(g)(7), (8), or (9), we propose to establish a compliance date of six months from the final rule's effective date (which would give developers approximately eight months from the final rule's publication date) to revise their existing API documentation to come into compliance with the final rule for these criteria."

2.2.3.6 App Registration/ Condition of Certification Requirements

Recommendation 24: The CMC TF recommends ONC 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 TF recommends clarification in the final rule preamble 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.

2.2.4 Applicability of Conditions and Maintenance of Certification Requirements for Self-Developers

Recommendation 25 [Placeholder]: The CMC TF will be advancing a recommendation to the HITAC for consideration at the May 13 HITAC meeting regarding the applicability of the Conditions and Maintenance of Certification requirements for real world testing, APIs, and attestations to self-developers and their certified Health IT Modules. The TF is still deliberating on this recommendation and has not come to consensus yet.

2.3 Updates to the 2015 Edition Certification Criteria

2.3.1 Electronic Health Information Export

Recommendation 26: The CMC TF recommends ONC provide clarity in the final rule preamble around the scope of the EHI export in the 2015 Edition certification criteria. The TF recommends the EHI Export scope be limited to EHI collected and retained by the certified EHR technology and apply only to the EHI that is commonly understood to be part of the legal medical record. The CMC TF further recommends that health IT developers be required to provide a plain language definition of EHI typically included in the legal medical record held by their certified Health IT Module as part of their export documentation.

Discussion:
The TF thinks narrowing the EHI export scope/certification criteria to the legal medical record is important in particular for research data stored in an EHR. The TF discussed other challenges with exporting data outside the legal medical record, including incomplete information such as a half-finished note.

The TF also acknowledged in its discussion that non-certified health IT might need similar EHI export capability to support a patient's access to his/her EHI and/or a provider's transition of its information/data to another health IT system, but the TF concluded that the information blocking provisions were sufficient to ensure health IT developers met the EHI export needs of patients and users in a similar manner and those systems should not be included in the scope of the 2015 Edition certification criteria for EHI export.

Recommendation 27: The CMC TF recommends ONC clarify in the final rule preamble section IV.B.4 that the export process must accommodate manual review by the API Data Provider to comply with state/local laws prior to being released. A state may have laws prohibiting release of certain EHI to a patient and the EHI export process would need to accommodate compliance.

Recommendation 28: The CMC TF recommends ONC include audit log data for the EHI Export transitions between health IT systems use case (but not for the EHI Export patient use case due to privacy of health system staff) in the final rule preamble section IV.B.4.

Recommendation 29: The CMC TF recommends ONC not require in the final rule preamble section IV.B.4 that the EHI export criterion include capabilities to permit health care providers to set date ranges/specific time period for EHI export due to the complexity experienced by health IT developers in complying with date range/time period flexibility in the View, Download, Transmit certification criterion. Additionally, patients should have access to all of their data regardless of time period.

2.3.2 Electronic Prescribing

Recommendation 30: The CMC TF recommends ONC make in the final rule regulatory text § 170.315(b)(11) and preamble section IV.B.2 e-Rx transactions optional that are not applicable to all settings and/or need piloting. If all transactions are required, this could jeopardize the timeline specified for availability/production use. The TF recommends the revisions below:

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.

2.3.3 Clinical Quality Measures – Export

Recommendation 31: The CMC TF recommends ONC update the clinical quality measurement proposal in the final rule regulatory text § 170.315(c)(3) and preamble section IV.B.3 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 with requirements for QRDA in domains that are not relevant to the care settings supported by their products. Inpatient Implementation Guides include hospital information (for example, hospital identifiers) that would not be relevant to an ambulatory setting and vice versa. We see this as an important technical correction for quality reporting use cases.

	All Products
QRDA I Export	Inpatient CMS IG

Instead, the TF recommends the adoption requirements look like:

	Products for Ambulatory Settings	**Products for Inpatient Settings**
QRDA I Import	Generic	Generic
QRDA I Export	Generic	Inpatient CMS IG

Recommendation 32: The CMC TF agrees quality reporting using FHIR-enabled APIs is a good aspirational direction for ONC to take and include in future rulemaking, but they are not ready today to replace or complement QRDA reports for quality reporting and improvement.

2.3.4 Privacy and Security Transparency Attestations Criteria (Encrypt Authentication Credentials and Multi-factor Authentication)

Recommendation 33: The CMC TF recommends ONC apply privacy and security attestations only to new certifications/new products after this rule is finalized (preamble section IV.B.6), not to products already in widespread use, where the widespread publication of the attestation on these criteria might create a vulnerability and unintended consequences if malicious actors had this information about existing production systems.

Recommendation 34: The CMC TF recommends ONC add a text box for developers to describe their yes/no attestations in certification (modify final rule regulatory text in § 170.315(d)(12)(i) and (ii) and § 170.315(d)(13)(i) and (ii), and preamble section IV.B.6). This would also help with clarity for use cases (login, signing EPCS, etc.). This will allow developers to provide clarity to stakeholders as to what use cases, third party considerations, workflows, etc., that they considered when attesting yes or no. The information provided will also be useful to ONC.

2.4. Modifications to the ONC Health IT Certification Program (No Recommendations)

2.4.1 Principles of Proper Conduct

2.5 Deregulatory Actions for Previous Rulemakings

2.5.1. Removal of Randomized Surveillance Requirements

Recommendation 35: The CMC TF recommends ONC not remove the prohibition on consecutive selection of one Health IT Module in the final rule regulatory text (preserve § 170.556(c)(6)) and preamble section III.B.1. The goal is that if the proposed deregulation is implemented to remove the requirement on ONC-ACBs to conduct random surveillance, ONC-ACBs may still randomly surveil but cannot consecutively select the same Health IT Module for random surveillance more than once in a 12-month period. If through random surveillance, an ONC-ACB discovers non-conformance in a Health IT Module, they would still be able to follow up on the same Health IT Module within the 12-month period through its reactive surveillance authority.

2.5.2 Removal of Certain 2015 Edition Certification Criteria

Recommendation 36: The CMC TF recommends ONC adopt a general principle in the final rule preamble section III.B.4 of not duplicating data-capture criteria within the certification criteria (such as demographics) for data classes included in USCDI and based on this principle, the TF recommends ONC consider other criteria, such as demographics, that could also be removed and do so in the final rule.