The Office of the National Coordinator for Health Information Technology

Health IT Advisory Committee

Conditions and Maintenance of Certification Requirements Task Force: Draft Recommendations to the HITAC

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Agenda

- Task Force Members
- Task Force Charge
- Recommendations
  - Conditions and Maintenance of Certification
  - Updates to the 2015 Edition Certification Criteria
  - Deregulatory Actions
- Questions and Feedback
- Vote on Recommendations

Task Force Roster

Name	Organization	Role
Denise Webb	**Individual**	**Chair**
Raj Ratwani	**MedStar Health**	**Chair**
Carolyn Petersen	Individual	Member
Ken Kawamoto	University of Utah Health	Member
Sasha Termaat	Epic	Member
Leslie Lenert	Medical University of South Carolina	Member
John Travis	Cerner	SME

Conditions of Certification Task Force Charge

- **Overarching Charge**: Provide 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.

- **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

Overarching Recommendation

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.
- **No change - Recommendation 1:** ONC should introduce a new Edition of certification rather than propose changes to the 2015 Edition.
- ***Questions and feedback***
- ***Vote on recommendation***

Conditions and Maintenance of Certification

Real World Testing

- **No change - Recommendation 2**: ONC should reconsider the due date for real world testing plans. The CMC TF recommends ONC provide more flexibility for deadline - avoid holidays, avoid overload for ONC-ACBs/federal government. The CMC TF recommends an alternative: anniversary date tied to the certification anniversary for the CEHRT being tested.
  - The CMC TF supports the idea of a pilot year and recommends having ONC-ACBs assess plans from pilot year then come up with a template for vendors to use.

- **No change - Recommendation 3:** ONC should provide more clarity around care settings/venue to what the test plan must cover. The goal is to make minimum expectations clear in regards to applicable care settings and venues (which settings, sufficient number of settings) for the health IT product.

- **No change - Recommendation 4:** ONC should provide guidelines or a template for a test plan. The template will help the process. The CMC TF supports the proposed pilot year and recommends that ONC-ACBs assess plans from the pilot year then provide a template for vendors to use addressing the minimum requirements for an acceptable test plan.

Real World Testing

- **No change - Recommendation 5**: ONC should provide clarity around how successful real world testing is met: (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 CMC TF reviewed and determined not all three elements are possible for *all* certification criteria proposed for real world testing.

- **No change - Recommendation 6:** ONC should clarify and define the terms, "scenario" and "use case" and if these terms mean the same thing, then choose and use just one of these terms in the rule. ONC should also clarify the term "workflow" as it is used in real world testing.

- **No change - Recommendation 7:** We recommend vendors be given discretion to incorporate permissible testing approaches, including, for example, automated testing and regression testing (also possibly automated).

Real World Testing

- **No change - Recommendation 9: ONC should clarify the expected involvement of providers and third parties to support the "real world" nature of the testing.**
  - The CMC TF suggests providers using the certified technology should be involved in real world testing with the health IT developers, but the final rule needs good guidance 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.
  - If there is provider involvement, ONC should adjust provider estimates in the cost impact analysis in the proposed rule.

Real World Testing

- **No change - Recommendation 10:** ONC should allow for flexibility for vendors with regard to real world testing where there is no difference in the testing approach, result or capability.

  The CMC TF suggests:

  - 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

Real World Testing

- **No change - Recommendation 11:** ONC should include a description of "measurement." ONC should provide clarity about the role of measurement and specify for what kinds and for what purposes or proof points. After the pilot year, consider updating metric expectations: where the real world testing is of both interoperability and use of received data, consider there be at least one metric of interoperability and one metric of use, which might correspond with metrics of use used in safety enhanced design testing.

- **No change - Recommendation 12:** ONC should elaborate and provide more clarity 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 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. ONC should 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.

Real World Testing

- **No change - Recommendation 13:** ONC should clarify 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 not have unlimited resources to assist other groups. ONC should clarify whether declining to participate in real world testing is considered to be information blocking. ONC should consider 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 rule should provide reasonable assurances to health IT developers who have tried to engage third parties in testing yet were not successful in getting their commitment to participate in testing.

- **No change - Recommendation 14:** ONC should review and revise Regulatory Impact time estimates that would be required to ensure they are accurate and align to the clarified understanding of the real world testing proposal.

Real World Testing

- **Revised - Recommendation 8:** ONC should provide clarification around testing the exchange of information, or about the use of the information. Testing the use of that information requires consideration of human factors and usability to understand whether the intended users efficiently and effectively use the presented information. When there are no end users of the product being tested, use-based testing would not be pertinent.
  - » 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 providers can process and use that information. When certified health IT products receive "foreign" data, we have heard user feedback desiring it be presented in the same view as the "native" data to be useful and reduce burden on providers using the technology. The intent of this task force is not to prescribe certain design approaches but to encourage user-centered design. The CMC TF recommends use of data testing validate the data a user receives in the certified health IT is viewable, actionable, and reportable along side the user's native data. ~~, they need to have the providers involved in the testing to determine if the providers can process and use that information when there is an exchange. The providers were not considered in the cost estimates for real world testing in the proposed rule preamble.~~
  - » The task force recognizes that the expense of this testing is significant, for both health IT developers and users of health IT. Users (providers) were not considered in the cost estimates for real world testing in the proposed rule preamble.

Real World Testing

- ***Questions and feedback***
- ***Vote on recommendations***

Attestations

- **No change - Recommendation 15:** ONC should include a specific deadline at the middle of the year and the end of year/ beginning of year. It would provide flexibility for the ONC-ACBs to work with developers to get those 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. ONC could specify, for example, that the deadline for the health IT developers to submit their semi-annual attestations to the ONC-ACB is the last Friday of January and July (this avoids holidays).
- ***Questions and feedback***
- ***Vote on recommendation***

Application Programming Interfaces

- **No change - Recommendation 16:** ONC should clarify and make an explicit statement of 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. Relationships prior to the involvement of an API Data Provider are particularly of interest.

- **No change - Recommendation 18:** ONC should move forward 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 CMC TF sees value in health IT developers harmonizing to a specified version/release.

- **No change - Recommendation 20:** ONC should address the legitimate and expected activity for SMART Guide to protect patient data with respect to providing persistent tokens to applications and their ability to keep the token confidential. Someone will need to ascertain that API Users provided a persistent token are creating products that secure the token appropriately, but it is not clear who plays that role. ONC will need to clarify who it is and how the determination is made.

Application Programming Interfaces

- **No change - Recommendation 24:** 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.

Application Programming Interfaces

- **Revised - Recommendation 17:** ONC should adopt solely 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). This was recommended as the first normative version, supporting enhanced capabilities (such as bulk data), and not dividing the focus of the industry with multiple standards.

- **New - Recommendation 19:** ONC should require compliance with HL7 US Core FHIR Implementation Guides derived from the Argonaut implementation guides, rather than the Argonaut implementation guides themselves. Where HL7 Implementation Guides are not available for the corresponding and required Argonaut functionality, ONC should facilitate their inclusion as HL7 standards. This is because Argonaut is a closed membership group with no opportunity for the vast majority of stakeholders such as EHR vendors and healthcare systems to provide input, whereas HL7 is an open-member, ANSI-accredited standards development organization which enables such stakeholder input.

Application Programming Interfaces

- **New - Recommendation 21**: ONC should provide formal guidance on compliance with relevant privacy and security regulations such as HIPAA of current uses of FHIR APIs, such as in SMART on FHIR applications or CDS Hooks services (e.g., sending of full patient demographic details in all cases, the use of broadly-scoped data access tokens).

- **Revised - 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 ~~(which~~ 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 the 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.

Application Programming Interfaces

- **Revised - Recommendation 23:** ONC should clarify what happens at 6 months and what happens at 24 months. The CMC TF was puzzled by requirements to update API documentation (6 months) prior to the requirement to update API capabilities (24 months).

- Specific recommendation: revise text 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***."

Application Programming Interfaces

- ***Questions and feedback***
- ***Vote on recommendations***

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

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

- **New – *Draft* Recommendation 25:** ONC should apply the Conditions and Maintenance of Certification requirements 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.
- *The CMC TF is still deliberating on a final recommendation for the committee concerning the Conditions and Maintenance of Certification requirements (real world testing, attestations, and APIs) applicability to self-developers and welcome questions/feedback from the committee.*

Updates to the 2015 Edition Certification Criteria

Electronic Health Information Export

- **No change - Recommendation 27:** ONC should clarify 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.

- **No change - Recommendation 28:** ONC should include audit log data for transitioning systems use case (not for patient use case due to privacy of health system staff).

Electronic Health Information Export

- **Revised - Recommendation 26:** 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.

Electronic Health Information Export

- **Revised- Recommendation 29:** ~~ONC should not require specific timeframe restrictions for data export, due to complexity experienced by health IT developers complying with the time frame flexibility/time frames in the View, Download, Transmit certification criterion.~~ The CMC TF recommends ONC not require 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.

Electronic Health Information Export

- ***Questions and feedback***
- ***Vote on recommendations***

Electronic Prescribing

- **Revised - Recommendation 30:** 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. The CMC TF recommends the revisions below:

~~(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).~~

Electronic Prescribing

(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.

Electronic Prescribing

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

Electronic Prescribing

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.

Electronic Prescribing

- ***Questions and feedback***
- ***Vote on recommendation***

Clinical Quality Measures - Export

- **Revised - Recommendation 31:** 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 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 import	Inpatient CMS IG
QRDA I EXport	Inpatient CMS IG
QRDA III export	Ambulatory CMS IG

Instead, the CMC 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
QRDA III export	Ambulatory CMS IG	Generic

Clinical Quality Measures - Export

- **No change - Recommendation 32:** The CMC TF agrees quality reporting using FHIR is a good aspirationall direction to take and a future recommendation, but it is not ready today.
- ***Questions and feedback***
- ***Vote on recommendations***

Privacy and Security-Related *Attestation* Criteria

- **Revised - Recommendation 34:** ONC should add a text box for developers to describe their yes/no attestations in certification. 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.

- **No change - Recommendation 33:** ONC should apply privacy and security attestations only to new certifications/new products after this rule is finalized, 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.

- ***Questions and feedback***

- ***Vote on recommendations***

Deregulatory Actions

Deregulatory Actions

Removal of Randomized Surveillance Requirements

- **No change - Recommendation 35:** ONC should not remove the prohibition on consecutive selection of one Health IT Module (preserve (c)(6)). 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.

Removal of Certain 2015 Edition Certification Criteria

- **No change - Recommendation 36:** ONC should adopt a general principle 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 CMC TF recommends ONC consider other criteria, such as demographics, that could also be removed and do so in the final rule.

Deregulatory Actions

- ***Questions and feedback***
- ***Vote on recommendations***