HIMSS Electronic Health Record Association

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Karen DeSalvo, MD, MPH, MSc
National Coordinator for Health Information Technology
Acting Assistant Secretary for Health
U.S. Department of Health and Human Services

Dear Dr. DeSalvo,

We are submitting the following comments on the Office of the National Coordinator for Health IT (ONC) 2015 Edition Certification Criteria on behalf of the over 30 member companies of the Electronic Health Record Association (EHRA). These comments reflect the expertise of health IT developers who focus on the EHR Incentive Program requirements for meaningful use and certification, and are a result of our collaborative efforts to bring the value of our collective experiences to policymakers and, ultimately, our customers.

The EHRA would like to make particular note of the following key points:

- "System Under Test" and "Test Lab Verification" numbering and alignment of columns is inconsistent and confusing. We make suggestions as to how this could be far less confusing for both EHR developers and Authorized Testing Labs (ATLs).
- We encourage the development of testing tools which produce results documents to enable a more efficient testing process where vendors can provide validation results produced by the testing tools as attestation documentation to demonstrate compliance.
- Each test procedure should clearly indicate whether it or a portion of it is focused on ambulatory or inpatient functionality.
- We recommend the use of documentation as much as possible to expedite the certification process. A 2014 Edition certification, along with documentation for the updated standard or vocabulary, should suffice without requirements for additional visual inspection. We encourage this flexibility in several draft test procedures where it is not currently indicated.
- The EHRA recommends the flexibility to allow vendors with EHRs certified for the 2014 Edition to demonstrate via visual inspection only additional functionality requirements for the 2015 Edition revised criteria, and not the entire proposed draft test procedure.
- Where visual inspection is indicated, it is often unclear as to what is being inspected. Please clarify whether the visual inspection is applicable to the demonstration of functionality or the documentation associated with use of the testing tool.

- Due to the large number of test procedures, and the lack of all the supporting information (e.g., test data, testing tools, uses cases, measure calculations), we anticipate having many more questions and comments. We request that ONC schedule listening sessions in the near future to discuss new concerns in advance of testing and certification preparations.

The EHRA would like to thank ONC for the recent listening sessions on the new certification criteria, and we look forward to our ongoing collaboration to help make this program as effective and efficient as possible.

Sincerely,

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Sarah Corley, MD
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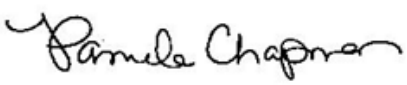
HIMSS EHR Association Executive Committee



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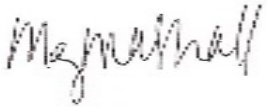

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About the EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of over 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit www.ehrassociation.org.

CC:
Alicia Morton, DNP, RN-BC, Director, Health IT Certification Program, ONC
Steve Posnack, Director, Office of Standards and Technology, ONC

General Comments

1. "System Under Test" and "Test Lab Verification" numbering is not always consistent, leaving it difficult to follow. The numbers on the left and the right do not align, and it is very difficult to determine the matching verification. Several Test Procedures align the system under test requirements in the left column with matching test lab verification in the right column for the functions defined. For example, it is easy to follow (b)(2) Clinical Information Reconciliation, but difficult to follow (b)(1) Transitions of Care.

There should be a clear relationship between the columns specifying one-to-one or one-to- many verifications that match the functional requirements. We suggest adding in blank spaces on the right if there is no verification required for the function numbered on the left, or formatting into a table to align tests with verifications such that multiple functions on the left such as 1, 1a, 1b, 1c align with the number 1 in the verification column, instead of numbering 1-4 on the left and 1, 2 on the right.

2. We have encouraged the development of testing tools which are capable of producing a results document to enable a more efficient testing process. Vendors should be able to provide validation results produced from the testing tools as attestation documentation to demonstrate compliance instead of repeating the testing tool process during the live certification process. The current process is quite time-consuming, when testing tools could be used independently of live testing to more efficiently demonstrate compliance.

3. We ask that steps required only for inpatient or ambulatory functionality be clearly identified at the beginning of a test procedure, and that steps related to the required functionality be clearly labeled as such.

4. We recommend the utilization of documentation as much as possible to expedite the certification process, both within the testing tools (as previously indicated in these general comments) and in criteria which are revised to reflect updated standards and or vocabularies since the 2014 Edition. A 2014 Edition certification, along with documentation for the updated standard or vocabulary, should suffice without requirements for additional visual inspection. We encourage the flexibility for documentation in several draft test procedures which did not indicate this flexibility.

5. We also encourage the flexibility that vendors with EHRs certified for the 2014 Edition may choose to demonstrate any additional functionality requirements for the 2015 Edition revised criteria, with requirements for a visual inspection only for the revised additional functionality and not the entire proposed draft test procedure.

6. In multiple testing steps, visual inspection is used. Please provide more information regarding what is being visually inspected.

7. We appreciate the opportunity to review the draft test procedures, and have provided a high-level review of these procedures. Due to the large number of test procedures available simultaneously, and all the essential information such as test data, testing tools, uses cases, measure calculations, etc., that support the test procedures being unavailable, we anticipate having many more questions and comments. Past experience has taught us that it is only possible to accurately review the test procedures when all information is available for a specific test procedure such that a comprehensive review may occur. We request that ONC schedule listening sessions in the near future to discuss new concerns in advance of testing and certification preparations.

§ 170.315 (a)(5)	Demographics COMMENTS: We request the option to meet this criterion by providing attestation documents for EHRs certified to 2014 standards for the data sets with updated standards/vocabulary, and that visual inspection only apply to the new items if necessary, rather than demonstrating the entire capabilities.
§ 170.315 (a)(6)	Problem List COMMENTS: We appreciate the option to only require attesting to the updated SNOMED standard for EHRs certified to 2014 standards. We request a breakdown of exactly what is expected prior to and during the actual certification demonstration to the ATL. Specifically, in regards to Step 1 under System Under Test in (i), are we expected to have the "problem list that has been produced over multiple previous encounters" already entered prior to testing, or do we enter that "live" as a part of the testing?
§ 170.315 (a)(9)	Clinical Decision Support COMMENTS: We appreciate identification of the negative tests. We request the option to meet this criterion through attestation of use of the updated standards for race, ethnicity, sex, preferred language, CCDA R2, and Info Button for EHRs previously certified to 2014 standards rather than demonstrating all steps which align with the 2014 Edition requirements.
§ 170.315 (a)(12)	Family Health History COMMENTS: We appreciate the option to only require attesting to the updated SNOMED standard for EHRs certified to 2014 standards.
§ 170.315 (a)(13)	Patient-Specific Education Resources COMMENTS: When we read Objective 5 Measure 2 of the recent final meaningful use (MU) rule summarizing Stage 3, this seems to require electronic export of the patient education in order for a provider to meet the objective. This test script shows no mention of electronic generation, and the automated/numerator or automated measure calculation is not available to review. We appreciate that the test scripts are not more prescriptive than the regulatory text regarding this certification criteria, yet we are concerned if meeting the above mentioned MU objective will require capabilities outside of 2015 certification.
§ 170.315 (a)(14)	Implantable Device List

	COMMENTS: We appreciate the flexibility to provide data for testing; however, we seek clarification regarding expectations for testing UDI formats. There are three (3) formats of UDIs available. Since each number-issuing agency has a different format and the test data is supplied by the vendor, we would expect to provide the data we choose. If there is a more specific requirement, such as that we should choose test data that includes all three formats, it should be clarified, or data should be provided if testing bodies expect support of all three formats. http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/UCM396595.doc
§ 170.315 (b)(1)	Transitions of Care COMMENTS: This test procedure is a good example of System Under Test and Test Lab Verification not aligning across the columns as we noted in our general comments above. The System Under Test and Test Lab Verification numbering is not always consistent, making it difficult to follow. The numbers on the left and the right do not align, and it is very difficult to determine the matching verification. Several test procedures align the System Under Test requirements in the left column with matching Test Lab Verification in the right column for the functions defined. For example, it is easy to follow (b)(2) Clinical Information Reconciliation, but difficult to follow (b)(1) Transitions of Care. There should be a clear relationship between the columns specifying one- to-one or one-to-many verifications that match the functional requirements. We suggest adding in blank spaces on the right if there is no verification required for the function numbered on the left, or formatting into a table to align tests with verifications such that multiple functions on the left such as 1, 1a, 1b, 1c align with the number 1 in the verification column instead of numbering 1-4 on the left and 1, 2 on the right. Remove or clarify the blank #8 under (i)(A) Test Lab Verification on page 4. Regarding (ii)(A) Negative Tests for invalid codes, is there an intention that every code value shall be validated as to whether or not it is valid for the given code system? Example: the Implementation Guide mandates the use of Medication Route FDA value set, but the content has some other code system. This is clearly an invalid condition to be detected. However, if the code system is correct, is there an intention that the code value, say, C38675, shall be validated as to whether or not it is a valid code from the Medication Route FDA value set? If different systems use the standards specified in certification “or an updated version”, will this cause any potential validation errors? We are concerned that undertaking this validation of all code sets requires some policy discussion and the possibility of a centralized code set validation. This test procedure is quite long, including repetitive technical standards and

	validation steps. Ideas to shorten the test procedure include removing duplicative requirements (CCDA), identify inpatient vs. ambulatory data more clearly and only list once, and only list one document generation alongside multiple validations of the same document. As we have previously suggested, there needs to be a much more clear alignment between the step or steps required for System Under Test alongside the step or steps required for Test Lab Verification to assure that the expectation is clear for the validation of testing. We are also concerned that ATLs may lay out this script differently if ATLs create their own scripts. From a transparency perspective, the test procedures should establish clear alignment that ATLs should follow when creating their test scripts. Overall, we can appreciate the duplication of information in each section regarding the standards, and realize some vendors might prefer this degree of detail. However, we generally support any efforts to shorten the overall procedure and align the System Under Test with Test Lab Verification to make the process more concise and easier to follow.
§ 170.315 (b)(2)	Clinical Information Reconciliation and Incorporation COMMENTS: We appreciate this good example of System Under Test and Test Lab Verification aligning, and have no concerns. It is easy to follow the steps that are required to demonstrate the functionality in sync with the verification requirements. Some vendors requested the possibility of combining this test procedure with clinical decision support (CDS) to demonstrate the multiple capabilities without having to do duplicate testing as has been suggested in past scenario-based testing discussions. Others made the assumption that coordination could occur with the ATLs to avoid duplicating steps for testing.
§ 170.315 (b)(3)	Electronic Prescribing COMMENTS: We appreciate this good example of System Under Test and Test Lab Verification aligning, and have no concerns. It is easy to follow the steps that are required to demonstrate the functionality in sync with the verification requirements.
§ 170.315 (b)(6)	Data Export COMMENTS: We ask for several clarifications on this test procedure for the additional functionality included in the testing. Regarding (iii) Timeframe Configuration- dates filtered, what patients get exported – those with encounters during filtered dates or those with any data updated within filtered dates? What gets included on the summary? Are we expected to evaluate the end date and exclude the more current data in the EHR that exists with (prescribed, updated, etc.) dates after the end date?

	In section (i), there is confusion between System Under Verification #3 and alignment with Test Lab Verification 4, negative test. Based upon our interpretation, we suggest this should be reworded: "4. Negative test: The tester verifies that an unauthorized user cannot create export summaries." The negative test is currently written as "The tester verifies that an unauthorized user cannot **modify which users can** create export summaries." (page 2)
§ 170.315 (c)(2)	Clinical Quality Measures – Import and Calculate COMMENTS: We are concerned with requirements and the complexity associated with any de-duplication of data requirements. We suggest that this automatic import be considered an option for manual importation of data into the EHR for generation of QRDA files. We would like to work with ONC to help define the expectations for this test procedure regarding de-duplication and importing capabilities.
§ 170.315 (c)(3)	Clinical Quality Measures – Report COMMENTS: Most of this criteria seems to be duplicative of steps covered in (c)(1) and (c)(2) with the exception of the optional submission to CMS. Should we expect additional guidelines on the programs that this reporting can be used for and how to go about testing submission to CMS?
§ 170.315 (c)(4)	Clinical Quality Measures - Filter COMMENTS: The title listed on this measure is incorrect. It reads "Record" and should say "Filter". Is the filtering measure specific or general? This requirement seems geared towards ambulatory settings. Is it possible for inpatient products to certify to this as well? The filter options (such as TIN, NPI, Practice Site Address) seem like ambulatory options. Who needs to generate the cryptographically signed file? We are expecting this to be done by the ATL and not the EHR.
§ 170.315 (d)(2)	Auditable Events and Tamper-Resistance COMMENTS: We appreciate the option to only require attesting to the updated standard for EHRs certified to 2014 standards.
§ 170.315 (d)(9)	Trusted Connection COMMENTS: We appreciate the option to only require attesting to the updated standard for

	EHRs certified to 2014 standards.
§ 170.315 (d)(10)	Auditing Actions on Health Information COMMENTS: We understand this to be an either/or option, so products can choose to be certified to (d)(2) or (d)(10) with most EHRs certifying to (d)(2). No additional comments, as this seems straightforward.
§ 170.315 (e)(1)	View, Download, and Transmit to 3rd Party COMMENTS: Align the System Under Test steps with the Test Lab Verification steps. We have some concern regarding criteria (i)(A) Test Lab Verification step 3 concerning the terminology "the correct scope has been defined". We interpret the meaning of "correct scope" for WCAG compliance to mean compliance on web pages associated with view, download or transmit (VDT) functions and nothing more. We generally appreciate the duplicative links and listed standards when the same information is needed for multiple steps in the test procedure. Some vendors expressed concern with the ability to make sure all duplications are corrected when any potential changes occur within the standards. (i)(B)(2) seems to be a duplicative validation. It is also numbered under the Test Lab Verification as if it is a continuation of (i)(B)(1)(ii). We do not believe that the reference to (b)(1) Transitions of Care under steps (i)(B)(2) or (I)(C)(2) is appropriate. This seems to imply that a product cannot be certified to (e)(1) without first also certifying to (b)(1). Steps 2 and 4 under (i)(C)(1)(i), (1)(C)(1)(ii) and (i)(C)(2) specify "The HIT developer accesses the third party email account and verifies the transmission was received and is correct." We appreciate the ability to define the email for testing these steps; however, there is no accommodating Test Lab Verification step. We support the flexibility associated with Function (D) Timeframe suggestion. The capabilities used by HIT vendors to produce these documents and select timeframes should remain flexible regarding methods used to satisfy the certification criteria across ATLs. The Certification Companion Guide should serve to further clarify that flexibility is intended for timeframes associated with either static documents or real-time generated documents, as well as timeframe selections associated with existing documents or data timeframes. We appreciate lack of specificity on whether we must generate multiple CDA documents from encounters/admissions within filtered dates or one CDA with only data within patient filtered dates. We suggest adding this clarifying information to the Certification Companion Guides to support such functionality.

§ 170.315 (e)(2)	Secure Messaging COMMENTS: We recommend that a 2014 Edition certified product should be able to meet this criterion by only attesting to use of the updated hashing algorithm.
§ 170.315 (e)(3)	Patient Health Information Capture COMMENTS: For external links, these will all likely include PHI. We appreciate the lack of specificity that allows us to provide only a link and wish to ensure that no ONC ATL will be overly prescriptive and expect authenticated access to external links beyond the linked website.
§ 170.315 (f)(2)	Transmission to Public Health Agencies - Syndromic Surveillance COMMENTS: We would appreciate the option for 2014 software to meet this criterion by providing attestation documentation to the updated standard. This criterion could be met if the testing tools provided vendors with result reports to submit. Vendors should be able to provide validation results produced from the testing tools as attestation documentation to demonstrate compliance instead of repeating the testing tool process during the live certification process.
§ 170.315 (f)(4)	Transmission to Cancer Registries COMMENTS: We request clarification on whether software certified to 2014 standards has the option to meet this criterion by only submission of attestation documentation to the updated standards.
§ 170.315 (f)(5)	Transmission to Public Health Agencies – Electronic Case Reporting COMMENTS: Criteria (i) Test Lab Verification step 2 should read “which encounters” instead of “whether encounters”. Criteria (iii)(A) Test Lab Verification step 1 states “that conforms to the standard specified in § 170.207(a)(4)”. This should be removed or clarified. It appears to belong in (iii)(B) for encounter diagnosis. Does the match to trigger the case reporting also need to conform to § 170.207(a)(4)? The Companion Guide mentions a testing tool not mentioned in the test procedure. Should we expect to use a testing tool and test data?
§ 170.315 (f)(6)	Transmission to Public Health Agencies – Antimicrobial Use and Resistance Reporting COMMENTS:

	With the clarification of the correct testing tool being listed, we have no additional comments.
§ 170.315 (f)(7)	Transmission to Public Health Agencies – Health Care Surveys COMMENTS: We seek clarification regarding this test procedure. We would appreciate a real-world use case for this. Are we being constrained to one particular value set used by the testing tool? Are we only being tested to one type of survey and, if so, what of all the other types of surveys that do not match testing tool validation or supplied data?
§ 170.315 (g)(3)	Safety-Enhanced Design COMMENTS: There were some concerns raised when usability testing might have occurred prior to the certification criteria, or risk was regarded low for some tasks that were not included to match every detail in the certification criteria. Also, we have some concerns that some functionality required in the certification criteria might not be required for use by providers and, as such, those tasks are not a part of usability tasks. For example, electronic prescribing functions related to fill list were mentioned (170.315 (b)(3) sub-bullets (B) and (E). As a result, we might not have tasks for every component, and there should be no expectation for these tasks. The proposed test measures strongly recommend "NIST use cases" be used for summative testing. We are concerned that this will be misleading to developers and testing bodies, as using the NIST use cases published in NISTIR 7804-1 would not properly test all 12 certification criteria. In addition, the NIST use cases test criteria that are not part of certification and might not be present in CEHRT. We are concerned that recommendations of these use cases would be understood as requirements by the ATLs. It would be unfortunate if the NIST use cases were taken as a de facto standard, or if developers were faulted for using equally vetted use cases. Therefore, we ask ONC to clarify that while the NISTIR 7804-1 use cases could be useful for some developers, they are not sufficient for certification and other use cases could be equally valid. We would prefer that such guidance be removed entirely from the test procedures to avoid confusion.
§ 170.315 (g)(4)	Quality Management System COMMENTS: The Testing Components grid includes visual inspection. We expected this criterion to be met by submitting documentation only. We would appreciate clarification on our option to apply our single QMS system that contains components of multiple standards to all criteria without specifying individual elements of our system, and that applying them to specific criteria is acceptable, along with the current proposal to apply individual QMS to all criteria,

	or to apply specific QMS standards to individual criteria.
§ 170.315 (g)(5)	Accessibility-Centered Design COMMENTS Although it seems tedious, we are generally appreciative of the opportunity for vendors to interpret what is appropriate and apply as we deem necessary.
§ 170.315 (g)(7)	Application Access - Patient Selection COMMENTS: The Testing Components grid does not include data exchange, even though we are sending and receiving data. We would appreciate clarification on who is doing these steps. Do you intend to have ATLs develop and make calls to APIs, or are we expected to call our own databases? Do you anticipate us giving ATLs our development guides?
§ 170.315 (g)(8)	Application Access - Data Category Request COMMENTS: We would appreciate clarification on exactly what steps are expected of us as vendors vs. steps performed by the ATLs regarding the listed steps under the Test Lab Verification. It is unclear. We appreciate the lack of specificity as to whether we must make one API that can request all data elements or multiple APIs that can access each element. We question the inclusion of "combinations" of data points expected to be called for in this test procedure. Is this accurate? If we verify combinations, we expect to define these per best use cases per EHR vendor.
§ 170.315 (h)(1)	Direct Project COMMENTS: We are not sure what to anticipate without any real-world use of the testing tool, so we are unable to provide feedback at this time. Though seemingly extensive, we do appreciate the clarifications that the negative testing steps provide.
§ 170.315(h)(2)	Direct Project, Edge Protocol, and XDR/XDM COMMENTS: Some steps under the Test Lab Verification seem to be negative testing, but they are not called out as such. (i)(C) step 6 is an example. We request clarification on what is expected in the logs for (i)(C) step 6 Visual Inspection under Test Lab Verification (page 12).