

General Comments

- We suggest allowing attestation for criteria where there have not been significant change and where there have not been issues noted by testing bodies or significant complaints by end users. For example, criteria such as problem lists, medications and medication allergy lists are very similar and straightforward core functionalities of EHRs that have been, present long before the meaningful use (MU) program and should not require visual inspection.
- For criteria that utilize testing tools to validate output from the EHR, no visual inspection should be required. Testing tools should produce output that validates the standard was applied properly. Vendors should be able to provide testing tool documentation as attestation of successful validation from the testing tools.
- Be consistent when determining whether visual inspection is required or attestation-only will suffice. Currently, some criteria are specified as visual and attestation, while some criteria are specified as attestation at a minimum. This causes confusion regarding what is required for testing components.
- When testing tools are required for data exchange, the test method steps should state when the tool will be used and what must be sent to the tool for validation. The developer must know ahead of time what is expected at what point in the process to validate using the test tool.
- In the interest of transparency, the testing labs should be required to post their processes, test scripts, and their procedures in advance testing. This advance disclosure will increase consistency across testing bodies. Any guidance given to ATLS by ONC should be shared publicly so that clear expectations are available to all stakeholders.
- Any criteria specifying data should include the data in the actual procedure so that it is available when reviewing the required steps. If specific data is expected to apply to specific steps, the test procedure should be organized such that the step-dependent data is provided for the step so that the expected result can be easily verified.
- Any criteria specifying attestation/documentation should clearly identify the specific questions or requirements that must be addressed for attestation. The document defining these requirements should be available as a part of the test procedure so that all vendors are required to provide the same degree of attestation.
- There are several criteria that specify attestation/documentation “at a minimum”. Please clarify the meaning of this phrase as it relates to the testing components which may also state visual inspection. We understand this phrase to mean that the vendor may choose attestation to demonstrate compliance rather than visual demonstration. We are concerned that criteria might not be tested equally if the intent is to provide flexibility for the ATLS to strengthen requirements beyond the minimum and discourage additional requirements for any criteria which ONC deems attestation as adequate.
- Piloting is important to identify any incorrect data, conflicting data, or inappropriate requirements for data (e.g., data that is not allowed by the software due to data-integrity checks).
- If the final testing tool is not available at this time or on the next version of these test methods, please include links to the current tool development prototypes so that developers can run preliminary tests prior to finalization of the tool. If final, validated, and piloted tools are not available at least 18 months prior to the functionality being required by end users to satisfy compliance with the program, alternative certification methodologies such as attestation should be deployed.
- Review of the Draft Test Procedures has raised several questions regarding field surveillance expectations. If these test procedures are expected to be followed for in-the-field surveillance, consideration must be given to the fact that end users may be using the product in a different

fashion than when it was tested, and will certainly not be familiar with the test scripts and certification testing process. Certification testing may be accomplished by demonstrating workflows that may not match the workflow chosen by the end user. ATLS and ACBs will be familiar with the test procedures, although they will not be familiar with the EHRs. We discourage the application of these test procedures by inexperienced personnel and reiterate the limitations of their usefulness for such activities.

- For any criteria that are gap eligible, the new test procedure should be unchanged for the 2015 Edition other than adding the clarifications, FAQs, and guidance as requested above. There should be a column to clearly show if each criterion is gap eligible.
- For all public health reporting criteria, the EHRA discourages employing use cases that require manual data entry. We support utilization of a select few comprehensive use cases instead of requiring multiple use cases. This should allow ATLS flexibility without burdening the preparatory process.

Format Comments

- Include the certification criterion language in the test procedure itself. As mentioned in the recent ONC-sponsored “mini-Kaizen” on certification processes, it would be ideal to have a single document including the requirement, intent of the requirement, expected methods of complying with requirement, expected result, and description of the test procedure, as well as link to the standards required, additional guidance, and relevant FAQs as released. Inclusion of this information will reduce confusion and increase conformity. This information could be presented in a columnar format with appropriate headings. There should also be specific guidance provided to auditors when there is leeway in how the requirements may be met.
- The test procedure should define the steps as they align with the criterion in the first column.
- The expected results column should include every expected result as it relates to the step or step(s) defined in the first column. If the expectation is just to achieve the final outcome without having to go through test steps as detailed in the procedure, it should be clearly stated. The expected results should list every result which will be used to score the test. Therefore, some flexibility can be included in the test steps so that the vendor may perform the test without such precise steps defined, but be able to demonstrate every expected result as specified through the workflow being demonstrated.
- See attached suggestions for the format described here.

170.315(a)(1) CPOE - Medications

- Clearly state that this criterion is eligible for gap certification.
- The test case shows the icon suggesting that it requires a visual inspection, but the text suggests that attestation is acceptable. The test should be clear as to what is required and the icons should only show what is required.
- We suggest using the 2014 certification test script for those who are required to test to this requirement.
- We recommend attestation for previously certified products.

170.315(a)(2) CPOE - Laboratory

Item #	Technical Outcome	Test Lab Verification	Test Approach
1	A user records, changes, or accesses an orderable test for a patient based upon the receiving laboratory's electronic Directory of Services, and enters the information based upon the orderable test requirements.	The tester verifies that selection of the laboratory order is based upon an orderable test from the electronic Directory of Services, and that the information that the user is required to enter is in accordance with the standard specified in §170.205(l)(2). The tester verifies that all of the required orderable test information for the specific orderable test has been entered correctly and without omissions, and that at a minimum laboratory orders are specified with the standard specified at §170.207(c)(3) for both inpatient and ambulatory settings.	Test data and visual inspection.

- Commercial labs are not using any standards for their Directory of Services, nor are they consistently all using LOINC for the subset of orderable tests that have been assigned a LOINC code, so there would be no real world testing possible for this measure. We suggest rewording this requirement to remove the word “electronic” before “Directory of Services”. We suggest that you select several of the national lab vendors (such as Quest or Lab Corps) to determine the orderable codes, the ask-on-entry (AOE) questions, and the test collection requirements. Then, allow the developer to select the lab vendor data set for whichever lab vendors they choose. [Here is a sample spreadsheet partially completed.](#)

This approach will allow developers to test with a real live interface that clients can then purchase. It would also be useful to collect information via attestation for the CHPL as to which commercial lab interfaces a vendor already has in production and available for deployment without any development lags. This approach would be much more useful than requiring compliance with a standard to import a lab directory of services that is not being used in the real world.

Item #	Technical Outcome	Test Lab Verification	Test Approach
1	New and updated Laboratory Order Compendiums are available for users from which to order.	The tester verifies that a new or updated Laboratory Order Compendium is received and incorporated in accordance with the standard specified at §170.205(l)(2). Furthermore the tester verifies that the orderable tests reflect the contents of the new or updated Laboratory Order Compendium.	eDOS testing tool and visual inspection.

- Testing should be done with order compendia from major national labs such as Quest or LabCorp. Developers should be able to select from among these national labs so that any development work done will be usable by their client base. If these labs do not support the standard specified, testing should be done using the methodology that would provide usable tools to the vendor's client base.

Vendors should attest to which lab vendors have compendia available for downloads and this information should be available on the CHPL.

Item #	Technical Outcome	Test Lab Verification	Test Approach
1	A user creates a laboratory order that is sent electronically in accordance with the standard specified in §170.205(l)(1), and at a minimum §170.207(c)(3).	The tester verifies the Health IT Module can create LOI messages for each supported laboratory order profile, in accordance with the standard specified in §170.205(l)(1), defined as Health IT Developer. At a minimum laboratory orders are specified with the standard specified at §170.207(c)(3).	Test data, LOI testing tool, and visual inspection.

- Include the plain language of the standards as well as a link to the actual standard.
- Since the Lab Order Interface (LOI) is still an early-stage draft standard for trial use (DSTU), it is not ready for certification testing. Consideration should be given to testing an existing ordering interface with one of the national lab vendors. Developers could attest to which lab providers they have production ordering interfaces and this could be listed on the CHPL. This approach would provide assurance that a working interface would be available to the providers' lab vendor(s) of choice and would not result in development of "throw away" code. We note that both Quest and LabCorp are committed members of the S&I Workgroup, and if ONC can get a commitment from major lab providers to support the LOI standard once it is finalized, test scripts could be updated in later years.

170.315(a)(3)_CPOE DI - Gap

- Recommend attestation for previously certified product.
- Recommend consistency between Test Approach and Testing Components regarding attestation as minimum.

170.315(a)(4) Drug-drug, Drug-allergy Interaction Checks CPOE

- The wording for this test method does not exactly match the certification criterion. We recommend adhering to the wording of the specific criterion instead of paraphrasing it.
- Please clarify. Our assumption is that EHR developers have to demonstrate one of the actions – viewed, accepted, declined, ignored, overridden, provided rationale, or other – but not all of the actions to demonstrate compliance with the criterion.
- We recommend attestation for previously certified products.

170.315(a)(5) Demographics

- Be consistent regarding how this testing will be done.
- If additional codes are used (e.g., undifferentiated), please specify whether it is acceptable to roll those up to unknowns since we do not want to lose granularity for our clients but also do not want to penalized for using that option.
- Please provide a better definition of what goes in the verification column.
- EHR Association recommends attestation instead of visual inspection.

170.315(a)(6) Vital Signs, BMI, and Growth Charts

- It is not possible to record or change calculated values – by definition, they are calculated based on other values entered into the medical record. Therefore, the test procedure should not require recording or modification to calculated values.
- There is too much specificity here. EHR developers will determine the optimal approach to implementing the collection of new data based on their individual EHRs' designs.
- Please provide more clarity around the metadata procedures.
- Same comment as the certification rule (should only be in one place).
- Please clarify which growth charts are to be shown. In the 2014 Edition, there were clear expectations defined in the test procedures:

Expected Testing Results

[IN170.314(a)(4)(iii) – 1.01-1.09] Each height and weight measurement of both male patient and female patient is accurately plotted against their age and then displayed on gender-based growth charts (2-20 years).

They also specified the test data to show:

Test Data

Test data is copied from ONC Test Method Test Data.

If different test data is used, test proctor must note this test data in the Test Result Verification section.

Test data can be preloaded prior to testing or loaded at the time of testing.

Male Patient – 1

Age: 2

Height: 3 ft 1 in OR 37 in OR 0.94 m OR 94 cm

Weight: 33 lbs OR 32 lbs 14 oz OR 15 kg OR 14,969 gm

Male Patient – 2

Age: 12

Height: 5 ft 1 in OR 61 in OR 1.55 m OR 155 cm

Weight: 99 lbs OR 98 lbs 11 oz OR 45 kg OR 44,906 gm

Female Patient – 3

Age: 5

Height: 3 ft 4 in OR 40 in OR 1.02 m OR 102 cm

Weight: 40 lbs OR 40 lbs 2 oz OR 18 kg OR 18,144 gm

Female Patient – 4

Age: 14

Height: 5 ft 3 in OR 63 in OR 1.60 m OR 160 cm

Weight: 110 lbs OR 110 lbs 1 oz OR 50 kg OR 49,895 gm

170.315(a)(7) Problem List

- Should be consistent testing requirements between problem list, medication list, medication allergy list.
- Should have consistent testing data requirements between all three.

- Recommend attestation to satisfy certification requirements.

170.315(a)(8)_Medication List - Gap

- Should be consistent testing requirements between problem list, medication list, medication allergy list.
- Should have consistent testing data requirements among all three.
- Recommend attestation to satisfy certification requirements.

170.315(a)(9) Medication Allergy List

- Should be consistent testing requirements between problem list, medication list, med allergy list.
- Should have consistent testing data requirements between all three.
- Recommend attestation to satisfy certification requirements.

170.315(a)(10) CDS

Item #	Technical Outcome	Test Lab Verification	Test Approach
1	<p>A specific set of users can select at least one electronic clinical decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) to be active in their Health IT Module, based on each one and at least one combination of the following data:</p> <ul style="list-style-type: none"> • Problem list; • Medication list; • Medication allergy list; • At least one demographic specified in §170.315(a)(5)(i) (preferred language, sex, race, ethnicity, and date of birth); • Laboratory tests; and • Vital signs 	<p>The tester verifies that authority to select clinical decision support interventions is limited to an identified set of users, and that an unauthorized user cannot select interventions. Additionally, the tester verifies that the identified users can select or activate one or more interventions based on each one and at least one combination of the referenced data in the Technical Outcome column.</p>	<p>At a minimum, visual inspection.</p>

- Take out the “The tester verifies that the Health IT Module enables interventions to be based on data referenced in Problem list; Medication list; etc.” in item 1 of 1.3. It does not seem to apply to this step for configuration to verify the interventions again.
- Item 2 in section 1.3 is confusing. The test procedure specifies a set of users to configure interventions based upon incorporation; however, the criterion specifies:
 - (B) *Technology must enable interventions to be:*
 - (1) *Based on the data referenced in paragraphs (a)(10)(i)(A) through (F) of this section.*
 - (2) *When a patient's medications, medication allergies, problems, and laboratory tests and values/results are incorporated from a transition of care/referral summary received and pursuant to paragraph (b)(2)(iii)(D) of this section.*
- The specified test procedure does not seem to address the requirement for the technology, but rather what a user must configure. We would not expect specific interventions based upon incorporation to be configured separately from the previous step but would expect the technology to demonstrate that it could provide interventions upon incorporation.
- Item 2 in section 1.5 is duplicative information in test lab verification.

- 1.6: We recommend using the same language as used in the criterion to avoid confusion regarding the requirement that the technology must be able to record at least one action, and not the language “when a user records an action”.
- Please clarify that individual users are not the ones who are necessarily configuring what CDS the end user sees. This is usually done at an administrative level for the entire practice. Better language might be demonstrate how the system supports a select group of users setting up CDS for one or more user types if the goal here is to show that CDS displays are variable based on role in the practice or other parameters.
- Please change language from select to “select, create, enable, activate, or use other method”.
- Please change “CDS intervention” to language that does not suggest that the CDS must be active. We suggest “CDS functionality”.
- Please clarify that one does not need to have a combination of all of the parameters but simply one pair of two under the technical outcome. Please change wording to “at least one combination of two items” in the test lab verification section.
- Please clarify that you require additional decision support for a medication allergy beyond a drug allergy interaction. Generally that is the extent of CDS that an end user would expect related to a medication allergy. If you are expecting additional CDS, please clarify if providing the monograph for the particular drug-allergen pair would meet this requirement.
- Please clarify that CDS does not require action on the part of the end user but could be passive decision support.
- Please clarify that you mean only that the specific end user who has not had the CDS enabled is not seeing the CDS rather than suggesting they are unable to perform some action. For example you might elect not to show the front desk staff an alert to provide a specific piece of patient education but you would not be preventing them from selecting and providing the patient education. The current wording suggests that they cannot perform an action rather than that they are not presented with the CDS.

Item #	Technical Outcome	Test Lab Verification	Test Approach
1	<p>A user can view diagnostic and therapeutic reference information for a clinical decision support intervention via the standard and implementation guide specified at §170.204(b)(3) or §170.204(b)(4). Additionally, the reference information is based on each one and at least one combination of the following:</p> <ul style="list-style-type: none"> • Problem list; • Medication list; and • At least one demographic specified in §170.315(a)(5) 	<p>The tester verifies that diagnostic and therapeutic reference information can be identified in accordance with the standard and implementation guide specified at §170.204(b)(3) or §170.204(b)(4)</p> <p>The tester verifies that diagnostic and therapeutic reference information is based on each one and at least one combination of the following:</p> <ul style="list-style-type: none"> • Problem list; • Medication list; and • At least one demographic specified in §170.315(a)(5) 	At a minimum, visual inspection.

- Please clarify that the CDS can be any type of CDS and not just diagnostic or therapeutic. If it is limited to those two subcategories of CDS, please assure that a reference site is provided that

supports the updated info button standard and has the appropriate diagnostic and therapeutic CDS available as vendors do not control what is available on third party sites.

- Please clarify whether you expect each category to show both diagnostic AND therapeutic CDS or just one or the other.
- Please clarify that only the CDS presented for certification needs to have all of the identified evidence references. The test procedure says ALL CDS and as there are thousands of types of CDS included in EHRs including passive information, it would be time and cost prohibitive to test it all. It also would have the unintended consequence of screen clutter and performance impairment to add this much additional information to products.

2	A user can review the attributes as indicated for all clinical decision support resources, specifically, "linked referential clinical decision support" and drug-drug, drug-allergy interaction checks in §170.315(a)(4): the developer of the intervention, and where clinically indicated, the bibliographic citation of the intervention (clinical research/guideline).	The tester verifies that the Health IT Module allows a user to review the attributes as indicated for all clinical decision support resources, specifically, "linked referential clinical decision" and drug-drug, drug-allergy interaction checks in §170.315(a)(4): the developer of the intervention, and where clinically indicated, the bibliographic citation of the intervention (clinical research/guideline).	At a minimum, visual inspection
---	--	--	---------------------------------

- Please clarify that CDS provided by knowledge content partners does not need to show the reference information beyond the global reference to the purveyor of that knowledge content.
- Please provide a reference site that supports CDS for lab values and is compliant with the updated Infobutton standard specified to use for testing and certification as this is not widely available in free content. The test steps also seem to suggest that the EHR vendor needs to show the bibliographic information for linked referential CDS. That is not always possible as vendors allow end users to configure their Infobutton link to whatever source they wish and not all sources may provide this data which is beyond the control of the EHR vendor.

Item #	Technical Outcome	Test Lab Verification	Test Approach
1	When a user takes an action in response to a clinical decision support intervention, their specific action and their user information is recorded.	The tester verifies that the Health IT Module records actions taken and by whom, in response to clinical decision support interventions.	At a minimum, visual inspection.

Item #	Technical Outcome	Test Lab Verification	Test Approach
2	A user can review the actions taken and by whom either on screen or via a report.	The tester verifies that the Health IT Module can generate either a human readable display or human readable report of actions taken and by whom in response to clinical decision support interventions.	At a minimum, visual inspection.

- Please clarify that the testing for tracking of end user actions in response to CDS can be limited to active alerts as it is not possible to track response to passive alerts when you cannot even be sure the end user saw the alerts. If all actions need to be tracked, this would have the unintended consequences of vendors limiting CDS to active interventions only. That could have a negative impact on productivity and safety.

170.315(a)(11) Drug - Formulary and Preferred Drug list

- No comments

170.315(a)(12) Smoking Status

- Need clarification on the SNOMED codes required. There are many additional codes that could be used to record more granular responses; however the developer may choose only to include the eight required from 2014 Edition. Is this use of a limited set of codes permissible since the CCDA documents specify the eight codes from 2014 Edition, or is the system required to include every code possible and map to the current eight codes?
- If there are additional expectations from the preamble, then we would like to see it in here.

170.315(a)(13) Image Result

- No comment

170.315(a)(14) Family Health History

- Recommend attestation to satisfy certification requirements.

170.315(a)(15) Family Health History Pedigree

- Would data exchange be appropriate as a testing component? If so, a definition of data exchange would be helpful as it applies to this criterion.
- We recommend a focus on the outcome for incorporation and have consistency across testing labs with regards to expectations.

170.315(a)(16) Patient List Creation

- We suggest a single step test procedure for this criterion rather than two steps as proposed
- Please clarify what is required for the test – e.g., is the output required to verify the test? If there is a requirement to send any output to the ATL, we recommend specifying this as a unique step.

170.315(a)(17) Patient-Specific Education Resources

- The “or” needs to be changed to an “and” under Test Lab Verification to match the criterion: “education resources can be identified based on data in the patient’s problem or medication list” in item 1 of 1.1.
- Many vendors may specify default languages and should be able to demonstrate a call on any one of those languages; however, patient education documents may only be available in a subset of languages. We anticipate the ability to demonstrate compliance with these default lists, and not every possibility for languages due to the limitations based upon the database accessed.
- This criterion specifies the identification of patient education documents by the EHR using Infobutton; however, the criterion does not specify that the EHR is to electronically display the information to the patient as is specified for numerator calculation in the automated measure (g)(1)/(g)(2). We understand the criterion only relates to identification of the education resource

and expect that providers will perform a manual step to specify what was given electronically as there is no requirement for the EHR to display electronically to the patient.

170 315(a)(18)_eMAR - Gap

- The second item, Step 5 under 1.2, is duplicative of steps already performed. The step specified for NTP validation should occur before starting the verification of the five rights. This test procedure could probably be consolidated into a couple of steps. If there is an expectation that a specific result occurs with the use of specific data, it seems necessary to perform more steps rather than to just demonstrate an outcome.

170 315(a)(21)_Social, Psychological and Behavioral Data

- The test procedure and criteria specify the user to record, change and access, at a minimum, one of the categories of data as specified in 170.207 (o) (1-x). We understand this language to mean that certification is dependent upon providing a minimum of one data category from those contained in (i)-(x) and not all data categories in (1)-(x).
- We recommend attestation to satisfy certification requirements.

170 315(b)(5)_Transmission of Laboratory Test Reports

- Attestation is listed in the testing components; however, it is not in the test approach. This reference to attestation should be consistent within the method.
- We encourage the use of attestation with the testing tool validation anytime visual inspection can be eliminated in an effort to save costly testing time. Testing tools should produce output that can validate the standard was applied properly. Developers should be able to provide testing tool documentation as attestation of successful validation from the testing tools.

170 315(b)(6)_Data Portability

- User manual attestation could be useful to satisfy this criterion's requirements for the user to execute the specified user capabilities without developer assistance. Attestation could save considerable time over visual inspection of these capabilities. Testing tool validation could satisfy the remainder of the criterion requirements.

170 315(c)(1)_Clinical Quality Measures

- Careful consideration must be given to the feasibility of clinically relevant data as required to be recorded in the EHR to avoid unrealistic situations.
- The previous 2014 Edition test procedures were more explicit in the details regarding the steps required and the interaction with Cypress. We encourage more specificity to the steps involved, and the requirements associated with the recording of data to avoid more inefficiency in the current test methodology.

170 315(c)(2)_CQMs - Import and Calculate

- Consideration should be given to allowing for in testing the different scenarios available to providers to calculate CQMs. EHRs are typically very different than data warehouses in their functionality. The EHR contains the information natively that will be used to calculate CQMs and should not be expected to perform import, as would be expected of a data warehouse. The test procedures in this case must take into account the different technology and application of testing procedures which would be necessary to demonstrate the ability to calculate CQMs. EHRs do not import the data;

EHRs record the data and the import function should not be applicable to EHRs used in provider workflow.

- We request clarification regarding a definition for “de-duplication” of data. If this phrase means that the EHR should be able to identify when a QRDA file is imported twice, then we understand and agree. If the definition involves the ability for the EHR to de-identify combinations of data which were recorded and imported, then de-identification of individual data presents profound difficulty.
- The test procedures, including test data, tooling, and expected outcomes, are insufficiently detailed to be considered a viable first draft. The procedures as written simply repeat the criteria in the NPRM and do not reflect the detail needed to evaluate ONC's/NIST's expectation of criteria interpretation and validation. The proposed timeline requires that the requirements of the Final Rule be complete at the time of the final rule and, therefore, we request that the test procedures including test data, test tooling, expected outcomes be released in reviewable draft form available for substantive comment prior to the final rule. Delay in providing a reviewable draft may inadvertently delay the availability of CEHRT and further complicate high quality implementations by providers to successfully achieve program outcomes.
- Please see the comments on this criterion in EHRA comments on the ONC 2015 edition NPRM. We disagree with the export sub-criteria as proposed. In context of the test procedure, the verification steps further elaborate this requirement to indicate a user can export at any time one or multiple patients including all of the data captured for each and every CQM. Data export from EMRs is not CQM-focused and should not require separate CQM capabilities for providers. We request that the export, export to standard, and one or more CQM extract for one or more patients be removed.
- Vendors are already successfully supporting providers in the capture of CQM data. The capture portion of this criterion could be gap certified based on existing certifications and attestation documentation showing providers how the system performs CQM data collection.
- The test procedure for "capture" proposes that the vendor enter all data for each and every CQM. This is a highly inefficient and ineffective test methodology and we recommend substantial change. The CQM data is very repetitive and can be more efficiently and effectively tested by demonstration of data entry of each category of data. CQMs have consistent cross-measure concepts such as medications administered, diagnoses, etc. If a vendor can demonstrate how the system is configured to accommodate the category, element type, value set and show entry and availability of a representative value in that category/element, this is sufficient.
- While EMR vendors certify to capture in order to show full CQM support, clients may utilize functionality or workflows that do not capture CQM data in the same way. The capture criteria/test procedure as written drives vendors to limit the workflows available to clients in order to capture data that will be registered in CQMs.

170 315(c)(4)_CQMs – Filter

- No comment

170 315(d)(1)_ (d)(9)

- No comment

170 315(d)(1)_Authentication, Access Control, Authorization

- No comment

170 315(d)(2)_Auditable Events and Tamper-Resistance

- No comment

170 315(d)(3)_Audit Report(s)

- No comment

170 315(d)(4)_Amendments

- No comment

170 315(d)(5)_Automatic Access Time-Out

- No comment

170 315(d)(6)_Emergency Access

- No comment

170 315(d)(7)_End-user Device Encryption

- No comment

170 315(d)(8)_Integrity

- No comment

170 315(d)(9)_Accounting of Disclosures

- No comment

170 315(f)(3)_Transmission to Public Health Agencies - Reportable Laboratory Tests and Values - Results

- Testing components indicate attestation can be used. However, the testing approach specifies visual inspection. This needs to be consistent.
- We encourage the use of attestation with the testing tool validation any time visual inspection can be eliminated in an effort to save costly testing time. Testing tools should produce output that can validate that the standard was applied properly. Developers should be able to provide testing tool documentation as attestation of successful validation from the testing tools.

170 315(f)(4)_Transmission to Cancer Registries

- Testing components indicate attestation can be used. However, the testing approach specifies visual inspection. The two different reference need to be consistent.
- We encourage the use of attestation with the testing tool validation anytime visual inspection can be eliminated in an effort to save costly testing time. Testing tools should produce output that can validate that the standard was applied properly. Developers should be able to provide testing tool documentation as attestation of successful validation from the testing tools.

170 315(f)(6)_Transmission to Public Health Agencies - Antimicrobial Use and Resistance

- Testing components indicate attestation can be used. However, the testing approach specifies visual inspection. The two different references need to be consistent.
- We encourage the use of attestation with the testing tool validation anytime visual inspection can be eliminated in an effort to save costly testing time. Testing tools should produce output which can

validate that the standard was applied properly. Developers should be able to provide testing tool documentation as attestation of successful validation from the testing tools.

170 315(g)(1)(2)_Automated Numerator and Measure Recording

- Provide consistency through language required for measurement. For example, unique patients seen vs. unique patients with office visits should be defined the same throughout all measures.

170 315(g)(3)_Safety Enhanced Design

- Remove visual inspection from testing components. We recommend attestation only.
- The test procedure under 1.2 requires that the vendor associate tasks with certification criteria. Safety enhanced design will often be performed independently of certification criteria that may be developed and, as such, there should not be an expectation of direct correlation between every task and certification criteria. Some tasks used within a safety enhance design test may exceed the requirements of certification criteria and as such cannot be directly associated.

170 315(g)(4)_Quality Management System

- If the developer uses a combination of available standards to define their quality management system (QMS), we would expect to apply the developer's QMS using a combination of standards across all criteria instead of trying to separate the individual standards and apply certain standards to certain criteria. We recommend this approach as acceptable although it is not specified in the criterion that such a combinations approach could be applied across all criteria.

170 315(g)(5)_Accessibility Technology Compatibility

- What is meant by "compatible"? Does that mean it can be read but cannot be actionable? Or are there more requirements under "compatible" which need to be defined?
- The criterion specifies the functionality for all user-facing criteria at 170 (a), (b) and (e). Does this accessibility technology compatibility apply to every component of each of the test procedures? It is appropriate to apply it to only some screens but not all.
- It appears that we are simply being asked to provide documentation for what we currently support. What does the test lab mean by "verifying"? Please clarify the extent of the attestation that could be required for such a range of functionality.

170 315(g)(6)_Consolidated CDA Creation Performance

- The definition of CCDAs "match" needs to be defined, and examples provided within the test procedure. There needs to be more specificity with regard to what constitutes the match and what is deemed not to match.
- Current work in HL7 task forces has identified clinical data consistent with the common clinical data set, which the module would use to create a valid document; and has provided examples of satisfactory documents matching the standards. However, we are unaware of a "gold standard" document that could be used as the reference data file match as specified.
- If defined, what would be the result if extra data was provided in the document when compared to this "gold standard"?
- The proposed draft test procedure states the test approach as the health IT module must consume the data as the minimum. However, the criteria establish the match based upon the entry of the data. We suggest the test approach validate the entry of data, and not the consumption of data.

170 315(g)(7)_Application Access to CCDS

- We have concerns about requirements specified for conformance when the API is unspecified.
- Given the potential choices for APIs and how each different type of API (e.g., REST or SOAP) could be used to demonstrate all requirements without knowing the specific API details, we ask ONC to please clarify the API selected for certification as soon as possible.
- Attestation is not indicated as a testing component. However, it should suffice for the documentation necessary to meet the terms of use.
- Clarification is requested with regards to the audience for the required documentation (e.g., developers, public, and clinicians).

170 315(g)(8)_Accessibility-Centered Design

- We understand it is acceptable that any of the available accessibility design standards and accessibility laws will apply to any criteria as listed in the NPRM.
- We request clarification for any further defined design associated with any criteria as acceptable due to concerns among testing labs where certain design standards may not be deemed appropriate.

170 315(i)(1)_Electronic Submission of Medical Documentation

- Please specify the documents and the associated standards and implementation guides that will be used to determine compliance.
- We recommend attestation for unstructured documents.
- We suggest that developers should be able to select some but not all of the document types which are proposed based upon what is relevant to the client base that would use the application. There should be flexibility in certification to allow developers to choose and certify only those relevant documents instead of all documents.
- Digital signature has a different meaning than electronic signature and requires definitive steps for testing tool validation.
- Careful attention must be given to the test procedure steps and alignment with all associated expected results and use of validation test tools.

170 315(a)(19)_Patient Health Information Capture

Item #	Technical Outcome	Test Lab Verification	Test Approach
1	A user identifies (labels documents), records, and accesses health information documentations associated with a particular patient.	The tester verifies a user can identify (e.g. label documents as advance directives, birth plans), record, and access the health information documents associated with a patient.	At a minimum, visual inspection of test data.

- It is not completely clear whether this criterion is limited to types of health information that might be created externally vs. documentation completed within the EHR since that too is health information documentation. The mention of “record” suggests that this criterion refers to internally created documentation. If this requirement is for only documentation created outside of the EHR, that should be specifically stated. If it is for internally created documentation, it should specify if there is a subset of information that must be labeled, or if every piece of documentation must be able to be labeled.

- Please clarify for testers and auditors that there are many ways that health information could be labeled. Examples could be titling a document, using a named template, locating the document within a labeled category, providing information about the type of document on “mouse-over” among other methodologies.

Item #	Technical Outcome	Test Lab Verification	Test Approach
1	A user provides a narrative that describes the location of a document.	The tester verifies that a user can reference the location of a health information document by providing narrative information.	Visual inspection of test data (health information narration).

- It is not clear if this narrative can be free text entered anywhere in the EHR, or if there are requirements for structured fields to support this location narrative.

Item #	Technical Outcome	Test Lab Verification	Test Approach
2	A user can access the document using a link to an internet site, where the document is stored.	The tester verifies a user can access the document using a link to an internet site where a health information document is stored.	Visual inspection of test data.

- Please provide a use case example of where a patient might store a health information document that could be accessed via a URL without any extra security.
- Please provide the URL to such a site so that vendors can test this since it is not a common situation where health information would be stored on the Internet. Generally, if a provider wishes to link to a document, they would scan the document and store it in the EHR itself.

Item #	Technical Outcome	Test Lab Verification	Test Approach
1	A user records and can subsequently access health information documents that were shared directly by a patient (e.g. via mobile phone, tablet, secure message).	The tester verifies a patient can provide health information from multiple sources, directly and electronically to the Health IT Module, and that it can be integrated into the patient record by a user.	Visual inspection of test data.

- The user would not record the information if it was information created by a patient, so the technical outcome should be worded as “the user can accept into the health IT module and subsequently access...”
- Please clarify whether the intention is that only documents need to be “integrated”, or whether it is intended that patient completed information might be provided in a non-document format.
- Please clarify that developers are not required to support all mentioned methods of sending data, such as the examples of mobile phone or tablet.
- Please clarify that “integrated” does not require that the information be imported into discrete fields or follow any particular format for the storage and display of the information.
- What is meant by the patient providing data from multiple sources (i.e., multiple devices)?
- Is it expected that patients might be completing online surveys and sending them via regular e-mail?
- Is it the intention that the module should incorporate information sent through insecure e-mail?

- Is it intended that the EHR is interfaced to wearable devices? The language referencing documents suggests not, but this is a very confusing requirement.
- If the intent is just that an EHR be able to import a document, that should be clearly stated with an indication as to whether there are specific types of documents that must be supported. Can a developer choose to only support one format such (e.g., PDF) and all external documents would need to be converted by the user into that format prior to importing them?

170 315(a)(20)_Implantable Device List

- Specifying “list” in the criteria and testing is too prescriptive and does not allow innovation regarding the display, which could be accomplished in multiple ways.
- Attestation is a testing component but not included in test approach. Please define the expectation for attestation satisfaction.
- Specify any format requirements (e.g., date) if specified in FDA documents.
- Should the testing components also include data exchange?

170 315(a)(22)_CDS - Knowledge Artifact

- No comment

170 315(a)(23)_CDS – Service

- It would be useful to identify some CDS service providers that could be used to fulfill this criterion.
- It would be helpful to provide a thorough acceptable services list along with definitions so that we might better understand the service expectation.
- We are unfamiliar with many of the terms defining the services in the examples provided and request links to service definitions and availability.
- Please specify the minimum requirements to be compliant with this criterion. To what degree must a service or service(s) be implemented for certification?
- Please provide a more thorough acceptable services list.

170 315(b)(1)_Transitions of Care

- Item 3 is listed as optional, however it is really conditional based upon the selection of SMTP. If SMTP is selected, then step 3 is required. Please adjust terminology to reflect this conditional status.
- Please clarify null vs. empty based upon guidance from the implementation guides.

170 315(b)(2)_Clinical Information Reconciliation and Incorporation

- The criterion is written with the wording “summary received is or can be properly matched to the correct patient”. However, the test procedure states “is” matched. The test procedure should use the same wording as the criteria.
- If there is any intention of automatic matching using algorithms only it should be stated. Otherwise, our interpretation of this criterion allows manual methods to confirm patient matching to the correct patient for document reconciliation.
- Test data should reconcile to the test procedure so that data is consistent with expectations for validation.

170 315(b)(3)_Electronic Prescribing

- Providing certification attestation from a third party vendor such as Surescripts should be an acceptable means of meeting the ONC requirements for the required message types and codified SIG criteria without the need for repetitive visual certification demonstration.
- The criterion specifies “all medications” in the metric standard. However, the language specifies liquid or volumetric dosing. The test should address only liquids, as many other dosage forms exist that do not adhere to volumetric measures at the container level (e.g., tablet packs).

170 315(b)(4)_Incorporate Laboratory Tests and Value Results

- Section 1.2 of the test procedure relates to information in the criteria related to requirements for test report display and as such the criteria have created test procedure requirements which should be reconsidered alerts and delays as specified in (g) and (h) are not typically displayed in reports, as these actions by the lab usually occur when the lab notifies providers outside the reporting process. This information is not typically available for display in the report format from laboratory vendors. If required, this criterion will be inconsistent with the CLIA requirements for laboratory actions.

170 315(b)(7)_Data Segmentation Send

- We encourage the use of attestation with the testing tool validation any time visual inspection can be eliminated in an effort to save costly testing time. Testing tools should produce output that can validate that the standard was applied properly. Developers should be able to provide testing tool documentation as attestation of successful validation from the testing tools.

170 315(b)(8)_Data Segmentation Receive

- It is our expectation that role-based security would accomplish both the ability to meet the document sequestration requirement for document storage as well as limited access by a certain set of providers. By applying the proper security to the metadata associated with the document, the document cannot be accessed for viewing regardless of where the document is stored.
- Provide further clarity for any expectation of physical document storage separately from other documents.

170 315(b)(9)_Care Plan

- No comments

170 315(e)(1)_View Download and Transmit to Third Party

- Please specify the required steps in much more detail. It is not clear what steps are required for the test procedure in the shortened format. We are concerned that many steps must be added to adequately align with the expected results.
- Any expected results for negative testing steps from previous 39 page procedure are not indicated in this procedure.
- Please align steps with the specified tool so that developers understand when to use the tool for a particular step.
- Include a link to the 42 CFR requirements as well as a plain English description of the required CLIA data elements.
- Please provide a link to each of the testing tools. Please specify the version and exact name of each of the testing tools.
- Under activity history log, please clarify that the only action and information that must be stored for an API call is the request for access by the API.

- Please clarify how testing of an API will occur. Is a test tool being developed? Is there an expectation that the testing labs will develop a product to make an API call for each vendor that they certify? Are ONC or NIST going to develop these products? Vendors would need immediate access to these products to begin testing.
- For criteria that utilize testing tools to validate output from the EHR, no visual inspection should be required. Testing tools should produce output that validates the standard was applied properly. Vendors should be able to provide testing tool documentation as attestation of successful validation from the testing tools.

170 315(e)(2)_Secure Messaging - Gap

- No comments

170 315(f)(1)_Transmission to Immunization Registries

- Will there be a proxy registry to use a tool to test? We encourage development of such a tool due to various discrepancies among registries.
- We suggest separating the steps for query for history and forecast and consider whether or not these should be separate criteria.
- We are concerned about the requirements for forecast display in consideration to various parameters which could apply. Is the forecast related to age parameters? Is the expected result met simply by providing the CDC forecast? Is it acceptable for the developer to display their own formatted forecast, or does the rule specify only the display of the forecast received?
- Is there any expectation that discrepancies in the forecasts are addressed in the display consideration?
- The test procedure implies reconciliation is necessary for this criterion. We suggest removal of the following test lab verification: “tester verifies that the immunization information returned in response to a query to the immunization registry for an evaluated immunization history and forecast for a patient is displayed correctly and without omission”. Reconciliation should not be included in the test procedure as the EHR cannot confirm such information.
- How would variation across states be accommodated?
- We encourage developments off a testing tool for any history or forecast requirements meeting the adopted standard?

170 315(f)(2)_Syndromic Surveillance

- No comments

170 315(f)(5)_Transmission to Public Health Agencies - Case Reporting

- No comments

170 315(h)(1)_Direct Project - Gap

- No comments

170 315(h)(2)_Direct Project Edge Protocol and XDR-XDM - Gap

- For each expected result using the certificate discovery tool and the testing tool, the steps need to be defined so that the developer can clearly understand the multiple steps involved in the procedure and when/how the tools are to be used for successful completion of the steps.

- An understanding of the tool components with regard to what generates an error would be helpful in pre-testing.
- We encourage the use of attestation with the testing tool validation anytime visual inspection can be eliminated in an effort to save costly testing time. Testing tools should produce output which can validate the standard was applied properly. Developers should be able to provide testing tool documentation as attestation of successful validation from the testing tools.

170 315(h)(3)_SOAP Transport and XDR-XDM - Gap

- We encourage the use of attestation with the testing tool validation anytime visual inspection can be eliminated in an effort to save costly testing time. Testing tools should produce output which can validate the standard was applied properly. Developers should be able to provide testing tool documentation as attestation of successful validation from the testing tools.

170 315(h)(4)_HPD Request

- As we reviewed the draft test procedures, several comments were raised about the criterion and any potential to expand the criterion to include expansion of acceptable methods to meet this criterion until we arrive at a common implemented standard. Through Direct Trust, developers are able to query for directory information using published directory information available between Direct Trust members without the use of the adopted standard. As an alternative to the use of the standard, we encourage attestation or demonstration to this query approach which exists in the marketplace today as an optional means of accomplishing this criterion.

170 315(h)(5)_HPD Response

- As we reviewed the draft test procedures, several comments were raised about the criterion and any potential to expand the criterion to include expansion of acceptable methods to meet this criterion until we arrive at a common implemented standard. Through Direct Trust, many developers are able respond to queries for directory information using published directory information available between Direct Trust members without the use of the adopted standard. As an alternative to the use of the standard, we encourage attestation or demonstration to this approach which exists in the marketplace today as an acceptable means of acquiring certification without requiring the use of the standard.

170 315(f)(7)_Transmission to Public Health Agencies - Healthcare Surveys

- Please provide real world examples of acceptable surveys that may be used to create the healthcare survey document as proposed.
- We encourage the use of attestation with the testing tool validation any time visual inspection can be eliminated in an effort to save costly testing time. Testing tools should produce output that can validate that the standard was applied properly. Developers should be able to provide testing tool documentation as attestation of successful validation from the testing tools.

Attachment A: Suggested Format

CRITERION TITLE (a)(1)
CRITERION DETAIL– state the criterion

TESTING COMPONENTS GRID – What is required for this test? Specify attestation, visual, data, testing tool, and/or data exchange.

Required Test	Requirements (enough detail to define steps)	Expected Results (as in 2014 Edition)	Additional Guidance (any clarifying intent, flexibility, preamble)
Step 1			
Step 2			
Step 3			

Step 1

- **Data Required**
 - Define the data required or state “vendor specified”
- **Standards & Vocabulary**
 - Provide the URL link within the document
- **Attestation**
 - If allowed, include specific questions expected to be addressed
- **Testing Tool Link**
 - If the final testing tool is not available, please include links to current tool development so that evaluation may occur prior to finalization
- **Optional Requirements**
 - Defined as above
- **Include the actual standard or vocabulary, not just the reference to certification rule**
 - For example, HL7 Version 3 Standard: Clinical Decision Support Knowledge Artifact Specification, Release 1.2 DSTU (July 2014) (“HeD standard Release 1.2”)
 - Provide the URL link within the document

Document History	Versions and Dates	Updates and Document Links	Summary of Changes
Dependencies	Privacy and security requirements		

--	--	--	--