

Summary of Comments for 2015 Edition NPRM Draft Test Procedures

On October 16, 2015, [ONC released the 2015 Edition Health Information Technology \(Health IT\) Certification Criteria, 2015 Edition Base Electronic Health Record \(EHR\) Definition, and ONC Health IT Certification Program Modifications \(80 FR 62601\)](#) (“2015 Edition Final Rule”). Beginning on October 22, 2015, the test procedures were made available in batches for public comment. Comments were accepted through November 30, 2015. The public comments were analyzed and used to modify the final test procedures, test data, and test tools, as well as the Certification Companion Guide. The following provides an overview of the comments received and ONC’s response to the comments. The document is organized by the criteria number. For certain criteria, separate comment periods were held in 2016 and 2017. This document was updated to include those comments and ONC’s response to the comments.

Please note that throughout the document, the comments and responses refer to sections of the test procedures, which were numbered using the criteria’s numbering system from the 2015 Edition Final Rule. Unless specified, when this document refers to criteria numbers, it is referring to the section in the test procedure, not the 2015 Edition Final Rule. The 2015 Test Procedures and Certification Companion Guides (CCGs) can be located on the [2015 Test Methods page](#).

1. § 170.315(a)(1) CPOE Medications

Comment

A few commenters requested additional clarification on the purpose and requirements of the optional reasons for order field. They requested clarification on if the field should be discrete and suggested a more precise label for the field would be helpful.

Response

See the (a)(1) Certification Companion Guide for clarification on the age requirements.

Comment

A commenter noted for consistency “Standard(s): None” should be added after (II) Optional.

Response

We agree with commenters and have added Standard(s): none to the Optional section.

2. § 170.315 (a)(2) CPOE – Laboratory

Comment

A commenter requested clarification whether the optional reason for order filed must be a discrete field.

Response

See the (a)(2) Certification Companion Guide for clarification on the age requirements.

Comment

A commenter requested that criteria (i) in the test procedure be revised from “orders” to “order” to align with the other CPOE test procedures.

Response

We agree with the commenter and have made this change.

3. § 170.315 (a)(3) CPOE – Diagnostic Imaging

Comment

A commenter requested clarification of if the optional reason for order filed must be a discrete field.

Response

See the (a)(3) Certification Companion Guide for clarification on the age requirements.

4. § 170.315 (a)(4) Drug-Drug, Drug-Allergy Interaction Checks for CPOE

Comment

A commenter requested a definition be provided for “indicate.”

Response

We clarify that how the interventions are automatically indicated to a user is at the discretion of the health IT developer, and they have the flexibility to implement this functionality based on their customer preferences and in line with their user-centered design requirements.

Comment

A few commenters requested that the test procedure be updated to provide direction to the tester on how to verify that adjustments made to the severity level actually change or do not change what is displayed to the end user. One commenter suggested using the approach from the 2014 Edition test method for 170.314(a)(2) to do so.

Response

We agree with commenters and have modified step 1 in section (ii)(A)-(B) to indicate that the System Under Test should adjust the severity level for the interaction that is demonstrated in section (i), during the demonstration. The tester should use visual inspection to verify that the change has been made.

Comment

A commenter noted that for the test lab verification for (a)(4)(i) it should read “based on the patient’s medication allergy list” not “based on the patient’s allergy list”.

Response

We have modified the (a)(4) test procedure to indicate that the interaction is based on the patient’s medication allergy list.

5. § 170.315 (a)(5) Demographics

Comment

A commenter requested the option to meet this criterion by providing attestation documents for EHRs certified to the 2014 Edition 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.

Response

The demographics criterion has been modified from the 2014 Edition and is therefore not eligible for gap certification. Consequently, health IT developers must demonstrate the functionality and cannot submit attestation documents to meet the criteria requirements.

Comment

A commenter noted that “decline to specify” (a)(5)(i) should apply to (a)(5)(i)(A), (B), (C), and (E).

Response

Health IT Modules must be able to record “decline to specify” for paragraphs A, B, D, and E. We have updated the (a)(5) test procedure to separate out recording of decline to specify for these elements into a separate step for clarity.

Comment

A commenter asked for clarification on how the requirement to record aligns with the requirement to only roll up the categories for aggregation that was included in the 2015 Edition Final Rule.

Response

We note that the term “roll-up” has been changed to aggregate to align to [80 FR 62747](#). We further clarify that the concepts in the “Race & Ethnicity” – CDC code system are pre-mapped to the race and ethnicity categories in the OMB Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15. Testing will verify that the more granular race and ethnicity codes are correctly mapped to the OMB standard.

Comment

A commenter requested clarification on how “Other Race” should be mapped to an OMB standard.

Response

The concepts in the “Race & Ethnicity” – CDC code system are pre-mapped to the race and ethnicity categories in the OMB Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15. Testing will verify that the more granular race and ethnicity codes are correctly mapped to the OMB standard.

Comment

A commenter requested that “preliminary” be added before “cause of death” for the Test Lab Verification (ii)(1).

Response

We have added the term preliminary before cause of death at the specified location.

Comment

A commenter requested clarification on if (i)(1) requires both the data elements to be recorded and that the patient declined to declare one of the data elements to occur simultaneously.

Response

We clarify that the user must be able to record whether the patient declined to specify a race, an ethnicity, and both. We have modified the test steps to break out demonstration of declination for the applicable data elements.

Comment

A commenter noted that date of birth is missing from the list of demographic data elements.

Response

We have added the date of birth to the list of demographic data elements.

6. § 170.315 (a)(6) Problem List

Comment

A commenter requested clarification on what is expected to have been done prior to and during the certification demonstration to the ONC-ATL. Should the problem list already have been entered prior to testing or should it be entered live as part of the testing?

Response

We note that it is at the discretion of the ONC-ATL to accept pre-entered data or to require entering of data live as part of the visual inspection process.

Comment

A commenter requested clarification on how a Health IT Module could demonstrate their capability to use the latest version of SNOMED CT without having to recertify to the entire criterion.

Response

ONC-ATLs and ONC-Authorized Certification Bodies (ACBs) have the discretion to offer streamlined testing (e.g., attestation) to SNOMED CT® (U.S. Edition) for systems that have been certified to the 2014 Edition problem list certification criterion (§ 170.314(a)(5)).

Comment

A commenter requested clarification of if this criterion should include a requirement to be able to access the problem list history.

Response

The final regulation text specifies active problem list.

7. § 170.315 (a)(7) Medication List

Comment

A commenter requested that the terminology “from the entire hospitalization” be replaced with “for the duration of the entire hospitalization” to ensure medications that were active upon admission are also included.

Response

We agree with the commenter and have made this change to the (a)(7) test procedure.

8. § 170.315 (a)(9) Clinical Decision Support

Comment

A commenter requested clarification if only two CDS interventions are required for testing in section (iii)(A-F) Test Lab Verification.

Response

We decline to specify in the test procedure the number of CDS interventions that must be demonstrated during testing. We do clarify that health IT developers will be required to demonstrate that a CDS intervention is based on each of the six data elements as well as a combination (two or more data elements). It is up to the discretion of the ONC-ATL as to the exact number of CDS interventions that must be demonstrated.

Comment

A commenter requested clarification on if the enable-disable functionality must be for each individual CDS rule or if it can be for a group of rules.

Response

The criteria is not prescriptive related to the level (individual versus data element group) at which a CDS intervention should be enabled. This portion of the criteria is unchanged from 2014 and should be configurable only by a limited set of users.

Comment

A few commenters requested that the test procedure allow for attestation for the 2014 Edition requirements that are unchanged. One commenter noted that the test of the diagnostic resources via Infobutton should be required.

Response

The 2015 Edition Final Rule did not indicate that this criterion is eligible for gap certification as it has been modified. Therefore attestation is not acceptable for this criterion. We note that [80 FR 62748](#) allows a Health IT Module to identify diagnostic and therapeutic reference information using the standard specified at 170.204(b)(3) or 170.204(b)(4). The (a)(9) test procedure therefore indicates that a Health IT Module must demonstrate that one of the standards is used, and we decline to require the use of Infobutton.

Comment

A commenter requested clarification that age, not data of birth, is the correct data element to be used for the Infobutton standard.

Response

See the (a)(9) Certification Companion Guide for clarification on the age requirements.

Comment

A number of commenters requested clarification on the cross-referenced criteria and whether the test procedure referenced the correct cross-reference, and if such reference indicated that there was a dependency in testing on the referenced criteria.

Response

We understand that the cross-referenced criteria was confusing to commenters. To make the (a)(9) test procedure clearer, we have removed the cross references.

Comment

A commenter requested clarification for (v)(A)(1-4) as to what the system must be able to prove during testing if the release and revision date are available for display within the system.

Response

Health IT developers would have to demonstrate that they have the ability to provide links to the release and revision date. We note that health IT developers have the option of which source attributes they demonstrate for testing.

Comment

A commenter requested for (ii)(A)(1) if the intervention and reference resources that are created should be based on a user's role, or if the configuring of those resources that must be based on a user's role.

Response

We have clarified in section (ii)(A) that both the configuration of the intervention and reference resources and the subsequent provision of each is based on a user's role.

Comment

A commenter indicated Test Lab Verification (i)(1) that "are based on interactions with the system" should read "are based on interactions within the system."

Response

We disagree with the commenter's recommendation. [80 FR 62748](#) states that "interventions provided to a user must occur when a user is interacting with technology." We decline to modify the (a)(9) test procedure.

Comment

A commenter suggested modifying the Test Lab Verification (iv)(B) to “...based on the required data elements (A), (B), and (D) and one combination of the data elements for the user...”.

Response

We decline to make this change to the (a)(9) test procedure and feel that the current language is clear in its intent.

9. § 170.315 (a)(10) Drug-Formulary and Preferred Drug List Checks

Comment

A commenter requested clarification on the definition of medication order. The commenter noted in some systems entering a new medication into the patient’s record via the medication list will also create a medication order.

Response

We have removed the language regarding a medication order and have changed it to medication. We believe this addresses the commenter’s concern.

Comment

A commenter noted that preferred drug lists are normally created with local content not real time checks so nothing is received automatically. The commenter suggests changing the requirement to the preferred drug list information is displayed automatically, rather than received automatically.

Response

We agree with the commenter and have modified the language in the (a)(10) test procedure to indicate that that the preferred drug list information is automatically displayed.

10. § 170.315 (a)(11) Smoking Status

Comment

A commenter requested clarification regarding whether this criterion requires a system to use the eight SNOMED-CT smoking statuses to be certified.

Response

See the (a)(11) Certification Companion Guide for clarification on this requirement.

11. § 170.315 (a)(12) Family Health History

Comment

Commenters requested clarification on how a Health IT Module could demonstrate the capability to use the latest version of SNOMED CT without having to recertify to the entire criterion.

Response

We note that per the preamble of the 2015 Edition Final Rule, health IT developers may submit documentation demonstrating that they use the latest version of SNOMED-CT. It is at the discretion of the ONC-authorized testing laboratories (ONC-ATLs) what level of documentation is required.

12. § 170.315 (a)(13) Patient-Specific Education Resources

Comment

A commenter requested clarification whether this test procedure meets the requirement of Objective 5 Measure 2 of Stage 3 of Meaningful Use. Objective 5 seems to require the electronic export of the patient education to meet the objective but the test procedure does not include a requirement for electronic generation.

Response

This criterion does not require the electronic export of patient education materials. We note that both the (g)(1) Automated Numerator Recording criterion and the (g)(2) Automated Measure Calculation criterion do require for purposes of incrementing the numerator that the patient education materials be electronically made available for Stage 2 measures.

Comment

A commenter noted an inconsistency between the regulatory text and the test procedure. The regulatory text calls for the Health IT Module to identify patient specific education resources while the Test Lab Verification (i)(A-B) uses “generated” and both columns in (ii) use “provides” instead. Generated and provides should be replaced by “identified” to align with the regulatory text.

Response

We agree with the commenter and have modified the language to indicate that the Health IT Module identifies the resources.

Comment

A commenter requested clarification on what counts towards the numerator for the measure. Clarification was requested on a Health IT Module identifying patient specific education, without any provider intervention, through available clinical data counting in the numerator.

Response

We note that calculation of Meaningful Use measures are not part of the (a)(13) criterion, but are part (g)(1) Automated Numerator Recording criterion and the (g)(2) Automated Measure Calculation.

13. § 170.315 (a)(14) Implantable Device List

Comment

A commenter requested clarification on the expected length of a UDI.

Response

See the (a)(14) Certification Companion Guide for a description of UDIs, including the expected length.

Comment

A few commenters requested clarification whether health IT developers will have the option to choose from among the three formats of UDIs available or if there is a more specific requirement that would require health IT developers to choose test data that includes all three formats.

Response

We have clarified in the (a)(14) test procedure that health IT developers are required to demonstrate all three formats of UDIs during testing.

Comment

A commenter requested clarification on what the source for the UDI that will be parsed is. The commenter notes the UDI per the FDA represents a set of up to 6 elements that make up the UDI. These can be represented as individual elements, and/or be present in a barcode on the label. This barcode, and the data string printed under that barcode, may contain other data as well. Therefore, that data string is not "the UDI," but would be the string from which to parse the UDI elements. The commenter suggests that for purposes of testing this criterion the data string should be the source.

Response

This requirement focuses on the ability to record the device identifier and the available production identifiers that make up the UDI per the FDA UDI regulation. It does not require or seek to prescribe whether or how technology should provide a user with the capability to enter or "capture" UDIs. While additional information beyond the UDI may be included in the machine readable or easily readable plain text, these additional data attributes are not included in this requirement and should not be recorded.

Comment

A commenter noted that the 2015 Edition preamble references "active UDIs." The commenter requested clarification that the intent is to reference the UDI for a device that is actually implanted (i.e., the device is actually "active" or "inactive"), while the UDI for either device is always active as it never changes.

Response

The (a)(14) test procedure has been updated to reflect the language from the 2015 Edition Final Rule. See the (a)(14) Certification Companion Guide for clarification on referencing the UDI for a device.

Comment

A few commenters requested clarification that when the criterion states to display the active UDIs for each implantable device it is acceptable to just display the individual UDI elements, without the barcode data string as printed on the label when present.

Response

See the (a)(14) Certification Companion Guide for clarification on displaying UDIs.

Comment

A commenter requested clarification for why a standard wasn't included for (a)(14)(ii).

Response

We refer the commenter to the preamble in the 2015 Edition Final Rule for a discussion on the inclusion or exclusion of standards [80 FR 62630](#).

Comment

A commenter requested clarification for (a)(14)(i) if the intent of the use of "identifiers" is that a single UDI for a patient be record or if multiple UDIs are required.

Response

We clarify that all UDIs for a patient should be recorded if the patient has multiple implantable devices.

14. § 170.315 (a)(15) Social, Psychological, and Behavioral Determinants Data

Comment

A commenter requested clarification on the definition of depression and if the aim is to capture a medical diagnosis only.

Response

We clarify that the depression that is recorded for this criterion is not the same as the diagnosis, and the aim is not to capture medical diagnosis only as this is typically captured in the patient's problem list.

Comment

A commenter stated that the test procedure should allow Health IT Modules to enable a user to document a response of declined to answer instead of limiting the answer responses to the indicated standards that in some instances do not include a LOINC code for patient declined to answer.

Response

Consistent with the certification criterion, we have modified the (a)(15) test procedure to make it clearer where "decline to specify" should be recorded. We clarify that the Health IT Module is not required to use the LOINC codes to record patient declination.

15. § 170.315 (b)(1) Transitions of Care

Comment

A commenter noted that the System Under Test and Test Lab Verification numbering is not always consistent and aligned making it difficult to follow. The commenter requested changes be made to provide a clear relationship for related content in the columns.

Response

We agree with the commenter that the lack of alignment between the two columns was confusing. We have added headers to each column to make it clear which steps in the System Under Test correspond to the steps in the Test Lab Verification column.

Comment

A commenter noted that "170.210(g) RFC 5905: Network Time Protocol Version 4: Protocol and Algorithms Specification, June 2010" should not be referenced because it is not part of the criterion.

Response

We agree with the commenter that this was an error and have removed the reference from the (b)(1) test procedure.

Comment

A commenter suggested that the test procedure should note that the Cognitive Status Observation template has been deprecated in C-CDA 2.1 and that the Mental Status Observation template has replaced it. The C-CDA validator should look for Mental Status Observation and issue an error if the deprecated Cognitive Status Observation is used instead.

Response

A note has been added to the (b)(1) Certification Companion Guide, please see it for further information.

Comment

A commenter requested clarification for (ii), on how to validate code sets so that validation is consistently performed and verified for certification. If the recipient of the C-CDA document is not licensed for a particular code set, the Health IT Module needs a mechanism to validate that the correct code set was still included. Similarly, code sets that are correctly included in the C-CDA document could appear invalid if the document includes a different version of the code set. A centralized web service or another source of truth to validate that code sets are included would seem to be a better approach.

Response

Health IT developers should anticipate that an ONC-ATL could ask them to test any code set. A centralized website or source of truth does not currently exist to validate codes against. Health IT developers may use the Standards and Implementation Testing Environment (SITE) or the Edge Test Tool (ETT) to test their products prior to presenting the product for testing to an ONC-ATL.

Comment

A commenter noted an inconsistency between the CDA header test data and the data elements required in the CDA R2.1 Implementation Guide and requested that the test procedure align with the CDA Implementation Guide.

Response

We note that the test procedure requirements align to [80 FR 62749](#). In some cases [80 FR 62749](#) may require data elements that are not required in the CDA Implementation Guide. In such cases, the requirements in [80 FR 62749](#) are what health IT developers should follow.

Comment

A commenter requested the test procedure clearly state the options available to Health IT Modules for edge certification.

Response

We have modified the (b)(1) test procedure to clearly state which sections are optional or alternates.

Comment

A commenter requested clarification on if the health IT developer needs to manually enter data or can the health IT developer parse the data received from the test case and then use that data to create documents to satisfy the create C-CDA requirement and send them to satisfy the send test cases? Or do the test cases need to be run with C-CDAs created from manually entered patient test data?

Response

We clarify that data must be manually entered into the Health IT Module.

Comment

A commenter requested clarification on what the term “roll-up” requires in the test procedure.

Response

We have removed this term and instead use the term aggregate, which is consistent with the certification criterion.

16. § 170.315 (b)(2) Clinical Information Reconciliation and Incorporation

Comment

Two commenters requested clarification on if the test procedure could be combined with the clinical decision support so health IT developers only have to demonstrate duplicate capabilities once. One commenter assumed that coordination could occur with the ONC-ATLs to avoid duplicating steps for testing.

Response

It is up to the discretion of the ONC-ATLs to combine or not combine test procedures together for purposes of streamlining the testing process.

Comment

A commenter requested for Test Lab Verification (iii)(A) that C-CDA 1.1 Referral Note should be removed as it is not included in that version of the C-CDA and that only CCD should be required when testing receipt of C-CDA 1.1

Response

We agree with the commenter and have clarified in the (b)(2) test procedure that the C-CDA R1.1 only requires the CCD document template.

Comment

A commenter noted for (iii)(A) that additional information would be required to test a reconciliation. The commenter recommended the test should at least require the inclusion of medication name, problem description, medication dose, and dosage form.

Response

We note that the (b)(2) test procedure cannot require more stringent capabilities than [80 FR 62749](#), which does not require the more detailed information.

Comment

A commenter requested clarification on what is considered a valid source for the data.

Response

We note that it is an expected best practice for health IT developers to implement data provenance and quality practices. However, we note that it is up to the health IT developer if they implement data provenance to show the source of the data. The 2015 Edition Final Rule does not specify what are considered valid sources.

17. § 170.315 (b)(3) Electronic Prescribing

Comment

A commenter noted inconsistency between System Under Test and Test Lab Verification in section (ii)(C). Cancel prescriptions (CANRES) are included in System Under Test but not Test Lab Verification, and section (ii)(F) does not include request and receive medication history information (RXHREQ).

Response

We corrected the (b)(3) test procedure to include the correct items in sections (ii)(C) and (ii)(F).

Comment

A few commenters noted that the test procedure requires functionality that is not needed to meet meaningful use. Commenters requested these items be removed or, at a minimum, split out so that health IT developers could certify to only those criteria required for meaningful use.

Response

As discussed in the preamble of the 2015 Edition Final Rule, the 2015 Edition is not limited to criteria that directly support meaningful use. Therefore, we decline to split out capabilities in the test procedure based on whether they are or are not required for meaningful use.

Comment

A commenter noted that software for acute care settings should not be required to demonstrate refill functions because CMS does not require eligible hospitals to do so for meaningful use.

Response

As discussed in the preamble of the 2015 Edition Final Rule, the 2015 Edition is not limited to criteria that directly support meaningful use.¹ We note that it is at the health IT developer's discretion to decide the criteria for which they seek certification; however, we decline to allow Health IT Modules to seek certification for only parts of a certification criterion, unless the test procedure specifies that a section is optional or alternative (which is based on the 2015 Edition Final Rule).

Comment

A commenter requested that the language in section (iv) be changed from "i.e." to "e.g." so that it is not implied that mL is the only metric unit of measure allowed.

Response

We disagree with the proposed change and clarified in the (b)(3) test procedure that mL is the only metric unit of measure allowed.

Comment

A commenter recommended that we clarify that a diagnosis would only be required on approved change prescriptions (CHGRES) or refill prescriptions (REFRES) when it was sent in the request.

Response

We clarified in the (b)(3) test procedure that the diagnosis will be tested on all transactions where a diagnosis can be sent.

¹ [80 FR 62603](#)

Comment

A commenter requested clarification in section (i)(F) regarding whether the standard supports the ability to retrieve information for sets of patients.

Response

The standard does not support a bulk medical history transaction.

18. § 170.315 (b)(4) Common Clinical Data Set Summary Record – Create

Comment

A commenter requested clarification regarding what level of review is required of testers to verify that the summary record is accurate and without omission.

Response

We clarified in the Common Clinical Data Set (CCDS) summary record instructions which fields must be verified in the Consolidated Clinical Document Architecture (C-CDA) via visual inspection.

Comment

A commenter requested clarification of which test cases are referenced by “each of the ambulatory and/or inpatient test cases referenced from the CCDS summary record documents.”

Response

We clarified in the (b)(4) test procedure which test cases must be used from the ETT: Message Validators – C-CDA R2.1 Validator.

Comment

A commenter noted that section (v), Test Lab Verification step 2 should also require verification of the provider’s name and office contact information.

Response

We added the provider’s name and office contact information to section (v) and note that the steps have been removed from that section.

Comment

A commenter noted that section (viii) should explicitly require multiple phone numbers and verify that they are present.

Response

We disagree with this suggestion and note that some test data may contain multiple phone numbers and other test data may only contain one phone number.

Comment

A commenter noted incorrect references to the appropriate steps in section (vi), Test Lab Verification and section (ii), System Under Test.

Response

We corrected these references in the updated (b)(4) test procedure.

19. § 170.315 (b)(5) Common Clinical Data Set Summary Record – Receive

Comment

A commenter noted that section (b)(5)(ii)(C), Display Section Views, should not require C-CDA 1.1 section views and should only require C-CDA 2.1 section views.

Response

We disagree with this suggestion and note that [80 FR 62750](#) states that section views must be displayed for documents formatted in accordance with § 170.205(a)(3) and § 170.205(a)(4).

Comment

A commenter requested clarification in section (ii)(A) on an acceptable output of parsing and how it differs from incorporate.

Response

Parsing the erroneous documents should print out the errors in a log file at a minimum for verification, they could also have displays to show it to end users.

Comment

A commenter suggested that the test procedure should note that the Cognitive Status Observation template has been deprecated in C-CDA 2.1 by the Mental Status Observation template in C-CDA 2.1.

Response

We added this clarification to the (b)(5) Certification Companion Guide.

Comment

A commenter requested that for C-CDA 1.1, Referral Note should be removed as it is not included in that version of the C-CDA and should only be required for C-CDA 2.1.

Response

See the (b)(5) Certification Companion Guide for clarification on what is required for testing.

Comment

A commenter suggested that section (i)(A) testing should not require C-CDA 1.1 documents to include data elements that were not required in the 2014 Edition of the CCDS.

Response

We disagree with this suggestion and note that [80 FR 62750](#) states that documents formatted in accordance with the standards adopted in § 170.205(a)(3) and § 170.205(a)(4) must both contain the CCDS as defined in the 2015 Edition.

Comment

A commenter requested clarification for section (ii) regarding how to validate code sets so that validation is consistently performed and verified for certification. If the recipient of the C-CDA document is not licensed for a particular code set, the Health IT Module requires a mechanism to validate that the correct code set was still included. Similarly, code sets that are correctly included in the C-CDA document could appear invalid if the document includes a different version of the code set. A centralized web service or another source of truth to validate that code sets are included would seem to be a better approach.

Response

Health IT developers should anticipate that an ONC-ATL could ask them to test any code set. A centralized website or source of truth that can be used to validate codes does not currently exist.

Comment

A commenter noted that section (i)(B) would be clearer if “Formatted according to at least one of the following standards:” was added after “Encounter diagnoses.”

Response

We added this clarification to the (b)(5) test procedure.

20. § 170.315 (b)(6) Data Export

Comment

A commenter requested clarification regarding whether “system administrator” is an acceptable role to meet the authorized user requirement.

Response

See the (b)(6) Certification Companion Guide for clarification on acceptable roles for this criterion.

Comment

A few commenters requested clarification for section (iii), Timeframe Configuration concerning what data, timeframe, and patients should be exported based on the dates filtered. Should it be patients with encounters during the filtered dates or those with any data updated within the filtered dates? Should only data from the filtered dates be included in the summary data and should more current data be excluded?

Response

We clarified that the health IT developer has discretion to decide how to pull encounters into the filtered days. We would expect that the health IT developer would inform the tester of its methodology during testing, so the tester can verify that the correct data is created.

Comment

A commenter noted a misalignment between section (i), System Under Verification step 3 and Test Lab Verification step 4 negative test. The commenter recommended that the negative test be reworded as follows: “4. Negative test: The tester verifies that an unauthorized user cannot create export summaries.”

Response

We corrected the misalignment by adding headers to clearly delineate the steps in System Under Test that match the Test Lab Verification.

Comment

A commenter requested clarification regarding whether all methods of exporting summaries will be tested.

Response

We decline to specify how many methods of exporting summaries are required for testing. We note that the ONC-ATL has discretion to decide the number of methods that will be tested, if a vendor has more than one method.

21. § 170.315 (b)(8) Data Segmentation for Privacy – Receive

Comment

A commenter requested clarification on how the C-CDA file must be received by the system being tested.

Response

There is no requirement in the test procedure on how the C-CDA file must be received; the vendor has discretion to determine how to demonstrate this during testing.

Comment

A commenter requested clarification on the definition of “sequester.” The commenter recommended that the definition should be a separate inbound message queue that is accessible only to users with appropriate security. The commenter also requested clarification regarding whether the test procedure dictates end-user display or technical approaches to how sequestering is implemented.

Response

See the (b)(8) Certification Companion Guide for clarification on “sequester.”

22. § 170.315 (b)(9) Care Plan

Comment

A commenter requested clarification concerning whether the tester should perform visual inspection of the human readable file or the XML coded text.

Response

The ONC-supplied care plan instructions indicate which data must be inspected using visual inspection. We have also updated the (b)(9) test procedure to indicate that the tester should create a human readable version of the C-CDA in order to perform this visual inspection.

23. § 170.315 (c)(1) Clinical Quality Measures – Record and Export

Comment

A commenter noted that Step (i)(2) indicates manual entry will be completed for each CQM. Cypress was designed to only test a select number of CQMs for this portion and not each and every certified CQM.

Response

Related to § 170.315 (c)(1), every clinical quality measure presented for certification will require manual entry. If testing includes § 170.315 (c)(2), Cypress will rely on the import to demonstrate the “recording” function. If a user interface is not available, a record entry can be demonstrated with the creation and import of structured documents.

Comment

A commenter requested clarification to what “data format” is referring to in ‘Setup’ step (i)(1).

Response

We modified the (c)(1) test procedure to outline the requirements based on the criteria selected for certification and testing.

Comment

A few commenters requested clarification to the specification that the SUT must demonstrate “automated recording of data needed for each of the certified CQMs” when this requirement is appropriately spelled out in § 170.315 (c)(2)(i). In addition, a few commenters requested clarification if batch and manual data entry or only one of the two options was required.

Response

We modified the (c)(1) test procedure to include a note that if the applicant is only testing/certifying to § 170.315 (c)(1), batch import is not required.

Comment

A commenter recommended combining the export of multiple measures at once for step 4 of the Test Lab Verification section under (ii) Export.

Response

We decline to modify Cypress and the (c)(1) test procedure as we have been very conscious to make Cypress as efficient as possible but batch will not be utilized to allow each measure to stand alone.

Comment

A commenter requested clarification on the spirit of the certification program in regards to the maximum number of patients that an EHR can export QRDA I documents for as their EHR freezes and crashes if more than a few patients are selected.

Response

We have no requirement on the specific number that must be exported, but the requirement is for a single patient or a group of patients. Please refer to the (c)(1) Certification Companion Guide for additional information.

Comment

A few commenters requested clarification on step 4 under criterion (i) under the Test Lab Verification. Is the intention that the Proctor will be visually validating all of the test data or if spot-checking is sufficient?

Response

Spot-checking of the data should be utilized but it is up to the ONC-ATL’s discretion to determine the amount of validation.

Comment

A few commenters noted that for consistency, under criterion (i) the heading above step 3 of the System Under Test should be updated from “Batch Entry” to “Automated Batch Entry” to match the heading of the Test Lab Verification.

Response

We agree with the commenter and have modified the (c)(1) test procedure to reflect “Record Batch Entry” in the System Under Test column and Test Lab Verification column.

Comment

A commenter noted an inconsistency under criterion (ii) the alternate for step 5 of the Test Lab Verification states “A user may use the Cypress Certification API to perform Step 3 of the System Under Test”, however there is no step 3 of the System Under Test.

Response

We corrected this in the updated the (c)(1) test procedure.

Comment

A commenter noted that the testing components have the documentation icon crossed out; however, criterion (ii) step 1 requires that documentation is submitted.

Response

We agree with the commenter and have made the change.

Comment

A commenter requested clarification on whether the test data for § 170.315 (c)(1) and § 170.315 (c)(2) is the same set of test data to be used for both criteria.

Response

The test data and patients are the same for § 170.315 (c)(1) and § 170.315 (c)(2).

Comment

A commenter requested clarification on when the test data for § 170.315 (c)(1) and § 170.315 (c)(2) would be available. In addition, the commenter requested the expected timeframe as to when vendors would be able to certify eQMs for the 2015 Edition.

Response

A mature set of test data was made available with the release of Cypress v3 on July 28th 2016. Testing was made available once the ONC-ATLs and ONC-ACBs received a scope expansion for the CQM criteria (§§ 170.315 (c)(1) - (4)).

Comment

A commenter requested clarification on what the tester is expected to see during Visual Inspection under criterion (i) step 3 under the Test Lab Verification.

Response

We modified the (c)(1) test procedure for clarification.

Comment

A commenter requested clarification on detailed information on what type of ‘documentation’ is required as per criterion (ii) step 1 under the System Under Test.

Response

We modified the (c)(1) test procedure for clarification on the type of documentation required for submission.

Comment

A commenter requested clarification on criterion (ii) step 1 under the Test Lab Verification and the requirement on a “QRDA I data file can be exported at any time (on demand) and without any developer assistance for one or more CQMs associated with one or more patients”. A few commenters recommended the step be updated to state “QRDA I data file(s) be exported at any time (on demand) and without any developer assistance for one or more patients for the eCQMs that the provider has chosen for the reporting period”. In addition, clarification was requested on whether any timing element is involved with the ‘on demand’ export.

Response

We have updated the (c)(1) test procedure to incorporate recommendations, and refer commenters to the (c)(1) Certification Companion Guide for further clarification.

Comment

A few commenters requested clarification on criterion (ii) step 2 under the Test Lab Verification that warnings are acceptable and will not cause a system to fail the certification step, including if additional data is included.

Response

We agree with part of what the commenters have requested and have clarified the step in the (c)(1) test procedure in regard to warnings, with additional clarification added to the (c)(1) Certification Companion Guide. Additional data outside of the measure(s) being reported, not test-specific but document-specific, should not be included.

Comment

A commenter recommended modification on criterion (ii) step 4 under the Test Lab Verification that a separate QRDA I file is not required for each CQM.

Response

We decline to make this change to the test procedure as the ability to export a QRDA I file for each measure is required for single measure testing. Additional clarification for this criterion has been added to the (c)(1) test procedure.

Comment

A commenter noted that in several encounters with a number of EHRs who can technically export QRDA I files, the process is so slow that it does not work in practice. The commenter suggested requiring the export take no more than a minute per 600 patients (i.e., 10 patients per second).

Response

We do not require a specific time frame by which an export must occur, as we must allow for variability within and across systems. Please refer to the (c)(1) Certification Companion Guide for additional clarification on the timeliness of exporting QRDA files.

24. § 170.315 (c)(2) Clinical Quality Measures – Import and Calculate

Comment

A commenter noted the inconsistency between the test procedure and Cypress on the “Group Support” alternative that is part of the test procedure but not an option to test within Cypress. Other commenters asked for clarification on how to accomplish “Group Support” and if the alternative can be used.

Response

We have modified the (c)(2) test procedure to remove the group support section.

Comment

A few commenters requested clarification on “a larger test deck will be imported that covers all or greater than 80% of possible measure pathways for testing”. Is this cited as a reference note or is an additional test verification test required? Another commenter suggested that the large deck could be incredibly time consuming and cumbersome that would not serve to eliminate submission errors for other programs.

Response

We have modified the (c)(2) test procedure to remove the reference to a larger test deck. The size of the test deck will not be decreased as the increase in size is an effort to increase test coverage, including every patient population, and to increase test rigor. The size of the test deck is not related to and is not intended to eliminate submission errors.

Comment

A commenter requested clarification on whether the test data for § 170.315 (c)(1) and § 170.315 (c)(2) is the same set of test data to be used for both criteria.

Response

The test data and patients are the same for § 170.315 (c)(1) and § 170.315 (c)(2).

Comment

A commenter requested clarification on the expectation for visual inspection for criterion (i) step 2 under the Test Lab Verification.

Response

It is at the discretion of the ONC-ATL to visually inspect a Health IT module's ability to import the CQM data specified in accordance with the standard.

Comment

A commenter requested clarification on whether all CQMs should be included in a single report or each must be run individually under criterion (ii) step 1 under the System Under Test. Another commenter recommended combining the test to include multiple measures at once.

Response

We have modified the (c)(2) test procedure to clarify that an aggregate report must be submitted for each of the CQMs presented for certification. We decline to modify Cypress and the (c)(2) test procedure as we have made every effort to make Cypress as efficient as possible, but the batch functionality will not be utilized to allow each measure to be tested individually.

Comment

A commenter requested clarification on the type of information that must be de-duplicated under criterion (ii) step 1 under the System Under Test. The recommendation was to specify whether the duplicate information would be included in one file or scattered across multiple files. If multiple, then specify what patient identifiers will be included to determine the files are for the same patient.

Response

See the (c)(2) Certification Companion Guide for clarification on systems and de-duplicate patient records.

Comment

A commenter noted under criterion (ii) step 1 under the Test Lab Verification that the standard 170.205(h)(2) applies to QRDA I documents only and not to aggregated reports in QRDA III format. The commenter recommended to either reference the standard 170.250(k)(2) instead if the document is in a specific format or to indicate that no specific format is required and the data could be displayed in any format.

Response

We have modified the (c)(2) test procedure to reference the standard 170.250(k)(1) and (2).

Comment

A commenter requested clarification on the “test artifact” and the format/organization of the “data generated by the Health IT Module” referenced under criterion (ii) step 5 under the Test Lab Verification. Another commenter requested clarification about the value that is added by including all of the test data.

Response

We have modified the (c)(2) test procedure for clarification on the first comment. Regarding the second comment, all of the test data used to test (c)(2) and all of the data generated by the Health IT module serves as additional sources of information and reference should errors occur during measure calculations. To assist developers in meeting this requirement, Cypress stores all of data that is uploaded into Cypress during a test event and this data is packaged into a single archived file when the test proctor downloads the Cypress generated report.

25. § 170.315 (c)(3) Clinical Quality Measures – Report

Comment

A commenter requested clarification under criterion (i) step 1 under the System Under Test as it is unclear as to the methodology for defining “specific patient population” and would like specificity be added to this step.

Response

We have modified the (c)(3) test procedure to clarify the step.

Comment

A commenter proposed an update in criterion (ii) under the System Under Test column for the statement “The QRDA reports created in Step 1...” to be updated to “Criterion (i)” than “Step 1”.

Response

We agree with the commenter and have modified the (c)(3) test procedure to state “Criterion (i)”.

Comment

A commenter requested clarification on the requirement for the format of the data file for transmission. The data file for transmission should include the machine readable (XML) format only, with an optional additional file in human readable format. In addition, clarification is sought as to the specific expectation of .zip file in submission.

Response

We would like to clarify that the data file format for transmission is not an ONC, but a CMS requirement. The data file submission formats are required by CMS and these requirements are separate from eCQM testing criteria.

Comment

A commenter requested adding clarification to clarify that QRDA Category III Reports are required for eligible providers (EP) eCQM only.

Response

We decline to add the clarification as vendors may certify any measure to the (c)(3) criteria and should select those that are relevant for the product they're certifying to. Please refer to the (c)(3) Certification Companion Guide for more information.

Comment

A commenter asked about certification for eligible hospital (EH) clinical quality measures and the support of the ONC 2015 Edition certification CQM specifications. Specifically, would it be acceptable if functionality needs to be changed from the version that was used for ONC 2014 Edition certification.

Response

Please refer to FAQ #42 and the (c)(3) Certification Companion Guide. If possible, the Health IT certified version to the ONC 2015 Edition should be a new version. If the software is unable to be versioned, it will only be expected to follow the newest ONC 2015 Edition.

Comment

A commenter noted that testing the optional offering for QRDA's validation using Cypress to validate that they can be electronically accepted by CMS is duplicative for vendors. They noted that vendors already perform this validation directly with CMS to the SEVT tool later in the process.

Response

Document validation required by (c)(3) is applicable across multiple CMS submission programs. CMS program specific criteria are not required for certification and are included as an optional feature in Cypress only for the benefit of pre-certification testing. Please also note that only test data is acceptable through the SEVT interface, while a downloadable version of the Cypress Validation Utility is available by itself or with Cypress v3. The optional offering has not been removed.

26. § 170.315 (c)(4) Clinical Quality Measures – Filter

Comment

A commenter requested clarification on whether the Cypress Gold Standard Test Data or other ONC provided test data would be used for step 1 for criterion (i) under System Under Test. In addition, the commenter asked about the value of providing all of the data in a test artifact (requested under Test Lab Verification step 2) if the data is provided to the developer.

Response

We have modified the (c)(4) test procedure to clarify the step. Regarding the second comment, all of the test data used to test (c)(4)(ii) and all of the data generated by the Health IT Module serves as additional sources of information and reference should errors occur during testing. To assist developers in meeting this requirement, Cypress stores all of data that is uploaded into Cypress during a test event and this data is packaged into a single archived file when the test proctor downloads the Cypress generated report.

Comment

Several commenters requested clarification on the requirement(s) for data filter elements; the minimum number of combinations, single-select or multi-select, how filtering should be accomplished on unstructured data, such as “Practice site address”, the CQM value sets and whether it references only the Dx codes for the individual CQM or all across all certified CQMs, etc.

Response

We have modified the (c)(4) test procedure to clarify the step. See the (c)(4) Certification Companion Guide for clarification on what is required for filtering for data elements that have unstructured data, such as “Practice site address”.

Comment

A commenter noted that the provider type was part of the data filter elements; however, it is not currently captured in the QRDA standard or included in the aggregate reports that are uploaded to Cypress. Because of this, the commenter asked for clarification on the verification of this data element.

Response

See the (c)(4) Certification Companion Guide for clarification on the mapping of the provider type.

Comment

A commenter requested the use of visual inspection instead of utilizing Cypress to verify the test lab filter data results due to the potential for errors because the patients may not display the same even though the sort filter is correct.

Response

In Cypress, the order of submitted data does not affect the results. ONC was not able to verify the possibility of error(s) as described by the commenter. If any Cypress results are believed to be incorrect during testing, please inform ONC so that these issues may be resolved.

27. § 170.315 (d)(1) Authentication, Access Control, Authorization

Comment

A commenter noted an inconsistency between the requirements for the System Under Test, which checks the authenticity of a user's unique identifier, and the Test Lab Verification, which checks that the Health IT Module can create a unique identifier.

Response

We modified the (d)(1) test procedure to indicate in the System Under Test column that prior to receiving authentication credentials for access, the user's unique identifier must be verified. Additionally, in the Test Lab Verification step, the tester verifies that the Health IT Module can create a user's unique identifier and that the newly created user identifier and authentication credentials enable access to electronic health information.

28. § 170.315 (d)(2) Auditable Events and Tamper-Resistance

Comment

A commenter requested clarification concerning whether a system administrator is considered a user for purposes of disabling the audit log.

Response

See the (d)(2) Certification Companion Guide for clarification on the user roles.

Comment

A commenter requested that we clarify what is meant by "specifying inquiry" in the audit log.

Response

See the (d)(2) Certification Companion Guide for clarification on specifying inquiry.

Comment

A commenter requested additional information on situations in which a change to user privileges needs to be audited. Would such a change be limited to those automatically granted during an emergency access event? Or would it include changes to user privileges performed by a system security administrator in governing the general security rights granted to a user?

Response

We decline to provide scenarios that would require auditing as this may unnecessarily limit the scope of the criterion. All changes need to be audited.

29. § 170.315 (d)(3) Audit Report(s)

Comment

A commenter requested that we clarify what is required by “specific time period.” Is a date sufficient or is time required as well? Is having only a date range acceptable if the report still shows events by date and time stamp?

Response

We note that § 170.210(e) specifies that data and time must be recorded.

Comment

A commenter noted that Network Time Protocol (NTP) was previously not a requirement for (d)(3). Commenter requested clarification concerning whether the NTP testing is required in instances where (d)(3) is being tested, but not (d)(2) or another NTP-required criteria.

Response

We note that the NTP requirement was introduced in the 2014 Edition; however, the 2014 Edition test procedure did not specifically check for NTP, though it is required by the standard. NTP is a requirement for the 2015 § 170.215(d)(3) Test Procedure within Step 2 in the Test Lab Verification. More detailed steps are also included in the [2015 Edition Network Time Protocol \(NTP\)](#) reference document.

Comment

A commenter noted that the use of the standards specified in § 170.210 (e)(2)(i) and (ii) and § 170.210 (e)(3) should be conditional for Health IT Modules that permit changes to the audit log status or encryption status and are not patient-specific.

Response

We agree with the commenter and have clarified in the (d)(3) test procedure which items are conditional.

30. § 170.315 (d)(4) Amendments

Comment

A commenter asked if the approval or denial of an amendment can be indicated in free text or if it must be discrete data.

Response

See the (d)(4) Certification Companion Guide for clarification on recording the approval or denial of an amendment.

Comment

A commenter asked for clarification of the link requirement of section (ii)(b). Should the link be to the amendment’s location or the original information in the patient’s chart?

Response

See the (d)(4) Certification Companion Guide for clarification on the link requirement.

31. § 170.315 (d)(5) Automatic Access Time-out

Comment

A commenter recommended changing “a user cannot access the session” to “a user cannot access health information” to align with the criteria.

Response

We agree with the commenter and have made the requested change.

Comment

A commenter noted an inconsistency in section (i) between the System Under Test and the Test Lab Verification requirements that necessitates adding a step for the user logging in and waiting a defined amount of time for a period of inactivity to System Under Test.

Response

We agree with the commenter and have added this step.

32. § 170.315 (d)(6) Emergency Access

Comment

A commenter asked for clarification regarding whether manual methods may still be used for emergency access. Does the requirement of (d)(2) to record changes to user privileges rule out the possibility of dedicated emergency access accounts for users?

Response

See the (d)(6) Certification Companion Guide for clarification on the methods used for emergency access.

33. § 170.315 (d)(7) End-User Device Encryption

Comment

A commenter asked for clarification on how a tester should verify that a Health IT Module prevents electronic health information from being stored locally on the end-user device.

Response

See the (d)(7) Certification Companion Guide for clarification on how a tester should verify that a Health IT Module prevents electronic health information from being stored locally on the end-user device.

Comment

A commenter requested clarification on why sections (i) and (ii) are listed as optional and what health IT developers must do to meet the requirements of (d)(7).

Response

We modified the (d)(7) test procedure to indicate that paragraphs (i) and (ii) are alternatives; they are not optional. See [80 FR 62752](#) for further clarification and the (d)(7) Certification Companion Guide for more detail on what a health IT developer must do to meet the requirement.

34. § 170.315 (d)(8) Integrity

Comment

A commenter requested clarification regarding whether hashing is required within the System Under Test? If so, what must be hashed during testing?

Response

We clarified that hashing of the message digest using an algorithm that meets, at a minimum, SHA-2 as specified by NIST is required as part of the criterion and will be tested in section (i).

Comment

A commenter asked for clarification regarding what a tester needs to see in order to verify the requirement. For instance, would a system that displays an indicator that the document/message was received intact meet the requirement?

Response

We added the following language to the (d)(8) test procedure regarding what a tester should see to verify the requirement: “The Health IT Module should show the received message, not an indicator. It should also show the received hash and a computed hash showing them as identical.”

35. § 170.315 (d)(9) Trusted Connection

Comment

A few commenters requested clarification of sections (i) and (ii) regarding the options health IT developers have available to them for demonstrating conformance with the requirements.

Response

We clarified in the (d)(9) test procedure the steps for visual inspection of a demonstration. ONC-ATLs have the discretion to verify the Health IT Module’s conformance with the criterion via documentation.

Comment

A commenter requested that section (i), System Under Test step 1 specify that the user is a representative of the health IT developer going through certification.

Response

We modified the (d)(9) test procedure to indicate that the health IT developer will identify the encryption algorithm during testing.

Comment

A commenter requested clarification regarding whether this criterion is focused on the Health IT Module's Secure Socket layer.

Response

See the (d)(9) Certification Companion Guide for clarification.

Comment

A commenter recommended noting in the test procedure that either message level or transport level criteria can be tested to this criterion.

Response

See the (d)(9) Certification Companion Guide for clarification on encrypting at the message level and transport level.

36. § 170.315 (d)(10) Auditing Actions on Health Information

Comment

A commenter asked for clarification regarding whether health IT developers can meet the requirement for NTPv3 or NTPv4 with attestation documentation in accordance with the standard specified in § 170.210(g).

Response

We modified the (d)(10) test procedure to indicate that the tester should verify through visual inspection of time clock synchronization with a time server that the date/time is recorded in accordance with the standard specified in § 170.210(g).

37. § 170.315 (e)(1) View, Download, and Transmit to 3rd Party

Comment

A commenter asked for clarification regarding whether lab result information can be provided within a clinical summary in the patient portal; or whether the full lab result report must be available in the portal. Another commenter sought clarification regarding whether a vendor can use a lab results interface and display capability, or a custom C-CDA that includes all the required Clinical Laboratory Improvement Amendments information, to pass certification.

Response

See the (e)(1) Certification Companion Guide for clarification on the inclusion of laboratory test reports and diagnostic image reports.

Comment

A commenter asked for clarification regarding section (i)(A), Test Lab Verification step 3 concerning the terminology “the correct scope has been defined.” The commenter interpreted the meaning of “correct scope” for web content accessibility guidelines (WCAG) compliance to mean compliance on webpages associated with view, download or transmit (VDT) functions and nothing more.

Response

We removed this language from the (e)(1) test procedure and reworded the test procedure to indicate that the internet-based technology is compliant with WCAG 2.0 Level A or AA.

Comment

A commenter noted that section (i)(B)(2) is a duplicative validation and that it is numbered under the Test Lab Verification as if it is a continuation of section (i)(B)(1)(ii).

Response

We clarified that section (i)(B)(2) tests the ability to download a human readable document. We updated the (e)(1) test procedure accordingly.

Comment

A commenter noted that the reference to (b)(1), Transitions of Care in sections (i)(B)(2) or (i)(C)(2) is inappropriate as it implies that a Health IT Module cannot be certified to (e)(1) without first also certifying to (b)(1).

Response

We clarified that the intention of referencing (b)(1) is that a system would receive a transition of care summary (via the (b)(1) requirements) and allow a patient to download and transmit the transition of care summary. We did not intend to imply that a Health IT Module must be certified to (b)(1) in order to be certified to (e)(1).

Comment

A commenter noted that Steps 2 and 4 under sections (i)(C)(1)(i), (1)(C)(1)(ii), and (i)(C)(2) specify that “The health IT developer accesses the third party email account and verifies the transmission was received and is correct.” This does not have a corresponding Test Lab Verification step.

Response

We corrected this in the updated (e)(1) test procedure to ensure that the tester verifies that the email was received.

Comment

A commenter requested that the Certification Companion Guide be clear that the encryption method for encrypted email is per the standard at § 170.315(d)(9), which may include Direct Secure Mail Transfer Protocol (SMTP).

Response

The (e)(1) test procedure indicates that the health IT developer may identify the encryption method used during testing. We decline to specify what encryption methods are allowed, since the 2015 Edition Final Rule does not make that specification.

Comment

A commenter noted that section (i)(A)(1)-(3) should ensure that C-CDAs of the required type are a means of data entry.

Response

We clarified in the (e)(1) test procedure that the health IT developer will download the test data from the ETT: Message Validators-C-CDA R2.1 Validator. We further clarify that the ONC-ATL has discretion to decide whether to require the health IT developer to manually enter the data or intake the data automatically as a C-CDA.

Comment

A commenter requested clarification regarding what patients, data, and timeframe should be exported based on the dates filtered. Should the output be a single document with all encounters or should each specific encounter have separate documents? Should it be patients with encounters during the filtered dates or those with any data updated within the filtered dates? Should only data from the filtered dates be included in the summary data and more current data be excluded. If the patient does not have any encounters during the specified time range, should the Health IT Module generate a patient-level document or not return a document? The commenter recommended that documents should be encounter-specific because this approach aligns with CDA standards and supports real-world scenarios.

Response

We clarified that it is not permissible for a Health IT Module to return an entire patient record that does not reflect the specific date or date range requested when a specific date or date range is requested. We also clarified that there is no need to allow for selection of a specific time within each date range. For example, “9/1/2015 to 10/1/2015” is sufficient, rather than “9/1/2015 at 9:00am to 10/1/2015 at 5:00pm.” However, health IT developers may choose to include additional functionality to make it easy for patients to locate the information they need.

Comment

A commenter noted that the Test Lab Verification is missing a corresponding reference to patient-authorized representatives.

Response

We have corrected this in the updated (e)(1) test procedure.

38. § 170.315 (e)(2) Secure Messaging

Comment

A commenter requested clarification regarding whether a Health IT Module must have a method to show a user all authorized patient representatives for a patient.

Response

We incorrectly included the patient authorized representative in the (e)(2) test procedure, which is not required by the 2015 Edition Final Rule. We removed this reference from the test procedure.

Comment

A commenter recommended that 2014 Edition certified health IT should be able to meet this criterion by only attesting to the use of the updated hashing algorithm.

Response

We note that this criterion is not eligible for gap certification. We clarify that the (e)(2) test procedure describes the steps for visual inspection of a demonstration. ONC-ATLs have the discretion to verify the Health IT Module's conformance with the criterion via documentation.

Comment

A commenter questioned whether we should include a negative test for attempting to send a message to an invalid or nonexistent user and receiving a delivery failure message.

Response

We agree with the commenter and have added a negative test to the (e)(2) test procedure.

Comment

A commenter noted that steps 6 and 7 should be out of scope for the criterion, as the functionality is for providers not patients or their authorized representative.

Response

We agree with the commenter and have removed these steps from the (e)(2) test procedure.

39. § 170.315 (e)(3) Patient Health Information Capture

Comment

A few commenters sought clarification on the requirements of section (e)(3)(ii). Two commenters recommended that the test procedure should only require a demonstration that the link can be accessed and anything required of the user beyond that should be out of scope (for instance providing security credentials to log-in). A commenter noted the need for additional information on what the requirement to “provide a reference” entails. Does this only require a description of the document’s location or should it also include a description of the document and/or how to access it? Two commenters requested clarification regarding whether the reference has to be to an online link.

Response

See the (e)(3) Certification Companion Guide for clarification on what “reference” requires.

Comment

A commenter asked for clarification of section (e)(3)(i) and if “directly and electronically” modifies how a user “identifies, records, and accesses” the information or modifies how the patient shares the information.

Response

We clarified that “directly and electronically” refers to the patient sharing the information, but the user is expected to electronically identify, record, and access the information using the Health IT Module.

Comment

A commenter noted that the example in section (e)(3)(i) should be removed or clarified as information will not necessarily be received as documents.

Response

We agree with the commenter and removed the examples from section (i). However, we did not remove the example in section (ii) as it is a direct quote from the 2015 Edition Final Rule.

Comment

A commenter requested clarification regarding whether (d)(7) or (d)(9) should be required for Health IT Modules certified to this criterion. The commenter also sought to clarify whether a document received for a patient and saved locally by a Health IT Module user would violate either (d)(7) or (d)(9).

Response

See the (e)(3) Certification Companion Guide for clarification on the security requirements for this criterion.

Comment

A commenter sought clarification in section (e)(3)(i) step 3 concerning whether a Health IT Module can satisfy the access requirement via the link to an external internet site where a health information document is stored.

Response

See the (e)(3) Certification Companion Guide for clarification on the use of links to external internet sites.

Comment

A commenter requested clarification regarding whether the test procedure must be run twice, once for the patient and once for the patient-authorized representative.

Response

We clarified that the test must be run twice, once for the patient and once for the patient-authorized representative.

40. § 170.315 (f)(2) Transmission to Public Health Agencies - Syndromic Surveillance

Comment

A commenter requested that the testing tools be able to provide health IT developers with validation result reports to submit and that these results should be able to be used to demonstrate compliance instead of repeating the testing tool process during the live certification process.

Response

We clarified that the test tool will produce a validation result report which the tester will use to verify the results. However, the health IT developer will be required to demonstrate that the Health IT Module can create the syndromic surveillance source data.

Comment

A commenter requested clarification regarding whether all data entry must be observed by the test lab or whether the health IT developer can pre-populate some or all of the test data for testing efficiency.

Response

The ONC-ATL has discretion to decide whether to allow pre-population of the test data.

Comment

A commenter noted that the 2015 Edition Final Rule indicated that this criterion should be gap eligible for ambulatory settings.

Response

We are unsure of where in the 2015 Edition Final Rule the reader is referring to. Table 6 of the rule indicates that this criterion is not gap eligible even for ambulatory settings. See the (f)(2) Certification Companion Guide for further clarification on this criterion for the ambulatory setting.

41. § 170.315 (f)(3) Transmission to Public Health Agencies – Reportable Laboratory Tests and Values/Results

Comment

A commenter requested clarification on whether all data entry must be observed by the test lab or can the health IT developer pre-populate some or all of the test data for testing efficiency.

Response

It is at the discretion of the ONC-ATL on whether or not they allow pre-population of the test data.

42. § 170.315 (f)(4) Transmission to Cancer Registries

Comment

A commenter asked for clarification on whether Health IT Modules certified to the 2014 Edition have the option to meet this criterion by submitting attestation documentation for updated standards only.

Response

We note that this criterion is not gap eligible and utilizes a new standard. Therefore, attestation documentation is not sufficient to demonstrate that a Health IT Module meets this criterion.

43. § 170.315 (f)(5) Transmission to public health agencies – electronic case reporting

Comment

A commenter noted concern regarding widely varying implementations and the potential impact on various stakeholders including Public Health Decision Support Intermediary systems (such as the Association of Public Health Laboratories (APHL) Informatics Messaging Services (AIMS) Platform) and decision support systems (such as the Reportable Conditions Knowledge Management System (RCKMS) local & state Public Health Agencies (PHAs)). The commenter requested that ONC consider providing more substantial test data or common test scenarios to help drive more consistency in development and testing with vendors and with documentation assessments performed by ONC-ACBs.

Response

ONC supports centralized intermediary systems such as RCKMS, which is hosted on the APHL AIMS platform; APHL hosts much of the infrastructure for the Digital Bridge, and participation in this initial implementation meets the requirements of certification. The (f)(5) Certification Companion Guide clarifies that either the test procedure or documentation of participation in an initial implementation, such as the Digital Bridge initiative, will suffice. See the (f)(5) Certification Companion Guide for additional details.

Comment

A commenter noted a gap with the existing 2015 Edition §170.315(f)(5) Certification requirement and requested clarification on §170.315(f)(5)(iii)(B)(4) for the following: (1) The RCTC Definition Version (i.e., what is captured in the @sdct:valueSetVersion of the CDA); (2) the triggered code value; and (3) the code system associated with the triggered code value would be able to uniquely identify the triggered code, which was stated to be the intent of §170.315(f)(5)(iii)(B)(4).

Response

We will defer to the authors of RCKMS to determine the appropriate solution. The solution must be future proof and guarantee the unique identity “trigger” that fired given all possible trigger distribution methodologies and trigger processing possibilities. Auditability of this potentially high-volume system using a distributed “code” methodology must be maintained.

Comment

A commenter noted a gap between the 2015 Edition §170.315(f)(5) Certification requirement and the existing HL7 eICR Implementation Guide (IG) §170.315(f)(5)(iii)(B)(1), which requires the Health IT Module be able to create a case report that includes the Common Clinical Data Set (CCDS). This is further highlighted in the test procedure for Criteria (iii)(B) for “System Under Test” item 2. However, analysis of the HL7 electronic Initial Case Report (eICR) Implementation Guide (IG) that was created to satisfy §170.315(f)(5)(iii) indicates that there are some gaps where certain items within the CCDS are not able to be included within the eICR. The commenter requests that only content from the Initial Electronic Case Reporting Implementation Guide Stu 1.1 is used for 2015 Edition testing and for ONC to not force the inclusion of CCDS data.

Response

At the time the proposed rule was authored, a data element based solution provided a best option without referencing a standard, such as Transitions of Care, that was unlikely to provide a permanent solution. The Common Clinical Data Set (CCDS) was the best set of elements to reference, and aligned closely with the anticipated set. Analysis post-rulemaking identified specific elements that state and local public health agencies were not allowed to collect by state and local regulation. ([80 FR 62667](#)) This resulted in a paring down the “original” list. We will leave the data elements list as is for those not participating in Digital Bridge and who do not wish to use a standard used by that program. Those not participating and wishing to demonstrate they use the standard used by Digital Bridge may do so. See the (f)(5) Certification Companion Guide for additional details.

Comment

A commenter noted receiving an error message when attempting to hyperlink to the Standard § 170.207(f)(2) “Race & Ethnicity – CDC” code system in the PHIN Vocabulary Access and Distribution System (VADS), Release 3.3.9.

Response

We have updated the (f)(5) test procedure with the correct link.

Comment

A commenter noted receiving an error message when attempting to hyperlink to the Standard § 170.207(f)(1) The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997.

Response

We have updated the (f)(5) test procedure with the correct link.

Comment

A commenter noted a typographical error within the link for Standard § 170.207(q)(1) International Telecommunication Union E.123:Notation for national and international telephone numbers, e-mail addresses and web addresses and International and Telecommunication Union E. 164: The international public telecommunication numbering plan.

Response

We have resolved the formatting issue with these links.

Comment

A commenter noted that the "Testing Components" section of the test procedure has the Documentation icon crossed out and only indicates Inspection as a testing component while it appears from the TLV section, that documentation review is required. The commenter asked for clarification as to whether documentation is sufficient for all of the steps of the criteria and/or where inspection is required.

Response

We clarify that documentation is sufficient as described in the "Test Lab Verification". The icons in the "Testing Components" have been corrected to reflect Documentation only.

Comment

A commenter noted that HL7 created the HL7 CDA R2 Implementation Guide: Public Health Case Report, Release 2 US Realm – the Electronic Initial Case Report (eICR) standard as a method to meet this measure. They noted that while they understand that the measure itself does not require any specific standard, they requested that we not preclude use of the eICR standard. They further requested that we make clarifications in test step (iii)(B) to ensure that the eICR standard can be used.

Response

We note that HL7 CDA R2 Implementation Guide: Public Health Case Report, Release 2 US Realm was not published as of the date the proposed rule was released. Proposed rules can only reference published standards. To reference a specific standard at this time, outside of the rule making process, would violate the rule making process. We have updated the (f)(5) Certification Companion Guide to provide methods and clarifications for demonstrating conformance with the certification criterion.

Comment

A commenter noted that steps on trigger tables are vague and there are no additional clarifications in the companion guide. Thus they asked for clarification that the system under test would provide (or find from another source) a table of trigger codes and document how they are consumed, without more specific expectations as to the format of the triggers or how it's implemented.

Response

We note that HL7 CDA R2 Implementation Guide: Public Health Case Report, Release 2 US Realm was not published as of the date the proposed rule was released. Proposed rules can only reference published standards. To reference a specific standard at this time, outside of the rule making process, would violate the rule making process. We have updated the (f)(5) Certification Companion Guide to provide methods and clarifications for demonstrating conformance with the certification criterion and a sample trigger table, the Reportable Conditions Trigger Codes (RCTC) used by Digital Bridge which can also be found at: <https://phinvads.cdc.gov/vads/SearchVocab.action>.

Comment

A commenter noted that the RCKMS/Digital Bridge case reporting system will require the latest eCR CDA IG version and further noted that the latest version does not include all of the data for the Common Clinical Data Set, nor does it include the trigger table row and version. They further noted that the proposed requirements would limit the ability for providers and hospitals to implement an MU3 certified electronic case report and suggests that MU 3 requirements f5 requirements should be consistent with the data content requirements for an eCR CDA.

Response

These two approaches to documenting an EHRs capacity to meet the requirement are discrete. At the time the proposed rule was published the best available set of data was the Common Clinical Data Set (CCDS). When the public health community identified the state and local public health data requirements for electronic case reporting, some elements of the CCDS were identified as not necessary and should not be sent. (80 FR 62667) The latest version of the eCR specification can support the requirement to identify the row and version of the trigger table.

44. § 170.315 (f)(6) Transmission to Public Health Agencies – Antimicrobial Use and Resistance Reporting

Comment

Two commenters requested clarification on whether the XML or human readable document should be visually inspected.

Response

We modified the (f)(6) test procedure to indicate that no visual inspection of the document is required. To clarify, the test tool will be used to validate the XML version of the document. The human readable document does not need to be validated.

45. § 170.315 (f)(7) Transmission to Public Health Agencies – Health Care Surveys

Comment

A commenter requested clarification on whether the XML or human readable document should be visually inspected.

Response

We have modified the (f)(7) test procedure to indicate that the tester must visually inspect both the XML and the human readable document.

Comment

A commenter requested additional information about the test procedure and a real-world use case as to where it would be used. Does the test procedure constrain the Health IT Module to one particular value set used by the testing tool? How many survey types will the Health IT Module be tested against and what about surveys that do not match the testing tool validation or supplied data?

Response

See the (f)(7) Certification Companion Guide for further clarification.

Comment

A commenter requested clarification on how health IT developers should identify which of the three implementation guides are applicable to their domain.

Response

See the (f)(7) Certification Companion Guide for further clarification.

46. § 170.315 (g)(1) Automated Numerator Recording

1.1 First Comment Period

Comment

A commenter requested that there be an explicit mapping of the data sets that must be used for each measure.

Response

We agree with the commenter and have clarified in the test data and in the (g)(1) test procedure which data sets are required for each measure.

Comment

A commenter noted a discrepancy between how (g)(1) and (g)(2) lists the required information. For Stage 3, (g)(2) does not distinguish between ambulatory and inpatient setting as is done elsewhere in (g)(1) and (g)(2).

Response

In the test data, we only differentiated between ambulatory and inpatient where it is necessary because the measures are different. For example, Stage 3, Objective 5, Measure 1 has different time requirements for making data available to patients/authorized representatives. On measures where both the inpatient and ambulatory calculation are the same, we have not differentiated between the two in the test data.

Comment

A commenter requested clarification on if or when a Health IT Module needs to be able to record both “controlled” or “not controlled” substances.

Response

See the (g)(2) Certification Companion Guide for clarification on including/excluding “controlled” and “not controlled” substances.

Comment

A commenter asked for clarification on whether a Health IT Module is allowed to not automatically record the numerator for a measure and, if so, how that should be tested.

Response

We agree with the commenter that the following statement in the (g)(1) test procedure was unclear: "The health IT developer identifies the method(s) by which the Health IT Module records all numerator measure elements for each measure. If the Health IT Module automatically records all the required values for the numerator, denominator and percentages, as applicable to §170.315(g)(2), for each measure, the user proceeds to create a measure report."

We have corrected this in the (g)(1) test procedure to remove ambiguity about the ability to automatically record the numerator.

Comment

A commenter requested additional information on how testing will be undertaken to measure patient access, noting that access to the information through an application of the patient’s choosing may not necessarily measure the Health IT Module, but rather the technology of a third party platform.

Response

We clarify that the criteria for application access, (g)(7), (g)(8), and (g)(9), requires that a named user is accessing the API. We believe that this requirement for how the API is accessed will allow Health IT Modules to calculate the measure correctly, even without data from a third party application.

Comment

A commenter noted that on page 11, the Test Lab Verification column is missing information for the tester to verify that the baseline, numerator, and delta reports are created correctly and without omission.

Response

This was an accidental omission. We have corrected this in the updated (g)(1) test procedure.

Comment

A commenter noted that on page 5 in Test Lab Verification, step 5 Observation Services Method should not include patients from Type (C) Admitted to the ED and discharged from the ED.

Response

We agree with the commenter and have corrected this in the updated (g)(1) test procedure.

1.2 Second Comment Period 10/30/16-11/30/16

Comment

A commenter noted that Required Test 7 – Clinical Information Reconciliation and Incorporation in the test procedure contained inaccurate language in the Stage 3 numerator measure elements, and that the ACI English statements were for the Medication Reconciliation measure, rather than the Clinical Information Reconciliation and Incorporation measure.

Response

We agree with the commenter and have corrected the (g)(1) test procedure to remove the summary of care record is requested and unavailable from the numerator statement. We also updated the ACI English statements to reflect the Clinical Information Reconciliation and Incorporation measure.

Comment

Commenters indicated that the Global Required Test for the All ED Visits Method should include types A, B, C, D, and E, not just C.

Response

We agree with commenters and have corrected this in the (g)(1) test procedure.

Comment

A number of commenters indicated that the CPOE measures should be eligible for gap certification, since they have not changed since 2014 Edition and are only applicable to the Medicaid EHR Incentive Program.

Response

We agree with commenters and clarify that the three Required Tests for CPOE are gap eligible.

47. § 170.315 (g)(2) Automated Measure Calculation

1.1 First Comment Period

Comment

A commenter requested that there be an explicit mapping of the data sets that must be used for each measure.

Response

We agree with the commenter and have clarified in the test data and in the (g)(2) test procedure which data sets are required for each measure.

Comment

A commenter noted a discrepancy between how (g)(1) and (g)(2) lists the required information. For Stage 3, (g)(2) does not distinguish between ambulatory and inpatient setting as in done elsewhere in (g)(1) and (g)(2).

Response

In the test data, we only differentiated between ambulatory and inpatient where it is necessary because the measures are different. For example, Stage 3 Objective 5, Measure 1 has different time requirements for making data available to patients/authorized representatives. On measures where both the inpatient and ambulatory calculations are the same, we have not differentiated between the two in the test data.

Comment

A commenter requested clarification on if or when a Health IT Module needs to be able to record both “controlled” or “not controlled” substances.

Response

See the (g)(2) Certification Companion Guide for clarification on including/excluding “controlled” and “not controlled” substances.

Comment

A commenter requested clarification on whether a Health IT Module is allowed to not automatically record the numerator for a measure and, if so, how that should be tested.

Response

We agree with the commenter that the following statement in the (g)(2) test procedure was unclear: "The health IT developer identifies the method(s) by which the Health IT Module records all numerator measure elements for each measure. If the Health IT Module automatically records all the required values for the numerator, denominator and percentages, as applicable to §170.315(g)(2), for each measure, the user proceeds to create a measure report."

We have corrected this in the (g)(2) test procedure to remove ambiguity about the ability to automatically record the numerator.

Comment

A commenter noted that test case 1.2 requirement that a summary of care is received but not incorporated should be optional as some Health IT Modules automatically incorporate received data when they query another system and thus this step is not feasible for those Health IT Modules.

Response

We clarify that it is at the discretion of the ONC-ATL to allow systems that automatically incorporate received data to indicate such to the ONC-ATL and not demonstrate that they cannot incorporate data for test case 1.2.

Comment

A commenter noted that on pages 6-7 in the Test Lab Verification column, step 5 Observation Services Method should not include patients from Type (C) Admitted to the ED and discharged from the ED.

Response

We agree with the commenter and have made this correction.

Comment

A commenter requested a number of clarifications for Stage 3 Objective 7 – Health Information Exchange Measure 2 based on inconsistencies between the measure and the CMS specification. The test data only counts reconciliation within the calendar year, but should be updated as the CMS specification allows reconciliation to count towards the numerator at any point after the transition of care. The Summary of Care Record Requested and Unavailable or Retrieved/Received Within Reporting Period column needs to be updated as providers are not required to reconcile information when a summary of care is unavailable.

Response

We agree with the commenter and have updated the test data to reflect the following:

- The scenarios for the Stage 3 measure require the provider to receive or query for a summary of care document and incorporate the received summary of care documents no earlier than the first day of the calendar year of the reporting period (for a 90-day reporting period only), during the reporting period (for a 90-day and full calendar year reporting period), or no later than the date of attestation to populate and record the numerator (for a 90-day and full calendar year reporting period).
- If a user requests a summary of care document prior to attestation and does not receive it, the transition of care will still increment the denominator.
- If a user queries for a summary of care document via a health information exchange and no results are returned, the transition of care will not increment the denominator.

Comment

Two commenters requested clarification on a number of criteria as to whether test data will be supplied or if the health IT developer is able to supply its own data.

Response

Health IT developers must use the ONC-provided test data, but may make reasonable modifications at the discretion of the ONC-ATL.

Comment

A commenter requested clarification on page 37 of the inclusion of the Stage 3 measure element numerator, a Patient or Patient Representative Sends Secure Electronic Message to EP/EH.

Response

We have corrected the (g)(2) test procedure to indicate that the numerator for Stage 3 Objective 6, Measure 2 increments when a provider sends a secure message to a patient/authorized representative or replies to a message from a patient/authorized representative.

Comment

A commenter requested a clarification for Stage 3 Objective 6 – Coordination of Care Through Patient Engagement Measure 2. The measure element “EP/EH Sends Secure Message to Provider Including Patient or Patient Representative” should be indicated as optional as this is not a certification requirement.

Response

In the Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 through 2017 Final Rule (42 CFR 412 and 495), CMS indicated that a secure message sent from provider to provider that includes the patient/authorized representative may increment the numerator. Therefore, we disagree with the recommendation, since it is a valid method for incrementing the numerator.

Comment

A commenter requested a number of clarifications for Stage 3 Objective 6 – Coordination of Care Through Patient Engagement Measure 1. The System Under Test column is missing the API measure language. According to the CMS Stage 3 Final Rule, this measure can count actions that occur before, during, or after the reporting period in 2016.

Response

We have corrected the System Under Test column to include the API measure language. In addition, we clarify that for Stage 2, the action may occur before, during, or after the reporting period but no earlier than the start of the calendar year and no later than the date of attestation. For Stage 3, the action must occur during the reporting period only.

Comment

A commenter requested a number of clarifications for Stage 3 Objective 5 – Patient Electronic Access Measure 1. The required timeline for the release of information is incorrect. For Health IT Modules where information is automatically released online without requiring provider action, testers should not have to verify that the numerator is not populated when the provider does not take any action(s) to release patient information online.

Response

We corrected the timeframes in the test data for release of the information. While we agree that some systems may automatically release the information, we disagree that we should not test when information is not released since CMS included specific guidance on this in 42 CFR Parts 412 and 495 Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 through 2017 Final Rule.

Comment

A commenter requested clarification for Stage 3 Objective 5 – Patient Electronic Access Measure 2 on how actions that take place outside of the reporting period count towards the numerator.

Response

We clarified that for Stage 3 Objective 5 Measure 2, the Eligible Provider/Eligible Hospital (EP/EH) must use Certified Electronic Health Record Technology (CEHRT) to identify patient-specific education resources and provide electronic access to those materials during the reporting period. Actions taken outside of the reporting period will not increment the numerator.

Comment

A commenter noted that the measure for Stage 3 Objective 4 – CPOE: Radiology needs to be updated to reflect the Stage 3 change to diagnostic imaging orders from radiology orders.

Response

We agree with the commenter and made this update.

1.2 Second Comment Period 10/30/16-11/30/16

Comment

Commenters indicated that the Global Required Test for the All ED Visits Method should include types A, B, C, D, and E, not just C.

Response

We agree with commenters and have corrected this in the (g)(2) test procedure.

Comment

A number of commenters indicated that the CPOE measures should be eligible for gap certification, since they have not changed since 2014 Edition and are only applicable to the Medicaid EHR Incentive program.

Response

We agree with commenters and clarify that the three Required Tests for CPOE are gap eligible.

Comment

A commenter noted that Required Test 7 – Clinical Information Reconciliation and Incorporation in the test procedure contained inaccurate language in the Stage 3 numerator measure elements, and that the ACI English statements were for the Medication Reconciliation measure, rather than the Clinical Information Reconciliation and Incorporation measure.

Response

We agree with the commenter and have corrected the (g)(2) test procedure to remove the summary of care record is requested and unavailable from the numerator statement. We also updated the ACI English statements to reflect the Clinical Information Reconciliation and Incorporation measure.

Comment

Commenters requested clarification on whether Health IT Modules needed to test more than one measure for the Global Required Test or just one measure, since the test procedure referred to both a single measure and multiple measures.

Response

We clarify that for the Global Required Test, only one measure must be demonstrated. Health IT developers may choose which measure to demonstrate, but we note that for testing the Inpatient calculation methods of Observation Only or All ED, only one measure, Modified Stage 2 – Patient Education, is applicable. No other measures allow an organization to choose the calculation method. The instructions in the (g)(2) test procedure have been updated accordingly.

48. § 170.315 (g)(1)&(2) Test Data

1.1 First Comment Period

Comment

A commenter asked for clarification on the 90-day and calendar year reporting periods.

Response

We added language to the test data document clarifying the 90-day and calendar year reporting periods and when actions are allowed to occur in order to increment the numerator for each required test.

Comment

A few commenters requested clarification on the use of “NA” versus 0 and where one should be used versus the other. One commenter noted that for consistency, 0 or greater values should be used rather than “NA”. A commenter asked for clarification of the difference between the test data stating 0 and “previously recorded”.

Response

We updated the test data to consistently use “NA” versus 0 and previously recorded. We have included notes in each required test where “NA” is used and what the “NA” means.

Comment

A few commenters asked for clarification on how measures where action is required within a certain amount of time are calculated. Should the day the patient is seen be considered the ‘1st’ business day? Why does the patient electronic access measure have a 49-144 hours criterion for timely access as the Final Rule requires 4 business days.

Response

We updated the test data to mirror the requirement in the 2015 Edition Final Rule. We decline to provide additional guidance on how health IT developers should calculate business days.

Comment

A commenter requested that for measures where action is allowed outside of the reporting period, the test case should look for the action during the calendar year or outside the calendar year.

Response

We updated the test data and the notes in the test data to indicate that where action may occur outside of the reporting period, it must occur after the start of the reporting year and prior to attestation (which may be after the calendar year ends).

1.2 Second Comment Period 10/30/16-11/30/16

Comment

A commenter indicated that the option to send a secure message to another provider and copy the patient should not be included in the test data since there is no corresponding function requirement in (e)(2). Another commenter indicated that this should be included not only as an option for Stage 3, but also for Modified Stage 2.

Response

We agree with the commenter that the (e)(2) criterion does not test this functionality; however, CMS included this as a valid option for incrementing the numerator in the Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 through 2017 Final Rule (42 CFR 412 and 495). Therefore, it is a valid option for testing. We added a note to the test data that if a system does not offer this functionality, it is at the discretion of the ONC-ATL not to test those scenarios. In addition, the Final Rule indicated that this method could only be used to increment the numerator for the Stage 3 measure. It is, therefore, only an option for the Stage 3 measure. We further clarify that when health IT developers submit their self-test reports to their ONC-ATL,

they must indicate which functions are performed automatically and indicate how each scenario sum was impacted by not testing a particular test case.

Comment

A number of commenters inquired about when actions must take place in order to increment the numerator. Commenters indicated that some measures required an action to occur during the reporting/performance period, but it should be the calendar year. There was also general confusion about when each measure must occur. Further, a number of commenters indicated that testing actions that occur outside of the required timeframe is incredibly difficult during the testing process and often requires health IT developers to modify how their Health IT Modules work in order to pass the test, creating a heavy burden for health IT developers and ONC-ATLs.

Response

We added two notes to the “Start Here” tab in each of the test data documents that clarify when actions must occur. Further, we updated the test data notes for each measure to indicate when actions must occur to increment the numerator and updated the column header text to indicate if a measure must occur during the reporting/performance period or the calendar year. In addition, we have removed the requirement to test actions occurring outside of the required timeframe from each Required Test and have moved this test to the Global Required Test. Health IT Modules will need to demonstrate once that they can correctly include or exclude actions occurring inside or outside of the required timeframe from a measure.

Comment

Multiple commenters indicated that the test data for Required Test 12 did not have the same data in Scenario 1.

Response

We agree with commenters and have updated the Scenario 1 test cases for Required Test 12 to align with the other Required Tests.

Comment

A number of commenters indicated that Scenario 2 and Scenario 5 in a number of the Required Tests should have test patients or, if not, should be eliminated.

Response

We clarify that, as in the 2014 Edition test data, Scenario 2 is only applicable to measures where the denominator is based on unique patients. It is not applicable to measures where the denominator is based on specific actions. Scenarios 2 and 5 cannot be tested for Required Tests 1, 7, 8, and 9, 10, 11, or 12. To maintain uniformity across all of the Required Tests, we have not deleted these scenarios from the test data. Rather, these scenarios have been grayed out on the Required Tests listed above.

Comment

Commenters requested that we clarify when patients are listed as new how they would have changed prescriptions. Other commenters requested that we remove the column for new or existing patient as they felt it did not add value to the test.

Response

We agree with the commenters that the new or existing patient column could be confusing with the test data setup and does not add beneficial testing rigor. We have deleted the new or existing patient column from the test data.

Comment

A number of commenters requested clarification on what must be tested for Required Tests where a Health IT Module automatically performs a function, including querying for a drug formulary, simultaneously making data available for view, download, transmit and to an API, data being automatically released to view, download, transmit, and an API, and receipt and incorporation of a summary of care document.

Response

Test notes have been added to each applicable Required Test to indicate that if a Health IT Module automatically performs a particular function, it is at the discretion of the ONC-ATL not to test a test case that assumes the function is not automatic. When health IT developers submit their self-test reports to their ONC-ATL, they must indicate which functions are performed automatically and indicate how each scenario sum was impacted by not testing a particular test case.

Comment

A number of commenters indicated that the (g)(1) test data contained references to incrementing the denominator.

Response

All references to incrementing the denominator have been removed from the (g)(1) test data.

Comment

Commenters indicated that the test data for Required Test 1 – ePrescribing required EHs to be able to refill medications for the Modified Stage 2 measure, but that EHs are only required to include refills for Stage 3 measures. Additionally, a commenter indicated that EHs are not required to include changed prescriptions for the Modified Stage 2 measure.

Response

We agree with commenters that refills should not be included for the Modified Stage 2 or Stage 3 measures, and we have removed refills from the test data. We clarify that for EHs, the Modified Stage 2 measure does include both new and changed prescriptions and reference commenters to the Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 through 2017 Final Rule (42 CFR 412 and 495). In addition, to avoid confusion between the EH and EP/EC measure requirements, we have modified the EP/EC test data to indicate the number of prescriptions written, and removed references to new, changed, and refill.

Comment

Commenters requested clarification on how the numerators increment for the Patient Electronic Access and View, Download, Transmit measures for Health IT Modules that are certified to (e)(1) and/or (g)(8)/(g)(9) and why some columns were grayed out versus having zeroes.

Response

See the Certification Companion Guide for an explanation of how the numerators increment for these measures and the documentation that health IT developers will be expected to submit for testing. In addition, to avoid confusion, we have separated the test data into three tabs: a) 2a and 4a is the test data for Health IT Modules that are certified for (e)(1) and (g)(8)/(g)(9); b) 2b and 4b is the test data for Health IT Modules that are certified for (e)(1); and c) 2c and 4c is the test data for Health IT Modules that are certified for (g)(8)/(g)(9). If a Health IT Module is not certified for any of these criteria, but is seeking certification to calculate these measures, they may choose which set of test data to use.

Comment

A few commenters were concerned about using the same test cases across each Required Test. They thought that the patient may not increment the denominator correctly if the patient is selected for more than one scenario or that reports would not increment the numerator correctly across measures.

Response

We believe the use of the same test cases across all measures mirrors the real-world scenario where patients are frequently in the denominator of each measure being calculated. We have clarified in the test procedure that we expect a health IT developer to enter data for a test case for all of the Required Tests they are submitting for certification, and to repeat this for each test case in a scenario and then proceed to run a measure report one time. We believe this addresses commenters concerns about denominators and numerators not incrementing correctly across measures. We also clarify that health IT developers must use all test cases in each scenario. Further, we have added a note to Required Test 3 that if a Health IT Module automatically makes patient education materials available to the patient electronically when the patient has a visit and has access to a patient portal or API, it is at the discretion of the ONC-ATL to allow the health IT developer to use different patient names for Required Test 3.

Comment

One commenter indicated that they preferred testing the group EC calculation method once at the global level. However, multiple commenters indicated concern about this method for testing the group calculation and indicated the individual EC calculation method also needed to be tested. These commenters felt that both the individual EC and the group EC calculation methods should be tested for each Required Test and not once as a global test.

Response

We agree with commenters that the test data was not setup to test the individual EC calculation method which calculates by TIN and NPI. We also agree with commenters that both the individual EC and group EC calculation methods must be tested for each Required Test. We have reformatted the EP/EC data to test three calculation methods for each Required Test: 1) EP, which calculates by an individual provider across all of her TINS; 2) Individual EC, which calculates by an individual TIN/NPI combination; and 3) Group EC, which calculates at the TIN level. Further, we clarify that for measures that measure activities by unique patient, there is a transitive affect for the numerator. This means that if a provider under one of her TIN/NPI combinations takes an action such as providing patient-specified education

resources, she will receive credit in the numerator for each of her TIN/NPI combinations, when those combinations exist in a single Health IT Module. Additionally, we clarify that for the Group EC calculation, patients must be de-duplicated both in the denominator and numerator, and that the same transitive affect applies in the Group EC calculation as in the Individual EC calculation, when using a single Health IT Module. The test data reflects the correct increments for the transitive effect and deduplication requirement.

Comment

A commenter requested clarification on the numerator incrementing for Required Test 5 – Medication Reconciliation (now Required Test 9). The commenter believed that once health information was reconciled at the first visit, it would not need to be reconciled again at a subsequent encounter as the numerator would have already incremented.

Response

We clarify that the denominator definition is not based on unique patients or encounters. Rather, every time the patient is transitioned or referred to a provider the denominator will increment (it will also increment for new patients who the EP/EC/EH have not previously encountered). Patients may be referred to the same provider more than once during a reporting/performance period, and each event would increment the denominator; therefore, in order to increment the numerator, reconciliation would need to be performed each time the patient is transitioned or referred.

Comment

A commenter asked for clarification on Required Test 6, and whether notes 2 and 3 were intended to indicate that the numerator should only be recorded once.

Response

We clarify that Required Test 6 is based on unique patients and therefore the numerator will only increment once.

Comment

A commenter asked if all of the denominator exclusions included in the OPSS Final Rule for Required Test 8 – Receive and Incorporate are in effect and indicated that the test data did not seem to link to the detailed exclusions. The provider requested an electronic summary of care record to be sent and did not receive an electronic summary of care document. The provider either (1) queried at least one external source via HIE functionality and did not locate a summary of care for the patient, or (2) confirmed that HIE functionality supporting query for summary of care documents was not operational in the provider’s geographic region and not available within the provider’s EHR network as of the start of the EHR reporting period.

A commenter also requested, if using check boxes, to indicate a summary of care record is unavailable is allowable. Finally, a commenter indicated that the column for Summary of Care Record Received through Request or Retrieval should be removed since the measure is incorporation.

Response

We are unable to accommodate all of the detailed exclusions for the denominator in the test data. However, we note that any of the detailed exclusions listed above would count as unavailable in the test data. ONC does not specify how health IT developers build into their systems a method for indicating if a summary of care record was unavailable. It is up to each health IT developer to determine the best method for indicating in their system that a summary of care

record was unavailable. We disagree with the commenter that the column for Summary of Care Record Received through Request or Retrieval should be removed.

Comment

A few commenters indicated that in Required Test 7 – Health Information Exchange, the column to indicate that the summary of care was received should be eliminated as CEHRT is not required to verify receipt.

Response

We disagree with the commenter that the column should be removed, since the measure requires confirmation of receipt in order for the numerator to increment. However, we clarify that a Health IT Module is not required to have an automated method for verifying receipt and could use many methods to verify that a summary of care was received, including a manual process.

Comment

In Required Test 3 – Patient-Specific Education, a commenter felt that the column indicating that the patient education was identified by CEHRT should be removed, since the numerator is based on the education being provided electronically to the patient.

Response

We disagree with the commenter that this column should be removed. The numerator is dependent both on CEHRT identifying the patient education and it being provided electronically to the patient. If CEHRT does not identify the patient education resource, but a resource is provided electronically, the numerator will not increment.

Comment

A commenter felt that a number of the test cases were duplicative and should be removed.

Response

We agree with the commenter that some test cases have the same qualities and will increment the numerator and/or denominator the same way. We disagree with the commenter that test cases that seem duplicative should be removed, as they may be relevant on Required Tests that contain more variables for determining if the numerator/and or denominator should increment. We have reduced the total number of test patients to eight for (g)(1) and 12 for (g)(2), which is a significant reduction from the 2014 Edition test requirements.

49. § 170.315 (g)(3) Safety-Enhanced Design

Comment

A number of commenters requested that the test procedure be updated to clarify that use of National Institute of Standards and Technology (NIST) use cases is not required for summative testing and that other approaches are acceptable. A few commenters noted that the NIST use cases do not cover all the functionality for which certification requires summative testing and includes some functionality that is outside the scope of certification. A few commenters were concerned about the requirement to provide a reason why a NIST use case was not used.

Response

We clarified that the NIST use cases are not required and we removed this reference from the (g)(3) test procedure to avoid confusion. We further clarified that health IT developers do not need to provide a reason for not using the NIST use cases. However, they are expected per the criterion to provide an explanation of the reason(s) why use of any of the existing UCD standards was impractical.

Comment

A commenter asked for clarification as to whether the standard deviation of task time is the same as Task Standard Deviations which is used in the NIST documents.

Response

We clarified in the updated (g)(3) test procedure that the standard deviation of the task performance time is what will be tested.

Comment

Two commenters noted the importance of having a test population that is representative of the intended user population.

Response

See the (g)(3) Certification Companion Guide for further clarification.

Comment

A commenter requested that health IT developers be required to publish the test scenarios used during the summative testing so that users can determine the effectiveness of the testing.

Response

The test scenarios that are submitted by the health IT developer will be published on the Certified Health IT Product List (CHPL).

50. § 170.315 (g)(4) Quality Management System

Comment

A commenter requested clarification on the level of document verification that is required by the test procedure.

Response

We clarified that it is at the discretion of the ONC-ATL what level of documentation must be submitted and the level of review they provide of that documentation.

Comment

A commenter noted that the legend includes visual inspection but they anticipate health IT developers will only submit documentation to meet the requirement.

Response

We removed visual inspection from the legend and clarify that health IT developers are only required to submit documentation to meet the criterion.

Comment

A commenter asked for clarification on options to apply a single QMS system that contains components of multiple standards to all criteria without specifying individual elements of a Health IT Module, 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.

Response

See the (g)(4) Certification Companion Guide for clarification on options for applying a single QMS system.

51. § 170.315 (g)(5) Accessibility-Centered Design

Comment

A commenter requested clarification on the level of document verification required by the test procedure.

Response

We clarified that it is at the discretion of the ONC-ATL what level of documentation must be submitted and the level of review they provide of that documentation.

52. § 170.315 (g)(6) Consolidated CDA Creation

Comment

A commenter requested clarification on where the “ONC-supplied certifying criteria instructions” will be made available.

Response

The ONC-supplied Certifying Criteria Instructions are located in the ETT Message Validator tool that is maintained by NIST.

53. § 170.315 (g)(7) Application Access - Patient Selection

Comment

A few commenters requested clarification on how this requirement will be tested and what verification process the tester will use. Who is expected to make a call to the Health IT Module's API? How will testers verify that patient data is accurate without test data?

Response

We clarify that this will be tested via visual inspection. The health IT developer will identify the software component or service that will make the call to the Health IT Module's API. The health IT developer is expected to provide their own test data and identify for the tester what data should be returned.

Comment

A commenter noted that the test procedure does not address the requirement to provide public documentation.

Response

We have updated the (g)(7) test procedure to include that the documentation must be available via a publically accessible hyperlink and that the tester will verify the link.

54. § 170.315 (g)(8) Application Access - Data Category Request

Comment

A few commenters requested clarification on how this requirement will be tested and what verification process the tester will use. Who is expected to make a call to the Health IT Module's API? How will testers verify that the patient data is accurate without test data?

Response

We clarify that this will be tested via visual inspection. The health IT developer will identify the software component or service that will make the call to the Health IT Module's API. The health IT developer is expected to provide their own test data and identify for the tester what data should be returned.

Comment

A commenter requested clarification on what steps for Test Lab Verification are performed by the ONC-ATL and which are performed by the health IT developer.

Response

As outlined in the (g)(8) test procedure, we anticipate that the health IT developer would perform the steps listed in the System Under Test column and that the tester would watch them perform these steps and verify that the Health IT Module performs to the criterion's requirements.

Comment

A few commenters requested clarification on the requirement to test combinations of data elements and noted that this requirement goes beyond the Final Rule. If this is a requirement the commenter requested that the combinations should be defined by use cases of the individual health IT developers.

Response

We agree with the commenters that this went beyond the criterion's requirements laid out in the 2015 Edition Final Rule and have removed this from the (g)(8) test procedure.

Comment

A commenter noted that the (i)(B) should be updated to include "per the health IT developer's technical document" to align with the 2015 Edition Final Rule.

Response

We disagree with the commenter and believe that this clarification does not need to be added.

Comment

A commenter requested that the Common Clinical Data Set (CCDS) and its representation in the API should be inclusive of care planning data to include Goals, Health Concerns, and assessment and plan data and not C-CDA sections as they are not appropriate for the API requirement.

Response

See the (g)(8) Certification Companion Guide for clarification on the CCDS.

Comment

A commenter requested clarification on how to interpret a specific date or date range and what data is expected to be returned from such a query.

Response

We clarified that it is at the health IT developer's discretion as to how they pull encounters into the filtered date range. We would expect that the health IT developer would inform the tester of their methodology during testing so that the tester can verify the correct data is created.

Comment

A commenter noted that the test procedure does not address the requirement to provide public documentation.

Response

We updated the (g)(8) test procedure to include that the documentation must be available via a publically accessible hyperlink and that the tester will verify the link.

55. § 170.315 (g)(9) Application Access - All Data Request

Comment

A commenter asked for clarification on what additional a value visual inspection provides on top of the other verification requirements.

Response

We believe that visual inspections are necessary to ensure that the API operates as indicated in the documentation to provide end-users with a high level of assurance that the Health IT Module will perform in the field.

Comment

A commenter requested clarification on how to interpret a specific date or date range and what data is expected to be returned from such a query.

Response

We clarified that it is at the health IT developer's discretion as to how they pull encounters into the filtered date range. We would expect that the health IT developer would inform the tester of their methodology during testing so that the tester can verify the correct data is created.

Comment

A commenter requested clarification for (ii)(A) on how a tester would verify that the documentation is "accurate and without omission."

Response

We do not intend that the tester would need to verify coding or in-depth technical language. We would expect that the tester would verify that based on the demonstration provided, the documentation provides the necessary components to connect to and utilize the Health IT Module's API.

Comment

A commenter noted that the test procedure does not address the requirement to provide public documentation.

Response

We have updated the (g)(9) test procedure to include that the documentation must be available via a publically accessible hyperlink and that the tester will verify the link.

56. § 170.315 (h)(1) Direct Project

Comment

A commenter expressed concern that early adopters of the 2015 Edition certification will have trouble finding three HISPs to partner test with and requested clarification on whether there are other avenues available for early adopters to meet this requirement.

Response

We clarify that the partners the Health IT Module chooses to test with do not have to be certified at the time of testing as long as the testing uses the Direct v1.2 in accordance with the standard specified at §170.202(a)(2): Applicability Statement for Secure Health Transport v1.2, formatted only as a “wrapped” message.

Comment

A commenter requested clarification on whether the partner testing requires three independent Direct messages to go to three independent HISPs or if a single message to three recipient with three different HISPs would suffice.

Response

We clarified that one message sent to three recipients on three different HISPs is sufficient to meet the criterion.

Comment

A commenter requested that the System Under Test column provide more detailed steps so that Health IT Modules can be appropriately prepared for testing or that the negative tests cases that are optional should be specified so.

Response

We agree and added more detail to the (h)(1) test procedure as well as describing the interaction with the test tool instructions.

57. § 170.315 (h)(2) Direct Project, Edge Protocol, and XDR/XDM

Comment

A commenter requested that the test procedure not require the sending of a message using multiple protocols but rather focus on the ability to serve as a universal receiver of all the protocols.

Response

We clarified in the (h)(2) test procedure which Edge Protocols are optional, such as POP3.

Comment

A commenter expressed concern that early adopters of the 2015 Edition certification will have trouble finding three HISPs to partner test with and requested clarification on whether there are other avenues available for early adopters to meet this requirement.

Response

We clarified that the partners the Health IT Module chooses to test with do not have to be certified at the time of testing as long as the testing uses the Direct v1.2 in accordance with the standard specified at §170.202(a)(2): Applicability Statement for Secure Health Transport v1.2, formatted only as a “wrapped” message.

Comment

A commenter noted that the test scripts should be updated to reflect that the Health IT Module under test is serving as the edge sender/receiver and the Edge Testing Tool (ETT) should be the sending/receiving HISP.

Response

We clarified in the (h)(2) test procedure and in the test tool instruction document who the sender and receiver are.

Comment

A commenter noted that the test scripts should be updated to allow any of the three SMTP edge protocols to meet the requirement to align with the Final Rule.

Response

We updated the (h)(2) test procedure to indicate that the edge protocols are optional and the Health IT Module must only certify to one at a minimum.

Comment

A commenter requested clarification as to whether any of the Test Lab Verification steps are negative tests.

Response

We added the wording “Negative Testing” to test steps that are negative tests.

Comment

A commenter requested clarification on what is expected in the logs for (i)(C) step 6 Visual Inspection under the Test Lab Verification column.

Response

We added content to the (h)(2) test procedure to indicate what must be reviewed by the tester in the logs.

Comment

A commenter asked for clarification on the steps that specify visual inspection of the logs. Must the information be in an audit log or are other forms of notification acceptable?

Response

We clarified in the (h)(2) test procedure that the tester is verifying the content of the ETT logs.

Comment

A commenter requested that the System Under Test column provide more detailed steps so that Health IT Modules can be appropriately prepared for testing or that the negative tests cases that are optional should be specified so.

Response

We agree with the commenter and added additional content to the (h)(2) test procedure as well as linking at appropriate places to the test tool's instruction guide.

Comment

A commenter noted that the Direct Certificate Discovery Tool (DCDT) test tool should not be referenced in this test procedure. The commenter suggested that the DCDT test tool have its own section. If that is not possible the commenter suggested separating out the instructions for each test tool (DCDT, ETT, and TTT) as unique subheadings within the table.

Response

We agree with the commenter on the organization of the document and have used headers to indicate how the different tools should be used during the testing process. We disagree with the commenter that the DCDT tool should not be referenced as it is necessary to use the tool to obtain the trust anchor.