Summary of Comment for 2015 Edition NPRM Draft Test Procedures

1. § 170.315(a)(1) CPOE Medications

Comment

A number of commenters requested that gap eligible be clearly indicated in the test procedure.

Response

We agree with commenters, and have updated the legend to include GAP as an option. If the GAP cell does not have a red X covering it, then the criteria is gap eligible and does not require retesting for products previously certified to 170.314(a)(1).

Comment

A number of commenters indicated that the test procedure seemed to contradict itself by including visual inspection in the legend, but stating in the test script that at a minimum attestation/documentation is the test approach. Additionally, a few commenters noted that CPOE is an important function and should therefore require demonstration rather than just attestation, while other commenters felt that attestation was sufficient.

Response

We agree that the test procedure contradicted itself. Note that the test approach column has been removed from the test procedures. Also as noted above this criteria is gap eligible, so the legend indicates both documentation/attestation and visual inspection (which would be used for products not seeking gap certification).

Comment

A few commenters indicated that the 2014 test script should be used for this criteria as it was unchanged.

Response

We clarify that for unchanged criteria, ATLs are free to use the 2014 test scripts at their discretion, but they are not required to do so.

2. § 170.315(a)(2) CPOE Laboratory

Comment

The majority of comments on the test procedure related to the lab compendia steps, including concerns about low adoption of the standard by labs and the order of the test steps.

Response

We thank commenters for their feedback. ONC removed the lab compendia requirements from the criteria in the 2015 Edition final rule. As such, the test procedure reflects the final criteria to record lab orders electronically and optionally record the reason for referral.

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

A number of commenters indicated that the test procedure seemed to contradict itself by including visual inspection in the legend, but stating in the test script that at a minimum attestation/documentation is the test approach. Additionally, a few commenters noted that CPOE is an important function and should therefore require demonstration rather than just attestation, while other commenters felt that attestation was sufficient.

Response

We agree that the test procedure contradicted itself. Note that the test approach column has been removed from the test procedures. Also we have clarified in the test procedure that the criteria is gap eligible, which is indicated in the legend. The legend indicates both documentation/attestation and visual inspection, to be used for products not seeking gap certification.

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

Comment

The majority of comments related to the criteria's requirement to record a user's response to a drug-drug, drug-allergy interaction check.

Response

We note that we did not include the requirement to record a user's response in the 2015 Edition final rule. It has been removed from the test procedure, and the criteria has been made gap eligible.

Comment

A number of commenters indicated that the test procedure was unclear in including visual inspection in the legend but indicating attestation/documentation in the test approach column.

Response

We agree with commenters that the draft test procedure was unclear. We clarify that this criteria is now gap eligible as indicated in the legend. We have removed the test approach column and expect that products being tested for the first time would be tested via visual inspection rather than attestation/documentation.

Comment

One commenter noted that the use of the word "or" in the following sentence seemed to indicate that Health IT Modules would only be tested for one or the other:

"The Health IT Module indicates to a user that a drug-drug OR drug-allergy contraindication is present, prior to completion of the order and based on a patient's medication list and medication allergy list.

Response

We agree that the use of the word or was confusing. We did not intend to indicate that Health IT Modules would only need to be tested for drug-drug contraindications or only to drug-allergy contraindications. We have modified this language in the updated test procedure.

5. § 170.315(a)(5) Demographics

Comment

A few commenters requested clarifications around rolling-up the more specific race and ethnicity codes to 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 codes. They also requested clarification on whether a Health IT Developer would need to demonstrate collection of all 900 plus codes.

Response

The test steps related to the roll-up of the "Race & Ethnicity – CDC" code system in the PHIN Vocabulary Access and Distribution System (VADS), Release 3.3.9 have been removed from the test procedure. In addition, we clarify that it is up to the ATL's discretion on the number of codes they test that the Health IT Module has the ability to record.

6. § 170.315(a)(6) Problem List

Comment

A number of commenters requested that the test procedure allow for attestation/documentation, since the only change to the criteria was to the SNOMED CT® U.S. Edition, September 2015 Release. However, a few commenters indicated that visual inspection should be required.

Response

We appreciate commenters' feedback. We note that it is up to the discretion of each ATL to allow documentation/attestation versus visual inspection for this criteria.

7. § 170.315(a)(7) Medication List

Comment

A number of commenters indicated that the test procedure seemed to contradict itself by including visual inspection in the legend, but stating in the test script that at a minimum attestation/documentation is the test approach. Commenters were also confused about the requirement for visual inspection since this criteria is gap eligible.

Response

We agree that the test procedure contradicted itself. Note that the test approach column has been removed from the test procedures. Also as noted above this criteria is gap eligible, so the legend indicates both documentation/attestation and visual inspection (which would be used for products not seeking gap certification). Additionally, we clarify that for unchanged criteria, ATLs are free to use the 2014 test scripts at their discretion, but they are not required to do so.

Comment

A commenter indicated that the phrasing used implied that a Health IT Module would have to record, change, and access a patient's active medication list and record, change, and access the historical medication list.

Response

We agree with the commenter that the test procedure was worded incorrectly. We have corrected this in the updated test procedure to indicate that a Health IT Module must allow a user to access the historical medication list.

8. § 170.315(a)(8) Medication Allergy List

Comment

A number of commenters indicated that the test procedure seemed to contradict itself by including visual inspection in the legend, but stating in the test script that at a minimum attestation/documentation is the test approach. Commenters were also confused about the requirement for visual inspection since this criteria is gap eligible.

Response

We agree that the test procedure contradicted itself. Note that the test approach column has been removed from the test procedures. Also as noted above this criteria is gap eligible, so the legend indicates both documentation/attestation and visual inspection (which would be used for products not seeking gap certification). Additionally, we clarify that for unchanged criteria, ATLs are free to use the 2014 test scripts at their discretion, but they are not required to do so.

Comment

A commenter indicated that the phrasing used implied that a Health IT Module would have to record, change, and access a patient's active medication allergy list and record, change, and access the historical medication allergy list.

Response

We agree with the commenter that the test procedure was worded incorrectly. We have corrected this in the updated test procedure to indicate that a Health IT Module must allow a user to access the historical medication allergy list.

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

Comment

A number of commenters indicated that the order of the test steps was not correct and that configuring the CDS would logically come before demonstrating the CDS intervention is available in the Health IT module.

Response

We note that the order in which the test steps are listed in the test procedures is a reflection of the sequence of the certification criterion and does not necessarily prescribe the order in which the test should take place. We do agree with commenters that the order of the test steps for CDS was confusing and in the 2015 Edition final rule the sequence of the criterion has been modified to follow a more logical flow. The test procedure still reflects the sequence of the criterion, but we believe the current order will be easier to follow.

Comment

Commenters were confused by some of the test steps that indicated the user should perform an action rather than the Health IT module being capable of performing the action. In addition, commenters indicated that end-users often don't perform configuration of the system, rather a system administrator configures the system.

Response

We agree with commenters that the terminology was incorrect. The updated test procedure reflects where the Health IT module should be capable of performing a capability and where a user performs a capability. In addition, we clarified that user includes and can be limited to a system administrator.

Comment

A commenter indicated that the wording in the test procedure seemed to indicate "that interventions must be demonstrated independently for each type of data alone." Additionally, commenters requested clarification on whether the combination of data elements was simply 2 or more or all of the data elements. Other commenters requested more specificity, such as what should be show for source attribution, while others requested links to the specific standards.

Response

We understand that CDS is rarely based on a single data element such as demographics, so we clarify that it is not our expectation that interventions be demonstrated for each data type individually. We also clarify that the combination of data elements refers to 2 or more, not a combination of all of the data elements. We have included links to the standards in the test procedures. We decline to include some of the specificity requested by commenters, where such specificity was beyond what was described in the 2015 Edition final rule.

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

Comment

A number of commenters pointed out that the test approach did not match the legend at the beginning, including that data was not indicated in the legend but was indicated in the test approach column.

Response

We appreciate commenters' feedback and agree that the draft test procedure's legend was not correctly labeled. We have corrected this in the final test procedure and ensured that the legend matches the test approach.

Comment

A few commenters requested that in Section 1.2 which stated, "Evaluate the capability of the Health IT Module to automatically check for a preferred drug list exists and indicate for a user the last update" that we either remove the word exists or change the "for" to "that."

Response

We agree with commenters and have removed the word exists from the test procedure.

Comment

We received one comment that requested changing Item 1.1 from "The tester verifies that the Health IT Module can automatically check for a drug formulary for a specific patient and medication." To "The tester verifies that the Health IT Module can automatically check against a drug formulary for a specific patient and medication."

Response

We thank the commenter for their feedback, but we have declined to make this change. The test procedure mirrors the language used in the rule.

11. § 170.315 (a)(11) Smoking Status

Comment

The majority of the comments received on this test procedure asked for clarification on how many codes would need to be recorded during the testing demonstration and the mapping of the codes to the eight SNOMED-CT codes.

Response

The 2015 Edition final rule removed the requirement to record all smoking statuses. In effect, the criteria is unchanged from the 2014 Edition and is therefore gap eligible. The test procedure has been updated to reflect the changes from the proposed rule to the 2015 Edition final rule.

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

Comment

A number of commenters requested that this criteria be gap eligible or that health IT developers only be required to submit documentation/attestation that they have implemented SNOMED CT® U.S. Edition, September 2015 Release, rather than demonstrating the function through visual inspection.

Response

We appreciate commenters' feedback. ONC did not indicate in the 2015 Edition final rule that Family Health History is gap eligible, and therefore, the test procedure cannot include a gap eligible option. The test procedure has been updated to indicate both documentation/attestation and visual inspection in the legend. We note that it is up to the discretion of each ATL to allow documentation/attestation versus visual inspection for this criteria.

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

Comment

A commenter requested clarification on who is considered a user in the test procedure and whether this should indicate that the system is performing the action, rather than a provider or other user.

Response

We agree with the commenter that use of the term "user" in the test procedure was confusing and did not accurately reflect the criteria. We have updated the test procedure to indicate that the health IT module is identifying patient-specified education resources, not a provider or other user.

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

Comment

A commenter requested clarity on whether providing a link to the GUDID was sufficient or if all of the data has to pulled from the GUDID into the module. A number of other comments requested changes to the criteria itself.

Response

We clarify that providing a link to the GUDID does not meet the intention of the criteria and will not be sufficient for certification. We decline to provide a response to comments related to the criteria itself and reference commenters to the 2015 Edition final rule.

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

Comment

A few commenters requested clarification on whether all of the LOINC codes would need to be demonstrated for each category during testing.

Response

It is up to the discretion of each ATL to determine how many LOINC codes must be demonstrated for each category of data. The test procedure requires a minimum of one code per category.

16. § 170.315 (b)(1) Transitions of Care

Comment

Commenters requested that ONC provide in the test procedure a list of the data elements that the ATL must verify manually and indicated that this has historically been an area of confusion due to the ambiguity of the standards. They requested ONC to clarify which data must be included in the C-CDA.

Response

We agree with commenters and have indicated the data elements that must be included in the C-CDA as well as those that must be visually inspected by the tester (for example, Reason for Referral).

Commenter

Commenters requested that the test tool and test data be available with the test procedure to provide adequate time for review and feedback.

Response

We note that the test tool and test data are available now, and we have provided hyperlinks to each in the test procedure.

Comment

A number of commenters submitted feedback that the validation of a C-CDA should not be included in this criteria. One commenter requested clarification on who should be notified of errors, i.e. which users are notified of vocabulary errors versus segment errors.

Response

C-CDA validation was finalized in the 2015 Edition final rule; we therefore decline to exclude validation from the test procedure. We also decline to specify which users should receive error messages upon validation. We leave this to the discretion of users and their vendors. Certification will verify the capability to provide such notification not to whom it is provided.

17. § 170.315 (b)(2) Clinical Information Reconciliation and Incorporation

Comment

Commenters requested clarification on whether the summary of care record must be automatically matched to a patient record. Other commenters provided feedback that vendors should not be required to certify for both R1.1 and R2.0. Commenters also requested clarify on which C-CDA validator would be used for this test procedure and asked for consistency across test procedures in the tool used. Finally, commenters requested that the test data and test tools be available with the draft test procedure.

Response

We clarified in the test procedure that the summary of care record can either be automatically or manually matched to a patient record. We also note that feedback on certifying to two standards does not apply to the test procedures, as the test procedures must include the criteria as finalized in the 2015 Edition. We clarify that the inconsistent use of the name of the C-CDA validator was unintentional. We have ensured that the tool name is used consistently across the draft test procedures. Finally, we note that the test data and test tool are available now, and we have provided a hyperlink to each in the test procedure.

18. § 170.315 (b)(3) ePrescribing

Comment

A number of commenters indicated that a number of messages listed together would not be initiated by the Health IT module, but rather by the pharmacy. They asked for clarification on what the expectation is for Health IT modules.

Response

We agree with commenters that a number of the messages do not originate in the Health IT module. We have modified the test procedure to indicate the messages that the Health IT module must be able to send, and those it must be able to receive from a pharmacy.

Comment

Commenters indicated that without the test data, the test procedure could not be properly evaluated and Health IT developers could not properly setup their systems.

Response

We note that the test data and test tool are available now, and we have provided hyperlinks to each in the test procedure.

Comment

A number of commenters indicated they go through rigorous testing to participate in ePrescribing networks and requested that certification from these types of third parties be acceptable to show compliance with the 2015 Edition criteria.

Response

In June, ONC published a Federal Register Notice indicating that non-governmental developed test methods, including tools, data, and procedures could be submitted to ONC for approval and use in the ONC Health IT Certification program. ONC is in the process of reviewing submissions and will post all approved test methods as they become available.

19. § 170.315 (b)(6) Data Export

Comment

Commenters requested that Health IT developers be able to submit documentation/attestation that a user can export the data at any time for any date range, rather than demonstrating the capability.

Response

We disagree with commenters that attestation is enough to demonstrate the user's ability to generate the data export. Over the last year, ONC has received feedback from users that they have experienced issues exporting data for the data portability criteria. As such, we believe that that portion of this criteria should be tested via visual inspection.

20. § 170.315 (b)(7) Data Segmentation for Privacy – Send

Comment

Commenters requested that the testing tool should be used, not demonstration to reduce the testing burden.

Response

We clarified in the test procedure that the test tool would be the primary testing method, and that visual inspection refers to the tester reviewing the test tool report, not a live demonstration.

21. § 170.315 (b)(9) Care Plan

Comment

Commenters requested clarification on the tool that would be used to test the Care Plan and asked for consistency in testing between (b)(1) Transitions of Care and (b)(9).

Response

We have clarified the tool that should be used for testing and included a hyperlink to the tool in the test procedure. We also aligned this test procedure with the methodology used in (b)(1).

22. § 170.315 (c)(1) Clinical Quality Measures – Record and Export

Comment

Commenters requested more detail on this test procedure, including which files needed to be exported, how the tools would be used for testing, and what level of visual inspection would be used to demonstrate record and export. Commenters also provided feedback on the criteria itself and disagreed with the scope of the updated criteria, while others asked that record be eligible for gap certification.

Response

We agree with commenters that the test procedure requires more detail, in particular how the tool and test data will be used for testing. We have added such detail, including the test data that will be used to demonstrate the capability to record. We clarify that visual inspection will be used to review the Cypress test tool reports and importing/recording of the Cypress test data for record. We decline to respond to comments about the criteria and instead refer commenters to the 2015 Edition final rule. The final rule did not indicate that any part of (c)(1) was gap eligible; therefore the test procedure does not indicate gap eligible.

23. § 170.315 (c)(2) Clinical Quality Measure – Import and Calculate

Comment

Commenters asked for clarity on use of the test tool versus use of visual inspection and indicated that the test tool was the more appropriate test method. Commenters also asked for more detail in the test procedure, including how the test tool and data will be used during the testing process.

Response

We clarify that in this test procedure visual inspection is not intended to indicate live demonstration, rather visual inspection of the report generated by the Cypress tool. We have also provided more detail in the test procedure regarding the use of the Cypress test tool and data.

Comment

One commenter indicated that EHRs should not import data for CQMs and that this criteria was more appropriate for data warehouses.

Response

We clarify that the ONC Health IT Certification program is not limited to EHRs. Any Health IT product can seek certification.

24. § 170.315 (c)(4) Clinical Quality Measure – Filter

Comment

Commenters requested more detail on this test procedure, particularly around how the tools would be used for testing.

Response

We have provided more detail in the test procedure regarding the use of the test tools and test data and have provided hyperlinks to each.

25. § 170.315 (d)(1) Authentication, Access, Control, Authorization

Comment

We received one comment requesting that negative testing steps be added to the test procedure.

Response

We agree with the commenter and have added a negative test to the test procedure to have the tester verify that a user with a disabled account cannot access the Health IT Module.

26. § 170.315 (d)(2) Auditable Events and Tamper-resistance

Comment

Commenters requested that we make it clear which steps in the test procedure are optional based on the Health IT Module's capability. For example, if the Health IT Module does not allow for deletion, demonstrating that capability should be optional.

Response

We agree with commenters and have clarified in the test procedure that Health IT Developers do not have to demonstrate recording of actions that their system does not allow. We propose that this would be accomplished by submitting documentation to the ATL about which actions the Health IT Module does not support.

27. § 170.315 (d)(3) Audit Report

Comment

A commenter indicated that the test component legend indicated that there were no testing components for this criteria.

Response

The legend incorrectly indicated that no testing components would be used for this criteria. We have corrected the legend in the updated test procedure to indicate that this criteria is gap eligible and requires visual inspection.

28. § 170.315 (d)(4) Amendments

Comment

A commenter requested clarification on whether the date and time of when the amendment is accepted or denied must be captured as it was in the 2014 Edition test procedure.

Response

We declined to include in the test procedure for this criteria a requirement that the date and time must be recorded. Per the 2015 Edition Final rule, the "tracking" or auditing of events such as data provenance and date and time is outside the scope of this criterion.

Comment

A commenter indicated that the test component legend indicated that there were no testing components for this criteria.

Response

The legend incorrectly indicated that no testing components would be used for this criteria. We have corrected the legend in the updated test procedure to indicate that this criteria is gap eligible and requires visual inspection.

29. § 170.315 (d)(5) Automatic Access Time-Out

Comment

A commenter indicated that the test component legend indicated that there were no testing components for this criteria.

Response

The legend incorrectly indicated that no testing components would be used for this criteria. We have corrected the legend in the updated test procedure to indicate that this criteria is gap eligible and requires visual inspection.

30. § 170.315 (d)(6) Emergency Access

Comment

A commenter requested that we break verifying access to users, verifying that authorized users can access, and verifying that unauthorized users cannot access into three steps.

Response

We agree with the commenter and have updated the test procedure accordingly.

31. § 170.315 (d)(7) End-User Device Encryption

Comment

A few commenters requested more detail on the level of inspection required to verify that no data is stored on end-user devices.

Response

We leave it to the discretion of each ATL to determine the level of visual inspection they will perform to verity that data is not stored on end-user devices.

Comment

A commenter requested clarification on whether each algorithm used is subject to testing if the use of multiple encryption algorithms is supported by the Health IT Module.

Response

If a Health IT Module uses multiple encryption algorithms, we would expect that each algorithm would be tested by the ATL.

32. § 170.315 (d)(8) Integrity

Comment

A number of commenters indicated that the 2014 Edition version focused on the transmitted message and verifying that it was received at the other end unaltered and were concerned that the 2015 Edition test procedure changed the focus.

Response

We proposed in the NPRM a change in how a Health IT Module would be tested and certified to this criterion. We explained that the 2015 Edition "integrity" criterion would be tested and certified to support the context for which it was adopted – upon receipt of a summary record in order to ensure the integrity of the information exchanged. The test procedure reflects this change which was finalized in the 2015 edition final rule.

33. § 170.315 (d)(11) Accounting of Disclosures

Comment

A few commenters requested clarification on whether NTP should be used to record the time, with one commenter requesting that it be required.

Response

We decline to require that NTP be used to record time in the test procedure, as the 2015 Edition final criteria does not include this requirement.

34. § 170.315 (e)(1) View, Download, and Transmit to a Third Party

Comment

Commenters noted that WCAG was missing from the test procedure, though it was included in the NPRM criteria.

Response

We appreciate commenters pointing out the omission of WCAG, which was an error in the test procedure. We have added testing steps for WCAG.

Comment

A number of commenters requested more detail in the test procedure around how the test tool and test data would be used during testing. They also indicated that without the test data, it would be difficult to provide feedback on the test procedure. Finally, commenters indicated that negative testing should be used.

Response

We agree with commenters and have provided more detail on how the test tool and data would be used during the testing process. We also note that the test tool and data are available now, and we have provided hyperlinks to each in the test procedure. We further clarify that visual inspection will be used to review the test documents from the test tool, where appropriate (i.e. C-CDA validator) and demonstration of activities where appropriate (i.e. verifying an email was sent and received by the email address). We agree with commenters that negative testing should be used and have included this in the test procedure.

Comment

Commenters submitted questions about the API requirement.

Response

We refer commenters to our response on (g)(7)-(g)(9) on APIs.

35. § 170.315 (e)(2) Secure Messaging

Comment

Commenters requested clarification on how encryption will be verified, and some suggested it should be via attestation/documentation.

Response

We agree with commenters and have clarified in the test procedure that Health IT developers must submit documentation about the encryption of the messages.

36. § 170.315 (f)(1) Transmission to Immunization Registries

Comment

A number of commenters indicated confusion on whether the test procedure was indicating that a test would be done with a live immunization registry or a test tool. Some were also confused on why visual inspection would be used, rather than a test tool. Finally, a commenter requested that the test tool be published with the final rule.

Response

We clarify that the NIST HL7 v2 Immunization Test Suite will be used for testing, not a live immunization registry. We also clarify that we intend for visual inspection to be used to review the report from the test tool and to review the data created by the Health IT module. The test tool is available now in conjunction with the test procedure.

Comment

Commenters requested a number of clarifications regarding the history and forecast portion of the test procedure, including: parameters such as date or age that should be used, whether reconciliation of the forecast is required, and how discrepancies should be handled.

Response

We note that the 2015 Edition final rule does not provide requirements around parameters for the history and forecast data, so we decline to provide such parameters in the test procedure. In addition, the 2015 Edition final rule removed the requirement to reconcile the history and forecast and instead requires that a user be able to request, access, and display this information. The test procedure reflects this change.

37. § 170.315 (f)(2) Transmission to Public Health Agencies – Syndromic Surveillance

Comment

A commenter requested that the test tool be published with the final rule.

Response

The test tool is available now in conjunction with the test procedure.

38. § 170.315 (f)(3) Transmission to Public Health Agencies - Reportable Laboratory Tests and Values/Results

Comment

Commenters requested clarification on the use of visual inspection when a test tool is being used. A commenter also requested that the test tool be published with the final rule.

Response

We clarify that we intend for visual inspection to be used to review the report from the test tool and to review the data created by the Health IT module. Additionally, the test tool is available now in conjunction with the test procedure.

39. § 170.315 (f)(4) Transmission to Cancer Registries

Comment

Commenters requested more detail be included in the test procedure, particularly on how the test tool and test data will be used.

Response

We have included more detail in the test procedure specifically on use of the test tool and data for testing. We note that the test tool and test data are available now, and we have included hyperlinks to each in the test procedure.

40. § 170.315 (f)(5) Transmission to Public Health Agencies – Case Reporting

Comment

Commenters requested clarification on the C-CDA to be used for this criteria and how it should be constrained. They also requested clarity on how visual inspection would be used versus attestation/documentation.

Response

In the test procedure we provided clarity on how the C-CDA should be constrained and identified the test tool that should be used during testing. We also clarify that visual inspection of the test tool report is sufficient, and we do not intend for there to be a live demonstration where the test tool is used.

41. § 170.315 (f)(6) Transmission to Public Health Agencies – Antimicrobial Use and Resistance Reporting

Comment

Commenters requested clarity on how visual inspection would be used versus attestation/documentation in regards to the tool. In addition, a commenter indicated that the C-CDA Validator published by Lantana would be a more appropriate test tool.

Response

We clarify that visual inspection of the test tool report is sufficient, and we do not intend for there to be a live demonstration where the test tool is used. In June, ONC published a Federal Register Notice indicating that non-governmental developed test methods, including tools, data, and procedures could be submitted to ONC for approval and use in the ONC Health IT Certification program. ONC is in the process of reviewing submissions and will post all approved test methods as they become available.

42. § 170.315 (f)(7) Transmission to Public Health Agencies – Health Care Surveys

Comment

Commenters requested that we provide examples of health care surveys in the test procedure. Commenters also requested clarity on how visual inspection would be used versus attestation/documentation in regards to the tool.

Response

We have provided a link to test data in the test procedure. We also clarify that visual inspection of the test tool report is sufficient, and we do not intend for there to be a live demonstration where the test tool is used.

43. § 170.315 (g)(3) Safety-Enhanced Design

Comment

Commenters requested clarification on what visual inspection would be used for.

Response

We clarify that in this test procedure visual inspection does not refer to a live demonstration, but rather a review of the documentation submitted by the Health IT developer.

44. § 170.315 (g)(4) Quality System Management

Comment

A commenter asked if they could demonstrate compliance to QMS using a combination of standards across all criteria instead of trying to separate the individual standards and apply certain standards to certain criteria.

Response

The 2015 Edition final rule indicates that if a single QMS was used, the Health IT developer must only demonstrate the single criteria. If multiple criteria were used, it must be demonstrated for each criteria. At this juncture we decline to allow for showing a combination of QMS across all criteria without identifying the specific criteria the standard applies to.

45. § 170.315 (g)(6) Consolidated CDA Creation

Comment

Commenters asked what test data would be used as the gold standard.

Response

We have included links to the test tool and test data in the test procedure and have provided hyperlinks to each.

46. § 170.315 (g)(7)-(9) Application Access

Comment

Commenters were concerned about how this criteria would be tested without a test tool or standard to test against. They also requested clarification on the use of visual inspection versus attestation/documentation.

Response

Since the 2015 Edition final rule did not specify a standard for the API, we cannot create a test tool that will support all Health IT modules. Consequently, in the test procedure we indicated that the Health IT developer can identify the third party application that accesses the API in lieu of a test tool. We also clarify that this criteria will be tested through a combination of documentation and live demonstration.

47. § 170.315 (h)(1) Direct Project

Comment

Commenters requested more detailed steps, particularly around MDN requirements and use of the test tool.

Response

We have added additional specificity to the test procedure, including what the expected MDN messages are and what triggers them.

48. § 170.315 (h)(2) Direct Project, Edge Protocol, and XDR/XDM

Comment

Commenters requested more detailed steps, clarification on the test tools that should be used.

Response

We have added additional specificity to the test procedure and clarified the test tools that will be used during testing.