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)(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.

10. § 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.

11. § 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.

12. § 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.

13. § 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.

14. § 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.

15. § 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.

16. § 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.

17. § 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.

18. § 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.

19. § 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.

20. § 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.

21. § 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.