



Feedback: ONC Health IT Certification Program 2015 Edition Test Methods

Allscripts, with a platform of clinical and business solutions for ambulatory, acute and post-acute care settings, is relied upon by the largest network of providers – over 180,000 physicians in more than 45,000 different practice locations, 1,500 hospitals and almost ten thousand extended care facilities. It is through our three decades of experience developing and deploying software to this vast network of providers, even in the midst of the tremendous change the industry has gone through in recent years, that we submit our suggestions here today.

170.315(a)(2) CPOE - Laboratory

Commercial labs don't universally follow standards for their Directory of Services, nor are they consistently using LOINC even for the subset of orderable tests that do have a LOINC code, which makes real world testing tremendously challenging for this measure. First, the word "electronic" should be removed before "Directory of Services". Also, ONC should work with some of the large national lab companies to determine the orderable codes, the "ask on entry" (AOE) questions, and the test collection requirements; these joint decisions should be shared with developers who can select the lab vendor data set for whichever lab vendors they choose.

We also suggest that ONC and the testing bodies include the plain language of the standards, as well as a link to the actual standard. This would be much more efficient.

170.315(a)(7) Problem List

The goal here should be consistent implementation of common actions regardless of clinical domain. To address this, there should be consistent testing requirements applied between problem list, medication list, and med allergy list. Additionally, there should be consistent testing data requirements across all three.

§170.315(b)(1) - Transitions of Care

Item 1.2 Validate and Display Transition of Care Documents

Executing test cases to detect invalid C-CDA document does not support clinically relevant steps and should be omitted. Rather invalid section and data should still be representing in human readable form.

§170.315(c)(2) CQMs – import and calculate

Item 1 Import

We would like more clarification on what is meant by "large amounts of data".

We request clarification regarding a definition for "de-duplication" of data. We would also like more clarification about the intent of "duplicate records are de-duplicated or eliminated". We would like to understand how duplication is to be measured and assessed. An HER can reasonably be expected to identify if a QRDA file is imported twice, but the system cannot de-identify combinations of data which were recorded and imported efficiently at this point.

We also would appreciate further clarification about which elements of the CQM workflow are to be inspected.

§170.315(e)(1) – View, Download, and Transmit to Third Party

Item 1.1 View, Download and Transmit to a Third Party

We request clarification in Section 1.1, item 4. As written it implies that the patient must first download the machine readable document and then transmit it. Download is not required to meet the transmit function.

Download and transmit are two separate requirements within the criterion. We believe they mean that the document that was available for download must also be available for transmit.



§170.315(f)(2) – Transmission to Public Health Agencies – syndromic surveillance

Item 1.1 Ambulatory Setting – Syndromic Surveillance

We request clarification on the phrase “..which can be sent by any electronic means.” Does this mean that we must demonstrate support for multiple electronic transmission methods? Or does it mean that we must demonstrate support for any single electronic transmission method?

§170.315(g)(1) and (g)(2) – Automated Numerator Recording and Automated Measure Calculation

The 2014 test procedure for this included a requirement to stratify the EP reports based on the provider and the EH/CAH reports based on the two methods available for counting ED patients (Observation services and All ED Visits).

This proposed test method does not address those requirements.

§170.315(g)(6) – Consolidated CDA Creation Performance

There is currently no “gold standard” for content expectations. It is inevitable that data over and above the “gold standard” will be included, as it’s impossible to control sources outside of the HER developer’s environment. Instead, we suggest that there is more to review against the HL7 Examples Task Force – they have identified clinical data consistent with the common clinical data set (for use in creating a valid document.

§170.315(g)(7) - Application Access to Common Clinical Data Set

Item 3 Data Requests, Response Scope and Return Format

We have concerns about requirements specified for conformance when the API is unspecified; even where we believe this implies FHIR, confirmation is necessary, of course. We request clarification as soon as possible, given the variety of types of API and how they could be used to demonstrate.

We would also like further clarification on how “all patient data returned” will be defined and assessed. Only a subset of CCDS is supported by §170.315(a)(4) “CCDA”

General

Additionally, we support the following suggestions made in the EHR Association’s comments:

- For criteria that utilize testing tools to validate output from the EHR, no visual inspection should be required. Testing tools should produce output that validates the standard was applied properly. Vendors should be able to provide testing tool documentation as attestation of successful validation from the testing tools. Further, the testing tools should clearly show pass / fail with explanations to reduce the room for misinterpretation.
- In the interest of transparency, the testing labs should be required to post their processes, test scripts, and their procedures in advance testing. This advance disclosure will increase consistency across testing bodies. Any guidance given to ATLS by ONC should be shared publicly so that clear expectations are available to all stakeholders.
- There are several criteria that specify attestation/documentation “at a minimum”. Please clarify the meaning of this phrase as it relates to the testing components which may also state visual inspection. We understand this phrase to mean that the vendor may choose attestation to demonstrate compliance rather than visual demonstration. We are concerned that criteria might not be tested equally if the intent is to provide flexibility for the ATLS to strengthen requirements beyond the minimum and discourage additional requirements for any criteria which ONC deems attestation as adequate.
- If the final testing tool is not available at this time or on the next version of these test methods, please include links to the current tool development prototypes so that developers can run preliminary tests prior to finalization of the tool. If final, validated, and piloted tools are not available at least 18 months prior to



the functionality being required by end users to satisfy compliance with the program, alternative certification methodologies such as attestation should be deployed.

- Review of the Draft Test Procedures has raised several questions regarding field surveillance expectations. If these test procedures are expected to be followed for in-the-field surveillance, consideration must be given to the fact that end users may be using the product in a different fashion than when it was tested, and will certainly not be familiar with the test scripts and certification testing process. Certification testing may be accomplished by demonstrating workflows that may not match the workflow chosen by the end user. ATLs and ACBs will be familiar with the test procedures, although they will not be familiar with the EHRs. We discourage the application of these test procedures by inexperienced personnel and reiterate the limitations of their usefulness for such activities.