ONC Health IT Certification Program
Program Guidance #15-02
Issued and Effective Date: May 11, 2015

Subject: Notice regarding required test report content for health IT certified to the 2014 Edition "safety enhanced design" certification criterion (45 CFR § 170.314(g)(3)) and the reporting to ONC of hyperlinks to test results with the required content.

Regulatory Requirements: An ONC-ACB must receive certain testing documentation before it issues a Complete EHR or EHR Module certification for § 170.314(g)(3). As specified in the 2014 Edition final rule (77 FR 54163, 54188), the "[s]ubmission of the information specified in the NISTIR 7742 template[1] will need to be submitted for each and every one of the applicable...certification criteria[2] specified in [§ 170.314(g)(3)] and for which certification is sought. This information will become part of the EHR technology's test report that is required to be made publicly available."

The following information/sections in NISTIR 7742 are required for submission to an ONC-ACB in order to meet the certification criterion and must be reviewed by ONC-ACBs for completeness:

- Name and version of the product
- Date and location of the test
- Test environment
- Description of the intended users
- Total number of participants
- Description of participants: their experience and demographic characteristics
- Description of the user tasks that were tested
- List of the specific metrics captured during the testing for effectiveness, efficiency and satisfaction
- Data scoring
- Results of the test and data analysis
- Major test findings
- Identified area(s) of improvement(s)

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[1] Customized Common Industry Format Template for Electronic Health Record Usability Testing (NISTIR 7742) template. http://www.nist.gov/manuscript-publication-search.cfm?pub_id=907312
[2] Four criteria were added to § 170.314(g)(3) through the 2014 Edition Release 2 final rule (79 FR 54430, 54436, and 54439), which brings the total certification criteria referenced in § 170.314(g)(3) to twelve.

There are illustrative tables on pages 11 and 20 of the NIST 7742 document that may not need to be populated, depending on the tasks tested. (77 FR 54188)

As part of an ONC-ACB's reporting requirements to ONC it must submit a hyperlink for each certified Complete EHR and certified EHR Module to which it issues a certification. The hyperlink is meant to enable the public to access the test results that the ONC–ACB used to certify the EHR technology (45 CFR 170.523(f)(8)).

ONC-ACB Implementation Requirements: Effective May 11, 2015, any certified health IT product submitted to ONC for posting on the ONC Certified Health IT Product List (CHPL) with a hyperlink to test results that do not include, as applicable, the required documentation referenced above for § 170.314(g)(3) will be rejected. Additionally, ONC-ACBs will have 90 calendar days to correct hyperlinks to test results for applicable certified Complete EHRs and certified EHR Modules issued a certification prior to May 11, 2015, which do not link to test reports that contain the required documentation associated with § 170.314(g)(3) as described in the 2014 Edition final rule and recited in this program guidance. ONC-ACB extension requests to comply with this requirement can be made and will be reviewed on a case-by-case basis.

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