DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 170

Acceptance and Approval of Non-Governmental Developed Test Procedures, Test Tools,

and Test Data for Use under the ONC Health IT Certification Program

AGENCY: Office of the National Coordinator for Health Information Technology (ONC),

Department of Health and Human Services.

ACTION: Republication.

SUMMARY: This document further informs the public of ONC's policy that permits any person

or entity to submit test procedures, test tools, and test data for approval and use under the ONC

Health IT Certification Program.

DATES: [Insert date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Alicia Morton, Director, ONC Health IT

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SUPPLEMENTARY INFORMATION:

On January 7, 2011, the Department of Health and Human Services issued a final rule

establishing a permanent certification program for the purposes of testing and certifying health

information technology ("Establishment of the Permanent Certification Program for Health

Information Technology," 76 FR 1262) ("Permanent Certification Program final rule"). The

permanent certification program was renamed the "ONC HIT Certification Program" in a final

rule published on September 4, 2012 (77 FR 54163) ("2014 Edition EHR Certification Criteria

final rule"). In the proposed rule entitled "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 16804, 16806), we propose to further rename the program as the "ONC Health IT Certification Program."

In the preamble of the Permanent Certification Program final rule, we stated that a person or entity may submit a test procedure or test tool (to note, which includes any associated test data) to the National Coordinator for Health Information Technology (the National Coordinator) to be considered for approval and use by NVLAP accredited testing laboratories. "The submission should identify the developer of the test tool and/or test procedure; specify the certification criterion or criteria that is/are addressed by the test tool and/or test procedure; and explain how the test tool and/or test procedure would evaluate a Complete EHR's, EHR Module's, or if the applicable, and other type of HIT's compliance with the applicable certification criterion or criteria. The submission should also provide information describing the process used to develop the test tool and/or test procedure, including any opportunity for the public to comment on the test tool and/or test procedure and the degree to which public comments were considered." (76 FR 1280) We also stated that "[i]n determining whether to approve a test tool and/or test procedure for purposes of the permanent certification program, the National Coordinator will consider whether it is clearly traceable to a certification criterion or criteria adopted by the Secretary; whether it is sufficiently comprehensive (i.e., assesses all required capabilities) for NVLAP-accredited testing laboratories to use in testing a Complete EHR's, EHR Module's, or other type of HIT's compliance with the certification criterion or criteria adopted by the Secretary; whether an appropriate public comment process was used

during the development of the test tool and/or test procedure; and any other relevant factors." (76 FR 1280)

During the time in which the ONC Health IT Certification Program has operated, health IT developers have suggested that testing efficiencies could be achieved if the ONC Health IT Certification Program were to leverage operational testing and certification, such as the ePrescribing (eRX) network testing (and certification). As indicated by the previously recited ONC policy, the National Coordinator is open to approving test procedures, test tools, and test data that meet the outlined approval requirements above for an applicable adopted certification criterion or criteria. By way of this document, we strongly encourage persons or entities to submit such test procedures, test tools, and test data to ONC if they believe such procedures, tools, and data could be used to meet ONC's certification criteria and testing approval requirements. We also note that there is no programmatic prohibition on the approval of multiple test procedures, test tools, and test data for a certification criterion or criteria.

Dated: May 21, 2015

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Alicia Morton

Director, ONC Health IT Certification Program

Office of the National Coordinator for Health Information Technology

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