

**MEMORANDUM OF UNDERSTANDING
BETWEEN
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF THE
NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY
AND
[INSERT NAME OF ENTITY]**

I. PURPOSE

This Memorandum of Understanding (MOU) is made and entered into on this day of [INSERT DATE XX OF MONTH, YEAR] ("Effective Date") by and between the U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology (ONC) and the [INSERT DATE] This MOU defines an agreement between the ONC and [INSERT NAME OF ENTITY] to maintain active collaboration in relation to [INSERT NAME OF ENTITY] approved testing method under the ONC Health IT Certification Program ("Program"). The purpose of this MOU is to set forth the terms, conditions and responsibilities of the ONC and [INSERT NAME OF ENTITY] associated with the approved testing method for the following criterion: [AND NAME § 170.315 (x)(x) -].

II. BACKGROUND

On June 9, 2015 the Department of Health and Human Services (HHS) published a notice in the Federal Register titled "Acceptance and Approval of Non-Governmental Developed Test Procedures, Test Tools, and Test Data for Use Under the ONC Health IT Certification Program." This notice informed the public of ONC's policy that permits any person or entity to submit test procedures, test tools, and test data (herein a "test method") to ONC to be considered for approval and use by accredited testing laboratories. The notice reiterated that in determining whether to approve a test method for purposes of the ONC Health IT Certification Program, the National Coordinator will consider whether it is clearly traceable to a certification criterion or criteria; whether it is sufficiently comprehensive for National Voluntary Laboratory Accreditation Program (NVLAP)-accredited testing laboratories to use in testing health IT's compliance with the certification criterion or criteria; whether an appropriate public comment process was used during the development of the test method; and any other relevant factors (76 FR 1280).

[New paragraph - ONC to describe evaluation and approval process]

III. RESPONSIBILITIES AND SCOPE OF WORK

The ONC and [INSERT NAME OF ENTITY] agree to the activities outlined below in order to maintain consistency and integrity in the testing processes that support certifications issued through the ONC Health IT Certification Program.

The ONC agrees to undertake the following activities:

- i. Notify [INSERT NAME OF ENTITY] of reported issues, complaints and feedback related to [INSERT NAME OF ENTITY] ' approved testing method;
- ii. Notify ONC-Authorized Testing Laboratories (ONC-ATLs) and [INSERT NAME OF ENTITY] of patches, upgrades, planned enhancements, and issues related to the [INSERT NAME OF TEST TOOL]n the interest of testing tool and process harmonization between governmental and non-governmental testing approaches;
- iii. Notify ONC-ATLs and [INSERT NAME OF ENTITY] of modifications to the test procedure and Certification Companion Guide related to the criterion at [INSERT CRITERION CITATION] that [INSERT NAME OF ENTITY] tests via the ONC Health IT Certification Program listserv;
- iv. Host all [INSERT NAME OF ENTITY] -approved test procedures on HealthIT.gov;

- v. Collaborate with [INSERT NAME OF ENTITY] to effectuate the release of, and any updates to [INSERT NAME OF ENTITY]-developed test procedures on HealthIT.gov;
- vi. Collaborate with [INSERT NAME OF ENTITY] on ONC listserv announcements and other public communications; and
- vii. Meet with [INSERT NAME OF ENTITY] on a semi-annual basis to review the progress of [INSERT NAME OF ENTITY] testing maintenance and development, address any unresolved issues, and ensure policy and technical alignment.

[INSERT NAME OF ENTITY] agrees to undertake the following activities:

- i. Fund the development, maintenance, and user support of its testing method;
- ii. Develop and maintain the test tool, test data, and test procedure as an ONC-approved alternative testing approach to meet the 2015 Edition certification criterion [INSERT CRITERION CITATION § 170.315(x)(x)] through the lifetime of the Edition of certification to which the certification criterion belongs or if [INSERT NAME OF ENTITY] seeks to have its approval removed;
- iii. Notify ONC of patches, upgrades, and planned enhancements to the approved testing method, including updates as a result of standards developing organization (SDO) published errata/corrections, within 30 days of any change;
- iv. Include support for ongoing surveillance activities conducted by ONC and its ONC-Authorized Certification Bodies (ONC-ACBs) to ensure that Health IT Modules continue to conform to the requirements of its certification, and provide support and SME expertise to support ongoing surveillance activities as needed;
- v. Notify ONC of modifications to the test procedure and other relevant testing documents related to the criterion at [INSERT CRITERION CITATION § 170.315(x)(x)] that [INSERT NAME OF ENTITY] tests to, and provide a copy of the modified version of the test procedure for posting to healthit.gov, within 30 days of any change;
- vi. Respond to approved testing method-related questions as requested by ONC, such as through the ONC-ATLs, ONC-ACBs, developers, and the public inquiry process;
- vii. Remain apprised of and closely adhere to the latest ONC Program requirements, health IT standards, criteria, and implementation specifications;
- viii. Ensure and report on the timely alignment of the approved testing method data, tool, and procedure with standards and specification updates that are relevant to the 2015 Edition certification criterion [INSERT CRITERION CITATION § 170.315(x)(x)]; and
- ix. Meet with ONC on a semi-annual basis to review the progress of [INSERT NAME OF ENTITY] testing maintenance and development, address any unresolved issues, and ensure policy and technical alignment.

IV. TERMS AND CONDITIONS

Neither ONC nor [INSERT NAME OF ENTITY] may assign or transfer all or any portion of this MOU without the prior written consent of the other partner. The provisions of this MOU may only be amended or waived by mutual written agreement by both partners. Partners agree to review jointly the terms and conditions of this MOU annually, and appropriate changes will be made by amendment to the original MOU. The individuals signing this MOU on behalf of their respective organizations represent and warrant (without personal liability therefor) that upon the signature of each, this MOU shall have been duly executed by the organization each person represents. Each partner will identify their own resources to implement this MOU. This agreement does not itself authorize the expenditure or reimbursement of any funds.

Partners further agree to review performance under this MOU to determine if expectations are being met and document a summary of their assessment. The ONC and [INSERT NAME OF ENTITY] hereby agree that, in the event of any dispute between the partners relating to this MOU or any amendments and/or revisions, the

partners shall first seek to resolve the dispute through informal discussions. Any disagreements that cannot be resolved shall be stated in writing by each partner and presented to the other partner for consideration. If agreement is not reached within 30 calendar days, the partners shall forward the written presentation of the disagreement to their respective higher officials for appropriate resolution.

This MOU shall take effect upon signing by both the ONC and [INSERT NAME OF ENTITY] and shall remain in effect indefinitely unless terminated in writing. Either partner may terminate this MOU for cause upon fourteen (14) days written notice to the other. Upon termination of this MOU, the partners will take all reasonable and necessary measures to conclude any work already commenced in accordance with this MOU.

V. PRINCIPAL CONTACTS

ORGANIZATION	ONC	[INSERT NAME OF ENTITY]	[INSERT NAME OF ENTITY]
Name			
Address			
E-Mail			
Phone			

Such principal contacts may be changed in writing from time to time by their respective organizations.

VI. APPROVAL

The undersigned concur with this Agreement.

[INSERT NAME OF ONC OFFICIAL]

[INSERT NAME OF OFFICIAL]

[INSERT NAME OF ONC OFFICIAL] Date
Office of Technology
Office of National Coordinator for Health IT, HHS
Office of the National Coordinator for Health IT, HHS

[INSERT SIGN.LINE FOR ENTITY OFFICIAL] Date