

**MEMORANDUM OF UNDERSTANDING
BETWEEN
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF THE
NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY
AND
HEALTHCARE INFORMATION AND MANAGEMENT SYSTEMS SOCIETY (HIMSS)**

I. PURPOSE

This Memorandum of Understanding (MOU) is made and entered into on this 28 of November, 2017 (“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 Healthcare Information and Management Systems Society (HIMSS). This MOU defines an agreement between the ONC and HIMSS to maintain active collaboration in relation to HIMSS’ 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 HIMSS associated with the approved testing method for the following criterion: § 170.315(f)(1) Transmission to immunization registries.

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).

ONC staff conducted, in consultation and with deep engagement with ONC Office of Standards and Technology leadership, a thorough review and assessment of the HIMSS Immunization Integration Program (IIP) testing documentation, processes, data and tool submitted for consideration for approval as an alternative test method for immunization transmission testing. Analyses included a review of documentation describing the HIMSS-IIP’s applicability to the standard required by § 170.315(f)(1), meetings with HIMSS, discussions with the National Institute of Standards and Technology (NIST) (developer of the common underlying tool), and a detailed review of HIMSS-IIP test cases including a side-by-side comparison with ONC test cases. As a result of this review and assessment, ONC submitted a recommendation to the ONC National Coordinator that the HIMSS-IIP test tool, test data and test procedure be approved as an alternative test method in the ONC Health IT Certification Program for § 170.315(f)(1)Transmission to immunization registries. The HIMSS test method was approved by ONC on October 5, 2017.

III. RESPONSIBILITIES AND SCOPE OF WORK

The ONC and HIMSS 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 HIMSS of reported issues, complaints and feedback related to HIMSS’ approved testing method;

- ii. Notify ONC-Authorized Testing Laboratories (ONC-ATLs) and HIMSS of patches, upgrades, planned enhancements, and issues related to the NIST Immunization Test Suite in the interest of testing tool and process harmonization between governmental and non-governmental testing approaches;
- iii. Notify ONC-ATLs and HIMSS of modifications to the test procedure and Certification Companion Guide related to the criterion at § 170.315(f)(1) that HIMSS tests via the ONC Health IT Certification Program listserv;
- iv. If applicable, host HIMSS-approved test procedures on HealthIT.gov
- v. If applicable, collaborate with HIMSS to effectuate the release of, and any updates to HIMSS-developed test procedures on HealthIT.gov;
- vi. Collaborate with HIMSS on ONC listserv announcements and other public communications; and
- vii. Meet with HIMSS on a semi-annual basis to review the progress of HIMSS testing maintenance and development, address any unresolved issues, and ensure policy and technical alignment.

HIMSS agrees to undertake the following activities:

- i. As necessary, 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 § 170.315(f)(1) through the lifetime of the Edition of certification to which the certification criterion belongs or if HIMSS seeks to have its approval removed;
- ii. Provide user support of its ONC-approved alternative test method;
- 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 planned modifications to the HIMSS IIP ONC Approved Test Method related to the criterion at § 170.315(f)(1), to include documentation supporting the traceability to criterion's requirements and the ONC Approved Test Method no less than 30 days in advance of any planned change as all modifications are subject to ONC review and may affect continued applicability as an Approved Alternative Test Method;
- 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 § 170.315(f)(1); and
- ix. Meet with ONC on a semi-annual basis to review the progress of HIMSS testing maintenance and development, address any unresolved issues, and ensure policy and technical alignment.

IV. TERMS AND CONDITIONS

Neither ONC nor HIMSS 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 HIMSS 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 HIMSS 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	HIMSS	HIMSS
Name	Steven Posnack	Thomas M. Leary	Eli Fleet
Address	HHS/ONC 330 C Street SW Washington, DC 20201	HIMSS 4300 Wilson Boulevard, Suite 250 Arlington, VA 22203	HIMSS 4300 Wilson Boulevard, Suite 250 Arlington, VA 22203
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Such principal contacts may be changed in writing from time to time by their respective organizations.

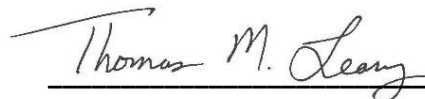
VI. APPROVAL

The undersigned concur with this Agreement.

Steven L. Posnack

Thomas M. Leary

12/8/2017

 11/28/2017

 Steven Posnack Date
 Director, Office of Standards and Technology
 Office of National Coordinator for Health IT, HHS
 Office of the National Coordinator for Health IT, HHS

 Thomas M. Leary Date
 Vice President, Government Relations
 HIMSS North America