



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Office of the National Coordinator
for Health Information Technology
Washington, D.C. 20201

TO: The National Coordinator
FROM: Steven Posnack, Director, Office of Standards and Technology

THROUGH: DNC
 COO
 Acting COS

DATE: 9/28/17

SUBJECT: Approval of HIMSS Immunization Integration Program (HIMSS-IIP)
Alternate Test Method Submission for § 170.315(f)(1) Transmission to
immunization registries – **DECISION**

**INPUT/
CONSULTED:** Alicia Morton; Daniel Chaput; John Snyder

ISSUE

The HIMSS-Immunization Integration Program (HIMSS-IIP) is a collaborative effort of Healthcare Information and Management Systems Society (HIMSS); ICSA Labs, an ONC-Authorized Testing Laboratory (ONC-ATL); and Chickasaw Nation Industries, Inc. (CNI) that is funded by the Centers for Disease Control and Prevention (CDC). In spring 2017, the collaboration submitted a request to have its testing methodology approved by ONC as an alternative to the current § 170.315(f)(1) Transmission to immunization registries test method used in the ONC Health IT Certification Program.

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 ONC-ATLs. 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 ONC-ATLs 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).

DISCUSSION

Summary of ONC Assessment

Between March 2017 and September 2017, ONC staff conducted a thorough review and assessment of the HIMSS-IIP documentation, processes, and tool submitted by the collaboration for approval as an alternative test method for § 170.315(f)(1) Transmission to immunization registries. Analyses included: a review of documentation describing the HIMSS-IIP’s applicability to the standard, meetings with the collaborative, discussions with 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.

The ONC analyses confirm the HIMSS-IIP approach to testing a Health IT Module for conformance to § 170.315(f)(1) covers the functional and standards conformance requirements stated in the regulation and is suitable as an alternative to the current ONC test method for § 170.315(f)(1).

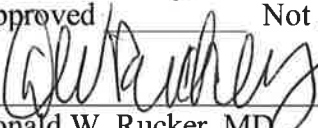

Anticipated Stakeholder Reaction

Much like the recent approval issued by ONC to NCQA regarding their alternative testing method for eCQMs, we expect that the industry will generally react positively to ONC approving the HIMSS-IIP as an alternative testing method under the Program. Moreover, the HIMSS-IIP testing method includes more comprehensive (“deeper test cases”) than ONC’s test data and is was developed with public health stakeholders at the local and state levels. Overall, we expect this approval to be viewed in line with the blog post ONC put out regarding a continued shift toward approving private-sector testing methods where such exist.

RECOMMENDATION

The Office of Standards and Technology (OST) recommends that you approve the HIMSS-IIP submission as an ONC-approved test method for the certification criterion adopted at 45 CFR 170.315(f)(1) Transmission to immunization registries.

DECISION

Approved <input checked="" type="checkbox"/>	Not Approved <input type="checkbox"/>	Need More Information <input type="checkbox"/>
		
Donald W. Rucker, MD		Date
National Coordinator for Health IT		