I. Person/Organization Name:

The HIMSS Immunization Integration Program (IIP)

II. Certification Criteria in Scope of Request:

45 CFR 170.315(f)(1)

For each criterion, indicate whether a test procedure(s), a test tool(s), or both will be submitted [Yes/No].

	170.315(f)(1)
Test Tool	Yes
Test Procedure	Yes

III. Explanation of Traceability and Comprehensiveness

For each of the specific functions expressed in each certification criterion, explain how the tool/procedure would evaluate compliance with certification criteria. *For the blank boxes under the "Test Procedure" and "Test Tool" columns please include a pointer/page citation to the applicable document which contains the specific content.*

A. 45 CFR 170.315(f)(1)

Criterion Paragraph	Test Procedure	Test Tool
(i) Create immunization information for electronic transmission in accordance with:	Pages 1-2, ONC IZ TP CNI Alignment Matrix	
(A) The standard and applicable implementation specifications specified in §170.205(e)(4).	Pages 3-5, ONC IZ TP CNI Alignment Matrix	Pages 1-13, ONC IZ Test Plan CNI Alignment Matrix
(B) At a minimum, the version of the standard specified in §170.207(e)(3) for historical vaccines.	Page 6, ONC IZ TP CNI Alignment Matrix	Pages 1-13, ONC IZ Test Plan CNI Alignment Matrix
(C) At a minimum, the version of the standard specified in §170.207(e)(4) for administered vaccines.	Page 7, ONC IZ TP CNI Alignment Matrix	Pages 1-13, ONC IZ Test Plan CNI Alignment Matrix
(ii) Enable a user to request, access, and display a patient's evaluated immunization history and the immunization forecast from an immunization registry in accordance with the standard at §170.205(e)(4).	Pages 7-13, ONC IZ TP CNI Alignment Matrix	Pages 10-13, ONC IZ Test Plan CNI Alignment Matrix

IV. Test Procedure/Test Tool Development Process

Please provide detailed information describing the process HIMSS IIP used to create the test procedure and test tool, including whether an opportunity for public comment was provided and the degree to which public comment was considered.

Under contracts with the Centers for Disease Control and Prevention (CDC) National Center for Immunization and Respiratory Diseases (NCIRD), Chickasaw Nation Industries (CNI) has developed and is now collaborating with HIMSS and ICSA Labs to disseminate, support the use of, and gain input on software capabilities, guidance, and testing tools that will advance the integration of immunization-related capabilities within electronic health records (EHRs) and other clinical software across the U.S. This program represents a process for defining, testing and validating EHR capabilities and guidance for a voluntary EHR immunization recognition program to complement the basic §170.315(f)(1) requirements while addressing workflow and data quality.

The Appendix provides a complete annotated list of the process, activities and project artifacts for all four phases of the program. If ONC wants access to any or all of these artifacts please provide the full name, business email address of the individual as well as the length of time access will be required and CNI will provide access to the SharePoint site where they are stored.

Phase 1 of the project included a literature review, interviews with over 60 stakeholders, and two face-to-face meetings with external stakeholders to develop clinical software requirements and testing proposals. The CNI team consulted existing consensus-based standards as the foundation for the capabilities, including the HL7 EHR Functional Model (v2), the HL7 Child Health Profile, the HL7 Public Health Profile, and the AHRQ Children's EHR Format.

Phase 2 of the project included identification of the 12 highest volume vendors by market share and performed a clinical software assessment, evaluating the software's ability to address the requirements established in Phase 1. An expert panel reviewed the results as well as the results of a stakeholder survey to provide recommendations for piloting software tests in the next phase.

Phase 3 of the project included evaluation of the pilot test scripts with three vendors to fully develop the test content and process. During Phase 3 of the project, we utilized a public survey hosted on the IIP website, along with a newly formed stakeholder-representative Technical Advisory Panel to get feedback on the procedure and tool. This analysis included eight different workflows for the tool.

Currently in Phase 4 of the project, we continue to leverage the feedback and guidance of the Technical Advisory Panel on the development of the tool, soliciting public comment via an email address on the IIP website as well as through other communications vehicles.

V. Other Relevant Factors

- Please describe what HIMSS IIP's communication approach would be to developers previously with tested products as well as ONC if testing errors/omissions are discovered.
    - After a thorough investigation, HIMSS (or ICSA Labs) will notify the developers of the issue in writing. The written communication will provide an overview of the issue, the results of the investigation, and the resolution. Should retesting be necessary, the developer will be asked to identify a date for such purpose.
    - ICSA Labs will forward any retest results to the ACB of any 2015 Edition certified SUTs that utilized the IIP test results for the purpose of gaining certification to criterion 170.315(f)(1) Transmission to Immunization Registries.
    - HIMSS will notify ONC directly and will include a root cause analysis, along with an overview of the issue, the results of the investigation, and the resolution.

- Please describe HIMSS IIP's methodology/planned methodology for keeping its testing regime current with any errors, omissions or other defects in implementation guides used in this process/product.
    - The test scripts are updated annually to keep the data current (i.e., make the patients a year younger, and advance the prior vaccine and clinical history by one year).
    - In addition to the annual update, interim releases are provided to address any errors, omissions or other defects that may impact ongoing testing, or that may be discovered during the testing process.

- Please describe HIMSS IIP's ability to perform/participate in re-testing pursuant to an ONC-ACB's request/directive to a developer as a result of product surveillance.
    - ICSA Labs will be available to work directly with an ACB's request to retest a product as part of the required surveillance process. ICSA Labs will ensure that all necessary retesting is performed within a reasonable timeframe.

- Please describe HIMSS IIP's methodology/planned lifecycle approach for maintaining past testing methods/tools, for how long, and how many past versions.
    - Test methods and tools that are superseded, cancelled, or removed for any reason are archived and maintained for a minimum of six years.

- Please consult with ONC staff about conducting side-by-side performance testing with the ONC approved test tool for this certification criterion. Note - ONC can work in collaboration with HIMSS IIP to facilitate such testing.
    - Upon completion and approval of submission of the worksheet, HIMSS staff will engage ONC to arrange side-by-side performance testing, and will keep ONC updated on changes and modification that may be required thereafter, including any re-testing that is required.

Appendix: Annotated list of activities and artifacts leading to the HIMSS IIP

EHR Certification Process – Phase 1 (October 2013 – October 2014)

1. EHR Certification Process – Literature Review (Work Product – December 16, 2013)
2. EHR Certification Process – EHR Certification Process – Interview Summary (Formal Deliverable 2)
    a. Findings from discussions with immunization providers, immunization information system stakeholders, EHR and other clinical software developers, intermediaries that facilitate information exchange, certification and accreditation bodies, and potential incentive providers.
    b. Topics covered
        i. Immunization-related EHR requirements
        ii. Value and incentives for immunization-related certification
        iii. Certification governance and processes
3. Initial EHR Certification Incentives and Requirements (Formal Deliverable 3 – March 2014)
    a. Completed with input and review by expert panel
    b. Value of immunization-related capabilities in EHRs and other clinical software
    c. Immunization-related requirements for EHRs and other clinical software (description of end-to-end workflow separated into 8 sub-workflows including clinical scenarios for each)
        i. Register and identify a Patient
        ii. Manage external query, response and reconciliation
        iii. Manage information for clinical decision making
        iv. Manage inventory
        v. Administer and report immunization
        vi. Manage cohort of patients
        vii. Manage adverse event reporting
        viii. Provide patient access
4. EHR Certification Requirements (Formal Deliverable 4 – April 28, 2014)
    a. Completed with input and review by expert panel
    b. Comprehensive review of existing standards (full list of original requirements in Appendix):
        i. HL7 EHR Functional Model version 2
        ii. HL7 Child Health Profile
        iii. HL7 Public Health Profile
        iv. AHRQ Children's EHR Format
    c. Alignment of requirements with traceability to existing standards
5. EHR Certification Tier Definitions (Formal Deliverable 5 – June 23, 2014)
    a. Completed with input and review by expert panel and a face-to-face meeting of stakeholders
    b. Evaluation of requirements by stakeholders participating in initial interviews regarding:
        i. Value
        ii. Current state of EHRs
        iii. Readiness
        iv. Complexity
    c. Determined which requirements should be basic functionality of all EHRs and which represent more comprehensive effort for a more advanced, or second tier of capabilities.
6. Certification Requirements and Processes (Formal Deliverable 6 – July 11, 2014)
    a. General software testing methods and uses
    b. Immunization-related testing methods
    c. Testing approach recommendations for scenario-based testing across eight general user workflows

7. Certification Governance (Formal Deliverable 7 – July 11, 2014)
    a. Overview of certification activities by function
        i. Facilitating consensus on requirements
        ii. Developing and applying test methods
        iii. Evaluating test results and rendering certification decisions
    b. Organizational and governance considerations
        i. General considerations
        ii. Organizational considerations
            1. Segregation of functions
            2. Leveraging existing programs for infrastructure
            3. Initial investments needed to capitalize on immunization-related certification program
            4. Leveraging project work products for initial requirements consensus process
8. Certification Implementation Plan (Formal Deliverable 8 – October 3, 2014)
    a. Report of Table-Top event reviewing simulated EHR testing for immunization-related functionality with stakeholders participating in initial interview process, including vendors
    b. Testing scenario
        i. Provide clinical scenario
        ii. Describe use case and request review
        iii. Develop threshold criteria for product certification
        iv. Develop evaluation criteria and input
    c. Analysis of Table-Top results and observations
    d. Recommendations and implementation plan for advancing immunization capabilities in EHRs
9. Certification Communications Plan (Formal Deliverable 9 – October 3, 2014)
    a. Key messages for target audiences
        i. Clinicians and other immunization providers
        ii. EHR and other clinical software developers
        iii. Immunization information system community
        iv. Others in a position to provide incentives

EHR Certification Process – Phase 2 (October 2014 – October 2015)

1. Approach for Gaining Input (Work Product – December 8, 2014)
    a. Methods for engaging target audiences
        i. Clinicians and other immunization providers
        ii. EHR and other clinical software vendors
        iii. Immunization community
        iv. Others in a position to drive adoption
    b. Methods for receiving input
2. List of Assessment Participants (Work Product – December 15, 2014)
    a. Criteria for EHR (vendor) selection
    b. Current market share of frequently used EHRs
    c. Recommendations for selection of EHR vendors for clinical software assessment)
3. Use Cases (Work Product – December 31, 2014)
    a. Update to use cases for each of the eight general user workflows based on feedback from Phase 1 work effort
4. Evaluator's Guide (Work Product – December 31, 2014)

   a. Pre-assessment materials for vendors participating in clinical software assessment regarding EHR capabilities
   b. EHR evaluator scripts
5. Immunization-Centric Pilot Demonstration Plan (Formal Deliverable 3 – March 16, 2015)
   a. Pilot demonstration vendor participants
   b. Pilot demonstration methodology
   c. Demonstrating the testing function of the certification process
   d. Demonstrating the evaluation function of the certification process
   e. Communications management process
6. Immunization-Centric EHR/Clinical Software Assessment (Formal Deliverable 4 – April 13, 2015)
   a. Demonstrations reviewed by 12 high-market share vendors to determine which requirements are supported:
      i. As capabilities in delivered product
      ii. As capabilities requiring local implementer support
      iii. As capabilities requiring vendor customization
      iv. Those not supported at all
   b. Functionality evaluation for each of the requirements for each vendor
   c. Usability findings for each of the requirements for each vendor
   d. General overview of findings
7. Summary of Input on Requirements and Usability Findings and Value Proposition (Work Products – June 22, 2015)
   a. Recap of methods for gaining input
   b. Input on immunization-related requirements
   c. Input on usability requirements
8. Evaluation Criteria and List of Entities to be Evaluated (Work Product – August 3, 2015)
   a. List of potential entities to perform certification
   b. Draft evaluation criteria for certification
9. Immunization-Related Guidance (Formal Deliverable 10A – September 28, 2015)
   a. Functional Test Development
   b. Usability general evaluation of evaluated capabilities in existing products
   c. Functional test details and guidance
   d. Usability – User Centered Design Primer
   e. Usability – General Guidance for Data Quality for Immunizations
   f. Usability – General Guidance for Immunization Forecasting

EHR Certification Process – Phase 3 (October 2015 – October 2016)

1. Evaluation Plan (Formal Deliverable 3 - March 14, 2016)
   a. Engaging stakeholders
   b. Describing the program
   c. Focusing on the evaluation design
   d. Gathering credible evidence
   e. Justifying conclusions
   f. Ensuring use and sharing lessons learned
2. Data collection plan (Formal Deliverable 4 - March 14, 2016)
   a. Goals and objectives of gaining user feedback
   b. Methods for gaining user feedback
   c. Overview of approach to gaining input on requirements and guidance
   d. Overview of approach to gaining input on test scripts and testing process

   e. Approval of methods for gaining user feedback
   f. Outreach approach
   g. Limitations of methods
3. Immunization-Centric Requirements, Guidance and Test Scripts Technical Panel Recommendations (Formal Deliverable 5 - September 16, 2016)
   a. Technical Advisory Panel membership
   b. Technical Advisory Panel recommendations for:
      i. Updates to EHR immunization-related capabilities
      ii. Updates to EHR immunization-related guidance
      iii. Updates to EHR immunization-related tests
      iv. Use of usability findings and guidance
      v. Testing and recognition process
4. Immunization-Centric Implementation Toolkit (Formal Deliverable 6 - October 10, 2016)
   a. Governance, attributes, and critical success factors
   b. Specific functions and activities
      i. Gaining consensus on capabilities
      ii. Developing and supporting use of testing methods
      iii. Evaluating and communicating testing and validation results
   c. Strategies for a sustainable program
   d. Final immunization-related capabilities, guidance and test scripts
5. Immunization-Related Guidance (Formal Deliverable 10a - October 10, 2016)
   a. Usability evaluation
   b. Functional test details
6. Immunization-Centric Marketing Materials (Formal Deliverable 8 - August 31, 2016)
   a. Approach for developing marketing materials
7. Communications and Dissemination Plan (Work Product – March 7, 2016)
   a. Clinicians and other immunization providers
   b. EHR and other software developers
   c. Immunization information systems
   d. Those who pay for health care
8. Evaluation Report (Formal Deliverable - October 6, 2016)
   a. Evaluation approach
   b. Evaluation findings and conclusions
      i. Evaluation goal 1 – steps for increasing level of program awareness
      ii. Evaluation goal 2 – level of use of program website
      iii. Evaluation goal 3 – input to support improvement of the program
      iv. Evaluation goal 4 – progress of independent body in operationalizing the program
   c. Considerations for Phase 4
9. Usability – User Centered Design for:
   a. Immunization reconciliation
   b. Immunization-related inventory management

EHR Certification Process – Phase 4 (October 2016 – October 2017)

1. CDC Immunization-Related Requirements Test Plan (January 5, 2017)
2. Updated EHR Immunization-Related Capabilities and Guidance (December, 2016)