New and Revised Standards and Certification Criteria for Health IT Modules

Key Information on New and Revised Standards and Certification Requirements

- ONC finalized their proposal to discontinue "Year Themed Editions" of Certified Health IT, indicating that they will update certification requirements when new standards are available.
- Health IT modules will be required to accommodate the data elements in USCDI v3, using the FHIR US Core 6.1.0 and C-CDA Companion Guide R4.1 by January 1, 2026.
- Implementation deadlines for all certification criteria utilizing USCDI v3 have also been pushed back to January 1, 2026.
- Health IT modules will be required to have the functionality to allow patients to restrict uses and disclosures of their personal health information by January 1, 2026

Discontinuing Yearly Themed Editions of Certification for Health IT

- ONC finalized their proposal to discontinue "Year Themed Editions" of Certified Health IT, indicating that they will update certification requirements when new standards are available.
- ONC did not follow HIMSS guidance to guarantee a two-year implementation period following the finalization of a new requirement, or adopt a pre-set schedule (once every two years) for making changes to certification requirements.
- The intent of ONC is:
    - to maintain a single set of certification criteria updated to include the most recent versions of adopted standards
    - to establish an incremental approach to health IT updates over time.
- The final rule establishes timelines based on the updates required for each criterion and a transition period allowing for either the prior adopted standard or the new standard to be used for a reasonable period of time.
- Standard Version Advancement Process (SVAP)
    - SVAP is a flexibility in certification allowing health IT developers to voluntarily use newer versions of adopted standards in their certified Health IT Modules provided:
    - Newer versions of the standards have been successfully tested in the required Real World Testing process for certification

- ONC Authorized Testing Laboratories (ONC-ATLs) must retaining records of Complete EHRs' and Health IT Modules' testing through a minimum of three years from the effective date of the removal of those certification criteria from the CFR.

Defining "New" and "Revised" Certification Criteria

- "New" certification criteria are those that only include capabilities never referenced in previously adopted certification criteria.
- "Revised" certification criteria include the capabilities referenced in a previously adopted edition of certification criteria as well as changed or additional new capabilities.
- "Unchanged" certification criteria are those that include the same capabilities as compared to prior certification criteria of adopted editions.

USCDI v3 Standard Adoption and Implementation

- The United States Core Data for Interoperability (USCDI) is a standardized set of health data classes and constituent data elements commonly exchanged across care settings for a wide range of uses. Version 1 (v1) of USCDI is currently required for certification.
- USCDI v3 must be implemented and will be the only USCDI standards used in Certified Health IT **after December 31, 2025.**
    - This was changed from a December 31, 2024 implementation date proposal in the NPRM
    - USCDI v1 will no longer be accepted for maintenance of certification or new certification starting on January 1, 2026.
- USCDI v3 must be implemented using the applicable (most recent) US Core Implementation Guide and C-CDA Companion Guide.
    - FHIR US Core 6.1.0
    - C-CDA Companion Guide R4.1
        - Further terminology bindings are defined in the HL7 US Core Implementation Guide.
- A certified Health IT module must incorporate all the data classes included in USCDI v3.
    - Developers of health IT modules seeking certification can't be selective in identifying which data classes they will support.

Certification Criteria that reference USCDI

- Health IT Modules certified to the following certification criteria must update to accommodate USCDI v3 data elements using FHIR US Core Implementation Guide version 6.1.0 and HL7 CDA R2 Implementation Guide: C-CDA Templates for Clinical Notes R4.1 Companion Guide, Release 3 by January 1, 2026.
    - The proposed rule indicated updates would be using FHIR US Core Implementation Guide version 6.1.0 and HL7 CDA R2 Implementation Guide: C-CDA Templates for Clinical Notes R2.1 Companion Guide.

New Data Classes and Data Class Elements USDCI v3 Will Support

Data Class	Data Class Elements
Social Determinants of Health	Problems/Health Concerns SDOH Assessment SDOH Goals SDOH Interventions
Care Team Member	Name Identifier Role Location Telecom
Clinical Notes: Discharge Summary	Admission and discharge dates and locations Discharge instructions Reason(s) for hospitalization
Clinical Tests	Clinical Test Clinical Test/Result Report
Diagnostic Imaging	Digital Imaging Test Digital Imaging Report
Encounter Information	Encounter Type Encounter Diagnosis Encounter Time Encounter Location Encounter Disposition
Health Insurance Information	Coverage Status Coverage Type Relationship to Subscriber Member Identifier Subscriber Identifier Group Identifier Payer Identifier
Health Status Assessments	Disability Status Mental/Cognitive Status Functional Status Pregnancy Status
Medications	Dose Dose Unit of Measure Indication Fill Status
Patient Demographics/Information	Current Address Previous Address Related Person's Name Related Person's Relationship Date of Death Occupation Occupation Industry Tribal Affiliation Sexual Orientation and Gender Identity (Sex
Problems	Date of Diagnosis (New Timing Req) Date of Resolution (New Timing Req)
Procedures	Reason for Referral

Minimum Vocabulary Standards for Code Sets

- Health IT Modules must be certified to utilize the following standards for code sets by January 1, 2026.
    - United States Core Data for Interoperability Standard Version 3
        - Unique Device Identifier(s) for a Patient's Implantable Device(s)
        - Vital Signs
    - US Core Implementation Guide 6.1.0
    - C-CDA Templates for Clinical Notes Companion Guide
        - Through December 31, 2025, HL7 CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2
        - Starting January 1, 2026, C-CDA Companion Guide R4.1 must be utilized
    - Minimum Standards" Code Sets Updates (must be implemented by January 1, 2026)
        - Problems
            - Incorporate SNOMED CT US Edition March 2022
        - Laboratory Tests
            - Incorporate LOINC Database version 2.72, February 16, 2022
        - Immunizations
            - Incorporate CVX – Vaccines Administered and National Drug Code Directory (NDC) – Vaccine NDC Linker
        - Race by Ethnicity
            - Incorporate CDC Race and Ethnicity Code Set Version 1.2 (July 15, 2021)
        - Numerical References
            - Incorporate updated Unified Code for Units of Measure, Revision 2.1 (revised November 21, 2017)
        - Sex
            - Reference updated SNOMED CT and LOINC Codes
        - Sexual Orientation and Gender Information (SOGI)
            - Changed heading from "sexual orientation and gender identity" to "sexual orientation and gender information"
            - Reference updated SNOMED CT ® U.S. Edition codes and LOINC ® codes for Pronouns.
        - Social, psychological, and behavioral data
            - References revised LOINC codes and revised Unified Code of Units of Measure
        - Provider type
            - References Medicare Provider and Supplier Taxonomy Crosswalk, October 29, 2021
        - Patient insurance
            - References Public Health Data Standards Consortium Source of Payment Typology Code Set December 2020 Version 9.2

Electronic Case Reporting Standards

- Health IT Module certified to Electronic Case Reporting Criteria must
    - Consume and process electronic case report trigger codes and parameters based on a match from Reportable Conditions Trigger Code value
    - Create a case report for electronic submission in accordance with electronic initial case report (eICR) profiles specified in the HL7 FHIR eCR IG
    - Support the receipt, consumption, and processing of reportability responses (RRs) HL7 FHIR eCR IG or the HL7 CDA RR IG
- Health IT Module need only support parsing and consuming the eRSD Specification Library and eRSD Supplemental Library

Synchronized Clock Standards

- Health IT Modules certified to applicable certification criteria continue to utilize any Network Time Protocol (NTP) standard that can ensure a system clock has been synchronized and meets time accuracy requirements

Standardized API for Patient and Population Services

- Finalized the following structure for API information requirements
    - API base standard.
    - API constraints and profiles.
    - Application access and launch.
    - Bulk export and data transfer standards.
    - API authentication, security, and privacy
- Native and Refresh Tokens
    - A Health IT Module's authorization server must issue a refresh token valid for a period of no less than three months to applications using the 'confidential app' profile according to the prescribed implementation specification.
        - A confidential app must meet criteria established in HL7 FHIR SMART Application Launch Framework
    - A Health IT Module's authorization server must issue a refresh token valid for a new period of no less than three months to applications using the 'confidential app' profile according to the prescribed implementation specification
        - Refresh token requirements fall under "service and support obligations" for developers of certified Health IT
- Access Token Revocation
    - A Health IT Module's authorization server must be able to revoke and must revoke an authorized application's access at a patient's direction within 1 hour of the request
    - Final rule is consistent with current industry standards for short-lived access tokens (IETF RFCs 6819 and 7009)

- SMART App Launch 2.0 Implementation Guide

- Developers of Health IT must utilize HL7 FHIR SMART Application Launch Framework Implementation Guide Release 2.0.0 (SMART v1 Guide), a profile of the Oauth 2.0 specification, to gain and maintain certification.
    - Deadline is January 1, 2026
- SMART v2.0 uses Oauth 2.0 standard to provide reliable and secure authorizations to meet "Standardized API for patient and population services" certification criterion" to receive patient EHI.
- SMART 1.0 IG can be used through December 31, 2025.

Patient Demographics and Observations Criterion

- In addition to carrying over current "Demographic" certification criterion, ONC will require developers of health IT to adopt the following data standards to meet Patient Demographic and Observations certification criterion.
    - Sex for Clinical Use
        - Clinical observations associated with the designation of male and female (in accordance with LOINC code standards)
    - Pronouns
        - determined by a patient and used when referring to the patient in speech, clinical notes, and in written instructions to caregivers
        - Must have a minimum of one value entered (can be more than one)
        - Must be consistent with LOINC terminology
    - Name to Use
        - determined by a patient and used when referring to the patient in speech, clinical notes, and in written instructions to caregivers
        - Must have a minimum of one value entered (can be more than one)
        - Must be consistent with LOINC terminology
    - Sex
        - Revised to definition found in SNOMED CT® U.S. Edition
- New and revised elements would need to be implemented by January 1, 2026 to meet the Patient Demographics and Observations Criterion for a Base EHR, and modules must meet the same criterion in order to be certified to that criterion by the same date.
- The transitions of care criterion define the minimum set of data elements to use for patient matching.
- The finalization of updates to data elements will have a compliance date of January 1, 2026.
    - Most recent version of SNOMED CT U.S. Edition
    - Adoption of USCDI v3

Patient Right to Request a Restriction on Use or Disclosure

- ONC is adopting a new certification criterion; "patient requested restrictions"

    - This is to enable a user to implement a process to restrict uses or disclosures of data in response to a patient request when such restriction is agreed to by the covered entity.
        - Patient (and/or their authorized representative) must be able to use an internet-based method to request a restriction on their data's use or disclosure
    - A user can flag data to be restricted from being used or disclosed.
    - This request will be standards agnostic.
- The patient requested restrictions" certification criterion will be required for the Privacy and Security Framework by January 1, 2026.

Requirement for Health IT Developers to Update their Previously Certified Health IT

- A Health IT Module may be certified to either the existing certification criterion or the revised certification criterion until the end of the transition period when the prior standard(s) and/or certification criterion no longer meet certification requirements.
- Condition of Certification
    - A health IT developer must provide an assurance that it will not inhibit a customer's timely access to interoperable health IT
- Maintenance of Certification Requirements
    - A health IT developer must update a Health IT Module, once certified to a certification criterion, to all applicable revised certification criteria.
    - A health IT developer must provide all Health IT Modules certified to a revised certification criterion to its customers of such certified health IT.
        - Timelines for compliance will be no less than 12 months to provide health IT certified to revised certification criteria to new customers.
- Real World Testing – Inherited Certified Status
    - Health IT developers to include in their real-world testing results report the newer version of those certified Health IT Module(s) that are updated using Inherited Certified Status after August 31 of the year in which the plan is submitted.