Standards And Implementation Specifications Adopted Under Section 3004 Of The Public Health Service Act, 45 Cfr Part 170, Subpart B

This document provides a summary of the standards and implementation specifications adopted by ONC on behalf of HHS under Section 3004 of the Public Health Service Act for illustrative purposes only. For the full description of standards adopted in 45 CFR Part 170, Supbart B, please review the complete text of the regulations at https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-B.

§ 170.202 TRANSPORT STANDARDS AND OTHER PROTOCOLS

Direct Project

- ONC Applicability Statement for Secure Health Transport, Version 1.2.
- ONC XDR and XDM for Direct Messaging Specification.
- ONC Transport and Security Specification.
- ONC Implementation Guide for Direct Edge Protocols.

Delivery notification

- ONC Implementation Guide for Delivery Notification in Direct.

§ 170.204 FUNCTIONAL STANDARDS

Accessibility

- Web Content Accessibility Guidelines (WCAG) 2.0, Level A Conformance.
- Web Content Accessibility Guidelines (WCAG) 2.0, Level AA Conformance.

Reference source

- HL7 Version 3 Standard: Context Aware Retrieval Application (Infobutton).
- HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application. ("Infobutton"), Knowledge Request, Release 2
- HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1
- HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application ("Infobutton"), Knowledge Request, Release 2
- HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton), Release 4

§ 170.205 CONTENT EXCHANGE STANDARDS AND IMPLEMENTATION SPECIFICATIONS FOR EXCHANGING ELECTRONIC HEALTH INFORMATION.

Patient summary record

- HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation.
- HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Volume 1 - Introductory Material, Release 2.1.
- HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Volume 2 - Templates and Supporting Material, Release 2.1.
- HL7 CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2.

Electronic prescribing

- National Council for Prescription Drug Programs (NCPDP): SCRIPT Standard Implementation Guide; Version 2017071.
- NCPDP SCRIPT Standard, Implementation Guide, Version 10.6.

Electronic submission to public health agencies for surveillance or reporting

- HL7 2.5.1.
- HL7 2.5.1 PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, Release 2.0, April 21, 2015 and Erratum to the CDC PHIN 2.0 Implementation Guide, August 2015; Erratum to the CDC PHIN 2.0 Messaging Guide, April 2015 Release for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings.

Electronic submission to immunization registries

- HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5 and HL7 Version 2.5.1 Implementation Guide for Immunization Messaging (Release 1.5) - Addendum, July 2015

Electronic transmission of lab results to public health agencies

- HL7 2.5.1 Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) with Errata and Clarifications, and ELR 2.5.1 Clarification Document for EHR Technology Certification,

Clinical quality measure data import, export and reporting

- HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I); Release 1, DSTU Release 3 (US Realm), Volume 1 - Introductory Material and HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I); Release 1, DSTU Release 3 (US Realm), Volume 2 - Templates and Supporting Material.
- CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2020.

Cancer information

- HL7 Clinical Document Architecture (CDA), Release 2.0, Normative Edition.
- HL7 CDA© Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1; DSTU Release 1.1, Volume 1 - Introductory Material and HL7 CDA© Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1; DSTU Release 1.1 (US Realm), Volume 2 - Templates and Supporting Material.

Clinical quality measure aggregate reporting

- Quality Reporting Document Architecture Category III, Implementation Guide for CDA Release 2.
- Errata to the HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture - Category III, DSTU Release 1 (US Realm), September 2014.
- CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2020.

Data segmentation for privacy

- HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1.

XDM package processing

- IHE IT Infrastructure Technical Framework Volume 2b (ITI TF-2b).

Public health - antimicrobial use and resistance information

- HL7 Implementation Guide for CDA® Release 2 - Level 3: Healthcare Associated Infection Reports, Release 1, U.S. Realm (selected sections).

Public health - health care survey information

- HL7 Implementation Guide for CDA® Release 2: National Health Care Surveys (NHCS), Release 1 - US Realm, HL7 Draft Standard for Trial Use, Volume 1 - Introductory Material and HL7 Implementation Guide for CDA® Release 2: National Health Care Surveys (NHCS), Release 1 - US Realm, HL7 Draft Standard for Trial Use, Volume 2 - Templates and Supporting Material.
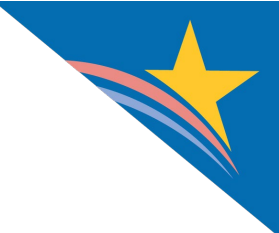
§ 170.207 VOCABULARY STANDARDS FOR REPRESENTING ELECTRONIC HEALTH INFORMATION

Problems

- IHTSDO SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release.
- IHTSDO SNOMED CT®, U.S. Edition, September 2015 Release.

Procedures

- The code set specified at 45 CFR 162.1002(a)(5).
- The code set specified at 45 CFR 162.1002(a)(4).
- The code set specified at 45 CFR 162.1002(c)(3) for the indicated procedures or other actions taken.

Laboratory tests

- Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.40, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc.
- Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.52, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc.

Medications

- RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, September 8, 2015 Release.

Immunizations

- HL7 Standard Code Set CVX - Vaccines Administered, updates through August 17, 2015.
- National Drug Code Directory (NDC) - Vaccine NDC Linker, updates through August 17, 2015.
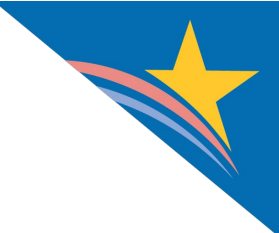
Race and Ethnicity

- The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997.
- CDC Race and Ethnicity Code Set Version 1.0 (March 2000).

Preferred language

- Request for Comments (RFC) 5646

Encounter diagnoses

- The code set specified at 45 CFR 162.1002(c)(2) for the indicated conditions.

Numerical references

- The Unified Code of Units of Measure, Revision 1.9.

Sex

- Birth sex must be coded in accordance with HL7 Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor.

Sexual orientation and gender identity

- Sexual orientation must be coded in accordance with, at a minimum IHTSDO SNOMED CT, U.S. Edition, September 2015 Release (for certain attributes) and HL7 Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor.
- Gender identity must be coded in accordance with, at a minimum IHTSDO SNOMED CT, U.S. Edition, September 2015 Release (for certain attributes) and HL7 Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor.

Social, psychological, and behavioral data

- Financial resource strain. Financial resource strain must be coded in accordance with, at a minimum, the version of LOINC® codes specified in paragraph (c)(3) of this section[1] and attributed with the LOINC® code 76513-1 and LOINC® answer list ID LL3266-5.
- Education. Education must be coded in accordance with, at a minimum, the version of LOINC® codes specified in paragraph (c)(3) of this section[2] and attributed with LOINC® code 63504-5 and LOINC® answer list ID LL1069-5.
- Stress. Stress must be coded in accordance with, at a minimum, the version of LOINC® codes specified in paragraph (c)(3) of this section[3] and attributed with the LOINC® code 76542-0 and LOINC® answer list LL3267-3.
- Depression. Depression must be coded in accordance with, at a minimum, the version of LOINC® codes specified in paragraph (c)(3) of this section[4] and attributed with LOINC® codes 55757-9, 44250-9 (with LOINC® answer list ID LL358-3), 44255-8 (with LOINC® answer list ID LL358-3), and 55758-7 (with the answer coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)).[5]

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[1] Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.52, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc.
[2] Ibid.
[3] Ibid.
[4] Ibid.
[5] The Unified Code of Units of Measure, Revision 1.9.

- Physical activity. Physical activity must be coded in accordance with, at a minimum, the version of LOINC® codes specified in paragraph (c)(3) of this section[6] and attributed with LOINC® codes 68515-6 and 68516-4. The answers must be coded with the associated applicable unit of measure in the standard specified in § 170.207(m)(1).

- Alcohol use. Alcohol use must be coded in accordance with, at a minimum, the version of LOINC® codes specified in paragraph (c)(3) of this section[7] and attributed with LOINC® codes 72109-2, 68518-0 (with LOINC® answer list ID LL2179-1), 68519-8 (with LOINC® answer list ID LL2180-9), 68520-6 (with LOINC® answer list ID LL2181-7), and 75626-2.

- Social connection and isolation. Social connection and isolation must be coded in accordance with, at a minimum, the version of LOINC® codes specified in paragraph (c)(3) of this section[8] and attributed with the LOINC® codes 76506-5, 63503-7 (with LOINC answer list ID LL1068-7), 76508-1 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)), 76509-9 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)), 76510-7 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)), 76511-5 (with LOINC answer list ID LL963-0), and 76512-3 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)).

- Exposure to violence (intimate partner violence). Exposure to violence: Intimate partner violence must be coded in accordance with, at a minimum, the version of LOINC® codes specified in paragraph (c)(3) of this section[9] and attributed with the LOINC® code 76499-3, 76500-8 (with LOINC® answer list ID LL963-0), 76501-6 (with LOINC® answer list ID LL963-0), 76502-4 (with LOINC® answer list ID LL963-0), 76503-2 (with LOINC® answer list ID LL963-0), and 76504-0 (with the associated applicable unit of measure in the standard specified in § 170.207(m)(1)).

Patient matching

- Phone number standard. ITU-T E.123, Series E: Overall Network Operation, Telephone Service, Service Operation and Human Factors, International operation - General provisions concerning users: Notation for national and international telephone numbers, email addresses and web addresses; and ITU-T E.164, Series E: Overall Network Operation, Telephone Service, Service Operation and Human Factors, International operation - Numbering plan of the international telephone service: The international public telecommunication numbering plan.
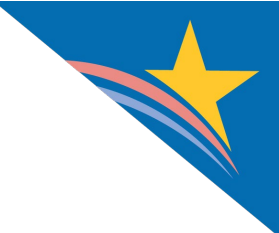
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[6] Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.52, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc.
[7] Ibid.
[8] Ibid.
[9] Ibid.

Provider type

- Crosswalk: Medicare Provider/Supplier to Healthcare Provider Taxonomy, April 2, 2015.

Patient insurance

- Public Health Data Standards Consortium Source of Payment Typology Code Set Version 5.0 (October 2011).

§ 170.210 STANDARDS FOR HEALTH INFORMATION TECHNOLOGY TO PROTECT ELECTRONIC HEALTH INFORMATION CREATED, MAINTAINED, AND EXCHANGED

Encryption and decryption of electronic health information

- Any encryption algorithm identified by the National Institute of Standards and Technology (NIST) as an approved security function in Annex A of the Federal Information Processing Standards (FIPS) Publication 140-2, October 8, 2014.

Hashing of electronic health information

- A hashing algorithm with a security strength equal to or greater than SHA-2 as specified by NIST in FIPS Publication 180-4 (August 2015).

Record treatment, payment, and health care operations disclosures.

- The date, time, patient identification, user identification, and a description of the disclosure must be recorded for disclosures for treatment, payment, and health care operations, as these terms are defined at 45 CFR 164.501.

Record actions related to electronic health information, audit log status, and encryption of end-user devices

- (RFC 5905) Network Time Protocol Version 4.
- Audit log content. ASTM E2147-18 (selected sections).

Encryption and hashing of electronic health information

- Any encryption and hashing algorithm identified by NIST as an approved security function in Annex A of the FIPS Publication 140-2

Synchronized clocks

- (RFC 5905) Network Time Protocol Version 4.

Audit log content.

- ASTM E2147-18.

§ 170.213 UNITED STATES CORE DATA FOR INTEROPERABILITY.

- The United States Core Data for Interoperability (USCDI) is a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange.

- United States Core Data for Interoperability (USCDI), July 2020 Errata, Version 1 (v1).

§ 170.215 APPLICATION PROGRAMMING INTERFACE STANDARDS.

- HL7® Fast Healthcare Interoperability Resources (FHIR®) Release 4.0.1.

- HL7 FHIR® US Core Implementation Guide STU 3.1.1.

- HL7 SMART Application Launch Framework Implementation Guide Release 1.0.0, including mandatory support for the "SMART Core Capabilities."

- FHIR Bulk Data Access (Flat FHIR) (v1.0.0: STU 1), including mandatory support for the "group-export" "OperationDefinition."

- OpenID Connect Core 1.0, incorporating errata set 1.