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 ASTP on behalf of HHS under Section 3004 of the Public Health Service Act. This list is provided for illustrative purposes only. For the full description of standards adopted in 45 CFR Part 170, Subpart 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

Delivery notification

- ONC Implementation Guide for Delivery Notification in Direct.

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.

§ 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.

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.

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.

Data segmentation for privacy

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

Electronic prescribing

- National Council for Prescription Drug Programs (NCPDP): SCRIPT Standard Implementation Guide; Version 2017071.
- NCPDP SCRIPT Standard, Implementation Guide, Version 2023011.

Electronic submission to immunization registries

- HL7 2.5.1.
- 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 submission to public health agencies for surveillance or reporting

- 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 transmission of lab results to public health agencies

- HL7 2.5.1.

- HL7 Version 2.5.1 Implementation Guide: 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.

Formulary and benefit

- NCPDP Formulary and Benefit Standard Version 60.

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.
- HL7® CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes STU Companion Guide, Release 4.1.

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.

Public health – electronic case reporting

- HL7® FHIR® Implementation Guide: Electronic Case Reporting (eCR)–US Realm 2.1.0–STU 2 US (HL7 FHIR eCR IG).
- HL7 CDA® R2 Implementation Guide: Public Health Case Report—the Electronic Initial Case Report (eICR) Release 2, STU Release 3.1–US Realm (HL7 CDA eICR IG).
- HL7® CDA® R2 Implementation Guide: Reportability Response, Release 1, STU Release 1.1–US Realm (HL7 CDA RR IG).
- Reportable Conditions Trigger Codes Value Set for Electronic Case Reporting.

Real-time prescription benefit

- NCPDP Real-Time Prescription Benefit Standard, Implementation Guide, Version 13.

XDM package processing

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

§ 170.207 Vocabulary standards for representing electronic health information

Encounter diagnoses

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

Immunizations

- HL7 Standard Code Set CVX–Vaccines Administered, dated through June 15, 2022.
- National Drug Code Directory (NDC)–Vaccine NDC Linker, dated July 19, 2022.
- 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.

Laboratory tests

- Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.72, a universal code system for identifying health measurements, observations, and documents produced by the Regenstrief Institute, Inc., February 16, 2022.
- 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, July 5, 2022.
- RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, September 8, 2015 Release.
- National Drug Codes.
- Code on Dental Procedures and Nomenclature.
- Health Care Financing Administration Common Procedure Coding System (HCPCS).
- Current Procedural Terminology, Fourth Edition (CPT-4).

Numerical references

- The Unified Code of Units of Measure, Revision 1.9.
- The Unified Code for Units of Measure, Version 2.1, November 21, 2017.

Patient insurance

- Public Health Data Standards Consortium Source of Payment Typology Code Set Version 5.0 (October 2011).
- Public Health Data Standards Consortium Users Guide for Source of Payment Typology, Version 9.2.

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.

Preferred language

- Request for Comments (RFC) 5646.

Problems

- SNOMED CT®, U.S. Edition, March 2022 Release.
- IHTSDO SNOMED CT®, U.S. Edition, September 2015 Release.

Procedures

- Health Care Financing Administration Common Procedure Coding System (HCPCS).
- Current Procedural Terminology, Fourth Edition (CPT-4).
- Code on Dental Procedures and Nomenclature.

Provider type

- Crosswalk: Medicare Provider/Supplier to Healthcare Provider Taxonomy, April 2, 2015.
- Medicare Provider and Supplier Taxonomy Crosswalk, 2021.

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).
- CDC Race and Ethnicity Code Set Version 1.2 (July 08, 2021).

Sex[1]

- HL7 Version 3 Standard.
- SNOMED CT®.

Social, psychological, and behavioral data

- Financial resource strain. Financial resource strain must be coded in accordance with LOINC ® code 76513-1 and LOINC ® answer list ID LL3266-5.

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[1] To learn more: USCDI v3 Data Elements Enforcement Discretion | HealthIT.gov

- Education. Education must be coded in accordance with LOINC® code 63504-5 and LOINC® answer list ID LL1069-5.
- Stress. Stress must be coded in accordance with LOINC® code 76542-0 and LOINC® answer list LL3267-3.
- Depression. Depression must be coded in accordance with LOINC® codes 55757-9, 44250-9 (with LOINC® answer list ID LL361-7), 44255-8 (with LOINC® answer list ID LL361-7), and 55758-7.
- Physical activity. Physical activity must be coded in accordance with LOINC® codes 68515-6 and 68516-4.
- Alcohol use. Alcohol use must be coded in accordance 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 LOINC® codes 76506-5, 63503-7 (with LOINC answer list ID LL1068-7), 76508-1, 76509-9, 76510-7, 76511-5 (with LOINC answer list ID LL963-0), and 76512-3.
- Exposure to violence (intimate partner violence). Exposure to violence: Intimate partner violence must be coded in accordance with 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.

§ 170.210 Standards for health information technology to protect electronic health information created, maintained, and exchanged

Audit log content

- ASTM E2147-18.

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.

Encryption and hashing of electronic health information

- Any encryption and hashing algorithm identified by the National Institute of Standards and Technology (NIST) as an approved security function in Annex A of the FIPS Publication 140-2.

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 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.

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.

Synchronized clocks

- The date and time recorded utilize a system clock that has been synchronized using any Network Time Protocol (NTP) standard.

§ 170.213 United States Core Data for Interoperability.

- United States Core Data for Interoperability (USCDI), July 2020 Errata, Version 1 (v1).
- United States Core Data for Interoperability Version 3 (USCDI v3).[2]

§ 170.215 Application Programming Interface Standards.

API base standard

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

API constraints and profiles

- HL7® FHIR® US Core Implementation Guide STU 3.1.1.
- HL7® FHIR® US Core Implementation Guide STU 6.1.0.

API authentication, security, and privacy

- OpenID Connect Core 1.0, incorporating errata set 1.

Application access and launch

- HL7® SMART Application Launch Framework Implementation Guide Release 1.0.0, including mandatory support for the "SMART Core Capabilities."
- HL7® SMART App Launch Implementation Guide Release 2.0.0, including mandatory support for the "Capability Sets" of "Patient Access for Standalone Apps" and "Clinician Access for EHR Launch"; all "Capabilities" as defined in "8.1.2 Capabilities," excepting the "permission-online" capability; "Token Introspection" as defined in "7 Token Introspection."

Bulk export and data transfer standards

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

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[2] To learn more: USCDI v3 Data Elements Enforcement Discretion | HealthIT.gov