Subpart B—Standards and Implementation Specifications for Health Information Technology

§ 170.200 Applicability.

The standards and implementation specifications adopted in this part apply with respect to Health Information technology.

[85 FR 70082, Nov. 4, 2020]

§ 170.202 Transport standards and other protocols.

The Secretary adopts the following transport standards:

(a) *Direct Project*. (1) [Reserved]

(2) *Standard*. ONC Applicability Statement for Secure Health Transport, Version 1.2 (incorporated by reference in § 170.299).

(b) *Standard*. ONC XDR and XDM for Direct Messaging Specification (incorporated by reference in § 170.299).

(c) *Standard*. ONC Transport and Security Specification (incorporated by reference in § 170.299).

(d) *Standard*. ONC Implementation Guide for Direct Edge Protocols (incorporated by reference in § 170.299).

(e) *Delivery notification*—(1) *Standard*. ONC Implementation Guide for Delivery Notification in Direct (incorporated by reference in § 170.299).

(2) [Reserved]

[77 FR 54284, Sept. 4, 2012, as amended at 79 FR 54478, Sept. 11, 2014; 80 FR 62743, Oct. 16, 2015; 85 FR 25940, May 1, 2020]

§ 170.204 Functional standards.

The Secretary adopts the following functional standards:

(a) *Accessibility*—(1) *Standard*. Web Content Accessibility Guidelines (WCAG) 2.0, Level A Conformance (incorporated by reference in § 170.299).

(2) *Standard*. Web Content Accessibility Guidelines (WCAG) 2.0, Level AA Conformance (incorporated by reference in § 170.299).

(b) *Reference source. Standard*. HL7 Version 3 Standard: Context-Aware Retrieval Application (Infobutton) (incorporated by reference in § 170.299).

(1)–(2) [Reserved]

(3) *Standard*. HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application. (''Infobutton''), Knowledge Request, Release 2 (incorporated by reference in § 170.299). *Implementation specifications*. HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1 (incorporated by reference in § 170.299).

(4) *Standard*. HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application (''Infobutton''), Knowledge Request, Release 2 (incorporated by reference in § 170.299). *Implementation specifications*. HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton), Release 4 (incorporated by reference in § 170.299).

[77 FR 54284, Sept. 4, 2012, as amended at 80 FR 62743, Oct. 16, 2015; 85 FR 25940, May 1, 2020]

§ 170.205 Content exchange standards and implementation specifications for exchanging electronic health information.

The Secretary adopts the following content exchange standards and associated implementation specifications:

(a) *Patient summary record*. (1) [Reserved]

(2) [Reserved]

(3) *Standard*. HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, (incorporated by reference in § 170.299). The use of the ''unstructured document'' document-level template is prohibited.

(4) *Standard*. 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 and 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 (incorporated by reference in § 170.299).

(5) *Standard*. HL7 CDA® R2 Implementation Guide: C–CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2 (incorporated by reference in § 170.299).

(b) *Electronic prescribing*—(1) *Standard*. National Council for Prescription Drug

693

Programs (NCPDP): SCRIPT Standard Implementation Guide; Version 2017071 (incorporated by reference in § 170.299).

(2) *Standard.* NCPDP SCRIPT Standard, Implementation Guide, Version 10.6 (incorporated by reference in § 170.299).

(c) [Reserved]

(d) *Electronic submission to public health agencies for surveillance or reporting.* (1) [Reserved]

(2) *Standard.* HL7 2.5.1 (incorporated by reference in § 170.299).

(3) [Reserved]

(4) *Standard.* HL7 2.5.1 (incorporated by reference in § 170.299). *Implementation specifications.* PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, Release 2.0, April 21, 2015 (incorporated by reference in § 170.299) 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 (incorporated by reference in § 170.299).

(e) *Electronic submission to immunization registries.* (1) [Reserved]

(2)–(3) [Reserved]

(4) *Standard.* HL7 2.5.1 (incorporated by reference in § 170.299). *Implementation specifications.* HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5 (incorporated by reference in § 170.299) and HL7 Version 2.5.1 Implementation Guide for Immunization Messaging (Release 1.5)—Addendum, July 2015 (incorporated by reference in § 170.299).

(f) [Reserved]

(g) *Electronic transmission of lab results to public health agencies. Standard.* HL7 2.5.1 (incorporated by reference in § 170.299). *Implementation specifications.* HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) (incorporated by reference in § 170.299) with Errata and Clarifications, (incorporated by reference in § 170.299) and ELR 2.5.1 Clarification Document for EHR Technology Certification, (incorporated by reference in § 170.299).

(h) *Clinical quality measure data import, export and reporting.* (1) [Reserved]

(2) *Standard.* 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 (incorporated by reference in § 170.299).

(3) *Standard.* CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2020 (incorporated by reference in § 170.299).

(i) *Cancer information.* (1) [Reserved]

(2) *Standard.* HL7 Clinical Document Architecture (CDA), Release 2.0, Normative Edition (incorporated by reference in § 170.299). *Implementation specifications.* 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 (incorporated by reference in § 170.299).

(j) [Reserved]

(k) *Clinical quality measure aggregate reporting*—(1) *Standard.* Quality Reporting Document Architecture Category III, Implementation Guide for CDA Release 2 (incorporated by reference in § 170.299).

(2) *Standard.* Errata to the HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture—Category III, DSTU Release 1 (US Realm), September 2014 (incorporated by reference in § 170.299).

(3) *Standard.* CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2020 (incorporated by reference in § 170.299).

(l)–(n) [Reserved]

694

(o) *Data segmentation for privacy*—(1) *Standard.* HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1 (incorporated by reference in § 170.299).

(2) [Reserved]

(p) *XDM package processing*—(1) *Standard.* IHE IT Infrastructure Technical Framework Volume 2b (ITI TF–2b) (incorporated by reference in § 170.299).

(2) [Reserved]

(q) [Reserved]

(r) *Public health—antimicrobial use and resistance information*—(1) *Standard.* The following sections of HL7 Implementation Guide for CDA® Release 2—Level 3: Healthcare Associated Infection Reports, Release 1, U.S. Realm (incorporated by reference in § 170.299). Technology is only required to conform to the following sections of the implementation guide:

(i) HAI Antimicrobial Use and Resistance (AUR) Antimicrobial Resistance Option (ARO) Report (Numerator) specific document template in Section 2.1.2.1 (pages 69–72);

(ii) Antimicrobial Resistance Option (ARO) Summary Report (Denominator) specific document template in Section 2.1.1.1 (pages 54–56); and

(iii) Antimicrobial Use (AUP) Summary Report (Numerator and Denominator) specific document template in Section 2.1.1.2 (pages 56–58).

(2) [Reserved]

(s) *Public health—health care survey information*—(1) *Standard.* 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 (incorporated by reference in § 170.299).

(2) [Reserved]

[75 FR 44649, July 28, 2010, as amended at 75 FR 62690, Oct. 13, 2010; 77 FR 54284, Sept. 4, 2012; 79 FR 54478, Sept. 11, 2014; 80 FR 62743, Oct. 16, 2015; 85 FR 25940, May 1, 2020; 85 FR 70082, Nov. 4, 2020]

§ 170.207 Vocabulary standards for representing electronic health information.

The Secretary adopts the following code sets, terminology, and nomenclature as the vocabulary standards for the purpose of representing electronic health information:

(a) *Problems.* (1) [Reserved]

(2) [Reserved]

(3) *Standard.* IHTSDO SNOMED CT® International Release July 2012 (incorporated by reference in § 170.299) and US Extension to SNOMED CT® March 2012 Release (incorporated by reference in § 170.299).

(4) *Standard.* IHTSDO SNOMED CT®, U.S. Edition, September 2015 Release (incorporated by reference in § 170.299).

(b) *Procedures.* (1) [Reserved]

(2) *Standard.* The code set specified at 45 CFR 162.1002(a)(5).

(3) *Standard.* The code set specified at 45 CFR 162.1002(a)(4).

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

(c) *Laboratory tests.* (1) [Reserved]

(2) *Standard.* 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. (incorporated by reference in § 170.299).

(3) *Standard.* 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. (incorporated by reference in § 170.299).

(d) *Medications.*

(1)–(2) [Reserved]

(3) *Standard.* RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, September 8, 2015 Release (incorporated by reference in § 170.299).

(e) *Immunizations.*

(1)–(2) [Reserved]

(3) *Standard.* HL7 Standard Code Set CVX—Vaccines Administered, updates through August 17, 2015 (incorporated by reference in § 170.299).

(4) *Standard.* National Drug Code Directory (NDC)—Vaccine NDC Linker,

695