

## Subpart B—Standards and Implementation Specifications for Health Information Technology

SOURCE: 75 FR 44649, July 28, 2010, unless otherwise noted.

### § 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