

§ 170.200

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 IT Modules.

[75 FR 44649, July 28, 2010, as amended at 80 FR 62743, Oct. 16, 2015; 85 FR 25940, May 1, 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 Re-

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trieval 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,