# **2. Understanding C-CDA and the C-CDA Companion Guide**

The C-CDA implementation guide (IG) is a library of CDA templates developed by HL7, IHE and the Health Information Technology Standards Panel (HITSP). It was developed within the ONC’s Standards and Interoperability (S&I) Framework to provide a definitive set of harmonized CDA templates for the US Realm.

C-CDA Companion Guides augment guidance in C-CDA implementation guides to address requirements specified by Meaningful Use regulations. The C-CDA R1.1 Companion Guide addresses ONC 2014 Edition Certified Electronic Health Record Technology (CEHRT) requirements. The C-CDA R2.1 Companion Guide addresses ONC 2015 Edition Certified Electronic Health Record Technology (CEHRT) requirements.

## **2.1. CDA and Layered Constraints**

Implementers wishing to certify creation of a C-CDA document according to CEHRT requirements, should view conformance as meeting the requirements of four sets of constraints:

· CDA R2 (Normative Web Edition 2010)

· C-CDA R2.1

· C-CDA R2.1 Errata (see Section 2.5)

· 2015 Edition CEHRT Requirements

Three of these four layers are fixed. The C-CDA R2.1 Errata is subject to change as new issues are identified and resolved. Section 2.5 describes the Errata process.

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| **Figure 1: CDA, C-CDA, Errata, and CEHRT Constraint Relationships** |

For example, to conform to Common Clinical Data Set (CCDS) requirements for Medications, an implementer must conform to:

1. Validates under the CDA\_SDTC schema (Available from the HL7 GForge SVN, <http://gforge.hl7.org/gf/project/strucdoc/frs/> )

2. Medications Section constraints as defined in C-CDA R2.1; and

3. Relevant technical corrections published in the C-CDA R2.1 Errata (See section 2.5); and

4. CEHRT Regulations for Medications.

## **2.2. Templates**

The C-CDA R2.1 Implementation Guide uses templates to define document conformance. Templates are used to define clinical documents that support information exchange across various care settings. Reference C-CDA R2.1 Volume 1, section 2.1 for a detailed description of CDA templates.



Figure 2: Template Structure of C-CDA

A CDA Document includes a header, which is the content above the <structuredBody> tag in a structured CDA Document or the content above the <nonXMLBody> tag in an unstructured CDA Document. A structured CDA Document additionally includes one or more section(s). Each section includes a single narrative text component that holds the human readable information in that section. A section may include clinical statements, called “entries”, which represent the section’s information in a machine processable format. Templates define the constraints which stipulate what may, should, or shall be populated in an instance of the document.

Figure 3: CDA Document Visualization

### **2.2.1. C-CDA 2.1 Document Templates**

Document templates defined in the C-CDA R2.1 Implementation Guide – along with those referenced by the 2015 Final Rule - are listed in Table 1 below.

**Table 1:C-CDA R2.1 Document-Level Templates**

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| --- | --- | --- |
| **Document Template** | **Description** | **CEHRT Requirement** |
| Care Plan | A Care Plan (including Home Health Plan of Care (HHPoC)) is a consensus-driven dynamic plan that represents a patient’s and Care Team Members’ prioritized concerns, goals, and planned interventions. | Yes, if certifying to 170.315(b)(9).  Otherwise, No. |
| Consultation Note | The Consultation Note is generated by a request from a clinician for an opinion or advice from another clinician. | No |
| Continuity of Care Document (CCD) | The Continuity of Care Document (CCD) represents a core data set of the most relevant administrative, demographic, and clinical information facts about a patient's healthcare, covering one or more healthcare encounters. It provides a means for one healthcare practitioner, system, or setting to aggregate all of the pertinent data about a patient and forward it to another to support the continuity of care. | Yes |
| Diagnostic Imaging Report | A Diagnostic Imaging Report (DIR) is a document that contains a consulting specialist’s interpretation of image data. It conveys the interpretation to the referring (ordering) physician and becomes part of the patient’s medical record. It is for use in Radiology, Endoscopy, Cardiology, and other imaging specialties. | No |
| Discharge Summary | The Discharge Summary is a document which synopsizes a patient's admission to a hospital, LTPAC provider, or other setting. It provides information for the continuation of care following discharge. | Yes |
| History and Physical | A History and Physical (H&P) note is a medical report that documents the current and past conditions of the patient. It contains essential information that helps determine an individual's health status. | No |
| Operative Note | The Operative Note is a frequently used type of procedure note with specific requirements set forth by regulatory agencies. The Operative Note is created immediately following a surgical or other high-risk procedure. It records the pre- and post-surgical diagnosis, pertinent events of the procedure, as well as the condition of the patient following the procedure. | No |
| Progress Note | This template represents a patient’s clinical status during a hospitalization, outpatient visit, treatment with a LTPAC provider, or other healthcare encounter. | No |
| Referral Note | A Referral Note communicates pertinent information from a provider who is requesting services of another provider of clinical or non-clinical services. | Yes |
| Transfer Summary | The Transfer Summary standardizes critical information for exchange of information between providers of care when a patient moves between health care settings. | No |
| Unstructured Document | An Unstructured Document (UD) document type can (1) include unstructured content, such as a graphic, directly in a text element with a mediaType attribute, or (2) reference a single document file, such as a word-processing document using a text/reference element. | No |

[Note: Care Plan Document is only required if certifying to 170.315(b)(9).]

Although MU2 certification does not permit the use of unstructured CDA documents (a CDA document with a structured header and a non-xml body conveying information as an embedded object or referenced file), there are many valid use cases where the exchange of information as an unstructured CDA may be appropriate and beneficial.

Section templates referenced by the above document templates along with a mapping to Common Clinical Data Set (CCDS) data elements are noted in Section 3 - Guidance for Implementing Standards for Certification.

## **2.3. CDA Schema Extensions**

CDA defines a standard Schema, based on the HL7 RIM, for all CDA documents. When there is a need to communicate information where there is no suitable representation in the Schema, the CDA standard permits extensions to be developed. These extensions are described in the context of the section where they are used.

The HL7 Structured Documents Work Group maintains a [complete list](http://wiki.hl7.org/index.php?title=CDA_R2_Extensions) of CDA R2 extensions that are approved for use within the sdtc namespace.

Note also that to perform schema validation on a CDA document instance properly, it is necessary to use the schema that includes the CDA R2 schema extensions. All extensions will use the namespace **urn:hl7-org:sdtc**. As a document consumer, the possibility of schema extensions needs to be considered.

### **2.3.1. CDA R2 Schema Extensions Used By C-CDA R2.1**

Table 1 CDA R2 extensions utilized by templates in C-CDA R2.1

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| **Extension** | **Description** |
| sdtc:raceCode | The raceCode extension allows for multiple races to be reported for a patient. |
| sdtc:ethnicGroupCode | The ethnicGroupCode extension allows for additional ethnicity groups for the recordTarget or subjectPerson. |
| sdtc:id | The id extension in the family history organizer on the related subject allows for unique identification of the family member(s). |
| sdtc:deceasedInd | The deceasedIndextension (= “true” or “false”) in the family history organizer on the related subject is used inside to indicate if a family member is deceased. |
| sdtc:deceasedTime | The deceasedTime extension in the family history organizer on the related subject allows for reporting the date and time a family member died. |
| sdtc:birthTime | The birthTime extension allows for the birth date of any person (not just the recordTarget) to be recorded. The purpose of this extension is to allow the recording of the subscriber or member of a health plan in cases where the health plan eligibility system has different information on file than the provider does for the patient. |
| sdtc:dischargeDispositionCode | The dischargeDispositionCode extension allows the provider to record a discharge disposition in an encounter activity. |
| sdtc:signatureText | The signatureText extension provides a location in CDA for a textual or multimedia depiction of the signature by which the participant endorses and accepts responsibility for his or her participation in the Act as specified in the Participation.typeCode. |

## **2.4. C-CDA R2.1 Schematron**

Schematron is a rule-based validation language for making assertions about the presence or absence of patterns in XML trees. Schematron is capable of expressing constraints above and beyond what is possible with XML Schema.

Schematron can be used to:

· extend structural validation by testing for co-occurrence constraints, non-regular constraints, and inter-document constraints; and

· express rules about complex structures within an XML document.

A Schematron for C-CDA R2.1 is available on the HL7 International Structured Documents Work Group [svn repository](http://gforge.hl7.org/gf/project/strucdoc/scmsvn/trunk/CDAR2.1/Schematron/?action=browse&path=%2Ftrunk%2FCDAR2.1%2FSchematron%2F). This Schematron can be used to confirm if a CDA document conforms to the constraints required by C-CDA R2.1.

## **2.5. C-CDA R2.1 Errata**

C-CDA R2.1 is considered a *Draft Standard for Trial Use* and as such, suggested corrections and improvements are regularly provided by the implementer community. The list of [all submitted DSTU comments](http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=168) is published on the HL7.org website. Only those comments marked as “Approved” are considered errata. The HL7 Structure Documents Work Group reviews the DSTU comments on a periodic basis and publishes an errata package to report changes that have been approved as technical corrections. A C-CDA implementation MUST take published errata into consideration. When an errata package is published it is announced through HL7 and errata packages are published on the HL7.org website (<http://www.hl7.org/implement/standards/product_brief.cfm?product_id=408> ). The errata package is published in the download kit for the standard. It includes a letter from HL7 summarizing the errata, a spreadsheet list of approved errata and the base Implementation Guide to which the errata must be applied.

Implementer should note that to maintain a current list of the approved technical errata for C-CDA R2.1 the DSTU Documents need to be downloaded regularly from the HL7.org website.