# **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.

The C-CDA Companion Guide augments guidance in the C-CDA implementation guide 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:

· Base CDA

· C-CDA R2.1

· C-CDA R2.1 Errata

· CEHRT Requirements

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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. CDA Section and Entry constraints as defined in base CDA; and

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

3. Relevant technical corrections published in the C-CDA R2.1 Errata[1]; 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.

A template’s design can represent a professional society recommendations or national clinical practice guidelines, for example. Templates also can include constraints requiring the use of standardized data sets for coded elements. They are modular in nature and provide the basis for reusability of CDA specifications.

Due to the structure of the base CDA standard, CDA templates tend to be modular and are intended to be used as a collection when defining a specific type of CDA document. A document level template defines the CDA header elements to be used and establishes constraints for the body of the document. When a CDA document is define to include a structured body, the document template specifies the set of section-level templates to be used to define the content in the document’s body. Section-level templates define the type of information to be contained in a particular type of section in a document and further constrain the templates to be used to represent that type of information as machine readable data called “entries”. Entry-level Templates establish the CDA patterns to express clinical concepts that belong in a particular section of a document.

Template designs range from simple to complex. A very straight forward template may simple define the type of information it intends to represent then define the code to be used to identify that type of information. A more complex template may define the type of information it intends to represent and then include a wide range of constraints on the numerous CDA attributes available to be constrained. These attributes include ids, codes, dates, values and other more specific attributes such as method codes and target sites. Their designs may be nested or recursive and they may reference other templates defined in the same IG, or a previously published IG.

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| **Figure 2: CDA Template Relationships** |

**A document template** describes the scope and intended use of a particular type of document. It often references a separate document templated called “the header template”. The header template is just a reusable document template that helps ensure consistency across a set of different types of CDA documents. template definesneeded toestablish thet for the contained in the document The document template defines which header template to use and defines the section templates to be used for the body of the document.

**A section template** describes the scope and intended use of a particular type or set of information typically contained as a logical grouping within a document. Sections are used to define a common set of clinical information, such as *History of* *Procedures*, *Prior* *Encounter*s, or *Planned Interventions*.

Section templates may be used by more than one document template. For example, the template defining the Medications section may be used in both a CCD and Referral Note document. A section template defines the type of information to be recorded in its narrative text element. It also may define zero, one or many different types of entry templates that can be used to represent the information it contains in machine readable data structures defined by the entry templates.

**An entry template** represent individual clinical statements as coded data elements. They define how to encode information for an administered medication or a procedure that has been performed. Entries are very specific templates that define how to represent an event, action, or observation contained within the section. An entry-level template may be referenced by multiple section-level templates.

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.

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

The following implementation rules apply when processing CDA R2 Schema Extensions:

· All extensions are optional.

· All extensions will use the namespace **urn:hl7-org:sdtc**

· All extension elements shall use the same HL7 vocabularies and data types used by CDA Release 2.0.

· All extension elements shall use the same conventions for order and naming as is used by the current HL7 tooling.

· All extension element shall appear in the XML where the expected RIM element of the same name would have appeared had that element not been otherwise constrained from appearing in the CDA XML schema.

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. [BF3]

[1] See also C-CDA R2.1 Errata in Section 2.5

[BF1]Where is this required? It’s required if certifying to 170.315(b)(9).

[BF2]Not permitted for certification, but certainly not prohibited from everyday use.

[BF3]May want to clarify that this is a comment list, and only entries marked as Approved are considered errata (even that is generous, as the errata must be published by SD).