# Recommended Approaches for Meeting Certification Requirements

In this section, whenever a section from the C-CDA Implementation Guide is mentioned, the appropriate chapter number from the guide will be specified.

## General Guidance

The following guidance elements are not specific to any one C-CDA template but rather are overarching guidance elements that apply to an entire C-CDA document.

### Conformance Statements

C-CDA R2.1 imposes constraints within templates based on conformance verbs defined in the [HL7 Version 3 Publishing Facilitator’s Guide](http://www.hl7.org/v3ballot/html/help/pfg/pfg.htm). Relevant conformance verbs are:

* SHALL – This word, or the term "REQUIRED”, mean that the definition is an absolute requirement of the specification.
* SHOULD – This word, or the adjective "RECOMMENDED", mean that there may exist valid reasons in particular circumstances to ignore a particular item, but the full implications must be understood and carefully weighed before choosing a different course.
* MAY – This word, or the adjective "OPTIONAL", mean that an item is truly optional. One vendor may choose to include the item because a particular marketplace requires it or because the vendor feels that it enhances the product while another vendor may omit the same item. An implementation which does not include a particular option MUST be prepared to interoperate with another implementation which does include the option, though perhaps with reduced functionality. In the same vein an implementation which does include a particular option MUST be prepared to interoperate with another implementation which does not include the option (except, of course, for the feature the option provides.)

Table 2 shows the relationship between conformance verb usage, minimum cardinality and permitted use of nullFlavor.

Table : Conformance Verbs, Cardinality and Use of nullFlavor

|  |  |  |
| --- | --- | --- |
| Conformance Verb | Minimum Cardinality | nullFlavor Permitted? |
| SHALL | 1 | Y (unless explicitly disallowed) |
| SHOULD | 0 | Y |
| MAY | 0 | Y |

### Use of Open Templates

It is important to emphasize the reusability and flexibility of templates so that implementations support the ability to customize CDA documents specific to the patient’s care , provider, or setting needs. While templates constrain CDA schema for specific uses, additional content may augment each document as needed for a particular circumstance. For example, if the CCDS Birth Sex data element needs to be shared in a Care Plan Document, the Social History Section would need to be added. This is allowed because the Care Plan Document template is an open template. Within Consolidated CDA, nearly all templates allow additional content and are described as *open* templates. Only the Estimated Date of Delivery and the Medication Free Text Sig entry-level templates are the only closed templates in the Consolidated CDA implementation guides. Other HL7 CDA Implementation Guides make greater use of closed templates.. Open and closed templates are detailed in Chapter 4.2.3 of the Consolidated CDA implementation guide.

### Declaring Section Template Conformance

Section 3.1.2 of the C-CDA Implementation Guide discusses the use of templateIDs and what needs to be included in a C-CDA document:

* The C-CDA R2.1 templateID
* The C-CDA R1.1 templateID must also be included when the C-CDA R2.1 templateID includes an extension

Conformance to a template from C-CDA R1.1 (defined prior to the practice of template versioning) is expressed by asserting the templateID in the root attribute with no version information included in the extension attribute.

<templateId root="2.16.840.1.113883.10.20.22.4.3" extension="2014-06-09"/>

<!--For backwards compatibility-->

<templateId root="2.16.840.1.113883.10.20.22.4.3"/>

The US Realm Header conformance requirement CONF:32936 details this:

* SHALL contain exactly one [1..1] templateId (CONF:1198-5252) such that it
  1. SHALL contain exactly one [1..1]  @root="2.16.840.1.113883.10.20.22.1.1" (CONF:1198-10036).
  2. SHALL contain exactly one [1..1] @extension="2015-08-01" (CONF:1198-  32503).

Section 3.1.2 offers a number of different examples at the document, section, and entry template-levels.

Also note, when a template conforms to another template­—for example, the Allergy – Intolerance Observation (V2) Conforms to Substance or Device Allergy – Intolerance Observation (V2)—it is best practice to include both templateIds:

<!—Substance or Device Allergy -->

<templateId root="2.16.840.1.113883.10.20.24.3.90" extension="2014-06-09" />

<!—Allergy – Intolerance Observation -->

<templateId root="2.16.840.1.113883.10.20.22.4.7" extension="2014-06-09" />

### Use of nullFlavor and Handling Missing Information

Section 3.6 of volume one of C-CDA 2.1, explains how @nullFlavor attributes are used to indicate exceptional values, or values which cannot be conveyed via other attributes or elements in a template.

The @nullFlavor attribute can convey significant information, especially when used with intervals. For example, in a Tobacco Use observation, where the effectiveTime represents the clinically relevant time a code applies, an effectiveTime/high/@nullFlavor=”UNK” indicates that the patient no longer uses whatever tobacco product is represented by value. If the nullFlavor were NA (not applicable), then the end time is not applicable which means the patient is still a user (however, since high effectiveTime is an optional field, the preferred way to communicate this is to omit the element entirely. Most other nullFlavors in this example (NI – no information, NAV – not available, NASK – not asked) convey the uncertainty of whether the patient is still a user of the substance.

This is also conveyed in section 3.3 of volume one of C-CDA 2.1. If a problem is resolved, its effectiveTime/high should contain a value or nullFlavor=UNK. If the nullFlavor=NA is definitely *not* resolved. And if the nullFlavor is anything else, then it is unclear as to whether the problem is still active or if it has been resolved.

The @nullFlavor attribute can convey when information is unknown. However, they SHALL NOT be used to bypass implementation guide requirements for convenience. (E.g. you may send a nullFlavor=UNK for a patient’s birthTime when it is not recorded in a chart, but you may not send it simply because it is too difficult to convert the method your system uses to record birth dates to an HL7 timestamp)  NullFlavor attributes need not be included for nonrequired elements, such as religiousAffiliationCode. If an element is optional and unknown, it may simply be omitted.

Chapter 3.6 of the C-CDA Implementation Guide details how to handle unavailable and unknown information. In HL7 V3, unavailable, unknown or incomplete data are handled with ‘flavors of null’ representing coded values that communicate the reasoning for missing information.

Asserting a value for missing data is necessary where entries are required to meet validation. In addition, communicating reasons for missing data is important in other circumstances as good practice. Indicating null flavors at the appropriate level of precision to convey reasoning for missing required or expected data is encouraged. The null flavor vocabulary domain within the CDA R2 details the complete hierarchy of null flavor values.

#### Options for data that is temporarily unavailable

For information that is not available at the time a CDA document is sent, the incomplete documents may be sent. If the document type being sent requires a section for which the information is not yet available, the required section needs to be included and the section-level “No Information” pattern using nullFlavor="NI" would be used. If the document type being sent indicates the section for which information is not yet available is an optional section, then inclusion of that section is not needed.

At a later point in time, when the information becomes available to complete the document, a new document is created and marked to communicate that it supersedes the previous version of the document. Specifically, the new document includes a new object identifier (OID) for the documentId, the relatedDocument/typeCode=”RPLC” and the relatedDocument/typeCode=”RPLC”/patentDocument/id element will be set to reference the prior document’s documentId.

An example includes the requirement of a Hospital Course section within a Discharge Summary. Typically, this section is not available at the time of a hospital discharge, but the Discharge Summary document type may still be used to meet the MU3 objective for transmitting health information within 36 hours of the hospital discharge. In this example, the incomplete Discharge Summary is sent at the time of discharge and a new Discharge Summary is sent communicating that it supersedes the previous version.

#### Unknown data in sections that require entries

The following guidelines clarify the use of the “No Information” nullflavor=”NI” pattern for section with no information:

* When data is available for a CCDS data element that is not required by the document template for the type of C-CDA document being created, the CCDS data elements need to be populated because all ToC documents require CCDS data elements to be populated. Examples include Goals and Health Concerns for Transitions of Care (b)(1) criteria.
* When data for a CCDS data element is not available and the data element is required by the Document Template for the type of C-CDA document being created, those data elements need to be included using the HL7 recommended “No Information” pattern from the Example Task Force.
* In cases where a SUT includes as part of the generated document sections which are optional for the document template and contain No Information, then they will be validated to follow the HL7 Example Task Force recommendations.

The machine-readable data required within these sections are specified for clinical best practice and should not be completely omitted. In these instances, unknown information may be used on the specific act, such as a Procedure Activity. Additionally, text describing any reasoning for the unknown information and a code indicating the precise unknown information are encouraged.

The key is to describe any unknown information as explicitly as possible to ensure accurate communication. Further guidance and examples are provided in Chapter 3.6 of the C-CDA Implementation Guide. The 2015 Edition CEHRT requirements also reinforce this concept, as quoted below.

“In our proposed rule we went further and said that if the provider does not have the information available to populate one or more of the fields listed, either because they can be excluded from recording such information (for example, vital signs) or because there is no information to record (for example, laboratory tests), the provider may leave the field(s) blank. The only exception to this is the problem list, medication list, and medication allergy list”.

In other words, problems, medications, and medication allergies cannot simply be “left blank”. The document must include the section and a null value. For these sections, the narrative text must explicitly indicate that the information is unknown..

#### Irrelevant (Not Pertinent) Data

In some circumstances, sharing too much information or irrelevant data can cause information overload and may have an undesirable impact on patient care. Creators of CDA documents must be mindful of the purpose of the document as well as the intended use so that only clinically relevant data is sent. Results from the recent HL7 Relevant and Pertinent Survey (add link- TBD or omit link if not available prior to ballot reconciliation for this document) suggest that systems consuming CDA documents should incorporate tools that improve the way information shared through a CDA document is viewed and processed. The survey includes additional recommendations for determining data relevance and pertinence.

### Representing “No-Known” Information vs. “No Information”

There is a distinction to be made between representing “No Information” (i.e., missing or unknown information – see 4.1.4), in the case where the author of the relevant CDA element cannot explicitly declare the presence or absence of some information, versus the case where the author is explicitly stating that there is “No Known” information. It is the difference between these statements: “I don’t know if the patient has any allergies” (no information) and “The patient states that he is not allergic to anything” (no known).

In cases where “No Known” information is being asserted, negation indicators should be used. A negation indicator (negationInd) is used to flag the actas described in the third example within Chapter 3.6 of the C-CDA Implementation Guide. Explicit codes for no known information, such as "no known allergies" within an Allergy Observation, are not recommended within Consolidated CDA. Rather, a negation indicator is to be used on the act along with a text description along with a code indicating the data that has no value.

To represent “No information” about a section, the section should be included and a null value used to convey that there is no information about this section. See section 4.1.4.2 of this guide for further information.

### Narrative Text Representation

Best practice for CDA creation is to represent all human readable text in the section, then reference the text from the discrete entries that represent the human readable information as machine processable data. Use of the text/reference construct to identify text is recommended in the HL7 CDA Standard. The use of code/originalText/reference and value/originalText/reference should be used where appropriate to point to the human readable information associated with the discrete entries.

In accordance with general CDA principals for human readability, every CDA shall be viewable through the use of a CDA stylesheet. Since many vendors and document sources wish to distinguish their expertise by using specific stylesheets, it is important to test early and often to make sure that the text has not become overly complicated, to the point where only the producing system can render the text with the specific stylesheet. Obviously document sources cannot test with all other CDA stylesheets, but it is recommended to regularly test using the [HL7 CDA stylesheet](http://gforge.hl7.org/gf/project/strucdoc/scmsvn/?action=browse&path=%2Ftrunk%2FCDA%2Fprocessable%2FCDA.xsl&view=log) approved by SDWG and managed in the HL7 GForge SVN (<http://gforge.hl7.org/gf/project/strucdoc/frs/> )

#### Multiple Views and styleCode

Experience sharing documents has proven that different users expect, even demand, different views. Patients and providers have different needs; specialists and general practice providers have different needs. The HL7 Relevant and Pertinent Survey identified the need to improve rendering capabilities for the information contained in CDA documents.

CDA documents support a technique for using multiple xml stylesheet processing instructions and a controlled vocabulary for the @styleCode attribute has been established by IHE. For more information on the use of styleCodes, reference the IHE Multiple Content Views (MCV) Profile - Published 2014-08-28[[1]](#footnote-1). The profile includes examples to show how these styleCodes can be used to improve rendering options.

To promote a more consistent user experience for the viewing of the human readable content, implementers are encouraged to use the set of @styleCode values established by the MCV Profile and listed in Table 4.1.6.1-1 below. These @styleCode values establish a common way to tag text as a code, a date, a dateTime, an alert, and many other generally useful concepts.

These styleCode values can be used to facilitate multiple clinical content rendering features. Systems that create CDA documents can use values from this table to improve the processing and rendering options for the information. Systems that render CDA document content with these styleCodes shall not omit or hide or otherwise obstructed from view information that uses these styleCodes unless they are using a specific rendering view that calls for such behavior.

Table 4.1.6.1-1: Addition styleCodes

| styleCode | Description | Suggested Rendering (Hints) |
| --- | --- | --- |
| xEmptySection | Section is empty | When showing other than complete content, do something special to show that the entire section is empty. |
| xHistoric | Content is Historic | When showing content that was assessed, these data should be hidden. |
| xAssessed | Content Assessed/Discussed this visit | When showing content that was assessed, these data shall be shown. |
| xDetail | Extra Detail – not necessarily for Patients | When showing patient related views, this content may be omitted. |
| xDate | Content is a Date | Show as a date. |
| xDateTime | Content is a Date with Time | Show as a date with time. |
| xCode | Content is a code from some code system. | Show as a code. |
| xPhone | Content is a telephone number | Show as a phone number. |
| xEmail | Content is an email address | Show as an email address. |
| xAddress | Content is a Street Address | Shows an address. |
| xPersonName | Content is a person name | Show as the name of a person. |
| xIdentifier | Content is an identifier | Show as an identifier. |
| xAlert | The content contains information of importance that needs to be used to alert the reader, for example level of severity considered life threatening. | Show in some manner to indicate an Alert. |
| xAbnormal | The content contains information that may be considered to be not within what are considered to be normal values. | Show in some manner to indicate a value that is not normal. |
| xHidden | Content may typically be repetitive and unnecessary to display. | Hide the content. |
| xLabel | The content is a label of some data, e.g., Refills: | Show content as a label. |
| xValue | The content contains a data that is a value, e.g., 98.6 | Show content as a clinical item status value. |
| xReaction | The content represents text about a reaction. | Show content as a reaction. |
| xComment | The content is comment text. | Show as a comment. |
| xCenter | Text to be centered | Alignment should be centered. |
| xRight | Text to be right justified | Alignment should be right. |
| xLeft | Text to be left justified | Alignment should be left. |
| xMono | Text to be output in a monospace font | Render in a monospace font. |
| xHighlight | Text to be highlighted | Render with highlight. |
| xStrikeout | Text to be shown as strikeout | Render with strikeout. |
| xHR | A horizontal line is to be drawn | Render a horizontal line. |
| xRowNormal | For example, to indicate an odd numbered row of a table. | Render table row as normal. |
| xRowAlt | For example, to indicate an even numbered row of a table. | Render table row as alternate. |
| xIndent |  | Render content indented. |
| xSecondary | This content is of secondary importance. | Render in some manner to indicate this content is of secondary importance, for example in a lighter font color. |

### Date/Time Guidance

#### Timestamp Representation

The value of a point in time is represented using the ISO 8601 compliant form traditionally in use with HL7. This is the form that has no decorating dashes, colons and no "T" between the date and time. In short, the syntax is "YYYYMMDDHHMMSS.UUUU[+|-ZZzz]" where digits can be omitted from the right side to express less precision. Common forms are "YYYYMMDD" and "YYYYMMDDHHMM", but the ability to truncate on the right side is not limited to these two variants.

This representation allows up to four decimals for specifying milliseconds and it also allows for timezone information to be specified using offsets from UTC. As an example of specifying time zone information, Eastern Standard Time (EST) is represented as -0500, while Eastern Daylight Time (EDT) is represented as -0400.

#### Date/Time Precision

When specifying dates and times, care should be taken to only specify as much precision as is known. The timestamp format allows for partial dates and partial times to be specified. Dates and Times **should not** be padded with zeroes as this implies a precision that is probably not true. A datetime of 20160101000000.0000 is explicitly representing the exact first millisecond on January 1st, 2016. Unless this is the exact millisecond that is intended to be represented, this datetime should be sent as 20160101 which is stating “sometime on January 1st, 2016”. Similarly, 2016010109 is stating “sometime after 09:00am on January 1st, 2016, but before 10:00am”.

When representing an interval of date/times, care must also be taken in the interpretation of the high point of the interval.  Here is the guidance from the HL7 Abstract Datatypes specification:

**NOTE:** The precision of a stated interval boundary is irrelevant for the interval. One might wrongly assume that the interval "[19870901;19870930]" stands for the entire September 1987 until end of the day of September 30. However, this is not so! The proper way to denote an entire calendar cycle (e.g., hour, day, month, year, etc.) in the interval notation is to use an open high boundary. For example, all of September 1987 is denoted as "[198709;198710["

For purposes of an interval, when a partial date/time is encountered, it **should** be acted upon as if the rest of the date/time was padded with 01 for months and days and 0s for hours, minutes, seconds, and milliseconds.  Thus the first interval above should be considered as [19870901000000.0000;19870930000000.0000], which then shows that it stands for the interval from September 1st, 1987 until the first instant of September 30th.  It thus does not actually include the rest of the instants of September 30th.  The second interval is considered as [19870901000000.0000;19871001000000.0000[.  It includes all of September 30th but does not include the first instant of October 1st because the interval is marked open.

Examples:

November 27, 1970: <date value=“19701127”/>

11:30:52.3333 on November 27, 1970: <date value=“19701127113052.3333”/>

The entire year of 1970: <interval><low value=“1970”/><high inclusive=“false” value=“1971”/></interval>

The entire month of September 1987: <interval><low value=“198709”/><high inclusive=“false” value=“198710”/></interval>

### Care Team Representation

Recommendations for care team representation are included below to show some of the possible options that implementers may be using to address representation of care team members. Industry consensus has not been reached in this area. Consequently, implementers should assume to see variability in the representation of care team members in the header and body of any given CDA document.

Care team members, including providers, are participants in the care of a patient. A patient’s care team may include individuals providing support to the patient, such as family members or caregivers, as well as providers and non-clinical providers, including nurses, social workers, behavioral health specialists, community-based providers, technicians, and assistants.

When capturing care team member information, it is recommended to capture the name, identification number, and contact information along with codes to indicate the type of provider and role in the patient’s care. Detailing the type of provider and role helps to distinguish care team members across care settings so that participants in the patient’s care are clear to recipients of the document.

Within CDA, care team members are represented as participants in elements of the document header associated with the patient, the clinical encounter and/or service event detailed in the document, and the document itself. Applicable header elements for capturing care team members from Chapter 1.1 of the C-CDA Implementation Guide are described in the following table.

**Table 3: Participants and Act Relationships for Recording Care Team Members in the Header**

|  |  |
| --- | --- |
| Participant | Description |
| Author | Care team member who generates content contained in the document.  *Examples: PCP, nurse practitioner, admitting physician* |
| dataEnterer | Care team member who enters information into the document by transferring content from another source, such as a paper chart.  *Examples: transcriptionist, technician* |
| informant | Care team member providing information about a patient contained in the document.  *Examples: PCP, family member, caregiver* |
| informationRecipient | Care team member who the document is intended for.  *Examples: PCP, caregiver, consulting physician* |
| legalAuthenticator | Care team member who authenticates content contained in the document and accepts legal responsibility.  *Examples: PCP, consulting physician, attending physician* |
| authenticator | Care team member who authenticates content contained in the document.  *Examples: PCP, consulting physician, attending physician* |
| participant | Other supporting care team members associated with the patient.  *Examples: Caregiver, family member, emergency contact* |
| documentationOf/  serviceEvent/  performer | Care team member who performs the service event detailed in the document.  *Examples: PCP, surgeon, consulting physician* |
| componentOf/  encompassingEncounter/ encounterParticipant | Care team member who participates in the encounter detailed in the document.  *Examples: PCP, consulting physician, attending physician* |

In most cases, a care team member may be fulfilling more than one responsibility recorded in the header. For example, a consulting physician who sees a patient in a clinical encounter may author a progress note, and authenticate it. Depending on the business environment, the physician may also be the legal authenticator of the document. In this example, the consulting physician is participating as the author, authenticator and legalAuthenticator.

In support of Meaningful Use goals to provide complete and accurate information and emerging MACRA requirements to support alternative payment models (APMs), it is recommended to capture care team member and provider name and contact information data requirements within the act relationships associated with the clinical encounter or service event detailed in the document header. This practice ensures that the recipient of the document knows the care team member(s) who participated in the clinical encounter or was responsible for the clinical encounter, or performed a service event.











### DisplayName Representation

When sending coded information, the CD datatype has a ‘displayName’ element. This element is intended to be a valid human readable representation of the concept defined by the code system and associated with the ‘code’ element at the time of data entry. As an example, for LOINC codes, the displayName should convey either the short name or long name in LOINC for the code used in the associated code element.

The displayName is included as a courtesy to an unaided human interpreter of a coded value. The display name adds no semantic meaning to the coded information and it SHALL never exist without an associated code. A display name may not be present if the code is an expression for which no display name has been assigned or can be derived. Also, the display name SHALL never modify the meaning of the code, which is to say the displayName must accurately represent the concept associated with the code. Display names SHALL not alter the meaning of the code value. Some CDA validation applications check to ensure the display name in the displayName element is associated with the coded concept in the code element as specified by the code system.

Rendering CDA entry information benefits from availability of the display name. In some cases, inclusion of the display name improves the human readability of discrete data. It also can aid implementation debugging and content validation.

When a CDA document includes coded data in discrete entries (such as allergen, medication, problem, etc.) to support machine processing, every discrete entry SHOULD include a text element containing the human readable representation of the information discretely represented by a code. Including the displayName from the associated code system for a particular code helps receivers who can process discrete entries but may not recognize the code that was sent.

For example, say a new version of SNOMED is released with a new problem code of 99999123 and a display name of “Obsessional thoughts of augmented reality video games” and this code is used in a Problem Concern entry. A processing system that does not recognize the SNOMED CT code 99999123 can still present to an end user in a structured way, a human readable representation of the coded problem concern by including the display name, date of onset, author, etc. in the narrative text. Using the displayName element, the human readable information can say, “Obsessional thoughts of augmented reality video games, began on July 6, 2016, as noted by Dr. Ishihara.” If display name were not available/used, the human readable text would only say, “Problem 99999123 began on July 6, 2016 as noted by Dr. Ishihara.”

On the other hand, when a CDA document includes human readable information and contains coded discrete entries (such as allergen, medication, problem, etc.) to support machine processing of the available human readable information, then every discrete entry SHOULD include an originalText element to link the coded information back to the original human readable information represented by that code. In this case, using the displayName element, allows the human readable information include a quality check. Using the above example, if the Problem Section dictated by Dr. Ishihara indicated, “The patient has obsessional thoughts of augmented reality video games. The obsession began on July 6, 2016”. In this case, the validation could confirm the display name in the displayName element is associated with the coded concept in the code element as specified by the code system. Human confirmation or natural language processing could be used to confirm the coded concept correctly represented the original text.

### Generating Unique Identifiers

The id element represents a globally unique identifier for a piece of data, be it document, section, entry, or sub-entry (such as an author). It should be unique within a document (for example, every instance of the same provider throughout a document should have the same id). But it should also be unique across instances of documents. If a CCD is created for a patient with an allergy to penicillin, the next time a CCD is generated for the same patient, the penicillin allergy should have the same id. If the allergy has changed slightly (such as adding a new comment or changing the severity of a reaction), it is still the same instance and should keep the same identifier. If the entry represents a new instance, however, such as a new prescription for the same medication, it should contain a new id to differentiate it from the previous prescription.

Consistent ids help with reconciliation of discrete data. If the penicillin allergy cited before was received and incorporated into a system, then a subsequent update can be immediately tied to the previously incorporated allergy without requiring additional reconciliation steps. If, however, a nullFlavor or newly-generated random id is sent with each new document, the allergy continues to appear as a brand new entry and decision logic must be performed (either automatic or manually reviewed by a clinician) to decide whether it should match to an existing allergy, be discarded as out of date, or be added as a brand new record. Consistent ids eliminate this extra step by ensuring every time a specific entry is referenced, it is tied to previous instances of the same entry.

A typical approach to unique ids is to create Globally Unique Identifiers (GUIDs) for each object in the database. It is important to actually store the GUID in the database, so when the record is sent again in the future its id is consistent. Another approach is to use Object Identifiers (OIDs). This requires some management to make sure the OID is globally unique. A vendor or specific implementation of software typically owns a unique OID that forms the root of all their OIDs. Unique branches can then be created for each implementation, server, data type, and record.

HL7 id elements contain two identifying elements: a root (which must be a GUID or an OID\*) and an optional extension (which can be any string of characters). If the extension is present, the combination of root + extension must be globally unique. This can allow a hybrid approach for either using GUIDs or OIDs. For example, a GUID or OID may be created for a local instance of an entire allergy database and sent as the root, and then the local identifier (such as a database row number, a filename, or any other string) of the allergy can be sent as the extension.

A vendor may use any approach as long as it is consistent and sends the same unique identifier for an entry each time it is included in a CDA document.

\* The root element may also be any string containing only letters and numbers without spaces or other punctuation, but it is more difficult to ensure uniqueness when this option is used than when a GUID or OID is used.

### Specifying Time Intervals for Sections

]In order to specify that the information represented in the section of a document is limited to information from a specific time interval, a new entry template has been defined called a Section Time Range Observation. The Section Time Range Observation entry represents the date and time range of the information contained in a section. It is an optional entry and may be used in any section.

The Section Time Range Observation template (urn:hl7ii:2.16.840.1.113883.10.20.22.4.201:2016-06-01) may be useful when a query for a C-CDA document may request a large amount of data--potentially years—and the system that creates the document supplied as a response, limits the data they return to a specific range of time. This template enables the system creating the document to assert the range of time constraining the data provided in a section.

## Document-Specific Guidance

The following guidance elements are organized into the document template that they refer to.

### US Realm Header

#### Language Code

Since the value set for Language Codes includes both 2-character codes (ISO 639-1) and 3-character codes (ISO 639-2) for most languages, the following guidance should be followed:

* Use the 2-character code from ISO 639-1 if one exists
* Use the 3-character code from ISO 639-2 if a 2-character code does not exist
* Country extensions to the language codes are allowed (ISO 3166-1)

#### Race and Ethnicity

Race and Ethnicity are required elements in the Common Clinical Data Set (CCDS) and must be included in C-CDA exchanges.

For both Race and Ethnicity, there are the singular data elements along with an extension element. The standard elements tend to have codes from a small value set while the extension elements allow for more detailed (granular) representation of either race or ethnicity, or for additional race(s). SDWG created extensions because the base CDA standard only allows one Race, and one Ethnicity code. The five minimum race and ethnicity categories defined by OMB Standards recorded in the code should be treated equally. The granular race and ethnicity codes should be treated equally.

For Race, the raceCode data element uses a value set (Race Category Excluding Nulls 2.16.840.1.113883.3.207.4.1.1.3) that has five race categories:

* American Indian or Alaska Native
* Asian
* Black or African American
* Native Hawaiian or Other Pacific Islander
* White

If race is not known, the raceCode data element may be populated with a nullFlavor of “UNK”.

The extension sdtc:raceCode uses a value set ( Race 2.16.840.1.113883.3.207.4.1.1.3) that allows for additional more detailed race concepts beyond the five categories. sdtc:raceCode should not be present if it is only repeating the code in raceCode.

The value set for ethnicGroupCode (Ethnicity 2.16.840.1.114222.4.11.837) includes only two concepts: Hispanic or Latino, and Not Hispanic or Latino. If ethnicity is not known, the ethnicGroupCode data element may be populated with a nullFlavor of “NL”.

The value set for sdtc:ethnicGroupCode. (Detailed Ethnicity 2.16.840.1.114222.4.11.877) includes more detailed ethnicities. sdtc:ethnicGroupCode should not be present if it is only repeating the code in ethnicGroupCode.

#### Encompassing Encounter and Service Events

The Discharge Summary Document and Referral Note are associated with a single encompassing encounter. The CCD may also be used to detail the provision of care within a single encounter. For single encounters, the componentOf/encompassingEncounter element in the header captures information about the encompassing encounter including the admission and discharge date and time, the location information for the health care facility such as the organization and the location of the facility. The encompassing encounter also captures information the key care team member responsible for the encounter and other care team members who may have participated in care deliver during the encounter. Key dates associated with the encounter such as the admission or discharge date for an inpatient encounter, or the start and completion for an ambulatory visit, or the admission and discharge for an Emergency Department visit, are recorded in the effectiveTime/low and effectiveTime/high of the encompassingEncounter.

The documentationOf/serviceEvent header element records care services that were provided during the encounter and each serviceEvent includes care team members participating in the specific service event.

Generally, service events, such as procedures, occur as part of a clinical encounter associated with a visit or hospitalization. For example, a patient may be referred by a general surgeon to a surgical specialist in an outpatient surgery center for a specific procedure. In this example, the general surgeon would be associated with the clinical encounter where the referral was made. The surgical specialist would be associated with the clinical encounter where the procedure was performed. In the CDA document detailing the encounter where the procedure was performed, the surgical specialist who performed the procedure (service) would also be included as a performer in the documentationOf/serviceEvent in the header. Other care team members could be captured as participants in the header elements associated with the encompassing encounter or as participants associated with the various services performed during the encounter.

A CCD also may serve as a summary across multiple encounters. In this case, the document header does not include a single encompassing encounter. Instead, the header includes a service even for provision of care during a certain range of time. The provision of care may include key care team members like the PCP and consulting physicians who may have performed the provision of care over time. Specific clinical encounter information is captured in the body of the document in the Encounters section along with associated care team members. Key dates associated with the encounters such as an admission or discharge date from an inpatient encounter, the start and completion of an ambulatory visit, or the admission and discharge from an Emergency Department visit are recorded in the effectiveTime/low and effectiveTime/high of the Encounter Activity entry in the Encounters Section.

**Table 4-1 Single Episode Transition of Care Document – example 1: CCD**

|  |  |
| --- | --- |
| The consulting physician in an ambulatory setting generates a CCD detailing an encounter to provide to the patient and the patient’s caregiver (*Clinical Summary Objective*). | |
| componentOf/encompassingEncounter | Captures information about the encompassing encounter including the admission and discharge date and time, the location information for the health care facility such as the organization and the location of the facility. Also captures the names and contact information of the consulting provider as the responsible party for the clinical encounter and the nurse practitioner as an encounterParticipant |
| documentationOf/serviceEvent | Captures the names and contact information for any known key care team members, such as the PCP, who may not be participating in the encounter |
| participant/ | Captures the names and contact information of supporting participants, including the patient’s caregiver |

**4-2 Single Episode Transition of Care Document – example 2: Discharge Summary**

|  |  |
| --- | --- |
| The discharging physician in an inpatient setting generates a CCD to detail the hospitalization to send to the patient’s PCP (*Transition of Care Objective*). | |
| componentOf/encompassingEncounter | Captures information about the encompassing encounter including the admission and discharge date and time, the location information for the health care facility such as the organization and the location of the facility. Also captures the names and contact information of the attending physician as the responsible party for the clinical encounter and the discharging physician and rounding physician as encounterParticipants. (see also 4.1.8 Care Team Member Representation). |
| documentationOf/serviceEvent | Captures a list of services performed during the encounter with the date and time they occured. Also captures the names and contact information for any known key care team members involved in performing the service(s). (see also 4.1.8 Care Team Member Representation). |

**Table 4-1: Multiple Encounter CCD**

|  |  |
| --- | --- |
| The PCP in an ambulatory setting generates a CCD to summarize a patient’s healthcare for transmission to the PHR (*View/Download/Transmit Objective*). | |
| This type of CCD does not contain a componentOf/encompassingEncounter | The cardinality of componentOf/encompassingEncounter in a CDA Document is [0..1], so in the header of a CCD about multiple encounters, this element of the header is not present. |
| documentationOf/serviceEvent | Captures the general service event for “Provision of Care” for the range of time indicated in the serviceEvent/effectiveTime/low and /high. The names and contact information for key care team members including the PCP and other active care providers, such as the patient’s physical therapist or dietician, would also be included (see also 4.1.8 Care Team Member Representation). |
| Encounters section | In the body of the document, the Encounters Section captures relevant encounters. Each Encounter Activity entry can included associated care team members. (See 4.3.2 Encounter Section) |

## Section-Specific Guidance

The following guidance elements have been grouped by the C-CDA section that they deal with.

### Allergies

There are three distinct dates associated with an Allergy Concern Act (3.5). Two of them are found on the Allergy Concern Act itself:

* The effectiveTime asserts the time period over which the allergy concern was being tracked. The low asserts when the concern became active while the high is used when asserting that an allergy is “completed”, i.e. no longer a concern.
* The latest author/time indicates when the allergy concern was last modified.
* The Allergy – Intolerance Observation (3.105.1) also has an effectiveTime and this is the time of the onset of the allergy for the patient.

For a provider seeing a patient in the clinic today, recording a new penicillin that developed five years ago, those dates would have the following values:

* act/effectiveTime/low – today
* act/effectiveTime/high – empty
* act/author/time – today
* act/../entryRelationship/observation/effectiveTime/low – five years ago
* act/../entryRelationship/observation/effectiveTime/high – empty

If an encounter updated a penicillin allergy that was recorded a month ago to indicate that it was no longer a concern, then the dates would have the following values:

* act/effectiveTime/low – a month ago
* act/effectiveTime/high – today (no longer a concern)
* act/author/time – today
* act/../entryRelationship/observation/effectiveTime/low – five years ago
* act/../entryRelationship/observation/effectiveTime/high - empty

### Encounters

The Encounters Section includes relevant and pertinent encounters which have already occurred for the patient. Future appointments and requested encounters should be communicated in the Plan of Care Section.

When the document is about a single encounter, this section SHALL contain information about that encounter but MAY also contain additional encounters. The Encounter Activity entry with an ID matching the encompassingEncounter header element represents the primary encounter being documented.

The Encounter Diagnosis is always represented as an entryRelationship to an Encounter Activity, even when the document is about a single encounter. Additional information, such as free-text notes may also be communicated using extra entryRelationships within the associated Encounter Activity. For example, a Comment Activity that includes additional textual documentation about the encounter may be included within the associated Encounter Activity. Historical encounters would each be documented as an Encounter Activity and information about that encounter would be recorded using an entryRelationship within that corresponding Encounter Activity.

### Immunizations

#### Recording Immunization Date

When recording the Immunization date, the effectiveTime element should just contain a single @value. Although there is a use case for using an interval when requesting an immunization, i.e. have this immunization done between date 1 and date 2, when recording an actual immunization (with moodCode = EVN), the effectiveTime should represent when the immunization was given and this will generally just be a single dateTime value.

#### Immunization Status Code

When recording the immunization status code, the normal value would be ‘completed’, as this represents an immunization that has been completely given. In extremely rare circumstances, a status of ‘active’ could be used. The use of ‘active’ implies that a single immunization is still on-going. This would not be appropriate for one shot in a series immunizations. Series immunizations should be represented with multiple Immunization Activity (3.41) entries, each with a status of ‘completed’.

#### Documenting Refusals

For documenting when an immunization was not given, due to a refusal, an Immunization Activity entry should be recorded with a negationInd equal to ‘true’ to indicate that the specific immunization was not given. There would then be an entryRelationship with the reason why the immunization was refused.

### Medications

The Medication Activity Entry records a medication that has been administered and used for statements about medications being taken. These two clinical statement patterns are identical, so the semantics is discerned through the context of use. The Medication Supply Order entry records activities associated with ordering medications. The Medication Dispense entry records when medications are dispensed.

Medications with a substanceAdministration/@moodCode="EVN"document actual use. A statement of this type can be interpreted to represent an actual administration of the medication. It also can be used to make a statement about the medication a patient takes.

Medication activities with substanceAdministration/@moodCode= "INT" document what a clinician intends a patient to be taking. For example, a clinician may intend that a patient begin taking Lisinopril 20 mg PO for blood pressure control. The Planned Medication Activity entry can also be used to record a medication that the physician intends the patient to take at some time in the future.

A Medication Supply Order is a represented as a supply/@moodCode=“ORD”. It documents what a clinician has ordered for a patient.

A Medication Dispense is a supply/@moodCode=“EVN”. It documents what has been dispensed to the patient.

The structure for medication information is complicated by the fact that any one of these templates may include other type of medication templates within an entryRelationship. Thus, the structure of a medication entry can be complex. To support interoperability, implementers should minimize the amount of template nesting used to express medication information.

When representing medications consideration needs to be given to the way date/time intervals are represented. See section 4.1.7.2 Date/Time Precision for additional information about how to represent and interpret date ranges that use an effectiveTime/low and effectiveTime/high.

### Problems

There are three distinct dates associated with an Problem Concern Act (3.78). Two of them are found on the Problem Concern Act itself:

* The effectiveTime asserts the time period over which the problem concern was being tracked. The low asserts when the concern became active while the high is used when asserting that a problem is “completed”, i.e. no longer a concern.
* The latest author/time indicates when the problem concern was last modified.
* The Problem Observation (3.79) also has an effectiveTime and this is the time when the problem was first noticed for the patient.

For a provider seeing a patient in the clinic today, observing that the patient had a history of heart attack that occurred five years ago, those dates would have the following values:

* act/effectiveTime/low – today
* act/effectiveTime/high – empty
* act/author/time – today
* act/../entryRelationship/observation/effectiveTime/low – five years ago
* act/../entryRelationship/observation/effectiveTime/high – empty

If an encounter updated the history of heart attack that was recorded a month ago to indicate that it was no longer a concern, then the dates would have the following values:

* act/effectiveTime/low – a month ago
* act/effectiveTime/high – today (no longer a concern)
* act/author/time – today
* act/../entryRelationship/observation/effectiveTime/low – five years ago
* act/../entryRelationship/observation/effectiveTime/high – empty

### Vital Signs

The 2015 Final Rule changed the code for Body Weight from the one specified in the C-CDA Implementation Guide – 3141-9: Body Weight Measured to 29463-7: Body Weight.

The Vital Sign Observation entry template includes a SHOULD recommendation for a set of codes to be used to represent various types of vital signs that can be measures as a physical quantity. Other concepts besides those listed in the Vital Sign Result ValueSet (urn:oid:2.16.840.1.113883.3.88.12.80.62 ) can be used so long as the measurement can be represented as a physical quantity.

Other types of observations that yield other types of results can be represented using the Result Observation entry template in the Results Section.

Additionally, if a more specific LOINC code is applicable (such as 8350-1 – body weight with clothes), it may be sent as a translation to the more general LOINC code of 29463-7 (Body Weight) .

<code code="29463-7" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" displayName="Body weight">

  <translation code="8350-1" codeSystem="2.16.840.1.113883.6.1" displayName="Body weight^with clothes" />

</code>

### Representing “Pregnant”, “Not Pregnant” and “Unknown”

To assert that a patient was pregnant during a specified date range, the Pregnancy Observation section (3.74) shall be used. The effectiveTime element will indicate the date range during which the patient was pregnant.

To assert that a patient was not pregnant during a specified date range, the Pregnancy Observation section should also be used, but with a negationInd set to ‘true’ to indicate that the patient was not pregnant during the date range specified by the effectiveTime element.

Finally, to indicate that it was unknown, then a nullFlavor should be used on the observation to indicate that the patient’s pregnancy status was unknown. An effectiveTime element can be included to assert the period over which it was unknown.

## Certification-Specific Guidance

The following guidance was determined from the two Implementation-A-Thons that HL7 and ONC jointly held in Orlando in January 2016 and Chicago in April 2016. The implementers and ONC jointly discussed these issues and came up with the following guidance.

### Implanted Devices

When recording devices that have been applied to or placed in a patient, they should all be placed in the Medical Equipment Section (2.37). If the CDA document is also documenting a procedure that applied or placed the device, then the device could also be enumerated under the details of that procedure. Detailing the device in the procedure details does not remove the need to list it in the Medical Equipment section.

Within the Medical Equipment section, each device is listed within a procedure act where the “inversion indicator” is true. This creates an unusual order for the information, because the inversion in the semantics is subtle. The subject of the statement really is the equipment, not the procedure. Each implanted device can be represented in an Individual Procedure Activity Procedure templateor groups of implanted devices can be represented within a Medical Equipment Organizer template. If information about the procedure that applied or placed the device is known, it should be included, otherwise as much information as is known should be specified.

When specifying the device, the UDI of the device must be used to identify the device. See Section 3.85 Product Instance in the C-CDA Implementation Guide for information on how to encode the UDI.

To declare that a patient has no implanted devices, the Medical Equipment section should be used that has a Procedure Activity Procedure entry with an effectiveTime that has a nullFlavor of ‘NA’ and a participantRole that has an id with a nullFlavor of ‘NA’ and a code of 40388003 – Implant. This combination states that the patient has not had a procedure to implant anything.

### Health Concerns vs. Problems

To satisfy the 2015 Edition CEHRT requirements, Transition of Care (ToC) documents[[2]](#footnote-2) should include both the Problem Section (2.53) and the Health Concerns Section (2.23), with content distinguished as described below.

#### Problem Section

The Problem Section contains the Problem List in a ToC document. These are the “tracked concerns” that the author includes on the list.

The list should only include **active** Problems that the author deems pertinent to the intended recipient. If there are historical problems that the author deems pertinent and chooses to include, these should clearly be indicated as not active.

The word “Concerns” should not be used in the title of the section, to avoid confusing users, since this is basically the same Problem List that has been produced in MU1 and MU2.

#### Health Concerns Section (in a ToC Document)

The Health Concerns Section contains, when available, concerns as expressed by the patient and/or the patient’s agent(s).

When the Problem Section and Health Concerns Section both appear in a single document, then the Health Concerns section should be titled **Additional Health Concerns** to distinguish it from the Problem List (the author’s priority concerns). If it were simply titled Health Concerns, some would think that it contains all concerns, including the Problem List. Also, the Health Concerns Section should be included after the Problem Section in the C-CDA document.

It should **not** duplicate the entries from the Problem List. However, it may include some of the same concepts/concerns that in the Problem List, but in the patient’s words.

It may be formatted as a “list” but may also be free form narrative not in any particular format. Whereas the Problems Section must contain both structured entries and narrative, the 2015 Edition CEHRT requirement for Health Concerns section is only narrative. C-CDA conformance requires structured entries which may be populated with relevant data or the appropriate nullFlavor.

Patient concerns may be specific to an encounter, or overarching concerns not specific to an encounter. Patient concerns are not limited to medical problems. For example, they can include things like barriers (lack of transportation, lack of finances, difficulty communicating with provider) or anything else that the patient chooses to express. The concerns should be relevant/current/”active”.

Also, the Additional Health Concerns section may contain concerns from members of the care team other than the author/attester of the document. The author/owner of each concern or group of concerns within the Additional Health Concerns section shall be clearly labeled (e.g. Patient, Nurse, Therapist).

### Plan of Treatment and Goals (in a ToC Document)

To satisfy the 2015 Edition CEHRT requirements, Transition of Care documents should include the Assessment Section (2.7) and the Plan of Treatment Section[[3]](#footnote-3) (2.48), or the Assessment and Plan Section (2.6). They also should include the Goals Section (2.22). Content should be distinguished as described below when **the Goals Section, and the Plan of Treatment Section or Assessment and Plan of Treatment Section, are both included within the same Transition of Care document**. This guidance does **not** apply to the Goals Section within a Care Plan document. There is no additional guidance for the **Assessment Section** beyond what is already in Consolidated CDA.

#### Plan of Treatment Section

The Plan of Treatment Section contains the treatment plan related to the encounter or service(s) being documented in the ToC document.

It may contain goals, as well as many other types of data including pending orders, interventions, encounters, services, and procedures for the patient. It is limited to prospective, unfulfilled, or incomplete orders and requests only. When used in a ToC document, which includes a Goals Section, **all** the goals (whether narrative only, or structured Goal Observation entries) from the patient or other care team members, should be recorded in the Goals Section, rather than in the Plan of Treatment Section, to avoid confusion as to “which/whose goals should be in which section?” Just as the patient’s health concerns should be placed in the Health Concerns Section, the patient’s goals should be placed in the Goals Section.

The Plan of Treatment Section shall always contain a narrative and may contain structured entries. If it contains structured entries, it may contain any allowable C-CDA entries except for Goal Observation entries.

While guidance has been provided to put all goals in the Goals section, it is not possible to prohibit words in the Plan of Treatment *narrative* *text* that sound like goals, intentions, desired outcomes, etc. The Plan of Treatment narrative should read as the author intends.

#### Goals Section

The Goals Section should contain, when available, all goals as expressed by the authoring provider, the patient, or any other members of the care team. Patient goals may be specific to an intervention or encounter, or overarching goals not specific to an intervention/encounter.

The Goals Section is only required by ONC to contain narrative.[[4]](#footnote-5) It may also contain structured entries or may contain no entries (except for the appropriate nullFlavor entries to satisfy C-CDA conformance for the Goals section).

If there are goals from multiple sources, for each goal or group of goals the author/owner of each goal (e.g., provider-expressed, patient-expressed) shall be clearly labeled for the user.

### Birth Sex and Administrative Gender

The administrativeGenderCode element in the header is used to represent the gender of a patient for administrative purposes. Here is the definition of this element in the HL7 Reference Information Model:

*The gender (i.e., the behavioral, cultural, or psychological traits typically associated with one sex) of a living subject as defined for administrative purposes. This attribute does not include terms related to clinical gender. Gender is a complex physiological, genetic, and sociological concept that requires multiple observations in order to be comprehensively described. The purpose of this attribute is to provide a high-level classification that can also be used for the appropriate allocation of inpatient bed assignment.*

The 2015 Edition CEHRT requirements include a requirement to collect Birth Sex. The administrativeGenderCode is not the appropriate place to specify Birth Sex. Birth Sex should be represented using the new Birth Sex Observation template (2.16.840.1.113883.10.20.22.4.200:2016-06-01). The Birth Sex data element uses the ONC Administrative Sex value set (2.16.840.1.113762.1.4.1) which contains only two concepts: Male (M) and Female (F). If the value/@code of the Birth Sex data element is not populated with a concept from this value set then it shall contain a nullFlavor of "UNK".

### Lab Tests with and without Results

The placement of Laboratory test information depends on whether those tests have results or not. If a Laboratory test has been ordered but no results have been received, then the test details should be placed in the Plan of Treatment section (2.48). With this section, the preference would be the Planned Observation (3.68), but it could also be found in the Planned Procedure (3.69) or the Planned Act (3.62), depending on the specific test being ordered.

For Laboratory tests that have been performed and have results or have pending results, those results are placed in the Results Section (2.64). If the results of a Laboratory test are found in the Results section, then the Laboratory test should not also be detailed in the Plan of Treatment section.

The effectiveTime or the Result Organizer is an interval that spans the effectiveTimes of the contained result observations. Because all contained result observations have a required time stamp, it is not required that this effectiveTime be populated.

### Smoking Status vs. Tobacco Use

In the Social History Section (V3) template there are two entry templates used for specifying a patient’s smoking status and overall tobacco use. The Smoking Status– Meaningful Use (V2) template is used to represent the patient’s current smoking status. Within this template, the effectiveTime is the date/time when the observation of the patient’s current smoking status was made. Within the Social History Section of a document there can be more than one Smoking Status observations recorded, as the person’s “current” smoking status may have been recorded at different points in time. The Smoking Status– Meaningful Use (V2) template shall not be used for identifying when the current smoking status started. That information is recorded using the Tobacco Use entry template.

To provide details of the patient’s smoking and overall tobacco use, the Tobacco Use (V2) entry shall be used. Within this entry, the effectiveTime represents the biologically relevant time of the observation. Thus, an observation of “cigarette smoker” would have an effectiveTime/low that details when the patient started smoking cigarettes and an effectiveTime/high that details when the patient stopped smoking cigarettes (assuming the patient had stopped smoking). If the patient is a current smoker, then the effectiveTime/high would not be specified, thus indicating that the “cigarette smoker” observation is still ongoing.

The Tobacco Use entry is used to describe the patient's particular uses of tobacco with the associated date ranges, whereas the Smoking Status - Meaningful Use (V2) template is used to represent a “snapshot in time” observation reflecting what the patient’s smoking status is at the point in time when the observation was made. Thus, when timing information is provided with ‘smoking status’ information, a Smoking Status entry would be used to record the current smoking status and a second Tobacco Use entry would be used to record the timing information.

1. http://ihe.net/uploadedFiles/Documents/PCC/IHE\_PCC\_Suppl\_MCV.pdf [↑](#footnote-ref-1)
2. “Transition of Care Documents” collectively refers to the three document types that 2015 Edition Certification requires that EHRs be able to send for transitions of care. These are the Continuity of Care Document (CCD), Discharge Summary, and Referral Note. [↑](#footnote-ref-2)
3. For simplicity, Plan of Treatment Section is used in this proposal. Per the ONC rule, alternatively there can be an Assessment and Plan Section (2.6). If the Assessment and Plan Section were used instead, the guidance still applies to the “Plan” aspect of that section. [↑](#footnote-ref-3)
4. 45 CFR Part 170, RIN 0991–AB93, 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications; Corrections and Clarifications. See Federal Register page 78760, Section III.A: Clarifications, *Common Clinical Data Set*. [↑](#footnote-ref-5)