# Recommended Approaches for Meeting Certification Requirements

[brief intro]

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 needs. While templates constrain CDA schema for specific uses, additional content may augment each document as needed for a particular circumstance. 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 closed. 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

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. In general, whenever a templateID is specified, there should be two instances, one with the extension and one without:

<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"/>

### Handling Missing Information and Use of nullFlavor

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 document may be sent even though it is not fully compliant. When the information is available to complete the document, a new document with a new object identifier (OID) is created and marked to communicate that it supersedes the previous version of the document.

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

Asserting a null flavor at the section level for sections with entries required by the document template or MU3 data requirements is not permitted. These include sections detailing patient allergies, immunizations, medications, problems, procedures, and results.

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

A circumstance where too much information or irrelevant data is provided presents opportunity for information overload and may have an undesirable impact on patient care. For example, MU3 requires the inclusion of medications. All current and active medications must be clear to the recipient, so detailing all historical medications is not recommended. 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.

### 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. In order to provide the potential for this to happen using a single CDA document, a technique for using multiple xml stylesheet processing instructions and a controlled vocabulary for the @styleCode attribute has been profiled by IHE. See [Multiple Content Views (MCV)](http://www.ihe.net/uploadedFiles/Documents/PCC/IHE_PCC_Suppl_MCV.pdf%22%20%5Co%20%22Multiple%20Content%20Views%20%28MCV%29) - Published 2014-08-28. Document Sources and vendors are encouraged to use the documented set of @styleCode values from Table 5.1.X-1: styleCode, to promote a more consistent user experience for the viewing of the human readable content. This table of @styleCode values establishes a common way to tag text as a code, a date, a dateTime, an alert, and many other generally useful concepts.

### 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”.

### Care Team Representation

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-physician providers, including nurses, 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 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, multiple participants will be the same care team member. For example, a consulting physician may see a patient in a clinical encounter, dictate a note, and legally authenticate the document. In this example, the consulting physician is participating as the encounterParticipant, author, and legalAuthenticator. In support of Meaningful Use goals to provide complete and accurate information, it is recommended to capture care team member and provider name and contact information data requirements within participants associated with the clinical encounter or service event detailed in the document. This practice ensures that the recipient of the document knows the care team member who participated in the clinical encounter or performed the service event for any follow-up communications.

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 who referred the patient is associated with the clinical encounter that represents the setting during which the procedure occurred. The surgical specialist is then associated with the procedure, or service event, that happened as part of the clinical encounter and is listed as a performer in the documentationOf/serviceEvent header element. Within the document detailing the procedure, these care team members would be captured as participants in distinct header elements associated with the clinical encounter from which the patient was referred or the procedure service event that transpired.

 The CCD may serve as a summary for a provision of care service event. In this case, the service event information covers a broader span of time (across encounters) rather than a narrower span of time (within an encompassing encounter).The provision of care occurs over a specified period of time that may include multiple clinical encounters. For the provision of care, key care team members like the PCP and consulting physicians perform the provision of care over time. Clinical encounter incounter information relevant for continuity of care is captured in the Encounters section in the document body along with associated care team members.

The CCD may also be used to detail the provision of care within a single encounter. For single encounters, key care team members are still performers of the provision of care captured in the documentationOf/serviceEvent header element while care team members participating in the specific clinical encounter are the encounterParticipants within the componentOf/encompassingEncounter header element. To help demonstrate care team member participants for the CCD, example scenarios are provided below.

**Table 4: Sample CCD Participant Scenarios**

|  |
| --- |
| **4-1 PCP generates for a patient**The PCP in an ambulatory setting generates a CCD to summarize a patient’s healthcare for transmission to the PHR (*View/Download/Transmit Objective*). |
| documentationOf/serviceEvent | Captures 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 |
| Encounters section | Captures relevant encounters and associated care team members  |

**4-2 Consultant generates to summarize an encounter**

|  |
| --- |
| 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*). |
| participant/ | Captures the names and contact information of supporting participants, including the patient’s caregiver |
| 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 |
| componentOf/encompassingEncounter | 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 |

**4-3 Discharge**

|  |
| --- |
| 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*).  |
| documentationOf/serviceEvent | Captures the names and contact information for any known key care team members, including the PCP |
| componentOf/encompassingEncounter | 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 |

### 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 as defined by the code system at the time of data entry. As an example, for LOINC codes, the displayName should convey either the LOINC short name or LOINC long name.

If the codeSystem does not define a human representation for the code or expression, then none can be provided. The displayName is included both as a courtesy to an unaided human interpreter of a code value and as a documentation of the name used to display the concept to the user. The display name has no functional meaning; it SHALL never exist without a code; and it SHALL never modify the meaning of the 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.

Display names SHALL not alter the meaning of the code value. Therefore, display names SHOULD NOT be presented to the user on a receiving application system without ascertaining that the display name adequately represents the concept referred to by the code value. Communication SHALL NOT simply rely on the display name. The display name's main purpose is to support implementation debugging.

### 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 than with the recognized patterns of GUID and Specifying Time Intervals for Sections

[guidance about when/why/how sections should include an effectiveDate time interval]

## 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 “NL”.

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.

### CCD Guidance

#### Sending a CCD for a single encounter

[guidance on how a CCD could/should be used when it is documenting a single encounter]

### Discharge Summary

#### Admission and Discharge Dates

[guidance on where admission and discharge dates should appear]

## 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 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 when the allergy was first noticed 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:

* effectiveTime/low – today
* effectiveTime/high – empty
* author/time – today
* observation/effectiveTime/low – five years ago
* 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:

* effectiveTime/low – a month ago
* effectiveTime/high – today
* author/time – today
* observation/effectiveTime/low – five years ago
* observation/effectiveTime/high – today

### Encounters

[guidance that encounter diagnosis belongs in the encounter section]

### 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

[guidance on differentiating between ordered medications and dispensed medications]

[guidance on medication boundaries – could perhaps be a general timestamp interval boundary guidance?]

[guidance on how to represent medications for discharge summaries]

### 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 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:

* effectiveTime/low – today
* effectiveTime/high – empty
* author/time – today
* observation/effectiveTime/low – five years ago
* 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:

* effectiveTime/low – a month ago
* effectiveTime/high – today
* author/time – today
* observation/effectiveTime/low – five years ago
* observation/effectiveTime/high – today

### 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.

### 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.

With the Medical Equipment section, the devices would be listed as part of the Procedure Activity Procedure template, either on its own or 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 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 entiry 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[[1]](#footnote-1) 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 of the person authoring/attesting the ToC document. These are the “tracked concerns” that the author decides should be 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.

The Problem Section should, by default, appear first in the C-CDA display. However, EHRs that receive the document are required (by certification requirements) to provide the capability for users to display only the Sections they want to see, in the sequence they want to see them.

#### 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.

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 Health Concerns section is only required to contain narrative. It may also contain structured entries or may contain no entries (except for the appropriate nullFlavor entries to satisfy C-CDA conformance for Health Concerns section).

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[[2]](#footnote-2) (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 plan *of the person authoring/attesting the ToC document*, typically a care provider such as a physician or nurse practitioner.

The Plan of Treatment 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* 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.[[3]](#footnote-4) 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.

[guidance about what effectiveTime means when used in the ResultsOrganizer vs in the observations themselves]

### Smoking Status vs. Tobacco Use

There are two templates used for specifying a patient’s smoking status and overall tobacco use. Smoking Status – Meaningful Use (3.100) is only 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. It **shall not** be used for identifying when the smoking status started.

To provide details of the patient’s smoking and overall tobacco use, the Tobacco Use section (3.107) shall be used. Within this section, the effectiveTime represents the 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. 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.

1. “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-1)
2. 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-2)
3. 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-4)