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HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1

Draft Standard for Trial Use

August 2015

Volume 1 — Introductory Material

Sponsored by:
Structured Documents Work Group
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SNOMED CT	International Healthcare Terminology Standards Developing Organization (IHTSDO) http://www.ihtsdo.org/snomed-ct/get-snomed-ct or info@ihtsdo.org
Logical Observation Identifiers Names & Codes (LOINC)	Regenstrief Institute
International Classification of Diseases (ICD) codes	World Health Organization (WHO)

Structure of This Guide

Two volumes comprise this *HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes*. Volume 1 provides narrative introductory and background material pertinent to this implementation guide, including information on how to understand and use the templates in Volume 2. Volume 2 contains the normative Clinical Document Architecture (CDA) templates for this guide along with lists of all templates, code systems, value sets, and changes from the previous version.

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1 INTRODUCTION

1.1 Purpose

This two-volume implementation guide (IG) contains an overview of Clinical Document Architecture (CDA) markup standards, design, and use (Volume 1) and a consolidated library of CDA templates for clinical notes applicable to the US Realm (Volume 2). These two volumes comprise a Draft Standard for Trial Use (DSTU).

It has been adapted from the Release 2.0 version of the Consolidated CDA Templates for Clinical Notes to support backward compatibility "on the wire" with the 1.1 Release of the templates described in this guide. This will enable implementers of systems conforming to this guide to produce documents that can be understood by systems which only support the C-CDA Release 1.1 specification.

The consolidated library incorporates previous efforts from Health Level Seven (HL7), Integrating the Healthcare Enterprise (IHE), the Health Information Technology Standards Panel (HITSP), the HL7 Health Story guides, HITSP C32, and related components of IHE Patient Care Coordination (IHE PCC). It has additional or enhanced document types for greater expressivity and decrease ambiguity (see Volume 2 Summary of Changes). Volume 1 adds new general guidance (see Volume 1 Summary of Changes).

This guide, in conjunction with the HL7 CDA Release 2 (CDA R2) standard, is to be used for implementing the following CDA documents and header constraints for clinical notes.

- Care Plan including Home Health Plan of Care (HHPoC)
- Consultation Note
- Continuity of Care Document (CCD)
- Diagnostic Imaging Reports (DIR)
- Discharge Summary
- History and Physical (H&P)
- Operative Note
- Procedure Note
- Progress Note
- Referral Note
- Transfer Summary
- Unstructured Document
- Patient Generated Document (US Realm Header)

1.2 Audience

The audience for this implementation guide includes architects and developers of healthcare information technology (HIT) systems in the US Realm that exchange patient clinical data. Business analysts and policy managers can also benefit from a basic understanding of the use of CDA templates across multiple implementation use cases.

1.3 Organization of the Guide

This implementation guide is organized into two volumes. Volume 1 contains primarily narrative text describing the Consolidated CDA Release 2 (C-CDA R2) guide, whereas Volume 2 contains normative CDA template definitions.

1.3.1 Volume 1 Introductory Material

This document, Volume 1, provides an overview of Clinical Document Architecture (CDA), summaries of recent changes to the standard, and information on how to understand and use the CDA templates provided in Volume 2.

- **Chapter 1**—Introduction
- **Chapter 2**—CDA R2 Background. This section contains selected background material on the CDA R2 base standard, to aid the reader in conceptualizing the "templated CDA" approach to implementation guide development.
- **Chapter 3**—Design Considerations. This section includes design considerations that describe overarching principles that have been developed and applied across the CDA templates in this guide. Material in this section can be thought of as "heuristics", as opposed to the formal and testable constraints found in Volume 2 of this guide.
- **Chapter 4**—Using This Implementation Guide. This section describes the rules and formalisms used to constrain the CDA R2 standard. It describes the formal representation of CDA templates, the mechanism by which templates are bound to vocabulary, and additional information necessary to understand and correctly implement the normative content found in Volume 2 of this guide.
- **Appendices**. The Appendices include a high-level change log, a summary of extensions to CDA R2, an excerpt of the Claims Attachments Implementation Guide covering Mime Multipart/Related Messages, and additional information.

1.3.2 Volume 2 CDA Templates and Supporting Material

Volume 2 includes CDA templates and prescribes their use for a set of specific document types. The main chapters are:

- **Chapter 1**—Document-Level Templates. This chapter defines the US Realm Header template for that applies across all of the consolidated document types. It defines each of the document types and header constraints specific to each as well as the section-level templates (required and optional) for each.

- **Chapter 2**—Section-Level Templates. This chapter defines the section templates referenced within the document types. Sections are atomic units, and can be reused by future specifications.
- **Chapter 3**—Entry-Level Templates. This chapter defines entry-level templates, called clinical statements. Machine processable data are sent in the entry templates. The entry templates are referenced by one or more section templates. Entry-level templates are always contained in section-level templates, and section-level templates are always contained in a document. Entries are atomic units, and can be reused by future specifications.
- **Chapter 4**—Participation and Other Templates. This chapter defines templates for CDA participants (e.g., author, performer) and other fielded items (e.g., address, name) that cannot stand on their own without being nested in another template.
- **Chapter 5**—Template Ids in This Guide
- **Chapter 6**—Value Sets in This Guide
- **Chapter 7**—Code Systems in This Guide

1.4 Contents of the Package

The following files comprise this implementation guide package:

Table 1: Contents of the Review Package

Filename	Description	Standards Applicability
CDAR2_IG_CCDA_CLINNOTES_R1_DSTU2.1_2015AUG_Vol1_Introductory_Material.docx	Implementation Guide Introductory Material	Normative
CDAR2_IG_CCDA_CLINNOTES_R1_DSTU2.1_2015AUG_Vol2_Templates_and_Supporting_Material.docx	Implementation Guide Template Library and Supporting Material	Normative
C-CDA R1.1 vs 2.0 Reviews.zip	Detailed comparison of C-CDA R1.1 versus R2.0 and updates made for C-CDA R2.1	Informative
C-CDA_R2-1_CCD.xml	Continuity of Care Document sample files	Informative
Link to SDWG SVN for other technical artifacts		Informative

2 CDA R2 BACKGROUND

CDA R2 is "… a document markup standard that specifies the structure and semantics of 'clinical documents' for the purpose of exchange" [CDA R2, Section 1.1][1]. Clinical documents, according to CDA, have the following characteristics:

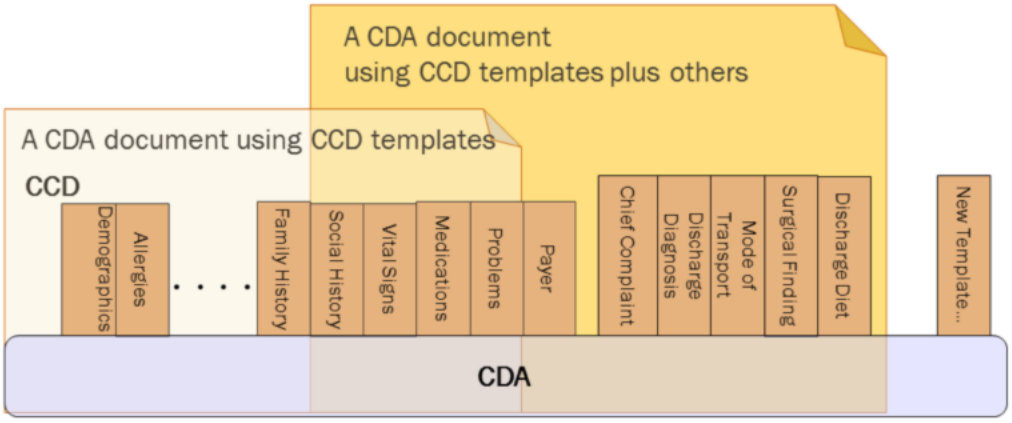
- Persistence
- Stewardship
- Potential for authentication
- Context
- Wholeness
- Human readability

CDA defines a header for classification and management and a document body that carries the clinical record. While the header metadata are prescriptive and designed for consistency across all instances, the body is highly generic, leaving the designation of semantic requirements to implementation.

2.1 Templated CDA

CDA R2 can be constrained by mechanisms defined in the "Refinement and Localization"[2] section of the *HL7 Version 3 Interoperability Standards*. The mechanism most commonly used to constrain CDA is referred to as a "CDA template." The "templated CDA" approach uses a library of modular CDA template definitions. Templates can be reused across any number of CDA document types, as shown in the following figure. Each template meets a defined purpose. Templates are managed over time through versioning. A template version is a specific set of conformance constraints designed to meet the template's purpose.

Figure 1: Templated CDA



[1] *HL7 CDA Release 2.* http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7
[2] http://www.hl7.org/v3ballot/html/infrastructure/conformance/conformance.htm

There are many kinds of templates that might be created. Among them, the most common are:

- **Document-level templates:** These templates constrain fields in the CDA header, and define containment relationships to CDA sections. For example, a History and Physical document-level template might require that the patient's name be present, and that the document contain a Physical Exam section.
- **Section-level templates:** These templates constrain fields in the CDA section, and define containment relationships to CDA entries. For example, a Physical Exam section-level template might require that the section/code be fixed to a particular LOINC code, and that the section contains a Systolic Blood Pressure observation.
- **Entry-level templates:** These templates constrain the CDA clinical statement model in accordance with real-world observations and acts. For example, a Systolic Blood Pressure entry-level template defines how the CDA Observation class is constrained (how to populate observation/code, how to populate observation/value, etc.) to represent the notion of a systolic blood pressure.
- **Other templates:** Templates that exist to establish a set of constraints that are reused in the CDA document. These other templates are only used within another template, rather than on their own as a complete clinical statement. For example, US Realm Date and Time (DTM.US.FIELDED) includes a set of common constraints for recording time. This template is referenced several times with other templates used in the implementation guide. They reduce the need to repeat constraints in templates that use the common set.

A CDA implementation guide (such as this one) includes references to those template versions that are applicable.

Regarding implementation, a CDA instance populates the template identifier (`templateId`) field where it wants to assert conformance to a given template version. On the receiving side, the recipient can then not only test the instance for conformance against the CDA Extensible Markup Language (XML) schema, but also test the instance for conformance against asserted templates.

2.1.1 Status of a Template Version

Each version of a template has a status. For example, a template version can be draft, active, or deprecated, etc. The HL7 Templates DSTU describes the various status states that may apply to a template version over the course of its lifecycle. Each version of a template has an associated status. Thus, one version of a template may be deprecated, while a newer version of that template may be draft or active.

2.1.1.1 Use of Deprecated Template Versions

Several templates used in C-CDA 1.1 were deprecated as of C-CDA R2. The status for these templates remains deprecated in this guide. Deprecation of a template version does not prohibit its use in a document; rather, it is a signal to implementers this version of the template may be permanently retired (terminated) in the future, which will end the lifecycle for the template. The list of deprecated templates appears below:

- Discharge Diet Section
- Implants Section
- Surgery Description Section
- Allergy Status Observation
- Cognitive Status Problem Observation
- Functional Status Problem Observation
- Pressure Ulcer Observation
- Problem Status

2.2 Current Project

This R2.1 guide was developed and produced by the HL7 Structured Documents Workgroup. It updates the C-CDA R2 (2014) guide to support "on-the-wire" compatibility with R1.1 systems.

The C-CDA Release 2.0 implementation guide was developed and produced through the joint efforts of HL7, two Sub-Work Groups of the Office of the National Coordinator (ONC) Standards and Interoperability (S&I) Framework — Longitudinal Care Plan (LCP) and Long-Term Post-Acute Care (LTPAC) Transition) — and through the SMART C-CDA Collaborative hosted by ONC and Harvard Medical School. This guide builds off of two earlier versions: C-CDA R1 (2011) and C-CDA R1.1 (2012)[3].

The ONC Longitudinal Care Coordination Standards and Interoperability (LCC S&I) Work Group and community providers identified a set of priority data elements for shared care and transfer of care for a patient moving from one setting to another. These data elements identified gaps in the existing CDA document types. The current project incorporates these data elements into this implementation guide. Three new document types (Referral Note, Transfer Summary, and Care Plan) and one existing document type (Consultation Note) address the gaps.

The S&I Framework's LCC Long-Term Post-Acute Care (LTPAC) Transition Sub Work Group (SWG) defined the data elements and assisted in the design of the CDA templates to properly express the concepts in the CDA representation of the Referral Note, Transfer Summary, and Consultation Note. The group's related work products can be found at the LCC Long-Term Post-Acute Care (LTPAC) Transition SWG website.[4]

The S&I Framework's LCC Longitudinal Care Plan (LCP) SWG defined the data elements and assisted in the design of the CDA templates to properly express the concepts in the CDA representation of the Care Plan. The group's related work can be found at the LCC

[3] *HL7 CDA2 IHE Health Story Consolidation.* http://www.hl7.org/documentcenter/private/standards/cda/CDAR2_IG_IHE_CONSOL_DSTU_R1dot1_2012JUL.zip

[4] S&I Framework, LCC LTPAC Transition SWG. http://wiki.siframework.org/LCC+Long-Term+Post-Acute+Care+%28LTPAC%29+Transition+SWG).

Longitudinal Care Plan (LCP) SWG website.[5] In addition, the LCP SWG worked with the HL7 Patient Care Work Group (PCWG) during development of the HL7 Care Plan Domain Analysis Model (DAM). The HL7 PCWG's related work can be found at the HL7 Care Plan DAM website.[6] The IHE PCC Work Group products were reviewed and many participants in the Work Group also participated in the S&I design sessions. The key work reviewed can be found in the IHE Patient Care Plan Content Profile.[7] All of these works and group discussions created the design of the CDA Care Plan, which is a static reflection of a dynamic care plan at a point in time.

Diverse document types meet varied types of patient care and coordination needs. The Transfer Summary document is exchanged by healthcare providers in instances when a patient moves between health care settings and care teams temporarily or permanently (e.g., long term care facility to hospital, hospital to skilled nursing facility or home health agency, or from one Primary Care Physician to a new Primary Care Physician). The Transfer Summary provides comprehensive information regarding the patient's history, current status, and care plan.

The Continuity of Care Document (CCD) is a subset of the Transfer Summary and contains just the most clinically important patient information. It is a snapshot in time and may be generated for a single visit or a set of visits. The CCD can be used as an alternative to the Transfer Summary when minimal information needs to be conveyed, or for reporting updates to clinical registries and centralized data repositories.

In cases when a provider requests consultation from another provider, a Referral Note document is exchanged to communicate the referral request and pertinent patient information. When the consultation is completed, the consulting provider may generate a Consultation Note to inform the requesting clinician of her opinion or advice. A patient with complex needs requires the care of multiple providers in various settings. In this situation, a Care Plan document provides a snapshot in time of current health concerns, goals, interventions and care coordination activities amongst providers, the patient, and the patient's caregivers.

The ONC-sponsored SMART (Substitutable Medical Apps and Reusable Technologies) project[8], in an effort to make C-CDA instances more reliably consumable by SMART applications for mobile devices, has analyzed real world C-CDA instances and identified common sources of ambiguity and misinterpretation. Many of the clarifications to C-CDA R1.1 templates, included here as C-CDA R2, are as a direct result of the SMART analysis.

[5] S&I Framework, LCC LCP SWG.
http://wiki.siframework.org/LCC+Longitudinal+Care+Plan+%28LCP%29+SWG
[6] HL7, Care Plan. http://wiki.hl7.org/index.php?title=Care_Plan
[7] IHE, Patient Care Plan Content Profile.
http://www.ihe.net/uploadedFiles/Documents/PCC/IHE_PCC_Suppl_PtCP.pdf
[8] SMART Platforms. http://smartplatforms.org

3 DESIGN CONSIDERATIONS

Design considerations describe overarching principles that have been developed and applied across the CDA templates in this guide. Material in this section can be thought of as "heuristics," as opposed to the formal, testable constraints found in Volume 2 of this guide.

3.1 Compatibility

This release contains new versions of templates included in C-CDA Release 2.0. Templates in this specification provide compatibility for software that supports template versions in the C-CDA R1.1 Implementation Guide. The new compatible template versions contain constraint modifications which enable compatibility with C-CDA 1.1. The constraints updated for C-CDA R2.1 are identified in the appendix Volume 2 Summary of Changes.

C-CDA Release 2.0 includes several templates not previously present in C-CDA Release 1.1. Software designed to support C-CDA Release 1.1 template versions may not support the new templates introduced in C-CDA Release 2.0. Except where explicitly prohibited by the C-CDA 1.1 specification, use of templates first released as part of C-CDA Release 2.0 is permitted.

New systems that wish to support C-CDA R1.1, R2.0, and R2.1, should review all specifications. A system developed strictly to the R2.1 version might not automatically support receiving R1.1 documents without additional development. Support for R2.0 conformant documents will require additional generation and import effort since different vocabulary requirements apply in several places.

Compatibility Principles

The baseline for C-CDA Release 2.1 is C-CDA Release 2.0. HL7 has applied these principles against templates present in C-CDA Release 1.1 and C-CDA R2.0 to create compatible template versions:

1. When a SHALL constraint present in C-CDA R1.1 is relaxed to SHOULD or MAY in C-CDA R2.0, the C-CDA R2.1 specification will increase the strength of that constraint to SHALL when compatibility is asserted.
2. When a SHALL constraint present is C-CDA R1.1 is removed in C-CDA R2.0, the C-CDA R2.1 specification will add that constraint when supporting compatibility.
3. When a SHOULD or MAY constraint present in C-CDA R1.1 is relaxed or removed in C-CDA R2.0, the C-CDA R2.1 specification will remain silent. As these constraints are not strictly required in a C-CDA R1.1 instance, they are not necessary for backwards compatibility. Implementers who wish to continue to convey data elements with a SHOULD or MAY constraint in C-CDA R1.1 can still report this information as it was done in C-CDA R1.1, so long as these are also conformant with this specification.
4. A SHALL, SHOULD or MAY constraint added in C-CDA R2.0 that is not explicitly prohibited in C-CDA R1.1 will be added to C-CDA R2.1.

5. When a vocabulary or value set binding has changed for an element to a new coding system in C-CDA R2.0, C-CDA R2.1 will — when supporting backwards compatibility — require the use of the old value set or vocabulary in *element*/code, the new value set or vocabulary in *element*/translation, and otherwise require the use of the new value set or vocabulary in code as it was constrained (with the same strength appearing) in C-CDA R2.0.

3.1.1 Support for specifications with dependencies on C-CDA Release 2.0

There are two options for other specifications that have built upon C-CDA Release 2.0:

1. Reference the C-CDA R2.1 implementation guide and the template versions defined herein, in order to ensure backward compatibility for software compliant with C-CDA R1.1.
2. Reference the C-CDA R2.0 implementation guide and the templates contained therein to support software that does not require backward compatibility. Software designed to receive documents conformant to C-CDA R2.0 or C-CDA R2.1 template versions will need to support vocabulary bindings that allow value set concepts to appear in either the code or the translation element.

The SDWG strongly encourages specifications built on C-CDA R2.0 to adopt option 1 since option 2 increases variability across implementations. After final publication of R2.1 SDWG will contact developers of prior specifications, which reference C-CDA R2.0, to discuss migration plans.

3.1.2 Assertion of Compatibility

Volume 2 of this guide includes a requirement that all C-CDA R2.1 conformant instances:

- Include a C-CDA R2.1 templateId,
- Additionally, when the C-CDA R2.1 templateId includes an extension, the C-CDA R1.1 templateId must also be included.

By including both templateIds the sending application is asserting conformance with C-CDA R2.1 and C-CDA R1.1. This requirement (CONF:32936) is included in the US Realm Header (V3):

SHALL contain exactly one [1..1] **templateId** (CONF:1198-5252) such that it

a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.1.1" (CONF:1198-10036).
b. **SHALL** contain exactly one [1..1] **@extension**="2015-08-01" (CONF:1198-32503).
c. When asserting this templateId, all document, section, and entry templates **SHALL** include a templateId root without an extension. See C-CDA R2.1 Volume 1 - Design Considerations for additional detail (CONF:1198-32936).

Figure 2: C-CDA R2.1 Discharge Summary header example

```
<ClinicalDocument xmlns="urn:hl7-org:v3"
                  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
                  xmlns:cda="urn:hl7-org:v3" xmlns:sdtc="urn:hl7-org:sdtc">

  <!-- ** CDA Header ** -->
  <realmCode code="US"/>
  <typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>

  <!-- US General Header Template -->
  <templateId root="2.16.840.1.113883.10.20.22.1.1" extension="2015-08-01"/>
  <!--Critical Change for backwards compatibility-->
  <templateId root="2.16.840.1.113883.10.20.22.1.1"/>

  <!-- *** Note: The next templateId, code and title will differ depending on
               what type of document is being sent. *** -->
  <templateId root="2.16.840.1.113883.10.20.22.1.8" extension="2015-08-01"/>
  <!--For backwards compatibility-->
  <templateId root="2.16.840.1.113883.10.20.22.1.8"/>
...
```

Figure 3: C-CDA R2.1 Problem List Section example

```
<section>
  <templateId root="2.16.840.1.113883.10.20.22.2.5.1"
              extension="2014-06-09"/>
  <!--For backwards compatibility-->
  <templateId root="2.16.840.1.113883.10.20.22.2.5.1"/>

  <code code="11450-4" codeSystem="2.16.840.1.113883.6.1"
                       displayName="Problem List"/>
  <title>Problem List</title>
...
```

Figure 4: C-CDA R2.1 Problem Concern Entry example

```
<entry>
  <act classCode="ACT" moodCode="EVN">
    <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"/>
    <id root="102ca2e9-884c-4523-a2b4-1b6c3469c397"/>
    <code code="CONC" codeSystem="2.16.840.1.113883.5.6"/>
...
```

3.2 CDA Participations

A CDA participant (e.g., Author, Informant), per the Reference Information Model (RIM), is “an association between an Act and a Role with an Entity playing that Role. Each

Entity (in a Role) involved in an Act in a certain way is linked to the Act by one Participation-instance. The kind of involvement in the Act is specified by the Participation.typeCode."

CDA principles when asserting participations include:

- **Participation persistence:** An object's participations (and participation time stamps) don't change just because that object is reused. For instance, authorship of an object doesn't change just because that object is now included in a summary document.
- **Participation evolution:** Additional participations (and participation time stamps) can be ascribed to an object over its lifetime. (In some cases, an electronic health record (EHR) system will create a new object instead of adding participants to an existing object, such as when an EHR has imported a CCD and the receiving clinician chooses to create a local problem list entry corresponding to a problem in the CCD).
- **Device participation:** Devices do not participate as legally responsible entities, but can participate as authors in some scenarios.

Meaningful Use Stage 2[9] criterion §170.314(b)(4) Clinical Information Reconciliation requires a system to "simultaneously display (i.e., in a single view) the data from at least two list sources in a manner that allows a user to view the data and their attributes, which must include, at a minimum, the **source** and **last modification date**."

CDA addresses this requirement via the Author Participation and its time stamp. CDA requires that Author and Author time stamp be asserted in the document header. From there, authorship propagates to contained sections and contained entries, unless explicitly overridden. Thus, all entries in CDA implicitly include Author and Author time stamp.

In this version of CDA, we have added a new Author Participation template (templateId 2.16.840.1.113883.10.20.22.4.119) to better ensure consistent representation. This template should be used to explicitly assert authorship and author time stamps, unless the values propagated from the document header hold true.

3.3 Determining the Status of Clinical Statement

A recipient must be able to determine whether the status of an entry — which can include a problem, a medication administration, etc. — is active, completed, or in some other state. Determination of the exact status is dependent on the interplay between an act's various components (such as `statusCode` and `effectiveTime`), and inconsistent modeling between different objects.

The following principles apply when representing or interpreting a clinical statement's status.

- **`The Act.statusCode` of the clinical statement specifies the state of the entry**: Per the RIM, the `statusCode` "reflects the state of the activity. In the

[9] US HHS, HIT. http://www.gpo.gov/fdsys/pkg/FR-2012-09-04/pdf/2012-20982.pdf

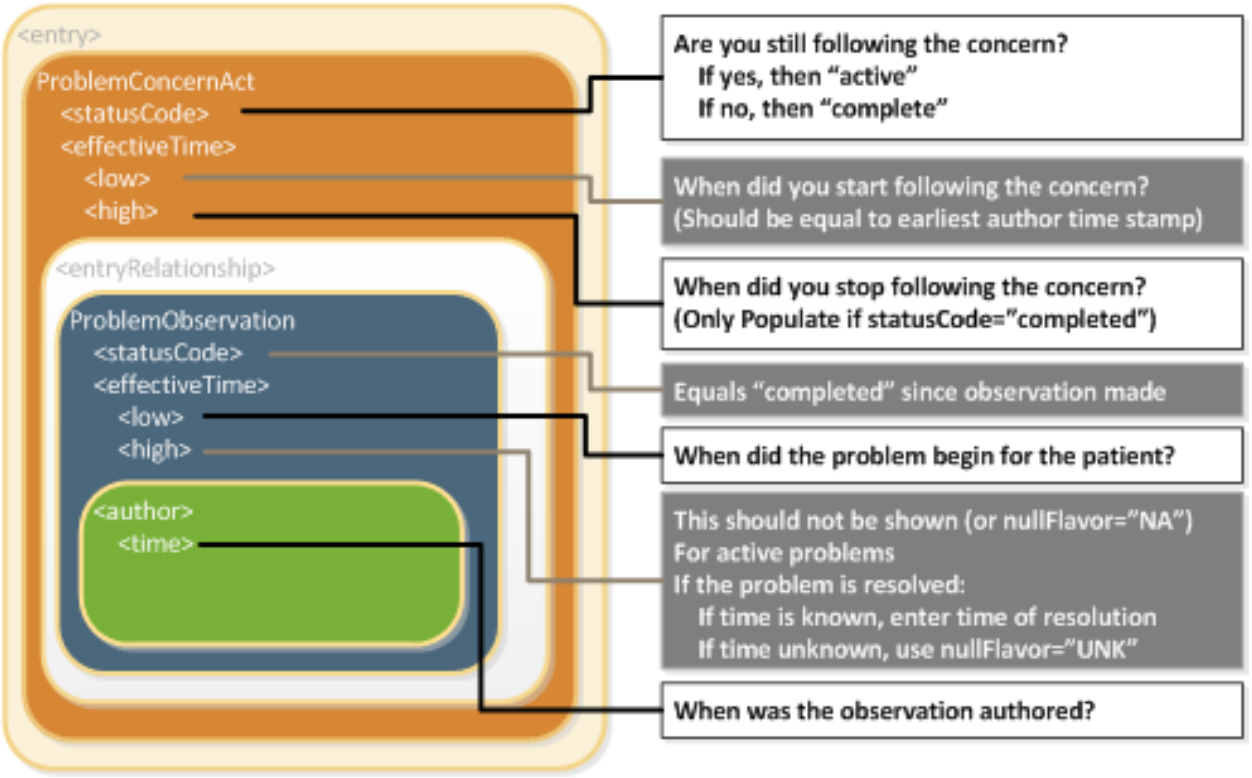
case of an Observation, this is the status of the activity of observing, not the status of what is being observed."

- **`Act.statusCode` and `Act.moodCode` are inter-related**: Generally, an act in EVN (event) mood is a discrete event (a user looks, listens, measures; records what was done or observed), so generally an act in EVN mood will have a `statusCode` of "completed." A prolonged period of observation is an exception, in which a user would potentially have an observation in EVN mood that is "active." For an Observation in RQO (request) mood, the `statusCode` generally remains "active" until the request is complete, at which time the `statusCode` changes to "completed." For an Observation in GOL (goal) mood, the `statusCode` generally remains "active" as long as the observation in question is still an active goal for the patient.
- **`Act.statusCode` and `Act.effectiveTime` are inter-related**: Per the RIM, the `effectiveTime`, also referred to as the "biologically relevant time," is the time at which the act holds for the patient. So, whereas the `effectiveTime` is the biologically relevant time, the `statusCode` is the state of the activity. For a provider seeing a patient in a clinic and observing a history of heart attack that occurred 5 years ago, the status of the observation is completed, and the `effectiveTime` is five years ago.

The Problem Concern Act (V2) (templateId 2.16.840.1.113883.10.20.22.4.3:2014-06-09) reflects an ongoing concern on behalf of the provider who placed the concern on a patient's problem list. So long as the provider has an ongoing concern — meaning that the provider is monitoring the condition, whether it includes problems that have resolved or not — the `statusCode` of the Problem Concern Act is "active." When the underlying condition is no longer an active concern, the `statusCode` of the Problem Concern Act is set to "completed." The `effectiveTime` of a Problem Concern Act reflects the time that the concern about an underlying condition — as such, the effectiveTime of the concern may not correspond to the `effectiveTime` of the condition. For example, a patient may have suffered a heart attack 5 years ago, but a physician may continue to have an active concern about the patient's cardiac condition.

A Problem Concern Act can contain one or more Problem Observations (templateId 2.16.840.1.113883.10.20.22.4.4:2014-06-09). Each Problem Observation is a discrete observation of a condition and therefore has a `statusCode` of "completed." The `statusCode` of the Problem Concern Act is the definitive indication of the status of the concern. The `effectiveTime` of the Problem Observation is the definitive indication of whether the underlying condition is resolved. This is shown graphically in the following figure.

Figure 5: Problem Concern Act



C-CDA 1.1 included several optional "status" observation templates such as Problem Status Observation and Allergy Status Observation. These "status" observation templates were deprecated when C-CDA R2.0 was released. (For more about deprecated templates, see the section titled Use of Deprecated Template Versions). In C-CDA R2.1, the "status" observation templates remain deprecated. To support backward compatibility, systems that consume CDA documents need to address the possibility that a "status" observation template may also be present. The following guidance should be followed if a CDA document includes a deprecated status observation:

Deprecated "status" observation template	**Implementer Guidance**
A status of "active"	If the parent Observation has an effectiveTime/high, the content contains conflicting information.
A status of "resolved"	If the parent Observation does not have an effectiveTime/high, the content contains conflicting information.
A status of "inactive"	If the parent Observation does not have an effectiveTime/high, the content has the potential to contain conflicting information.

3.4 Rendering Header Information for Human Presentation

Metadata carried in the header may already be available for rendering from EHRs or other sources external to the document. An example of this would be a doctor using an EHR that already contains the patient's name, date of birth, current address, and phone number. When a CDA document is rendered within that EHR, those pieces of information may not need to be displayed since they are already known and displayed within the EHR's user interface.

Good practice recommends that the following be present whenever the document is viewed:

- Document title and document dates
- Service and encounter types, and date ranges as appropriate
- Names of all persons along with their roles, participations, participation date ranges, identifiers, address, and telecommunications information
- Names of selected organizations along with their roles, participations, participation date ranges, identifiers, address, and telecommunications information
- Date of birth for `recordTarget`(s)
- Patient identifying information

In Operative and Procedure Notes, the following information is typically displayed in the EHR and/or rendered directly in the document:

- The performers of the surgery or procedure, including any assistants
- The surgery or procedure performed (`serviceEvent`)
- The date of the surgery or procedure

3.5 Narrative Reference

The C-CDA R1.1 release recommended that clinical statements include a link between the narrative (section.text) and coded clinical data (entry). Rather than repeat these constraints in every applicable entry, SDWG agreed in R2.0 to apply the following constraint to all entry templates, unless explicitly prohibited.

SHOULD contain zero or one [0..1] **text** (CONF:XXXX).

a. The text, if present, **SHOULD** contain zero or one [0..1] **reference/@value** (CONF: XXXX).

   i. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA R2.0, section 4.3.5.1) (CONF: XXXX).

MAY contain zero or one [0..1] original**Text** (CONF:XXXX).

a. The originalText, if present, **SHOULD** contain zero or one [0..1] **reference/@value** (CONF:XXXX).

i. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA R2.0, section 4.3.5.1) (CONF:XXXX).

3.6 Unknown and No Known Information

Information technology solutions store and manage data, but sometimes data are not available. An item may be unknown, not relevant, or not computable or measureable, such as where a patient arrives at an emergency department unconscious and with no identification.

In many cases, the C-CDA standard will stipulate that a piece of information is required (e.g., via a SHALL conformance verb). However, in most of these cases, the standard provides an "out", allowing the sender to indicate that the information isn't known.

Here, we provide guidance on representing unknown information. Further details can be found in the HL7 V3 Data Types Release 1 specification that accompanies the CDA R2 normative standard. However, it should be noted that the focus of Consolidated CDA is on the unambiguous representation of known data, and that in general, the often subtle nuances of unknown information representation are less relevant to the recipient.

Many fields in C-CDA contain a "@nullFlavor" attribute, used to indicate an exceptional value. Some flavors of Null are used to indicate that the known information falls outside of value set binding constraints. Not all uses of the @nullFlavor attribute are associated with a case in which information is unknown. Allowable values for populating the attribute give details about the reason the information is unknown, as shown in the following example.

Figure 6: nullFlavor Example

```
<birthTime nullFlavor="UNK"/>   <!--Sender does not know the birthTime, but a
proper value is applicable -->
```

Use null flavors for unknown, required, or optional attributes:

NI	No information. This is the most general and default null flavor.
NA	Not applicable. Known to have no proper value (e.g., last menstrual period for a male).
UNK	Unknown. A proper value is applicable, but is not known.
ASKU	Asked, but not known. Information was sought, but not found (e.g., the patient was asked but did not know).
NAV	Temporarily unavailable. The information is not available, but is expected to be available later.
NASK	Not asked. The patient was not asked.

MSK There is information on this item available but it has not been provided by the sender due to security, privacy, or other reasons. There may be an alternate mechanism for gaining access to this information.

OTH The actual value is not an element in the value domain of a variable. (e.g., concept not provided by required code system).

The list above contains those null flavors that are commonly used in clinical documents. For the full list and descriptions, see the `nullFlavor` vocabulary domain in the CDA R2 normative edition.[10]

Any **SHALL**, **SHOULD** or **MAY** conformance statement may use `nullFlavor`, unless the `nullFlavor` is explicitly disallowed (e.g., through another conformance statement which includes a **SHALL** conformance for a vocabulary binding to the @code attribute, or through an explicit **SHALL NOT** allow use of `nullFlavor` conformance).

Figure 7: Attribute Required (nullFlavor not allowed)

1. **SHALL** contain exactly one [1..1] `code` (CONF:15407).
   a. This `code` **SHALL** contain exactly one [1..1] **`@code`**="`11450-4`" Problem List (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:15408).

   or

2. **SHALL** contain exactly one [1..1] **`effectiveTime/@value`** (CONF:5256).

Figure 8: Allowed nullFlavors When Element is Required (with xml examples)

1. **SHALL** contain at least one `[1..*] id`
2. **SHALL** contain exactly one `[1..1] code`
3. **SHALL** contain exactly one `[1..1] effectiveTime`

```
<entry>
  <observation classCode="OBS" moodCode="EVN">
    <id nullFlavor="NI"/>
    <code nullFlavor="OTH">
      <originalText>New Grading system</originalText>
    </code>
    <statusCode code="completed"/>
    <effectiveTime nullFlavor="UNK"/>
    <value xsi:type="CD" nullFlavor="OTH">
      <originalText>Spiculated mass grade 5</originalText>
    </value>
  </observation>
</entry>
```

[10] *HL7 CDA Release 2.* http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7

If a sender wants to state that a piece of information is unknown, the following principles apply:

1. If the sender doesn't know an attribute of an act, that attribute can be null.

Figure 9: Unknown Medication Example

1. **SHALL** contain exactly one `[1..1] code`

```
<entry>
  <text>patient was given a medication but I do not know what it was</text>
  <substanceAdministration moodCode="EVN" classCode="SBADM">
    <consumable>
      <manufacturedProduct>
        <manufacturedLabeledDrug>
          <code nullFlavor="NI"/>
        </manufacturedLabeledDrug>
      </manufacturedProduct>
    </consumable>
  </substanceAdministration>
</entry>
```

2. If the sender doesn't know if an act occurred, the `nullFlavor` is on the act (detail could include specific allergy, drug, etc.).

Figure 10: Unknown Medication Use of Anticoagulant Drug Example

```
<entry>
  <substanceAdministration moodCode="EVN" classCode="SBADM" nullFlavor="NI">
    <text>I do not know whether or not patient received an anticoagulant
          drug</text>
    <consumable>
      <manufacturedProduct>
        <manufacturedLabeledDrug>
          <code code="81839001" displayName="anticoagulant drug"
                codeSystem="2.16.840.1.113883.6.96"
                codeSystemName="SNOMED CT"/>
        </manufacturedLabeledDrug>
      </manufacturedProduct>
    </consumable>
  </substanceAdministration>
</entry>
```

3. If the sender wants to state "no known", a `negationInd` can be used on the corresponding act (`substanceAdministration`, `Procedure`, etc.)

   Previously, CCD, IHE, and HITSP recommended using specific codes to assert no known content, for example `160244002 No known allergies` or `160245001 No current problems or disability`. Specific codes are still allowed; however, use of these codes is not recommended.

   These next examples illustrate nuances of representing information in coded fields when information is a negative assertion, for example it is not the case that the patient has an allergy or it is not the case that a patient takes a medication. The phrases "no known allergies" or "no known medications" are typically associated with this type of negative assertion.

Figure 11: No Known Medications Example

```
<entry>
  <substanceAdministration moodCode="EVN" classCode="SBADM" negationInd=”true”>
    <text>No known medications</text>
    <consumable>
      <manufacturedProduct>
        <manufacturedLabeledDrug>
          <code code="410942007" displayName="drug or medication"
                codeSystem="2.16.840.1.113883.6.96"
                codeSystemName="SNOMED CT"/>
         </manufacturedLabeledDrug>
       </manufacturedProduct>
     </consumable>
  </substanceAdministration>
</entry>
```

Figure 12: Value Known, Code for Value Not Known

```
<entry>
  <observation classCode="OBS" moodCode="EVN">
    …
    <value xsi:type="CD" nullFlavor="OTH">
      <originalText>Spiculated mass grade 5</originalText>
    </value>
  </observation>
</entry>
```

Figure 13: Value Completely Unknown

```
<entry>
  <observation classCode="OBS" moodCode="EVN">
    …
    <value xsi:type="CD" nullFlavor="UNK"/>
  </observation>
</entry>
```

Figure 14: Value Known, Code in Required Code System Not Known But Code from Another Code System is Known

```
<entry>
  <observation classCode="OBS" moodCode="EVN">
    …
    <value xsi:type="CD" nullFlavor="OTH">
      <originalText>Spiculated mass grade 5</originalText>
      <translation code="129742005" displayName="spiculated lesion"
                codeSystem="2.16.840.1.113883.6.96"
                codeSystemName="SNOMED CT"/>/>
    </value>
  </observation>
</entry>
```

4 USING THIS IMPLEMENTATION GUIDE

This chapter describes the rules and formalisms used to constrain the CDA R2 standard. It describes the formal representation of CDA templates, the mechanism by which templates are bound to vocabulary, and additional information necessary to understand and correctly implement the normative content found in Volume 2 of this guide.

4.1 Levels of Constraint

The CDA standard describes conformance requirements in terms of three general levels corresponding to three different, incremental types of conformance statements:

- Level 1 requirements impose constraints upon the CDA Header. The body of a Level 1 document may be XML or an alternate allowed format. If XML, it must be CDA-conformant markup.
- Level 2 requirements specify constraints at the section level of a CDA XML document: most critically, the section code and the cardinality of the sections themselves, whether optional or required.
- Level 3 requirements specify constraints at the entry level within a section. A specification is considered "Level 3" if it requires any entry-level templates.

Note that these levels are rough indications of what a recipient can expect in terms of machine-processable coding and content reuse. They do not reflect the level or type of clinical content, and many additional levels of reusability could be defined.

The contexts table for each document type lists the sections defined in the document template.

4.2 Conformance Conventions Used in This Guide

4.2.1 Templates and Conformance Statements

Conformance statements within this implementation guide are presented as constraints from Trifolia Workbench, a template repository. An algorithm converts constraints recorded in Trifolia to a printable presentation. Each constraint is uniquely identified by an identifier at or near the end of the constraint (e.g., CONF:86-7345). The digits in the conformance number before the hyphen identify which implementation guide the template belongs to and the number after the hyphen is unique to the owning implementation guide. Together, these two numbers uniquely identify each constraint. These identifiers are persistent but not sequential. Conformance numbers in this guide associated with a conformance statement that is carried forward from a previous version of this guide will carry the same conformance number from the previous version. This is true even if the previous conformance statement has been edited. If a conformance statement is entirely new it will have a new conformance number.

Bracketed information following each template title indicates the template type (section, observation, act, procedure, etc.), the object `identifier (OID)` or `uniform resource`

name (URN), and whether the template is open or closed. The identifier OID is the templateId/@root value; all templateIds have an @root value. Versioned templates also have an @extension value, which is a date identifying the version of this template; such templates are identified by URN and the HL7 version (urn:hl7ii). The URN identifier includes both the @root and @extension value for the templateId (for example, identifier urn:hl7ii:2.16.840.1.113883.10.20.5.5.41:2014-06-09).

Each section and entry template in Volume 2 of this guide includes a context table. The "Contained By" column indicates which templates use this template, and if the template is optional or required in the containing template. The "Contains" column indicates any templates that the template uses.

Table 2: Contexts Table Example—Allergy Concern Act (V2)

Contained By:	Contains:
Allergies and Intolerances Section (entries optional) (V2) (optional) Allergies and Intolerances Section (entries required) (V2) (required)	Allergy - Intolerance Observation (V2) Author Participation

Each entry template also includes a constraints overview table to summarize the constraints in the template.

Table 3: Constraints Overview Example—Allergy Concern Act (V2)

XPath	Card.	Verb	Data Type	CONF#	Value
act (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.30:2014-06-09)					
@classCode	1..1	SHALL		1098-7469	2.16.840.1.113883.5.6 (HL7ActClass) = ACT
@moodCode	1..1	SHALL		1098-7470	2.16.840.1.113883.5.1001 (ActMood) = EVN
templateId	1..1	SHALL		1098-7471	
@root	1..1	SHALL		1098-10489	2.16.840.1.113883.10.20.22.4.30
@extension	1..1	SHALL		1098-32543	2014-06-09
...					

The expression “such that it” at the end of one conformance statement links that conformance statement to the following subordinate conformance statement to further constrain the first conformance statement. To understand the full effect of this conformance construct, the two conformances must be considered as a single compound requirement. The subordinate conformance statement functions as a subordinate clause (like a "where" clause), which is being applied on the first conformance statement.

The following example shows a compound conformance statement made up of two conformance statements joined by a "such that it" clause. The effect of this syntax can be interpreted as a "where" clause. Thus…

2. **SHALL** contain exactly one [1..1] **templateId** (CONF:81-7899) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.31" (CONF:81-10487).

...is understood as:

> This template **SHALL** contain exactly one [1..1] **templateId** where it contains exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.31".

This means that you must have a template id with **@root**="2.16.840.1.113883.10.20.22.4.31", but you can also have other template ids with different valued attributes.

The following figure shows a typical template's set of constraints presented in this guide. The next chapters describe specific aspects of conformance statements—open vs. closed templates, conformance verbs, cardinality, vocabulary conformance, containment relationships, and null flavors.

Figure 15: Constraint Conformance Including "such that it" Syntax Example

Age Observation

[observation: identifier urn:oid:2.16.840.1.113883.10.20.22.4.31 (open)]

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:81-7613).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:81-7614).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:81-7899) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.31" (CONF:81-10487).

...

4.2.2 Template Versioning

A new version of an existing implementation guide reuses templates from the previous version. During the ballot phase or update phase, templates carry the designation "Published" to indicate the template is unchanged from the previous version or "Draft" to indicate a new or revised template. Substantial revisions to previously published templates are indicated by the version number (V2, V3, etc.) in all phases: ballot, update, and published guides.

If there are no substantive changes to a template that has been successfully published, the template will carry the same templateId/@root (identifier oid) and templateId/@extension as in the previous implementation guide. (In the case of older templates, the @extension attribute will not be present.) During a new ballot or update phase, "Published" is appended to the main heading for the template to indicate that the template cannot be commented on in the ballot or update. The "Published" designation is removed in the final publication versions.

A revised version of a previously published template keeps the same `templateId/@root` as the previous version but is assigned a new `templateId/@extension`. The notation "(Vn)" (V2, V3, etc.) is also added to the template name. Versions are not necessarily forward or backward compatible. A versioning may be due to substantive changes in the template or because a contained template has changed. The "(Vn)" designation is persistent; it appears with that template when it is used in subsequent guides. During a new ballot or update phase, "Draft" is appended to the main heading for the template to indicate that it may be voted on in the ballot or commented on in the update; the "Draft" designation is removed in the final publication versions.

Structured Documents Working Group collaborated with Templates Working Group to establish template versioning recommendations, recently published in the following specification: HL7 Templates Standard: Specification and Use of Reusable Information Constraint Templates, Release 1. SDWG will leverage that specification to create guidance for template IDs and template versioning for future CDA implementation guides, including future versions of C-CDA, but that work is still in progress. The versioning approach used in this version of C-CDA is likely to be close to the final guidance, but has not been formally approved by SDWG for all implementation guides at this time.

4.2.3 Open and Closed Templates

In open templates, all of the features of the CDA R2 base specification are allowed except as constrained by the templates. By contrast, a closed template specifies everything that is allowed and nothing further may be included.

Estimated Date of Delivery (`templateId 2.16.840.1.113883.10.20.15.3.1`) is an example of a closed template in this guide.

Open templates allow HL7 implementers to develop additional structured content not constrained within this guide. HL7 encourages implementers to bring their use cases forward as candidate requirements to be formalized in a subsequent version of the standard to maximize the use of shared semantics.

4.2.4 Conformance Verbs (Keywords)

The keywords **SHALL, SHOULD, MAY, NEED NOT, SHOULD NOT,** and **SHALL NOT** in this document are to be interpreted as described in the HL7 Version 3 Publishing Facilitator's Guide.[11]

- **SHALL**: an absolute requirement
- **SHALL NOT**: an absolute prohibition against inclusion
- **SHOULD/SHOULD NOT**: best practice or recommendation. There may be valid reasons to ignore an item, but the full implications must be understood and carefully weighed before choosing a different course
- **MAY/NEED NOT**: truly optional; can be included or omitted as the author decides with no implications

[11] HL7, *Version 3 Publishing Facilitator's Guide.* http://www.hl7.org/v3ballot/html/help/pfg/pfg.htm

The keyword "**SHALL**" allows the use of `nullFlavor` unless the requirement is on an attribute or the use of `nullFlavor` is explicitly precluded.

When conformance statements are nested (or have subordinate clauses) the conformance statements are to be read and interpreted in hierarchical order. These hierarchical clauses can be interpreted as "if then, else" clauses. Thus…

a. This structuredBody **SHOULD** contain zero or one [0..1] **component** (CONF:1098-29066) such that it
    i. **SHALL** contain exactly one [1..1] **Plan of Treatment Section (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.2.10:2014-06-09) (CONF:1098-29067).

…is understood as:

a. It is recommended (**SHOULD**) that the structureBody contains a component.
    i. **If** the component exists, **then** it must contain a Plan of Treatment Section (V2),
    ii. **else** the component does not exist, and the conformance statement about the Plan of Treatment Section (V2) should be skipped.

In the case where the higher level conformance statement is a **SHALL,** there is no conditional clause. Thus…

b. This structuredBody **SHALL** contain exactly one [1..1] **component** (CONF:1098-29086) such that it
    i. **SHALL** contain exactly one [1..1] **Problem Section (entries required) (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.2.5.1:2014-06-09) (CONF:1098-29087).

…means that the structuredBody is always required to have a component.

4.2.5 Cardinality

The cardinality indicator (0..1, 1..1, 1..*, etc.) specifies the allowable occurrences within a document instance. The cardinality indicators are interpreted with the following format “m…n” where m represents the least and n the most:

- 0..1 zero or one
- 1..1 exactly one
- 1..* at least one
- 0..* zero or more
- 1..n at least one and not more than n

When a constraint has subordinate clauses, the scope of the cardinality of the parent constraint must be clear. In the next figure, the constraint says exactly one participant is to be present. The subordinate constraint specifies some additional characteristics of that participant.

Figure 16: Constraints Format – only one allowed

1. **SHALL** contain exactly one [1..1] **participant** (CONF:2777).
    a. This participant **SHALL** contain exactly one [1..1] **@typeCode**="LOC" (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) (CONF:2230).

In the next figure, the constraint says only one participant "like this" is to be present. Other participant elements are not precluded by this constraint.

Figure 17: Constraints Format – only one like this allowed

1. **SHALL** contain exactly one [1..1] **participant** (CONF:2777) such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="LOC" (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) (CONF:2230).

4.2.6 Optional and Required with Cardinality

The terms *optional* and *required* describe the *lower* bound of cardinality as follows:

Optional means that the number of allowable occurrences of an element may be 0; the cardinality will be expressed as [0..1] or [0..*] or similar. In these cases, the element may not be present in the instance. Conformances formulated with **MAY** or **SHOULD** are both considered "optional" conformances.

Required means that the number of allowable occurrences of an element must be at least 1; the cardinality will be expressed as [m..n], where m >=1 and n >=1 (for example, [1..1] or [1..*]). In these cases, the element must be present in the instance. Conformance statements formulated with SHALL are required conformances. If an element is required but it is not known, the @nullFlavor attribute must be used. See Unknown and No Known Information.

4.2.7 Containment Relationships

Containment constraints between a section and its entries allow indirect containment in this guide. This means that where a section asserts containment of an entry, that entry either can be a direct child or a further descendent of that section.

For example, in the following constraint:

1. **SHALL** contain at least one [1..*] **entry** (CONF:8647) such that it
    a. **SHALL** contain exactly one [1..1] **Advance Directive Observation** (templateId:2.16.840.1.113883.10.20.22.4.48) (CONF:8801).

The Advance Directive Observation can be a direct child of the section (i.e., section/entry/AdvanceDirectiveObservation) or a further descendent of that section (i.e., section/entry/…/AdvanceDirectiveObservation). Either of these are conformant.

All other constraints are direct and do not allow an indirect containment relationship, for example:

1. **SHALL** contain exactly one [1..1] templateId/@root="2.16.840.1.113883.10.20.22.2.21" (CONF:7928).

The templateId must be a direct child of the section (i.e., section/templateId).

4.2.8 Vocabulary Conformance

The templates in this document use terms from several code systems. These vocabularies are defined in various supporting specifications and may be maintained by other bodies, as is the case for the LOINC® and SNOMED CT® vocabularies.

Note that value set identifiers (e.g., ValueSet 2.16.840.1.113883.1.11.78 Observation Interpretation (HL7) **DYNAMIC**) used in the binding definitions of template conformance statements do not appear in the XML instance of a CDA document. The definition of the template must be referenced to determine or validate the vocabulary conformance requirements of the template.

Value set bindings adhere to HL7 Vocabulary Working Group best practices, and include both an indication of stability and of coding strength for the binding. Value set bindings can be **STATIC**, meaning that they bind to a specified version of a value set, or **DYNAMIC**, meaning that they bind to the most current version of the value set. If a **STATIC** binding is specified, a date **SHALL** be included to indicate the value set version. If a **DYNAMIC** binding is specified, the value set authority and link to the base definition of the value set **SHALL** be included, if available, so implementers can access the current version of the value set. When a vocabulary binding binds to a single code, the stability of the binding is implicitly **STATIC**.

Figure 18: Binding to a Single Code

2. **SHALL** contain exactly one [1..1] **code** (CONF:15403). a) This code **SHALL** contain exactly one [1..1] **@code**="11450-4" Problem List (CONF:15408). b) This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC 2.16.840.1.113883.6.1 **STATIC**) (CONF: 31141).

The notation conveys the actual code (11450-4), the code's displayName (Problem List), the OID of the codeSystem from which the code is drawn (2.16.840.1.113883.6.1), and the codeSystemName (LOINC).

HL7 Data Types Release 1 requires the codeSystem attribute unless the underlying data type is "Coded Simple" or "CS", in which case it is prohibited. The displayName and the codeSystemName are optional, but recommended, in all cases.

The above example would be properly expressed as follows.

Figure 19: XML Expression of a Single-Code Binding

```
<code code="11450-4" codeSystem="2.16.840.1.113883.6.1"/>

<!-- or -->

<code code="11450-4" codeSystem="2.16.840.1.113883.6.1"
      displayName="Problem List"
      codeSystemName="LOINC"/>
```

A full discussion of the representation of vocabulary is outside the scope of this document; for more information, see the *HL7 V3 Normative Edition 2010*[12] sections on Abstract Data Types and XML Data Types R1.

There is a discrepancy between the HL7 R1 Data Types and this guide in the in the implementation of translation code versus the original code. The R1 data type requires the original code in the root. The convention agreed upon for this implementation guide specifies a code from the required value set be used in the element and other codes not included in the value set are to be represented in a translation for the element. This discrepancy is resolved in HL7 Data Types R2.

In the next example, the conformant code is SNOMED-CT code 206525008.

Figure 20: Translation Code Example

```
<code code='206525008'
      displayName='neonatal necrotizing enterocolitis'
      codeSystem='2.16.840.1.113883.6.96'
      codeSystemName='SNOMED CT'>
   <translation code='NEC-1'
      displayName='necrotizing enterocolitis'
      codeSystem='2.16.840.1.113883.19'/>
</code>
```

Value set tables are present below a template, or are referenced if they occur elsewhere in the specification, when there are value set bindings in the template. The value set table provides the value set identifier, a description, and a link to the source of the value set when possible. Ellipses in the last row indicate the value set members shown are examples and the true source must be accessed to see all members.

If a value set binding has a **DYNAMIC** stability, implementers creating a CDA document must go to the location in the URL to check for the most current version of the value set expansion.

[12] *HL7 Version 3 Interoperability Standards,* http://www.hl7.org/memonly/downloads/v3edition.cfm - V32010

Table 4: Example Value Set Table (Referral Types)

Value Set: Referral Types 2.16.840.1.113883.11.20.9.56 A value set of SNOMED-CT codes descending from "3457005" patient referral (procedure). Value Set Source: http://vtsl.vetmed.vt.edu/TerminologyMgt/RF2Browser/ISA.cfm?SCT_ConceptID=3457005			
Code	**Code System**	**Code System OID**	**Print Name**
44383000	SNOMED CT	2.16.840.1.113883.6.96	Patient referral for consultation
391034007	SNOMED CT	2.16.840.1.113883.6.96	Refer for falls assessment (procedure)
86395003	SNOMED CT	2.16.840.1.113883.6.96	Patient referral for family planning (procedure)
306106002	SNOMED CT	2.16.840.1.113883.6.96	Referral to intensive care service (procedure)
306140002	SNOMED CT	2.16.840.1.113883.6.96	Referral to clinical oncology service (procedure)
396150002	SNOMED CT	2.16.840.1.113883.6.96	Referral for substance abuse (procedure)
...			

4.2.9 Data Types

All data types used in a CDA document are described in the CDA R2 normative edition.[13] All attributes of a data type are allowed unless explicitly prohibited by this specification.

4.2.10 Document-Level Templates "Properties" Heading

In Volume 2 of this implementation guide, each document-level template has a "Properties" heading for ease of navigation. The Properties heading is an organizational construct, underneath which relevant CDA act-relationships and roles are called out as headings in the document.

4.3 XML Conventions Used in This Guide

4.3.1 XPath Notation

Instead of the traditional dotted notation used by HL7 to represent RIM classes, this document uses XML Path Language (XPath) notation[14] in conformance statements and elsewhere to identify the XML elements and attributes within the CDA document instance to which various constraints are applied. The implicit context of these expressions is the root of the document. This notation provides a mechanism that will be familiar to developers for identifying parts of an XML document.

XPath statements appear in this document in a `monospace font`.

[13] *HL7 CDA Release 2.* http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7
[14] W3C, XML Path Language. http://www.w3.org/TR/xpath/

XPath syntax selects nodes from an XML document using a path containing the context of the node(s). The path is constructed from node names and attribute names (prefixed by a '@') and catenated with a '/' symbol.

Figure 21: XML Document Example

```
<author>
  <assignedAuthor>
  ...
    <code codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'
          code='17561000' displayName='Cardiologist' />
  ...
  </assignedAuthor>
</author>
```

In the above example, the `code` attribute of the code could be selected with the XPath expression in the next figure.

Figure 22: XPath Expression Example

```
author/assignedAuthor/code/@code
```

4.3.2 XML Examples and Sample Documents

Extensible Mark-up Language (XML) examples appear in figures in this document in this `monospace font`. XML elements (`code, assignedAuthor,` etc.) and attribute names (`SNOMED CT, 17561000`, etc.) also appear in this `monospace font`. Portions of the XML content may be omitted from the content for brevity, marked by an ellipsis (...) as shown in the example below.

Figure 23: ClinicalDocument Example

```
<ClinicalDocument xmls="urn:h17-org:v3">
  ...
</ClinicalDocument>
```

5 REFERENCES

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APPENDIX A — ACRONYMS AND ABBREVIATIONS

ADL	Activities of Daily Living
C-CDA R1, R1.1, R2	Consolidated CDA (Release 1, 1.1, and 2)
CCD	Continuity of Care Document
CDA, CDA R2	Clinical Document Architecture (Release 2)
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CID	content identifier
CPT	Current Procedural Terminology
CVX	Codes for Vaccine Administered
DAM	Domain Analysis Model
DI	device identifier
DICOM	Digital Imaging and Communications in Medicine
CMET	Common Message Element Type
DIR	Diagnostic Imaging Report
DME	durable medical equipment
DRIV	is derived from
DSTU	Draft Standard for Trial Use
EHR	electronic health record
EMR	electronic medical record
EVN	event
FDA	Food and Drug Administration
FIPS	Federal Information Processing Standards
GOL	goal
H&P	History and Physical
HCT/P	Human Cell & Tissue Products
HHPoC	Home Health Plan of Care
HIBCC	Health Industry Business Communications Council
HIE	health information exchange
HISP	health information service provider
HIT	healthcare information technology
HITSP	Health Information Technology Standards Panel
HL7	Health Level Seven

HTML	Hypertext Markup Language
IADL	Instrumental Activities of Daily Living
ICCBBA	International Council for Commonality in Blood Banking Automation, Inc.
ICD	International Classification of Diseases
ICF	International Classification of Functioning, Disability and Health
IG	implementation guide
IHE	Integrating the Healthcare Enterprise
PCC	Patient Care Coordination
IHTSDO	International Health Terminology Standard Development Organisation
RFC	Request for Comments
ITI	information technology infrastructure
LCC	Longitudinal Care Coordination
LCP	Longitudinal Care Plan
LOINC	Logical Observation Identifiers Names and Codes
LTPAC	Long-Term Post-Acute Care
MHTML	MIME HTML
MIME	Multipurpose Internet Mail Extensions
MPHO	Medical Products of Human Origin
NA	not applicable
NDC	National Drug Code
NDFRT	National Drug File Reference Terminology
NEMA	National Electrical Manufacturers Association
NHSN	National Healthcare Safety Network
NI	no information
NLM	National Library of Medicine
NPI	National Provider Identifier
NPO	nothing by mouth
NPP	non-physician provider
NUBC	National Uniform Billing Committee
NUCC	National Uniform Claim Committee
OID	object identifier
ONC	Office of National Coordinator
OTH	not an element in the value domain

PCDATA	Parsed Character Data
PCWG	Patient Care Work Group
PDF	Portable Document Format
PGD	Patient Generated Document
PGP	Pretty Good Privacy
PHQ	Patient Health Questionnaire
PHR	personal health record
PI	Production Identifier
PKCS#7	public-key cryptography standard seven (Cryptographic Message Syntax Standard
RFC	request for comment
RIM	Reference Information Model
RMIM	Refined Message Information Model
RQO	request
RSNA	Radiological Society of North America
S&I	Standards and Interoperability
sdtc	Standard Duty Title Code
SDWG	Structured Documents Working Group
SMART	Substitutable Medical Applications & Reusable Technology
SNF	Skilled Nursing Facility
SNOMED CT	Systemized Nomenclature for Medicine – Clinical Terms
SOP	Service Object Pair
SPL	Structured Product Labeling
SR	Structured Report
SSN	Social Security Number
SWG	Sub Work Group
TPN	Total Parenteral Nutrition
UCUM	Unified Code for Units of Measure
UD	Unstructured Document
UDI	Unique Device Identification
UML	Unified Modeling Language
UNII	Unique Ingredient identifier
UNK	unknown
URL	uniform resource locator

URN	uniform resource name
UUID	universally unique identifier
VIS	Vaccine Information Statement
WADO	Web Access to Persistent DICOM Objects
XDS-SD	Cross Enterprise Sharing of Scanned Documents
XML	eXtensible Markup language
XML-DSIG	XML digital signature
XPath	XML Path Language

APPENDIX B — HIGH-LEVEL CHANGE LOG

This implementation guide builds on *HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Release 2.0.* (NOV 2014).

Volume 1 Summary of Changes

- Chapter 2.1 Templated CDA - New section added for Status of a Template Version, and Use of Deprecated Template Versions
- Chapter 3.1 Compatibility - New section describing the compatibility principles for Release 2.1
- Chapter 3.3 Determining the Status of Clinical Statement - Updated prose based on latest knowledge from SDWG
- Chapter 3.5 Narrative Reference - New section
- Chapter 4.2.7 Containment Relationships - New Section

Volume 2 Summary of Changes

For detailed comparison of C-CDA R1.1 versus C-CDA R2.0, and the updates for C-CDA R2.1, see the zip of C-CDA R1.1 vs 2.0 Reviews included with C-CDA R2.1 publication package.

Table 5: High-Level Change Log

Type of Template	Template	Summary of New Content or Update to Template
US Realm Header	US Realm Header (V3) 2.16.840.1.113883.10.20.22.1.1:2015-08-01	Added R1.1 requirement that Birthplace state must be present if a U.S. Address. Added R1.1 value set requirement for languageCommunication.
Document	Care Plan (V2) 2.16.840.1.113883.10.20.22.1.15:2015-08-01	Updated to reference a contained template that has been versioned.
Document	Consultation Note (V3) 2.16.840.1.113883.10.20.22.1.4:2015-08-01	Added R1.1 requirement to include an Assessment and Plan, or Assessment Section and a Plan of Treatment Section; Added R1.1 requirement to include a Reason for Referral or Reason for Visit Section.
Document	Continuity of Care Document (CCD) (V3) 2.16.840.1.113883.10.20.22.1.2:2015-08-01	Updated to reference a contained template that has been versioned.
Document	Diagnostic Imaging Report (V3) 2.16.840.1.113883.10.20.22.1.5:2015-08-01	Updated to reference a contained template that has been versioned.
Document	Discharge Summary (V3) 2.16.840.1.113883.10.20.22.1.8:2015-08-01	Updated to reference a contained template that has been versioned.
Document	History and Physical (V3) 2.16.840.1.113883.10.20.22.1.3:2015-08-01	Updated to reference a contained template that has been versioned.
Document	Operative Note (V3) 2.16.840.1.113883.10.20.22.1.7:2015-08-01	Updated to reference a contained template that has been versioned.
Document	Procedure Note (V3) 2.16.840.1.113883.10.20.22.1.6:2015-08-01	Updated to reference a contained template that has been versioned.
Document	Progress Note (V3) 2.16.840.1.113883.10.20.22.1.9:2015-08-01	Updated to reference a contained template that has been versioned.

Document	Referral Note (V2) 2.16.840.1.113883.10.20.22.1.14:2015-08-01	Updated to reference a contained template that has been versioned.
Document	Transfer Summary (V2) 2.16.840.1.113883.10.20.22.1.13:2015-08-01	Updated to reference a contained template that has been versioned.
Document	Unstructured Document (V3) 2.16.840.1.113883.10.20.22.1.10:2015-08-01	Updated mediaType value set SupportedFileFormats 2.16.840.1.113883.11.20.7.1 from DYNAMIC to STATIC.
Document	US Realm Header - Patient Generated Document (V2) 2.16.840.1.113883.10.20.29.1:2015-08-01	Updated to reference a contained template that has been versioned.
Section	Admission Diagnosis Section (V3) 2.16.840.1.113883.10.20.22.2.43:2015-08-01	Added R1.1 requirement for section/code. The R2.0 code is required in the translation element.
Section	Admission Medications Section (entries optional) (V3) 2.16.840.1.113883.10.20.22.2.44:2015-08-01	Updated to reference a contained template that has been versioned.
Section	Allergies and Intolerances Section (entries optional) (V3) 2.16.840.1.113883.10.20.22.2.6:2015:08-01	Updated to reference a contained template that has been versioned.
Section	Allergies and Intolerances Section (entries required) (V3) 2.16.840.1.113883.10.20.22.2.6.1:2015-08-01	Updated to reference a contained template that has been versioned.
Section	Complications Section (V3) 2.16.840.1.113883.10.20.22.2.37:2015-08-01	Updated to reference a contained template that has been versioned.
Section	Discharge Diagnosis (V3) 2.16.840.1.113883.10.20.22.2.24:2015-08-01	Added R1.1 requirement for section/code. The R2.0 code is required in the translation element.
Section	Discharge Medications Section (entries required) (V3) 2.16.840.1.113883.10.20.22.2.11.1:2015-08-01	Added R1.1 requirement for section/code. The R2.0 code is required in the translation element.
Section	Encounters Section (entries optional) (V3) 2.16.840.1.113883.10.20.22.2.22:2015-08-01	Updated to reference a contained template that has been versioned.
Section	Encounters Section (entries required) (V3) 2.16.840.1.113883.10.20.22.2.22.1:2015-08-01	Updated to reference a contained template that has been versioned.

Section	Family History Section (V3) 2.16.840.1.113883.10.20.22.2.15:2015-08-01	Updated to reference a contained template that has been versioned.
Section	Health Concerns Section (V2) 2.16.840.1.113883.10.20.22.2.58:2015-08-01	Updated to reference a contained template that has been versioned.
Section	History of Past Illness Section (V3) 2.16.840.1.113883.10.20.22.2.20:2015-08-01	Updated to reference a contained template that has been versioned.
Section	Immunizations Section (entries optional) (V3) 2.16.840.1.113883.10.20.22.2.2:2015-08-01	Updated to reference a contained template that has been versioned.
Section	Immunizations Section (entries required) (V3) 2.16.840.1.113883.10.20.22.2.2.1:2015-08-01	Updated to reference a contained template that has been versioned.
Section	Interventions Section (V3) 2.16.840.1.113883.10.20.21.2.3:2015-08-01	Updated to reference a contained template that has been versioned.
Section	Mental Status Section (V2) 2.16.840.1.113883.10.20.22.2.56:2015-08-01	Updated to reference a contained template that has been versioned.
Section	Payers Section (V3) 2.16.840.1.113883.10.20.22.2.18:2015-08-01	Updated to reference a contained template that has been versioned.
Section	Physical Exam Section (V3) 2.16.840.1.113883.10.20.2.10:2015-08-01	Updated to reference a contained template that has been versioned.
Section	Postprocedure Diagnosis Section (V3) 2.16.840.1.113883.10.20.22.2.36:2015-08-01	Updated to reference a contained template that has been versioned.
Section	Preoperative Diagnosis Section (V3) 2.16.840.1.113883.10.20.22.2.34:2015-08-01	Updated to reference a contained template that has been versioned.
Section	Problem Section (entries optional) (V3) 2.16.840.1.113883.10.20.22.2.5:2015-08-01 Problem Section (entries required) (V3) 2.16.840.1.113883.10.20.22.2.5.1:2015-08-01	Updated to reference a contained template that has been versioned.
Section	Problem Section (entries required) (V3) 2.16.840.1.113883.10.20.22.2.5.1:2015-08-01	Updated to reference a contained template that has been versioned.
Section	Procedure Findings Section (V3) (optional) 2.16.840.1.113883.10.20.22.2.28:2015-08-01	Updated to reference a contained template that has been versioned.

Section	Results Section (entries optional) (V3) 2.16.840.1.113883.10.20.22.2.3:2015-08-01	Updated to reference a contained template that has been versioned.
Section	Results Section (entries required) (V3) 2.16.840.1.113883.10.20.22.2.3.1:2015-08-01	Updated to reference a contained template that has been versioned.
Section	Social History Section (V3) 2.16.840.1.113883.10.20.22.2.17:2015-08-01	Updated to reference a contained template that has been versioned.
Section	Vital Signs Section (entries optional) (V3) 2.16.840.1.113883.10.20.22.2.4:2015-08-01	Updated to reference a contained template that has been versioned.
Section	Vital Signs Section (entries required) (V3) 2.16.840.1.113883.10.20.22.2.4.1:2015-08-01	Updated to reference a contained template that has been versioned.
Entry	Advance Directive Observation(V3) 2.16.840.1.113883.10.20.22.4.48:2015-08-01	Added R1.1 requirement for observation/code. The R2.0 code is required in the translation element. Added R1.1 requirement for participant/templateId.
Entry	Advance Directive Organizer (V2) 2.16.840.1.113883.10.20.22.4.108:2015-08-01	Updated to reference a contained template that has been versioned.
Entry	Allergy Concern Act (V3) 2.16.840.1.113883.10.20.22.4.30:2015-08-01	Added R1.1 requirement for observation/effectiveTime.
Entry	Coverage Activity (V3) 2.16.840.1.113883.10.20.22.4.60:2015-08-01	Updated to reference a contained template that has been versioned.
Entry	Deceased Observation (V3) 2.16.840.1.113883.10.20.22.4.79:2015-08-01	Updated to reference a contained template that has been versioned.
Entry	Encounter Activity (V3) 2.16.840.1.113883.10.20.22.4.49:2015-08-01	Updated to reference a contained template that has been versioned.
Entry	Encounter Diagnosis (V3) 2.16.840.1.113883.10.20.22.4.80:2015-08-01	Updated to reference a contained template that has been versioned.
Entry	Family History Observation (V3) 2.16.840.1.113883.10.20.22.4.46:2015-08-01	Added R1.1 recommendation for observation/code. The R2.0 code is recommended in the translation element.
Entry	Family History Organizer (V3) 2.16.840.1.113883.10.20.22.4.45:2015-08-01	Updated to reference a contained template that has been versioned.

Entry	Health Concern Act (V2) 2.16.840.1.113883.10.20.22.4.132:2015-08-01	Updated to reference a contained template that has been versioned.
Entry	Hospital Admission Diagnosis (V3) 2.16.840.1.113883.10.20.22.4.34:2015-08-01	Updated to reference a contained template that has been versioned.
Entry	Hospital Discharge Diagnosis (V3) 2.16.840.1.113883.10.20.22.4.33:2015-08-01	Updated to reference a contained template that has been versioned.
Entry	Immunization Activity (V3) 2.16.840.1.113883.10.20.22.4.52:2015-08-01	Added R1.1 requirement for observation/@negationInd.
Entry	Intervention Act (V2) 2.16.840.1.113883.10.20.22.4.131:2015-08-01	Updated to reference a contained template that has been versioned.
Entry	Longitudinal Care Wound Observation (V2) 2.16.840.1.113883.10.20.22.4.114:2015-08-01	Updated to reference a contained template that has been versioned.
Entry	Mental Status Observation (V3) 2.16.840.1.113883.10.20.22.4.74:2015-08-01	Added R1.1 requirement for observation/code. The R2.0 code is required in the translation element.
Entry	Mental Status Organizer (V3) 2.16.840.1.113883.10.20.22.4.75:2015-08-01	Added R1.1 requirement to include organizer/code. The R2.0 organizer/code is optional.
Entry	Number of Pressure Ulcers Observation (V3) 2.16.840.1.113883.10.20.22.4.76:2015-08-01	Added R1.1 requirement for observation/code. The R2.0 code is required in the translation element.
Entry	Planned Intervention Act (V2) 2.16.840.1.113883.10.20.22.4.146:2015-08-01	Updated to reference a contained template that has been versioned.
Entry	Policy Activity (V3) 2.16.840.1.113883.10.20.22.4.61:2015-08-01	Added R1.1 recommendation for act/code. The R2.0 code is recommended in the translation element.
Entry	Postprocedure Diagnosis (V3) 2.16.840.1.113883.10.20.22.4.51:2015-08-01	Updated to reference a contained template that has been versioned.
Entry	Preoperative Diagnosis (V3) 2.16.840.1.113883.10.20.22.4.65:2015-08-01	Updated to reference a contained template that has been versioned.
Entry	Problem Concern Act (V3) 2.16.840.1.113883.10.20.22.4.3:2015-08-01	Updated to reference a contained template that has been versioned.
Entry	Problem Observation (V3) 2.16.840.1.113883.10.20.22.4.4:2015-08-01	Added R1.1 recommendation for observation/code. The R2.0 code is recommended in the translation element.

Entry	Result Observation (V3) 2.16.840.1.113883.10.20.22.4.2:2015-08-01	Added R1.1 requirement for observation/value. The R2.0 guidance on observation/value is also included.
Entry	Result Organizer (V3) 2.16.840.1.113883.10.20.22.4.1:2015-08-01	Updated to reference a contained template that has been versioned.
Entry	Risk Concern Act (V2) 2.16.840.1.113883.10.20.22.4.136:2015-08-01	Updated to reference a contained template that has been versioned.
Entry	Social History Observation (V3) 2.16.840.1.113883.10.20.22.4.38:2015-08-01	Added R1.1 recommendation for observation/code. The R2.0 code is recommended in the translation element.
Entry	Vital Signs Organizer (V3) 2.16.840.1.113883.10.20.22.4.26:2015-08-01	Added R1.1 requirement for organizer/code. The R2.0 code is required in the translation element. Added R1.1 requirement for organizer/effectiveTime.

APPENDIX C — EXTENSIONS TO CDA R2

Where there is a need to communicate information for which there is no suitable representation in CDA R2, extensions to CDA R2 have been developed. These extensions are described above in the context of the section where they are used. This section serves to summarize the extensions and provide implementation guidance.

Extensions created for this guide include:

- `sdtc:raceCode` - The `raceCode` extension allows for multiple races to be reported for a patient.
- `sdtc:ethnicGroupCode` - The `ethnicGroupCode` extension allows for additional ethnicity groups for the recordTarget or subjectPerson.
- `sdtc:id` - The id extension in the family history organizer on the related subject allows for unique identification of the family member(s).
- `sdtc:deceasedInd` - The `deceasedIndextension` (= "true" or "false") in the family history organizer on the related subject is used inside to indicate if a family member is deceased.
- `sdtc:deceasedTime` - The `deceasedTime` extension in the family history organizer on the related subject allows for reporting the date and time a family member died.
- `sdtc:birthTime` - The `birthTime` extension allows for the birth date of any person to be recorded. The purpose of this extension is to allow the recording of the subscriber or member of a health plan in cases where the health plan eligibility system has different information on file than the provider does for the patient.
- `sdtc:dischargeDispositionCode` - The `dischargeDispositionCode` extension allows the provider to record a discharge disposition in an encounter activity.
- `sdtc:signatureText` - The `signatureText` extension provides a location in CDA for a textual or multimedia depiction of the signature by which the participant endorses and accepts responsibility for his or her participation in the Act as specified in the `Participation.typeCode`. Details of what goes in the field are described in the HL7 Implementation Guide for CDA® Release 2: Digital Signatures and Delegation of Rights, Release 1.

To resolve issues that need to be addressed by extension, the developers of this guide chose to approach extensions as follows:

- An extension is a collection of element or attribute declarations and rules for their application to the CDA Release 2.0.
- All extensions are optional. An extension may be used, but need not be under this guide.
- A single namespace for all extension elements or attributes that may be used by this guide will be defined.

- The namespace for extensions created by the HL7 Structured Documents Working Group (formerly Structured Documents Technical Committee) shall be urn:hl7-org:sdtc.
- This namespace shall be used as the namespace for any extension elements or attributes that are defined by this implementation guide.
- Each extension element shall use the same HL7 vocabularies and data types used by CDA Release 2.0.
- Each extension element shall use the same conventions for order and naming as is used by the current HL7 tooling.
- An extension element shall appear in the XML where the expected RIM element of the same name would have appeared had that element not been otherwise constrained from appearing in the CDA XML schema.

APPENDIX D — MIME MULTIPART/RELATED MESSAGES

The following text is taken from the Claims Attachments Implementation Guide (AIS00000) in Section 2.4.[15] For up-to-date guidance, refer to the latest edition of that specification.

MIME Multipart/Related Messages

An attachment is comprised of the CDA document, including any supporting files necessary to render the attested content of the document. Two Internet request for comments (RFCs) are needed to properly construct the mime multipart message. When supporting files are needed, the collection of information shall be organized using a MIME multipart/related package constructed according to RFC 2557. Within the MIME package, supporting files must be encoded using Base-64. RFC-4648 should be used when encoding the contents of the MIME package using Base-64. Finally, RFC-2392 may be used to reference other content that appears in the same X12 transaction to use the same content to answer multiple questions for a single claim. Internet RFCs can be downloaded from the RFC editor page at http://www.rfc-editor.org.

RFC-2557 MIME Encapsulation of Aggregate Documents, Such as HTML (MHTML)

This RFC describes how to construct a MIME multipart/related package, and how URLs are resolved within content items of that package. RFC-2557 can be obtained at: http://www.rfc-editor.org/rfc/rfc2557.txt

A MIME multipart/related package is made up of individual content items. Each content item has a MIME header identifying the item. Each content item is delimited from other content items using a string of application specified text. In addition, there must be an ending boundary. The actual content is recorded between these delimiter strings using a BASE-64 encoding of the content item. There is also a MIME header for the entire package.

The first content item of a multipart/related message supporting attachments is the CDA document, containing the header and structured or non-structured body. Subsequent content items included in this package will contain additional content that appears within the body of the document. The CDA document will reference these additional content items by their URLs.

Referencing Supporting Files in Multipart/Related Messages

Because the CDA document and its supporting files may have already existed in a clinical information system, references may already exist within the CDA document to URLs that are not accessible outside of the clinical information system that created the document. When the CDA document is sent via attachments, these URLs may no longer be accessible by the receiving information system. Therefore, each content item that is referenced by a URL within the CDA document must be included as a content item in

[15] http://www.hl7.org/documentcenter/public/wg/ca/CDAR2AIS0000R030_ImplementationGuideDraft.pdf

the MIME package. Each content item may specify the URL by which it is known using the Content-Location header. The receiver of this MIME package shall translate URL references according the RFC-2557. This will ensure resolution of the original URL to the correct content item within the MIME package. Thus, URL references contained within an original document need not be rewritten when the CDA package is transmitted. Instead, these URLs are simply supplied as the value of the Content-Location header in the MIME package.

This capability allows for the same content item to be referred to more than once in a MIME multipart/related package without requiring the content item to be supplied twice. However, it does not allow a separate MIME multipart/related package to contain references to information sent in a previously recorded package.

Referencing Documents from Other Multiparts within the Same X12 Transactions

RFC-2392 is used when referencing content across MIME package boundaries, but still contained within the same X12 transaction (ST to SE). This can occur when the same document answers multiple questions for a single claim. Each component of a MIME package may be assigned a content identifier using the Content-ID header for the content item. For example, this header would appear as:

Content-ID: <07EE4DAC-76C4-4a98-967E-F6EF9667DED1>

This content identifier is a unique identifier for the content item, which means it must never be used to refer to any other content item. RFC-2392 defines the cid: URL scheme (http: and ftp: are two other URL schemes). This URL scheme allows for references by the Content-ID header to be resolved. The URL for the content item identified above would be:

cid:07EE4DAC-76C4-4a98-967E-F6EF9667DED1

Receivers of the MIME multipart message must be able to resolve a cid: URL to the content item that it identifies. Senders must ensure that they only refer to items that have already been transmitted to the receiver by their cid: URL. Thus, this implementation guide prohibits forward URL references using the cid: URL scheme.

Content items shall not be referenced across X12 transactions using the cid: URL scheme. For example, if the payer previously requested information using a 277, and the provider returned that information in a MIME multipart/related package in a 275, and then the payer requested additional information in another 277, the provider may not refer to the content item previously returned in the prior 275 transaction.

APPENDIX E — CARE PLAN RELATIONSHIPS

Care Plan Relationships and HL7 RIM Terms

The HL7 RIM and CDA Refined Message Information Model (RMIM) together with `actRelationshipType` codes and `act moodCodes` very effectively express the relationship between Care Plan components. The following tables highlight the main `moodCodes` and `relationshipCodes` used in the CDA Care Plan.

Table 6: moodCodes

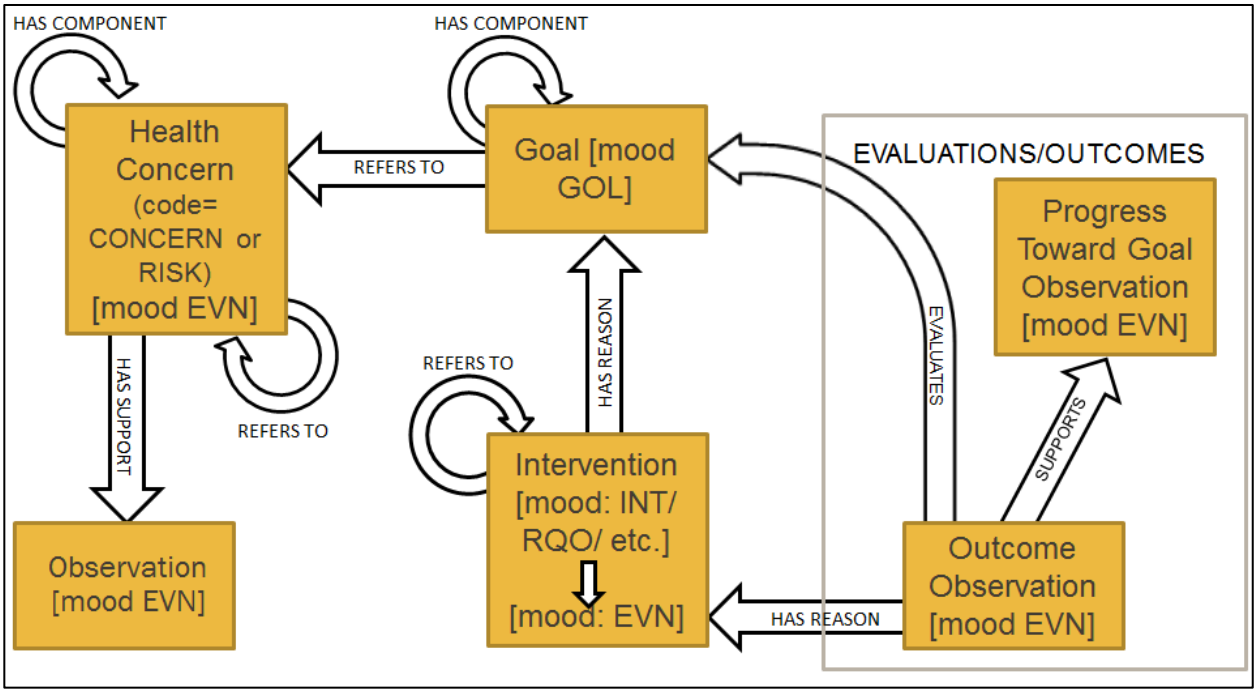
Code	Display Name	Meaning
EVN	Event	An actual occurrence of an event – something happened
INT	Intent	An intended or planned event
RQO	Request	A request or order to perform something
GOL	Goal	A goal or objective

Table 7: actRelationship TypeCodes

Code	Display Name	Meaning
COMP	Has component	Shows that one component is part of another (overall goal has components consisting of one or more goals)
REFR	Refers to	Shows a general relationship between components (a goal refers to a health concern)
SPRT	Has support	Show that the one component is supporting evidence for another (Health Concern has support from a problem observation)
RSON	Has reason	Show the reason or rationale for a something (intervention has reason of achieving a goal)
GEVL	Evaluates goal	Used to link an observation (intent or actual) to a goal to indicate that the observation evaluates the goal

The following diagram shows the components of a Care Plan and the flow between them, expressed by HL7 `moodCodes` and `relationshipCodes`.

Figure 24: Care Plan Relationship Diagram

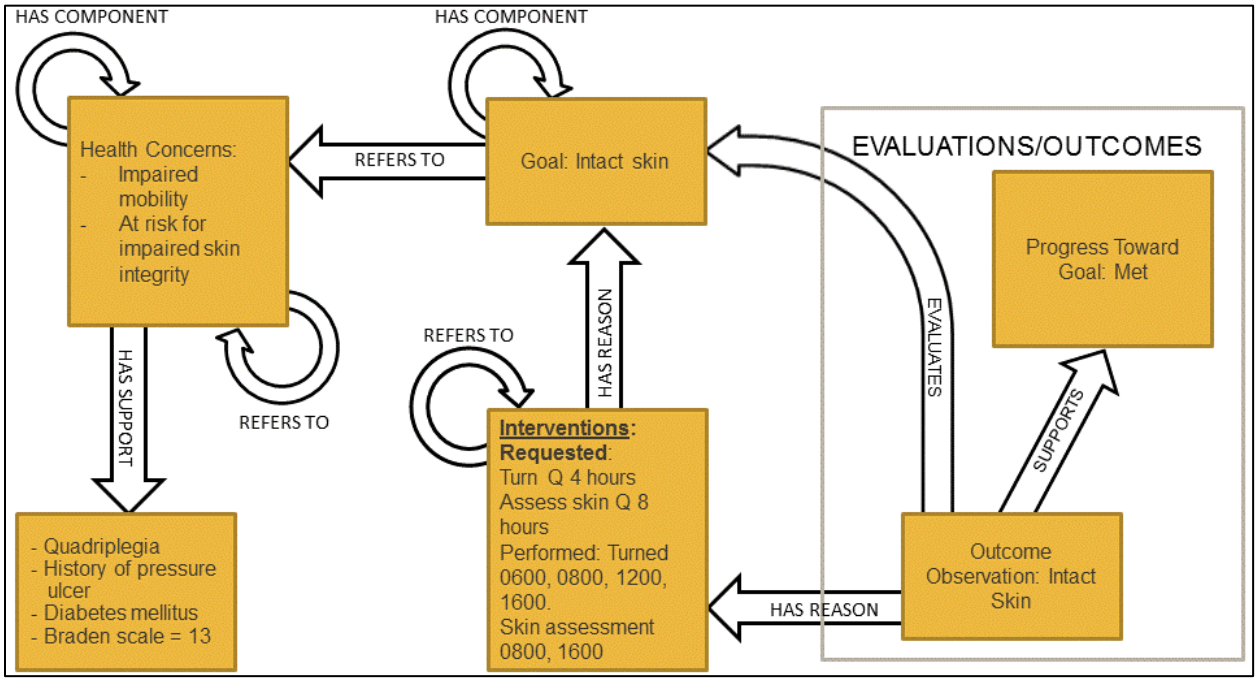


Care Plan Relationships Story Board Example

Joe is a 24 year-old male quadriplegic with diabetes mellitus admitted to an inpatient unit from his home. During the admission assessment, the nurse notes that he has no sensation from the shoulders down. He is confined to a wheelchair and requires two-person assist. His skin is occasionally moist. Joe reports that he is a "good eater" and is on a diabetic diet. The nurse completes the Braden Skin Scale. The score is 13. Further assessment by the nurse reveals skin is intact with no pressure ulcers.

The following diagram shows the components of a Care Plan and the flow between them expressed using HL7 `moodCodes` and `relationshipCodes` with components of the Care Plan relationship storyboard applied to the diagram.

Figure 25: Care Plan Relationship Diagram - Instantiated



APPENDIX F — UNIQUE DEVICE IDENTIFICATION (UDI) ISSUING AGENCY FORMATS

Each issuing agency has its own specified format for representing the two main components of a UDI – the Device Identifier (DI) and Production Identifiers (PI). The device identifier is a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device. The production identifier is the conditional, variable portions of a UDI that identifies one or more of the following when included on the label of the device and include: lot or batch within which a device was manufactured; serial number of a specific device; expiration date of a specific device; date a specific device was manufactured; and for an HCT/P regulated as a device, the distinct identification code required by 21 CFR 1271.290(c). The format of each issuing agency's UDI is outlined in the tables below. These issuing agencies maintain responsibility for the uniqueness of their device identifiers.

Table 8: GS1 UDI Format[16]

Issuing Agency	Data Delimiters	Identifier	Data type	Human Readable Field Size	Database Field Size
GS1	(01)	DI	numeric	16	14
GS1	(11)	Manufacturing/ Production Date	numeric [YYMMDD]	8	6
GS1	(17)	Expiration Date	numeric [YYMMDD]	8	6
GS1	(10)	Batch/Lot Number	alphanumeric	22	20
GS1	(21)	Serial Number	alphanumeric	22	20
GS1		**Maximum Base UDI**	**alphanumeric**	**76**	**66**
ex: (01) 51022222233336(11)141231(17)150707(10)A213B1(21)1234					

[16] http://www.gs1.org/

Table 9: Health Industry Business Communications Council (HIBCC) UDI Format[17]

Issuing Agency	Data Delimiters	Identifier	Data Type	Human Readable Field Size	Database Field Size
HIBCC	+	DI	alphanumeric	7 to 24	6 to 23
HIBCC	$	Lot Number Only	alphanumeric	19	18
HIBCC	$$7	Lot Number Only (alternative option)	alphanumeric	21	18
HIBCC	$$	Expiration Date followed by Lot Number	Expiration Date: numeric [MMYY]	6	4
			Lot Number: alphanumeric	18	18
HIBCC	$$2	Expiration Date followed by Lot Number	Expiration Date: numeric [MMDDYY]	9	6
			Lot Number: alphanumeric	18	18
HIBCC	$$3	Expiration Date followed by Lot Number	Expiration Date: numeric [YYMMDD]	9	6
			Lot Number: alphanumeric	18	18
HIBCC	$$4	Expiration Date followed by Lot Number	Expiration Date: numeric [YYMMDDHH]	11	8
			Lot Number: alphanumeric	18	18
HIBCC	$$5	Expiration Date followed by Lot Number	Expiration Date: numeric [YYJJJ] – Julian Date format	8	5
			Lot Number: alphanumeric	18	18
HIBCC	$$6	Expiration Date followed by Lot Number	Expiration Date: numeric [YYJJJHH] – Julian Date format with Hour option	10	7
			Lot Number: alphanumeric	18	18
HIBCC	$+	Serial Number only	alphanumeric	20	18
HIBCC	$$+7	Serial Number only (alternative option)	alphanumeric	22	18
HIBCC	$$+	Expiration Date followed by Serial Number	Expiration Date: numeric [MMYY]	7	4
			Serial Number: alphanumeric	18	18
HIBCC	$$+2	Expiration Date followed by Serial	Expiration Date: numeric [MMDDYY]	10	6

[17] http://www.hibcc.org/

Issuing Agency	Data Delimiters	Identifier	Data Type	Human Readable Field Size	Database Field Size
		Number	Serial Number: alphanumeric	18	18
HIBCC	$$+3	Expiration Date followed by Serial Number	Expiration Date: numeric [YYMMDD]	10	6
			Serial Number: alphanumeric	18	18
HIBCC	$$+4	Expiration Date followed by Serial Number	Expiration Date: numeric [YYMMDDHH]	12	8
			Serial Number: alphanumeric	18	18
HIBCC	$$+5	Expiration Date followed by Serial Number	Expiration Date: numeric [YYJJJ]	9	5
			Serial Number: alphanumeric	18	18
HIBCC	$$+6	Expiration Date followed by Serial Number	Expiration Date: numeric [YYJJJHH]	11	7
			Serial Number: alphanumeric	18	18
HIBCC	/S	Supplemental Serial Number, where lot number also required and included in main secondary data string	alphanumeric	20	18
HIBCC	/16D	Manufacturing Date (supplemental to secondary barcode)	numeric [YYYYMMDD]	12	8
HIBCC		Maximum Base UDI	alphanumeric	70 to 87	58 to 75
Ex of Human Readable Barcode: +H123PARTNO1234567890120/$$420020216LOT123456789012345/SXYZ456789012345678/16D20130202C					

Table 10: International Council for Commonality in Blood Banking Automation, Inc. (ICCBBA) UDI Format[18]

Issuing Agency	Data Delimiters	Identifier	Data type	Human Readable Barcode Field Size	Database Field Size
ICCBBA	=/	DI	alphanumeric	18	16
ICCBBA	=,	Serial Number	alphanumeric	8	6
ICCBBA	=	Donation Identification Number	alphanumeric	16	15
ICCBBA	=>	Expiration Date	numeric [YYYJJJ]	8	6
ICCBBA	=}	Manufacturing Date	numeric [YYYJJJ]	8	6
ICCBBA	&,1	MPHO Lot Number	alphanumeric	21	18
ICCBBA		**Maximum Base UDI for HCT/Ps**	**alphanumeric**	**79**	**67**
Ex of Human Readable Barcode:=/A9999XYZ100T0944=,000025=A99971312345600=>014032=}013032&,1000000000000XYZ123					

Table 11: ICCBBA UDI Format for Blood Bags Only

Issuing Agency	Identifying Symbol	Identifier	Data type	Eye Readable Barcode Field Size	Database Field Size
ICCBBA	=)	DI for blood containers (bags)	alphanumeric	12	10
ICCBBA	&)	Lot Number for blood containers (bags)	alphanumeric	12	10
ICCBBA		**Maximum Base UDI for Blood Bags**	**alphanumeric**	**24**	**20**
Ex of Human Readable Barcode: =)1TE123456A&)RZ12345678					

[18] http://iccbba.org/