HL7 CDA® R2 Implementation Guide: Pharmacist Care Plan Document, Release 1 - US Realm Volume 1 — Introductory Material

September 2017

1st Comment-Only Ballot

Sponsored by:
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Acknowledgments

This guide was produced and developed through the efforts of a project supported by the Office of the National Coordinator (ONC) High Impact Pilot (HIP) Grant, National Council for Prescription Drug Programs (NCPDP), Pharmacy Health Information Technology (HIT) Collaborative, and Health Level Seven (HL7) Structured Documents Work Group and Pharmacy Work Group, which provided expert advice and input to the representation pharmacy and patient care related medication clinical statements.

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Structure of This Guide

Two volumes comprise this *HL7 CDA® 2 Implementation Guide: Pharmacist Care Plan Document, Release 1 - US Realm*. 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 Clinical Document Architecture (CDA) templates for this guide along with lists of templates, code systems, and value sets used.

Contents

Figures

Tables

1   INTRODUCTION

1.1   Purpose

This document describes constraints on the Clinical Document Architecture Release 2 (CDA R2) header and body elements for the Pharmacist Care Plan, which are derived from requirements set forth by the Pharmacy Health Information Technology (HIT) Collaborative[1] and the National Council for Prescription Drug Programs (NCPDP) WG10 Professional Pharmacy Services,[2] vendors, and Health Level Seven (HL7) stakeholder workgroups. Templates in this US Realm implementation guide are specific to pharmacy management treatment and interventions that will promote interoperability and will create information suitable for reuse in quality measurement, public health reporting, research, and reimbursement.

This guide contains a library of Clinical Document Architecture (CDA) templates, and is compliant with the *HL7 CDA R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1* (C-CDA R2.1).[3]

1.2   Audience

The audience for this document includes pharmacy vendors, software developers, and implementers with reporting capabilities within their electronic health record (EHR) systems; developers and analysts in receiving institutions; and local, regional, and national health information exchange networks who wish to create or process pharmacy clinical documents according to this specification.

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   Approach

The approach taken here is consistent with balloted implementation guides for CDA. These publications view the ultimate implementation specification as a series of layered constraints. CDA itself is a set of constraints on the HL7 Reference Information Model (RIM) defined in the CDA R2 Refined Message Information Model (RMIM). Implementation guides such as this add constraints to CDA through conformance statements that further define and restrict the sequence and cardinality of CDA objects and the vocabulary sets for coded elements.

This implementation guide is a conformance profile, as described in the "Refinement and Localization"[4] section of the *HL7 Version 3 Standard*. The base standard for this implementation guide is the *HL7 Clinical Document Architecture, Release 2.0* (CDA R2 Normative Edition).[5] As defined in that document, this implementation guide is both an annotation profile and a localization profile. It does not describe every aspect of CDA.

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[1] Pharmacy HIT Collaborative. http://www.pharmacyhit.org/

[2] NCPDP. http://www.ncpdp.org/About-Us

[3] *HL7 Consolidated CDA R2.1.*
http://www.hl7.org/implement/standards/product_brief.cfm?product_id=408

[4] *HL7 V3: Refinement, Constraint and Localization.*
http://www.hl7.org/v3ballot/html/infrastructure/conformance/conformance.htm

[5] *HL7 CDA R2.* http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7

The development of this guide includes a review and analysis of the *Pharmacist eCare Plan: Guidance on the Use of the HL7 CDA Consolidated Templates for Clinical Notes R2.1 Care Plan*[6] and *HL7/NCPDP CDA® R2 Implementation Guide: Medication Therapy Management (MTM) Templates, Release 1 - US Realm.*[7] Templates were re-used wherever possible.

1.4 Organization of the Guide

This implementation guide is organized into two volumes. Volume 1 contains primarily narrative text describing this implementation guide, whereas Volume 2 contains normative CDA R2 template definitions.

1.4.1 Volume 1 Introductory Material

This document, Volume 1, provides an overview of CDA, 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 and Pharmacist Use Cases** contains project background and an introduction to the CDA R2 base standard to aid the reader in conceptualizing the "templated CDA" approach to implementation guide development.

- **Chapter 3—Design Considerations** describes 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** 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.

- **Chapter 5—References** lists documents and sources cited by this guide.

- **Appendices** include acronyms and abbreviations, CDA R2 extensions, and MIME multipart/related messages.

1.4.2 Volume 2 CDA Templates and Supporting Material

Volume 2 includes CDA templates and prescribes their use for a specific document type, the Pharmacist Care Plan. The main chapters are:

- **Chapter 1—Document-Level Templates** defines the document constraints that apply to the Pharmacist Care Plan Document.

- **Chapter 2—Section-Level Templates** defines the section templates in the Pharmacist Care Plan Document.

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[6] NCPDP, *Pharmacist eCare Plan.* http://ncpdp.org/NCPDP/media/pdf/Pharmacist-eCare-Plan.pdf

[7] *HL7 CDA R2: Medication Therapy Management.* http://www.hl7.org/implement/standards/product_brief.cfm?product_id=414

- **Chapter 3—Entry-Level Templates** defines the entry template in the Pharmacist Care Plan Document.

- **Chapter 4—Participation and Other Templates** defines templates for other fielded items (e.g., address, name) that cannot stand on their own without being nested in another template.

- **Chapters 5, 6, and 7** provide tables of the template IDs, value sets, and code systems used in the guide.

1.5 Contents of the Package

The following files comprise the package:

Table 1: Contents of the Package

Filename	Description	Standards Applicability
CDAR2_IG_CCDA_MTM_CAREPLAN_R1_O1 _2017SEP_Introductory_Material	Implementation Guide Introductory Material	Normative
CDAR2_IG_CCDA_MTM_CAREPLAN_R1_O1 _2017SEP_ Templates_and_Supporting.docx	Implementation Guide Template Library and Supporting Material	Normative
CDAR2_IG_CCDA_MTM_CAREPLAN_R1_O1 _2017SEP_USE_CASE_4.xml	Pharmacy Care Plan Sample	Informative
CDAR2_IG_CCDA_MTM_CAREPLAN_R1_O1 _2017SEP_USE_CASE_4.html	Pharmacy Care Plan Sample HTML Rendering	Informative
CDA_SDTC.xsd	Schema file	Informative
CDA.xsl	Stylesheet for rendering	Informative
CDAR2_IG_CCDA_MTM_CAREPLAN_R1_O1 _2017SEP_VOC.xml	Vocabulary file	Informative
CDAR2_IG_CCDA_MTM_CAREPLAN_R1_O1 _2017SEP.sch	Schematron	Informative

2 CDA R2 BACKGROUND AND PHARMACIST USE CASES

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]. 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" section of the *HL7 Version 3 Interoperability Standards*. The mechanism most commonly used to constrain CDA is referred to as "templated CDA". In this approach, a library is created containing modular CDA templates such that the templates can be reused across any number of CDA document types. The following figure illustrates that the Continuity of Care Document (CCD) templates library can be reused by other CDA documents.

Figure 1: Templated CDA
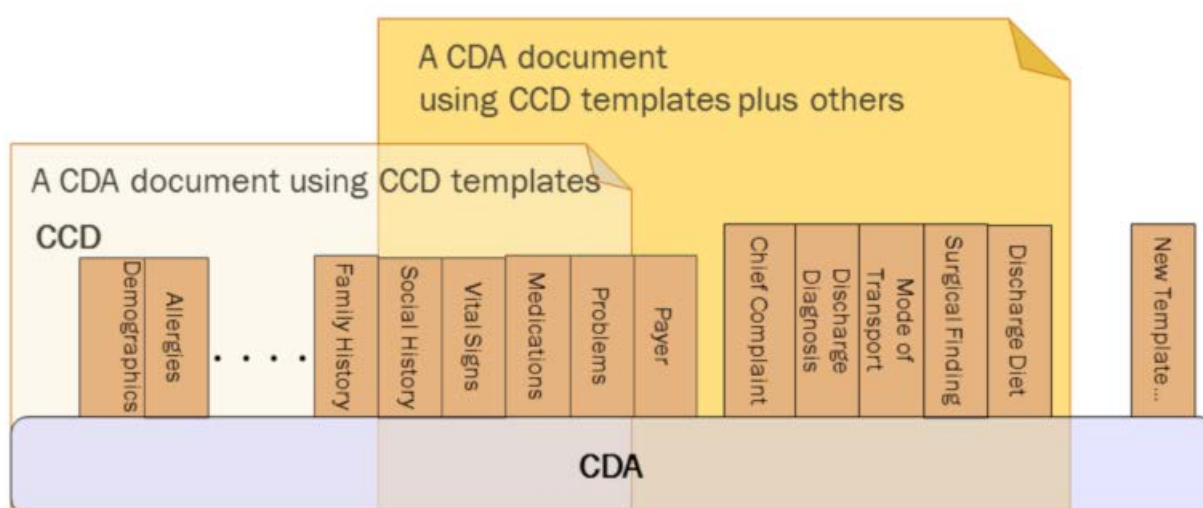
Many different kinds of templates may be created. Among them, the most common are:

- **Document-level templates**: These templates constrain fields in the CDA header, and define containment relationships to CDA sections. For example, a

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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 contain 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.

A CDA implementation guide (such as this one) includes reference to those templates that are applicable. On the implementation side, a CDA instance populates the template identifier (templateId) field where it wants to assert conformance to a given template. On the receiving side, the recipient can test the instance for conformance against the CDA Extensible Markup Language (XML) schema, and can test the instance for conformance against asserted templates.

Consolidated CDA (C-CDA) is a library of templates based on CDA R2. This implementation guide is conformant to templates in the C-CDA R2.1 standard.

2.2 Project Background

Pharmacists work in multiple environments (community, hospital, long term care, clinics, etc.) and increasingly participate in patient-centered care teams providing essential clinically-oriented patient care services such as medication therapy management, clinical reconciliation (medication, allergies and problems), patient immunization management, disease state monitoring, and therapy adherence programs. These services reduce adverse drug events, improve patient safety, and optimize medication use and health outcomes. Pharmacists are integral members of the health care team and have unique and frequent access to patients, routinely working with patients to facilitate understanding and compliance with drug regimens, reconcile medications from multiple prescribers, and monitor effectiveness of the treatment. These activities affect the treatment plans of other caregivers. Having a medication-related plan of care shared with those providers and incorporated with care plans developed by other care team members is critical to the overall success of patients reaching their proposed care goals of care.

Today, pharmacists document within proprietary systems that do not export and cannot receive standards-based data. Where care plan information is shared from pharmacy management systems, it is done using proprietary interfaces and free text; there is no standard covering pharmacist care plans. Thus, sharing data requires time consuming redundant data entry which is a major factor limiting care planning. Furthermore, care plan documentation that is free text is inconsistent and incapable of supporting electronic quality measurement and reporting. The HL7 C-CDA Care Plan cited in the Office of the National Coordinator (ONC) for Health Information Technology (IT) *2017 Interoperability Standards Advisory* (ISA)[8] is insufficient in supporting pharmacy-focused activities such as medication therapy management, therapy

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[8] ONC, *2017 Interoperability Standards Advisory.*
https://www.healthit.gov/sites/default/files/2017_isa_reference_edition-final.pdf

adherence, and additional medication-specific goals of therapy that support medication optimization.

2.3   Current Project

The current project specifies the Pharmacist Care Plan, an electronic care plan document with enhanced medication management content based on the templates in C-CDA R2.1. The Pharmacist Care Plan is a standardized, interoperable document containing information on medication-related activities, as well as patient-provider shared goals and plans for care. The Pharmacist Care Plan identifies resources and obstacles to patient compliance with the recommended treatment. This type of data is not often captured in a structured and standard format that can be used for research, quality measurement, or public health reporting. The Pharmacist Care Plan supports the strategy of interoperability and information exchange promoting coordination of care among a variety of settings, thus improving the quality of care for the patient.

The Pharmacist Care Plan serves two needs. It supports the CMS Medicare Part D Enhanced Medicare Therapy Management (MTM) program that started on January 1, 2017. The program launched a pilot in five Medicare Part D regions. Program participants in these regions have the opportunity coordinate care with pharmacy providers on issues related to medication management and adverse outcomes through the MTM model of enhanced care, which includes an individual's goals for therapy and outcomes.

Secondly, the movement towards value-based payment (VBP) models has recognized pharmacists as an important part of the well-connected care team that addresses the needs of the patient.[9] In a VBP model, a patient's care is coordinated, managed, and supported through documentation of goals and outcomes. The Pharmacist Care Plan provides that documentation for medications.

The current project builds on the work started in the NCPDP *Pharmacist eCare Plan*, which provides guidance for pharmacist and vendors as they implement the standard CDA R2.1 Care Plan document. The Pharmacist Care Plan electronic document standardizes exchange of information on medications dispensed and medication therapy problems which are not specified in the current Care Plan document type.

In parallel to the CDA specification development, the project created complementary Fast Healthcare Interoperability Resources (FHIR) profiles for the Pharmacist Care Plan, reusing foundational work from the C-CDA on FHIR project. This foundation includes the US Realm Header, FHIR US Core profiles, and the FHIR version of the C-CDA Care Plan.

The project has implemented both the CDA and the FHIR Pharmacist Care Plan specifications in a pilot at Community Care of North Carolina (CCNC). Please note, the FHIR Pharmacist Care Plan is balloted separately from this standard. The burden of redundant data entry is a major factor limiting care planning to less than 15% of the CCNC population, which includes many at risk and care-intensive patients. Resolving redundant data entry and providing standard, structured data will enhance the ability of pharmacists to engage with patients and will improve the patient experience of care through comprehensive medication review with the pharmacists and care managers. Facilities received Pharmacist Care Plan files in both CDA and FHIR formats from implementing EHRs. In addition, participating systems converted CDA-based Pharmacist Care Plans to the FHIR format using provided transformation files.

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[9] Fattori, "The Rising Star in the Value-Based Community." http://sco.lt/5qIvGT

2.4 Use Cases

This implementation guide meets the need of four use cases unique to the pharmacy environment. Though the scope of the pilot testing focused on Use Case 4, the standard was designed to meet the needs for clinical data exchange in each of the cases described in this section.

Figure 2: Pharmacist Use Case 1
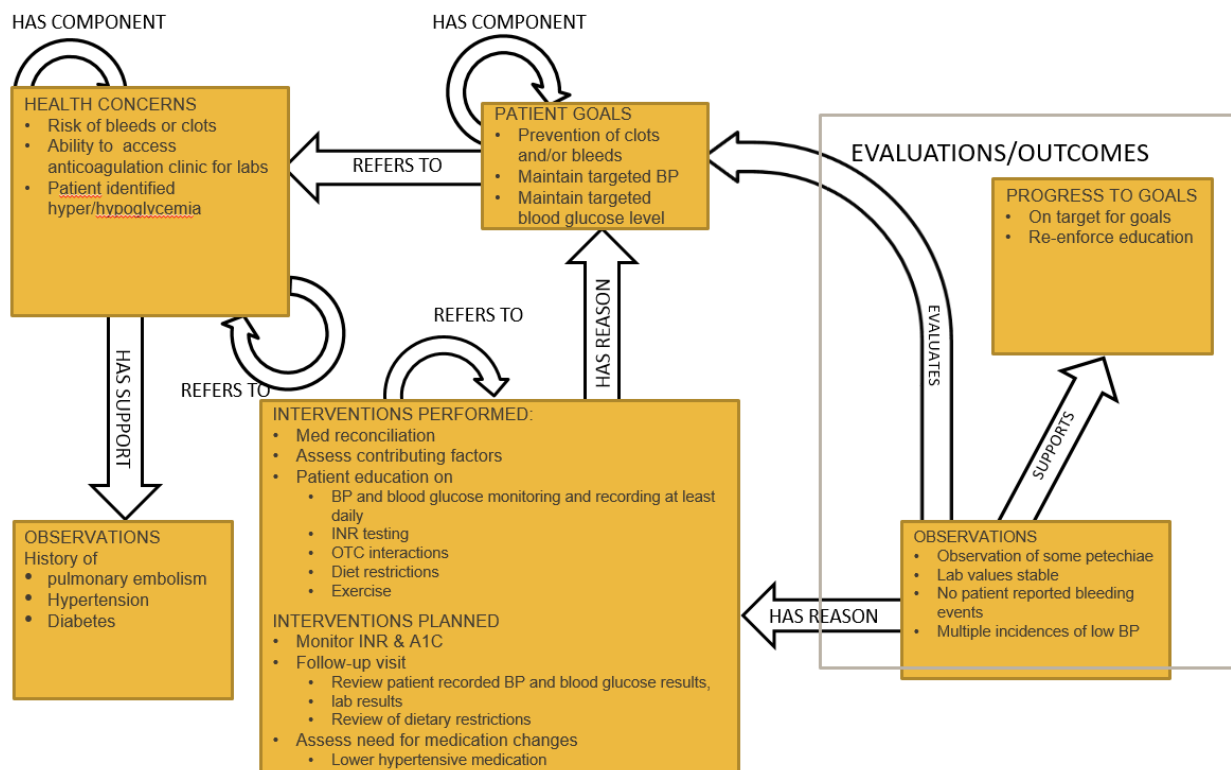
Use Case 1: **New condition for a patient risk at risk for a pulmonary embolism.** The community pharmacist meets with the patient and the caregiver after a recent discharge from a hospital for a pulmonary embolism. The patient is diagnosed with hypertension and diabetes. The patient has been enrolled in a diabetes outpatient clinic and has now been referred to an anticoagulation outpatient clinic.

The community pharmacist coordinates medication therapy management services (including reconciliation of medications, allergies and indications for medication use) with the primary care provider (PCP) and the diabetes and anticoagulation clinics and documents the patient's medication-related goals. The pharmacy generates the Pharmacist Care Plan to share medication related goals and electronically delivers the Care Plan to the patient, the PCP, and the outpatient clinics for chronic care management and care coordination

Figure 3: Pharmacist Use Case 2

HAS COMPONENT

HAS COMPONENT

HEALTH CONCERNS
- Risk deep vein thrombosis
- Risk of uncontrolled pain
  - Side effects of uncontrolled pain
    - Depression
    - Dietary disturbances
    - Cognitive disturbances

REFERS TO

PATIENT GOALS
- Pain Management pre op and post op
- Prevention of DVT
- Prevention of infection

EVALUATIONS/OUTCOMES

PROGRESS TO GOAL
Pre op goal met

HAS SUPPORT

REFERS TO

REFERS TO

HAS REASON

EVALUATES

SUPPORTS

OBSERVATIONS
Scheduled for hip replacement

INTERVENTIONS PERFORMED
- Targeted med review
- PDMP check
- Assess potential allergies/interactions
- Pain assessment
- Patient education and counseling on
  - Pain management
  - Side effects of uncontrolled pain
  - Symptoms of DVT

INTERVENTIONS PLANNED
- Post discharge med reconciliation
- Assessment of Pain
- Assessment of side effects of pain management education

HAS REASON

OBSERVATIONS
- No indication of controlled substance misuse
- Moderate controlled pain on baseline assessment
- No allergy/interaction findings
- No indication of infection
- Patient understands symptoms to be monitored

Use Case 2: Patient scheduled for a hip replacement. The pharmacist, under a collaborative practice agreement with the orthopedic surgeon, counsels the patient prior to the procedure to ensure there are no medication-related problems. After the surgery, the pharmacist coordinates medication-related goals with the patient pertaining to deep vein thrombosis risk and pain management.

The community pharmacist uses a health IT system to document patient care. The health IT system generates the Pharmacist Care Plan to share the medication related goals electronically with the patient, orthopedic surgeon, PCP, home health care agency, and the rehabilitation center for care coordination.

Figure 4: Pharmacist Use Case 3
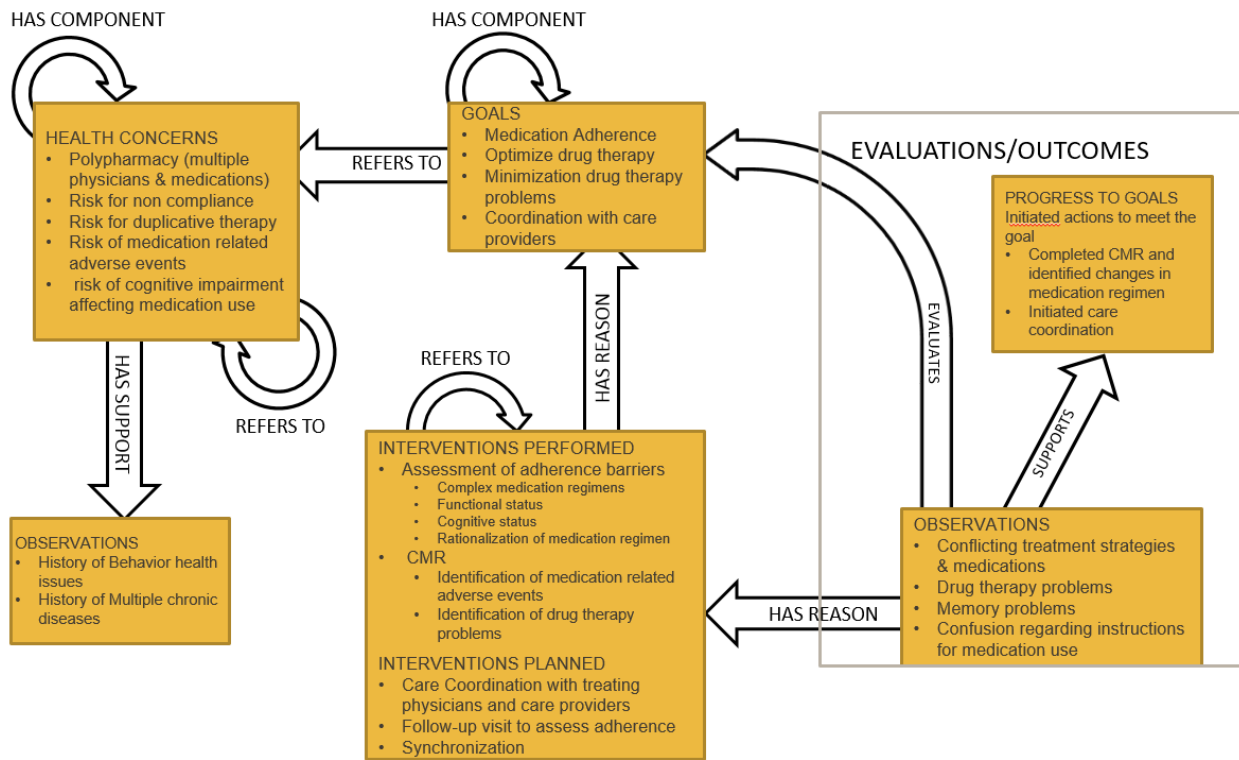
Use Case 3: Patient with behavior health issues and multiple chronic diseases meets with a consultant pharmacist for the yearly comprehensive medication review to meet Medicare Part D MTM requirement. The pharmacist documents conflicting treatment strategies and medications. The pharmacist recommends strategies/alterations to existing treatment, development of a manageable medication schedule, patient education, and outcome follow-up.

The community pharmacist uses a health IT system to document patient care. The health IT system generates the Pharmacist Care Plan to share the medication related goals and strategies electronically with the patient, the psychiatrist, the outpatient psychiatric clinic, and the PCP or chronic care management and care coordination.

Figure 5: Pharmacist Use Case 4
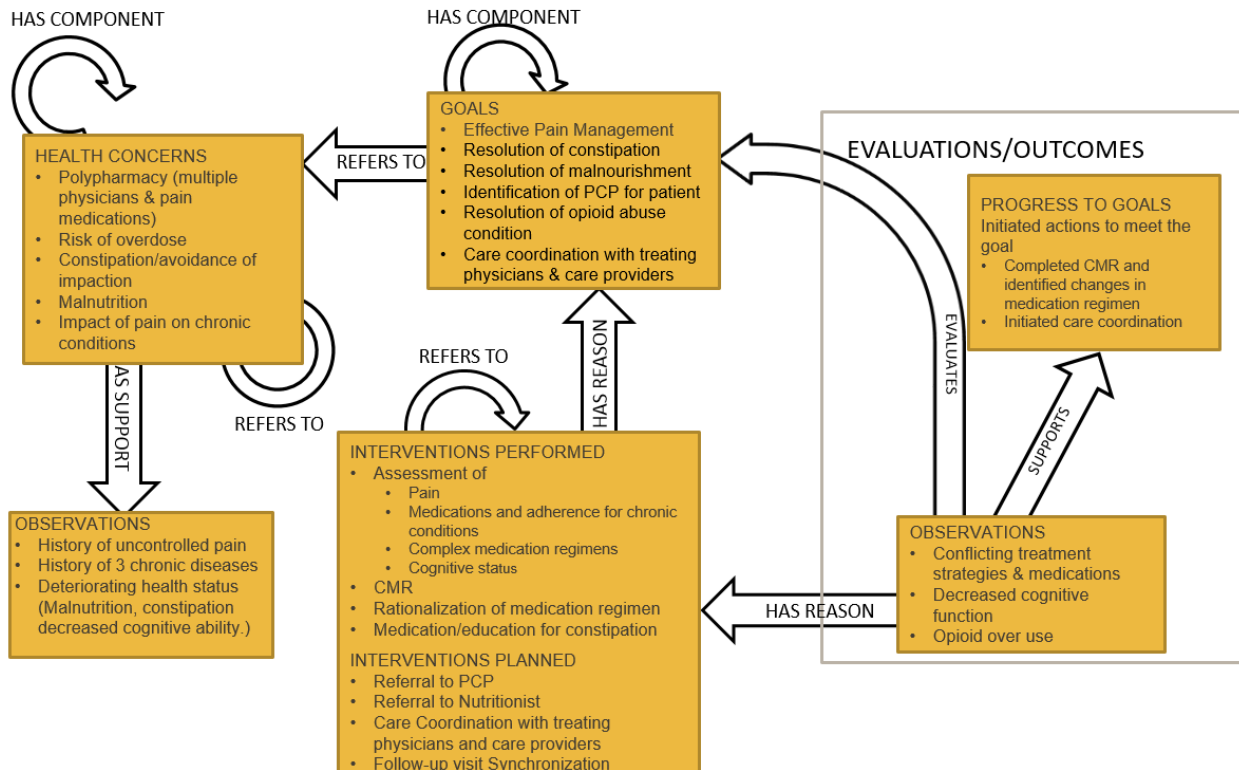
Use Case 4: Patient comes to the community pharmacy to pick up hydrocodone, which has been e-prescribed and complaints of constipation. The pharmacist reviews the state Prescription Drug Monitoring Program (PDMP) database, and discovers that multiple physicians have treated the patient for pain. The pharmacist suspects the patient may have an opioid abuse condition. Through patient counseling, the pharmacist discovers the patient is malnourished, has three chronic care conditions, complains of constipation, and has no PCP. The pharmacist performs comprehensive medication review and helps the patient identify a PCP.

The community pharmacist documents conflicting treatment strategies and medications including the need for naloxone. The pharmacist recommends strategies/alterations to existing treatment, pain management, development of a manageable medication schedule, nutritional counseling, patient education, and outcome follow-up.

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 and testable constraints found in Volume 2 of this guide.

3.1 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, therefore there is no strict requirement to render directly from 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)

3.2 Unknown and No Known Information

In a number of cases, specifications for data collection allow the entry of "UNKNOWN" to represent the case in which desired information is not available. This concept is captured, within this implementation guide, through use of the nullFlavor "UNK". An item may be unknown, not relevant, or not computable or measurable, such as when a patient arrives at an Emergency Department unconscious and with no identification.

The templates and value sets used in this guide are prescriptive about where a nullFlavor can be used and which values are appropriate. The following information serves as a general guide.

In many cases, the CDA standard stipulates 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.

If an instance needs to contain a value such as UNK, that value is passed in the "@nullFlavor" attribute 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.

Any **SHALL**, **SHOULD** and **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>
```

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, Integrating the Healthcare Enterprise (IHE), and the Health Information Technology Standards Panel (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 and 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>
```

3.3 Asserting an Act Did Not Occur with a Reason

The `negationInd` attribute, if true, specifies that the act indicated was observed to not have occurred (which is subtly but importantly different from having not been observed). NegationInd='true' is an acceptable way to make a clinical assertion that something did not occur, for example, "no gestational diabetes".

A nested reason for the act not being done can be represented through the use of an `entryRelationship` clinical statement with an `actRelationship` type of "RSON".

Figure 15: Asserting an Act Did Not Occur with Reason

```
<entry>
  <substanceAdministration classCode="SBADM" moodCode="EVN" negationInd="true">
    <templateId root="2.16.840.1.113883.10.20.22.4.52"/>
    <statusCode code="completed"/>
    <effectiveTime nullFlavor="NI"/>
    <doseQuantity nullFlavor="NI"/>
    <consumable>
      <manufacturedProduct>
        <templateId root="2.16.840.1.113883.10.20.22.4.54"/>
        <!-- ********  Immunization Medication Information   ******** -->
          <manufacturedMaterial>
            <code code="88"
                  codeSystem="2.16.840.1.113883.6.59"
                  displayName="Influenza virus vaccine"
                  codeSystemName="CVX">
            </code>
          </manufacturedMaterial>
      </manufacturedProduct>
    </consumable>
    <entryRelationship typeCode="RSON">
      <observation classCode="OBS" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.24.3.88"/>
          <code code="410666004"
                codeSystem="2.16.840.1.113883.6.96"
                displayName="reason"
                codeSystemName="SNOMED CT"/>
          <value xsi:type="CD"
                code="275984001"
                codeSystem="2.16.840.1.113883.6.96"
                codeSystemName="SNOMED CT"
                displayName="Immunization refused"/>
      </observation>
    </entryRelationship>
  </substanceAdministration>
</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. This guide further constrains templates in the C-CDA R2.1 standard.

4.1 Conformance Conventions Used in This Guide

4.1.1 Errata or Enhancements

Comments regarding errata or enhancements may be noted on the HL7 STU Comments page: http://www.hl7.org/dstucomments/

4.1.2 Templates and Conformance Statements

Conformance statements within this implementation guide are presented as constraints from Trifolia Workbench, a template repository.[10] 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: 81-7345). 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 carry the same conformance number as the previous version. This is true even if the previous conformance statement has been edited. If a conformance statement is entirely new it has 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. New and 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`).

Templates in Volume 2 of the guide include contexts tables with a "Contained By" column indicating which documents or sections use this template and a "Contains" column indicating any entries that the template uses. Templates also include constraints overview tables. Constraints overview tables summarize the constraint statements following the table. Value set tables, where applicable, and brief XML example figures are included with most explanations.

A typical template, as presented in this guide, is shown in the Constraints Format Example figure below. The next sections describe specific aspects of conformance statements—open vs. closed statements, conformance verbs, cardinality, vocabulary conformance, and containment relationships.

---

[10] Lantana Consulting Group, Trifolia Workbench. http://trifolia.lantanagroup.com

Severity Observation

`[observation: templateId 2.16.840.1.113883.10.20.22.4.8(open)]`

Table xxx: Severity Observation Contexts

Used By:	Contains Entries:
Reaction Observation (optional) Allergy - Intolerance Observation (optional) Substance or Device Allergy - Intolerance Observation (required)	

This clinical statement represents the gravity of the problem, such as allergy or reaction, …

Table yyy: Severity Observation Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Fixed Value
observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.8']					
@classCode	1..1	SHALL		7345	2.16.840.1.113883.5.6 (HL7ActClass) = OBS

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:7345).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 ActMood) **STATIC** (CONF:7346).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:7347) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.8" (CONF:10525).
4. **SHALL** contain exactly one [1..1] **code**="SEV" Severity Observation (CodeSystem: 2.16.840.1.113883.5.4 ActCode) **STATIC** (CONF:7349).
5. **SHOULD** contain zero or one [0..1] **text** (CONF:7350).
   a. This text, if present, **SHOULD** contain zero or one [0..1] **reference/@value** (CONF:7351).
      i. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:7378).
6. …

4.1.3 Template Versioning

The versioning of a new template is indicated by "(Vn)" ((V2), V3, etc.) in the template name. A revised version of a previously published template keeps the same `templateId/@root` as the previous version but is assigned a new `templateId/@extension`. Versions are not necessarily forward or backward compatible. Versioning may be due to substantive changes in the template and/or the fact that a contained template has changed. The "(Vn)" designation is persistent; it appears with that template when it is used in subsequent guides.

4.1.4 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. Templates included in the Pharmacist Care Plan are open.

4.1.5 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; 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

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...

    a. 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.

---

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

4.1.6 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 17: 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 18: 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).
```

4.1.7 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 is 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 is expressed as [m..n] where m>=1 and n>=m (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 is not known (and would otherwise be omitted if it were optional), the @nullFlavor attribute must be used. See Unknown and No Known Information.

4.1.8 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® (Logical Observation Identifiers Names &

Codes) and SNOMED CT® (Systematized Nomenclature of Medicine, Clinical Terms) vocabularies.

Note that value set identifiers (e.g., ValueSet 2.16.840.1.113883.1.11.78 Observation Interpretation (HL7) **DYNAMIC**) do not appear in CDA XML instances; they tie the conformance requirements of an implementation guide to the appropriate code system for validation.

Value set bindings adhere to HL7 Vocabulary Working Group best practices, and include both a conformance verb (**SHALL**, **SHOULD**, **MAY**, etc.) and an indication of **DYNAMIC** vs. **STATIC** binding. Value set constraints can be **STATIC**, meaning that they are bound to a specified version of a value set, or **DYNAMIC**, meaning that they are bound to the most current version of the value set. 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. Throughout this implementation guide, the majority of bindings between coded attributes and the cited value sets are dynamic.

When a vocabulary binding binds to a single code, the stability of the binding is implicitly **STATIC**. A simplified constraint, used when the binding is to a single code, includes the meaning of the code, as follows.

Figure 19: 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 20: 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 Version 3 Normative Edition, 2010*[12] sections on Abstract Data Types and XML Data Types R1.

There is a discrepancy in the implementation of translation code versus the original code between HL7 Data Types R1 and the convention agreed upon for this specification.

---

[12] *HL7 Version 3 Normative Edition, 2010.*
http://www.hl7.org/implement/standards/product_brief.cfm?product_id=161

The R1 data type requires the original code in the root. 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.

Figure 21: 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>
```

In many cases, vocabularies are further constrained into value sets for use within this guide. Value set tables are present below a template, or are referenced if they occur elsewhere in this 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. Value set names and OIDs are summarized Volume 2 in Chapter 6: Value Sets in this Guide.

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

4.1.9 Containment Relationships

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

For example:

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).

In this constraint, 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 containment relationships are direct, for example:

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

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

4.1.10 Data Types

All data types used in a CDA document are described in the CDA R2 Normative Edition. All attributes of a data type are allowed unless explicitly prohibited by this specification.

4.1.11 Document-Level Templates "Properties" Heading

In Volume 2, 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.

4.2 XML Conventions Used in This Guide

4.2.1 XPath Notation

Instead of the traditional dotted notation used by HL7 to represent RIM classes, this document uses XML Path Language (XPath) notation[13] 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 is familiar to developers for identifying parts of an XML document.

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

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 22: 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 23: XPath Expression Example

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

4.2.2 XML Examples and Sample Documents

XML examples appear in figures in this document 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 24: ClinicalDocument Example

```
<ClinicalDocument xmls="urn:hl7-org:v3">
  ...
</ClinicalDocument>
```

Within the narrative, XML element (`code`, `assignedAuthor`, etc.) and attribute (`SNOMED CT`, `17561000`, etc.) names also appear in `this monospace font`.

---

[13] W3C, XML Path Language. http://www.w3.org/TR/xpath/

5   REFERENCES

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Appendix A — ACRONYMS AND ABBREVIATIONS

ADL	activities of daily living
BSA	body surface area
CCD	Continuity of Care Document
CCNC	Community Care of North Carolina
CDA	Clinical Document Architecture
CDC	Centers for Disease Control and Prevention
CONF	conformance
CVX	Vaccine Administered
DI	Device Identifier
EHR	Electronic Health Record
FHIR	Fast Healthcare Interoperability Resources
HIBCC	Health Industry Business Communications Council
HIE	health information exchange
HIPAA	Health Insurance Portability and Accountability Act of 1996
HIT	health information technology
HITSP	Health Information Technology Standards Panel
HL7	Health Level Seven
IADL	Instrumental Activity of Daily Living
ICCBBA	Formerly, the International Council for Commonality in Blood Banking Automation
IG	implementation guide
IHE	Integrating the Healthcare Enterprise
IHTSDO	International Health Terminology Standard Development Organisation
LOINC	Logical Observation Identifiers Names and Codes
MHTML	MIME HTML
MTM	Medication Therapy Management
NCPDP	National Council for Prescription Drug Programs
NDFRT	National Drug File - Reference Terminology
NHIS	National Health Interview Survey
NHSN	National Healthcare Safety Network
NPI	National Provider Identifier
NUBC	National Uniform Billing Committee
NUCC	National Uniform Claim Committee
OID	object identifier
ONC	Office of the National Coordinator for Health Information Technology

PCP	primary care provider
PDMP	Prescription Drug Monitoring Program
PI	Production Identifier
R2, R2.1	Release 2, Release 2.1, etc.
RFC	request for comments
RIM	Reference Information Model
RMIM	Refined Message Information Model
SDWG	Structured Documents Work Group
SNOMED CT	Systematized Nomenclature of Medicine, Clinical Terms
SPL	Structured Product Labeling
STU	Draft Standard for Trial Use
UCUM	Unified Code for Units of Measure
UDI	Unique Device Identification
V2, V3	Version 2, Version 3, etc.
VBP	value-based payment
WG	Work Group
XML	Extensible Mark-up Language
XPath	XML Path Language

Appendix B — 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. (An extension is a collection of element or attribute declarations and rules added to the base CDA R2 standard.) This section summarizes the applicable extensions and provides implementation guidance. For a full list of approved extension see HL7's wiki page for CDA_R2_Extensions.[14] 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 multiple ethnicities to be reported for a patient.

- sdtc:signatureText – The **signatureText** extension adds an attribute for **authenticator** and **legalAuthenticator** to record encoded digital signature information.

- 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 **deceasedInd** extension (= "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.

Extensions are designed as follows:

- Extension element names shall be derived from attributes defined in the RIM.

- A single namespace has been defined for all extensions created by the HL7 Structured Documents Working Group (formerly Structured Documents Technical Committee) which is urn:hl7-org:sdtc.

- This namespace shall be used as the namespace for any extension elements or attributes that are used by this implementation guide.

- Each extension element shall use the same HL7 vocabularies and data types used by CDA R2.

- Each extension element shall use the same conventions for order and naming as is used by the current HL7 tooling.

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[14] HL7 CDA R2 Extensions webpage. http://wiki.hl7.org/index.php?title=CDA_R2_Extensions

- 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 C — MIME MULTIPART/RELATED MESSAGES

The contents of this appendix were added in the event that implementers want additional guidance when referencing external observations or documents.

The following text is taken from the Claims Attachments Implementation Guide (AIS00000) in Section 2.4 http://www.hl7.org/documentcenter/public/wg/ca/CDAR2AIS0000R030_Implementat ionGuideDraft.pdf. 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 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.