



HL7 CDA® R2 Implementation Guide:
National Health Care Surveys (NHCS),
Edition 4 - US Realm

Volume 1 — Introductory Material

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HL7 STU Ballot

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Structure of This Guide

Two volumes comprise this *HL7 CDA® R2 Implementation Guide: National Health Care Surveys Edition 4 - 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.

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1 INTRODUCTION

Notes to Ballot Readers

This section will be removed in the published version of the IG.

Items for Voting

This ballot contains two volumes. Below are descriptions of items that may be voted on in each volume.

Volume 1:

The body of the document up until the appendices MAY be voted on.

Volume 2:

Templates that are part of this implementation guide new or revised are signified by the wording “part of National Health Care Surveys” below the template name. **These MAY be voted on.**

Templates that have been brought in unchanged from another implementation guide are signified by the wording “part of <name of IG>” (where <name of IG> is NOT "National Health Care Surveys") below the template name. **These MAY NOT be voted on.**

Primary Diagnosis Observation

We welcome comments/discussion around the inclusion of the Primary Diagnosis Observation template. Primary diagnosis is defined as the condition that is the chief reason for providing care and further, for inpatients, it is the condition, after study, which occasioned the admission to hospital. This template is contained in the current visit (encounter) templates (Current Emergency Department Visit, Current Inpatient Visit, Current Outpatient Visit). The primary diagnosis is an important piece of information for us to collect. If it is possible to get the principal diagnosis associated with the outpatient (OP) visit this would be equivalent to primary diagnosis for our purposes.

USCDI Mapping

We have provided draft XPath mappings from the relevant United States Core Data for Interoperability (USCDI) data classes/elements to their CDA XML IG locations. These mappings have been added to the *CDAR2_IG_NHCS_E4_S5_Mapping_Tables.xlsx* spreadsheet.

1.1 Purpose

This two-volume implementation guide contains a collection of Clinical Document Architecture (CDA) templates (Volume 2) for the National Center for Health Statistics (NCHS) National Health Care Surveys applicable to the US Realm and it contains narrative introductory and background material pertinent to this implementation guide (Volume 1), including information on how to understand and use the templates in Volume 2. These two volumes constitute a Standard for Trial Use (STU).

CDA templates included in Volume 2 represent healthcare data collected by the NCHS within the Division of Health Care Statistics (DHCS). The data are collected through surveys of ambulatory, inpatient, and outpatient care services in the United States: the National Ambulatory Medical Care

Survey (NAMCS) and the National Hospital Care Survey (NHCS).¹ These surveys produce nationally representative data to answer key questions about health care usage, quality, and disparities for public health professionals, researchers, and health care policy makers.

This implementation guide specifies National Health Care Surveys with three document types:

- **Emergency Department Encounter**, for data collected by NHCS (NHCS-ED)
- **Inpatient Encounter**, for data collected by NHCS (NHCS-IP)
- **Outpatient Encounter**, for data collected NHCS (NHCS-OPD) and NAMCS

Note: Value sets in this Implementation Guide are developed by outside entities (e.g., HL7) and cannot be altered by NCHS. In compliance with Executive Order 14168 (January 20, 2025), the National Health Care Surveys will only publish patient encounter records where the “patient sex” or “gender” variable options are “male” or “female.” In addition, we will not publish any data related to structured evaluation of risk for the social determinants of health domains. These actions will be implemented pending further direction by the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health IT.

1.2 Background

The NAMCS collect objective, reliable information about the provision and use of ambulatory medical care services in the United States. Findings are based on a visits to health care providers at sampled health centers. Previously, sample visits to non-federally employed, office-based physicians were also included.

The NHCS is designed to provide reliable and timely healthcare utilization data for hospital-based settings. Non-federal, non-institutional hospitals with six or more staffed inpatient beds are randomly selected to provide nationally representative data on hospital utilization. Participating hospitals are asked to submit all inpatient discharges and emergency department visits for a 12-month period.

Previous versions of this implementation guide also supported a third survey, the National Hospital Ambulatory Medical Care Survey (NHAMCS) which collected data on the use and provision of ambulatory care services in hospital emergency departments. NCHS conducted NHAMCS annually 1992 through 2022. To collect NHAMCS data, information was manually abstracted from patient medical records. The widespread use of electronic health records now allows this information to be shared electronically. The data historically gathered by NHAMCS is now collected through the NHCS.² While there are some differences (detailed in the guide), NAMCS and NHCS capture information about the patient, the visit, signs and symptoms, diagnoses, procedures, medications, and discharge disposition.

Historically, human abstractors have collected NAMCS data, while NHCS data have been obtained by the electronic submission of administrative claims (X12N Health Care Claim: Institutional Implementation Guide (837I)). This implementation guide builds on the standard CDA visit report to allow:

- Data from a greater number of visits to be collected
- More complete data, especially clinical data, to be obtained by electronic means than can be obtained by human abstractors or administrative claims

¹ CDC, National Health Care Surveys. <https://www.cdc.gov/nchs/healthcare-surveys/about/index.html>

² CDC, NHAMCS. <https://www.cdc.gov/nchs/nhamcs/about/>

- Enhancement of the surveys by incorporating readily available data such as the patient problem list, and vital statistics measures including height and weight
- Significantly more standardized data to be collected than previously

Previously, NAMCS required manual data abstraction. During NAMCS data collection in physician offices and community health centers, field representatives (Field Reps) visited practice locations to obtain the data. The Field Reps asked practice context and practice management questions. These "Induction" questions are at the individual provider-level and practice-level and are outside of the scope of this implementation guide. Providers were assigned a randomly-selected, one-week reporting period, during which data for a random sample of patient visits were recorded by the visiting Field Reps. Data captured included information on patient symptoms, diagnoses, and medications. The data also included information on procedures, patient management, and planned future treatment. Data were entered into a computer-assisted tool and later aggregated and sent back to NCHS for data processing. The NAMCS community health center data were sampled from three randomly-selected health care providers (including physicians, nurse practitioners, physician assistants, and certified nurse midwives) practicing at the sampled community health center. This manual data abstraction process was cumbersome, resource intensive, costly, and effectively limits the data pool.

NHCS has been collecting electronic claims data since 2011. Since 2015, NHCS has also collected electronic health record (EHR) data either informed by previous releases of this implementation guide or Consolidated CDA (C-CDA) guidance. Participating hospitals are asked to submit all inpatient discharges and emergency department visits for a 12-month period. Automating the surveys processes using CDA streamlines data collection and facilitates survey participation by providing all physicians and hospitals with a familiar and standard process. Templates included in this guide align with the C-CDA Release 2.1 (C-CDA R2.1) implementation guide, which is the standard indicated by Promoting Interoperability (formerly Meaningful Use) requirements. The templates in this guide expand on the scope of the original survey data elements in that they do not constrain the data collected to the narrow lists on the survey instruments, allowing data collection of any medication, lab result, procedure, or diagnosis recorded.

Implementers use this guide to submit data to fulfill requirements of the National Health Care Surveys covered under this guide by automatic extraction of the data from a practice's EHR system or clinical data repository.

Although EHR extraction offers new potential for automating the survey process or parts thereof, the challenges of automating data extraction are acknowledged in literature. For example, according to Garrido et. al (2013)³, "Even with improved standardization of terminologies and codes, EHR content, structure, and data format vary, as do local data capture and extraction procedures." NCHS is and has been dealing with EHR content, structure, and data format challenges already, even with manual abstraction. We believe that this implementation guide, with its further alignment with data standards, will promote movement towards standardization of EHR content, structure, data format, and data capture and extraction procedures for data elements of interest to the surveys—such as diagnoses, medication, and procedures. Such data are also of interest to a wide variety of other stakeholders.

We agree with Garrido and colleagues that "Within a single institution, significant differences in denominators, numerators, and rates arise from different electronic data sources, and documentation habits of providers vary. Data entered into the EHR may not be interpreted or recognized, resulting in

³ Garrido T, et. al. "e-Measures: insight into the challenges and opportunities of automating publicly reported quality measures." *J Am Med Inform Assoc.* Jan 2014; 21(1):181-184 doi: 10.1136/amiajnl-2013-001789. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3912717/>

substantial numerator loss and underestimates of the delivery of clinical preventive services." It is important, however, to note that the National Health Care Surveys are not used to evaluate quality of care within single institutions or via clinical quality measures within single or multiple institutions. These concerns are, therefore, not relevant to the National Health Care Surveys. The data collection process will be reviewed for accuracy of automated reporting and to ensure that new extraction procedures do not excessively burden clinicians or their supporters. NCHS will do this through planned implementation and collection trials. NCHS plans to submit the results of this evaluation for publication.

The intent of this implementation guide is to obtain as much survey information as possible from data currently available in EHRs. It is understood that not all of the data items indicated on the surveys may be captured by EHR systems at this time. (See [Unknown and No Known Information](#) section below for further detail.) However, see [Data Inclusion Guidance for Implementers](#) for specific direction on location and provider information and coded data elements for which null values SHALL NOT be submitted. If participants in these surveys wish to document additional details to meet the survey requirements now by configuring encounter forms or other templates in the EHR, they may do so, however, this is not required for submission and this implementation guide does not give a site guidance on how to do so.

This implementation guide is published as a STU, allowing users to comment during the trial period (see [Errata or Enhancements](#)).

1.3 Current Project

This *HL7 CDA® R2 Implementation Guide: National Health Care Surveys Edition 4* specification was developed and produced by the Health Level Seven (HL7) Public Health Work Group and co-sponsored by the HL7 Structured Documents Work Group. It is an STU update to the *HL7 CDA® R2 Implementation Guide: National Health Care Surveys Release 1*, STU Release 3.1.

The current project contains updates to support USCDI version 3 (USCDI-v3) and to address the STU comments that have been submitted to HL7 at [https://jira.hl7.org/issues/?jql=project%20%3D%20%22CDA%20Specification%20Feedback%22%20AND%20Specification%20%3D%20%22National%20Health%20Care%20Surveys%20\(NHCS\)%20\(CDA\)%20%5BCDA-nhcs%5D%22](https://jira.hl7.org/issues/?jql=project%20%3D%20%22CDA%20Specification%20Feedback%22%20AND%20Specification%20%3D%20%22National%20Health%20Care%20Surveys%20(NHCS)%20(CDA)%20%5BCDA-nhcs%5D%22).

In addition, this CDA implementation guide aligns with the *HL7 FHIR® Implementation Guide: National Health Care Surveys (NHCS), Edition 2 – US Realm* (in ballot, September 2025).

1.4 Audience

The audience for this implementation guide includes the architects and developers of HIT systems in the US Realm that exchange patient clinical data in ambulatory, inpatient, and outpatient care settings.

1.5 Organization of the Guide

This implementation guide is organized into two volumes. Volume 1 contains primarily narrative text describing this guide to the three National Health Care Surveys, whereas Volume 2 contains normative CDA template definitions.

1.5.1 Volume 1 Introductory Material

This document, Volume 1, provides an overview of CDA and information on how to understand and use the CDA templates provided in Volume 2.

- **Chapter 1**—Introduction
- **Chapter 2**—CDA R2 Background. This chapter contains selected background material on the CDA Release 2 (CDA R2) base standard, to aid the reader in conceptualizing the "templated CDA" approach to implementation guide development.
- **Chapter 3**—Design Considerations. This chapter includes design considerations that describe overarching principles applied across the CDA templates in this guide. Material in this chapter 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 chapter describes the rules and formalisms used to constrain the CDA R2 base 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 an overview of changes from the previous release, a summary of extensions to CDA R2, and an excerpt of the HL7 *Additional Information Specification Implementation Guide* covering MIME Multipart/Related Messages.

1.5.2 Volume 2 CDA Templates and Supporting Material

Volume 2 includes CDA templates and prescribes their use for a set of specific document types representing the National Health Care Surveys. The main chapters are:

- **Chapter 1**—Document-Level Templates. This chapter defines the US Realm Header template that applies across three document types representing the Emergency Department Encounter (NHCS-ED), Inpatient Encounter (NHCS-IP), and Outpatient Encounter (NHCS-OPD and NAMCS). 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 (coded) 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.
- **Chapter 4**—Sub-Entry Templates. This chapter defines sub-entry templates referenced within entry templates.

- **Chapter 5**—Participation and Other Templates. This chapter defines templates for CDA participants (e.g., author) and other fielded items (e.g., address, name) that cannot stand on their own without being nested in another template.
- **Chapters 6-8** include template IDs, value sets, and code systems used in this guide.
- **Chapter 9**—Changes from Previous Version. This chapter provides detailed change logs.

1.6 Contents of the Package

The following files comprise the implementation guide package:

Table 1: Contents of the Package

Filename	Description	Standards Applicability: Normative	Standards Applicability: Informative
CDAR2_IG_NHCS_E4_S5_V1_Introductory_Material	Implementation Guide Introductory Material	Chapter 1 Chapter 4 Appendix A Appendix C	Chapter 3 Appendix B
CDAR2_IG_NHCS_E4_S5_V2_Templates_and_Supporting	Implementation Guide Template Library and Supporting Material (including deprecated templates)	Templates Appendixes	Examples
CDAR2_IG_NHCS_E4_S5_Mapping_Tables.xlsx	Mappings from survey data elements to CDA templates	n/a	Mapping table
CDAR2_IG_NHCS_E4_S5_IPE.xml (located in Github - see link below)	Inpatient Encounter Sample	n/a	Sample file
CDAR2_IG_NHCS_E4_S5_OPE.xml (located in Github - see link below)	Outpatient Encounter Sample	n/a	Sample file
CDAR2_IG_NHCS_E4_S5_EDE.xml (located in Github - see link below)	Emergency Department Sample	n/a	Sample file
CDAR2_IG_NHCS_E4_S5_IPE.html (located in Github - see link below)	Inpatient Encounter Sample HTML rendering	n/a	Sample file rendering
CDAR2_IG_NHCS_E4_S5_OPE.html (located in Github - see link below)	Outpatient Encounter Sample HTML rendering	n/a	Sample file rendering
CDAR2_IG_NHCS_E4_S5_EDE.html (located in Github - see link below)	Emergency Department Sample HTML rendering	n/a	Sample file rendering
CDAR2_IG_NHCS_E4_S5.sch (located in Github - see link below)	Schematron for validation	n/a	Schematron file
CDAR2_IG_NHCS_E4_S5.xml (located in Github - see link below)	Schematron vocabulary file	n/a	Vocab file
https://github.com/HL7/CDA-nhcs-4.0	XML and Related files (Schematron, sample, html, stylesheet)	n/a	XML and related files
https://github.com/HL7/cda-core-2.0/tree/master/schema/extensions	Latest CDA Schema		
_readme.txt	Text file describing contents of the package	n/a	Readme file

Note: Any conflict between informative and normative content should be resolved in favor of the normative specifications.

1.7 Data Inclusion Guidance for Implementers

NHCS and NAMCS are encounter-based surveys, so entries in each encounter must maintain linkage to the underlying encounter information. Clinical Document Architecture (CDA) intentionally avoids over-specifying many things by design, however key location and performer data are required for encounter linkage and inference.

Validating the Service Delivery Locations (SDLOC) against sampled NHCS hospitals and NAMCS locations is essential for maintaining the integrity of the surveys. It ensures that NCHS analyzes data only from participants at valid, sampled sites, helping to prevent bias from non-sampled or out-of-scope facilities. SDLOC are essential linkage and inference in CDA documents. For encounters, SDLOC indicates where care was delivered. For entries like procedures and results, SDLOC identifies the specific location of the clinical act.

1. SDLOCs should be included in every encounter entry, and SDLOCs should be specified for each individual care activity.
2. SDLOC should include elements that support linkage and inference, in the following order of precedence: facility/hospital National Provider Identifier (NPI), facility/hospital address, and facility/hospital name.

Including performer information for sampled NAMCS providers is critical to ensure that clinical data are accurately attributed to the sampled providers, supporting valid inferences about care delivery.

1. Provider information, especially for the sampled provider, should be included either in the encounter entry or in the document header.
2. Provider information should include elements that support linkage and inference, in the following order of precedence: NPI and name.

If a document cannot be matched to a sampled location and/or provider, it will be excluded.

Given that we process millions of encounters each year, deduplication is essential. Therefore, please include document set identification on all CDA documents. Alternatively, you may submit only the most current version.

Entry identifiers are critical for linkage and inference in CDA documents. They provide explicit references between entries, encounters, and related acts. When consistently assigned and reused, they enable precise, high-confidence associations across the document.

Timestamps are essential for linkage and inference in CDA because they anchor clinical events in time, enabling linkage between entries and encounters. Overlapping or aligned timestamps associate procedures, observations, or results with the correct visit when direct references are missing. The more precise the timestamp, the stronger the inference.

NCHS approaches mapping entries to encounters using linkage and inference in the following order of precedence:

1. Entry Relationship – Explicit linkage through the entryRelationship element using semantic relationship types.
2. Containment – Based on where the entry is physically located in the document hierarchy.

3. Cross-Referencing – Matching shared identifiers directly embedded in entries and encounters.
4. Fuzzy Matching – Associating entries and encounters using overlapping timestamps or contextual attributes.

These methods resolve the inherent ambiguity in the CDA standard when associating entries with encounters. If none of these mapping methods apply, the entry cannot be reliably associated with an encounter and will be excluded.

Some entries may be matched to an encounter only using fuzzy matching. For instance, with conditions and medications, we often only receive a timestamp, which is sufficient for us to determine if it is associated with an encounter.

Section text must adhere to the same requirements as entries, particularly for sections with optional entries. You may structure your text as you prefer but ensure that all relevant data is included so we can effectively map the text contents to an encounter.

When submitting data to NCHS, implementers must submit coded data when available, and not submit nulls for the data listed in the following Table 2.

Table 2: Optional Enhancements

Section	Containing Entries	Entry
Diagnosis/Problem		
<ul style="list-style-type: none"> • Problem Section • Encounters Section • Health Concerns Section 	<ul style="list-style-type: none"> • Problem Concern Act • Encounter Activity / Encounter Diagnosis • Health Concern Act / Encounter Diagnosis • Health Concern Act • Health Concern Act / Hospital Admission Diagnosis 	Problem Observation
Medication		
<ul style="list-style-type: none"> • Discharge Medications Section • Medications Section • Plan of Treatment Section 	<ul style="list-style-type: none"> • Planned Supply • Planned Medication Activity • Medication Supply Order • Medication Dispense • Medication Activity 	Medication Information
Payment		
Payers Section	Coverage Activity	Policy Activity
Procedure		
Procedures Section		Procedure Activity Act
Procedures Section		Procedure Activity Observation
Procedures Section		Procedure Activity Procedure
Vital Signs		
<ul style="list-style-type: none"> • Vital Signs Section • Health Concerns Section 	<ul style="list-style-type: none"> • Vital Signs Organizer • Health Concern Act 	Vital Sign Observation

2 CDA R2 BACKGROUND

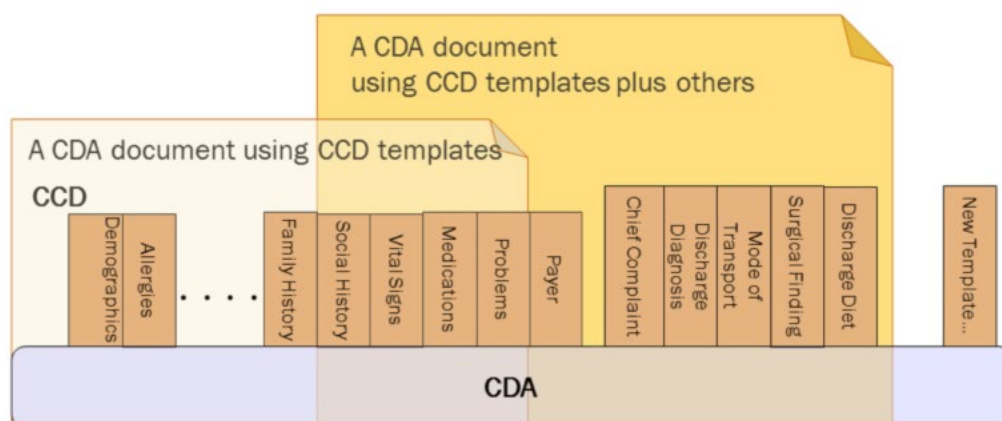
CDA is "... a document markup standard that specifies the structure and semantics of 'clinical documents' for the purpose of exchange" [CDA R2, Section 1.1].⁴ Clinical documents, according to CDA, have the following characteristics:

- 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.

CDA R2 can be constrained by mechanisms defined in the "Refinement and Localization"⁵ 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, as shown in the following figure.

Figure 1: Templated CDA



There are many different 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, an NAMCS document-level template might require that the provider's ID be present, and that the document contain a Services and Procedures Section.
- **Section-level templates:** These templates constrain fields in the CDA section and define containment relationships to CDA entries. For example, a Services and Procedures Section-

⁴ HL7 CDA Release 2. http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7

⁵ HL7 Version 3 Standard. <http://www.hl7.org/v3ballot/html/infrastructure/conformance/conformance.htm> (Login required.)

level template might require that the section/code be fixed to a particular LOINC code, and that the section contain a Provided Service Observation.

- **Entry-level templates:** These templates constrain the CDA clinical statement model in accordance with real world observations and acts. For example, a Primary Diagnosis Observation 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 particular observation.

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 both test the instance for conformance against the CDA XML (Extensible Markup Language) schema and test the instance for conformance against asserted templates.

3 DESIGN CONSIDERATIONS

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

3.1 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.
- **Device participation:** Devices do not participate as legally responsible entities but can participate as authors in some scenarios.

Meaningful Use Stage 2 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".⁶

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.

3.2 Rendering Header Information for Human Presentation

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)

⁶ HHS, Standards, Implementation Specifications, and Certification Criteria for EHR Technology (Final Rule). <http://www.gpo.gov/fdsys/pkg/FR-2012-09-04/pdf/2012-20982.pdf>

3.3 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 measurable, such as where a patient arrives at an emergency department unconscious and with no identification.

In many cases, the implementation guide 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.

Note that when submitting data to NCHS, implementers must submit coded data when available, and not submit nulls for the [data listed in Table 2](#), in section [1.7 Data Inclusion Guidance for Implementers](#).

Here, we provide guidance on representing unknown information. Further details can be found in the *HL7 V3 Data Types, Release One* specification that accompanies the CDA R2 base standard. However, it should be noted that the focus 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 contain an "@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 more details about the reason the information is unknown, as shown in the following example.

Figure 2: nullFlavor Example

```
<name>
  <given nullFlavor="MSK" />
  <family nullFlavor="MSK" />
</name> <!--Sender has masked (MSK) the patient's name due to security, privacy, or
other reasons -->
```

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 3: 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 4: 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 5: Unknown Medication Example

```

<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 6: 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, the Continuity of Care Document (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 7: 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 8: 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 9: Value Completely Unknown

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

Figure 10: 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>
```


3.4 Use of Qualifiers

Post-coordination in a code system is when two or more codes are used to represent a single concept. When using a code system (such as SNOMED CT) that supports post-coordination it is possible to build up terms from combinations of codes.

For example, the C-CDA Medication Activity template has an element `approachSiteCode` which is the CD data type and is bound to the Body Site (2.16.840.1.113883.3.88.12.3221.8.9) value set. While most of the terms in the Body Site value set are pre-coordinated, it is likely that all possible combinations of body site are not accounted for. In these cases, post-coordination becomes necessary and allows, for example, the SNOMED code for “back of left hand” to be represented by the combination of a code for “hand”, a code for “left”, and a code for “back of”.

The CD data type has a qualifier element that consists of a name/value pair. Name is the CV data type and value is the CD data type. Value is used to hold the qualifying code (“left” or “back of” in our example above) and name is used to describe the relationship between the value and the parent element.

The following is an example of the use of qualifier:

Figure 11: Qualifier Example

```
<approachSiteCode code="302539009"
  codeSystem="2.16.840.1.113883.6.96"
  codeSystemName="SNOMED CT"
  displayName="hand">
  <qualifier>
    <name code="78615007"
      codeSystem="2.16.840.1.113883.6.96"
      displayName="with laterality"/>
    <value code="7771000"
      codeSystem="2.16.840.1.113883.6.96"
      displayName="left"/>
  </qualifier>
  <qualifier>
    <name code="10546003"
      codeSystem="2.16.840.1.113883.6.96"
      displayName="site"/>
    <value code="255551008"
      codeSystem="2.16.840.1.113883.6.96"
      displayName="back of"/>
  </qualifier>
</approachSiteCode>
```

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 required and optional sections.

4.2 Conformance Conventions Used in This Guide

4.2.1 Errata or Enhancements

Comments regarding errata or enhancements may be noted by creating an issue on the HL7 Jira Site (<https://jira.hl7.org/secure/Dashboard.jspa>) and selecting

- Project = "CDA Specification Feedback (CDA)"
- Specification = "National Health Care Surveys (NHCS) (CDA)"
- Raised in Version = "1.3.1"

4.2.2 Templates and Conformance Statements

Conformance statements within this implementation guide are presented as constraints from Trifolia Workbench, a template repository.⁷ 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

⁷ Lantana Consulting Group, Trifolia Workbench. <https://trifolia.lantanagroup.com/>

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 this template uses.

Figure 12: Context Table Example: Encounter Diagnosis (V3)

Contained By:	Contains:
Encounter Activity (V3) (optional)	Problem Observation (V3) (required)

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

Figure 13: Constraints Overview Example: Encounter Diagnosis (V3)

XPath	Card.	Verb	Data Type	CONF#	Value
act (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.80:2015-08-01)					
@classCode	1..1	SHALL		1198-14889	urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = ACT
@moodCode	1..1	SHALL		1198-14890	urn:oid:2.16.840.1.113883.5.1001 (HL7ActMood) = EVN
templateId	1..1	SHALL		1198-14895	
@root	1..1	SHALL		1198-14896	2.16.840.1.113883.10.20.22.4.80
@extension	1..1	SHALL		1198-32542	2015-08-01
code	1..1	SHALL		1198-19182	
@code	1..1	SHALL		1198-19183	29308-4
@codeSystem	1..1	SHALL		1198-32160	urn:oid:2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1
entryRelationship	1..*	SHALL		1198-14892	
@typeCode	1..1	SHALL		1198-14893	urn:oid:2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ
observation	1..1	SHALL		1198-14898	Problem Observation (V3) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.4:2015-08-01)

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...

1. **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 statements, conformance verbs, cardinality, vocabulary conformance, containment relationships, and null flavors.

Figure 14: Constraints Format Example

Encounter Diagnosis (V3)

[act: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.80:2015-08-01 (open)]

Published as part of Consolidated CDA Templates for Clinical Notes (US Realm)
DSTU R2.1

1. **SHALL** contain exactly one [1..1] @classCode="ACT" (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6 **STATIC**) (CONF:1198-14889).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001 **STATIC**) (CONF:1198-14890).
3. **SHALL** contain exactly one [1..1] templateId (CONF:1198-14895) such that it
 - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.80" (CONF:1198-14896).
 - b. **SHALL** contain exactly one [1..1] @extension="2015-08-01" (CONF:1198-32542).
4. **SHALL** contain exactly one [1..1] code (CONF:1198-19182).
 - a. This code **SHALL** contain exactly one [1..1] @code="29308-4" Diagnosis (CONF:1198-19183).
 - b. This code **SHALL** contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.1" (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:1198-32160).
5. **SHALL** contain at least one [1..*] entryRelationship (CONF:1198-14892) such that it
 - a. **SHALL** contain exactly one [1..1] @typeCode="SUBJ" (CodeSystem: HL7ActRelationshipType urn:oid:2.16.840.1.113883.5.1002 **STATIC**) (CONF:1198-14893).
 - b. **SHALL** contain exactly one [1..1] [Problem Observation \(V3\)](#) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.4:2015-08-01) (CONF:1198-14898).

4.2.3 Template Versioning – General Approach

Under the "templated CDA" approach a new implementation guide can use existing CDA templates from previously published implementation guides. 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 (SDWG) 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.*⁸ 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.

4.2.4 Template Versioning – NHCS Update Specific Approach

Due to the fact that updates are being released in parallel for two different versions of this IG (STU2.1 – this IG, and STU3.1), the notation in template name versioning has been slightly altered for clarity.

As above, a revised version of a previously published template keeps the same `templateId/@root` as the previous version but is assigned a new `templateId/@extension`. However, specific to this IG the `templateId/@extension` string will be suffixed with “<.STU release number>”, eg: “2022-01-01.3.1” and the template name notation will be “(Vn:<STU release number>)” (V2:3.1, V3:3.1, etc.).

4.2.5 Open and Closed Templates

In open templates, all 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.

4.2.6 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*.⁹

- **SHALL**: an absolute requirement
- **SHALL NOT**: an absolute prohibition against inclusion

⁸ HL7 Templates Standards. <http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=132>

⁹ HL7, *Version 3 Publishing Facilitator's Guide*.

<https://www.hl7.org/documentcenter/public/wg/projman/misc/pfg.pdf>

- **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

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...

- 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.

4.2.7 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 15: 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 16: 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).

4.2.8 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 is not known (and would otherwise be omitted if it were optional), the @nullFlavor attribute must be used. See [Unknown and No Known Information](#).

4.2.9 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 Work 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 17: 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 18: 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*¹⁰ 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 19: 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>
```

¹⁰ HL7 Version 3 Interoperability Standards, Normative Edition 2010.
<http://www.hl7.org/memonly/downloads/v3edition.cfm - V32010>

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 Uniform Resource Locator (URL) to check for the most current version of the value set expansion.

Figure 20: Example Value Set Table (Language)

Value Set: Language 2.16.840.1.113883.1.11.11526 A value set of codes defined by Internet RFC 4646 (replacing RFC 3066). Please see ISO 639 language code set maintained by Library of Congress for enumeration of language codes. Value Set Source: http://www.ietf.org/rfc/rfc4646.txt			
Code	Code System	Code System OID	Print Name
aa	Language	2.16.840.1.113883.6.121	Afar
ab	Language	2.16.840.1.113883.6.121	Abkhazian
ace	Language	2.16.840.1.113883.6.121	Achinese
ach	Language	2.16.840.1.113883.6.121	Acoli
ada	Language	2.16.840.1.113883.6.121	Adangme
ady	Language	2.16.840.1.113883.6.121	Adyghe; Adygei
ae	Language	2.16.840.1.113883.6.121	Avestan
af	Language	2.16.840.1.113883.6.121	Afrikaans
...			

4.2.10Containment 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, 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 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).

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

4.2.11 Data Types

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

4.2.12 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) notation¹¹ 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.

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 an "@") and concatenated 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

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

¹¹ XML Path Language. <http://www.w3.org/TR/xpath/>

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

This publication package includes complete XML sample documents as listed in the [Contents of the Package](#) table.

REFERENCES

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- *HL7 Additional Information Specification Implementation Guide*, Release 3.0 Draft Standard (March 2007). http://www.hl7.org/documentcenter/public/wg/ca/CDAR2AIS0000R030_ImplementationGuideDraft.pdf
- *HL7 CDA® R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes, US Realm* (C-CDA), all published versions. http://www.hl7.org/implement/standards/product_brief.cfm?product_id=492
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- Lantana Consulting Group, Trifolia Workbench. <https://trifolia.lantanagroup.com/>
- ONC, U.S. Core Data for Interoperability (USCDI). <https://www.healthit.gov/isa/us-core-data-interoperability-uscdi>
- XML Path Language (XPath), Version 1.0. <http://www.w3.org/TR/xpath/>

APPENDIX A — ACRONYMS AND ABBREVIATIONS

CCD	Continuity of Care Document
C-CDA	Consolidated CDA
CCU	critical care unit
CDA	Clinical Document Architecture
CDC	Centers for Disease Control and Prevention
CNM	Certified Nurse Midwife
CPT	Current Procedural Terminology
CVX	Codes for Vaccine Administered
DHCS	Division of Health Care Statistics
DI	Device Identifier
DME	durable medical equipment
DSTU	Draft Standard for Trial Use
E&M	evaluation and management
ED	emergency department
EHR	electronic health record
FDA	Food and Drug Administration
FIPS	Federal Information Processing Standards
HCPCS	Healthcare Common Procedure Coding System
HHS	Health and Human Services
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
HSLOC	Healthcare Service Location
HTML	HyperText Markup Language
ICCBBA	International Council for Commonality in Blood Banking Automation, Inc.
ICD	International Classification of Diseases
ICU	intensive care unit
IHE	Integrating the Healthcare Enterprise
IHTSDO	International Health Terminology Standard Development Organization

IP	inpatient
IP	intellectual property
LOINC	Logical Observation Identifiers Names and Codes
MIME	Multipurpose Internet Mail Extensions
MU	Meaningful Use
NAMCS	National Ambulatory Medical Care Survey
NCHS	National Center for Health Statistics
NCIt	National Cancer Institute (NCI) Thesaurus
NDFRT	National Drug File, Reference Terminology
NHAMCS	National Hospital Ambulatory Medical Care Survey
NHCS	National Hospital Care Survey, National Health Care Surveys
NHIS	National Health Interview Survey
NHSN	National Healthcare Safety Network
NICU	neonatal intensive care unit
NP	Nurse Practitioner
NPO	<i>nil per os</i> (nothing through the mouth)
NUBC	National Uniform Billing Committee
NUCC	National Uniform Claim Committee
OID	object identifier
OMB	Office of Management and Budget
ONC	Office of the National Coordinator for Health Information Technology
OP	outpatient
OPD	outpatient department
OTC	over the counter
PA	Physician Assistant
PCP	Primary Care Provider
PDF	portable document format
PHIN VADS	Public Health Information Network, Vocabulary Access and Distribution System
PHWG	Public Health Working Group
PI	Production Identifier
POA	present on admission
QRDA	Quality Reporting Document Architecture
R1, R2	Release 1, Release 2, etc.

RFC	request for comments
RIM	Reference Information Model
RTF	Rich Text Format
Rx	prescription
sdtc	Standard Duty Title Code
SDWG	Structured Documents Working Group
SNOMED CT	Systemized Nomenclature for Medicine – Clinical Terms
STU	Standard for Trial Use
TPN	total parenteral nutrition
UCUM	Unified Code for Units of Measure
UDI	Unique Device Identification
URL	Uniform Resource Locator
URN	uniform resource name
USCDI	U.S. Core Data for Interoperability
V1, V2	Version 1, Version 2, etc.
VIS	vaccine information statement
XML	Extensible Markup Language
XPath	XML Path Language

APPENDIX B — HIGH-LEVEL CHANGES FROM PREVIOUS RELEASES

This appendix summarizes the main changes in this release. See Volume 2 for a detailed list of changes.

Edition 4 (4.0.0)

Volume 1

One new section was added: “1.7-Data Inclusion Guidance for Implementers”.

Volume 2

Document-Level Templates

No new document-level templates were added.

All four document-level templates were updated and versioned:

- National Health Care Surveys (V6)
- Emergency Department Encounter (NHCS-ED) (V7)
- Inpatient Encounter (NHCS-IP) (V7)
- Outpatient Encounter (NHCS-OPD, NAMCS) (V7)

Section-Level Templates

No new NHCS-defined section-level templates were added.

Six NHCS-defined section-level templates were updated:

- Chief Complaint and Reason for Visit Section with NullFlavor (V5)
- Emergency Department Encounters Section (V5)
- Inpatient Encounters Section (V5)
- Medical Equipment Section (UDI) (V2)
- NHCS Social History Section (V3)
- Outpatient Encounters Section (V6)

Eight C-CDA section-level templates were added and versioned to support USCDI-v3:

- Allergies and Intolerances Section (entries optional) (NHCS V4)
- Allergies and Intolerances Section (entries required) (NHCS V4)
- Functional Status Section (NHCS V3)
- Goals Section (NHCS V2)
- Health Concerns Section (NHCS V3)
- Immunizations Section (entries required) (NHCS V4)
- Medications Section (entries required) (NHCS V3)
- Mental Status Section (NHCS V4)

Fourteen previously used C-CDA section-level templates were versioned to support USCDI-v3:

- Discharge Medications Section (entries optional) (NHCS V4)
- Discharge Medications Section (entries required) (NHCS V4)
- Encounters Section (entries optional) (NHCS V4)
- Immunizations Section (entries optional) (NHCS V4)
- Medical Equipment Section (NHCS V3)

- Medications Section (entries optional) (NHCS V3)
- Payers Section (NHCS V4)
- Plan of Treatment Section (NHCS V3)
- Problem Section (entries optional) (NHCS V4)
- Problem Section (entries required) (NHCS V4)
- Procedures Section (entries optional) (NHCS V3)
- Procedures Section (entries required) (NHCS V3)
- Results Section (entries optional) (NHCS V4)
- Social History Section (NHCS V4)

Three section-level templates were removed:

- Immunizations Section (V2)
- Medications Section (V2)
- Payment Sources Section (V3:3.1)

Four deprecated section-level templates were removed:

- Patient Information Section (DEPRECATED)
- Problems Section (DEPRECATED)
- Services and Procedures Section (DEPRECATED)
- Triage Section (DEPRECATED)

Entry-Level Templates

Seven NHCS-defined entry-level templates were updated:

- Current Emergency Department Visit (V5)
- Current Inpatient Visit (V4)
- Current Outpatient Visit (V6)
- Patient's Reason for Visit Observation (V2) (template previously deprecated)
- Primary Diagnosis Observation (V5)
- Principal Diagnosis (V3)
- Procedure Activity Procedure (UDI) (V2)

Seventeen previously used C-CDA section-level templates were versioned to support USCDI-v3:

- Discharge Medication (NHCS V5)
- Encounter Activity (NHCS V4)
- Encounter Diagnosis (NHCS V4)
- Goal Observation (NHCS V3)
- Immunization Activity (NHCS V4)
- Medical Equipment Organizer (NHCS V2)
- Medication Activity (NHCS V3)
- Nutrition Recommendation (NHCS)
- Planned Procedure (NHCS V4)
- Problem Concern Act (NHCS V4)
- Problem Observation (NHCS V5)
- Procedure Activity Act (NHCS V3)
- Procedure Activity Observation (NHCS V3)
- Procedure Activity Procedure (NHCS V4)
- Reaction Observation (NHCS V3)
- Result Organizer (NHCS V5)

- Social History Observation (NHCS V5)

Fourteen C-CDA entry-level templates were added and versioned to support USCDI-v3:

- Allergy - Intolerance Observation (NHCS V3)
- Allergy Concern Act (NHCS V4)
- Assessment Scale Observation (NHCS V3)
- Basic Industry Observation (NHCS)
- Basic Occupation Observation (NHCS)
- Disability Status Observation (NHCS)
- Functional Status Observation (NHCS V3)
- Functional Status Organizer (NHCS V3)
- Health Concern Act (NHCS V4)
- Hospital Admission Diagnosis (NHCS V4)
- Mental Status Observation (NHCS V4)
- Mental Status Organizer (NHCS V4)
- Substance or Device Allergy - Intolerance Observation (NHCS V3)
- Tribal Affiliation Observation (NHCS)

32 deprecated entry-level templates were removed:

- Admission Diagnosis Observation (DEPRECATED)
- Admission Priority Observation (DEPRECATED)
- Adverse Effect of Medical Treatment (DEPRECATED)
- Cause of Injury, Poisoning, or Adverse Effect (DEPRECATED)
- Clinical Note and External Document Reference (DEPRECATED)
- Discharge Status Observation (DEPRECATED)
- Episode of Care Observation (DEPRECATED)
- Follow-up Attempt Outcome Observation (DEPRECATED)
- Hospital Admission Encounter (DEPRECATED)
- Injury or Poisoning Observation (DEPRECATED)
- Listed for Admission to Hospital Act (DEPRECATED)
- Major Reason for Visit (DEPRECATED)
- New Patient Act (DEPRECATED)
- Number of Visits in the Last 12 Months (DEPRECATED)
- Observation Unit Stay Encounter (DEPRECATED)
- On Oxygen on Arrival Observation (DEPRECATED)
- Ordered Service Act (DEPRECATED)
- Ordered Service Observation (DEPRECATED)
- Ordered Service Procedure (DEPRECATED)
- Pain Assessment Scale Observation (DEPRECATED)
- Patient Residence Observation (DEPRECATED)
- Patient Seen in this ED in last 72 Hours and Discharged (DEPRECATED)
- Point of Origin Observation (DEPRECATED)
- Present on Admission Observation (DEPRECATED)
- Problem/Diagnosis/Symptom/Condition Observation (DEPRECATED)
- Procedure Follow-Up Attempt Observation (DEPRECATED)
- Provided Service Act (DEPRECATED)

- Provided Service Observation (DEPRECATED)
- Provided Service Procedure (DEPRECATED)
- Specialty Unit Stay Encounter (DEPRECATED)
- Transport Mode to Hospital Observation (DEPRECATED)
- Triage Level Assigned Observation (DEPRECATED)

Release 1 STU 3.1

Volume 1

One section was renamed: “4.2.3 – Template Versioning – General Approach”

One new section was added: “4.2.4 - Template Versioning – NHCS Update Specific Approach”.

Volume 2

Document-Level Templates

No new document-level templates were added.

All four document-level templates were updated and versioned:

- National Health Care Surveys (V5:3.1)
- Emergency Department Encounter (NHCS-ED, NHAMCS-ED) (V6:3.1)
- Inpatient Encounter (NHCS-IP) (V6:3.1)
- Outpatient Encounter (NHCS-OPD, NAMCS, NHAMCS-OPD) (V5:3.1)

Section-Level Templates

No new section-level templates were added.

Two section-level templates were updated and versioned:

- Payment Source Section (V3:3.1)
- Social History Section (V2:3.1)

Entry-Level Templates

No new entry-level templates were added.

One entry-level templates were updated and versioned:

- [C-CDA] Gender Identity Observation (V3)

Release 1 STU Release 3

Volume 1

Three sections were updated:

- Purpose
- Background
- Current Project

Volume 2

Document-Level Templates

No new document-level templates were added.

All four document-level templates were updated and versioned:

- National Health Care Surveys (V4)
- Emergency Department Encounter (NHCS-ED, NHAMCS-ED) (V5)
- Inpatient Encounter (NHCS-IP) (V5)
- Outpatient Encounter (NHCS-OPD, NAMCS, NHAMCS-OPD) (V4)

Section-Level Templates

One new section-level templates was added:

- Medical Equipment Section (UDI)

Five re-used section-level templates were added:

- Assessment Section
- Medical Equipment Section (V2)
- Plan of Treatment Section (V2)
- Problem Section (entries required) (V3)
- Procedures Section (entries required) (V2)

Three section-level templates were deprecated:

- Problems Section (DEPRECATED)
- Services and Procedures Section (DEPRECATED)
- Triage Section (DEPRECATED)

Four section-level templates were updated and versioned:

- Emergency Department Encounters Section (V4)
- Inpatient Encounters Section (V4)
- Outpatient Encounters Section (V5)
- Patient Information Section (V5)

Entry-Level Templates

Re-used entry-level templates were added: all templates contained in the following C-CDA sections:

- Assessment Section
- Medical Equipment Section (V2)
- Plan of Treatment Section (V2)
- Problem Section (entries required) (V3)
- Procedures Section (entries required) (V2)
- Social History Section (V3)

Eight entry-level templates were added:

- Birth Sex Observation
- Medical Equipment Organizer
- Non-Medicinal Supply Activity (V2)
- Non-Medicinal Supply Activity (UDI)
- Procedure Activity Procedure (V2)
- Procedure Activity Procedure (UDI)
- Product Instance
- UDI Organizer

Six entry-level templates were updated and versioned:

- Current Emergency Department Visit (V4)
- Current Inpatient Visit (V3)
- Current Outpatient Visit (V5)
- Gender Identity Observation (V2)
- Primary Diagnosis Observation (V4)
- Principal Diagnosis (V2)

Thirteen sub-entry templates were added (UDI):

- Brand Name Observation
- Catalog Number Observation
- Company Name Observation
- Device Identifier Observation
- Distinct Identification Code Observation
- Expiration Date Observation
- Implantable Device Status Observation
- Latex Safety Observation
- Lot or Batch Number Observation
- Manufacturing Date Observation
- Model Number Observation
- MRI Safety Observation
- Serial Number Observation

Twenty entry-level templates were deprecated

- Admission Priority Observation (DEPRECATED)
- Pain Assessment Scale Observation (DEPRECATED)
- Triage Level Assigned Observation (DEPRECATED)
- Cause of Injury, Poisoning, or Adverse Effect (DEPRECATED)
- Patient Residence Observation (DEPRECATED)
- Discharge Status Observation (DEPRECATED)
- Hospital Admission Encounter (DEPRECATED)
- Observation Unit Stay Encounter (DEPRECATED)
- Specialty Unit Stay Encounter (DEPRECATED)
- Episode of Care Observation (DEPRECATED)
- Follow-up Attempt Outcome Observation (DEPRECATED)
- Major Reason for Visit (DEPRECATED)
- Listed for Admission to Hospital Act (DEPRECATED)
- Number of Visits in the Last 12 Months (DEPRECATED)
- On Oxygen on Arrival Observation (DEPRECATED)
- Patient Seen in this ED in Last 72 Hours and Discharged (DEPRECATED)
- Point of Origin Observation (DEPRECATED)
- Adverse Effect of Medical Treatment (DEPRECATED)
- Procedure Follow-Up Attempt Observation (DEPRECATED)
- Transport Mode to Hospital Observation (DEPRECATED)

Release 1 STU Release 2

Volume 1

One new section was added: “Current Project”.

Volume 2

Document-Level Templates

No new document-level templates were added.

All four document-level templates were updated and versioned:

- National Health Care Surveys (V3)
- Emergency Department Encounter (NHCS-ED, NHAMCS-ED) (V4)
- Inpatient Encounter (NHCS-IP) (V4)
- Outpatient Encounter (NHCS-OPD, NAMCS, NHAMCS-OPD) (V4)

Section-Level Templates

No new section-level template were added.

Ten section-level templates were updated and versioned:

- Emergency Department Encounters Section (V3)
- Immunizations Section (V2)
- Inpatient Encounters Section (V3)
- Medications Section (V2)
- Outpatient Encounters Section (V4)
- Patient Information Section (V4)
- Payment Sources Section (V2)
- Problems Section (V4)
- Services and Procedures Section (V2)
- Triage Section (V2)

Entry-Level Templates

One new entry-level template was added:

- Gender Identity Observation

Two entry-level templates owned by C-CDA R2.1 were added:

- External Document Reference
- Hospital Admission Diagnosis

Three entry-level templates owned by C-CDA R2.1 Supplemental Templates for Pregnancy Status were added:

- Estimated Date of Delivery (SUPPLEMENTAL PREGNANCY)
- Estimated Gestational Age of Pregnancy
- Pregnancy Observation (SUPPLEMENTAL PREGNANCY)

Five entry-level templates were updated and versioned:

- Patient Residence Observation (V2)
- Primary Diagnosis Observation (V3)
- Current Emergency Department Visit (V3)
- Current Outpatient Visit (V4)
- Hospital Admission Encounter (V2)

Twelve entry-level templates were deprecated:

- Admission Diagnosis Observation (DEPRECATED)
- Clinical Note and External Document Reference (DEPRECATED)
- New Patient Act (DEPRECATED)
- Ordered Service Act (DEPRECATED)
- Ordered Service Observation (DEPRECATED)
- Ordered Service Procedure (DEPRECATED)
- Injury or Poisoning Observation (DEPRECATED)
- Present on Admission Observation (DEPRECATED)
- Problem/Diagnosis/Symptom/Condition Observation (DEPRECATED)
- Provided Service Act (DEPRECATED)
- Provided Service Observation (DEPRECATED)
- Provided Service Procedure (DEPRECATED)

APPENDIX C — EXTENSIONS TO CDA R2

Extensions to CDA R2 have been developed for cases where there is a need to communicate information for which there is no suitable representation in CDA R2. (See http://wiki.hl7.org/index.php?title=CDA_R2_Extensions for further details about CDA R2 extensions.) This section serves to itemize the extensions that are used in the guide and provide implementation guidance.

Extensions used in this guide include:

- `sdtc:raceCode` - The `sdtc:raceCode` extension allows for multiple races to be reported for a patient.
- `sdtc:ethnicGroupCode` - The `sdtc:ethnicGroupCode` extension is used to record additional ethnicity groups for the `recordTarget` or `subjectPerson`.
- `sdtc:birthTime` - The `sdtc:birthTime` element 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 `sdtc:dischargeDispositionCode` element allows the provider to record a discharge disposition in an encounter activity.
- `sdtc:signatureText` - The `sdtc:signatureText` element 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 CDA Digital Signature Standard balloted in Fall of 2013.

To resolve issues that need to be addressed by extensions, 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 it is not necessary to use an extension.
- 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.