CDAR2_IG_NHCS_R1_DSTU1.2_2016AUG_Vol1

HL7 CDA® R2 Implementation Guide: National Health Care Surveys Release 1, DSTU Release 1.2 – US Realm

HL7 Draft Standard for Trial Use (DSTU)

August 2016

Volume 1 — Introductory Material

Sponsored by:
Public Health and Emergency Response Work Group
Structured Documents Work Group

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Logical Observation Identifiers Names & Codes (LOINC)	Regenstrief Institute
International Classification of Diseases (ICD) codes	World Health Organization (WHO)
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Structure of This Guide

Two volumes comprise this *HL7 CDA® R2 Implementation Guide: National Health Care Surveys Release 1, DSTU Release 1.2 - 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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Acknowledgments

This guide was developed and produced under the guidance of the Centers for Disease Control and Prevention/National Center for Health Statistics (CDC/NCHS) through the collaboration of the Division of Health Care Statistics (DHCS) and the Classifications and Public Health Data Standards Staff (CPHDSS).

The editors appreciate the support and sponsorship of the Health Level Seven (HL7) Structured Documents Working Group (SDWG) and the HL7 Public Health and Emergency Response Work Group (PHER WG).

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1 INTRODUCTION

1.1 Note to Update Readers—Items for Comment

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

Volume 1:

1. The body of the document up until the appendices **MAY** be commented on.

Volume 2: Templates that are new or changed **MAY** be commented on; templates that are unchanged from the previous release **MAY NOT** be commented on.

2. Templates that are new or substantially revised are signified by "Draft as part of National Health Care Surveys Release 1, DSTU Release 1.2 – US Realm" under the template name. **These MAY be commented on.**
   EXAMPLE:

   Clinical Note and External Document Reference

   `[externalDocument: identifier urn:hl7ii:2.16.840.1.113883.10.20.34.3.44:2016-07-01 (open)]`

   Draft as part of National Health Care Surveys Release 1, DSTU Release 1.2 - US Realm

3. Templates that have been brought in unchanged from the previous release have "Published as part of <name of IG>" under the template name. **These MAY NOT be commented on.**
   EXAMPLE:

   Chief Complaint and Reason for Visit Section

   `[section: identifier urn:oid:2.16.840.1.113883.10.20.22.2.13 (open)]`

   Published as part of Consolidated CDA Templates for Clinical Notes (US Realm) DSTU R1.1

Changes made in this release are summarized in the Appendix in High-Level Changes from Previous Releases. Volume 2 of this guide contains a detailed section on "Changes from Previous Version".

1.2 Purpose

This two-volume implementation guide contains an overview of Clinical Document Architecture (CDA) markup standards, design, and use (Volume 1) and a collection of CDA templates for the Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS), National Health Care Surveys applicable to the US Realm (Volume 2). These two volumes constitute a Draft Standard for Trial Use (DSTU).

CDA templates included in Volume 2 represent healthcare data collected by the CDC NCHS within the Division of Health Care Statistics (DHCS). The data are collected

through three surveys of ambulatory, inpatient, and outpatient care services in the United States: the National Ambulatory Medical Care Survey (NAMCS), the National Hospital Care Survey (NHCS) and the National Hospital Ambulatory Medical Care Survey (NHAMCS).[1] These surveys produce nationally representative data to answer key questions about health care usage, quality, and disparities that are of interest to 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 and NHAMCS
- **Inpatient Encounter**, for data collected by NHCS
- **Outpatient Encounter**, for data collected NHCS, NAMCS, and NHAMCS

1.3 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 sample of visits to non-federally employed, office-based physicians, as well as visits to health care providers at community health centers.

The NHCS provides accurate and reliable health care statistics on the latest use of hospitals and hospital-based care organizations in the United States. Findings are based on all inpatient discharges and all emergency department and outpatient department visits at a sample of non-federal, non-institutional hospitals with six or more staffed inpatient beds.

The NHAMCS collects data on the use and provision of ambulatory care services in hospital emergency, outpatient departments, and ambulatory surgery centers. Findings are based on a national sample of visits to the emergency departments, outpatient departments of general and short-stay hospitals, and ambulatory surgery centers.

While there are some differences (detailed in the guide), all three surveys capture information about the patient, the visit, signs and symptoms, diagnoses, procedures, medications, and discharge disposition.

Traditionally, human abstractors have collected NAMCS and NHAMCS 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
- 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

[1] CDC, National Health Care Surveys. http://www.cdc.gov/nchs/dhcs.htm

The NAMCS and NHAMCS have traditionally required manual data abstraction. In the NAMCS data collection in physician offices, U.S. Census field representatives (Field Reps) visit physician practice locations to obtain the data. The Field Reps ask physicians practice context and practice management questions. These "Physician Induction" questions are at the practice level and are outside of the scope of this implementation guide. Physicians are assigned a randomly-selected, one-week reporting period, during which data for a random sample of patient visits are recorded by the visiting Field Reps on an encounter form. Data captured include information on patient symptoms, diagnoses, and medications. The form also includes information on diagnostic procedures, patient management, and planned future treatment. Data are entered into a computer-assisted tool and are later aggregated and sent back to NCHS for data processing. The NAMCS data collection in community health centers is conducted in a similar manner (e.g., induction questions, and visit data abstraction and transmission) except that Field Reps collect information on visits seen by three randomly-selected health care providers (including physicians, nurse practitioners, physician assistants, and certified nurse midwives) practicing at the sampled community health center. In NHAMCS, Field Reps conduct induction interviews with the sampled hospitals and collect sampled visit data over a four-week reporting period from randomly selected emergency services areas, outpatient department clinics, and affiliated ambulatory surgery centers. Visit data captured on the patient and services used are largely similar between NHAMCS and NAMCS. This manual data abstraction process is cumbersome, resource intensive, costly, and effectively limits the data pool.

Automating the survey process 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 CDA R2 (Release 2) implementation guide, which is the standard indicated by 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 service, 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 electronic health record (EHR) system or clinical data repository. In cases where there is only partial fulfillment of the requirements of the National Health Care Surveys covered under this guide by a practice’s use of this guide, Field Reps may be sent into the practice to complete the requirements. In these cases, Field Rep data collection forms will be pre-populated with the data enabled by this guide, thus significantly reducing the data collection burden.

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 T, et. al (2013)[2], "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

[2] 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/

manual abstraction. We believe that this implementation guide 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 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 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. NCHS already deals with varying provider documentation habits in the current process via paper and EHR manual abstraction and will closely monitor the effects of varying provider documentation habits during EHR extraction. This implementation guide is published as a DSTU, allowing users to comment during the trial period (see Errata or Enhancements). Instructions for submitting comments are available on the Health Level Seven (HL7) STU Comments site at: http://www.hl7.org/dstucomments/. 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. Submission of survey data from EHRs that do not contain all of the desired data elements specified in this implementation guide can be accepted, but each survey submission must include all of the required data elements specified in the implementation guide. Some of the survey data elements that are not common in EHRs at present have been included in a Health Statistics profile of the HL7 EHR-S Public Health Functional profile. Future EHR functionality will address this gap. 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.

1.4 Audience

The audience for this implementation guide includes the architects and developers of healthcare information technology (HIT) systems in the US Realm that exchange patient clinical data in ambulatory 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 Health Level Seven (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, NHAMCS-ED), Inpatient Encounter (NHCS-IP), and Outpatient Encounter (NHCS-OPD, NAMCS, NHAMCS-OPD). 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**—Participation and Other Templates. This chapter defines templates for CDA participants (e.g., author, performer) and other fielded items (e.g., address, name) that cannot stand on their own without being nested in another template.
- **Chapters 5-7** include template IDs, value sets, and code systems used in this guide.
- **Chapter 8**—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
CDAR2_IG_NHCS_R1_DSTU1.2_2016JUL _V1_Introductory_Material.docx	Implementation Guide Introductory Material	Normative
CDAR2_IG_NHCS_R1_DSTU1.2_2016JUL _V2_Templates_and_Supporting.docx	Implementation Guide Template Library and Supporting Material	Normative
CDAR2_IG_NHCS_R1_DSTU1.2_2016JUL _IPE.xml	Inpatient Encounter Sample	Informative
CDAR2_IG_NHCS_R1_DSTU1.2_2016JUL _OPE.xml	Outpatient Encounter Sample	Informative
CDAR2_IG_NHCS_R1_DSTU1.2_2016JUL _EDE.xml	Emergency Department Sample	Informative
CDA.xsl	Stylesheet for rendering	Informative
_readme.txt	Text file describing contents of the package	Informative

2 CDA R2 BACKGROUND

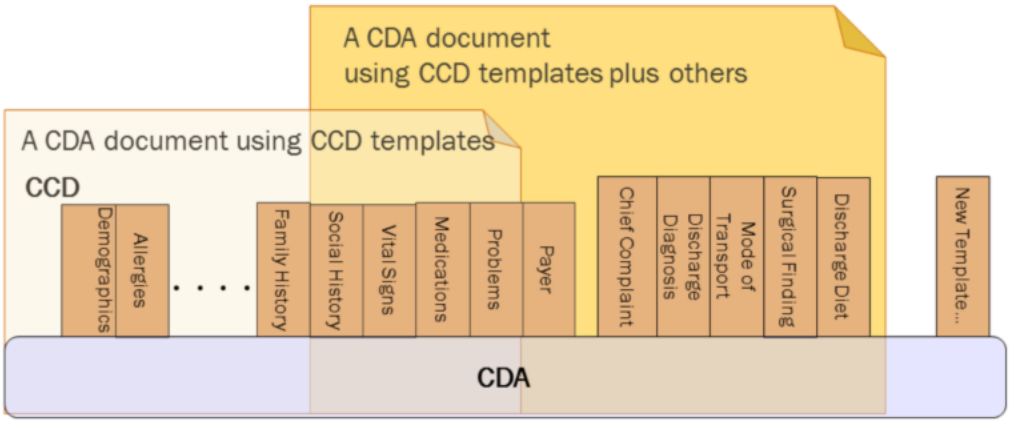
CDA is "… a document markup standard that specifies the structure and semantics of 'clinical documents' for the purpose of exchange" [CDA R2, Section 1.1].[3] Clinical documents, according to CDA, have the following characteristics:

- 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"[4] 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

[3] *HL7 CDA Release 2.* http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7
[4] *HL7 Version 3 Standard.*
http://www.hl7.org/v3ballot/html/infrastructure/conformance/conformance.htm (Login required.)

NAMCS document-level template might require that the provider's ID be present, and that the document contain a Services section.

- **Section-level templates:** These templates constrain fields in the CDA section, and define containment relationships to CDA entries. For example, a Services section-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 Provided Service 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".[5]

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

[5] 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

- Names of selected organizations along with their roles, participations, participation date ranges, identifiers, address, and telecommunications information
- Date of birth for `recordTarget`(s)

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 measureable, 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.

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 Consolidated CDA (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 on the HL7 DSTU Comments page: http://www.hl7.org/dstucomments/.

4.2.2 Templates and Conformance Statements

Conformance statements within this implementation guide are presented as constraints from Trifolia Workbench, a template repository.[6] An algorithm converts constraints recorded in Trifolia to a printable presentation. Each constraint is uniquely identified by an identifier at or near the end of the constraint (e.g., CONF:86-7345). The digits in the conformance number before the hyphen identify which implementation guide the template belongs to and the number after the hyphen is unique to the owning implementation guide. Together, these two numbers uniquely identify each constraint. These identifiers are persistent but not sequential. Conformance numbers in this guide associated with a conformance statement that is carried forward from a previous version of this guide will carry the same conformance number from the previous version. This is true even if the previous conformance statement has been edited. If a conformance statement is entirely new it will have a new conformance number.

Bracketed information following each template title indicates the template type (section, observation, act, procedure, etc.), the object `identifier (OID)` or `uniform resource name (URN)`, and whether the template is open or closed. The `identifier OID` is the `templateId/@root value`; all `templateIds` have an `@root` value. Versioned templates also have an `@extension` value, which is a date identifying the version of this template; such templates are identified by `URN` and the HL7 version (`urn:hl7ii`). The `URN` identifier includes both the `@root` and `@extension` value for the `templateId` (for example, `identifier urn:hl7ii:2.16.840.1.113883.10.20.5.5.41:2014-06-09`).

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

Figure 12: Context Table Example: Asthma Diagnosis Observation

Contained By:	Contains:
Diagnoses Section (optional)	Condition Control Observation Severity Observation (V2)

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

[6] Trifolia Workbench, https://trifolia.lantanagroup.com/

Figure 13: Constraints Overview Example: Asthma Diagnosis Observation

XPath	Card.	Verb	Data Type	CONF#	Fixed Value
observation[templateId/@root = '2.16.840.1.113883.10.20.34.3.5']					
@classCode	1..1	SHALL		1106-334	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
@moodCode	1..1	SHALL		1106-335	2.16.840.1.113883.5.1001 (ActMood) = EVN
templateId	1..1	SHALL		1106-443	
@root	1..1	SHALL		1106-444	2.16.840.1.113883.10.20.34.3.5
value	1..1	SHALL	CD	1106-336	2.16.840.1.114222.4.11.7432 (Asthma (NCHS))
...					

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

Asthma Diagnosis Observation

`[observation: templateId 2.16.840.1.113883.10.20.34.3.5 (open)]`

1. Conforms to **Diagnosis Observation** template `(identifier: urn:oid:2.16.840.1.113883.10.20.34.3.1)`.
2. **SHALL** contain exactly one [1..1] **@classCode**="`OBS`" Observation (CodeSystem: `HL7ActClass 2.16.840.1.113883.5.6`) (CONF:1106-334).
3. **SHALL** contain exactly one [1..1] **@moodCode**="`EVN`" Event (CodeSystem: `ActMood 2.16.840.1.113883.5.1001`) (CONF:1106-335).
4. **SHALL** contain exactly one [1..1] **templateId** (CONF:1106-443) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="`2.16.840.1.113883.10.20.34.3.5`" (CONF:1106-444).
5. **SHALL** contain exactly one [1..1] **value** with @xsi:type="CD", where the code **SHALL** be selected from ValueSet **Asthma (NCHS)** `2.16.840.1.114222.4.11.7432` **DYNAMIC** (CONF:1106-336).
6. ...

4.2.3 Template Versioning

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*.[7] 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 Open and Closed Templates

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

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

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

4.2.5 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.*[8]

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

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...

[7] *HL7 Templates Standards*. http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=132
[8] HL7, *Version 3 Publishing Facilitator's Guide.* http://www.hl7.org/v3ballot/html/help/pfg/pfg.htm

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.

4.2.6 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 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).

4.2.7 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 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.

4.2.8 Vocabulary Conformance

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

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

Value-set bindings adhere to HL7 Vocabulary Working Group best practices, and include both an indication of stability and of coding strength for the binding. Value set bindings can be **STATIC**, meaning that they bind to a specified version of a value set, or **DYNAMIC**, meaning that they bind to the most current version of the value set. If a **STATIC** binding is specified, a date **SHALL** be included to indicate the value set version. If a

DYNAMIC binding is specified, the value set authority and link to the base definition of the value set **SHALL** be included, if available, so implementers can access the current version of the value set. When a vocabulary binding binds to a single code, the stability of the binding is implicitly **STATIC**.

Figure 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*[9] 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.

[9] *HL7 Version 3 Interoperability Standards,* Normative Edition 2010.
http://www.hl7.org/memonly/downloads/v3edition.cfm - V32010

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>
```

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
…			

4.2.9 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, 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).

4.2.10 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.

4.2.11 Document-Level Templates "Properties" Heading

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

4.3 XML Conventions Used in This Guide

4.3.1 XPath Notation

Instead of the traditional dotted notation used by HL7 to represent RIM classes, this document uses XML Path Language (XPath) notation[10] in conformance statements and elsewhere to identify the Extensible Markup Language (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 a '@') and concatenated with a '/' symbol.

[10] XML Path Language. http://www.w3.org/TR/xpath/

Figure 21: XML Document Example

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

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

Figure 22: XPath Expression Example

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

4.3.2 XML Examples and Sample Documents

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

Figure 23: ClinicalDocument Example

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

This publication package includes complete XML sample documents as listed in the Contents of the Package table.

5 REFERENCES

- CDC, Ambulatory Health Care Data. http://www.cdc.gov/nchs/ahcd.htm
- CDC, National Health Care Surveys. http://www.cdc.gov/nchs/dhcs.htm
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APPENDIX A — ACRONYMS AND ABBREVIATIONS

BCG	Bacillus Calmette–Guérin
CCD	Continuity of Care Document
C-CDA	Consolidated CDA
CDA	Clinical Document Architecture
CDC	Centers for Disease Control and Prevention
cid	content-id field
CPHDSS	Classifications and Public Health Data Standards Staff
CPT	Current Procedural Terminology
CTAS	Canadian Triage and Acuity Scale
CVX	Codes for Vaccine Administered
DHCS	Division of Health Care Statistics
DI	Device Identifier
DSTU	Draft Standard for Trial Use
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	healthcare information technology
HITSP	Health Information Technology Standards Panel
HL7	Health Level Seven
HTML	HyperText Markup Language
ICCBBA	International Council for Commonality in Blood Banking Automation, Inc.
ICD	International Classification of Diseases
IHE	Integrating the Healthcare Enterprise
IHTSDO	International Health Terminology Standard Development Organization
INR	international normalized ratio

IP	inpatient
IP	intellectual property
LOINC	Logical Observation Identifiers Names and Codes
MHTML	MIME HTML
MIME	Multipurpose Internet Mail Extensions
MU	Meaningful Use
NAMCS	National Ambulatory Medical Care Survey
NCHS	National Center for Health Statistics
NDC	National Drug Code
NHAMCS	National Hospital Ambulatory Medical Care Survey
NHCS	National Hospital Care Survey
NHIS	National Health Interview Survey
NHSN	National Healthcare Safety Network
NUBC	National Uniform Billing Committee
OID	object identifier
OMB	Office of Management and Budget
OPD	outpatient department
OTC	over the counter
PDF	portable document format
PHER WG	Public Health and Emergency Response Working Group
PHIN VADS	Public Health Information Network, Vocabulary Access and Distribution System
PI	Production Identifier
PQ	physical quantity
R1, R2	Release 1, Release 2, etc.
RFC	request for comments
RIM	Reference Information Model
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
UCUM	Unified Code for Units of Measure

UDI	Unique Device Identification
UNII	Unique Ingredient identifier
URL	Uniform Resource Locator
URN	uniform resource name
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. The majority of the changes were made in response to approved DSTU comments located here: http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=179.

2nd Update to Release 1 DSTU 1

Volume 1

One new section was added: "Use of Qualifiers".

Volume 2

Many templates were versioned due to the versioning of contained templates (see the section "Changes from Previous Version" in Volume 2 of this guide for a detailed view of these changes).

Document-Level Templates

No new document-level templates were added.

Several document-level templates were updated due to the versioning of contained template.

Section-Level Templates

No new section-level templates were added.

Several section-level templates were updated due to the versioning of contained templates.

The following section-level templates were updated with changes:

- Inpatient Encounters Section (V2)
- Patient Information Section (V2)
- Problems Section (V3)
- Reasons for Visit Section (V2) (was Patient's Reason for Visit Section)

Entry-Level Templates

One new entry-level template was added:

- Clinical Note and External Document Reference

The following entry-level templates were retired:

- Asthma Diagnosis Observation
- Co-Morbid Condition Observation

Value Sets

Many of the value sets were updated with current URLs.

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.

APPENDIX D — MIME MULTIPART/RELATED MESSAGES

Note: The following text is taken from the *HL7 Additional Information Specification Implementation Guide* (AIS00000), Section 2.4.[11] For up-to-date guidance, refer to the latest edition of that specification.

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

[11] *HL7 Additional Information Specification Implementation Guide*.
http://www.hl7.org/documentcenter/public/wg/ca/CDAR2AIS0000R030_ImplementationGuideDraft.pdf

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.