CDAR2\_FD\_2013January



**HL7 Implementation Guide for CDA® Release 2:**

**Form Definition Document, Release 1**

April 2013

**HL7 DSTU Ballot**

**Sponsored by:
Structured Documents Work Group**

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Acknowledgments

This implementation guide was produced and developed under the sponsorship of the Center for Clinical Standards and Quality of the Centers for Medicare & Medicaid Services (CMS). Throughout the development of this guide, multiple industry stakeholders provided input and translation of business and technical requirement through the Office of the National Coordinator for Health Information Technology (ONC) Standards and Interoperability (S&I) Framework Patient Assessment Summary Work Group.

The co-editors appreciate the support and sponsorship of the Health Level Seven (HL7) Structured Documents Working Group (SDWG) and all the volunteers, staff, and contractors participating in the S&I Framework.

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# Introduction

## Purpose

This document describes constraints on the Clinical Document Architecture (CDA) Release 2 (R2) header and body elements for patient Questionnaire Assessments. Questionnaire Assessments contain multiple questions with specific answers. These questions typically assess a variety of clinical domains including, but not limited to, the patient’s functional, cognitive, medical, and health status. The instruments may include assessment scales to quantify the evaluation. These types of assessments are used in a variety of healthcare settings including, but not limited to, nursing facilities, home health agencies, residential care facilities, and long-term care hospitals, and outpatient settings.

In addition, this guide defines constraints for the uniform assessment instrument known as Continuity Assessment Record and Evaluation (CARE), which is a standardized set of data elements that captures health and functional status data for beneficiaries regardless of payor or provider type across settings over time. CARE is intended for use in the United States, in a variety of settings including, but not limited to, post-acute and long-term care settings.

## Audience

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

## Approach

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

This implementation guide is R2 of the Questionnaire Assessment Draft Standard for Trial Use (DSTU). The [Background](#_Background) and [Current Project](#_Current_Project) sections describe the development of the DSTU.

## CDA R2

CDA R2 is “… a document markup standard that specifies the structure and semantics of ‘clinical documents’ for the purpose of exchange” [CDA R2, Section 1.1; see [References](#_References)]. 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.

## Background

The Questionnaire Assessment DSTU was developed and published in 2009 to specify a standard for electronic submission of questionnaire assessment tools that allowed healthcare facilities to communicate questionnaire assessment reports in an interoperable, industry-standard format. The guide consisted of two parts: a framework applicable to all questionnaire assessment tools and an implementation of that framework for the Minimum Data Set (MDS) 3.0[[1]](#footnote-2) as it existed in early 2009.

## Current Project

The intent of the current project is two-fold: carry forward the *Implementation Guide for CDA Release 2 CDA Framework for Questionnaire Assessments (Universal Realm)* and provide specific guidance on implementing the CARE Questionnaire Assessment Forms used in long-term care hospital (LTCH) settings.

The intent of the Questionnaire Assessment Framework is a generic standard that may be applied to patient questionnaire assessment tools that are used to assess patient medical, cognitive, functional, and health status. The intent is not to define a standard framework for all assessment types such as an acute hospital admission physical assessment, shift assessments, or discharge assessments. Please see the [Questionnaire Assessment Framework](#_Questionnaire_Assessment_Framework) chapter for detailed discussion of questionnaire assessment tools. Examples of instruments used in the United States are the MDS 3.0 used in nursing homes, and Outcome and Assessment Information Set (OASIS), which is used in the home health setting.[[2]](#footnote-3)

The evolving versions of the MDS may be implemented in the CDA standard using this standard framework. The MDS is not being updated within this HL7 document. Please see [Appendix E: Additional CMS Assessments](#Appemdix_E) for information regarding the current MDS.

The second part of this project applies the LTCH CARE assessment tools to the Questionnaire Assessment CDA Framework. This implementation guide will define additional constraints needed to support implementation of this standard. Further details on the CARE project are discussed in [Chapter 3.3: The CARE Project](#_The_CARE_Project).

## Scope

This implementation guide is a conformance profile, as described in the “Refinement and Localization”[[3]](#footnote-4) section of the *HL7 Version 3 Interoperability Standards*. The base standard for this implementation guide is the *HL7 Clinical Document Architecture, Release 2.0.*[[4]](#footnote-5) This implementation guide does not describe every aspect of CDA. Rather, it defines constraints on the base CDA used in Questionnaire Assessments in the Universal Realm and a CARE document in the US realm. Additional optional CDA elements, not included here, can be included and the result will be compliant with the specifications in this guide.

## Organization of This Guide

This guide includes a set of CDA Templates and prescribes their use within a Questionnaire Assessment CDA document. The main chapters are:

Chapter 2: [Questionnaire Assessment Framework](#_Questionnaire_Assessment_Framework) describes the concept of questionnaire assessments, their psychometric properties, and the application of Model of Use vs. Model of Meaning representation to these tools.

Chapter 3: [CARE-Based Questionnaire Assessment](#_CARE_Based_Questionnaire) describes an overview of the CARE project and discusses the application of the Questionnaire Framework structure and patterns to the CARE instrument.

Chapter 4: [Document-Level Templates](#_Document_level_templates) defines the document constraints that apply to Questionnaire Assessment Documents.

Chapter 5: [Section-Level Templates](#_Section-Level_Templates) defines the section templates in Questionnaire Assessment Documents.

Chapter 6: [Entry-Level Templates](#_Entry-Level_Templates_1) defines the entry template in Questionnaire Assessment Documents.

Chapter 7: [Unspecified Templates](#_Unspecified_Templates) defines templates that are not document, section or entry templates in the Questionnaire Assessment Document.

Chapter 8: [CARE Data Sets in Questionnaire Assessment](#_CARE_Data_Sets) provides samples of the data tables which identifies each CARE item by question and answer value set, pattern type, and which form the CARE item is used.

## Conformance Conventions Used in This Guide

### Errata or Enhancements

Comments regarding errata or enhancements may be noted on the HL7 DSTU Comments page: <http://www.hl7.org/dstucomments/>. This implementation guide references several templates that have been balloted and published elsewhere. The [Previously Published Templates](#Appendix_F) appendix lists these templates.

### Templates and Conformance Statements

Conformance statements within this implementation guide are presented as constraints from Trifolia Workbench, a template repository. An algorithm converts constraints recorded in a Templates Database to a printable presentation. Each constraint is uniquely identified by an identifier at or near the end of the constraint (e.g., CONF:7345). These identifiers are persistent but not sequential.

Bracketed information following each template title indicates the template type (section, observation, act, procedure, etc.), the templateId, and whether the template is [open or closed](#_Open_and_Closed).

Each section and entry template in the guide includes a context table. The "Used By" column indicates which documents or sections use this template, and the "Contains Entries" column indicates any entries that the template uses. Value set tables, where applicable, and brief XML example figures are included with most explanations. The tables contained in this guide contain codes that represent the specific questions and answer value sets in the LTCH CARE Questionnaire and Assessment. A description of each column header is provided in the table [LTCH CARE Question and Pattern Table Headings Defined](#LTCH_CARE_Question_and_Pattern_Table), samples of questions are in the table [CARE Questionnaire Pattern Data Example](#CARE_Questionnaire_Pattern_Data_EX), and their corresponding answers are found in the table [CARE Answer Codes](#CARE_Answer_Codes_Example). The question and answer tables contain links to the full CARE data files. The following figure shows a typical template explanation presented in this guide. The next sections describe specific aspects of conformance statements—open vs. closed statements, conformance verbs, cardinality, vocabulary conformance, containment relationships, and null flavors.

Figure 1: Constraints format example

**Severity Observation**

[observation: templateId 2.16.840.1.113883.10.20.22.4.8(open)]

Table xxx: Severity Observation Contexts

| Used By: | Contains Entries: |
| --- | --- |
| Reaction ObservationAllergy Observation  |  |

This clinical statement represents the severity of the reaction to an agent. A person may manifest many symptoms …

Table yyy: Severity Observation Contexts

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.8'] |
|  |  @classCode | 1..1 | SHALL |  | [7345](#C_7345) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
| … |  |  |  |  |  |  |

1. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:7345).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:7346).
3. SHALL contain exactly one [1..1] templateId (CONF:7347) such that it
	1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.8" (CONF:10525).
4. SHALL contain exactly one [1..1] code="SEV" Severity Observation (CodeSystem: ActCode 2.16.840.1.113883.5.4) (CONF:7349).
5. SHOULD contain zero or one [0..1] text (CONF:7350).
	1. The text, if present, SHOULD contain zero or one [0..1] reference/@value (CONF:7351).
		1. This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:7378).
6. SHALL contain exactly one [1..1] statusCode="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:7352).
7. …

### 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. The templates in this IG are open.

### 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*[[5]](#footnote-6):

* 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.

### 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 2: Constraints format—only one allowed

1. SHALL contain exactly one [1..1] **participant** (CONF:2777).

 a. This participantSHALL 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 3: 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).

### 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 occurences 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.

*Required* means that the number of allowable occurences 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. If an element is required, but is not known (and would otherwise be omitted if it were optional), it must be represented by a [nullFlavor](#_Null_Flavor_2).

### Vocabulary Conformance

Some of the vocabulary bindings differ in this guide than in most CDA implementation guides. The style for the binding is carried forward from the release 1 Questionnaire Assessment. There are a set of patterns in this guide where the observation/codes and observation/values contain LOINC® question and LOINC answer code pairs.

Figure 4: CARE vocabulary binding example

1. SHALL contain exactly one [1..1] code (CONF:xxxx).

 a. This code SHALL contain exactly one [1..1] @code (CodeSystem: LOINC

 2.16.840.1.113883.6.1) (CONF:xxxx).

 i. Where @**code** is equal to the LOINC question code from [LTCH CARE Tables V1\_01.xlsx](file:///%5C%5Ccos%5Cshare%5C2006_0022_Continua%5CContinua%2B%5CPro11-01%20Text%20Based%20Questionnaire%5CHL7%20related%5CHL7%20Track%5CTBQ%5CImplementation%20Guides%5CLTCH%20CARE%20Tables%20V1_01.xlsx)

 (CONF:xxxx).

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

Value-set bindings adhere to HL7 Vocabulary Working Group best practices, and include both a conformance verb (shall, should, may, etc.) and an indication of dynamic vs. static binding. Value-set constraints can be static, meaning that they are bound to a specified version of a value set, or dynamic, meaning that they are bound to the most current version of the value set. A simplified constraint, used when the binding is to a single code, includes the meaning of the code, as follows.

Figure 5: Binding to a single code

1. … code/@code="11450-4" Problem List (CodeSystem: 2.16.840.1.113883.6.1 LOINC).

The notation conveys the actual code (11450-4), the code’s displayName (Problem List), the object identifier (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 6: XML expression of a single-code binding

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

<!-- or -->

<code code="11450-4" codeSystem="2.16.840.1.113883.6.1"

 displayName="Problem List"

 codeSystemName=”LOINC”/>

A full discussion of the representation of vocabulary is outside the scope of this document; for more information, see the *HL7 Version 3 Interoperability Standards,* Normative Edition 2010[[6]](#footnote-7) sections on Abstract Data Types and XML Data Types R1.

There is a discrepancy in the implementation of translation code versus the original code between HL7 Data Types R1 and the convention agreed upon for this specification. The R1 data type requires the original code in the root. This implementation guide specifies the standard code in the root, whether it is original or a translation. This discrepancy is resolved in HL7 Data Types R2.

Figure 7: 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>

### Null Flavor

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. In HL7, a *flavor* of null, or nullFlavor, describes the reason for missing data.

For example, where a response to a question is required, but can't be assessed (e.g., because the patient is in a coma or because old records aren't available), the assessor may need to respond with an “unable to assess,” which can be reflected as an exceptional value with nullFlavor "UNK" (unknown). An “unable to assess” response SHOULD be represented as observation/value/@nullFlavor=”UNK.”

Figure 8: Base question/answer pattern with NULL example

 <observation classCode="OBS" moodCode="EVN">

 <code code="LOINCQuestionCodeTheQuestion"

 codeSystem="2.16.840.1.113883.6.1">

 <translation code="TheLocalCode" codeSystem="TheLocalCodeSystemOID"/>

 </code>

 <statusCode code="completed"/>

 <value xsi:type="ANY" nullFlavor=”UNK”/>

 </observation>

The patient’s birth date would be represented with a nullFlavor of “NAV,” which is the code for “temporarily unavailable.” When the patient regains consciousness or a relative arrives, the patient’s birthdate likely will become known.

Figure 9: nullFlavor example

<birthTime nullFlavor=”NAV”/> <!--coding an unknown birthdate-->

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.

This above list 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 normative edition.[[7]](#footnote-8)

Any SHALL conformance statement may use nullFlavor, unless the attribute is required or the nullFlavor is explicitly disallowed. SHOULD and MAY conformance statement may also use nullFlavor.

Figure 10: Attribute required

1. SHALL contain exactly one [1..1] **code/@code**="11450-4" Problem List (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:7878)

 or

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

Figure 11: 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="NAV">

 <originalText>Spiculated mass grade 5</originalText>

 </value>

 </observation>

</entry>

Figure 12: nullFlavor explicitly disallowed

1.SHALL contain exactly one [1..1] **effectiveTime** (CONF:5256).

 a. SHALL NOT contain [0..0] nullFlavor (CONF:52580).

### Data Types

All data types used in a CDA document are described in the CDA R2 normative edition.[[8]](#footnote-9) All attributes of a data type are allowed unless explicitly prohibited by this specification.

Each CARE question is assigned HL7V3 data type which can be found in the column labeled “data type” in the corresponding tables found in [LTCH CARE Tables V1\_01.xlsx.](file:///%5C%5Ccos%5Cshare%5C2006_0022_Continua%5CContinua%2B%5CPro11-01%20Text%20Based%20Questionnaire%5CHL7%20related%5CHL7%20Track%5CTBQ%5CImplementation%20Guides%5CLTCH%20CARE%20Tables%20V1_01.xlsx)

## XML Conventions Used in This Guide

### XPath Notation

Instead of the traditional dotted notation used by HL7 to represent RIM classes, this document uses XML Path Language (XPath) notation[[9]](#footnote-10) in conformance statements and elsewhere to identify the Extended 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.

Figure 13: 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 14: XPath expression example

author/assignedAuthor/code/@code

### XML Examples and Sample Documents

XML examples appear in figures in this document in this monospace font. Portions of the XML content may be omitted from the content for brevity, marked by an ellipsis (...) as shown in the example below.

Figure 15: ClinicalDocument example

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

 ...

</ClinicalDocument>

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

This package includes complete sample documents as listed in the [Content of the Package](#T_Contents_of_the_Package) table below.

## Rendering Header Information for Human Presentation

Metadata carried in the header may already be available for rendering from EHRs or other sources external to the document; therefore, there is no strict requirement to render directly from the document header. An example of this would be a doctor using an EHR that already contains the patient’s name, date of birth, current address, and phone number. When a CDA document is rendered within that EHR, those pieces of information may not need to be displayed since they are already known and displayed within the EHR’s user interface.

Good practice would recommend that the following information 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)

## Content of the Package

The following files comprise this package.

Table 1: Content of the Package

|  |  |  |
| --- | --- | --- |
| Filename | Description | Applicability |
| CDAR2\_QA\_R2\_D1\_2012DEC | This implemenation guide. | Normative |
| LTCH CARE Tables V1\_01.xls | Spreadsheet contains information on CARE item codes, descriptions, data types, response patterns, CARE LOINC question codes, CARE LOINC answer codes, and information on data available with each LTCH CARE Tool.  | Informative |
| QuestionaireAssessment.xml | The sample CDA XML file that includes examples of the generic and CARE specific templates discussed in this guide.  | Informative |
| CDA.xsl | Stylesheet for display of CDA instances. | Informative |
| QAIG\_CARE\_Schematron.sch | ISO schematron using XPath 1 to validate CARE Questionnairre Assesment CDA instances against implementation guide-specific constraints.  | Informative |

# Questionnaire Assessment Framework

The Questionnaire Assessment Framework allows for standard electronic submission of the CDA Questionnaire Assessments between healthcare facilities to communicate reports in an interoperable, industry-standard format. This framework is further constrained to describe specifics for the CARE Questionnaire Assessment Instrument that is used in the United States.

## Questionnaire Assessment Description

Questionnaire Assessments are question-based instruments that have psychometric properties. Psychometric properties are elements that contribute to the statistical adequacy of an instrument in terms of reliability, validity, and internal consistency.

Psychometric properties in Questionnaire Assessments are based on psychometric theory [Nunnaly[[10]](#footnote-11)] and survey theory [Aday[[11]](#footnote-12)]. The reliability and validity of responses to questions can be affected by several factors. These include (a) the exact wording of the question and allowable response set (this combination is called an item), (b) the order in which questions are asked, (c) presentation features such as fonts and how questions are laid out on a page, (d) who asks the question (e.g., computer, doctor, peer), and (e) who does the answering (e.g., patient, parent, friend). In some cases, minor changes to any of those parameters can have dramatic effects on the responses given by subjects (for a review, see White, *JAMIA* 2002.)[[12]](#footnote-13) Minor changes to the wording or order of questions most often affect “latent variables.” Latent variables are not directly observable as are physical findings. Instead, measures of these variables (e.g., intelligence, pain, self-efficacy, and many aspects of functional status) depend upon how the questions are asked. These items are therefore measurable entities; however, they may not be observables.

Psychometricians and instrument developers measure the reliability and validity of instruments, the items they contain, and scale scores derived from those items using several branches of statistics. In a manner similar to clinical trials, these researchers recruit trial subjects and normal controls and have each of them complete the instruments in ideal and real-world conditions. Often when developing these instruments, researchers will use multiple questions to assess a particular construct since each may assess different facets of the latent variables. Researchers then remove redundant items after using factor analysis to identify items that co-vary exactly with other item clusters. They also test whether the items have discriminative power, predictive validity, and other statistical properties needed to make the instrument a good screening, diagnostic, outcomes, or related type of instrument. Some researchers will also assess the impact of changing the order of items on the outcomes, but, since this method involves larger sample sizes, it is not commonly done. The whole instrument development process often takes from months to years. Although instrument users may be inclined to alter the wording of items and add or remove others, such changes can invalidate the psychometric properties that have been so laboriously calculated for these instruments.

Some question-based instruments collect information on a mixture of latent and observable variables. Observables (e.g., physical findings) can typically be defined by a collection of observable entities and are not affected by the order in which the items are asked. However, the latent variable in the same instrument can be affected by how the questions about observable entities are asked, for example, if an instrument had a single latent variable about confidence in health status plus review-of-symptoms style observables. If the other questions are about fatal or debilitating diseases that match amorphous symptoms, the answer about confidence in health status is likely to be different depending upon whether it is asked first or last. Emotionally charged latent variables may similarly introduce reporting bias into responses about such review-of-symptoms questions.

Thus, if the instrument contains any latent variables, or has been psychometrically validated (e.g., for concurrent, predictive, or discriminative validity), then it is safest to treat the instrument as a whole as a measurable entity and to also treat each item within the instrument as a measureable entity.

In summary, the scope of this IG is to provide a CDA framework for question-based instruments that have been either psychometrically validated or that can be reasonably expected to have psychometric properties. To represent the exact questions and responses on an assessment questionnaire this specification defines a required "model of use" representation.

## Questionnaire Assessment Model of Use vs. Model of Meaning

### Model of Use

Model of Use representation is an information model that is structured in a way suggested by the particular intended use of the information that is represented by that model. For example, a database that is structured with tables and fields that match specific user interface forms and the data entry box on those forms is a Model of Use representation. Model of Use representation will support queries of the type “Find all patients with Answer X to Question Y on Form Z.”

### Model of Meaning

Model of Meaning representation is an information model that is designed to provide a common representation of particular types of information that is reusable between different use cases. A Model of Meaning representation combines structural and terminological component in ways that avoid ambiguity and minimize alternative representations of similar meanings. For example, a model that specifies how SNOMED-CT expressions are used to represent clinical findings and procedures agnostic of the user interface or the tool of origin is Model of Meaning representation. Model of Meaning representation will support queries of the type "Find all patients with Condition X, regardless of the form used to collect the data."

### Questionnaire Assessment Representation

The question and answer CDA patterns defined in this guide are Model of Use patterns. The CDA patterns are intended to reflect the intended use and structure of the questionnaire assessments tools they represent.

Some of the questions and responses on a questionnaire tool are amenable to partial or complete formal modeling using constructs provided by the HL7 RIM coupled with standard terminologies. When true, Model of Meaning representation should be adhered to within the framework of this specification. In some cases, precedent for Model of Meaning representation exists for concepts in questionnaire assessments. For example, HL7 published in December 2012 a Long-Term Post-Acute Care (LTPAC) Summary[[13]](#footnote-14) which is a Model of Meaning representation of a subset of prioritized clinical concepts from the MDS and OASIS assessment instruments.

If an organization chooses to communicate assessment instrument concepts outside the instrument, the Model of Meaning representation of these concepts should adhere to the CDA Refined Message Information Model (RMIM). If within the United States, the Model of Meaning representation should adhere to templates from the *HL7 Implementation Guide for CDA Release 2.0, Consolidated CDA Templates.[[14]](#footnote-15)*

# Document-Level Templates

# Section-Level Templates

This section contains the section-level templates used by the CARE Questionnaire Assessment Document in this consolidated guide. Section-level templates are always included in a document.

# Entry-Level Templates

The XML patterns below represent samples of the “model of use” question and answer patterns. The data type in the Observation/value of the answer will vary based on the question/answer pattern.

The question/answer pair in the CARE Questionnaire Assessment Document is represented in an observation entry template where the question ID is the observation and the value is derived from a defined answer set. The observation values vary based on the pattern type. The variability for each CARE assessment question/answer patterns entries is identified as illustrated in Section 7.3.2 CARE Questionnaire Pattern Data, [CARE Questionnaire Pattern Data Table Example Excerpt](#CARE_Questionnaire_Pattern_Data_EX) in the column titled “CARE response pattern.”

Where a response to a question is required, but can't be assessed (e.g., because the patient is in a coma or because old records aren't available), the assessor may need to respond with an “unable to assess,” which can be reflected as an exceptional value with nullFlavor "UNK" (unknown).

## Assertion Pattern

[observation: templateId 2.16.840.1.113883.10.20.25.4.7 (open)]

Table 28: Assertion Pattern Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Generic Section Pattern](#S_Generic_Section_Pattern) (optional)[Question Answer Pattern Organizer](#E_Question_Answer_Pattern_Organizer_) (optional) |  |

The assertion pattern is used for questions that assert a problem/need.

A nullFlavor on observation/code may indicate a specific problem was not observed "NI," unknown "UNK" or not applicable "NA," If a patient had another problem or need, this could be specified on observation/value with the nullFlavor "OTH."

If the patient was observed to not have the problem or need, a negationInd=true may be used to assert the absence of the condition.

Table 29: Assertion Pattern Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.25.4.7'] |
|  |  @nullFlavor | 0..1 | MAY |  | [23409](#C_23409) | 2.16.840.1.113883.11.20.10.17 (NullValues\_UNK\_NI\_NA) |
|  |  @negationInd | 0..1 | MAY |  | [23246](#C_23246) | true |
|  |  templateId | 1..1 | SHALL |  | [17454](#C_17454) |  |
|  |  @root | 1..1 | SHALL |  | [17455](#C_17455) | 2.16.840.1.113883.10.20.25.4.7 |
|  |  code | 1..1 | SHALL |  | [23234](#C_23234) |  |
|  |  @code | 1..1 | SHALL |  | [23236](#C_23236) | ASSERTION |
|  |  @codeSystem | 1..1 | SHALL |  | [23239](#C_23239) | 2.16.840.1.113883.5.4 (ActCode) |
|  |  statusCode | 1..1 | SHALL |  | [23242](#C_23242) |  |
|  |  @code | 1..1 | SHALL |  | [23243](#C_23243) | completed |
|  |  @codeSystem | 0..1 | SHALL |  | [23244](#C_23244) | 2.16.840.1.113883.5.14 (ActStatus) |
|  |  value | 1..1 | SHALL | CD | [23240](#C_23240) |  |
|  |  @nullFlavor | 0..1 | MAY |  | [23423](#C_23423) | 2.16.840.1.113883.5.1008 (HL7NullFlavor) = OTH |

1. MAY contain zero or one [0..1] @nullFlavor, which SHALL be selected from ValueSet NullValues\_UNK\_NI\_NA 2.16.840.1.113883.11.20.10.17 DYNAMIC (CONF:23409).
2. MAY contain zero or one [0..1] @negationInd="true" TRUE (CONF:23246).
3. SHALL contain exactly one [1..1] templateId (CONF:17454) such that it
	1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.25.4.7 " (CONF:17455).
4. SHALL contain exactly one [1..1] code (CONF:23234).
	1. This code SHALL contain exactly one [1..1] @code="ASSERTION" (CONF:23236).
	2. This code SHALL contain exactly one [1..1] @codeSystem (CodeSystem: ActCode 2.16.840.1.113883.5.4) (CONF:23239).
5. SHALL contain exactly one [1..1] statusCode (CONF:23242).
	1. This statusCode SHALL contain exactly one [1..1] @code="completed" (CONF:23243).
	2. This statusCode SHALL contain exactly one [1..1] @codeSystem (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:23244).
6. SHALL contain exactly one [1..1] value with @xsi:type="CD" (CONF:23240).
	1. This value MAY contain zero or one [0..1] @nullFlavor="OTH" Other (CodeSystem: HL7NullFlavor 2.16.840.1.113883.5.1008) (CONF:23423).
	2. This value MAY contain zero or one [0..1] @nullFlavor="OTH" Other (CodeSystem: HL7NullFlavor 2.16.840.1.1138[0..83.5.1008) (CONF:23423).

Figure 36: Assertion Pattern example

<observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.25.4.7"/>
 <code code="ASSERTION"
 codeSystem="2.16.840.1.113883.5.4"/>
 <statusCode code="completed"/>
 <value xsi:type="CD" code="54620-0"
 displayName=" Can recall location of room in last 7 days MDSv3"
 codeSystem="LOINC"
 codeSystemName="2.16.840.1.113883.6.1">
 <translation code="C0900B"
 codeSystem="2.16.840.1.113883.4.340"
 codeSystemName="MDSv3"
 displayName="Staff asmt mental status: recall location of room"
 />
 </value>
</observation>

Figure 37: Assertion Pattern—specific problem not observed example

<observation classCode="OBS" moodCode="EVN" nullFlavor="NI">
 <templateId root="2.16.840.1.113883.10.20.25.4.7"/>
 <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"
 codeSystemName="HL7ActCode"/>
 <statusCode code="completed"/>
 <value xsi:type="CD" code="LocalizedAnswerValueCode"
 displayName="Asthma"
 codeSystem="LocalizedSystemCode">
 <translation code="G3" displayName="Asthma"
 codeSystem="LocalizedAnswerValueSetOID"/>
 </value>
</observation>

Figure 38: Assertion Pattern—category problem/need unknown example

<observation classCode="OBS" moodCode="EVN" nullFlavor="UNK">
 <templateId root="2.16.840.1.113883.10.20.25.4.7"/>
 <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"
 codeSystemName="HL7ActCode"/>
 <statusCode code="completed"/>
 <value xsi:type="CD" code="LocalizedAnswerValueCode"
 displayName="Emphysema"
 codeSystem="LocalizedSystemCode">
 <translation code="G4" displayName="Emphysema"
 codeSystem="LocalizedAnswerValueSetOID"/>
 </value>
</observation>

Figure 39: Assertion Pattern—question not applicable example

<observation classCode="OBS" moodCode="EVN" nullFlavor="NA">
 <templateId root="2.16.840.1.113883.10.20.25.4.7"/>
 <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"
 codeSystemName="HL7ActCode"/>
 <statusCode code="completed"/>
 <value xsi:type="CD" code="LocalizedAnswerValueCode"
 displayName="Anemia"
 codeSystem="LocalizedSystemCode">
 <translation code="G5" displayName="Anemia"
 codeSystem="LocalizedAnswerValueSetOID"/>
 </value>
</observation>

Figure 40: Assertion Pattern—asserting patient does not have the problem example

<observation classCode="OBS" moodCode="EVN" negationInd="true">
 <!--Assertion Pattern Template ID -->
 <templateId root="2.16.840.1.113883.10.20.25.4.7"/>
 <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"
 codeSystemName="HL7ActCode"/>
 <statusCode code="completed"/>
 <value xsi:type="CD" code="LocalizedAnswerValueCode"
 displayName="Congestive Heart Failure"
 codeSystem="LocalizedSystemCode">
 <translation code="G2"
 displayName="Congestive Heart Failure"
 codeSystem="LocalizedAnswerValueSetOID"/>
 </value>
</observation>

Figure 41: Assertion Pattern—stating patient has some other problem (OTH)

<observation classCode="OBS" moodCode="EVN">
 <!--Assertion Pattern Template ID -->
 <templateId root="2.16.840.1.113883.10.20.25.4.7"/>
 <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"
 codeSystemName="HL7ActCode"/>
 <statusCode code="completed"/>
 <value xsi:type="CD" nullFlavor="OTH">
 <translation code="G0650Y" displayName="Other"
 codeSystem="LocalizedAnswerValueSetOID"/>
 </value>
</observation>

## Question Answer Pattern

[observation: templateId 2.16.840.1.113883.10.20.25.4.5 (open)]

The Question Answer Pattern entry template may be used for question and answer patterns found in assessment instruments as described in the model of use. The observation/value of in the question/answer pattern will vary depending the pattern.

Table 32: Question Answer Pattern Constraints Overview

| **Name** | **XPath** | **Card.** | **Verb** | **Data Type** | **CONF#** | **Fixed Value** |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.25.4.5'] |
|  |  @classCode | 1..1 | SHALL |  | [17430](#C_17430) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  |  @moodCode | 1..1 | SHALL |  | [17431](#C_17431) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  |  templateId | 1..1 | SHALL |  | [17428](#C_17428) |  |
|  |  @root | 1..1 | SHALL |  | [17429](#C_17429) | 2.16.840.1.113883.10.20.25.4.5 |
|  |  code | 1..1 | SHALL |  | [17434](#C_17434) |  |
|  |  translation | 1..1 | SHALL |  | [17497](#C_17497) |  |
|  |  statusCode | 1..1 | SHALL |  | [17438](#C_17438) |  |
|  |  @code | 1..1 | SHALL |  | [23433](#C_23433) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  |  value | 1..1 | SHALL |  | [17439](#C_17439) |  |
|  |  entryRelationship | 1..\* | MAY |  | [22625](#C_22625) |  |
|  |  @typeCode | 1..1 | SHALL |  | [22626](#C_22626) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR |

1. SHALL contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:17430).
2. SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:17431).
3. SHALL contain exactly one [1..1] templateId (CONF:17428) such that it
	1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.25.4.5" (CONF:17429).
4. SHALL contain exactly one [1..1] code (CONF:17434).

The translation code further specifies the source instrument and the associated code system.

* 1. This code SHALL contain exactly one [1..1] translation (CONF:17497).
1. SHALL contain exactly one [1..1] statusCode (CONF:17438).
	1. This statusCode SHALL contain exactly one [1..1] @code="completed" (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:23433).
2. SHALL contain exactly one [1..1] value (CONF:17439).

The Model of Use question and answer observation may contain one or more entryRelationships with a corresponding Model of Meaning Representation. A standard Model of Meaning representation may be expressed in a variety of applicable clinical vocabularies (e.g., SNOMED CT®, ICF, et cetera), coupled with the HL7 RIM. In many cases, precedent Model of Meaning representation exists and should be ahered to within the framework of the Consoldiated CDA specification.[[15]](#footnote-16) Additional information on the Model of Meaning can be found in the [Model of Meaning](#_Model_of_Meaning) section of this guide.

1. MAY contain zero or more [0..\*] entryRelationship (CONF:22625).
	1. The entryRelationship, if present, SHALL contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:22626).

Figure 43: Question Answer Pattern example

<!-- Typical or Other Response Pattern conform to this pattern. -->
 <observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.25.4.5"/>
 <id nullFlavor="NI"/>
 <code code="54597-0" displayName="Comatose in last 7 days MDSv3"
 codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC">
 <translation code="B0100" displayName="Comatose"
 codeSystem="2.16.840.1.113883.4.340"
 codeSystemName="MDSv3"/>
 </code>
 <statusCode code="completed"/>
 <!--The VALUE ANSWER representation will change depending on the Pattern Type:Typical Response or Other Response. -->
 <!--This example uses a Typical Response Pattern -->
 <value xsi:type="CD" code="LA32-8"
 codeSystem="2.16.840.1.113883.4.340">
 <translation code="0" codeSystem="MDSv3"/>
 </value>
 </observation>

Figure 44: Model of Use example

<!-- Model of Meaning Example -->
<observation classCode="OBS" moodCode="EVN">
 <!-- Cognitive Status Problem Observation -->
 <templateId root="2.16.840.1.113883.10.20.22.4.73"/>
 <id root="4b1d59f3-b6d2-41eb-bd91-f78a78a8ec79"/>
 <code code="373930000"
 codeSystem="2.16.840.1.113883.6.96"
 displayName="Cognitive Function Finding"/>
 <statusCode code="completed"/>
 <effectiveTime>
 <low value="20120928"/>
 </effectiveTime>
 <value xsi:type="CD" code="271591004"
 codeSystem="2.16.840.1.113883.6.96"
 displayName="fully conscious"/>
</observation>
</entryRelationship>

Other Response Pattern

[observation: templateId 2.16.840.1.113883.10.20.25.4.6 (open)]

Table 33: Other Response Pattern Contexts

| **Used By:** | **Contains Entries:** |
| --- | --- |
| [Generic Section Pattern](#S_Generic_Section_Pattern) (optional)[Question Answer Pattern Organizer](#E_Question_Answer_Pattern_Organizer_) (optional) |  |

The other response pattern template is used when questions require a specific non-coded answer such as an integer, text, number string, physical quantity, time stamp. The data type "ED" should only be used when a more specific data type cannot be assigned.

Table 34: Other Response Pattern Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.25.4.6'] |
|  |  templateId | 1..1 | SHALL |  | [17456](#C_17456) |  |
|  |  @root | 1..1 | SHALL |  | [17457](#C_17457) | 2.16.840.1.113883.10.20.25.4.6 |
|  |  value | 1..1 | SHALL |  | [17442](#C_17442) |  |

1. Conforms to [**Question Answer Pattern**](#Question_Answer_Pattern) template (2.16.840.1.113883.10.20.25.4.5).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:17456) such that it
	1. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.25.4.6" (CONF:17457).
3. **SHALL** contain exactly one [1..1] **value** (CONF:17442).
	1. The observation/value in Other Response Data Type Pattern **SHOULD** be assigned the most specific data type possible (CONF:17444).

Figure 45: Other Response Pattern example

<observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.25.4.5"/>
 <templateId root="2.16.840.1.113883.10.20.25.4.6"/>
 <code code="LocalizedCode" codeSystem="LocalizedCodeSystem">
 <translation code="E1" displayName="Weight (in kilos)"
 codeSystem="ToolCodeSystemOID"/>
 </code>
 <statusCode code="completed"/>
 <value xsi:type="PQ" value="80" unit="[kg]"/>
</observation>

Typical Response Pattern

[observation: templateId 2.16.840.1.113883.10.20.25.4.8 (open)]

Table 37: Typical Response Pattern Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Generic Section Pattern](#S_Generic_Section_Pattern) (optional)[Question Answer Pattern Organizer](#E_Question_Answer_Pattern_Organizer_) (optional) |  |

The typical response pattern template is used for questions where only one answer can be chosen and the answer is coded. The corresponding code is represented as a code, the score is represented in observation/value/translation/@code, where the corresponding codeSystem is LocalizedCodeSystemOID.

Table 38: Typical Response Pattern Constraints Overview

| **Name** | **XPath** | **Card.** | **Verb** | **Data Type** | **CONF#** | **Fixed Value** |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.25.4.8'] |
|  |  templateId | 1..1 | SHALL |  | [17458](#C_17458) |  |
|  |  @root | 1..1 | SHALL |  | [17459](#C_17459) | 2.16.840.1.113883.10.20.25.4.8 |
|  |  value | 1..1 | SHALL | CD | [17447](#C_17447) |  |
|  |  @code | 1..1 | SHALL |  | [17448](#C_17448) |  |
|  |  translation | 1..1 | SHALL |  | [17449](#C_17449) |  |

1. Conforms to [Question Answer Pattern](#_Question_Answer_Pattern) template (2.16.840.1.113883.10.20.25.4.5).
2. SHALL contain exactly one [1..1] templateId (CONF:17458) such that it
	1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.25.4.8 " (CONF:17459).
3. SHALL contain exactly one [1..1] value with @xsi:type="CD" (CONF:17447).
	1. This value SHALL contain exactly one [1..1] @code (CONF:17448).
	2. This value SHALL contain exactly one [1..1] translation (CONF:17449).
		1. If numeric score or code, observation/value/@ code SHALL be the code or score and Observation/value/translation/@code valued with the answer set OID. Translation code system is a special OID assigned to the answer list (CONF:17450).

Figure 47: Typical Response Pattern

<observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.25.4.5"/>
 <templateId root="2.16.840.1.113883.10.20.25.4.8"/>
 <code code="LocalizedCode" codeSystem="LocalizedCodeSystem">
 <translation code="ToolID"
 displayName=" Benutzen Sie einen Rollstuhl?"/>
 </code>
 <statusCode code="completed"/>
 <value xsi:type="CD" code="LocalizedAnswerValueCode"
 codeSystem="LocalizedSystemCode">
 <translation code="3"
 codeSystem="LocalizedAnswerValueSetOID"/>
 </value>
</observation>

## Question Answer Pattern Organizer

[Organizer: templateId 2.16.840.1.113883.10.20.25.4.9 (open)]

Table 41: Question Answer Pattern Organizer Contexts

| **Used By:** | **Contains Entries:** |
| --- | --- |
| [Generic Section Pattern](#S_Generic_Section_Pattern) (optional) | [Assertion Pattern](#E_Assertion_Pattern)[Other Response Pattern](#E_Other_Response_Pattern)[Typical Response Pattern](#E_Typical_Response_Pattern) |

This template contains information for a question with multiple responses (e.g. check all that apply) or can be used to group question and answer responses that are related.

A nullFlavor of "NI" would indicate a group of question was not documented or problem observed. A nullFlavor of "NA" would state the group of questions were not applicable to the patient.

Table 42: Question Answer Pattern Organizer Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | Organizer[templateId/@root = '2.16.840.1.113883.10.20.25.4.9'] |
|  |  @nullFlavor | 0..1 | MAY |  | [23252](#C_23252) | 2.16.840.1.113883.11.20.10.17 (NullValues\_UNK\_NI\_NA) |
|  |  @classCode | 1..1 | SHALL |  | [23261](#C_23261) | 2.16.840.1.113883.5.4 (ActCode) = Cluster |
|  |  @moodCode | 1..1 | SHALL |  | [23296](#C_23296) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  |  templateId | 1..1 | SHALL |  | [23253](#C_23253) |  |
|  |  @root | 1..1 | SHALL |  | [23254](#C_23254) | 2.16.840.1.113883.10.20.25.4.9 |
|  |  code | 1..1 | SHALL |  | [23297](#C_23297) |  |
|  |  translation | 0..\* | MAY |  | [23435](#C_23435) |  |
|  |  statusCode | 1..1 | SHALL |  | [23298](#C_23298) |  |
|  |  @code | 1..1 | SHALL |  | [23299](#C_23299) | 2.16.840.1.113883.5.14 (ActStatus) = completed |
|  |  component | 0..\* | MAY |  | [23384](#C_23384) |  |
|  |  observation | 1..1 | SHALL |  | [23402](#C_23402) |  |
|  |  component | 0..\* | MAY |  | [23401](#C_23401) |  |
|  |  observation | 1..1 | SHALL |  | [23403](#C_23403) |  |
|  |  component | 0..\* | MAY |  | [23424](#C_23424) |  |
|  |  observation | 1..1 | SHALL |  | [23425](#C_23425) |  |

1. MAY contain zero or one [0..1] @nullFlavor, which SHALL be selected from ValueSet NullValues\_UNK\_NI\_NA 2.16.840.1.113883.11.20.10.17 DYNAMIC (CONF:23252).
2. SHALL contain exactly one [1..1] @classCode="Cluster" (CodeSystem: ActCode 2.16.840.1.113883.5.4) (CONF:23261).
3. SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:23296).
4. SHALL contain exactly one [1..1] templateId (CONF:23253) such that it
	1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.25.4.9" (CONF:23254).
5. SHALL contain exactly one [1..1] code (CONF:23297).
	1. This code MAY contain zero or more [0..\*] translation (CONF:23435).
6. SHALL contain exactly one [1..1] statusCode (CONF:23298).
	1. This statusCode SHALL contain exactly one [1..1] @code="completed" (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:23299).
7. MAY contain zero or more [0..\*] component (CONF:23384) such that it
	1. SHALL contain exactly one [1..1] [Other Response Pattern](#E_Other_Response_Pattern) (templateId:2.16.840.1.113883.10.20.25.4.6) (CONF:23402).
8. MAY contain zero or more [0..\*] component (CONF:23401) such that it
	1. SHALL contain exactly one [1..1] [Assertion Pattern](#E_Assertion_Pattern) (templateId:2.16.840.1.113883.10.20.25.4.7) (CONF:23403).
9. MAY contain zero or more [0..\*] component (CONF:23424) such that it
	1. SHALL contain exactly one [1..1] [Typical Response Pattern](#E_Typical_Response_Pattern) (templateId:2.16.840.1.113883.10.20.25.4.8) (CONF:23425).

Figure 49: Question Answer Pattern Organizer

<organizer classCode="CLUSTER" moodCode="EVN">
 <!-- Question Answer Pattern Organizer templateID -->
 <templateId root="2.16.840.1.113883.10.20.25.4.9"/>
 <code code="54895-8"
 displayName="Staff Assessment of Mental Status MDSv3"
 codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC">
 <translation code="C0900"
 codeSystem="2.16.840.1.113883.4.340"
 displayName="Staff Assesmement of Mental Status"/>
 </code>
 <statusCode code="completed"/>
 <!-- "Check all that apply" -->
 <!-- MAY contain an Assertion, Typical Response or Other Pattern templates-->
 <component>
 <observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.25.4.7"/>
 ...
 </observation>
 </component>
 <component>
 <observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.25.4.7"/>
 ...
 </observation>
 </component>
 <component>
 <observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.25.4.7"/>
 ...
 </observation>
 </component>
</organizer>

Figure 50: Question Answer Pattern Organizer—category problem/need
not observed/not documented

<organizer classCode="CLUSTER" moodCode="EVN" nullFlavor="NI">
 <!-- Question Answer Pattern Organizer templateID -->
 <templateId root="2.16.840.1.113883.10.20.25.4.9"/>
 <code code="54895-8"
 displayName="Staff Assessment of Mental Status MDSv3"
 codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC">
 <translation code="C0900"
 codeSystem="2.16.840.1.113883.4.340"
 displayName="Staff Assesmement of Mental Status"/>
 </code>
 <statusCode code="completed"/>
</organizer>

Figure 51: Question Answer Pattern Organizer—category problem/need unknown

<organizer classCode="CLUSTER" moodCode="EVN" nullFlavor="UNK">
 <!-- Question Answer Pattern Organizer templateID -->
 <templateId root="2.16.840.1.113883.10.20.25.4.9"/>
 <code code="54895-8"
 displayName="Staff Assessment of Mental Status MDSv3"
 codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC">
 <translation code="C0900"
 codeSystem="2.16.840.1.113883.4.340"
 displayName="Staff Assesmement of Mental Status"/>
 </code>
 <statusCode code="completed"/>
</organizer>

Figure 52: Question Answer Pattern Organizer—stating category of question not applicable

<organizer classCode="CLUSTER" moodCode="EVN" nullFlavor="NA">
 <!-- Question Answer Pattern Organizer templateID -->
 <templateId root="2.16.840.1.113883.10.20.25.4.9"/>
 <code code="54895-8" displayName="Staff Assessment of Mental Status MDSv3"
 codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC">
 <translation code="C0900" codeSystem="2.16.840.1.113883.4.340"
 displayName="Staff Assesmement of Mental Status"/>
 </code>
 <statusCode code="completed"/>
</organizer>

**Requirements from the Form Definition Project that could be used to enhance the existing templates; create new templates where necessary.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Question/Answer Type** | **Description** | **Additional parameters** | **Allowed answer(s)** |
| 1 | Free text answer | Maximum number of characters | One answer: Character string |
| 2 | Integer | MaximumMinimum | One answer: Integer |
| 3 | Real | MaximumMinimum | One answer: Real |
| 4 | Date | MaximumMinimum | One answer: Point in time (TS) |
| 5 | Time | Maximum Minimum | One answer: Point in time (TS) |
| 6 | Multiple choice | Minimum number of allowed answersMaximum number of allowed answersAnswer\_options | Number ofAnswer\_options\_ID’s |
| 7 | Visual analog scale; slider  | Maximum Minimum | One answer: Real |
| 8 | Visual discrete scale; slider with labels | Answer\_options | One Answer\_options\_ID |
| 9 | Multi-media(e.g. take a picture of the part of your body that causes your pain, or an audio recording of the answer of the patient) | Multimedia\_type According to Media type defined in  | One answer: Multimedia item |

**Examples for Question/ Answer Type:**

**Multiple choice:**

|  |  |  |
| --- | --- | --- |
| **Element/ Attribute** | **Definition** | **Multiplicity** |
| Question ID | This uniquely identifies a question within the Questionnaire document.  | [1..1] |
| Question text | “Compared to last week, how would you rate your health status in general?” | [1..1] |
| Answer options |  A1 | The same as last week | [2..n] |
|  A2 | Better than last week |
|  A3 | Worse than last week |
| Min. of Answers | Indicates the minimum number of answer options a patient should select. | [0..1] |
| Max. of Answers | Indicates the maximum number of answer options a patient should select. | [0..1] |
| Multimedia item | Reference to a multimedia item that needs to be rendered simultaneous with the question text. | [0..1] |
| Skip | Indicates whether it is allowed to skip this question (Skip=TRUE) or not (Skip=FALSE). By default the value of Skip could be “FALSE”. |  [0..1] |

**Template multiple choice question:**

| **Name** | **XPath** | **Card.** | **Verb** | **Data Type** | **CONF#** | **Fixed Value** |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.25.4.5'] |
|  |  @classCode | 1..1 | SHALL |  | [17430](#C_17430) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  |  @moodCode | 1..1 | SHALL |  | [17431](#C_17431) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  |  templateId | 1..1 | SHALL |  | [17428](#C_17428) |  |
|  |  @root | 1..1 | SHALL |  | [17429](#C_17429) | 2.16.840.1.113883.10.20.25.4.5 |
|  |  id | 1..1 | SHALL |  | NCONF |  |
|  |  code | 1..1 | SHALL |  | [17434](#C_17434) |  |
|  |  originalText | 1..1 | SHALL |  | NCONF |  |
|  |  value | 2..n | SHALL |  | NCONF |  |
|  |  entryRelationship | 0..\* | MAY |  | [22625](#C_22625) |  |
|  |  @typeCode | 1..1 | SHALL |  | [22626](#C_22626) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR |
|  |   |  |  |  |  |  |
|  |  referenceRange | 0..1 | SHOULD |  | NCONF |  |
|  |  observationRange | 1..1 | SHALL |  | NCONF |  |
|  |  @classCode | 1..1 |  |  | NCONF |  |
|  |  @moodCode | 1..1 | SHALL |  | NCONF |  |
|  |  @value | 1..1 | SHALL |  | NCONF |  |

**Numeric:**

|  |  |  |
| --- | --- | --- |
| **Element/Attribute** | **Definition** | **Multiplicity** |
| Question ID | This uniquely identifies a question within the Questionnaire document.  | [1..1] |
| Question text | “How many hour do you sleep on average during night?” | [1..1] |
| Answer |  | [1..1] |
| Low value | Used to indicate the low boundary e.g. “0” | [0..1] |
| High value | Used to indicate the low boundary e.g. “24” | [0..1] |
| Skip | Indicates whether it is allowed to skip this question (Skip=TRUE) or not (Skip=FALSE). By default the value of Skip could be “FALSE”. |  [0..1] |

**Template numeric question:**

| **Name** | **XPath** | **Card.** | **Verb** | **Data Type** | **CONF#** | **Fixed Value** |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.25.4.5'] |
|  |  @classCode | 1..1 | SHALL |  | [17430](#C_17430) | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
|  |  @moodCode | 1..1 | SHALL |  | [17431](#C_17431) | 2.16.840.1.113883.5.1001 (ActMood) = EVN |
|  |  templateId | 1..1 | SHALL |  | [17428](#C_17428) |  |
|  |  @root | 1..1 | SHALL |  | [17429](#C_17429) | 2.16.840.1.113883.10.20.25.4.5 |
|  |  id | 1..1 | SHALL |  | NCONF |  |
|  |  code | 1..1 | SHALL |  | [17434](#C_17434) |  |
|  |  @text | 1..1 | SHALL |  | NCONF |  |
|  |  value | 1..1 | SHALL | INT | NCONF |  |
|  |  entryRelationship | 1..\* | MAY |  | [22625](#C_22625) |  |
|  |  @typeCode | 1..1 | SHALL |  | [22626](#C_22626) | 2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR |
|  |  referenceRange | 0..1 | SHOULD |  | NCONF |  |
|  |  observationRange | 1..1 | SHALL |  | NCONF |  |
|  |  @classCode | 1..1 |  |  | NCONF |  |
|  |  @moodCode | 1..1 | SHALL |  | NCONF |  |
|  |  @value | 1..1 | SHALL |  | NCONF |  |

**Free text:**

|  |  |  |
| --- | --- | --- |
| **Element/Attribute** | **Definition** | **Multiplicity** |
| Question ID | This uniquely identifies a question within the Questionnaire document.  | [1..1] |
| Question text | “Why do you feel worse?” | [1..1] |
| Answer |  Example “I didn’t drink coffee☺”. | [1..1] |
| Skip | Indicates whether it is allowed to skip this question (Skip=TRUE) or not (Skip=FALSE). By default the value of Skip could be “FALSE”. |  [0..1] |

**Template free text question:**

**Free text question with Logical Expression:**

|  |  |  |
| --- | --- | --- |
| **Element/Attribute** | **Definition** | **Multiplicity** |
| Question ID | This uniquely identifies a question within the Questionnaire document.  | [1..1] |
| Pre-condition | This element holds the logical expression. e.g. ask this question **ONLY** if answer to “Question 1” is “a2” **AND** answer to “Question 2” is “b3”. | [0..1] |
| Question text | “Why do you feel worse?” | [1..1] |
| Answer |  Example “I didn’t drink coffee☺”. | [1..1] |
| Skip | Indicates whether it is allowed to skip this question (Skip=TRUE) or not (Skip=FALSE). By default the value of Skip could be “FALSE”. |  [0..1] |

**Discrete Slider:**

|  |  |  |
| --- | --- | --- |
| **Element/Attribute** | **Definition** | **Multiplicity** |
| Question ID | This uniquely identifies a question within the Questionnaire document.  | [1..1] |
| Question text | “what is the percentage you were not happy?” | [1..1] |
| Answer options | It will contain the list of values that would be used to construct/render a discrete slider. This is similar to a multiple choice question, however the visualization is different. The multiple answer options could be considered as labels on the “Discrete Slider”.Note: only one option needs to be selected. | [2..\*] |
| Skip | Indicates whether it is allowed to skip this question (Skip=TRUE) or not (Skip=FALSE). By default the value of Skip could be “FALSE”. |  [0..1] |

**Template for discrete slider question:**

1. Template IDs Used in This Guide

This appendix lists all templateIds used in this guide in [alphabetical order](#Alphabetical_List_of_Templates) and in [containment order](#Template_Containments).

Table 52: Alphabetical List of Templates by Type

| Template Title | Template Type | templateId |
| --- | --- | --- |
| CARE [Questionnaire](#CARE_Questionnaire_Assessment) Assessment | document | 2.16.840.1.113883.10.20.25.1.1 |
| [Questionnaire Assessment Framework](#D_Questionnaire_Assessment_Framework) | document | 2.16.840.1.113883.10.20.25.1.3 |
| [US Realm Header](#D_US_Realm_Header) | document | 2.16.840.1.113883.10.20.22.1.1 |
| [CARE Section Pattern](#CARE_Section_Pattern) | section | 2.16.840.1.113883.10.20.25.2.11 |
| [Generic Section Pattern](#S_Generic_Section_Pattern) | section | 2.16.840.1.113883.10.20.25.2.1 |
| [Assertion Pattern](#E_Assertion_Pattern) | entry | 2.16.840.1.113883.10.20.25.4.7 |
| [CARE Assertion Pattern](#E_CARE_Assertion_Pattern) | entry | 2.16.840.1.113883.10.20.25.4.3 |
| [CARE Other Response Pattern](#CARE_Other_Response_Pattern) | entry | 2.16.840.1.113883.10.20.25.4.2  |
| [CARE Question Answer Pattern Organizer](#E_CARE_Question_Answer_Pattern_Organize) | entry | 2.16.840.1.113883.10.20.25.4.10 |
| [CARE Typical Response Pattern](#CARE_Typical_Response_Pattern) | entry | 2.16.840.1.113883.10.20.25.4.1 |
| [Other Response Pattern](#E_Other_Response_Pattern) | entry | 2.16.840.1.113883.10.20.25.4.6 |
| [Question Answer Pattern](#Question_Answer_Pattern) | entry | 2.16.840.1.113883.10.20.25.4.5 |
| [Question Answer Pattern Organizer](#E_Question_Answer_Pattern_Organizer_) | entry | 2.16.840.1.113883.10.20.25.4.9 |
| [Typical Response Pattern](#E_Typical_Response_Pattern) | entry | 2.16.840.1.113883.10.20.25.4.8 |

Table 53: Template Containments

| Template Title | Template Type | templateId |
| --- | --- | --- |
| CARE Questionnaire [Assessment](#CARE_Questionnaire_Assessment) | document | 2.16.840.1.113883.10.20.25.1.1 |
| [CARE Section Pattern](#CARE_Section_Pattern) | section | 2.16.840.1.113883.10.20.25.2.11 |
| [CARE Assertion Pattern](#E_CARE_Assertion_Pattern) | entry | 2.16.840.1.113883.10.20.25.4.3 |
| [CARE Other Response Pattern](#CARE_Other_Response_Pattern) | entry | 2.16.840.1.113883.10.20.25.4.2  |
| [CARE Question Answer Pattern Organizer](#E_CARE_Question_Answer_Pattern_Organize) | entry | 2.16.840.1.113883.10.20.25.4.10 |
| [CARE Assertion Pattern](#E_CARE_Assertion_Pattern) | entry | 2.16.840.1.113883.10.20.25.4.3 |
| [CARE Typical Response Pattern](#CARE_Typical_Response_Pattern) | entry | 2.16.840.1.113883.10.20.25.4.1 |
| [Questionnaire Assessment Framework](#D_Questionnaire_Assessment_Framework) | document | 2.16.840.1.113883.10.20.25.1.3 |
| [Generic Section Pattern](#S_Generic_Section_Pattern) | section | 2.16.840.1.113883.10.20.25.2.1 |
| [Assertion Pattern](#E_Assertion_Pattern) | entry | 2.16.840.1.113883.10.20.25.4.7 |
| [Other Response Pattern](#E_Other_Response_Pattern) | entry | 2.16.840.1.113883.10.20.25.4.6 |
| [Question Answer Pattern Organizer](#E_Question_Answer_Pattern_Organizer_) | entry | 2.16.840.1.113883.10.20.25.4.9 |
| [Assertion Pattern](#E_Assertion_Pattern) | entry | 2.16.840.1.113883.10.20.25.4.7 |
| [Other Response Pattern](#E_Other_Response_Pattern) | entry | 2.16.840.1.113883.10.20.25.4.6 |
| [Typical Response Pattern](#E_Typical_Response_Pattern) | entry | 2.16.840.1.113883.10.20.25.4.8 |
| [US Realm Header](#D_US_Realm_Header) | document | 2.16.840.1.113883.10.20.22.1.1 |
| [Question Answer Pattern](#Question_Answer_Pattern) | entry | 2.16.840.1.113883.10.20.25.4.5 |

1. Code Systems Used in this Guide

For the user’s convenience, this table summarizes the code systems (vocabularies) used in this guide.

Table 54: List of Code Systems

|  |
| --- |
| Root OIDs |
| codeSystem | codeSystemName |
| 2.16.840.1.113883.5.1119 | AddressUse |
| 2.16.840.1.113883.5.1119 | AddressUse |
| 2.16.840.1.113883.5.1 | AdministrativeGender |
| 2.16.840.1.113883.4.340 | CMS Local Codes |
| 2.16.840.1.113883.5.25 | Confidentiality |
| 2.16.840.1.113883.5.43 | EntityNamePartQualifier |
| 2.16.840.1.113883.5.45 | EntityNameUse |
| 2.16.840.1.113883.6.92 | FIPS 5-2 (State) |
| 2.16.840.1.113883.1.11.11526 | Internet Society Language |
| 1.0.3166.1 | ISO 3166-1 Country Codes: |
| 2.16.840.1.113883.5.60 | LanguageAbilityMode |
| 2.16.840.1.113883.5.61 | LanguageAbilityProficiency |
| 2.16.840.1.113883.6.1 | LOINC |
| 2.16.840.1.113883.5.2 | MaritalStatus |
| 2.16.840.1.113883.6.238 | Race and Ethnicity - CDC |
| 2.16.840.1.113883.6.238 | Race and Ethnicity - CDC |
| 2.16.840.1.113883.5.1076 | ReligiousAffiliation |
| 2.16.840.1.113883.5.110 | RoleClass |
| 2.16.840.1.113883.5.111 | RoleCode |
| 2.16.840.1.113883.6.231 | US Postal Codes |

This guide also provides the value set identifiers for the code systems.

Table 55: Value Set Identifiers for Code Systems

|  |  |  |  |
| --- | --- | --- | --- |
| Value Set Identifier | Value Set Name | Code System Identifier | Code System Name |
| 2.16.840.1.113883.11.16492 | LogicalObservationIdentifierNamesAndCodes | 2.16.840.1.113883.6.1 | LOINC |
| 2.16.840.1.113883.11.20.10.18 | Questionnaire Assessment item identifiers | 2.16.840.1.113883.4.340 | CMS Local Codes |

1. Additional CMS Assessments

The Centers for Medicare and Medicaid Services (CMS) requires use of specific, standardized questionnaire assessments for several long-term and post-acute care settings, including the following instruments:

*Minimum Data Set 3.0 (MDS3.0)*

|  |  |
| --- | --- |
| Setting:  | Medicare or Medicaid certified nursing facilities |
| URL: | <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/NHQIMDS30.html> |

*Outcome and Assessment Information Set - C (OASIS-C)*

|  |  |
| --- | --- |
| Setting: | Medicare certified home health agencies |
| URL: | <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/OASIS/index.html?redirect=/oasis/> |

The HL7 Implementation Guide for CDA Release 2: CDA Framework for Questionnaire Assessments, Release 2, DSTU, April 21, 2010 provided LOINC mapping and value sets for MDS 3.0 v1.00.1 data elements. The MDS 3.0 has evolved since the publication of the DSTU and the LOINC mapping and value sets provided in the DSTU do not fully support the MDS 3.0 v.1.10.1 currently in use. As part of a contract between the Department of Health and Human Services Office of the Assistant Secretary of Planning and Evaluation and the American Health Information Management Association Foundation, and with the support of the Standards and Interoperability Framework Longitudinal Coordination of Care Workgroup and the Keystone Beacon project, the LOINC mapping and value sets from the DSTU have been updated to reflect the MDS3.0 v.1.10.1. In addition, this collaborative effort has produced LOINC mapping and value sets to support the OASIS-C.

The updated LOINC mapping and value sets identified for the MDS 3.0 v.1.10.1 and the OASIS-C have been rendered in a manner that mimics the presentation of CARE data elements in this implementation guide. It is anticipated that presentation of the LOINC mapping and value set information in this manner will facilitate the representation of MDS 3.0 and OASIS-C assessments in CDAs that are conformant to this guide. These tools are available at <http://sibrowser.siframework.org/>.

1. Previously Published Templates

The following templates were first published in implementation guides other than Questionnaire Assessment and are re-used and republished in this guide. Enhancements or errata requested in these templates may be noted on the HL7 DSTU comments page <http://www.hl7.org/dstucomments/>. Specifically, these CDA templates are from [HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, Release 1—US Realm](http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=69) templates. For more information on the reuse of templates please see [Templated CDA](file://F:\..\..\..\..\..\..\..\..\..\..\..\..\..\..\..\..\..\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.IE5\AppData\Local\Microsoft\AppData\Local\Microsoft\Windows\AppData\Local\Microsoft\Windows\Zabrina\Desktop\QRDA%20Ballot%20Final\CDAR2_QRDA_DSTUR2#_Templated_CDA) in this document.

Table 56: Previously Published Templates

| Template Title | Template Type | templateId |
| --- | --- | --- |
| [US Realm Header](#D_US_Realm_Header) | document | 2.16.840.1.113883.10.20.22.1.1 |
| [US Realm Address (AD.US.FIELDED](#O_US_Realm_Address_(AD.US.FIELDED))) | unspecified | 2.16.840.1.113883.10.20.22.5.2 |
| [US Realm Date and Time (DTM.US.FIELDED)](#O_US_Realm_Date_and_Time_(DTM.US.FIELDED) | unspecified | 2.16.840.1.113883.10.20.22.5.4 |
| [US Realm Patient Name (PTN.US.FIELDED)](#O_US_Realm_Patient_Name_(PTN.US.FIELDED)) | unspecified | 2.16.840.1.113883.10.20.22.5.1 |
| [US Realm Person Name (PN.US.FIELDED)](#O_US_Realm_Person_Name_(PN.US.FIELDED)) | unspecified | 2.16.840.1.113883.10.20.22.5.1.1 |

1. Extensions TO CDA R2

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

Extensions in this guide include:

* sdtc:raceCode—The raceCode extension allows for multiple races to be reported for a patient.
* sdtc:deceasedInd—The deceasedIndextension (= “true” or “false”) in the family history organizer on the related subject is used inside to indicate if a family member is deceased.
* sdtc:deceasedTime—The deceasedTime extension in the family history organizer on the related subject allows for reporting the date and time a family member died.
* sdtc:birthTime—The <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.

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

* An extension is a collection of element or attribute declarations and rules for their application to the CDA Release 2.0.
* 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.
1. <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/index.html?redirect=/NursingHomeQualityInits/> [↑](#footnote-ref-2)
2. <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/OASISC.html> [↑](#footnote-ref-3)
3. <http://www.hl7.org/v3ballot/html/infrastructure/conformance/conformance.htm> [↑](#footnote-ref-4)
4. *HL7 Clinical Document Architecture (CDA Release 2).* <http://www.hl7.org/implement/standards/cda.cfm> [↑](#footnote-ref-5)
5. Publishing Facilitator's Guide. <http://www.hl7.org/v3ballot/html/help/pfg/pfg.htm> [↑](#footnote-ref-6)
6. <http://www.hl7.org/memonly/downloads/v3edition.cfm#V32010> (must be a member to view) [↑](#footnote-ref-7)
7. *HL7 Clinical Document Architecture (CDA Release 2).* <http://www.hl7.org/implement/standards/cda.cfm> [↑](#footnote-ref-8)
8. *HL7 Clinical Document Architecture (CDA Release 2).* <http://www.hl7.org/implement/standards/cda.cfm> [↑](#footnote-ref-9)
9. <http://www.w3.org/TR/xpath/> [↑](#footnote-ref-10)
10. Nunnally JC, Bernstein IH. *Psychometric Theory, 3rd ed*. New York: McGraw-Hill, 1994. [↑](#footnote-ref-11)
11. Aday LA. *Designing and Conducting Health Surveys: A Comprehensive Guide, 2nd ed*. San Francisco: Jossey-Bass 1996. [↑](#footnote-ref-12)
12. White TM, Hauan MJ. Extending the LOINC® Conceptual Schema to Support Standardized Assessment Instruments. *J Am Med Inform Assoc* 2002;9,586–99. [↑](#footnote-ref-13)
13. *HL7 Implementation Guide for CDA Release 2.0, Long-Term Post-Acute Care (LTPAC) Summary*, December 2012, found on <http://www.hl7.org/dstucomments/> [↑](#footnote-ref-14)
14. *HL7 Implementation Guide for CDA Release 2.0, Consolidated CDA Templates*. July 2012. <http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258> [↑](#footnote-ref-15)
15. • HL7 Implementation Guide for CDA Release 2.0, Consolidated CDA Templates. July 2012. http://www.hl7.org/implement/standards/product\_brief.cfm? product\_id=258 [↑](#footnote-ref-16)