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| **eHealth Exchange** |
| **2016 Consolidated CDA (C-CDA) Continuity of Care Document (CCD) Content Testing Profile v0.4** |



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| eHealth Exchange Testing Workgroup  04/11/2016 |

**Change Log**

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| --- | --- | --- |
| **Date** | **Version** | **Description** |
| 11/2/2015 | Initial Draft v0.1 | Initial rough draft |
| 11/5/2015 | Version 0.2 | Added comments and fixed formatting and font issues found and updated table of contents |
| 02/29/2016 | Version 0.3 | Comments received since 11/5/2015 incorporated. Added HL7 C-CDA CCD v2.1 requirements & additional clarification based on implementation FAQs tracked by the testing workgroup |
| 4/11/2016 | Version 0.4 | Updated Test Methods to align with MU 2015 Edition Test Procedures and Test Data leveraged by Authorized Testing Labs |
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# Introduction

The eHealth Exchange continues to support the content requirements and specifications defined within the 2014 Edition Meaningful Use program. In addition, the Testing Workgroup recommends the addition of testing compliance to the 2015 Edition Meaningful Use (MU3) Program Certification requirements that reference the latest Draft Standard for Trial Use (DSTU) HL7 C-CDA version 2.1 standards. These standards were published in August 2015 and are referenced in the standards and implementation guides chapter 3 of this document. This content testing documentation builds upon the [Bridge C32](http://sequoiaproject.org/wp-content/uploads/2015/03/bridge-c32-ballot-v1-3-0-2013-05-13-clean.xls) content requirements previously published by the eHealth Exchange. eHealth Exchange participants should strive to support the appropriate document types to support their various use cases. The reality of today is that 90% or more of the eHealth Exchange participants create on-demand documents when queried and respond with a Continuity of Care Document (CCD) document type. There are 12 document templates in the HL7 C-CDA version 2.1 standards but the Testing Workgroup felt the focus should begin with testing conformance to the base specification requirements during the 2016 Pilot planned to run April – June 2016.

This content testing documentation adds the additional content requirements from the [Transitions of Care Implementation guidance published by HL7](http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=168). The HL7 implementation guide provides meaningful use and additional clinical guidance for information that may be exchanged by nodes among eHealth Exchange participants to address particular use cases or business needs. The eHealth Exchange participants act as nodes on the eHealth Exchange network and enable their connected stakeholders to exchange clinical document content to make use of the discovery and information exchange capabilities and rest upon a foundational set of messaging, security, and privacy services.

In addition, this documentation leverages the test methods for evaluating conformance to the certification criteria defined in 45 CFR Part 170 Subpart II of the certification criteria defined in 45 CFR Part 170 Subpart II of the[2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications final rule](https://www.healthit.gov/policy-researchers-implementers/2015-edition-final-rule) as published in the Federal Register on October 16, 2015.  It references the Testing and Test Methods for the 2015 Edition Test Methods for the following (see page 52 for full test procedure definitions):

<https://www.healthit.gov/policy-researchers-implementers/2015-edition-test-method>

1. Test Procedure for §170.315 (b)(4) Common Clinical Data Set Summary Record - Create
2. Test Procedure for §170.315 (b)(5) Common Clinical Data Set Summary Record - Receive

The overall goal for mirroring the 2015 Edition Meaningful Use Test Procedures above is to ensure the participant organization can share robust clinical data. Therefore, the following will be tested by leveraging the same associated test data to verify the participant has the capabilities properly implemented and configured among all connected stakeholders. Overall their content document submission for review **SHALL** test the following:

1. Test the content and format of the C-CDA Continuity of Care document template, covering the electronic exchange of health information between Health Information Organizations (HIOs) and
2. To test for the adherence to a standard set of vocabularies.

This document provides the testing methodology and scenarios that will eventually be required for interoperability testing and exchange of content documents between eHealth Exchange participants. The outcome from the content testing pilot will provide a feedback loop from real world deployments to HL7 and is expected to inform the new Companion Guide currently under development by the Structured Documents and other Workgroups within HL7. In addition, the Testing Workgroup will leverage lessons learned from the pilot testing participants to determine future requirements for all eHealth Exchange participants to be tested for future conformance.

The eHealth Exchange Testing Workgroup will collaborate with the Specification Factory Workgroup to develop a timeline to implement a pilot based on the test procedures produced in this effort as well as a timeline as to when these test procedures will be considered required for all eHealth Exchange participants. This timeline will be presented to the Sequoia Project Coordinating Committee for review and approval, considering any additional information gathered during the pilot testing period.

# Use Case Scenarios

## Treatment/Transitions of care

### Existing Use Cases

### Use Case 1: Hospital Discharge

This use case describes the situation where a patient’s care is transitioned or referred to another care provider.  The health information systems of the two provider organizations should be able to successfully transfer a notification of the patient discharge.  The notification may include important patient data elements that facilitate the effective transfer of the patient's care from the first provider organization to the second.

1. Communicate a patient discharge to an external organization
2. Similar to a transition of care
3. Transport is tested separately from content requirements but can Include provider to provider referral using DIRECT

Goals:

To be able to electronically send a discharge for a patient from a hospital encounter from a care provider Sender to care provider Receiver with the appropriate patient demographic, administrative and clinical data to ensure a smooth transition of care.

### Use Case 2: Provider to Provider Referral

This use case describes the situation where a patient’s care is transitioned or referred to another care provider.  The health information systems of the two provider organizations should be able to successfully transfer a notification of the patient referral.  The notification may include important patient data elements that facilitate the effective transfer of the patient's care from the first provider organization to the second.

1. Communicate a patient referral to an external organization
2. Similar to a transition of care
3. Transport is tested separately from content requirements but can Include provider to provider referral

**Goals**:

To be able to electronically send a referral for a patient from care provider Sender to care provider Receiver with the appropriate patient demographic, administrative and clinical data to ensure a smooth transition of care.

### Use Case 3: Unplanned TOC – ED Summary

### Use Case 4: Single Encounter Summary

### Use Case 5: Multiple episode push or inquiry document

Cross encounter use case spanning period of time – longitudinal care record – TOC/Care Summary

# Referenced Standards and Implementation Guides

|  |  |
| --- | --- |
| **HL7 Standard or Implementation Guide** | **URL** |
| HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial Use (July 2012) | <http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258> |
| HL7 Implementation Guide: S&I Framework Transitions of Care Companion Guide to Consolidated-CDA for Meaningful Use Stage 2, Release 1 – US Realm (September 2014) | <http://www.hl7.org/implement/standards/product_brief.cfm?product_id=374> |
| HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1 – Volume 1 – Introductory Material  (August 2015) | http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=168 |
| HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1- Volume 2 – Templates and Supporting Materials  (August 2015) | <http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=168> |

Two volumes comprise this HL7 Implementation Guide for CDA ® Release 2: Consolidated CDA Templates for Clinical Notes*.*

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

HL7 is developing a Companion Guide for C-CDA Release 2.1 and the Testing Workgroup intends to update this document once it becomes publicly available. In the meantime, we recommend developers follow the guidance provided by the HL7 CDA Example Task Force for implementation of the C-CDA Release 2.1 standard.

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| Following is a non-exhaustive list of third-party terminologies that may require a separate license: Terminology | Owner/Contact |
| Current Procedures Terminology (CPT) code set | American Medical Association http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt/cpt-products-services/licensing.page? |
| SNOMED CT | International Healthcare Terminology Standards Developing Organization (IHTSDO) http://www.ihtsdo.org/snomed-ct/get-snomed-ct or info@ihtsdo.org |
| Logical Observation Identifiers Names & Codes (LOINC) | Regenstrief Institute |
| International Classification of Diseases (ICD) codes | World Health Organization (WHO) |

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| ***Clarifications:***  In order to facilitate the translation of SNOMED CT® codes to ICD-10-CM in administrative systems, developers are encouraged to reference the publicly available mapping that the National  Library of Medicine provides. [https://www.nlm.nih.gov/research/umls/mapping\_projects/snomedct\_to\_icd10cm.html  We provide the following OIDs to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards.   * ICD-10 Procedure Coding System OID: 2.16.840.1.113883.6.4 * SNOMED CT® OID: 2.16.840.1.113883.6.96 [see also 80 FR 62612]   Health IT Modules can present for certification to a more recent version of SNOMED CT®, U.S. Edition than the September 2015 Release per ONC’s policy that permits certification to a more recent version of certain vocabulary standards. |

# Testing Approach

The testing approach will include a business process and technical process to facilitate the onboarding of eHealth Exchange participants. The general process is outlined below but it is expected that the existing process documentation and participant testing applications will need to be updated before this is formalized and required by all participants.

## Testing Process

1. Submission Form Completion (describes the participant’s content, data limits included in each section, terminology coding, reports inclusion, etc.
2. Testing

* Focus is on C-CDA Release 1.1 and C-CDA Release 2.1 CCD document template
* Candidate create samples based on 2015 Edition Meaningful Use Test Procedure test data

The pilot process will include a period to identify gaps and verify coverage for the testing tools that are participating in pilot testing efforts. These content testing tools are referenced in chapter 9 of this document but at a minimum it is expected that the following combination of document compliance testing will be administered:

1. [NIST Edge Testing Tool (ETT)](https://edge.nist.gov/ttt/#/validators) (compliance with specs + MU 2015 EDITION)

AND

1. [Standards Implementation Testing Environment (SITE)](http://sitenv.org/c-cda-validator) (compliance with specs + MU 2015 EDITION + smart quality scoring

AND

1. Gazelle External Validaiton Service for Sequoia C-CDA Release 1.1 & Release 2.1 Validators (No MU coverage but provides additional CDA validation not covered currently by ETT and SITE
2. Enhanced smart quality scoring via Diameter Health CCD Analyzer

AND

1. Visual inspection of
   1. XML Document Samples
   2. Participant user interface for display to clinicians for narrative text, sections and structured entries as they relate to the XML document samples provided

## Content Testing Process

|  |
| --- |
| 1. System Under Test (SUT) submits CCD document for Inpatient and/or Ambulatory with appropriate test data.   a. See test cases in chapter 10 for appropriate test procedures and test data for Inpatient and Ambulatory 2. SUT self-tests with SITE and Gazelle tooling and makes improvements as appropriate prior to submission  a. Repeat until all Errors are eliminated  b. Warnings from the tooling should be reviewed by SUT for potential improvement  c. If SUT finds inappropriate error(s) or warning(s), please provide details in an email to testing@sequoiaproject.org 3. The SUT emails the submission form and the CCD sample(s) to [testing@sequoiaproject.org](mailto:testing@sequoiaproject.org) 4. The Testing Lab reviews submission form and content testing CCD submission(s) for completeness  a. If submission is complete, the testing lab confirms receipt  5. The Testing Lab schedules a manual review for the Receive Test Case as described in Section 10.1.2 in this document.  6. The Testing Lab validates the CCD submission(s) with the three testing tools as described in Section 9 of this document. |

## Content Testing Timeline & Milestones

|  |  |  |
| --- | --- | --- |
| Milestone Descriptions | Target Date | Status |
| Publish 1st Draft Enhanced Content Testing Documentation | 11/15 | Completed |
| Industry Tooling Self Scoring and Assessment | 01/16 | Completed |
| Publish Content Testing Documentation Package | 04/16 | Completed |
| Pilot Trial Period (April – June 2016) | 06/16 | In Process |
| Gather Tooling Improvements | 06/16 | In Process |
| Testing Workgroup to Summarize Testing | 07/16 | Not Started |
| Testing Workgroup Provides Feedback to HL7/ONC | Ongoing | Not Started |
| Present Draft to CC for review: | 06/16 | Not Started |
| Participant Input:   * Post draft to eHealth Exchange Wiki * Review updates with Specification Factory * Review updates on Informational Call | 07/16 | Not Started |
| Participant Input (Webinar to review updates): | 07/16 | Not Started |
| CC Approval: | 08/16 | Not Started |
| 30 day public comment notice to participants: | 08/16 | Not Started |
| Objection Period Ends: | 09/16 | Not Started |
| Target Effective Date: | 10/16 | Not Started |

## Outstanding Questions

1. Do systems that do not create content but rather only pass through HIT Certified Modules for MU 2014 Edition or MU 2015 Edition certified products get a waiver?
2. Shallnew and existing eHealth Exchange participants be required to test after trial period?
3. What is pass/fail criteria?
4. How do we ensure the tested systems are realistic? (similar to what is implemented in production and include fully populated CCD C-CDA document?
5. How do we measure value gained to ensure at the end that the content is good and drives data sharing, usage, and patient outcomes?
6. What should be required for each Participant on the eHealth Exchange to ensure data quality monitoring once moved into production as new stakeholders are connected to their exchange gateways?
   * inside the organization?
   * using real patient data, during production?
7. Should the Testable assertion in section 5.9 of this document be required? Is Self-Attestation appropriate, or do we need to gather other supporting information?
8. Additional FAQs and Pain Points are being tracked as a separate Appendix to this document as collaboration with HL7 for suggested improvements to documentation and standards continue. See Appendix A.

# Consolidated Clinical Document Architecture (C-CDA) Continuity of Care Document (CCD) Background and Conformance Requirements

This document type was derived from HITSP C32 and CCD Release 1.0 and is defined in both the HL7 C-CDA CCD Release 1.1 and Release 2.1 Implementation Guides. The Continuity of Care Document (CCD) represents a core data set of the most relevant administrative, demographic, and clinical information facts about a patient's healthcare, covering one or more healthcare encounters. It provides a means for one healthcare practitioner, system, or setting to aggregate all of the pertinent data about a patient and forward it to another to support the continuity of care.

The primary use case for the CCD is to provide a snapshot in time of the most relevant administrative, demographic, and clinical information facts about a patient’s healthcare, covering one or more healthcare encounters. It provides a means for one healthcare practitioner, system, or setting to aggregate all of the pertinent data about a patient and forward it to another to support the continuity of care.

The key characteristic of a CCD is that the ServiceEvent is constrained to "PCPR". This means it does not function to report new ServiceEvents associated with performing care. It reports on care that has already been provided. The CCD provides a historical tally of the care over a range of time and is not a record of new services delivered.

CCD was defined from HL7 Clinical Document Architecture (CDA) structures and ASTM Continuity of Care Record (CCR) clinical models. Consolidated CDA imposes constraints within templates based on conformance verbs defined in IETF RFC 2119.

## Conformance Verbs

The keywords SHALL, SHOULD, MAY, NEED NOT, SHOULD NOT, and SHALL NOT in this documentation are to be interpreted as described in the HL7 Version 3 Publishing Facilitator’s Guide (HL7, *Version 3 Publishing Facilitator's Guide.* http://www.hl7.org/v3ballot/html/help/pfg/pfg.htm ). To determine constraints for the recommended approach, applications of conformance verbs from Consolidated CDA were determined as follows:

* **SHALL:** an absolute requirement.
  + Required by MU 2014 EDITION regulations
  + Required in the Consolidated CDA document template specification
* **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.

Conformance verbs, when used in the Consolidated CDA implementation guide, are written in all capital letters and bolded within a conformance statement. Figure 3 demonstrates conformance statements sampled from the Allergies Section with entries required template.

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

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

a. This structuredBody **SHOULD** contain zero or one [0..1] **component** (CONF:1098-29066) such that it

i. **SHALL** contain exactly one [1..1] **Plan of Treatment Section (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.2.10:2014-06-09) (CONF:1098-29067).

...is understood as:

a. It is recommended (**SHOULD**) that the structureBody contains a component.

i. **If** the component exists, **then** it must contain a Plan of Treatment Section (V2),

ii. **else** the component does not exist, and the conformance statement about the Plan of Treatment Section (V2) should be skipped.

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

b. This structuredBody **SHALL** contain exactly one [1..1] **component** (CONF:1098-29086) such that it

i. **SHALL** contain exactly one [1..1] **Problem Section (entries required) (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.2.5.1:2014-06-09) (CONF:1098-29087).

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

## 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.

### Optional and Required with Cardinality

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

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

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

**Figure X: Sample Representation of CDA Conformance**

|  |
| --- |
| 1. Conforms to **Allergies Section (entries optional)** template (2.16.840.1.113883.10.20.22.2.6). 2. **SHALL** contain exactly one [1..1] **templateId** (CONF:7527) such that it    1. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.2.6.1" (CONF:10379). 3. **SHALL** contain exactly one [1..1] **code** (CONF:15349). 4. This code **SHALL** contain exactly one [1..1] **@code**="48765-2" Allergies, adverse reactions, alerts (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:15350). |

## 

## Template – Driven Approach

Conformance statements within these test methods documentation are presented as constraints from Trifolia Workbench, a template repository. An algorithm converts constraints recorded in Trifolia to a printable presentation within the HL7 C-CDA standards specifications. 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.

The Consolidated CDA implementation guide employs the concept of "templates." Templates are declared at the document, section, and entry level of CDA documents. The Consolidated CDA Implementation Guide defines an initial set of commonly used clinical documents whose contents are harmonized, thus ensuring semantic interoperability across current and future document models. Templates capture specific uses and can represent professional society recommendations, national clinical practice guidelines, and standardized data sets. Templates are designed to create standardized clinical documents that are specifically intended to support clinical workflows in various use cases.

**Document-level templates:** These templates constrain fields in the CDA header, and define containment relationships to CDA sections. For example, the Continuity of Care Document (CCD) template contains patient summary data defined by the ASTM Continuity of Care Record (CCR) represented in the CDA XML format. Understanding the purpose of a template helps to ensure that implementations support the inclusion of clinical information that is relevant to the intended use. In the case of the CCD, the clinical content is limited to the most relevant patient data captured during one or more encounters to ensure continuity of patient care. Similarly, the Problem Observation entry template captures a single problem or diagnosis for the patient and is limited to information about the problem or diagnosis, such as the diagnosis or observation date and the code representing the diagnosis or observation.

Templates are available in different types that reflect levels of a CDA document. Starting at the top of a document, the **header** **template** describes the scope and intended use of the document. The header includes the metadata, or data about the document data, that details contextual information, such as who created the document, encounter or event time and location, and patient demographics. In the broadest sense, header templates are documents with no defined body content.

Content comprising the document body and additional constraints on the header are expressed within **document templates** that define the clinical information contained based on the purpose for the document.

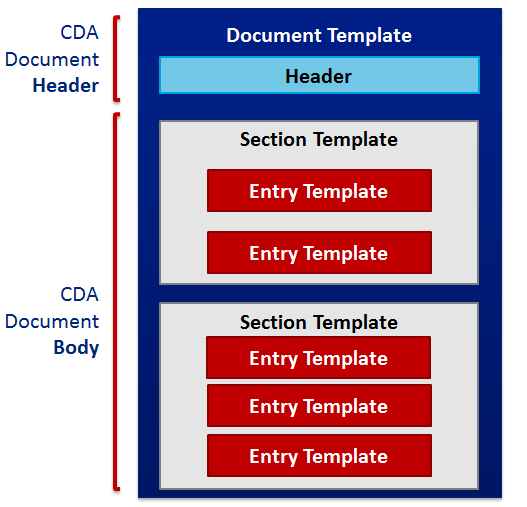
Contents of the document body are comprised of **section and entry templates**. These templates specify standardized patterns used to express clinical concepts and provide the basis for reusability of CDA documents. Document templates include section and entry templates as needed, but the section and entry templates are not limited to a certain document. For example, the same Medications section may be used in more than one type of document, as in the case of the CCD and Consultation Note.

The Section-level templates constrain fields in the CDA section, and define containment relationships to CDA entries that revolve around a common clinical concept, such as Procedures or Encounters. The Procedures section template captures information relative to patient procedures detailed in the entry templates that specify the procedure.

The **entry-level templates** constrain the CDA clinical statement model in accordance with real-world observations and acts. The **entry-level templates** represent individual clinical statements through coded data elements, such as a specific medication or procedure. Entries are very specific templates intended to capture an event, action, or observation relative to the clinical concept captured in the Section. Each **document template** defines a collection of required and optional sections as well as the entries within sections. Figure 2 depicts the template types in the CDA document.

Lastly, there are also **Other templates** that exist to establish a set of constraints that are reused in the CDA document. These other templates are only used within another template, rather than on their own as a complete clinical statement. For example, US Realm Date and Time (DTM.US.FIELDED) includes a set of common constraints for recording time. This template is referenced several times with other templates used in the testing documentation.

**Figure X: CDA Template Types**

****

### Template Versioning

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

#### Status of a Template Version

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

#### Use of Deprecated Template Versions

Several templates used in C-CDA 1.1 were deprecated as of C-CDA R2. The status for these templates remains deprecated in the Release 2.1 guide. Deprecation of a template version does not prohibit its use in a document, rather, it is a signal to implementers this version of the template may be permanently retired (terminated) in the future, which will end the lifecycle of the template. The list of deprecated templates appears below:

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

### Document-Level Templates

The Continuity of Care Document (CCD) is a subset of the Transfer Summary and contains just the most clinically important patient information. It is a snapshot in time and may be generated for a single visit or a set of visits. The CCD can be used as an alternative to the Transfer Summary when minimal information needs to be conveyed, or for reporting updates to clinical registries and centralized data repositories. Document-level templates describe the purpose and rules for constructing a conforming CDA document. Document templates include constraints on the CDA header and indicate contained section-level templates.

Each document-level template contains the following information:

* Scope and intended use of the document type
* Description and explanatory narrative
* Template metadata (e.g., templateId)
* Header constraints (e.g., document type, template id, participants)
* Required and optional section-level templates

**Table X: Required and Optional Sections for Continuity of Care Document (CCD) & Unstructured Document Types**

|  |  |  |
| --- | --- | --- |
| **Document Type**  **Preferred LOINC**  **templateId** | **Required Sections** | **Optional Sections** |
| Continuity of Care Document (CCD) (V3) (Summarization of Episode Note)  34133-9 (required)  2.16.840.1.113883.10.20.22.1.2:2014-06-09 | Allergies and Intolerances Section (entries required) (V3)  Medications Section (entries required) (V2)  Problem Section (entries required) (V3)  Procedures Section (entries required) (V2)  Results Section (entries required) (V3)  Social History Section (V3)  Vital Signs Section (entries required) (V3) | Advance Directives Section (entries optional) (V3)  Encounters Section (entries optional) (V3)  Family History Section (V3)  Functional Status Section (V2)  Immunizations Section (entries required) (V3)  Medical Equipment Section (V2)  Mental Status Section (V2)  Nutrition Section  Payers Section (V3)  Plan of Treatment Section (V2) |
| Unstructured Document (V3)  Non-preferred  2.16.840.1.113883.10.20.22.1.10:2014-06-09 | N/A | N/A |

#### Levels of Constraint

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

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

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

## Compatibility Principles

This updated testing documentation contains new versions of templates included in C-CDA Release 2.0. Systems under test may want to support compatible template versions in the HL7 C-CDA R1.1 Implementation Guide. The new compatible template versions contain constraint modifications which enable compatibility with C-CDA 1.1 and are identified in the updated C-CDA R2.1 Volume 2 Summary of Changes Appendix.

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

**Compatibility Principles**

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

1. When a SHALL constraint present in C-CDA R1.1 is relaxed to SHOULD or MAY in C-CDA R2.0, the C-CDA R2.1 specification will increase the strength of that constraint to SHALL when compatibility is asserted.
2. When a SHALL constraint present is C-CDA R1.1 is removed in C-CDA R2.0, the C-CDA R2.1 specification will add that constraint when supporting compatibility.
3. When a SHOULD or MAY constraint present in C-CDA R1.1 is relaxed or removed in C-CDA R2.0, the C-CDA R2.1 specification will remain silent. As these constraints are not strictly required in a C-CDA R1.1 instance, they are not necessary for backwards compatibility. Implementers who wish to continue to convey data elements with a SHOULD or MAY constraint in C-CDA R1.1 can still report this information as it was done in C-CDA R1.1, so long as these are also conformant with this specification.
4. A SHALL, SHOULD or MAY constraint added in C-CDA R2.0 that is not explicitly prohibited in C-CDA R1.1 will be added to C-CDA R2.1.
5. When a vocabulary or value set binding has changed for an element to a new coding system in C-CDA R2.0, C-CDA R2.1 will — when supporting backwards compatibility — require the use of the old value set or vocabulary in *element*/code, the new value set or vocabulary in *element*/translation, and otherwise require the use of the new value set or vocabulary in code as it was constrained (with the same strength appearing) in C-CDA R2.0.

### HL7 C-CDA R2.1 Assertion of Compatibility

The HL7 C-CDA R2.1 volume 2 guides includes a requirement that all C-CDA R2.1 conformant instances:

* + \_Include a C-CDA R2.1 templateId,
  + \_Additionally, when the C-CDA R2.1 templateId includes an extension, the C-CDA R1.1 templateId must also be included.

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

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

a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.1.1" (CONF:1198-10036).

b. **SHALL** contain exactly one [1..1] **@extension**="2015-08-01" (CONF:1198-32503).

c. When asserting this templateId, all document, section, and entry templates **SHALL** include a templateId root without an extension. See C-CDA R2.1 Volume 1 - Design Considerations for additional detail (CONF:1198-32936).

## Determining the Status of Clinical Statement

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

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

* **The Act.statusCode of the clinical statement specifies the state of the entry**: Per the RIM, the statusCode “reflects the state of the activity. In the case of an Observation, this is the status of the activity of observing, not the status of what is being observed.”
* **Act.statusCode and Act.moodCode are inter-related**: Generally, an act in EVN (event) mood is a discrete event (a user looks, listens, measures; records what was done or observed), so generally an act in EVN mood will have a statusCode of “completed.” A prolonged period of observation is an exception, in which a user would potentially have an observation in EVN mood that is “active.” For an Observation in RQO (request) mood, the statusCode generally remains “active” until the request is complete, at which time the statusCode changes to “completed.” For an Observation in GOL (goal) mood, the statusCode generally remains “active” as long as the observation in question is still an active goal for the patient.
* **Act.statusCode and Act.effectiveTime are inter-related**: Per the RIM, the effectiveTime, also referred to as the “biologically relevant time,” is the time at which the act holds for the patient. So, whereas the effectiveTime is the biologically relevant time, the statusCode is the state of the activity. For a provider seeing a patient in a clinic and observing a history of heart attack that occurred 5 years ago, the status of the observation is completed, and the effectiveTime is five years ago.

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

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

**Figure X: componentOf/encompassingEncounter Header Element**



HL7 C-CDA 1.1 included several optional “status” observation templates such as Problem Status Observation and Allergy Status Observation. These “status” observation templates were deprecated when C-CDA R2.0 was released. (For more about deprecated templates, see the section titled Use of Deprecated Template Versions). In C-CDA R2.1, the “status” observation templates remain deprecated. To support backward compatibility, systems that consume CDA documents need to address the possibility that a “status” observation template may also be present. The following guidance should be followed if a CDA document includes a deprecated status observation:

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

## Narrative Reference

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

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

* 1. The text, if present, **SHOULD** contain zero or one [0..1] **reference/@value** (CONF: XXXX).
     1. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA R2.0, section 4.3.5.1) (CONF: XXXX).

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

* 1. The originalText, if present, **SHOULD** contain zero or one [0..1] **reference/@value** (CONF:XXXX).
     1. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA R2.0, section 4.3.5.1) (CONF:XXXX).

## Overall Document Testable Assertions:

Do we need to include the following testable assertions in testing? Is Self-Attestation appropriate, or do we need to gather other supporting information? Please provide your suggested edit/additions/deletions during the public comment to [testing@sequoiaproject.org](mailto:testing@sequoiaproject.org).

Testable Assertion 5.9.1; Systems receiving CDA documents **SHALL** be capable of rendering all human-readable content of CDA documents received. Inclusion of additional sections or content does not affect validation as long as conformance to the specified template is maintained.

**Testable Assertion 5.9.2;** While some systems **MAY** create CCDs with only the five minimum required sections,

**Testable Assertion 5.9.3;** others **MAY** include additional optional CCD sections (up to all 21).

**Testable Assertion 5.9.4;** Still, others **MAY** include additional templates not included in the CCD document template definition.

**Testable Assertion 5.9.5;** The **receiving system** is not required to parse the structured entries (machine-readable fields) in the additional sections,

**Testable Assertion 5.9.6;** but it **SHALL** be able to display the entire CDA document, including narrative blocks, in human-readable form.

**Testable Assertion 5.9.7;** CDA R2 requirements affecting design[[1]](#footnote-2) are provided directly from the standard for reference below: There **SHALL** be a deterministic way for a recipient of an arbitrary CDA document to render the attested content.

**Testable Assertion 5.9.8;** Human readability **SHALL NOT** require a sender to transmit a special style sheet along with a CDA document. It must be possible to render all CDA documents with a single style sheet and general-market display tools.

**Testable Assertion 5.9.9;** Human readability applies to the authenticated content. There **MAY** be additional information conveyed in the document that is there primarily for machine processing that is not authenticated and need not be rendered.

**Testable Assertion 5.9.10;** When structured content is derived from narrative, there **SHALL** be a mechanism to describe the process (e.g. by author, by human coder, by natural language processing algorithm, by specific software) by which machine-processable portions were derived from a block of narrative.

**Testable Assertions 5.9.11;** When narrative is derived from structured content, there **SHALL** be a mechanism to identify the process by which narrative was generated from structured data.

**Testable Assertion 5.9.12;** Document Sources **SHALL** provide the capability to send all data for Meaningful Use,

**Testable Assertion 5.9.13;** but **SHOULD** also provide flexibility for clinicians to select the pertinent information to send for a transition of care and/or clinical summary for a patient.

**Testable Assertion 5.9.16;** There **MAY** be certain tests that can be completed to validate that vendors can properly express the absence of information, however. For example, a vendor may include a flavor of null to indicate that there are no known medications, or no known allergies, which are Meaningful Use Stage 1 requirements, rather than leave these sections blank. Once a vendors’ EHR product version passes Stage 2 certification, they will have demonstrated that their version of an EHR is capable of creating a Consolidated CDA document containing all required Meaningful Use data. Beyond vendors simply being able to provide all the Meaningful Use data, however, the Transitions of Care Initiative highly recommends that vendor products offer "selectability" through flexible user interfaces that allow providers to easily select pertinent data, or to be able to not have any data included in certain sections, so they are satisfied with the outgoing clinical documents.

**Testable Assertion 5.9.17;** Providers **SHOULD** use certified document source modular capabilities, where available, to select or deselect information such that the clinical document is relevant for the receiving clinician and/or the patient. The following guidance for providers assumes that they are using certified Document Source technology from vendors that are capable of providing all required Meaningful Use data. Furthermore, it assumes that the Document Source offers the selectability features recommended above. Providers, unlike vendors, do not undergo certification using test data. Rather, they meaningfully use certified EHR technology to exchange data in ways intended to improve coordination of care for real patients among real providers. In the ONC S&I ToC Initiative, consensus was obtained on the importance of including information relevant to the specific transition of care circumstance, and warned against the risks, to adoption and quality of care provided, of sending the recipient clinician too much data (e.g. all of the information in the EHR on the patient) rather than a tailored message. There are concerns that if too much information is included, the recipient clinician may miss the relevant key data on the patient. Using the example of the closed-loop referral, current clinical practice involves the sending clinician composing a referral letter with pertinent positive and negative clinical information about the patient pertaining to the question that the clinician is asking of the consultant.

**Testable Assertion 5.9.18;** Therefore, any given instance of a CDA document, produced for a real patient in the context of a specific transition of care, **MAY** not contain all data that is available. Some legitimate reasons for a Consolidated CDA document not containing all MU required data include:

**Testable Assertion 5.9.19;** Data **MAY** exist but cannot be obtained (e.g. patient was unconscious so birth date and other demographic information was not obtained even though they are required, or the patient was asked about medications and did not know them).

* The data was not generated for this instance (e.g. patient had a visit with the physician, but there were no tests performed so there are no results in the Results Section, even though that section is required).
* The author exercised clinical judgment to limit the summary to information deemed by the sender to be pertinent to the receiver (e.g. PCP has captured the patient’s smoking status and vital signs (weight, blood pressure and temperature which were unremarkable), but knows that those are not relevant to the Podiatrist to whom the patient is being referred for an ingrown toenail). The author should have the ability through the EHR to select for inclusion in the document only those results that are relevant to the care transition.

**Testable Assertion 5.9.20;** Chapter 1.8.8 of the Consolidated CDA implementation guide details how to handle unavailable and unknown information. **In HL7 V3, unavailable, unknown or incomplete data are handled with ‘flavors of null’ representing coded values that communicate the reasoning for missing information.** **Asserting a value for missing data is necessary where entries are required to meet validation.** In addition, communicating reasons for missing data is important in other circumstances as good practice. Indicating null flavors at the appropriate level of precision to convey reasoning for missing required or expected data is encouraged. **The null flavor vocabulary domain within the CDA R2 details the complete hierarchy of null flavor values.**

**Testable Assertion 5.9.21; Problems, medications, and medication allergies sections SHALL NOT be “left blank”, but must include the section and a null value describing the unknown data.**

**Testable Assertion 5.9.22;** Creators of CDA documents **SHALL** be mindful of the purpose of the document as well as the intended use so that only clinically relevant data is sent.

* + A circumstance where too much information or irrelevant data is provided presents opportunity for information overload and may have an undesirable impact on patient care. For example, MU 2014 EDITION requires the inclusion of medications. All current and active medications must be clear to the recipient, so detailing all historical medications is not recommended.

## Assessing C-CDA CCD Documents for 2014 Edition Meaningful Use

The CCD document template may be found in Section 3.1 of the Consolidated CDA implementation guide Release 1.1 .

This section details the body constraints for select CDA documents and results of the assessment. The US Realm Clinical Document Header **SHALL** be required for all document templates. Please reference the CCD\_CCDA\_MU\_eHEX\_Content\_Checklist-2016-04-11.xlsx for individual conformance requirements.

Considerations are provided below for implementations of the Consolidated CDA General Header template to achieve MU 2014 EDITION requirements for encounter and care team information. Further guidance as determined by the Transitions of Care (ToC) ONC Initiative Consensus Recommendations can be summarized below

### ONC TOC Consolidated CDA IG Chapter References

**Table X: Initiative Consensus Recommendations and Consolidated CDA(C-CDA) IG Chapters**

| **MU 2014 EDITION Data Requirement** | **Consensus Recommendations** | **C-CDA IG (Release 1.1) Chapter** | **C-CDA IG (Release 2.1)**  **Chapter** |
| --- | --- | --- | --- |
| Patient Name; Sex; Date of Birth; Race; Ethnicity; Preferred Language | Header element: Record Target | 2.2.1 | Volume 2  Section 1.1 |
| Provider Name & Contact Information [participating in the encounter]; Date and Location of Visit or Hospitalization; Care Team Members [participating in the encounter] | Header element:  Component Of Encompassing Encounter | 2.2.13 | Volume 2  Section 1.1 |
| Provider Name & Contact Information [performing the service event]; Care Team Members [performing the service event] | Header element:  Documentation Of Service Event | 2.2.11 | Volume 2  Section 1.1 |
| Medication Allergies | Allergies Section | 4.2 | Volume 2  Section 2.4.1 |
| Functional Status; Cognitive Status | Functional Status Section | 4.14 | Volume 2  Section 2.20 |
| Discharge Instructions or Clinical Instructions | Hospital Discharge Instructions Section (inpatient settings) or Instructions Section | 4.23 or 4.28 | Volume 2 Section 3.4 |
| Immunizations | Immunizations Section | 4.27 | Volume 2 Section 2.32.1 |
| Medications | Medications Section (entries required) or Hospital Discharge Medications (inpatient settings) | 4.33 or 4.24 | Volume 2 Section 2.38 |
| Care Plan, including goals and instructions; Future Scheduled Tests and Appointments; Referrals to Other Providers; Diagnostic Test(s) Pending | Plan of Care Section or Assessment and Plan Section | 4.39 and/or 4.4 | Volume 2 Section 2.48 |
| Problems | Problems Section (entries required) | 4.44 | Volume 2 Section 2.53.1 |
| Procedures | Procedures Section (entries required) | 4.52 | Volume 2 Section 2.61.1 |
| Reason for Referral | Reason for Referral Section | 4.53 | Volume 2 Section 2.62 |
| Reason for Visit or Hospitalization | Reason for Visit or Chief Complaint or Chief Complaint and Reason for Visit | 4.54 and/or 4.7 | Volume 2 Section 2.63 |
| Laboratory Test(s); Results of Laboratory Test(s) | Results Section (entries required) | 4.55 | Volume 2 Section 2.64.1 |
| Smoking Status | Social History Section | 4.57 | Volume 2 Section 2.66 |
| Vital Signs | Vital Signs Section | 4.60 | Volume 2 Section 2.70.1 |

## Header Constraints Specific to CCD

### Rendering Header Information for Human Presentation

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

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

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

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

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

### Document Meta Data Care Team Members and Provider Names and Contact Information Considerations

A CDA participant (i.e., 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 not included in a summary document.
* Participation evolution: Additional participations (and participation time stamps) can be ascribed to an object over its lifetime. (In some cases, an electronic health record (EHR) system will create a new object instead of adding participants to an existing object, such as when an EHR has imported a CCD and the receiving clinician chooses to create a local problem list entry corresponding to a problem in the CCD).
* Device participation: Devices do not participate as legally responsible entities, but can participate as authors in some scenarios.

Meaningful Use 2014 Edition criterion §170.314(b)(4) Clinical Information Reconciliation requires a system to “simultaneously display (i.e., in a single view) the data from at least two list sources in a manner that allows a user to view the data and their attributes, which must include, at a minimum, the **source** and **last modification date**.”

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

The HL7 C-CDA 2.1 version added a new Author Participation template (templateId 2.16.840.1.113883.10.20.22.4.119) to better ensure consistent representation. This template should be used to explicitly assert authorship and author time stamps, unless the values propagated from the document header hold true.

Care team members, including providers, are participants in the care of a patient. A patient’s care team may include individuals providing support to the patient, such as family members or caregivers, as well as providers and non-physician providers, including nurses, technicians, and assistants. When capturing care team member information, it is recommended to capture the name, identification number, and contact information along with codes to indicate the type of provider and role in the patient’s care. Detailing the type of provider and role helps to distinguish care team members across care settings so that participants in the patient’s care are clear to recipients of the document.

Within CDA, care team members are represented as participants in elements of the document header associated with the patient, the clinical encounter and/or service event detailed in the document, and the document itself. Applicable header elements for capturing care team members from Section 2.2 of the Consolidated CDA implementation guide are described in the following table.

**Table X: Participants in the Header**

|  |  |
| --- | --- |
| Participant | Description |
| author | Care team member who generates content contained in the document.  Examples: PCP, nurse practitioner, admitting physician |
| dataEnterer | Care team member who enters information into the document by transferring content from another source, such as a paper chart.  Examples: transcriptionist, technician |
| informant | Care team member providing information about a patient contained in the document.  Examples: PCP, family member, caregiver |
| informationRecipient | Care team member who the document is intended for.  Examples: PCP, caregiver, consulting physician |
| legalAuthenticator | Care team member who authenticates content contained in the document and accepts legal responsibility.  Examples: PCP, consulting physician, attending physician |
| authenticator | Care team member who authenticates content contained in the document.  Examples: PCP, consulting physician, attending physician |
| participant | Other supporting care team members associated with the patient.  Examples: Caregiver, family member, emergency contact |
| documentationOf/  serviceEvent/  performer | Care team member who performs the service event detailed in the document.  Examples: PCP, surgeon, consulting physician |
| componentOf/  encompassingEncounter/ encounterParticipant | Care team member who participates in the encounter detailed in the document.  Examples: PCP, consulting physician, attending physician |

In most cases, multiple participants will be the same care team member. For example, a consulting physician may see a patient in a clinical encounter, dictate a note, and legally authenticate the document. In this example, the consulting physician is participating as the encounterParticipant, author, and legalAuthenticator. In support of Meaningful Use goals to provide complete and accurate information, it is recommended to capture care team member and provider name and contact information data requirements within participants associated with the clinical encounter or service event detailed in the document. This practice ensures that the recipient of the document knows the care team member who participated in the clinical encounter or performed the service event for any follow-up communications.

Generally, service events, such as procedures, occur as part of a clinical encounter associated with a visit or hospitalization. For example, a patient may be referred by a general surgeon to a surgical specialist in an outpatient surgery center for a specific procedure. In this example, the general surgeon who referred the patient is associated with the clinical encounter that represents the setting during which the procedure occurred. The surgical specialist is then associated with the procedure, or service event, that happened as part of the clinical encounter and is listed as a performer in the documentationOf/serviceEvent header element. Within the document detailing the procedure, these care team members would be captured as participants in distinct header elements associated with the clinical encounter from which the patient was referred or the procedure service event that transpired.

The CCD serves as a summary for a provision of care service event. The provision of care occurs over a specified period of time that may include multiple clinical encounters. For the provision of care, key care team members like the PCP and consulting physicians perform the provision of care over time. Other clinical encounters relevant to communicate for continuity of care purposes would be captured in the Encounters section in the document body along with associated care team members. The CCD **MAY** also be used to detail a single encounter within the provision of care. For single encounters, key care team members are still performers of the provision of care captured in the documentationOf/serviceEvent header element while care team members participating in the specific clinical encounter are the encounterParticipants within the componentOf/encompassingEncounter header element. To help demonstrate care team member participants for the CCD, example scenarios are provided below.

**Tables X: Sample CCD Participant Scenarios**

|  |  |
| --- | --- |
| The PCP in an ambulatory setting generates a CCD to summarize a patient’s healthcare for transmission to the PHR (*View/Download/Transmit Objective*). | |
| documentationOf/serviceEvent | Captures names and contact information for key care team members including the PCP and other active care providers, such as the patient’s physical therapist or dietician |
| Encounters section | Captures relevant encounters and associated care team members |

|  |  |
| --- | --- |
| The consulting physician in an ambulatory setting generates a CCD detailing an encounter to provide to the patient and the patient’s caregiver (*Clinical Summary Objective*). | |
| participant/ | Captures the names and contact information of supporting participants, including the patient’s caregiver |
| documentationOf/serviceEvent | Captures the names and contact information for any known key care team members, such as the PCP, who may not be participating in the encounter |
| componentOf/encompassingEncounter | Captures the names and contact information of the consulting provider as the responsible party for the clinical encounter and the nurse practitioner as an encounterParticipant |

|  |  |
| --- | --- |
| The discharging physician in an inpatient setting generates a CCD to detail the hospitalization to send to the patient’s PCP (*Transition of Care Objective*). | |
| documentationOf/serviceEvent | Captures the names and contact information for any known key care team members, including the PCP |
| componentOf/encompassingEncounter | Captures the names and contact information of the attending physician as the responsible party for the clinical encounter and the discharging physician and rounding physician as encounterParticipants |

The Consolidated CDA implementation guide includes specific guidance on participants for each document, with example participant scenarios provided in Section 3.7.1.5.

Location of Visit or Hospitalization and Date of Visit or Admission and Discharge

Dates and locations for visits and hospitalizations are captured as the clinical encounter setting detailed within the componentOf/encompassingEncounter header element. The date of the visit is captured in the effectiveTime for the clinical encounter and specific dates for hospitalizations can be specified using effectiveTime/low for the admission date and effectiveTime/high for the discharge date. Within the componentOf/encompassingEncounter, the location for the visit or hospitalization is captured as the healthcareFacility/location. When the location of the visit or hospitalization is part of an organization, such as an emergency department within a hospital, the healthcareFacility/location would describe the emergency department and the hospital would be the healthcareFacility/serviceProviderOrganization.

### componentOf/encompassingEncounter Header Element

The componentOf/encompassingEncounter element captures care team member and provider information, date of visit or admission and discharge, and location of visit or hospitalization when the document is detailing an encounter. If the document is detailing a service event, care team members or providers performing the service event are captured in the documentationOf/serviceEvent header element.

Through analysis of Consolidated CDA, the ToC Initiative has determined the following elements within the componentOf/encompassingEncounter header element are recommended to capture Care Team Members, Provider Names and Contact Information, Date of Visit or Hospitalization Admission and Discharge Dates, and Location of Visit or Hospitalization MU 2014 EDITION data requirements. The structure of the componentOf/encompassingEncounter header element is described hierarchically with corresponding constraints (e.g., SHALL, SHOULD, MAY) as specified in Section 2.2.13 of the Consolidated CDA implementation guide. Elements without a constraint are not specified within the General Header template, but guidance may be found within Sections 3.2 and 3.4 of the Consolidated CDA implementation guide for the Consultation Note and Discharge Summary document templates. Descriptions of select elements are provided in [brackets] and elements representing MU 2014 EDITION data requirements are shaded in red.

**Figure X: componentOf/encompassingEncounter Header Element**

|  |
| --- |
| **componentOf/encompassingEncounter** |
| SHALL **id** |
| SHALL **effectiveTime** [date of visit or hospitalization] |
| **low** [admission date] |
| **high** [discharge date] |
| **location** |
| **healthcareFacility** |
| **id** |
| **code** |
| **location** [location of visit or hospitalization] |
| **name** |
| **addr** |
| **serviceProviderOrganization** [provider’s organization] |
| **id** |
| **name** |
| **telecom** |
| **addr** |
| **standardIndustryClassCode** [type of facility] |
| **responsibleParty** [care team member or provider responsible for the encounter] |
| **assignedEntity** |
| **assignedPerson or representedOrganization** |
| **name** [care team member or provider name] |
| **addr** [care team member or provider contact information] |
| **telecom** [care team member or provider contact information] |
| **encounterParticipant** [care team member or provider participating in the encounter] |
| **typeCode** [type of care team member or provider] |
| **effectiveTime** [time of participation in the encounter] |
| **assignedEntity** |
| **assignedPerson or representedOrganization** |
| **name** [care team member or provider name] |
| **addr** [care team member or provider contact information] |
| **telecom** [care team member or provider contact information] |

### documentationOf/serviceEvent Header Element

The documentationOf/serviceEvent element captures care team member and provider information, date of visit or admission and discharge, and location of visit or hospitalization when the document is detailing a service event.

Through analysis of Consolidated CDA, the ToC Initiative has determined the following elements within the documentationOf/serviceEvent header element are recommended to capture service event Care Team Members and Provider Names and Contact Information MU 2014 EDITION data requirements. The structure of the documentationOf/serviceEvent header element is described hierarchically with corresponding constraints as specified in Section 2.2.11 of the Consolidated CDA implementation guide. Elements without a constraint are not specified within the General Header template, but guidance may be found within Section 3.1 of the Consolidated CDA implementation guide for the CCD document template. Descriptions of select elements are provided in [brackets] and elements representing MU 2014 EDITION data requirements are shaded in red.

**Figure X: documentationOf/serviceEvent Header Element**

|  |
| --- |
| **documentationOf/serviceEvent** |
| SHALL **effectiveTime** [date of visit or hospitalization] |
| SHALL **low** [admission date] |
| **high** [discharge date] |
| SHOULD **performer** [care team member or provider performing the service event] |
| SHALL **typeCode** [type of care team member or provider participation in service event] |
| MAY **functionCode** [care team member or provider role in service event] |
| SHALL **assignedEntity** |
| SHALL **id** |
| SHOULD **code** [care team member or provider type] |
| **addr** [care team member or provider contact information] |
| **telecom** [care team member or provider contact information] |
| **assignedPerson** |
| **name** [care team member or provider name] |

### Authorization/consent

The header can record information about the patient’s consent.

The type of consent (e.g., a consent to perform the related serviceEvent) is conveyed in consent/code. Consents in the header have been finalized (consent/statusCode must equal Completed) and should be on file. The HL7 specifications do not address how Privacy Consent is represented, but does not preclude the inclusion of ‘Privacy Consent’.

### Patient Information

This category captures MU 2014 EDITION requirements pertaining to patient information and elements within the General Header template that meet the requirement for an MU 2014 EDITION Objective.

Considerations for implementations of the Consolidated CDA general header template to achieve MU 2014 EDITION requirements for patient information within the Record Target header element are provided below.

#### **Patient Name, Sex, and Date of Birth**

No further considerations are needed for implementing these MU 2014 EDITION data requirements in the header.

#### **Patient Preferred Language**

Consolidated CDA specifies RFC 4646 SHALL be used for the language value set. RFC 4646, which is maintained by The Internet Society, describes the structure, content, construction, and semantics of language tags. The RFC 4646 specifies how the MU 2014 EDITION-required ISO 639-2 alpha-3 codes are used, so it is allowable in Consolidated CDA. For situations where the patient language is unknown or declined to provide, the ability to capture these details within the EHR is required by the 2014 Ed. CEHRT. Allowable representations for the MU 2014 EDITION summary types include null values (e.g., ASKU) or special codes “undetermined” (UND) or “missing” (MIS) from ISO 639-2.

#### **Patient Race and Ethnicity**

These data elements require the use of the Office of Management and Budget (OMB) Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997. Consolidated CDA specifies a CDC Race and Ethnicity value set containing applicable codes reflecting the OMB standard for the requirement. In instances where the patient declines to provide their race or ethnicity or it is unknown, HL7 null values may be used.

For indicating multiple race codes for a patient, a CDA R2 extension is specified: sdtc:raceCode. Additional information on CDA R2 extensions and their use is available in Appendix G of the Consolidated CDA implementation guide.

#### recordTarget Header Element

Through analysis of Consolidated CDA, the ToC Initiative has determined the following elements within the recordTarget header element are recommended to capture Patient Name, Sex, Date of Birth, Preferred Language, Race, and Ethnicity MU 2014 EDITION data requirements. The structure of the recordTarget header element is described hierarchically with corresponding constraints as specified in Section 2.2.1 of the Consolidated CDA implementation guide. Descriptions of select elements are provided in [brackets] and elements representing MU 2014 EDITION data requirements are shaded in red.

**Figure XX: recordTarget Header Element**

|  |
| --- |
| **recordTarget** |
| SHALL **patientRole** |
| SHALL **id** |
| SHALL **addr** |
| SHALL **telecom** |
| SHALL **patient** |
| SHALL **name** [patient name] |
| SHOULD **administrativeGenderCode** [sex] |
| SHALL **birthTime** [date of birth] |
| SHOULD **maritalStatusCode** |
| MAY **religiousAffiliationCode** |
| MAY **raceCode** [race] |
| MAY **sdtc:raceCode** [additional race] |
| MAY **ethnicGroupCode** [ethnicity] |
| MAY **guardian** |
| MAY **birthPlace** |
| SHOULD **languageCommunication** [preferred language] |
| SHALL **languageCode** |
| MAY **preferenceInd** |
| MAY **providerOrganization** |

### 

# Consolidated CDA (CCD) Section Requirements & Meaningful Use Requirements

## CCD Section-Level Templates

A requirement and function of sections, per the base CDA standard, is that section templates

MUST contain human-readable content and MAY contain machine-readable data. At a minimum, CDA requires human-readability, meaning that the CDA document can be displayed on a standard web browser and be understood when read. Therefore, even when the document is sent to an organization without an electronic health record (EHR), the recipient clinician can still read the content and provide care accordingly. At a higher degree, machine-readable data in entry templates can be "consumed" by an information system and integrated for applications such as medication reconciliation or clinical decision support.

## Section-Level Testable Assertions

A requirement and function of sections, per the base CDA standard, is that section templates

**SHALL** contain human-readable content and **MAY** contain machine-readable data. At a minimum, CDA requires human-readability, meaning that the CDA document can be displayed on a standard web browser and be understood when read. Therefore, even when the document is sent to an organization without an electronic health record (EHR), the recipient clinician can still read the content and provide care accordingly. At a higher degree, machine-readable data in entry templates can be "consumed" by an information system and integrated for applications such as medication reconciliation or clinical decision support.

**Table XX: MU 2014 Edition Mapping to Consolidated CDA Sections & Requirements**

|  |  |  |  |
| --- | --- | --- | --- |
| MU 2014 EDITION Data Requirements | Consolidated CDA Section | C-CDA CCD 1.1 | C-CDA CCD 2.1 |
|  | Advance Directives (entries optional) | **O** | **O** |
| Medication allergies | Allergies and Intolerances (entries required) | **R** | **R** |
|  | Encounters (entries optional) | **O** | **O** |
|  | Family History | **O** | **O** |
| Functional Status; Cognitive Status | Functional Status | **O** | **O** |
| Discharge instructions (Inpatient setting) | Hospital Discharge Instructions |  |  |
| Immunizations | Immunizations (entries optional) | **O** | **O** |
| Clinical instructions; Recommended patient decision aids | Instructions |  |  |
|  | Medical Equipment | **O** | **O** |
| Medications | Medications (entries required) | **R** | **R** |
|  | Mental Status |  | **O** |
|  | Nutrition |  | **O** |
|  | Payers | **O** | **O** |
| Care plan, including goals and instructions; Future appointments; Future scheduled tests; Referrals to other providers; Diagnostic tests pending | Plan of Care or Assessment and Plan of Treatment | **O** | **O** |
| Problems | Problem (entries required) | **R** | **R** |
| Procedures | Procedures (entries required) | **O** | **R** |
| Reason for Referral | Reason for Referral |  |  |
| Reason(s) for visit or Reason(s) for hospitalization (Inpatient setting) | Reason for Visit or Chief Complaint or Chief Complaint and Reason for Visit |  |  |
| Laboratory Tests; Values/results of laboratory tests | Results (entries required) | **R** | **R** |
| Smoking status | Social History | **O** | **R** |
| Vital signs | Vital Signs (entries optional) | **O** | **R** |

## Transitions of Care Recommended CCD Body Constraints

The following table describes the CCD body constraints hierarchically for the recommended approach. Sections indicated as the consensus recommendation for MU2 requirements are shaded in red. Please note that the CCD\_C-CDA\_MU\_eHEX\_Content\_Checklist-(DATE XXX).xls corresponds with this table for CCD Body Constraints and the following sections provide additional guidance regarding structure and vocabularies to be leveraged.

**Figure XX: Transitions of Care Recommended CCD Body Constraints**

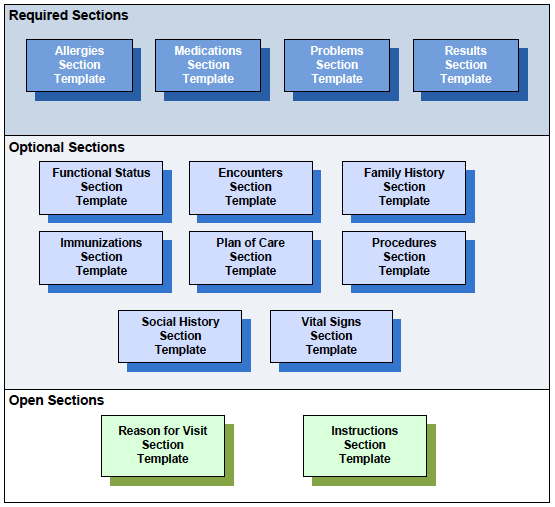
| **CCD Body Constraints** |
| --- |
| **SHOULD** Advance Directives (entries optional: 2.16.840.1.113883.10.20.22.2.21) |
| **MAY** Advance Directives Observation(2.16.840.1.113883.10.20.22.4.48) |
| **SHALL** Allergies (entries required 2.16.840.1.113883.10.20.22.2.6.1) |
| **SHALL** Allergy Problem Act (2.16.840.1.113883.10.20.22.4.30) |
| **SHALL** Allergy Observation(2.16.840.1.113883.10.20.22.4.7) |
| **MAY** Allergy Status Observation (2.16.840.1.113883.10.20.22.4.28**)(Deprecated)** |
| **SHOULD** Reaction Observation (2.16.840.1.113883.10.20.22.4.9) |
| **SHALL** Severity Observation (2.16.840.1.113883.10.20.22.4.8) |
| ***SHALL*** *Reason for Visit (2.16.840.1.113883.10.20.22.2.12)* |
| **MAY** Family History (2.16.840.1.113883.10.20.22.2.15) |
| **MAY** Family History Organizer (2.16.840.1.113883.10.20.22.4.45) |
| **SHALL** Family History Observation (2.16.840.1.113883.10.20.22.4.46) |
| **MAY** Age Observation (2.16.840.1.113883.10.20.22.4.31) |
| **MAY** Family History Death Observation (2.16.840.1.113883.10.20.22.4.47) |
| **SHALL** Functional Status(2.16.840.1.113883.10.20.22.2.14) |
| **MAY** Functional Status Result Organizer(2.16.840.1.113883.10.20.22.4.66) |
| **SHALL** Functional Status Result Observation(2.16.840.1.113883.10.20.22.4.67) |
| **MAY** Assessment Scale Observation (2.16.840.1.113883.10.20.22.4.69) |
| **MAY** Cognitive Status Result Organizer (2.16.840.1.113883.10.20.22.4.75) |
| **SHALL** Cognitive Status Result Observation (2.16.840.1.113883.10.20.22.4.74) |
| **MAY** Functional Status Problem Observation(2.16.840.1.113883.10.20.22.4.68)**(Deprecated)** |
| **MAY** Cognitive Status Problem Observation(2.16.840.1.113883.10.20.22.4.73) **(Deprecated)** |
| **SHALL** Immunizations (entries required 2.16.840.1.113883.10.20.22.2.2.1) |
| **SHALL** Immunization Activity (2.16.840.1.113883.10.20.22.4.52) |
| **SHALL** Immunization Medication Information (2.16.840.1.113883.10.20.22.4.54) |
| **MAY** Immunization Refusal Reason(2.16.840.1.113883.10.20.22.4.53) |
| **MAY** Indication(2.16.840.1.113883.10.20.22.4.19) |
| **MAY** Medication Dispense (2.16.840.1.113883.10.20.22.4.18) |
| **MAY** Reaction Observation (2.16.840.1.113883.10.20.22.4.9) |
| **SHOULD** Severity Observation (2.16.840.1.113883.10.20.22.4.8) |
| ***SHALL*** *Instructions**(2.16.840.1.113883.10.20.22.2.45)* |
| ***SHOULD*** *Instructions**(2.16.840.1.113883.10.20.22.4.20)* |
| **MAY** Medical Equipment(2.16.840.1.113883.10.20.22.2.23) |
| **SHOULD** Non-Medicinal Supply Activity (2.16.840.1.113883.10.20.22.4.50) |
| **MAY** Product Instance (2.16.840.1.113883.10.20.22.4.37) |
| **SHALL** Medications (entries required 2.16.840.1.113883.10.20.22.2.1.1) |
| **SHALL** Medication Activity(2.16.840.1.113883.10.20.22.4.16) |
| **SHALL** Medication Information(2.16.840.1.113883.10.20.22.4.23) |
| **MAY** Medication Supply Order (2.16.840.1.113883.10.20.22.4.17) |
| **MAY** Drug Vehicle (2.16.840.1.113883.10.20.22.4.24) |
| **MAY** Indication(2.16.840.1.113883.10.20.22.4.19) |
| **MAY** Instructions(2.16.840.1.113883.10.20.22.4.20) |
| **SHOULD** Payers(2.16.840.1.113883.10.20.22.2.18) |
| **SHOULD** Coverage Activity (2.16.840.1.113883.10.20.22.4.60) |
| **SHALL** Policy Activity(2.16.840.1.113883.10.20.22.4.61) |
| **SHALL** Plan of Care (2.16.840.1.113883.10.20.22.2.10) |
| **MAY** Plan of Care Activity Act (2.16.840.1.113883.10.20.22.4.39) |
| **MAY** Plan of Care Activity Encounter (2.16.840.1.113883.10.20.22.4.40) |
| **MAY** Plan of Care Activity Observation (2.16.840.1.113883.10.20.22.4.44) |
| **MAY** Plan of Care Activity Procedure(2.16.840.1.113883.10.20.22.4.41) |
| **MAY** Plan of Care Substance Administration (2.16.840.1.113883.10.20.22.4.42) |
| **MAY** Plan of Care Activity Supply (2.16.840.1.113883.10.20.22.4.43) |
| **SHALL** Problem (entries required: 2.16.840.1.113883.10.20.22.2.5.1) |
| **SHALL** Problem Concern Act (2.16.840.1.113883.10.20.22.4.3) |
| **SHALL** Problem Observation(2.16.840.1.113883.10.20.22.4.4) |
| **SHALL** Procedures (entries required: 2.16.840.1.113883.10.20.22.2.7.1) |
| **MAY** Procedure Activity Act(2.16.840.1.113883.10.20.22.4.12) |
| **MAY** Procedure Activity Observation (2.16.840.1.113883.10.20.22.4.13) |
| **MAY** Procedure Activity Procedure (2.16.840.1.113883.10.20.22.4.14) |
| ***SHOULD*** *Reason for Referral (1.3.6.1.4.1.19376.1.5.3.1.3.1)* |
| **SHALL** Results (entries required: 2.16.840.1.113883.10.20.22.2.3.1) |
| **SHALL** Result Organizer (2.16.840.1.113883.10.20.22.4.1) |
| **SHALL** Result Observation(2.16.840.1.113883.10.20.22.4.2) |
| **SHALL** Social History (2.16.840.1.113883.10.20.22.2.17) |
| **MAY** Social History Observation(2.16.840.1.113883.10.20.22.4.38) |
| **SHALL** Smoking Status Observation(2.16.840.1.113883.10.22.4.78) |
| **SHALL** Vital Signs (entries required: 2.16.840.1.113883.10.20.22.2.4.1) |
| **SHALL** Vital Signs Organizer(2.16.840.1.113883.10.20.22.4.26) |
| **SHALL** Vital Sign Observation (2.16.840.1.113883.10.20.22.4.27) |

The CCD is a core data set of the most relevant administrative, demographic, and clinical information facts about a patient's healthcare, covering one or more healthcare encounters. **Please note that the use of the unstructured document template for MU2 requirements is prohibited.**

### Options for Systems Sending and Receiving CDA Documents

To meet the varying business needs of healthcare organizations, the ability to include additional content beyond the Consolidated CDA document template is allowable and maintains compliance with the underlying CDA R2 standard. This means that open document templates may be supplemented by additional CDA section or entry templates and remain a fully complian CDA document, which is shown in Figure XX below.

**Figure XX: Example CCD with open sections**



Systems receiving CDA documents must be capable of rendering all human-readable content of CDA documents received. This ensures that any additional content beyond template definitions are at least displayable. As discussion in section 5.9 of this guide, inclusion of additional sections or content does not affect validation as long as conformance to the specific template is maintained. However, the validator will ignore additional content beyond the template.

**Principles in Practice:** While some systems may create CCDs with only the five minimum required sections, others may include additional optional CCD sections (up to all 17). Still, others may include additional templates not included in the CCD document type definition. The receiving system is not required to parse the structured entries (machine-readable fields) in the additional sections, but it must be able to display the entire CDA document, including narrative blocks, in human-readable form.

## Advance Directives Section 42348-3 (Entries Optional)

This section contains data defining the patient’s advance directives and any reference to supporting documentation. **The most recent and up-to-date directives are required, if known, and should be listed in as much detail as possible.**

This section contains data such as the existence of living wills, healthcare proxies, and CPR and resuscitation status. If referenced documents are available, they can be included in the CCD exchange package.

NOTE: The descriptions in this section differentiate between “advance directives” and “advance directive documents”. The former are the directions whereas the latter are legal documents containing those directions. Thus, an advance directive might be “no cardiopulmonary resuscitation”, and this directive might be stated in a legal advance directive document.

### Structure

The structure of the Advanced Directives Section with coded entries section is described hierarchically with corresponding entry-level constraints as specified in Section 4.1 of the R1.1 Consolidated CDA implementation guide.

**Table X: R1.1 Advance Directives Section (entries optional)**

| Used By: | Contains Entries: |
| --- | --- |
| Advance Directives (optional)  (2.16.840.1.113883.10.20.22.2.21) | Advance Directive Observation  (2.16.840.1.113883.10.20.22.4.48) |

The structure of the Advanced Directives Section with coded entries section is described hierarchically with corresponding entry-level constraints as specified in Section 2.3 of the Volume 2 R2.1 Consolidated CDA implementation guide.

**Table XX: R2.1 Advance Directives Section Structure (entries optional (V3) Constraints Overview section (identifier: urn: hl7ii:2.16.840.1.113883.10.20.22.2.6.1:2015-08-01)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **XPath** | **Cardinality** | **Verb** | **CONF#** | **Value** |
| templateID | 1..1 | SHALL | 1198-7928 |  |
| @root | 1..1 | SHALL | 1198-10376 | 2.16.840.1.113883.10.20.22.2.21 |
| @extension | 1..1 | SHALL | 1198-32497 | 2015-08-01 |
| code | 1..1 | SHALL | 1198-15340 |  |
| @code | 1..1 | SHALL | 1198-15342 | 42348-3 |
| @codeSystem | 1..1 | SHALL | 1198-30812 | urn:oid:2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1 |
| title | 1..1 | SHALL | 1198-7930 |  |
| text | 1..1 | SHALL | 1198-7931 |  |
| entry | 0..\* | MAY | 1198-7957 |  |
| observation | 1..1 | SHALL | 1198-15443 | Advance Directive Observation (V3) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.48:2015-08-01 |
| entry | 0..\* | MAY | 1198-32891 |  |
| Organizer | 1..1 | SHALL | 1198-32892 | Advance Directive Organizer (V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.108:2015-08-01 |

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:1198-7928) such that it

a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.2.21" (CONF:1198-10376).

b. **SHALL** contain exactly one [1..1] **@extension**="2015-08-01" (CONF:1198-32497).

2. **SHALL** contain exactly one [1..1] **code** (CONF:1198-15340).

a. This code **SHALL** contain exactly one [1..1] **@code**="42348-3" Advance Directives (CONF:1198-15342).

b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:1198-30812).

3. **SHALL** contain exactly one [1..1] **title** (CONF:1198-7930).

4. **SHALL** contain exactly one [1..1] **text** (CONF:1198-7931).

5. **MAY** contain zero or more [0..\*] **entry** (CONF:1198-7957) such that it

a. **SHALL** contain exactly one [1..1] **Advance Directive Observation (V3)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.48:2015-08-01) (CONF:1198-15443).

6. **MAY** contain zero or more [0..\*] **entry** (CONF:1198-32891) such that it

a. **SHALL** contain exactly one [1..1] **Advance Directive Organizer (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.108:2015-08-01) (CONF:1198-32892).

### Vocabulary

|  |  |  |  |
| --- | --- | --- | --- |
| ***Advance Directive Type Code Value Set SHALL be used:*** Value Set: AdvanceDirectiveTypeCode 2.16.840.1.113883.1.11.20.2 STATIC 2006-10-17 | | | |
| Code System(s): | | SNOMED CT 2.16.840.1.113883.6.96 | |
| **Code** | **Code System** | | **Print Name** |
| 52765003 | SNOMED CT | | Intubation |
| 61420007 | SNOMED CT | | Tube Feedings |
| 71388002 | SNOMED CT | | Other Directive |
| 78823007 | SNOMED CT | | Life Support |
| 89666000 | SNOMED CT | | CPR |
| 225204009 | SNOMED CT | | IV Fluid and Support |
| 281789004 | SNOMED CT | | Antibiotics |
| 304251008 | SNOMED CT | | Resuscitation |

## Allergies Section 48765-2 (Entries Required)(V3)

This section lists and describes any medication allergies, adverse reactions, idiosyncratic reactions, anaphylaxis/anaphylactoid reactions to food items, and metabolic variations or adverse reactions/allergies to other substances (such as latex, iodine, tape adhesives) used to assure the safety of health care delivery. At a minimum, it should list currently active and any relevant historical allergies and adverse reactions.

### Structure

The structure of the Allergies Section with coded entries section is described hierarchically with corresponding entry-level constraints as specified in Section 4.2 of the R1.1 Consolidated CDA implementation guide.

Table XX: R1.1 & TOC Medication Allergies MU2 Data Requirement in Consolidated CDA

| **Section(s)** | **Associated Entry(ies)** |
| --- | --- |
| **Allergies with coded entries required [2.16.840.1.113883.10.20.22.2.6.1:2015-08-01 (open)]** | * Allergy Problem Act (2.16.840.1.113883.10.20.22.4.30) * Allergy Observation (2.16.840.1.113883.10.20.22.4.7) |

Table XX: 1.1 and TOC Allergies Section Structure

|  |
| --- |
| **Allergies (entries required)** |
| SHALL **Allergy Problem Act** |
| SHALL **Allergy Intolerance Observation** |
| MAY **Allergy Status Observation (Deprecated 2.1)** |
| SHOULD **Reaction Observation** |
| SHOULD **Severity Observation** |

The structure of the Allergies Section with coded entries section is described hierarchically with corresponding entry-level constraints as specified in Section 2.4 of the Volume 2 R2.1 Consolidated CDA implementation guide.

**Table XX: 2.1 Allergies and Intolerances Section Structure (entries required (V3) Constraints Overview [section (identifier: urn: hl7ii:2.16.840.1.113883.10.20.22.2.6.1:2015-08-01)]**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **XPath** | **Cardinality** | **Verb** | **CONF#** | **Value** |
| @nullFlavor | 0..1 | MAY | 1198-32824 | urn:oid:2.16.840.1.113883.5.1008 (HL7NullFlavor) = NI |
| templateId | 1..1 | SHALL | 1198-7527 |  |
| @root | 1..1 | SHALL | 1198-10379 | 2.16.840.1.113883.10.20.22.2.6.1 |
| @extension | 1..1 | SHALL | 1198-32545 | 2015-08-01 |
| code | 1..1 | SHALL | 1198-15349 |  |
| @code | 1..1 | SHALL | 1198-15350 | 48765-2 |
| @codeSystem | 1..1 | SHALL | 1198-32140 | urn:oid:2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1 |
| title | 1..1 | SHALL | 1198-7534 |  |
| text | 1..1 | SHALL | 1198-7530 |  |
| entry | 1..1 | SHALL | 1198-7531 |  |
| act | 1..1 | SHALL | 1198-15446 | Allergy Concern Act (V3) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.30:2015-08-01 |

1. Conforms to **Allergies and Intolerances Section (entries optional) (V3)** template (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.2.6:2015-08-01).

2. **MAY** contain zero or one [0..1] **@nullFlavor**="NI" No information (CodeSystem: HL7NullFlavor urn:oid:2.16.840.1.113883.5.1008) (CONF:1198-32824).

3. **SHALL** contain exactly one [1..1] **templateId** (CONF:1198-7527) such that it

a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.2.6.1" (CONF:1198-10379).

b. **SHALL** contain exactly one [1..1] **@extension**="2015-08-01" (CONF:1198-32545).

4. **SHALL** contain exactly one [1..1] **code** (CONF:1198-15349).

a. This code **SHALL** contain exactly one [1..1] **@code**="48765-2" Allergies, adverse reactions, alerts (CONF:1198-15350).

b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:1198-32140).

5. **SHALL** contain exactly one [1..1] **title** (CONF:1198-7534).

6. **SHALL** contain exactly one [1..1] **text** (CONF:1198-7530).

If section/@nullFlavor is not present:

7. **SHALL** contain at least one [1..\*] **entry** (CONF:1198-7531) such that it

a. **SHALL** contain exactly one [1..1] **Allergy Concern Act (V3)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.30:2015-08-01) (CONF:1198-15446).

### Vocabulary

Medication Allergies **SHALL** be coded using RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, August 6, 2012 Release. Use of either the Medication Brand Name or the Medication Clinical Information value sets specified in Consolidated CDA meets this requirement. ***Note that RxNorm describes the medication to which the patient is allergic, not the type of reaction.***

### Allergy Status Observation (2.16.840.1.113883.10.20.22.4.28) (Deprecated 2.1)

HITSP Problem Status Value Set SHALL be used for Allergy Status Observation

**Table XX: HITSP Problem Status Value Set**

|  |  |  |
| --- | --- | --- |
| Value Set: HITSPProblemStatus 2.16.840.1.113883.3.88.12.80.68 DYNAMIC  Code System: SNOMED CT 2.16.840.1.113883.6.96 | | |
| **Code** | **Code System** | **Display Name** |
| 55561003 | SNOMED CT | Active |
| 73425007 | SNOMED CT | Inactive\* |
| 413322009 | SNOMED CT | Resolved\*\* |

\*An inactive problems refers to one that is quiescent, and may appear again in future.

\*\* A resolved problem refers to one that used to affect a patient, but does not any more.

C-CDA 1.1 included several optional “status” observation templates such as Problem Status Observation and Allergy Status Observation. These “status” observation templates were deprecated when C-CDA R2.0 was released. In C-CDA R2.1 the status’ observation templates remain deprecated. To support backward compatibility, systems that consume CDA documents need to address the possibility that a “status” observation template may be present. The following guidance should be followed if a CDA document includes a deprecated status observation:

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

### Severity Observation (2.16.840.1.113883.10.20.22.4.8)

**Table XX: Problem Severity Value Set**

|  |  |  |  |
| --- | --- | --- | --- |
| Value Set: Problem Severity 2.16.840.1.113883.3.88.12.3221.6.8 DYNAMIC | | | |
| Code System(s): | | SNOMED CT 2.16.840.1.113883.6.96 | |
| Description: | | This is a description of the level of the severity of the problem. | |
| **Code** | **Code System** | | **Print Name** |
| 255604002 | SNOMED CT | | Mild (qualifier value) |
| 371923003 | SNOMED CT | | Mild to moderate (qualifier value) |
| 6736007 | SNOMED CT | | Moderate (severity modifier) (qualifier value) |
| 371924009 | SNOMED CT | | Moderate to severe (qualifier value) |
| 24484000 | SNOMED CT | | Severe (severity modifier) (qualifier value) |
| 399166001 | SNOMED CT | | Fatal (qualifier value) |

## Encounters Section 46240-8 (Entries Optional)

This section lists and describes any healthcare encounters pertinent to the patient’s current health status or historical health history. An Encounter is an interaction, regardless of the setting, between a patient and a practitioner who is vested with primary responsibility for diagnosing, evaluating, or treating the patient’s condition. It may include visits, appointments, as well as non-face-to-face interactions. It is also a contact between a patient and a practitioner who has primary responsibility for assessing and treating the patient at a given contact, exercising independent judgment. This section **may contain all encounters for the time period being summarized**, but **should include notable encounters**.

Note: In the TOC Implementation Guide, it is recommended that the Encounters with coded entries required **SHOULD** be used in general; however, for Hospital Discharge Summary the Hospital Discharge Diagnosis **SHALL** be used. For the Operative Note and Procedure

Note, the Post-operative Diagnosis and Post-procedure Diagnosis **MAY** be used respectively.

### Structure

The structure of the Encounters Section with coded entries section is described hierarchically with corresponding entry-level constraints as specified in Section 4.11 of the R1.1 Consolidated CDA implementation guide.

**Table XX: R1.1 Encounters Section (entries optional)**

| Used By: | Contains Entries: |
| --- | --- |
| Encounters  (2.16.840.1.113883.10.20.22.2.22) | Indication  (2.16.840.1.113883.10.20.22.4.19) |

The structure of the Encounters Section with coded entries section is described hierarchically with corresponding entry-level constraints as specified in Section 2.16 of the Volume 2 R2.1 Consolidated CDA implementation guide.

**Table XX: 2.1 Encounters Section (entries optional) (V3) Constraints Overview**

**[section (identifier: urn: hl7ii:2.16.840.1.113883.10.20.22.2.22:2015-08-01) (open)]**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **XPath** | **Cardinality** | **Verb** | **CONF#** | **Value** |
| templateId | 1..1 | SHALL | 1198-7940 |  |
| @root | 1..1 | SHALL | 1198-10386 | 2.16.840.1.113883.10.20.22.2.22 |
| @extension | 1..1 | SHALL | 1198-32547 | 2015-08-01 |
| code | 1..1 | SHALL | 1198-15461 |  |
| @code | 1..1 | SHALL | 1198-15462 | 46240-8 |
| @codeSystem | 1..1 | SHALL | 1198-31136 | urn:oid:2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1 |
| title | 1..1 | SHALL | 1198-7942 |  |
| text | 1..1 | SHALL | 1198-7943 |  |
| entry | 0..\* | SHOULD | 1198-7951 |  |
| encounter | 1..1 | SHALL | 1198-15465 | Encounter Activity (V3) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.49:2015-08-01 |

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:1198-7940) such that it

a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.2.22" (CONF:1198-10386).

b. **SHALL** contain exactly one [1..1] **@extension**="2015-08-01" (CONF:1198-32547).

2. **SHALL** contain exactly one [1..1] **code** (CONF:1198-15461).

a. This code **SHALL** contain exactly one [1..1] **@code**="46240-8" Encounters (CONF:1198-15462).

b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:1198-31136).

3. **SHALL** contain exactly one [1..1] **title** (CONF:1198-7942).

4. **SHALL** contain exactly one [1..1] **text** (CONF:1198-7943).

5. **SHOULD** contain zero or more [0..\*] **entry** (CONF:1198-7951) such that it

a. **SHALL** contain exactly one [1..1] **Encounter Activity (V3)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.49:2015-08-01) (CONF:1198-15465).

### Vocabulary

Encounter Diagnoses **SHALL** be coded using either SNOMED CT® or ICD-10-CM[[2]](#footnote-3) vocabularies.

It is important to note that Encounter Diagnoses recommended to be captured within the problems list using SNOMED CT® with translations to ICD-10-CM occurring within the administrative system. Use of Problems with coded entries required or Hospital Discharge Diagnosis will vary depending on ambulatory or inpatient care setting.

**Table XXX: Encounter Type Value Set**

|  |  |  |
| --- | --- | --- |
| Value Set: EncounterTypeCode 2.16.840.1.113883.3.88.12.80.32 DYNAMIC  Code System: CPT-4 2.16.840.1.113883.6.12  This value set includes only the codes of the Current Procedure and Terminology designated for Evaluation and Management (99200 – 99607) (subscription to AMA Required http://www.amacodingonline.com/) | | |
| **Code** | **Code System** | **Print Name** |
| 99201 | CPT-4 | Office or other outpatient visit (problem focused) |
| 99202 | CPT-4 | Office or other outpatient visit (expanded problem (expanded) |
| 99203 | CPT-4 | Office or other outpatient visit (detailed) |
| 99204 | CPT-4 | Office or other outpatient visit (comprehensive, (comprehensive - moderate) |
| 99205 | CPT-4 | Office or other outpatient visit (comprehensive, comprehensive-high) |
| … | CPT-4 | |

## Family History Section 10157-6

The Family History section contains data defining the patient’s genetic relatives in terms of possible or relevant health risk factors that have a potential impact on the patient’s healthcare risk profile.

### Structure

The structure of the Family History Section with coded entries section is described hierarchically with corresponding entry-level constraints as specified in Section 4.12 of the R1.1 Consolidated CDA implementation guide.

**Table xx: R1.1 Family History Observation Contexts**

|  |  |
| --- | --- |
| **Used By:** | **Contains Entries:** |
| Family History Organizer (optional) | Age Observation  Family History Death Observation |

The structure of the Family History Section with coded entries section is described hierarchically with corresponding entry-level constraints as specified in Section 2.17 of the Volume 2 R2.1 Consolidated CDA implementation guide.

**Table XX: 2.1 Family History Section (V3) Constraints Overview**

**[section (identifier: urn: hl7ii:2.16.840.1.113883.10.20.22.2.15:2015-08-01) (open)]**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **XPath** | **Cardinality** | **Verb** | **CONF#** | **Value** |
| templateId | 1..1 | SHALL | 1198-7932 |  |
| @root | 1..1 | SHALL | 1198-10388 | 2.16.840.1.113883.10.20.22.2.15 |
| @extension | 1..1 | SHALL | 1198-32607 | 2015-08-01 |
| code | 1..1 | SHALL | 1198-15469 |  |
| @code | 1..1 | SHALL | 1198-15470 | 10157-6 |
| @codeSystem | 1..1 | SHALL | 1198-32481 | urn:oid:2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1 |
| title | 1..1 | SHALL | 1198-7934 |  |
| text | 1..1 | SHALL | 1198-7935 |  |
| entry | 0..\* | MAY | 1198-32430 |  |
| organizer | 1..1 | SHALL | 1198-32431 | Family History Organizer (V3) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.45:2015-08-01 |

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:1198-7932) such that it

a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.2.15" (CONF:1198-10388).

b. **SHALL** contain exactly one [1..1] **@extension**="2015-08-01" (CONF:1198-32607).

2. **SHALL** contain exactly one [1..1] **code** (CONF:1198-15469).

a. This code **SHALL** contain exactly one [1..1] **@code**="10157-6" Family History (CONF:1198-15470).

b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:1198-32481).

3. **SHALL** contain exactly one [1..1] **title** (CONF:1198-7934).

4. **SHALL** contain exactly one [1..1] **text** (CONF:1198-7935).

5. **MAY** contain zero or more [0..\*] **entry** (CONF:1198-32430) such that it

a. **SHALL** contain exactly one [1..1] **Family History Organizer (V3)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.45:2015-08-01) (CONF:1198-32431).

### Vocabulary

**Table XXX: Family History Related Subject Value Set (excerpt)**

|  |  |  |
| --- | --- | --- |
| Value Set: FamilyHistoryRelatedSubjectCode 2.16.840.1.113883.1.11.19579 DYNAMIC  Code System: RoleCode 2.16.840.1.113883.5.111 (any subtype of RoleCode: FAMMEMB)  See HL7 Vocabulary Domains included in the CDA R2 Normative Web Edition http://www.hl7.org/documentcenter/private/standards/cda/r2/cda\_r2\_normativewebedition2010.zip | | |
| **Code** | **Code System** | **Print Name** |
| CHILD | RoleCode | Child |
| CHLDADOPT | RoleCode | Adopted Child |
| DAUADOPT | RoleCode | Adopted Daughter |
| SONADOPT | RoleCode | Adopted Son |
| CHLDINLAW | RoleCode | Child in-law |

***Table XXX: AgePQ\_UCUM Value Set***

|  |  |  |  |
| --- | --- | --- | --- |
| Value Set: AgePQ\_UCUM 2.16.840.1.113883.11.20.9.21 DYNAMIC | | | |
| Code System(s): | | Unified Code for Units of Measure (UCUM) 2.16.840.1.113883.6.8 | |
| Description: | | A valueSet of UCUM codes for representing age value units | |
| **Code** | **Code System** | | **Print Name** |
| min | UCUM | | Minute |
| h | UCUM | | Hour |
| d | UCUM | | Day |
| wk | UCUM | | Week |
| mo | UCUM | | Month |
| a | UCUM | | Year |

## Functional Status 47420-5 (Required)

### Structure

The Functional Status contains observations and assessments of a patient’s physical abilities. A patient’s functional status may include information regarding the patient’s ability to perform Activities of Daily Living (ADLs) in areas such as Mobility (e.g., ambulation), Self-Care (e.g., bathing, dressing, feeding, grooming) or Instrumental Activities of Daily Living (IADLs) (e.g., shopping, using a telephone, balancing a check book). Problems that impact function (e.g., dyspnea, dysphagia) can be contained in the section. Since MU2 does not specify associated vocabularies and Consolidated CDA does not require entries, **narrative text SHALL be required but structured entries are optional.** If structured entries are used, Consolidated CDA defines many entry templates that can be used to represent Functional and Cognitive Status. Additional examples are available in Section 4.14 of the R1.1 Consolidated CDA implementation Guide.

It is important to note that MU2 does not stipulate which types of functional status should be documented. However, ONC asks, "that stakeholders consider whether the recently developed six-question 'data standard for disability status' adopted for population health surveys sponsored by HHS" HL7 IG: S&I FW Trans of Care Comp Guide to C-CDA for MU ST2, R1.1 – US Realm Page **43** of **85.** That questionnaire is available through the Office of Minority Health16 that provides examples of functional and cognitive statuses that clinicians using Consolidated CDA documents may consider as a starting point. The six-question survey includes questions about difficulties hearing, seeing, remembering/concentrating/making decisions, walking/climbing stairs, dressing/bathing, and doing errands alone.

The Functional Status section describes the patient’s physical state, status of functioning, and environmental status at the time the document was created. A patient’s physical state may include information regarding the patient’s physical findings as they relate to problems, including but not limited to:

• Pressure Ulcers

• Amputations

• Heart murmur

• Ostomies

A patient’s functional status may include information regarding the patient relative to their general functional and cognitive ability, including:

• Ambulatory ability

• Mental status or competency

• Activities of Daily Living (ADLs), including bathing, dressing, feeding, grooming

• Home or living situation having an effect on the health status of the patient

• Ability to care for self

• Social activity, including issues with social cognition, participation with friends and acquaintances other than family members

• Occupation activity, including activities partly or directly related to working, housework or volunteering, family and home responsibilities or activities related to home and family

• Communication ability, including issues with speech, writing or cognition required for communication

• Perception, including sight, hearing, taste, skin sensation, kinesthetic sense, proprioception, or balance

A patient’s environmental status may include information regarding the patient’s current exposures from their daily environment, including but not limited to:

• Airborne hazards such as second-hand smoke, volatile organic compounds, dust, or other allergens

• Radiation

• Safety hazards in home, such as throw rugs, poor lighting, lack of railings/grab bars, etc.

• Safety hazards at work, such as communicable diseases, excessive heat, excessive noise, etc.

The patient's functional status may be expressed as a problem or as a result observation. A functional or cognitive status problem observation describes a patient’s problem, symptoms or condition. A functional or cognitive status result observation may include observations resulting from an assessment scale, evaluation or question and answer assessment.

Any deviation from normal function displayed by the patient and recorded in the record should be included. Of particular interest are those limitations that would interfere with self-care or the medical therapeutic process in any way. In addition, a note of normal function, an improvement, or a change in functioning status may be included.

The structure of the Functional Status section is described hierarchically with corresponding entry-level constraints as specified in Section 4.14 of the R1.1 Consolidated CDA implementation guide.

**Table XX: Functional and Cognitive Status MU 2014 EDITION Data Requirements in Consolidated CDA**

|  |  |
| --- | --- |
| **Section(s)** | **Associated Entry(ies)** |
| **Functional Status (2.16.840.1.113883.10.20.22.2.14)** | * Functional Status Problem Observation (Deprecated in 2.1) (2.16.840.1.113883.10.20.22.4.68) * Functional Status Result Observation (2.16.840.1.113883.10.20.22.4.67) * Cognitive Status Problem Observation (Deprecated in 2.1) (2.16.840.1.113883.10.20.22.4.73) * Cognitive Status Result Observation (2.16.840.1.113883.10.20.22.4.74) |

The C-CDA Cognitive Status Observation template has been deprecated in Release 2.1 and has been replaced with the Mental Status Observation template. Developers should use the Mental Status Observation template for cognitive status and be aware that the C-CDA validator will issue an error if the deprecated Cognitive Status Observation is used instead.

**Table XX: R1.1 Functional Status Section Structure**

|  |
| --- |
| **Functional Status** |
| MAY **Assessment Scale Observation** |
| MAY **Caregiver Characteristics** |
| MAY **Cognitive Status Problem Observation (Deprecated in 2.1)** |
| MAY **Cognitive Status Result Observation** |
| MAY **Cognitive Status Result Organizer** |
| MAY **Functional Status Problem Observation (Deprecated in 2.1)** |
| MAY **Functional Status Result Observation** |
| MAY **Functional Status Result Organizer** |
| MAY **Non-Medicinal Supply Activity** |
| MAY **Highest Pressure Ulcer Stage** |
| MAY **Number of Pressure Ulcer Observation** |
| MAY **Pressure Ulcer Observation** |

The structure of the Functional Status Section with coded entries section is described hierarchically with corresponding entry-level constraints as specified in Section 2.20 of the Volume 2 R2.1 Consolidated CDA implementation guide.

**Table XX: 2.1 Functional Status Section (V2) Constraints Overview**

**[section (identifier: urn: hl7ii:2.16.840.1.113883.10.20.22.2.14:2014-06-09)]**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **XPath** | **Cardinality** | **Verb** | **CONF#** | **Value** |
| templateId | 1..1 | SHALL | 1098-7920 |  |
| @root | 1..1 | SHALL | 1098-10389 | 2.16.840.1.113883.10.20.22.2.14 |
| @extension | 1..1 | SHALL | 1098-32567 | 2014-06-09 |
| code | 1..1 | SHALL | 1098-14578 |  |
| @code | 1..1 | SHALL | 1098-14579 | 47420-5 |
| @codeSystem | 1..1 | SHALL | 1098-30866 | urn:oid:2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1 |
| title | 1..1 | SHALL | 1098-7922 |  |
| text | 1..1 | SHALL | 1098-7923 |  |
| entry | 0..\* | MAY | 1098-14414 |  |
| organizer | 1..1 | SHALL | 1098-14415 | Functional Status Organizer (V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.66:2014-06-09 |
| entry | 0..\* | MAY | 1098-14418 |  |
| observation | 1..1 | SHALL | 1098-14419 | Functional Status Observation (V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.67:2014-06-09 |
| entry | 0..^ | MAY | 1098-14426 |  |
| observation | 1..1 | SHALL | 1098-14427 | Caregiver Characteristics (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.72 |
| entry | 0..\* | MAY | 1098-14580 |  |
| observation | 1..1 | SHALL | 1098-14581 | Assessment Scale Observation (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.69 |
| entry | 0..\* | MAY | 1098-14582 |  |
| supply | 1..1 | SHALL | 1098-30783 | Non-Medicinal Supply Activity (V2) (identifier:  urn:hl7ii:2.16.840.1.113883.10.20.22.4.50:2014-06-09 |
| entry | 0..\* | MAY | 1098-32792 |  |
| observation | 1..1 | SHALL | 1098-31009 | Self-Care Activities (ADL and IADL) (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.128 |
| entry | 0..\* | MAY | 1098-16779 |  |
| observation | 1..1 | SHALL | 1098-31011 | Sensory Status (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.127 |
| entry | 0..\* | MAY | 1098-14424 |  |
| observation | 1..1 | SHALL | 1098-14425 | Cognitive Status Problem Observation (DEPRECATED) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.73:2014-06-09 |
| entry | 0..\* | MAY | 1098-14422 |  |
| observation | 1..1 | SHALL | 1098-14423 | Functional Status Problem Observation (DEPRECATED) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.68:2014-06-09 |
| entry | 0..\* | MAY | 1098-16777 |  |
| Observation | 1..1 | SHALL | 1098-16778 | Pressure Ulcer Observation (DEPRECATED) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.70:2014-06-09 |

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:1098-7920) such that it

a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.2.14" (CONF:1098-10389).

b. **SHALL** contain exactly one [1..1] **@extension**="2014-06-09" (CONF:1098-32567).

2. **SHALL** contain exactly one [1..1] **code** (CONF:1098-14578).

a. This code **SHALL** contain exactly one [1..1] **@code**="47420-5" Functional Status (CONF:1098-14579).

b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:1098-30866).

3. **SHALL** contain exactly one [1..1] **title** (CONF:1098-7922).

4. **SHALL** contain exactly one [1..1] **text** (CONF:1098-7923).

5. **MAY** contain zero or more [0..\*] **entry** (CONF:1098-14414) such that it

a. **SHALL** contain exactly one [1..1] **Functional Status Organizer (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.66:2014-06-09) (CONF:1098-14415).

6. **MAY** contain zero or more [0..\*] **entry** (CONF:1098-14418) such that it

a. **SHALL** contain exactly one [1..1] **Functional Status Observation (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.67:2014-06-09) (CONF:1098-14419).

7. **MAY** contain zero or more [0..\*] **entry** (CONF:1098-14426) such that it

a. **SHALL** contain exactly one [1..1] **Caregiver Characteristics** (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.72) (CONF:1098-14427).

8. **MAY** contain zero or more [0..\*] **entry** (CONF:1098-14580) such that it

a. **SHALL** contain exactly one [1..1] **Assessment Scale Observation** (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.69) (CONF:1098-14581).

9. **MAY** contain zero or more [0..\*] **entry** (CONF:1098-14582) such that it

a. **SHALL** contain exactly one [1..1] **Non-Medicinal Supply Activity (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.50:2014-06-09) (CONF:1098-30783).

10. **MAY** contain zero or more [0..\*] **entry** (CONF:1098-32792) such that it

a. **SHALL** contain exactly one [1..1] **Self-Care Activities (ADL and IADL)** (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.128) (CONF:1098-31009).

11. **MAY** contain zero or more [0..\*] **entry** (CONF:1098-16779) such that it

a. **SHALL** contain exactly one [1..1] **Sensory Status** (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.127) (CONF:1098-31011).

12. **MAY** contain zero or more [0..\*] **entry** (CONF:1098-14424) such that it

a. **SHALL** contain exactly one [1..1] **Cognitive Status Problem Observation (DEPRECATED)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.73:2014-06-09) (CONF:1098-14425).

13. **MAY** contain zero or more [0..\*] **entry** (CONF:1098-14422) such that it

a. **SHALL** contain exactly one [1..1] **Functional Status Problem Observation (DEPRECATED)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.68:2014-06-09) (CONF:1098-14423).

14. **MAY** contain zero or more [0..\*] **entry** (CONF:1098-16777) such that it

a. **SHALL** contain exactly one [1..1] **Pressure Ulcer Observation (DEPRECATED)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.70:2014-06-09) (CONF:1098-16778).

### Vocabulary

The following tables are referenced by the C-CDA CCD Sections within the base R1.1 document.

**Table XXX: Problem type value set**

|  |  |  |  |
| --- | --- | --- | --- |
| Value Set: Problem Type 2.16.840.1.113883.3.88.12.3221.7.2 STATIC 2012-06-01 | | | |
| Code System(s): | | SNOMED CT 2.16.840.1.113883.6.96 | |
| Description: | | This value set indicates the level of medical judgment used to determine the existence of a problem. | |
| **Code** | **Code System** | | **Print Name** |
| 404684003 | SNOMED CT | | Finding |
| 409586006 | SNOMED CT | | Complaint |
| 282291009 | SNOMED CT | | Diagnosis |
| 64572001 | SNOMED CT | | Condition |
| 248536006 | SNOMED CT | | Finding of functional performance and activity |
| 418799008 | SNOMED CT | | Symptom |
| 55607006 | SNOMED CT | | Problem |
| 373930000 | SNOMED CT | | Cognitive function finding |

**Table XXX: Problem Value Set (excerpt)**

|  |  |  |  |
| --- | --- | --- | --- |
| Value Set: Problem 2.16.840.1.113883.3.88.12.3221.7.4 DYNAMIC | | | |
| Code System(s): | | SNOMED CT 2.16.840.1.113883.6.96 | |
| Description: | | Problems and diagnoses. Limited to terms descending from the Clinical Findings (404684003) or Situation with Explicit Context (243796009) hierarchies.  http://phinvads.cdc.gov/vads/ViewValueSet.action?id=70FDBFB5-A277-DE11-9B52-0015173D1785 | |
| **Code** | **Code System** | | **Print Name** |
| 46635009 | SNOMED CT | | Diabetes mellitus type 1 |
| 234422006 | SNOMED CT | | Acute porphyria |
| 31712002 | SNOMED CT | | Primary biliary cirrhosis |
| 302002000 | SNOMED CT | | Difficulty moving |
| 15188001 | SNOMED CT | | Hearing loss |
| 48167000 | SNOMED CT | | Amnesia |
| … |  | |  |

### Clinical Guidance

The Functional Status section can record unstructured and structured data to represent physical state (e.g., pressure ulcers, amputations), activities of daily living (e.g., bathing, eating), cognitive ability (e.g., mental status or competency, problem solving), perception (e.g., sight, hearing), and much more. Since MU 2014 Edition does not specify associated vocabularies and Consolidated CDA does not require entries, narrative text is required but structured entries are optional. If structured entries are used, Consolidated CDA defines many entry templates that can be used to represent Functional and Cognitive Status. Additional examples are available in Section 4.14 of the Consolidated CDA implementation Guide.

It is important to note that MU 2014 Edition does not stipulate which types of functional status should be documented. However, ONC asks, "that stakeholders consider whether the recently developed six-question 'data standard for disability status' adopted for population health surveys sponsored by HHS" would be appropriate. That questionnaire is available through the Office of Health[[3]](#footnote-4) that provides examples of functional and cognitive statuses that clinicians using Consolidated CDA documents may consider as a starting point. The six-question survey includes questions about difficulties hearing, seeing, remembering/concentrating/making decisions, walking/climbing stairs, dressing/bathing, and doing errands alone.

The Functional Status section describes the patient’s physical state, status of functioning, and environmental status at the time the document was created.

A patient’s physical state may include information regarding the patient’s physical findings as they relate to problems, including but not limited to:

Pressure Ulcers; Amputations; Heart murmur; Ostomies

A patient’s functional status may include information regarding the patient relative to their general functional and cognitive ability, including:

Ambulatory ability; Mental status or competency; Activities of Daily Living (ADLs), including bathing, dressing, feeding, grooming; Home or living situation having an effect on the health status of the patient;

Ability to care for self;

Social activity, including issues with social cognition, participation with friends and acquaintances other than family members;

Occupation activity, including activities partly or directly related to working, housework or volunteering, family and home responsibilities or activities related to home and family;

Communication ability, including issues with speech, writing or cognition required for communication;

Perception, including sight, hearing, taste, skin sensation, kinesthetic sense, proprioception, or balance

A patient’s environmental status may include information regarding the patient’s current exposures from their daily environment, including but not limited to:

Airborne hazards such as second-hand smoke, volatile organic compounds, dust, or other allergens; Radiation; Safety hazards in home, such as throw rugs, poor lighting, lack of railings/grab bars, etc.; Safety hazards at work, such as communicable diseases, excessive heat, excessive noise, etc.

The patient's functional status may be expressed as a problem or as a result observation. A functional or cognitive status problem observation describes a patient’s problem, symptoms or condition. A functional or cognitive status result observation may include observations resulting from an assessment scale, evaluation or question and answer assessment.

Any deviation from normal function displayed by the patient and recorded in the record should be included. Of particular interest are those limitations that would interfere with self-care or the medical therapeutic process in any way. In addition, a note of normal function, an improvement, or a change in functioning status may be included.

## Immunizations 11369-6 (Entries Optional)

### Structure

The structure of the Immunizations with coded entries required section is described hierarchically with corresponding entry-level constraints as specified in Section 4.27 of the R1.1 Consolidated CDA implementation guide.

The Immunizations Section defines a patient's current immunization status and pertinent immunization history. The primary use case for the Immunization Section is to enable communication of a patient's immunization status. The section should include current immunization status, and may contain the entire immunization history that is relevant to the period of time being summarized.

The structure of the Immunizations Section with coded entries section is described hierarchically with corresponding entry-level constraints as specified in Section 4.27 of the R1.1 Consolidated CDA implementation guide.

**Table XX: R1.1 Immunizations MU 2014 EDITION Data Requirement in Consolidated CDA**

| **Section(s)** | **Associated Entry(ies)** |
| --- | --- |
| [**Immunizations with coded entries required (2.16.840.1.113883.10.20.22.2.2.1)**](#_Immunizations_(entries_required)) | * Immunization Activity (2.16.840.1.113883.10.20.22.4.52) |

**Table XX: R1.1 Immunizations Section/Entry Structure**

|  |
| --- |
| **Immunizations (entries required)** |
| SHALL **Immunization Activity** |
| MAY **Indication** |
| MAY **Instructions** |
| MAY **Medication Supply Order** |
| MAY **Medication Dispense** |
| MAY **Reaction Observation** |
| MAY **Immunization Refusal Reason** |
| MAY **Precondition for Substance Administration** |

The structure of the Immunizations Section with coded entries section is described hierarchically with corresponding entry-level constraints as specified in Section 2.32 of the Volume 2 R2.1 Consolidated CDA implementation guide.

**Table XX: 2.1 Immunizations Section (entries optional) (V3) Constraints Overview**

**[section (identifier: urn: hl7ii:2.16.840.1.113883.10.20.22.2.2:2015-08-01)]**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **XPath** | **Cardinality** | **Verb** | **CONF#** | **Value** |
| templateId | 1..1 | SHALL | 1198-7965 |  |
| @root | 1..1 | SHALL | 1198-10399 | 2.16.840.1.113883.10.20.22.2.2 |
| @extension | 1..1 | SHALL | 1198-32529 | 2015-08-01 |
| code | 1..1 | SHALL | 1198-15367 |  |
| @code | 1..1 | SHALL | 1198-15368 | 11369-6 |
| @codeSystem | 1..1 | SHALL | 1198-32146 | urn:oid:2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1 |
| title | 1..1 | SHALL | 1198-7967 |  |
| text | 1..1 | SHALL | 1198-7968 |  |
| entry | 0..\* | SHOULD | 1198-7969 |  |
| substanceAdministration | 1..1 | SHALL | 1198-15494 | Immunization Activity (V3) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.52:2015-08-01 |

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:1198-7965) such that it

a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.2.2" (CONF:1198-10399).

b. **SHALL** contain exactly one [1..1] **@extension**="2015-08-01" (CONF:1198-32529).

2. **SHALL** contain exactly one [1..1] **code** (CONF:1198-15367).

a. This code **SHALL** contain exactly one [1..1] **@code**="11369-6" Immunizations (CONF:1198-15368).

b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:1198-32146).

3. **SHALL** contain exactly one [1..1] **title** (CONF:1198-7967).

4. **SHALL** contain exactly one [1..1] **text** (CONF:1198-7968).

5. **SHOULD** contain zero or more [0..\*] **entry** (CONF:1198-7969) such that it

a. **SHALL** contain exactly one [1..1] **Immunization Activity (V3)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.52:2015-08-01) (CONF:1198-15494).

### Vocabulary

Immunizations **SHALL** be coded using the HL7 Standard Code Set CVX -- Vaccines Administered, with updates through July 11, 2012.

**Table XXX: Vaccine Administered (Hepatitis B) Value Set (excerpt)**

|  |  |  |  |
| --- | --- | --- | --- |
| Value Set: Vaccine Administered Value Set 2.16.840.1. 113883.3.88.12.80.22 DYNAMIC | | | |
| Code System(s): | | Vaccines administered (CVX) 2.16.840.1.113883.12.292  http://phinvads.cdc.gov/vads/ViewCodeSystem.action?id=2.16.840.1.113883.12.292 | |
| **Code** | **Code System** | | **Print Name** |
| 82 | CVX | | adenovirus vaccine, NOS |
| 54 | CVX | | adenovirus vaccine, type 4, live, oral |
| 55 | CVX | | adenovirus vaccine, type 7, live, oral |
| 24 | CVX | | anthrax vaccine |
| … \_ | | | |

### Clinical Guidance

Consistent with this requirement, ToC recommends the following guidance on capturing immunizations administered, whether during the visit or prior to the visit. Immunization history would typically imply the entire record of all immunizations that an individual has received in their lifetime. **Note that MU 2014 EDITION explicitly requires immunizations administered during the visit for the Clinical Summary (EP only).**

In the case of pediatric patients, records typically would include all immunizations received since birth. Adult records, however, often do not include a complete immunization history, particularly in a hospital system where such information might not be easily obtained. **The template for capturing immunizations would be the same, whether a record includes all immunizations in an individual’s past or a more limited subset.** When immunizations are included as part of information exchange during a care transition, there are two important instances that do not represent a complete immunization history:

* One instance would be the immunizations administered during an encounter or hospitalization, or in an ambulatory system, this might include a series of immunizations, such as Hepatitis B, given over multiple encounters.
* The other instance is relevant immunizations. Pneumococcal pneumonia vaccine is indicated to be given to certain high-risk populations, such as individuals with chronic lung disease. A PCP referring a patient to a pulmonary specialist for evaluation of their chronic lung disease would want to indicate in the document sent to the specialist that the patient had received this particular immunization, but would not necessarily want to indicate that the patient had received a tetanus immunization recently because of an injury.

ToC recommends the following guidance on capturing immunizations administered, whether during the visit or prior to the visit.

Immunization history would typically imply the entire record of all immunizations that an individual has received in their lifetime. Note that MU2 explicitly requires immunizations administered during the visit for the Clinical Summary (EP only).

In the case of pediatric patients, records typically would include all immunizations received since birth. Adult records, however, often do not include a complete immunization history, particularly in a hospital system where such information might not be easily obtained. The template for capturing immunizations would be the same, whether a record includes all immunizations in an individual’s past or a more limited subset. When immunizations are included as part of information exchange during a care transition, there are two important instances that do not represent a complete immunization history:

One instance would be the immunizations administered during an encounter or hospitalization, or in an ambulatory system, this might include a series of immunizations, such as Hepatitis B, given over multiple encounters. The other instance is relevant immunizations. Pneumococcal pneumonia vaccine is indicated to be given to certain high-risk populations, such as individuals with chronic lung disease. A PCP referring a patient to a pulmonary specialist for evaluation of their chronic lung disease would want to indicate in the document sent to the specialist that the patient had received this particular immunization, but would not necessarily want to indicate that the patient had received a tetanus immunization recently because of an injury.

ToC recommends the following guidance on capturing immunizations administered, whether during the visit or prior to the visit.

Immunization history would typically imply the entire record of all immunizations that an individual has received in their lifetime. Note that MU2 explicitly requires immunizations administered during the visit for the Clinical Summary (EP only).

In the case of pediatric patients, records typically would include all immunizations received since birth. Adult records, however, often do not include a complete immunization history, particularly in a hospital system where such information might not be easily obtained. The template for capturing immunizations would be the same, whether a record includes all immunizations in an individual’s past or a more limited subset. When immunizations are included as part of information exchange during a care transition, there are two important instances that do not represent a complete immunization history:

One instance would be the immunizations administered during an encounter or hospitalization, or in an ambulatory system, this might include a series of immunizations, such as Hepatitis B, given over multiple encounters.

The other instance is relevant immunizations. Pneumococcal pneumonia vaccine is indicated to be given to certain high-risk populations, such as individuals with chronic lung disease. A PCP referring a patient to a pulmonary specialist for evaluation of their chronic lung disease would want to indicate in the document sent to the specialist that the patient had received this particular immunization, but would not necessarily want to indicate that the patient had received a tetanus immunization recently because of an injury.

## Instructions 69730-0 Section (V2)

### Structure

The structure of the Instructions section is described hierarchically with corresponding entry-level constraints as specified in Section 4.28 of the R1.1 Consolidated CDA implementation guide.

**Table XX: R1.1 Instructions Section Structure**

|  |
| --- |
| **Instructions** |
| SHOULD **Instructions** |

The Instructions section can be used in several ways, such as to record patient instructions within a Medication Activity or to record fill instructions within a supply order. The act/code defines the type of instruction. Though not defined in this template, a Vaccine Information Statement (VIS) document could be referenced through act/reference/externalDocument, and patient awareness of the instructions can be represented with the generic participant and the participant/awarenessCode.

**Table XX: R1.1 Clinical or Discharge Instructions MU 2014 EDITION Data Requirement in C-CDA**

| **Section(s)** | **Associated Entry(ies)** |
| --- | --- |
| **Instructions (2.16.840.1.113883.10.20.22.2.45)** | * Instructions (2.16.840.1.113883.10.20.22.4.20) |
| **Hospital Discharge Instructions (2.16.840.1.113883.10.20.22.2.41)** |  |

Sections that are **bolded** are the ToC consensus recommendation to meet the requirement. The entries are not required by MU 2014 Edition or by the Consolidated CDA templates. The Hospital Discharge Instructions Section Structure, as specified in Section 4.23 of the Consolidated CDA implementation guide, consists of narrative block and does not specify any entries.

The structure of the Discharge Instructions section, as specified in Section 4.23 of the Consolidated CDA implementation guide, consists of a narrative block and does not specify any entries

The structure of the Instructions Section with coded entries section is described hierarchically with corresponding entry-level constraints as specified in Section 2.34 of the Volume 2 R2.1 Consolidated CDA implementation guide.

**Table XX: 2.1 Instructions Section (V2) Constraints Overview**

**[section (identifier: urn: hl7ii:2.16.840.1.113883.10.20.22.2.45:2014-06-09)]**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **XPath** | **Cardinality** | **Verb** | **CONF#** | **Value** |
| @nullFlavor | 0..1 | MAY | 1098-32835 | urn:oid:2.16.840.1.113883.5.1008 (HL7NullFlavor) = NI |
| templateId | 1..1 | SHALL | 1198-7965 |  |
| @root | 1..1 | SHALL | 1098-10112 | 2.16.840.1.113883.10.20.22.2.45 |
| @extension | 1..1 | SHALL | 1098-32599 | 2014-06-09 |
| code | 1..1 | SHALL | 1098-15375 |  |
| @code | 1..1 | SHALL | 1098-15376 | 69730-0 |
| @codeSystem | 1..1 | SHALL | 1098-32148 | urn:oid:2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1 |
| title | 1..1 | SHALL | 1098-10114 |  |
| text | 1..1 | SHALL | 1098-10115 |  |
| entry | 1..\* | SHALL | 1098-10116 |  |
| act | 1..1 | SHALL | 1098-31398 | Instruction (V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.20:2014-06-09 |

1. **MAY** contain zero or one [0..1] **@nullFlavor**="NI" No information (CodeSystem: HL7NullFlavor urn:oid:2.16.840.1.113883.5.1008) (CONF:1098-32835).

2. **SHALL** contain exactly one [1..1] **templateId** (CONF:1098-10112) such that it

a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.2.45" (CONF:1098-31384).

b. **SHALL** contain exactly one [1..1] **@extension**="2014-06-09" (CONF:1098-32599).

3. **SHALL** contain exactly one [1..1] **code** (CONF:1098-15375).

a. This code **SHALL** contain exactly one [1..1] **@code**="69730-0" Instructions (CONF:1098-15376).

b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:1098-32148).

4. **SHALL** contain exactly one [1..1] **title** (CONF:1098-10114).

5. **SHALL** contain exactly one [1..1] **text** (CONF:1098-10115).

If section/@nullFlavor is not present:

6. **SHALL** contain at least one [1..\*] **entry** (CONF:1098-10116).

a. Such entries **SHALL** contain exactly one [1..1] **Instruction (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.20:2014-06-09) (CONF:1098-31398).

## Hospital Discharge Instructions Section 8653-8

### Structure

The structure of the Hospital Discharge Instructions Section with coded entries section is described hierarchically with corresponding entry-level constraints as specified in Section 4.23 of the R1.1 Consolidated CDA implementation guide.

The Hospital Discharge Instructions section records instructions at discharge.

**Table XX: R1.1 Hospital Discharge Instructions Section Contexts**

| Used By: | Contains Entries: |
| --- | --- |
| [Discharge Summary](#D_Discharge_Summary) (optional)  (2.16.840.1.113883.10.20.22.2.41) |  |

The structure of the Hospital Discharge Instructions Section with coded entries section is described hierarchically with corresponding entry-level constraints as specified in Section 4.23 of the R1.1 Consolidated CDA implementation guide.

The structure of the Hospital Discharge Instructions Section with coded entries section is described hierarchically with corresponding entry-level constraints as specified in Section 2.29 of the Volume 2 R2.1 Consolidated CDA implementation guide.

**Table XX: 2.1 Hospital Discharge Instructions Section Constraints Overview**

**[section (identifier: urn: hl7ii:2.16.840.1.113883.10.20.22.2.41 (open)]**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **XPath** | **Cardinality** | **Verb** | **CONF#** | **Value** |
| templateId | 1..1 | SHALL | 81-9919 |  |
| @root | 1..1 | SHALL | 81-10395 | 2.16.840.1.113883.10.20.22.2.41 |
| code | 1..1 | SHALL | 81-15357 |  |
| @code | 1..1 | SHALL | 81-15358 | 8653-8 |
| @codeSystem | 1..1 | SHALL | 81-26481 | urn:oid:2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1 |
| title | 1..1 | SHALL | 81-9921 |  |
| text | 1..1 | SHALL | 81-9922 |  |

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:81-9919) such that it

a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.2.41" (CONF:81-10395).

2. **SHALL** contain exactly one [1..1] **code** (CONF:81-15357).

a. This code **SHALL** contain exactly one [1..1] **@code**="8653-8" Hospital Discharge Instructions (CONF:81-15358).

b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:81-26481).

3. **SHALL** contain exactly one [1..1] **title** (CONF:81-9921).

4. **SHALL** contain exactly one [1..1] **text** (CONF:81-9922).

### Vocabulary

**Table XXX: Patient Education Value Set**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Value Set: Patient Education 2.16.840.1.113883.11.20.9.34 DYNAMIC | | | | |
| Code System(s): | | SNOMED CT 2.16.840.1.113883.6.96 | | |
| Description: | | Limited to terms descending from the Education (409073007) hierarchy.  Code system browser: <https://uts.nlm.nih.gov/snomedctBrowser.html> | | |
| **Code** | **Code System** | | **Print Name** | |
| 311401005 | SNOMED CT | | Patient Education | |
| 171044003 | SNOMED CT | | Immunization Education | |
| 243072006 | SNOMED CT | | Cancer Education | |  |
| … |  | |  | |
|  | | | | |

### Clinical Guidance from TOC Implementation Guide

ToC has interpreted the MU2 data requirement for Clinical Instructions and Discharge Instructions to capture care instructions for the patient. Use of the Instructions or Discharge Instructions sections distinguishes from any other instructions associated with a specific act or order, such as medication instructions or care plan instructions.

## Medical Equipment 46264-8 (Optional)

### Structure

The Medical Equipment section defines a patient’s implanted and external medical devices and equipment that their health status depends on, as well as any pertinent equipment or device history. This section is also used to itemize any pertinent current or historical durable medical equipment (DME) used to help maintain the patient’s health status. All equipment relevant to the diagnosis, care, and treatment of a patient **SHOULD** be included.

Devices applied to, or placed in, the patient are represented with the Procedure Activity Procedure (V2) template. Equipment supplied to the patient (e.g., pumps, inhalers, wheelchairs) is represented by the Non-Medicinal Supply Activity V2 template.

These devices may be grouped together within a Medical Equipment Organizer. The organizer would probably not be used with devices applied in or on the patient but rather to organize a goup of medical supplies the patient has been supplied with.

The structure of the Medical Equipment Section with coded entries section is described hierarchically with corresponding entry-level constraints as specified in Section 4.30 of the R1.1 Consolidated CDA implementation guide.

**Table X: R1.1 Medical Equipment Section Contexts**

| Used By: | Contains Entries: |
| --- | --- |
| Medical Equipment (optional)  (2.16.840.1.113883.10.20.22.2.23) | Non-Medicinal Supply Activity  (2.16.840.1.113883.10.20.22.4.50) |

The structure of the Medical Equipment Section with coded entries section is described hierarchically with corresponding entry-level constraints as specified in Section 2.37 of the Volume 2 R2.1 Consolidated CDA implementation guide.

**Table XX: 2.1 Medical Equipment Section (V2) Constraints Overview**

**[section (identifier: urn: hl7ii:2.16.840.1.113883.10.20.22.2.23]**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **XPath** | **Cardinality** | **Verb** | **CONF#** | **Value** |
| templateId | 1..1 | SHALL | 1098-7944 |  |
| @root | 1..1 | SHALL | 1098-10404 | 2.16.840.1.113883.10.20.22.2.23 |
| @extension | 1..1 | SHALL | 1098-32523 | 2014-06-09 |
| code | 1..1 | SHALL | 1098-15381 |  |
| @code | 1..1 | SHALL | 1098-15382 | 46264-8 |
| @codeSystem | 1..1 | SHALL | 1098-30828 | urn:oid:2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1 |
| title | 1..1 | SHALL | 1098-7946 |  |
| text | 1..1 | SHALL | 1098-7947 |  |
| entry | 0..\* | MAY | 1098-7948 |  |
| organizer | 1..1 | SHALL | 1098-30351 | Medical Equipment Organizer (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.135 |
| entry | 0..\* | SHOULD | 1098-31125 |  |
| supply | 1..1 | SHALL | 1098-31861 | Non-Medicinal Supply Activity (V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.50:2014-06-09 |
| entry | 0..^ | SHOULD | 1098-31885 |  |
| Procedure | 1..1 | SHALL | 1098-31886 | Procedure Activity Procedure (V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.14:2014-06-09 |

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:1098-7944) such that it

a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.2.23" (CONF:1098-10404).

b. **SHALL** contain exactly one [1..1] **@extension**="2014-06-09" (CONF:1098-32523).

2. **SHALL** contain exactly one [1..1] **code** (CONF:1098-15381).

a. This code **SHALL** contain exactly one [1..1] **@code**="46264-8" Medical Equipment (CONF:1098-15382).

b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:1098-30828).

3. **SHALL** contain exactly one [1..1] **title** (CONF:1098-7946).

4. **SHALL** contain exactly one [1..1] **text** (CONF:1098-7947).

5. **MAY** contain zero or more [0..\*] **entry** (CONF:1098-7948) such that it

a. **SHALL** contain exactly one [1..1] **Medical Equipment Organizer** (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.135) (CONF:1098-30351).

6. **SHOULD** contain zero or more [0..\*] **entry** (CONF:1098-31125) such that it

a. **SHALL** contain exactly one [1..1] **Non-Medicinal Supply Activity (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.50:2014-06-09) (CONF:1098-31861).

7. **SHOULD** contain zero or more [0..\*] **entry** (CONF:1098-31885) such that it

a. **SHALL** contain exactly one [1..1] **Procedure Activity Procedure (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.14:2014-06-09) (CONF:1098-31886).

## 

## Medications Section 10160-0

### Structure

The Medications Section contains a patient's current medications and pertinent medication history. At a minimum, the currently active medications are listed. An entire medication history is an option. The section can describe a patient's prescription and dispense history and information about intended drug monitoring.

This section requires either an entry indicating the subject is not known to be on any medications or entries summarizing the subject's medications.

The structure of the Medications Section with coded entries required section is described hierarchically with corresponding entry-level constraints as specified in Section 4.33 of the R1.1 Consolidated CDA implementation guide.

**Table XX: Medications MU 2014 EDITION Data Requirement in Consolidated CDA**

| **Section(s)** | **Associated Entry(ies)** |
| --- | --- |
| Medications Administered (2.16.840.1.113883.10.20.22.2.38) | * Medication Activity (2.16.840.1.113883.10.20.22.4.16) * Drug Vehicle (2.16.840.1.113883.10.20.22.4.24) * Medication Information (2.16.840.1.113883.10.20.22.4.23) |
| [**Medications with coded entries required (2.16.840.1.113883.10.20.22.2.1.1)**](#_Medications_(entries_required)) | * Medication Activity (2.16.840.1.113883.10.20.22.4.16) * Drug Vehicle (2.16.840.1.113883.10.20.22.4.24) * Medication Information (2.16.840.1.113883.10.20.22.4.23) |
| Hospital Admission Medications (2.16.840.1.113883.10.20.22.2.44) | * Admission Medication (2.16.840.1.113883.10.20.22.4.36) * Medication Activity (2.16.840.1.113883.10.20.22.4.16) * Drug Vehicle (2.16.840.1.113883.10.20.22.4.24) * Medication Information (2.16.840.1.113883.10.20.22.4.23) |
| Hospital Discharge Medications with coded entries required (2.16.840.1.113883.10.20.22.2.11.1) | * Discharge Medication (2.16.840.1.113883.10.20.22.4.35) * Medication Activity (2.16.840.1.113883.10.20.22.4.16) * Drug Vehicle (2.16.840.1.113883.10.20.22.4.24) * Medication Information (2.16.840.1.113883.10.20.22.4.23) |

**Table XX: R1.1 Medications Section/Entry Structure**

|  |
| --- |
| **Medications (entries required)** |
| SHALL **Medication Activity** |
| SHALL **Medication Information** |
| MAY **Drug Vehicle** |
| MAY **Indication** |
| MAY **Instructions** |
| MAY **Medication Supply Order** |
| MAY **Medication Dispense** |
| MAY **Reaction Observation** |
| MAY **Precondition for Substance Administration** |

The structure of the Medications Section with coded entries section is described hierarchically with corresponding entry-level constraints as specified in Section 2.39.1 of the Volume 2 R2.1 Consolidated CDA implementation guide.

**Table XX: 2.1 Medications Section (entries required) (V2) Constraints Overview**

**[section (identifier: urn: hl7ii:2.16.840.1.113883.10.20.22.2.1.1:2014-06-09]**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **XPath** | **Cardinality** | **Verb** | **CONF#** | **Value** |
| @nullFlavor | 0..1 | MAY | 1098-32845 | urn:oid:2.16.840.1.113883.5.1008 (HL7NullFlavor) = NI |
| templateId | 1..1 | SHALL | 1098-7568 |  |
| @root | 1..1 | SHALL | 1098-10433 | 2.16.840.1.113883.10.20.22.2.1.1 |
| @extension | 1..1 | SHALL | 1098-32499 | 2014-06-09 |
| code | 1..1 | SHALL | 1098-15387 |  |
| @code | 1..1 | SHALL | 1098-15388 | 10160-0 |
| @codeSystem | 1..1 | SHALL | 1098-30825 | urn:oid:2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1 |
| title | 1..1 | SHALL | 1098-7570 |  |
| text | 1..1 | SHALL | 1098-7571 |  |
| entry | 1..\* | SHALL | 1098-7572 |  |
| substanceAdminstration | 1..1 | SHALL | 1098-10077 | Medication Activity (V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.16:2014-06-09 |

1. Conforms to **Medications Section (entries optional) (V2)** template (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.2.1:2014-06-09).

2. **MAY** contain zero or one [0..1] **@nullFlavor**="NI" No information (CodeSystem: HL7NullFlavor urn:oid:2.16.840.1.113883.5.1008) (CONF:1098-32845).

3. **SHALL** contain exactly one [1..1] **templateId** (CONF:1098-7568) such that it

a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.2.1.1" (CONF:1098-10433).

b. **SHALL** contain exactly one [1..1] **@extension**="2014-06-09" (CONF:1098-32499).

4. **SHALL** contain exactly one [1..1] **code** (CONF:1098-15387).

a. This code **SHALL** contain exactly one [1..1] **@code**="10160-0" History of medication use (CONF:1098-15388).

b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:1098-30825).

5. **SHALL** contain exactly one [1..1] **title** (CONF:1098-7570).

6. **SHALL** contain exactly one [1..1] **text** (CONF:1098-7571).

If section/@nullFlavor is not present:

7. **SHALL** contain at least one [1..\*] **entry** (CONF:1098-7572) such that it

a. **SHALL** contain exactly one [1..1] **Medication Activity (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.16:2014-06-09) (CONF:1098-10077).

### Vocabulary

Medications **SHALL** be coded using RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, August 6, 2012 Release. Use of either the Medication Brand Name or the Medication Clinical Information value sets specified in Consolidated CDA meets this requirement.

***Note that RxNorm describes the medication to which the patient is allergic, not the type of reaction.***

### Clinical Guidance

Consistent with the MU 2014 EDITION requirement for the inclusion of medications or medications administered during the visit, ToC describes any medication list exchanged at a care transition to include an up-to-date, reconciled medication list. Inclusion of medications that have been discontinued is not recommended. Medications administered during the visit or that were provided during the hospital stay are not included in the reconciled list, but may be described in the narrative or in a section separate from the reconciled medication list if relevant for continuity of care. Note that MU 2014 EDITION explicitly requires medications administered during the visit for the Clinical Summary (EP only).

## Payers Section 48768-6

### Structure

The Payers section contains data on the patient’s payers, whether a ‘third party’ insurance, self-pay, other payer or guarantor, or some combination of payers, and is used to define which entity is the responsible fiduciary for the financial aspects of a patient’s care.

Each unique instance of a payer and all the pertinent data needed to contact, bill to, and collect from that payer should be included. Authorization information that can be used to define pertinent referral, authorization tracking number, procedure, therapy, intervention, device, or similar authorizations for the patient or provider, or both should be included. At a minimum, the patient’s pertinent current payment sources should be listed.

The sources of payment are represented as a Coverage Activity, which identifies all of the insurance policies or government or other programs that cover some or all of the patient's healthcare expenses. The policies or programs are sequenced by preference. The Coverage Activity has a sequence number that represents the preference order. Each policy or program identifies the covered party with respect to the payer, so that the identifiers can be recorded.

The structure of the Payers Section with coded entries section is described hierarchically with corresponding entry-level constraints as specified in Section 4.37 of the R1.1 Consolidated CDA implementation guide.

**Table XX: R1.1 Payers Section**

| **Section(s)** | **Associated Entry(ies)** |
| --- | --- |
| Payers (2.16.840.1.113883.10.20.22.2.18) | Coverage Activity  2.16.840.1.113883.10.20.22.4.60) (CONF:8905). |

Figure XX: Payers section UML Diagram



1. **SHALL** contain exactly one [1..1] **templateId** (CONF:7924) such that it

a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.2.18" (CONF:10434).

2. **SHALL** contain exactly one [1..1] **code** (CONF:15395).

a. This code **SHALL** contain exactly one [1..1] **@code**="48768-6" Payers (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:15396).

3. **SHALL** contain exactly one [1..1] **title** (CONF:7926).

The structure of the Payers Section with coded entries section is described hierarchically with corresponding entry-level constraints as specified in Section 2.46 of the Volume 2 R2.1 Consolidated CDA implementation guide.

**Table XX: 2.1 Payers Section (V3) Constraints Overview**

**[section (identifier: urn: hl7ii:2.16.840.1.113883.10.20.22.2.18:2015-08-01]**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **XPath** | **Cardinality** | **Verb** | **CONF#** | **Value** |
| templateId | 1..1 | SHALL | 1198-7924 |  |
| @root | 1..1 | SHALL | 1198-10434 | 2.16.840.1.113883.10.20.22.2.18 |
| @extension | 1..1 | SHALL | 1198-32597 | 2016-08-01 |
| code | 1..1 | SHALL | 1198-15395 |  |
| @code | 1..1 | SHALL | 1198-15396 | 48768-6 |
| @codeSystem | 1..1 | SHALL | 1198-32149 | urn:oid:2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1 |
| title | 1..1 | SHALL | 1198-7926 |  |
| text | 1..1 | SHALL | 1198-7927 |  |
| entry | 0..\* | SHOULD | 1198-7959 |  |
| act | 1..1 | SHALL | 1198-15501 | Coverage Activity (V3) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.60:2015-08-01 |

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:1198-7924) such that it

a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.2.18" (CONF:1198-10434).

b. **SHALL** contain exactly one [1..1] **@extension**="2015-08-01" (CONF:1198-32597).

2. **SHALL** contain exactly one [1..1] **code** (CONF:1198-15395).

a. This code **SHALL** contain exactly one [1..1] **@code**="48768-6" Payers (CONF:1198-15396).

b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:1198-32149).

3. **SHALL** contain exactly one [1..1] **title** (CONF:1198-7926).

4. **SHALL** contain exactly one [1..1] **text** (CONF:1198-7927).

5. **SHOULD** contain zero or more [0..\*] **entry** (CONF:1198-7959) such that it

a. **SHALL** contain exactly one [1..1] **Coverage Activity (V3)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.60:2015-08-01) (CONF:1198-15501).

## Plan of Care 18776-5 or Assessment and Plan

### Structure

The Plan of Care section contains data that defines pending orders, interventions, encounters, services, and procedures for the patient. It is limited to prospective, unfulfilled, or incomplete orders and requests only, which are indicated by the @moodCode of the entries within this section. All active, incomplete, or pending orders, appointments, referrals, procedures, services, or any other pending event of clinical significance to the current care of the patient should be listed unless constrained due to privacy issues. The plan may also contain information about ongoing care of the patient and information regarding goals and clinical reminders. Clinical reminders are placed here to provide prompts for disease prevention and management, patient safety, and health-care quality improvements, including widely accepted performance measures. The plan may also indicate that patient education will be provided.

The structure of the Plan of Care section is described hierarchically with corresponding entry-level constraints as specified in Section 4.39 of the R1.1 Consolidated CDA implementation guide.

**Table XX: R1.1 Care Plan MU 2014 EDITION Data Requirements in Consolidated CDA**

| **Section(s)** | **Associated Entry(ies)** |
| --- | --- |
| **Plan of Care (2.16.840.1.113883.10.20.22.2.10)** | * Plan of Care Activity Act (2.16.840.1.113883.10.20.22.4.39) * Plan of Care Activity Encounter (2.16.840.1.113883.10.20.22.4.40) * Plan of Care Activity Observation (2.16.840.1.113883.10.20.22.4.44) * Plan of Care Activity Procedure (2.16.840.1.113883.10.20.22.4.41) * Plan of Care Activity Substance Administration (2.16.840.1.113883.10.20.22.4.42) * Plan of Care Activity Supply (2.16.840.1.113883.10.20.22.4.43) |
| Assessment and Plan (2.16.840.1.113883.10.20.22.2.9) | * Plan of Care Activity Act (2.16.840.1.113883.10.20.22.4.39) * Plan of Care Activity Encounter (2.16.840.1.113883.10.20.22.4.40) * Plan of Care Activity Observation (2.16.840.1.113883.10.20.22.4.44) * Plan of Care Activity Procedure (2.16.840.1.113883.10.20.22.4.41) * Plan of Care Activity Substance Administration (2.16.840.1.113883.10.20.22.4.42) * Plan of Care Activity Supply (2.16.840.1.113883.10.20.22.4.43) |

**Table XX: R1.1 Plan of Care Structure**

|  |
| --- |
| **Plan of Care** |
| MAY **Plan of Care Activity Act** |
| MAY **Plan of Care Activity Encounter** |
| MAY **Plan of Care Activity Observation** |
| MAY **Plan of Care Activity Procedure** |
| MAY **Plan of Care Activity Substance Administration** |
| MAY **Plan of Care Activity Supply** |
| MAY **Instructions** |

This section, formerly known as "Plan of Care", contains data that define pending orders, interventions, encounters, services, and procedures for the patient. It is limited to prospective, unfulfilled, or incomplete orders and requests only. These are indicated by the @moodCode of the entries within this section. All active, incomplete, or pending orders, appointments, referrals, procedures, services, or any other pending event of clinical significance to the current care of the patient should be listed.

This section may also contain information about ongoing care of the patient, clinical reminders, patient’s values, beliefs, preferences, care expectations, and overarching care goals.

Clinical reminders are placed here to provide prompts for disease prevention and management, patient safety, and healthcare quality improvements, including widely accepted performance measures.

Values may include the importance of quality of life over longevity. These values are taken into account when prioritizing all problems and their treatments.

Beliefs may include comfort with dying or the refusal of blood transfusions because of the patient’s religious convictions.

Preferences may include liquid medicines over tablets, or treatment via secure email instead of in person.

Care expectations may range from being treated only by female clinicians, to expecting all calls to be returned within 24 hours.

Overarching goals described in this section are not tied to a specific condition, problem, health concern, or intervention. Examples of overarching goals could be to minimize pain or dependence on others, or to walk a daughter down the aisle for her marriage.

The plan may also indicate that patient education will be provided.

The structure of the Plan of Care section is described hierarchically with corresponding entry-level constraints as specified in Section 2.48 of the Volume 2 R2.1 Consolidated CDA implementation guide.

**Table XX: 2.1 Plan of Treatment Section (V2) Constraints Overview**

**[section (identifier: urn: hl7ii:2.16.840.1.113883.10.20.22.2.10:2014-06-09]**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **XPath** | **Cardinality** | **Verb** | **CONF#** | **Value** |
| templateId | 1..1 | SHALL | 1098-7723 |  |
| @root | 1..1 | SHALL | 1098-10435 | 2.16.840.1.113883.10.20.22.2.10 |
| @extension | 1..1 | SHALL | 1098-32501 | 2014-06-09 |
| code | 1..1 | SHALL | 1098-14797 |  |
| @code | 1..1 | SHALL | 1098-14750 | 18776-5 |
| @codeSystem | 1..1 | SHALL | 1098-30813 | urn:oid:2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1 |
| title | 1..1 | SHALL | 1098-16986 |  |
| text | 1..1 | SHALL | 1098-7725 |  |
| entry | 0..\* | MAY | 1098-7726 |  |
| observation | 1..1 | SHALL | 1098-147511 | Planned Observation (V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.44:2014-06-09 |
| entry | 0..\* | MAY | 1098-8805 |  |
| encounter | 1..1 | SHALL | 1098-30472 | Planned Encounter (V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.40:2014-06-09 |
| entry | 0..\* | MAY | 1098-8807 |  |
| Act | 1..1 | SHALL | 1098-30473 | Planned Act (V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.39:2014-06-09 |
| entry | 0..\* | MAY | 1098-8809 |  |
| procedure | 1..1 | SHALL | 1098-30474 | Planned Procedure (V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.41:2014-06-09 |
| entry | 0..\* | MAY | 1098-8811 |  |
| substanceAdminstration | 1..1 | SHALL | 1098-30475 | Planned Medication Activity (V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.2  0.22.4.42:2014-06-09 |
| entry | 0..\* | MAY | 1098-8813 |  |
| supply | 1..1 | SHALL | 1098-30476 | Planned Supply (V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.43:2014-06-09 |
| entry | 0..\* | MAY | 1098-14695 |  |
| act | 1..1 | SHALL | 1098-31397 | Instruction (V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.20:2014-06-09 |
| entry | 0..\* | MAY | 1098-29621 |  |
| act | 1..1 | SHALL | 1098-30868 | Handoff Communication Participants (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.141 |
| entry | 0..\* | MAY | 1098-31841 |  |
| act | 1..1 | SHALL | 1098-31864 | Nutrition Recommendation (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.130 |
| entry | 0..\* | MAY | 1098-32353 |  |
| substanceAdminstration | 1..1 | SHALL | 1098-32354 | Planned Immunization Activity (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.120 |
| entry | 0..\* | MAY | 1098-32887 |  |
| observation | 1..1 | SHALL | 1098-32888 | Goal Observation (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.121 |

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:1098-7723) such that it

a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.2.10" (CONF:1098-10435).

b. **SHALL** contain exactly one [1..1] **@extension**="2014-06-09" (CONF:1098-32501).

2. **SHALL** contain exactly one [1..1] **code** (CONF:1098-14749).

a. This code **SHALL** contain exactly one [1..1] **@code**="18776-5" Plan of Treatment (CONF:1098-14750).

b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:1098-30813).

3. **SHALL** contain exactly one [1..1] **title** (CONF:1098-16986).

4. **SHALL** contain exactly one [1..1] **text** (CONF:1098-7725).

5. **MAY** contain zero or more [0..\*] **entry** (CONF:1098-7726) such that it

a. **SHALL** contain exactly one [1..1] **Planned Observation (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.44:2014-06-09) (CONF:1098-14751).

6. **MAY** contain zero or more [0..\*] **entry** (CONF:1098-8805) such that it

a. **SHALL** contain exactly one [1..1] **Planned Encounter (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.40:2014-06-09) (CONF:1098-30472).

7. **MAY** contain zero or more [0..\*] **entry** (CONF:1098-8807) such that it

a. **SHALL** contain exactly one [1..1] **Planned Act (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.39:2014-06-09) (CONF:1098-30473).

8. **MAY** contain zero or more [0..\*] **entry** (CONF:1098-8809) such that it

a. **SHALL** contain exactly one [1..1] **Planned Procedure (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.41:2014-06-09) (CONF:1098-30474).

9. **MAY** contain zero or more [0..\*] **entry** (CONF:1098-8811) such that it

a. **SHALL** contain exactly one [1..1] **Planned Medication Activity (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.42:2014-06-09) (CONF:1098-30475).

10. **MAY** contain zero or more [0..\*] **entry** (CONF:1098-8813) such that it

a. **SHALL** contain exactly one [1..1] **Planned Supply (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.43:2014-06-09) (CONF:1098-30476).

11. **MAY** contain zero or more [0..\*] **entry** (CONF:1098-14695) such that it

a. **SHALL** contain exactly one [1..1] **Instruction (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.20:2014-06-09) (CONF:1098-31397).

12. **MAY** contain zero or more [0..\*] **entry** (CONF:1098-29621) such that it

a. **SHALL** contain exactly one [1..1] **Handoff Communication Participants** (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.141) (CONF:1098-30868).

13. **MAY** contain zero or more [0..\*] **entry** (CONF:1098-31841) such that it

a. **SHALL** contain exactly one [1..1] **Nutrition Recommendation** (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.130) (CONF:1098-31864).

14. **MAY** contain zero or more [0..\*] **entry** (CONF:1098-32353) such that it

a. **SHALL** contain exactly one [1..1] **Planned Immunization Activity** (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.120) (CONF:1098-32354).

15. **MAY** contain zero or more [0..\*] **entry** (CONF:1098-32887) such that it

a. **SHALL** contain exactly one [1..1] **Goal Observation** (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.121) (CONF:1098-32888).

### Clinical Guidance from TOC Implementation Guide

The Recommended Patient Decision Aids MU2 data requirement includes any materials, such as patient education, provided to the patient to inform care decisions. Types of materials provided to the patient can be coded within the Instructions entry, although coded entries for types of Instructions are not required by MU2. Additional guidance on capturing Recommended Patient Decision Aids is available in Section 4.28 of the Consolidated CDA implementation guide within the Instructions section.

**Table 12: R1.1 Clinical or Discharge Instructions MU2 Data Requirement in Consolidated CDA**

| **Section(s)** | **Associated Entry(ies)** |
| --- | --- |
| Instructions (2.16.840.1.113883.10.20.22.2.45) | • Instructions (2.16.840.1.113883.10.20.22.4.20) |
| Hospital Discharge Instructions (2.16.840.1.113883.10.20.22.2.41) |  |

### Instructions Section Structure

The structure of the Instructions section is described hierarchically with corresponding entry-level constraints as specified in Section 4.28 of the Consolidated CDA implementation guide.

**Table 13: Instructions Section Structure**

|  |
| --- |
| **Instructions** |
| SHOULD Instructions |

### R1.1 Hospital Discharge Instructions Section Structure

The structure of the Discharge Instructions section, as specified in Section 4.23 of the Consolidated CDA implementation guide, consists of a narrative block and does not specify any entries.

The structure of the Plan of Care section is described hierarchically with corresponding entry-level constraints as specified in Section 4.39 of the Consolidated CDA implementation guide.

MAY Plan of Care Activity Act

MAY Plan of Care Activity Encounter

MAY Plan of Care Activity Observation

MAY Plan of Care Activity Procedure

MAY Plan of Care Activity Substance Administration

MAY Plan of Care Activity Supply

MAY Instructions

To capture the care planning data elements, the recommendation is to use the Plan of Care section. It is important to note that pending tests not yet performed are noted within the care plan, while tests that have been or that are being performed, including pending results, are noted within the Results section. Entries within the Plan of Care or Assessment and Plan sections will vary depending on the associated care plan activity. Please note that local policy determines if the Plan of Care section should be separate or combined with the Assessment section.

Table 11: Care Plan MU2 Data Requirements in Consolidated CDA

### R1.1 CCD Considerations: Care Plan

Care Plan, including Goals and Instructions, Future Scheduled Tests and Appointments, Diagnostic Tests Pending, and Referrals to Other Providers

To capture the care planning data elements, the recommendation is to use the Plan of Care section. It is important to note that pending tests not yet performed are noted within the care plan, while tests that have been or that are being performed, including pending results, are noted within the Results section. Entries within the Plan of Care or Assessment and Plan sections will vary depending on the associated care plan activity. Please note that local policy determines if the Plan of Care section should be separate or combined with the Assessment section.

### R1.1 CCD Considerations: Clinical Instructions

Clinical Instructions, Discharge Instructions and Recommended Patient Decision Aids

ToC has interpreted the MU 2014 EDITION data requirement for Clinical Instructions and Discharge Instructions to capture care instructions for the patient. Use of the Instructions or Discharge Instructions sections distinguishes from any other instructions associated with a specific act or order, such as medication instructions or care plan instructions.

The Recommended Patient Decision Aids MU 2014 EDITION data requirement includes any materials, such as patient education, provided to the patient to inform care decisions. Types of materials provided to the patient can be coded within the Instructions entry, although coded entries for types of Instructions are not required by MU 2014 EDITION. Additional guidance on capturing Recommended Patient Decision Aids is available in Section4.28 of the Consolidated CDA implementation guide within the Instructions section.

## Problem Section 11450-4 (Entries Required)

### Structure

This section lists and describes all relevant clinical problems at the time the document is generated. At a minimum, all pertinent current and historical problems should be listed. Overall health status may be represented in this section.

The structure of the Problem with entries required section is described hierarchically with corresponding entry-level constraints as specified in Section 4.44 of the R1.1 Consolidated CDA implementation guide.

**Table XX: R1.1 Problem MU2 Data Requirement in Consolidated CDA**

| **Section(s)** | **Associated Entry(ies)** |
| --- | --- |
| [**Problem with coded entries required (2.16.840.1.113883.10.20.22.2.5.1)**](#_Problem_(entries_required)) | 1. Problem Concern Act (2.16.840.1.113883.10.20.22.4.3) 2. Problem Observation (2.16.840.1.113883.10.20.22.4.4) |

**Table XX: R1.1 Problem Section Structure**

|  |
| --- |
| **Problem (entries required)** |
| SHALL **Problem Concern Act** |
| SHALL **Problem Observation** |
| MAY **Age Observation** |
| MAY **Problem Status Observation (Deprecated 2.1)** |
| MAY **Health Status Observation** |

The structure of the Problem Section is described hierarchically with corresponding entry-level constraints as specified in Section 2.53 of the Volume 2 R2.1 Consolidated CDA implementation guide.

**Table XX: 2.1 Problem Section (entries required) (V3) Constraints Overview**

**[section (identifier: urn: hl7ii:2.16.840.1.113883.10.20.22.2.5.1:2015-08-01]**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **XPath** | **Cardinality** | **Verb** | **CONF#** | **Value** |
| @nullFlavor | 0..1 | MAY | 1198-32864 | urn:oid:2.16.840.1.113883.5.1008 (HL7NullFlavor) = NI |
| templateId | 1..1 | SHALL | 1198-9179 |  |
| @root | 1..1 | SHALL | 1198-32510 | 2.16.840.1.113883.10.20.22.2.5.1 |
| @extension | 1..1 | SHALL | 1198-32501 | 2015-08-01 |
| code | 1..1 | SHALL | 1198-15409 |  |
| @code | 1..1 | SHALL | 1198-15410 | 11450-4 |
| @codeSystem | 1..1 | SHALL | 1198-31142 | urn:oid:2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1 |
| title | 1..1 | SHALL | 1198-9181 |  |
| text | 1..1 | SHALL | 1198-9182 |  |
| entry | 1..\* | SHALL | 1198-9183 |  |
| act | 1..1 | SHALL | 1198-15506 | Problem Concern Act (V3) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.3:2015-08-01 |
| entry | 0..1 | MAY | 1198-30479 |  |
| observation | 1..1 | SHALL | 1198-30480 | Health Status Observation (V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.5:2014-06-09 |

1. Conforms to **Problem Section (entries optional) (V3)** template (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.2.5:2015-08-01).

2. **MAY** contain zero or one [0..1] **@nullFlavor**="NI" No information (CodeSystem: HL7NullFlavor urn:oid:2.16.840.1.113883.5.1008) (CONF:1198-32864).

3. **SHALL** contain exactly one [1..1] **templateId** (CONF:1198-9179) such that it

a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.2.5.1" (CONF:1198-10441).

b. **SHALL** contain exactly one [1..1] **@extension**="2015-08-01" (CONF:1198-32510).

4. **SHALL** contain exactly one [1..1] **code** (CONF:1198-15409).

a. This code **SHALL** contain exactly one [1..1] **@code**="11450-4" Problem List (CONF:1198-15410).

b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:1198-31142).

5. **SHALL** contain exactly one [1..1] **title** (CONF:1198-9181).

6. **SHALL** contain exactly one [1..1] **text** (CONF:1198-9182).

If section/@nullFlavor is not present:

7. **SHALL** contain at least one [1..\*] **entry** (CONF:1198-9183) such that it

a. **SHALL** contain exactly one [1..1] **Problem Concern Act (V3)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.3:2015-08-01) (CONF:1198-15506).

8. **MAY** contain zero or one [0..1] **entry** (CONF:1198-30479) such that it

a. **SHALL** contain exactly one [1..1] **Health Status Observation (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.5:2014-06-09) (CONF:1198-30480).

### Vocabulary

Problems **SHALL** use values specified in IHTSDO SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release. Use of the Problem value set specified in Consolidated CDA meets this requirement.

## Procedures Section 47519-4 (Entries Required)

### Structure

The structure of the Procedures with coded entries required section is described hierarchically with corresponding entry-level constraints as specified in Section 4.52 of the R1.1 Consolidated CDA implementation guide.

SHOULD contain zero or one [0..1] Procedures Section (entries required) (templateId:2.16.840.1.113883.10.20.22.2.7.1) (CONF:9451).

Procedure act is for procedures the alter that physical condition of a patient (Splenectomy). Observation act is for procedures that result in new information about a patient but do not cause physical alteration (EEG). Act is for all other types of procedures (dressing change).

Since CPT codes comprise level 1 of HCPCS, a specific OID for HCPCS or the combination of HCPCS and CPT-4 is not needed. The use of ICD-10-PCS or CDT is optional. If choosing to support the optional vocabularies of ICD-10-PCS or CDT, the requirement is not met unless SNOMED CT® or HCPCS/CPT-4 is supported as well.

This section defines all interventional, surgical, diagnostic, or therapeutic procedures or treatments pertinent to the patient historically at the time the document is generated. The section should include notable procedures, but can contain all procedures for the period of time being summarized. The common notion of "procedure" is broader than that specified by the HL7 Version 3 Reference Information Model (RIM), therefore this section contains procedure templates represented with three RIM classes: Act. Observation, and Procedure. Procedure act is for procedures the alter that physical condition of a patient (Splenectomy). Observation act is for procedures that result in new information about a patient but do not cause physical alteration (EEG). Act is for all other types of procedures (dressing change).

**Table XX: R1.1 Procedures Section Structure**

|  |
| --- |
| **Procedures (entries required)** |
| MAY **Procedure Activity Procedure** |
| MAY **Procedure Activity Observation** |
| MAY **Procedure Activity Act** |

The structure of the Procedures Section is described hierarchically with corresponding entry-level constraints as specified in Section 2.61.1 of the Volume 2 R2.1 Consolidated CDA implementation guide.

**Table XX: 2.1 Procedures Section (entries required) (V2) Constraints Overview**

**[section (identifier: urn: hl7ii:2.16.840.1.113883.10.20.22.2.7.1:2014-06-09]**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **XPath** | **Cardinality** | **Verb** | **CONF#** | **Value** |
| @nullFlavor | 0..1 | MAY | 1098-32876 | urn:oid:2.16.840.1.113883.5.1008 (HL7NullFlavor) = NI |
| templateId | 1..1 | SHALL | 1098-7891 |  |
| @root | 1..1 | SHALL | 1098-10447 | 2.16.840.1.113883.10.20.22.2.7.1 |
| @extension | 1..1 | SHALL | 1098-32533 | 2014-06-09 |
| code | 1..1 | SHALL | 1098-15425 |  |
| @code | 1..1 | SHALL | 1098-15426 | 47519-4 |
| @codeSystem | 1..1 | SHALL | 1098-31138 | urn:oid:2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1 |
| title | 1..1 | SHALL | 1098-7893 |  |
| text | 1..1 | SHALL | 1098-7894 |  |
| entry | 1..\* | SHALL | 1098-7895 |  |
| act | 0..1 | MAY | 1098-32877 | Procedure Activity Act (V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.12:2014-06-09 |
| observation | 0..1 | MAY | 1098-32878 | Procedure Activity Observation (V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.13:2014-06-09 |
| procedure | 0..1 | MAY | 1098-15512 | Procedure Activity Procedure (V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.14:2014-06-09 |

1. Conforms to **Procedures Section (entries optional) (V2)** template (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.2.7:2014-06-09).

2. **MAY** contain zero or one [0..1] **@nullFlavor**="NI" No information (CodeSystem: HL7NullFlavor urn:oid:2.16.840.1.113883.5.1008) (CONF:1098-32876).

3. **SHALL** contain exactly one [1..1] **templateId** (CONF:1098-7891) such that it

a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.2.7.1" (CONF:1098-10447).

b. **SHALL** contain exactly one [1..1] **@extension**="2014-06-09" (CONF:1098-32533).

4. **SHALL** contain exactly one [1..1] **code** (CONF:1098-15425).

a. This code **SHALL** contain exactly one [1..1] **@code**="47519-4" History of Procedures (CONF:1098-15426).

b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:1098-31138).

5. **SHALL** contain exactly one [1..1] **title** (CONF:1098-7893).

6. **SHALL** contain exactly one [1..1] **text** (CONF:1098-7894).

If section/@nullFlavor is not present there **SHALL** be at least one entry conformant to Procedure Activity Act (V2) (templateId 2.16.840.1.113883.10.20.22.4.12:2014-06-09) **OR** Procedure Activity Observation (V2) (templateId: 2.16.840.1.113883.10.20.22.4.13:2014-06-09) **OR** Procedure Activity Procedure (V2) (templateId: 2.16.840.1.113883.10.20.22.4.14:2014-06-09)

7. **SHALL** contain at least one [1..\*] **entry** (CONF:1098-7895) such that it

a. **MAY** contain zero or one [0..1] **Procedure Activity Act (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.12:2014-06-09) (CONF:1098-32877).

b. **MAY** contain zero or one [0..1] **Procedure Activity Observation (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.13:2014-06-09) (CONF:1098-32878).

c. **MAY** contain zero or one [0..1] **Procedure Activity Procedure (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.14:2014-06-09) (CONF:1098-15512).

### Vocabulary

Procedures require the combination of both HCPCS[[4]](#footnote-5) and CPT-4[[5]](#footnote-6), or IHTSDO SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release*.* Since CPT codes comprise level 1 of HCPCS, a specific OID for HCPCS or the combination of HCPCS and CPT-4 is not needed. The use of ICD-10-PCS[[6]](#footnote-7) or CDT[[7]](#footnote-8)is optional. If choosing to support the optional vocabularies of ICD-10-PCS or CDT, the requirement is not met unless SNOMED CT® or HCPCS/CPT-4 is supported as well.

## Reason for Referral Section 42349-1

### Structure

This section describes the clinical reason why a provider is sending a patient to another provider for care. The reason for referral may become the reason for visit documented by the receiving provider.

The structure of the Reason for Referral, as specified in Section 4.53 of the R1.1 Consolidated CDA implementation guide, consists of a narrative block and does not specify any entries. Recommendation is to use the Reason for Referral section for the MU 2014 Edition data requirement so that the referring provider’s intentions are clear to the consulting provider.

Table XX: R1.1 Reason for Referral MU2 Data Requirement in Consolidated CDA

| **Section(s)** | **Associated Entry(ies)** |
| --- | --- |
| [**Reason for Referral (1.3.6.1.4.1.19376.1.5.3.1.3.1)**](#_Reason_for_Visit) |  |

The structure of the Reason for Referral Section is described hierarchically with corresponding entry-level constraints as specified in Section 2.62 of the Volume 2 R2.1 Consolidated CDA implementation guide.

**Table XX: 2.1 Reason for Referral Section (V2) Constraints Overview**

**[section (identifier: urn: hl7ii:1.3.6.1.4.1.19736.1.5.3.1:2014-06-09]**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **XPath** | **Cardinality** | **Verb** | **CONF#** | **Value** |
| templateId | 1..1 | SHALL | 1098-7844 |  |
| @root | 1..1 | SHALL | 1098-10468 | 1.3.6.1.4.1.19376.1.5.3.1.3.1 |
| @extension | 1..1 | SHALL | 1098-32571 | 2014-06-09 |
| code | 1..1 | SHALL | 1098-15427 |  |
| @code | 1..1 | SHALL | 1098-15428 | 42349-1 |
| @codeSystem | 1..1 | SHALL | 1098-30867 | urn:oid:2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1 |
| title | 1..1 | SHALL | 1098-7846 |  |
| text | 1..1 | SHALL | 1098-7847 |  |
| entry | 0..\* | MAY | 1098-30808 |  |
| observation | 1..1 | SHALL | 1098-30897 | Patient Referral Act (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.140 |

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:1098-7844) such that it

a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.5.3.1.3.1" (CONF:1098-10468).

b. **SHALL** contain exactly one [1..1] **@extension**="2014-06-09" (CONF:1098-32571).

2. **SHALL** contain exactly one [1..1] **code** (CONF:1098-15427).

a. This code **SHALL** contain exactly one [1..1] **@code**="42349-1" Reason for Referral (CONF:1098-15428).

b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:1098-30867).

3. **SHALL** contain exactly one [1..1] **title** (CONF:1098-7846).

4. **SHALL** contain exactly one [1..1] **text** (CONF:1098-7847).

5. **MAY** contain zero or more [0..\*] **entry** (CONF:1098-30808) such that it

a. **SHALL** contain exactly one [1..1] **Patient Referral Act** (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.140) (CONF:1098-30897).

## Reason for Visit or Chief Complaint or Chief Complaint and Reason for Visit

### Structure

The Reason for Visit section records the patient’s reason for the patient's visit (as documented by the provider). Local policy determines whether Reason for Visit and Chief Complaint are in separate or combined sections.

The recommendation is to use the Reason for Visit section to capture the provider perspective of the Reason for Visit in ambulatory settings or the Reason for Hospitalization in inpatient settings. It is important to distinguish the Reason for Visit section, which captures the provider’s description of the reason for a visit, and the Chief Complaint section, which captures the patient’s description of the reason they are seeking medical attention. Please note that local policy determines if the Reason for Visit should be separate or combined with the Chief Complaint section.

The structure of the Reason for Visit, as specified in Section 4.54 of the R1.1 Consolidated CDA implementation guide, consists of a narrative block and does not specify any entries.

**Table XX: R1.1 Reason for Visit or Hospitalization MU 2014 Edition Data Requirement in C-CDA**

| **Section(s)** | **Associated Entry(ies)** |
| --- | --- |
| Chief Complaint (1.3.6.1.4.1.19376.1.5.3.1.1.13.2.1) |  |
| Chief Complaint and Reason for Visit (2.16.840.1.113883.10.20.22.2.13) |  |
| Encounters with coded entries optional (2.16.840.1.113883.10.20.22.2.22) | * Indication (2.16.840.1.113883.10.20.22.4.19) |
| Encounters with coded entries required (2.16.840.1.113883.10.20.22.2.22.1) | * Indication (2.16.840.1.113883.10.20.22.4.19) |
| Hospital Admission Diagnosis (2.16.840.1.113883.10.20.22.2.43) | * Hospital Admission Diagnosis (2.16.840.1.113883.10.20.22.4.34) |
| Preoperative Diagnosis (2.16.840.1.113883.10.20.22.2.35) | * Preoperative Diagnosis (2.16.840.1.113883.10.20.22.4.65) |
| **Reason for Visit (2.16.840.1.113883.10.20.22.2.12)** |  |

The structure of the Reason for Visit Section, as specified in Section 2.63 of the Volume 2 R2.1 Consolidated CDA implementation guide, consists of a narrative block and does not specify any entries.

**Table XX: 2.1 Reason for Visit Section Constraints Overview**

**[section (identifier: urn:oid:2.16.840.1.113883.10.20.22.2.12]**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **XPath** | **Cardinality** | **Verb** | **CONF#** | **Value** |
| templateId | 1..1 | SHALL | 81-7836 |  |
| @root | 1..1 | SHALL | 81-10448 | 2.16.840.1.113883.10.20.22.2.12 |
| code | 1..1 | SHALL | 81-15429 |  |
| @code | 1..1 | SHALL | 81-15430 | 29299-5 |
| @codeSystem | 1..1 | SHALL | 81-26494 | urn:oid:2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1 |
| title | 1..1 | SHALL | 81-7838 |  |
| text | 1..1 | SHALL | 81-7839 |  |

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:81-7836) such that it

a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.2.12" (CONF:81-10448).

2. **SHALL** contain exactly one [1..1] **code** (CONF:81-15429).

a. This code **SHALL** contain exactly one [1..1] **@code**="29299-5" Reason for Visit (CONF:81-15430).

b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:81-26494).

3. **SHALL** contain exactly one [1..1] **title** (CONF:81-7838).

4. **SHALL** contain exactly one [1..1] **text** (CONF:81-7839).

### Clinical Guidance

Reason for Visit Section or Chief Complaint Section or Chief Complaint and Reason for Visit Section can be used for either Reason for Visit or Reason for Hospitalization (inpatient settings) requirement

The recommendation is to use the Reason for Visit section to capture the provider perspective of the Reason for Visit in ambulatory settings or the Reason for Hospitalization in inpatient settings. It is important to distinguish the Reason for Visit section, which captures the provider’s description of the reason for a visit, and the Chief Complaint section, which captures the patient’s description of the reason they are seeking medical attention. Please note that local policy determines if the Reason for Visit should be separate or combined with the Chief Complaint section.

## Results Section 30954-2 (Entries Required)

### Structure

The Results section contains the results of observations generated by laboratories, imaging procedures, and other procedures. These coded result observations are contained within a Results Organizer in the Results Section. The scope includes observations such as hematology, chemistry, serology, virology, toxicology, microbiology, plain x-ray, ultrasound, CT, MRI, angiography, echocardiography, nuclear medicine, pathology, and procedure observations. The section often includes notable results such as abnormal values or relevant trends, and could contain all results for the period of time being documented.

Laboratory results are typically generated by laboratories providing analytic services in areas such as chemistry, hematology, serology, histology, cytology, anatomic pathology, microbiology, and/or virology. These observations are based on analysis of specimens obtained from the patient and submitted to the laboratory.

Imaging results are typically generated by a clinician reviewing the output of an imaging procedure, such as where a cardiologist reports the left ventricular ejection fraction based on the review of a cardiac echocardiogram.

Procedure results are typically generated by a clinician to provide more granular information about component observations made during a procedure, such as where a gastroenterologist reports the size of a polyp observed during a colonoscopy.

The structure of the Results with coded entries required section is described hierarchically with corresponding entry-level constraints as specified in Section 4.55 of the R1.1 Consolidated CDA implementation guide.

**Table XX: R1.1 Results Section Structure**

|  |
| --- |
| **Results (entries required)** |
| SHALL **Result Organizer** |
| SHALL **Result Observation** |

**Table XX: R1.1 Laboratory Tests and Result Values MU 2014 Edition Data Requirements in Consolidated CDA**

|  |  |
| --- | --- |
| **Section(s)** | **Associated Entry(ies)** |
| **Results with coded entries required (2.16.840.1.113883.10.20.22.2.3.1)** | Results Organizer (2.16.840.1.113883.10.20.22.4.1)  Results Observation (2.16.840.1.113883.10.20.22.4.2) |
| Hospital Discharge Studies Summary  (2.16.840.1.113883.10.20.22.2.16) | Results Organizer (2.16.840.1.113883.10.20.22.4.1)  Results Observation (2.16.840.1.113883.10.20.22.4.2) |

The structure of the Results with coded entries required section is described hierarchically with corresponding entry-level constraints as specified in Section 2.64.1 of the Volume 2 R2.1 Consolidated CDA implementation guide.

**Table XX: 2.1 Results Section (entries required) (V3) Constraints Overview**

**[section (identifier: urn:oid:2.16.840.1.113883.10.20.22.2.3.1:2015-08-01)]**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **XPath** | **Cardinality** | **Verb** | **CONF#** | **Value** |
| #nullFlavor | 0..1 | MAY | 1198-32875 | urn:oid:2.16.840.1.113883.5.1008 (HL7NullFlavor) = NI |
| templateId | 1..1 | SHALL | 1198-7108 |  |
| @root | 1..1 | SHALL | 1198-9137 | 2.16.840.1.113883.10.20.22.2.3.1 |
| @extension | 1..1 | SHALL | 1198-32592 | 2015-08-01 |
| code | 1..1 | SHALL | 1198-15433 |  |
| @code | 1..1 | SHALL | 1198-15434 | 30954-2 |
| @codeSystem | 1..1 | SHALL | 1198-31040 | urn:oid:2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1 |
| title | 1..1 | SHALL | 1198-8892 |  |
| text | 1..1 | SHALL | 1198-7111 |  |
| entry | 1..\* | SHALL | 1198-7112 |  |
| organizer | 1..1 | SHALL | 1198-15516 | Result Organizer (V3) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.1:2015-08-01 |

1. Conforms to **Results Section (entries optional) (V3)** template (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.2.3:2015-08-01).

2. **MAY** contain zero or one [0..1] **@nullFlavor**="NI" No information (CodeSystem: HL7NullFlavor urn:oid:2.16.840.1.113883.5.1008) (CONF:1198-32875).

3. **SHALL** contain exactly one [1..1] **templateId** (CONF:1198-7108) such that it

a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.2.3.1" (CONF:1198-9137).

b. **SHALL** contain exactly one [1..1] **@extension**="2015-08-01" (CONF:1198-32592).

4. **SHALL** contain exactly one [1..1] **code** (CONF:1198-15433).

a. This code **SHALL** contain exactly one [1..1] **@code**="30954-2" Relevant diagnostic tests and/or laboratory data (CONF:1198-15434).

b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:1198-31040).

5. **SHALL** contain exactly one [1..1] **title** (CONF:1198-8892).

6. **SHALL** contain exactly one [1..1] **text** (CONF:1198-7111).

If section/@nullFlavor is not present:

7. **SHALL** contain at least one [1..\*] **entry** (CONF:1198-7112) such that it

a. **SHALL** contain exactly one [1..1] **Result Organizer (V3)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.1:2015-08-01) (CONF:1198-15516).

### Vocabulary

Laboratory Tests and Values of Laboratory Results **SHALL** use the Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.40. If using the Discharge Summary document template in inpatient settings, the Hospital Discharge Studies Summary section **SHALL** include coded entries to capture Laboratory Results.

## Social History 29762-2

### Structure

This section contains social history data that influence a patient’s physical, psychological or emotional health. Social history can have significant influence on a patient’s physical, psychological and emotional health and wellbeing so should be considered in the development of a complete record. Demographic data, such as marital status, race, ethnicity, and religious affiliation, is capture in the header.

The structure of the Social History section is described hierarchically with corresponding entry-level constraints as specified in Section 4.57 of the R1.1 Consolidated CDA implementation guide.

**Table XX: R1.1 Smoking Status MU 2014 Edition Data Requirement in Consolidated CDA**

|  |  |
| --- | --- |
| **Section(s)** | **Associated Entry(ies)** |
| [**Social History (2.16.840.1.113883.10.20.22.2.17)**](#_Social_History_Section) | Smoking Status Observation (2.16.840.1.113883.10.22.4.78) |

**Table XX: R1.1 Social History Section Structure**

|  |
| --- |
| **Social History** |
| MAY **Social History Observation** |
| MAY **Pregnancy Observation** |
| SHOULD **Smoking Status Observation** |
| MAY **Tobacco Use** |

The structure of the Social History with coded entries required section is described hierarchically with corresponding entry-level constraints as specified in Section 2.66 of the Volume 2 R2.1 Consolidated CDA implementation guide.

**Table XX: 2.1 Social History Section (V3) Constraints Overview**

**[section (identifier: urnhl7ii:2.16.840.1.113883.10.20.22.2.17:2015-08-01)]**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **XPath** | **Cardinality** | **Verb** | **CONF#** | **Value** |
| templateId | 1..1 | SHALL | 1198-7936 |  |
| @root | 1..1 | SHALL | 1198-10449 | 2.16.840.1.113883.10.20.22.2.17 |
| @extension | 1..1 | SHALL | 1198-32494 | 2015-08-01 |
| code | 1..1 | SHALL | 1198-14819 |  |
| @code | 1..1 | SHALL | 1198-14820 | 29762-2 |
| @codeSystem | 1..1 | SHALL | 1198-30814 | urn:oid:2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1 |
| title | 1..1 | SHALL | 1198-7938 |  |
| text | 1..1 | SHALL | 1198-7939 |  |
| entry | 0..\* | MAY | 1198-7953 |  |
| observation | 1..1 | SHALL | 1198-14821 | Social History Observation (V3) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.38:2015-08-01 |
| entry | 0..\* | MAY | 1198-9132 |  |
| observation | 1..1 | SHALL | 1198-14822 | Pregnancy Observation (identifier: urn:oid:2.16.840.1.113883.10.20.15.3.8 |
| entry | 0..\* | SHOULD | 1198-14823 |  |
| observation | 1..1 | SHALL | 1198-14824 | Smoking Status - Meaningful Use (V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.78:2014-06-09 |
| entry | 0..\* | MAY | 1198-16816 |  |
| observation | 1..1 | SHALL | 1198-16817 | Tobacco Use (V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.85:2014-06-09 |
| entry | 0..\* | MAY | 1198-28361 |  |
| observation | 1..1 | SHALL | 1198-28362 | Caregiver Characteristics (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.72 |
| entry | 0..\* | MAY | 1198-28366 |  |
| observation | 1..1 | SHALL | 1198-28367 | Cultural and Religious Observation (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.111 |
| entry | 0..\* | MAY | 1198-28825 |  |
| observation | 1..1 | SHALL | 1198-28826 | Characteristics of Home Environment (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.109 |

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:1198-7936) such that it

a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.2.17" (CONF:1198-10449).

b. **SHALL** contain exactly one [1..1] **@extension**="2015-08-01" (CONF:1198-32494).

2. **SHALL** contain exactly one [1..1] **code** (CONF:1198-14819).

a. This code **SHALL** contain exactly one [1..1] **@code**="29762-2" Social History (CONF:1198-14820).

b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:1198-30814).

3. **SHALL** contain exactly one [1..1] **title** (CONF:1198-7938).

4. **SHALL** contain exactly one [1..1] **text** (CONF:1198-7939).

5. **MAY** contain zero or more [0..\*] **entry** (CONF:1198-7953) such that it

a. **SHALL** contain exactly one [1..1] **Social History Observation (V3)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.38:2015-08-01) (CONF:1198-14821).

6. **MAY** contain zero or more [0..\*] **entry** (CONF:1198-9132) such that it

a. **SHALL** contain exactly one [1..1] **Pregnancy Observation** (identifier: urn:oid:2.16.840.1.113883.10.20.15.3.8) (CONF:1198-14822).

7. **SHOULD** contain zero or more [0..\*] **entry** (CONF:1198-14823) such that it

a. **SHALL** contain exactly one [1..1] **Smoking Status - Meaningful Use (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.78:2014-06-09) (CONF:1198-14824).

8. **MAY** contain zero or more [0..\*] **entry** (CONF:1198-16816) such that it

a. **SHALL** contain exactly one [1..1] **Tobacco Use (V2)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.85:2014-06-09) (CONF:1198-16817).

9. **MAY** contain zero or more [0..\*] **entry** (CONF:1198-28361) such that it

a. **SHALL** contain exactly one [1..1] **Caregiver Characteristics** (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.72) (CONF:1198-28362).

10. **MAY** contain zero or more [0..\*] **entry** (CONF:1198-28366) such that it

a. **SHALL** contain exactly one [1..1] **Cultural and Religious Observation** (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.111) (CONF:1198-28367).

11. **MAY** contain zero or more [0..\*] **entry** (CONF:1198-28825) such that it

a. **SHALL** contain exactly one [1..1] **Characteristics of Home Environment** (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.109) (CONF:1198-28826).

### Vocabulary

Smoking Status **SHALL** use the values and SNOMED CT® codes listed in the table below. Please note that values for unknown or no value smoking statuses are specified by MU 2014 Edition, so null values are not used for missing information.

**Table XX: Smoking Status Codes**

|  |  |
| --- | --- |
| **Description** | **SNOMED CT® Code** |
| Current every day smoker | 449868002 |
| Current some day smoker | 428041000124106 |
| Former smoker | 8517006 |
| Never smoker | 266919005 |
| Smoker, current status unknown | 77176002 |
| Unknown if ever smoked | 266927001 |
| Heavy tobacco smoker | 428071000124103 |
| Light tobacco smoker | 428061000124105 |

## Vital Signs 8716-3 (Entries Optional)

### Structure

The structure of the Vital Signs with coded entries required section is described hierarchically with corresponding entry-level constraints as specified in Section 4.60 of the R1.1 Consolidated CDA implementation guide.

MAY contain zero or one [0..1] Vital Signs Section (entries optional) (templateId:2.16.840.1.113883.10.20.22.2.4) (CONF:9983).

The Vital Signs section contains relevant vital signs for the context and use case of the document template, such as blood pressure, heart rate, respiratory rate, height, weight, body mass index, head circumference, and pulse oximetry, temperature, and body surface area. The section should include notable vital signs such as the most recent, maximum and/or minimum, baseline, or relevant trends.

Vital signs are represented in the same way as other results, but are aggregated into their own section to follow clinical conventions.

**Table XX: R1.1 Vital Signs MU 2014 Edition Data Requirements in Consolidated CDA**

| **Section(s)** | **Associated Entry(ies)** |
| --- | --- |
| Vital Signs with coded entries optional (2.16.840.1.113883.10.20.22.2.4) | Vital Signs Organizer (2.16.840.1.113883.10.20.22.4.26)  Vital Signs Observation (2.16.840.1.113883.10.20.22.4.27) |
| **Vital Signs with coded entries required**  **(2.16.840.1.113883.10.20.22.2.4.1)** | Vital Signs Organizer (2.16.840.1.113883.10.20.22.4.26)  Vital Signs Observation (2.16.840.1.113883.10.20.22.4.27) |

**Table XX: R1.1 Vital Signs Section Structure**

|  |
| --- |
| **Vital Signs (entries required)** |
| SHALL **Vital Signs Organizer** |
| SHALL **Vital Sign Observation** |

The structure of the Vital Signs Section is described hierarchically with corresponding entry-level constraints as specified in Section 2.70.1Volume 2 R2.1 Consolidated CDA implementation guide.

**Table XX: 2.1 Vital Signs Section (entries optional) (V3) Constraints Overview**

**[section (identifier: urnhl7ii:2.16.840.1.113883.10.20.22.2.4:2015-08-01)]**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **XPath** | **Cardinality** | **Verb** | **CONF#** | **Value** |
| templateId | 1..1 | SHALL | 1198-7268 |  |
| @root | 1..1 | SHALL | 1198-10451 | 2.16.840.1.113883.10.20.22.2.4 |
| @extension | 1..1 | SHALL | 1198-32584 | 2015-08-01 |
| code | 1..1 | SHALL | 1198-15242 |  |
| @code | 1..1 | SHALL | 1198-15243 | 8716-3 |
| @codeSystem | 1..1 | SHALL | 1198-30902 | urn:oid:2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1 |
| title | 1..1 | SHALL | 1198-9966 |  |
| text | 1..1 | SHALL | 1198-7270 |  |
| entry | 0..\* | SHOULD | 1198-7271 |  |
| organizer | 1..1 | SHALL | 1198-15517 | Vital Signs Organizer (V3) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.26:2015-08-01 |

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:1198-7268) such that it

a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.2.4" (CONF:1198-10451).

b. **SHALL** contain exactly one [1..1] **@extension**="2015-08-01" (CONF:1198-32584).

2. **SHALL** contain exactly one [1..1] **code** (CONF:1198-15242).

a. This code **SHALL** contain exactly one [1..1] **@code**="8716-3" Vital Signs (CONF:1198-15243).

b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:1198-30902).

3. **SHALL** contain exactly one [1..1] **title** (CONF:1198-9966).

4. **SHALL** contain exactly one [1..1] **text** (CONF:1198-7270).

5. **SHOULD** contain zero or more [0..\*] **entry** (CONF:1198-7271) such that it

a. **SHALL** contain exactly one [1..1] **Vital Signs Organizer (V3)** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.26:2015-08-01) (CONF:1198-15517).

### Vocabulary

MU 2014 Edition requires the following vital signs to be captured:

height, weight, blood pressure, and BMI.

Vital Sign observations are recommended to be captured within coded entries of the Vital Signs section. While MU 2014 EDITION does not require a particular vocabulary, ToC recommends the use of Logical Observation Identifiers Names and Codes (LOINC®) to be consistent with Health IT Standards Committee (HIT SC) recommendations.

# Using CDA Documents to Meet the Needs of Care Transitions

**The goal of the approach is to address the needs of providers in a care transition, beyond Meaningful Use.**

The approach is informed by the collective efforts of the Transitions of Care Initiative to identify and define the core clinical information that should be exchanged in every patient care transition. The core clinical information includes MU 2014 EDITION requirements as the minimum data set and a robust set of clinical information to meet the needs of clinicians and ensure continuity of care for a given clinical scenario. The ToC recommended approach is the representation of core clinical information in Consolidated CDA.

## Handling Missing or Irrelevant Clinical Data

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

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

Many fields in C-CDA contain a “@nullFlavor” attribute, used to indicate an exceptional value. Some flavors of Null are used to indicate that the known information falls outside of value set binding constraints. Not all uses of the @nullFlavor attribute are associated with a case in which information is unknown.

Section 1.8.8 of the Consolidated CDA implementation guide details how to handle unavailable and unknown information. Further details can be found in the HL7 V3 Data Types Release 1 specification that accompanies the CDA R2 normative standards. However, it should be noted that the focus of Consolidated CDA is on the ambiguous representation of known data, and that in general, the often subtle nuances of unknown representation are less relevant to the recipient.

In HL7 V3, unavailable, unknown or incomplete data are handled with ‘flavors of null’ representing coded values that communicate the reasoning for missing information. Asserting a value for missing data is necessary where entries are required to meet validation. In addition, communicating reasons for missing data is important in other circumstances as good practice. Indicating null flavors at the appropriate level of precision to convey reasoning for missing required or expected data is encouraged. The null flavor vocabulary domain within the CDA R2 details the complete hierarchy of null flavor values.

### **Options for data that is temporarily unavailable**

For information that is not available at the time a CDA document is sent, the incomplete document may be sent even though it is not fully compliant. When the information is available to complete the document, a new document with a new object identifier (OID) is created and marked to communicate that it supersedes the previous version of the document.

### **Unknown data in sections that require entries**

**Asserting a null flavor at the section level for sections with entries required by the document template or MU2 data requirements is not permitted. These include sections detailing patient allergies, immunizations, medications, problems, procedures, and results. The machine-readable data required within these sections are specified for clinical best practice and should not be completely omitted. In these instances, unknown information may be used on the specific act, such as a Procedure Activity.**

**Additionally, text describing any reasoning for the unknown information and a code indicating the precise unknown information are encouraged. The key is to describe any unknown information as explicitly as possible to ensure accurate communication. Further guidance and examples are provided in Section 1.8.9 of the Consolidated CDA implementation guide. The CMS Final Rule for EHR Incentive Program, Stage 2 also reinforces this concept, as quoted below.**

**“In our proposed rule we went further and said that if the provider does not have the information available to populate one or more of the fields listed, either because they can be excluded from recording such information (for example, vital signs) or because there is no information to record (for example, laboratory tests), the provider may leave the field(s) blank. The only exception to this is the problem list, medication list, and medication allergy list”.**

**In other words, problems, medications, and medication allergies cannot simply be “left blank”, but must include the section and a null value describing the unknown data.**

### **None or "no known" data**

In scenarios where the data reflects a value of ‘none’, negation indicators should be used. Examples include stating that a patient has no allergies or that administrating a certain immunization is inadvisable (contraindication). For scenarios like these, a negation indicator (negationInd) is used to flag the actas described in the third example within Section 1.8.9 of the R1.1 Consolidated CDA implementation guide. Explicit codes for no known information, such as "no known allergies" within an Allergy Observation, are not recommended within Consolidated CDA. Rather, a negation indicator is to be used on the act along with a text description along with a code indicating the data that has no value. For the purposes of this guide, emphasis is on distinguishing between statements of ‘no known’, which employ negation indicators, and ‘I don’t know’, which employ null flavors.

### **Irrelevant (Not Pertinent) Data**

A circumstance where too much information or irrelevant data is provided presents opportunity for information overload and may have an undesirable impact on patient care. For example, MU2 requires the inclusion of medications. All current and active medications must be clear to the recipient, so detailing all historical medications is not recommended. Creators of CDA documents must be mindful of the purpose of the document as well as the intended use so that only clinically relevant data is sent.

## Use of NULL Flavors and Negation Indicators

To communicate unknown, not relevant, or not computable or measurable data, the following practices are recommended for the approach.

1. Any **SHALL** conformance statement may use a null flavor to indicate unknown data, unless the attribute is required or the null flavor is explicitly disallowed.
2. **SHOULD** and **MAY** conformance statement may also use a null flavor.
3. Negation indicators **SHALL** be used for any required attribute reflecting the assertion of "no known" data (e.g., "no known allergies").

It is recommended to use the HL7 null flavor that most precisely describes the reason, e.g., ASKU (asked but unknown) is more precise than UNK (unknown), and NAV (temporarily unavailable) is more precise than ASKU (e.g., patient was asked and did not know, but will find out the answer). Additional guidance on null flavors and negation indicators are provided in section 5 of this guide and Sections 1.8.8 and 1.8.9 of the Consolidated CDA implementation guide.

Section 3.6 of the C-CDA R2.1 Volume 1 guide provides further details on using null flavors for unknown, required, or optional attributes:

NI No information. This is the most general and default null flavor.

NA Not applicable. Known to have no proper value (e.g., last menstrual period for a male).

UNK Unknown. A proper value is applicable, but is not known.

ASKU Asked, but not known. Information was sought, but not found (e.g., the patient was asked but did not know).

NAV Temporarily unavailable. The information is not available, but is expected to be available later.

NASK Not asked. The patient was not asked.

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

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

The list above contains those null flavors that are commonly used in clinical documents. For the full list and descriptions, see the nullFlavor vocabulary domain in the CDA R2 normative edition.10. In addition, examples of these nullFlavor can also be found in the HL7 C-CDA Implementation Guide R2.1 Volume 1, Section 3.6.

# Meaningful Use 2015 Edition CEHRT Alignment

## Transitions of Care §170.315

The eHealth Exchange chose to align this content testing program with Meaningful Test Methods to ease the burden of implementers and their vendors. While vendor products have been certified for meaningful use with the Transitions of Care criteria, there appears to be variability regarding what is configured and implemented across the nation today with participants of the eHealth Exchange. The testing workgroup chose to align with the 2015 Testing and Test Methods. Detailed information regarding the full Meaningful Use Requirements can be found here: <https://www.healthit.gov/policy-researchers-implementers/2015-edition-test-method>.

The testing workgroup acknowledges that transport testing is currently covered by the existing programs and has modified the test procedures to only require the content related testing for create and receive content.

Transitions of Care Criterion for Eligible Professionals (EP) and Eligible Hospitals (EH).

1. Eligible Provider (EP) Objective:The EP who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary of care record for each transition of care or referral
2. Eligible Hospital(EH) Objective: The EH that transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary of care record for each transition of care or referral

## Referenced MU 2015 EDITION Guides and Data Requirements

The 2015 Ed. CEHRT specifies summary types that include MU 2015 EDITION data requirements to be formatted using Consolidated CDA for the objective. Please note that these test procedures have been reduced to eliminate transport testing at this time as it is covered by the existing Smoke and Security tests required by participants and product vendors. The references below are for the 2015 Edition Meaningful Use Certification program sponsored by ONC.

**Table XX: Common Clinical Data Set Summary Record - create**

|  |  |
| --- | --- |
| 2015 CEHRT Criterion | Summary Type |
| 2015 Edition Certification Companion Guide Common Clinical Data Set Summary Record – create – 45 CFR 170.315(b)(4) | <https://www.healthit.gov/sites/default/files/2015Ed_CCG_b4-CCDS-summary-record-create.pdf> and;  https://www.healthit.gov/sites/default/files/170\_315b4\_common\_clinical\_data\_set\_summary\_record-create\_v1\_0.pdf |
| 2015 Edition Certification Companion Guide | https://www.healthit.gov/sites/default/files/2015ed\_ccg\_g6-ccda-creation-performance\_1.pdf |
| 2015 Edition Common Clinical Data Set – 45 CFR 170.102 | https://www.healthit.gov/sites/default/files/2015Ed\_CCG\_CCDS.pdf |
| 2015 Edition Common Clinical Data Set (CCDS) Reference Document | https://www.healthit.gov/sites/default/files/ccds\_reference\_document\_v1\_0.pdf |
| 2015 Edition § 170.315(g)(6) Consolidated CDA Creation Performance | https://www.healthit.gov/sites/default/files/170\_315g6\_consolidated\_cda\_creation\_performance\_v1\_0\_3.pdf |

**Table XX: Common Clinical Data Set Summary Record – receive**

|  |  |
| --- | --- |
| 2015 CEHRT Criterion | Summary Type |
| 2015 Edition Certification Companion Guide Common Clinical Data Set Summary Record – receive – 45 CFR 170.315(b)(5) | https://www.healthit.gov/sites/default/files/2015Ed\_CCG\_b5-CCDS-summary-record-receive.pdf |
| 2015 Edition Certification Companion Guide | https://www.healthit.gov/sites/default/files/2015ed\_ccg\_g6-ccda-creation-performance\_1.pdf |
| 2015 Edition Common Clinical Data Set – 45 CFR 170.102 | https://www.healthit.gov/sites/default/files/2015Ed\_CCG\_CCDS.pdf |
| 2015 Edition Common Clinical Data Set (CCDS) Reference Document | https://www.healthit.gov/sites/default/files/ccds\_reference\_document\_v1\_0.pdf |
| 2015 Edition § 170.315(g)(6) Consolidated CDA Creation Performance | https://www.healthit.gov/sites/default/files/170\_315g6\_consolidated\_cda\_creation\_performance\_v1\_0\_3.pdf |

# Testing Tools

During the pilot phase planned for April – June 2016, multiple tooling offerings will be vetted with static documents to determine requirements coverage and gaps for the overall level of testing outlined within this testing document. This section will be updated upon findings from the tooling pilot to be conducted in parallel with the documentation pilot testing with voluntary requests from existing eHealth Exchange Participants. The following tools will be considered during the pilot phase, but this list is subject to change upon recognition of new tooling being available that would benefit this program in general:

## Art décor/Gazelle Objects Checker

IHE Services in Europe have bundled Art Décor with Gazelle Objects Checker for CDA Conformance Testing as part of the IHE International Scheme Testing. The tooling was piloted in April 2015 with the first vendors receiving certification reports. The tooling is ISO 17025 Compliant for Conformity Assessment, but covers only the HL7 C-CDA CCD R1.1 and R2.0 versions presently. Initial testing of this tool has shown it reports on warnings and errors not found by other testing tooling to be used by this pilot/program. Testing for version HL7 C-CDA CCD 2.1 will be added to this tooling during the pilot for participants to leverage..

(<http://gazelle.ihe.net/content/gazelle-objectschecker)>

## Diameter Health

Diameter Health is focused on using C32 CCDs and C-CDA 1.1 documents as the fuel for its application suite and is actively working with both health systems and HIEs on a software application called “CCD Analyzer”. The CCD Analyzer tool has 200+ rules that grade C32/C-CDA for semantic and clinical completeness and syntax, focusing on the primary sections that are required by Meaningful Use. Diameter Health focuses on things that are not simple schema/schematron rules available in in the NIST TTT and NIST ETT tools. This tool is proprietary, but Sequoia staff will provide the pilot participants a report to include feedback from this tooling. ([www.diameterhealth.com)](http://www.diameterhealth.com))

## SITE: Standards Implementation & Testing Environment – C-CDA Sandbox

The Standards Implementation & Testing Environment (SITE) is a centralized collection of tools and resources designed to assist the developers and implementers of Health Information Technology standards in their efforts to adopt EHR standards and achieve interoperability. SITE is divided into sandboxes, one for each supported standard. The Consolidated CDA (C-CDA) Sandbox will be evaluated. Please note that this tooling will continue to be updated during the pilot period with improvements from the HL7 work underway currently and from this pilot’s feedback. (<http://sitenv.org/c-cda)>

# CCD C-CDA Content Test Procedures & Test Data

## Test Procedures

### TC: CCDA-CCD-CREATE-0001.0 HL7 C-CDA CCD record – create

#### Preconditions

This test method will validate that the system under test (SUT) can create a transition of care/referral summary formatted in accordance with the standards and guidance referenced in the 2016 content testing package documentation. This will include document-template conformance that demonstrates a valid implementation of the HL7 C-CDA CCD document template for HL7 C-CDA CCD R1.1 and/or R2.1.

In addition, the document created will be scored for vocabulary conformance to the required vocabulary standards (and value sets). These value sets and vocabulary standards can be found referenced to the 2014 or 2015 ONC requirements here:

* <https://www.healthit.gov/policy-researchers-implementers/meaningful-use-stage-2-0/standards-hub>

It is recommended that health IT developers and providers follow the guidance provided in the HL7 Implementation Guide: S&I Framework Transitions of Care Companion Guide to Consolidated-CDA for Meaningful Use Stage 2, Release 1 – US Realm. This Companion Guide includes industry best practices guidance for consistent implementation of the C- CDA Release 1.1 standard, including mapping Common MU Data Set elements into the C-CDA standard. HL7 is developing a Companion Guide for C-CDA Release 2.1 and the eHealth Exchange Testing Workgroup intends to update this document once it becomes publicly available. In the meantime, we recommend developers follow the guidance provided by the HL7 CDA Example Task Force for implementation of the C- CDA Release 2.1 standard.

#### Data Load Set – [TC: CCDA-CCD-CREATE-0001.0 HL7 C-CDA CCD record – create](https://ehealth-exchange-testing.wikispaces.com/file/view/170.315_b4_ccds_create.zip/579820043/170.315_b4_ccds_create.zip)

The System Under Test will determine if they wish to test Inpatient or Ambulatory or Both and choose the corresponding test data found in the file linked above. This zip file linked above contains both inpatient and ambulatory data to be used by systems under test.

Inpatient:

* 170.315\_b4\_ccds\_create\_inp\_sample1\_v1.pdf
* 170.315\_b4\_ccds\_create\_inp\_sample2\_v1.pdf

Ambulatory:

* 170.315\_b4\_ccds\_create\_amb\_sample1\_v1.pdf
* 170.315\_b4\_ccds\_create\_amb\_sample2\_v1.pdf

Negative Tests: NT\_\*\_r11\*.xml NT\_\*\_r21\*.xml (not in scope for the pilot)

#### Test Tools

* + 1. Edge Testing Tool (ETT) https://edge.nist.gov/ett/#/validators
    2. SITE Testing Tools <http://sitenv.org/c-cda-validator>
    3. Gazelle/Objects Checker <https://gazelle.ihe.net/EVSClient/cda/validator.seam?extension=C-CDA>
    4. Diameter Health CCD Analyzer reports will be provided by Sequoia Staff during the pilot

#### Test Steps

1. SUT uses the specified Test Data - Set that matches the type they will be testing and produces an HL7 C-CDA CCD Document. The naming convention for the file should be “[Applicant Name]\_CCDA\_[Type]\_CCD\_submission[x]” where ‘Type’ is either Inpatient or Ambulatory and ‘x’ is the attempt number.
2. Applicant emails the C-CDA Message File to [testing@sequoiaproject.org](mailto:testing@sequoiaproject.org).
3. eHeallth Exchange tester downloads the Applicant’s C-CDA CCD document file from the email to the Applicants Box folder.
4. eHealth Exchange tester uploads and validates the SUT CCD file(s) against the following tools:
   * + - 1. [NIST Edge Testing Tool (ETT)](http://edge.nist.gov/ett/#/home) (compliance with specs + MU 2014 EDITION/R1.1)
     1. <http://edge.nist.gov/ett/#/validators>
     2. eHealth Exchange tester determines which validator to use (CCDA R1.1) based on survey form answers (
     3. File is uploaded after appropriate Inpatient and/or Ambulatory choices are checked in the validator.



AND/OR



1. [NIST Edge Testing Tool (ETT)](http://edge.nist.gov/ett/#/home) (compliance with specs \_ MU 2015 EDITION)
2. <http://edge.nist.gov/ett/#/home> eHealth Exchange Tester selects appropriate choices that must be one of the following for step #3 of the tool for Sender SUT Test Data from Survey form:
   * + 1. 170.315\_b4\_CCDS\_Amb
       2. 170.315\_b4\_CCDS\_Inp
3. eHealth Exchange Tester uploads file received from SUT and clicks validate
4. A summary of this tooling report is included in the SUT Summary report
5. eHealth Exchange tester uploads and validates the SUT CCD file(s) against the following tools:
6. eHealth Exchange tester uploads uploads and validates the SUT CCD file(s) against the following tools as determined by the submission form:
   * + - 1. [Standards Implementation Testing Environment (SITE)](http://sitenv.org/c-cda-validator) (compliance with specs + MU 2014 EDITION + smart quality scoring

<http://sitenv.org/c-cda-validator>

eHealth Exchange tester determines which validator to use (CCDA R1.1) based on survey form answers for Ambulatory or Inpatient

R1.1 = Transitions of Care Ambulatory Summary – 170.314(b)(2) Transition of Care/Referral Summary – For Ambulatory

R1.1 = Transitions of Care Inpatient Summary – 170.314(b)(2) Transition of Care/Referral summary – For Inpatient

File is uploaded after appropriate Inpatient and/or Ambulatory choices are checked in the validator and Validate Document Blue Box is clicked.

Validation Report will open in a separate window and provide a C-CDA Validation Summary. In order to also have this tool provide a scorecard, scroll to the bottom of the report past all informational feedback and click the Smart C-CDA Validation Button.



eHealth Exchange tester saves the results from the validation report to the SUT folder on Box.

1. [Standards Implementation Testing Environment (SITE)](http://sitenv.org/c-cda-validator) (compliance with specs + MU 2015 EDITION + smart quality scoring

<http://sitenv.org/c-cda-validator> - select Sender for #1 of Directions

eHealth Exchange tester selects which validator to use (CCDA R2.1) based on survey form answers for Ambulatory or Inpatient

170.315)b4\_CCDS\_Amb

170.315\_b4\_CCDS\_Inp

eHealth Exchange tester selects which sample corresponds to test data used by SUT.

Inpatient 170.315\_b4\_ccds\_create\_inp\_sample1\_v5.pdf

Inpatient 170.315\_b4\_ccds\_create\_inp\_sample2\_v5.pdf

Ambulatory 170.315\_b4\_ccds\_create\_amb\_sample1\_v5.pdf

Ambulatory 170.315\_b4\_ccds\_create\_amb\_sample2\_v5.pdf

* + - * 1. File is uploaded after appropriate Inpatient and/or Ambulatory choices are checked in the validator and Validate Document Blue Box is clicked.
        2. Validation Report will open in a separate window and provide a C-CDA Validation Summary. In order to also have this tool provide a scorecard, scroll to the bottom of the report past all informational feedback and click the Smart C-CDA Validation Button.

1. [Gazelle External Validation Service](https://gazelle.ihe.net/EVSClient/cda/validator.seam?extension=C-CDA) for Sequoia C-CDA Release 1.1 & Release 2.1 Validators (No MU coverage but provides additional CDA validation not covered currently by ETT and SITE
   * + - 1. eHealth Exchange tester uploads XML sample file and selects appropriate validator for C-CDA Release 1.1 or 2.0
2. Enhanced smart quality scoring via Diameter Health CCD Analyzer
   * + - 1. eHealth Exchange tester uploads XML sample file to CCD Analyzer
         2. eHealth Exchange testers saves report to box and summarizes all findings to the summary report and provides it to the SUT Primary Point of Contact as stated in the submission form.
3. eHealth Exchange Tester performs visual inspection of XML Document Sample(s) to verify the requirements as outlined in the 2014 and/or 2015 Edition Common Clinical Data Set (CCDS) Reference Document Version 1.0
   1. Required 2014 Edition Reference Test Lab Verification (Page 2) AND/OR
   2. Optional 2015 Edition Reference Test Lab Verification (Page 10)

The Summary Report will include all errors, warnings and a summary of overall findings and scorecard results to the primary point of contact identified on the submission form.

Applicant has the ability to fix the errors and resubmit to [testing@sequoiaproject.org](mailto:testing@sequoiaproject.org).

The document created will be validated for the data included in the Common Clinical Data Set definition below and following the guidance in the ccds\_reference\_document\_v1\_0.pdf in the testing documentation package:

1. Participant to create a transition of care/referral summary formatted in accordance with with HL7 C-CDA Continuity of Care Document (CCD) template R1.1 and optionally for R2.1 that includes, at a minimum:
   * 1. The Common Clinical Data Set –means the following data expressed:
        1. Patient name (C-CDA R2.1 allows suffix to be included as an additional qualifier to the last name field
        2. Sex
        3. Date of birth
        4. Race
        5. Ethnicity
        6. Preferred language
        7. Smoking status
        8. Problems
        9. Medications
        10. Medication allergies
        11. Laboratory test(s)
        12. Laboratory value(s)/result(s)
        13. Vital signs
            1. Patient’s diastolic blood pressure
            2. Patient’s systolic blood pressure
            3. Body height
            4. Body weight
            5. Heart rate
            6. Respiratory rate
            7. Body temperature
            8. Pulse Oximetry
            9. Inhaled oxygen concentration must be exchanged in numerical values only and with the associated applicable unit of measure for vital sign measurement in this documentation.
            10. Optional: The patient’s BMI percentile per age and sex for youth 2-20 years of age, weight for age per length and sex for children less than 3 years of age, and head occipital-frontal circumference for children less than 3 years of age must be recorded in numerical values only in accordance with the standard specified in [Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.52, Released June 2015](http://loinc.org/downloads) and with the associated applicable unit of measure for the vital sign measurement in the standard specified in The Unified Code of Units of Measure, Revision 1.9, October 23, 2013.
     2. Encounter diagnosis (included encounter diagnoses using either ICD-10-CM or SNOMED CT codes)
     3. Cognitive status
     4. Functional status
     5. **Ambulatory setting only**. The reason for referral; and referring or transitioning provider’s name and office contact information
     6. **Inpatient setting only**. Discharge instructions
     7. Patient matching data. First name, last name, previous name, middle name (including middle initial), suffix, date of birth, address, phone number, and sex. The following constraints apply:
        1. Date of birth constraint
           1. The year, month and day of birth must be present for a date of birth. The technology must include a null value when the date of birth is unknown.
           2. Optional. When the hour, minute and second are associated with a date of birth the technology must demonstrate the correct time zone offset is included.
        2. Phone number constraint. Represent phone number (home, business, cell) in accorded with the associated documentation. All phone numbers must be included when multiple phone numbers are present.
        3. Sex constraint. Represent sex in accordance with the associated documentation.
     8. Optional. The SUT can create a C-CDA (formatted to Release 2.1) that includes encounter diagnoses using either ICD-10-CM or SNOMED CT© codes (International Health Terminology Standards Development Organization (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) U.S. Edition, September 2015 Release). SUT can present a more recent version of SNOMED CT®, U.S. Edition than the September 2015 Release to a more recent version of certain vocabulary standards.
     9. Optional. The SUT can create a C-CDA that includes cognitive status. The C-CDA Cognitive Status Observation template has been deprecated in Release 2.1 and has been replaced with the Mental Status Observation template. Developers should use the Mental Status Observation template for cognitive status and be aware that the C-CDA validator will issue an error if the deprecated Cognitive Status Observation is used instead.
     10. Optional. The SUT can create a C-CDA (formatted to Release 2.1) that includes functional status.
     11. Optional. The SUT can create a C-CDA (formatted to Release 2.1) that includes certain data to assist with patient matching. Unless otherwise specified, the SUT should follow the guidance in C-CDA Release 2.1 for formatting the data. C-CDA Release 2.1 allows suffix to be included as an additional quality to the last name field. We recommend receiving systems follow the guidance in CAQH Phase II Core 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule version 2.1.0 for normalizing last name before sending ToC/referral summary documents. “Previous name” is intended to capture situations where a patient may use an alias (e.g., maiden name, family name, legally changed last name). C-CDA 2.1 cannot distinguish between historical and current address, but can accommodate more than one address. The C-CDA validation tool will test adherence to the use of the HL7 postal format for address.

### TC: CCDA-CCD-RECEIVE-0001.0 HL7 C-CDA CCD record – RECEIVE

1. **Receive.** The eHealth Exchange tester uses visual inspection to verify that the Heatlh IT Module can successful receive the applicable types of transitions of care/referral summaries for each CCS summary record document received by the Health IT Module either as a
2. C-CDA R1.1 document formatted as a CCD or a C-CDA with no specific document template according to the standards outlined in this testing package; or
3. C-CDA R2.1 formatted in accordance with the standard specified in § 170.205(a)(4) as a Continuity of Care, Referral Note or (for inpatient setting only) as a Discharge Summary.
4. For each CCDS summary record document received by the SUT, the tester verifies the content specified in (b)(5)(i)(A-F) as applicable, using Visual Inspection.

|  |  |  |
| --- | --- | --- |
| **Criteria (b)(5)(i) (A-F)** | **System Under Test** | **Test lab Verification** |
| (i)(A) | The Common Clinical Data Set  Each of these documents includes, at a minimum, the Common Clinical Data Set as specified in the CCDS Reference Document for C-CDA R2 R1.1 or C-CDA R2 R2.1, as applicable. | The tester verifies the applicable types of transitions of care/referral summaries received in (b)(5)(i) include the following data elements, as applicable:  • Common Clinical Data Set in accordance with the CCDS Reference Document for either C-CDA R2 R1.1 or C-CDA R2 R2.1 based upon the document type received. |
| (i)(B) | Encounter Diagnoses  The transition of care/referral summary received in (b)(5)(i) includes at a minimum encounter diagnoses using at least one standard, either   * the standard specified at §170.207(i), code set specified at 45 CFR 162.1002(c)(2) for the indicated conditions or the standard specified at § 170.207(a)(4). ICD-10-CM as maintained and distributed by HHS, for the following conditions:   1. (i)  Diseases;   2. (ii)  Injuries;   3. (iii)  Impairments;   4. (iv)  Other health problems and their   manifestations; and   * 1. (v)  Causesofinjury,disease,impairment,orother   health problems;   * or at a minimum the version of the standard   specified at §170.207 | The verification of the applicable types of transitions of care/referral summaries received in (b)(5)(i) includes the following data element in accordance to the standard adopted in § 170.205(a)(3) or § 170.205(a)(4):  • Encounter diagnoses, formatted in accordance to one of the following standards:   1. The standard specified in § 170.207(i). 2. At a minimum, the standard specified in § 170.207(a)(4). |
| (i)(C ) | Cognitive Status  The transition of care/referral summary received in (b)(5)(i) includes the Cognitive Status, when present, in the C-CDA R2 R1.1 or C-CDA R2 R2.1 document. | The verification of the applicable types of transitions of care/referral summaries received in (b)(5)(i) includes the Cognitive status, when present, in accordance to the standard adopted in § 170.205(a)(3) or § 170.205(a)(4). |
| (i)(C ) | Functional Status  The transition of care/referral summary received in (b)(5)(i) includes the Functional Status when present in the C-CDA R2 R1.1 or C-CDA R2 R2.1 document. | The verification of the applicable types of transitions of care/referral summaries received in (b)(5)(i) includes the Functional Status when present in accordance to the standard adopted in § 170.205(a)(3) or § 170.205(a)(4) as applicable. |
|  | Ambulatory setting only  For the ambulatory setting only, the transition of care/referral summary received in (b)(5)(i) includes, at a minimum:   * reason for referral; * referring or transitioning provider’s name; and * office contact information. | For the ambulatory setting only, the verification of the applicable types of transitions of care/referral summaries received in(b)(5)(i) includes the following data elements in accordance to the standard adopted in § 170.205(a)(3) or § 170.205(a)(4) as applicable:  • • •  reason for referral; referring or transitioning provider’s name; and  office contact information. |
|  | Inpatient setting only  For the inpatient setting only, the transition of care/referral summary received in (b)(5)(i) includes the discharge instructions. | For the inpatient setting only, the verification of the applicable types of transitions of care/referral summaries received in (b)(5)(i) includes the discharge instructions in accordance to the standard adopted in § 170.205(a)(3) or § 170.205(a)(4) as applicable. |

* 1. **Display.** HIT Module technology must be able to electronically display in human readable format the data included in transition of care/referral summaries received and formatted according to any of the following standards (and applicable implementation specifications) specified in: § 170.205(a)(3), and § 170.205(a)(4).
  2. Display section views. Allow for individual display of each section (and the accompanying document header information) that is included in the transition of care/referral summary received and formatted in accordance with the standards adopted in § 170.205(a)(3), and § 170.205(a)(4) in a manner that enables the user to:
     1. Directly display only the data within a particular section;
     2. Set a preference for the display order of specific sections; and
     3. Set the initial quantity of sections to be displayed..
  3. **Test Data** 
     1. Inpatient Setting - 170.315\_b5\_ccds\_inp\_\*\_r21\_ sample\*.xml (all samples)
     2. 170.315\_b5\_ccds\_inp\_\*\_r11\_ sample\*.xml (all samples) Ambulatory Setting - 170.315\_b5\_ccds\_amb\_\*\_r21\_sample\*.xml (all samples)
     3. 170.315\_b5\_ccds\_amb\_\*\_r11 \_sample\*.xml (all samples)

The overall goal for mirroring the 2015 Edition Meaningful Use Test Procedures above is to ensure the participant organization can share robust clinical data. Therefore, the following will be tested by leveraging the same associated test data to verify the participant has the capabilities properly implemented and configured among all connected stakeholders.

# Appendix A: C-CDA CCD Implementation FAQs

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| **Index** | **Questions** | **Category** |
| 1 | How does a CCDA implementer differentiate in the structured entries between different sub-sections of the Results section, like lab (chemistry/hematology, radiology, pathology, etc.? This is particularly important if the receiver needs to parse out the different sub-sections, and present them to a user in different tabs of their GUI. | CCD Results |
| 2 | Where do I include clinical notes in a summary of care document - e.g., encounters, procedures, results sections? | General - Notes |
| 3 | When I issue a query for a date range what sections in a summary of care should the range be applied against? | General CCD |
| 4 | Is a summary of care or continuity of care document based on a single encounter, multiple encounters, episodic of care? | General - CCD |
| 5 | Do I use the summary of care or continuity of care document like a table of content referring to specific other documents for the detailed clinical notes? other documents might be a discharge summary, operative note, progress lab, labs? Or, can on include clinical notes/reports inside the CCD health summary? | General - Notes |
| 6 | How do I handle external references that may cross security contexts? | General - Links |
| 7 | For a query, how do I deem what is the minimal necessary information required to satisfy a request? | General - data limits |
| 8 | How is embedded formatting handled within text elements? | General - Notes |
| 9 | What consistency should be enforced between the narrative block and the structured entries? | General - Narratives |
| 10 | What date ranges or max number of occurrences should be applied to each section of the CCD? | same as #7 |
| 11 | How do we prevent duplicative information within the CCD? How do we deal with the presence of duplicate information within the CCD? | General - CCD dup data |
| 12 | What happens when the CCD is simply too large due to "excessive" amounts of data contained therein--for instance, what if everything is simply "stuffed" into the summary of care section? Should the summary of care section, as a matter of best practice, be advised to serve as an index into other sections/areas that contain the relevant data? | General - CCD size |
| 13 | What is the minimal set of metadata that a Content Consumer should display from a query response to help providers have sufficient information to choose from the returned list? | General - metadata |
| 14 | Some provider comments recently are: It is just a CCD….where is the narrative? Where are the operative and procedure notes? | General - Notes |
| 15 | How do we encourage the industry to move beyond the use of the CCD document type of C-CDA R1.1? What would encourage the use of the other document types? Relates to the question above on where is the narrative? | General –  other CCDA templates |
| 16 | How do we handle versioning? | General - versioning |
| 17 | How do we handle consistency of meta-information for class and type codes? | QD - doc class code |
| 18 | Too many documents response to queries. What is the best set of filters (metadata constraints) in order to reduce the size of the query response? | QD response |
| 19 | How do systems handle query response for content and/or document types that a Content Consumer cannot handle? What is done to prevent errors from happening for content that a Consumer cannot handle? Are content that cannot be handled filtered out of the query responses before display? | QD response |
| 20 | Lack of basic understanding and consistent implementation on service start and stop (to/from) for a query? | Query for Doc |
| 21 | Is there general recognition that it is not programatically feasible to determine whether or not the content of an On-Demand Document Entry has previously been retrieved? This is sometimes a surprise to Community implementations where some endpoints wish to determine from query response whether or not to retrieve content. | RD response |
| 22 | Has there been any use of metadata (submission sets attribute/folder) to associate, for instance a C62 (unstructured document) with a C32? [This is not the same as the XDS Submission Set attribute provided as part of the QD process] | same as #6 |
| 23 | We are also interested in how to get participant test systems to a place where they are better ready to test with each other after they complete the current eHealth Exchange testing conducted within the Developers Integration Lab (DIL) testing environment. For instance, how much of certification is happening with harnesses or limited systems & does it really test the actual software/systems that would be used | Testing |
| 24 | How do systems support Unstructured Document? Are systems capable of opening the package and displaying the wrapped content? | Unstructured CCDA |

1. Taken from section 1.2.3 of the CDA R2 specification available through HL7. [↑](#footnote-ref-2)
2. International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10 CM) [↑](#footnote-ref-3)
3. [http://minorityhealth.hhs.gov/templates/ content.aspx?ID=9228#4](http://minorityhealth.hhs.gov/templates/content.aspx?ID=9228#4) [↑](#footnote-ref-4)
4. Health Care Financing Administration Common Procedure Coding System [↑](#footnote-ref-5)
5. Current Procedural Terminology, Fourth Edition [↑](#footnote-ref-6)
6. International Classification of Diseases, 10th Revision, Procedure Coding System [↑](#footnote-ref-7)
7. Code on Dental Procedures and Nomenclature [↑](#footnote-ref-8)