|  |
| --- |
| **eHealth Exchange** |
| **2015 Consolidated CDA (C-CDA) Continuity of C­are Document (CCD) Test Cases v0.2** |



|  |
| --- |
| eHealth Exchange Testing Workgroup  11/5/2015 |

**Change Log**

|  |  |  |
| --- | --- | --- |
| **Date** | **Version** | **Description** |
| 11/2/2015 | Initial Draft v0.1 | Initial rough draft |
| 11/5/2015 | Version 0.2 | Added comments and fixed formating and font issues found and updated table of contents. |
|  |  |  |
|  |  |  |

Table of Contents

[1.1 Introduction 4](#_Toc434460283)

[1.2 Use Case Scenarios 5](#_Toc434460284)

[1.2.1 Use Case 1: Hospital Discharge 5](#_Toc434460285)

[1.2.2 Use Case 2: Provider to Provider Referral 5](#_Toc434460286)

[1.2.3 Use Case 3: Unplanned TOC – ED Summary 5](#_Toc434460287)

[1.2.4 Use Case 4: Single Encounter Summary 5](#_Toc434460288)

[1.2.5 Use Case 5: Multiple episode push or inquiry document 5](#_Toc434460289)

[1.3 Standards and Implementation Guides Referenced 5](#_Toc434460290)

[1.3.1 HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial Use 5](#_Toc434460291)

[1.3.2 HL7 Implementation Guide: S&I Framework Transitions of Care Companion Guide to Consolidated-CDA for Meaningful Use Stage 2, Release 1 – US Realm 5](#_Toc434460292)

[1.4 Testing Approach 5](#_Toc434460293)

[1.4.1 Testing Process 6](#_Toc434460294)

[1.4.2 eHealth Exchange Testing Plan 7](#_Toc434460295)

[1.4.3 Pilot Timeline Plan implementation 7](#_Toc434460296)

[1.4.4 Outstanding Questions 8](#_Toc434460297)

[1.5 Continuity of Care Document (CCD) Conformance Verbs 8](#_Toc434460298)

[1.5.1 Template – Driven Approach 9](#_Toc434460299)

[1.5.2 Overall Document Testable Assertions: 10](#_Toc434460300)

[1.6 Assessing Consolidated CDA Documents 12](#_Toc434460301)

[1.6.1 ONC TOC Consolidated CDA IG Chapter References 13](#_Toc434460302)

[1.6.2 Header Constraints Specific to CCD 14](#_Toc434460303)

[1.7 Consolidated CDA (CCD) Section Requirements & Meaningful Use Requirements 19](#_Toc434460304)

[1.7.1 CCD Section-Level Templates 19](#_Toc434460305)

[1.7.2 Section-Level Testable Assertions 19](#_Toc434460306)

[1.7.3 Transitions of Care Recommended CCD Body Constraints 20](#_Toc434460307)

[1.7.4 Advance Directives (entries optional) 22](#_Toc434460308)

[1.7.5 Allergies (Entries Required) 22](#_Toc434460309)

[1.7.6 Encounters (Entries Optional) 24](#_Toc434460310)

[1.7.7 Family History 25](#_Toc434460311)

[1.7.8 Functional Status (Required) 26](#_Toc434460312)

[1.7.9 Immunizations (Entries Optional) 30](#_Toc434460313)

[1.7.10 Instructions 32](#_Toc434460314)

[1.7.11 Medical Equipment (Optional) 33](#_Toc434460315)

[1.7.12 Medications 34](#_Toc434460316)

[1.7.13 Payers 35](#_Toc434460317)

[1.7.14 Plan of Care or Assessment and Plan 36](#_Toc434460318)

[1.7.15 Problem (Entries Required) 39](#_Toc434460319)

[1.7.16 Procedures (Entries Required) 39](#_Toc434460320)

[1.7.17 Reason for Referral 40](#_Toc434460321)

[1.7.18 Reason for Visit or Chief Complaint or Chief Complaint and Reason for Visit 40](#_Toc434460322)

[1.7.19 Results (Entries Required) 42](#_Toc434460323)

[1.7.20 Social History 43](#_Toc434460324)

[1.7.21 Vital Signs (Entries Optional) 44](#_Toc434460325)

[1.8 Using CDA Documents to Meet the Needs of Care Transitions 45](#_Toc434460326)

[1.8.1 Handling Missing or Irrelevant Clinical Data 45](#_Toc434460327)

[1.8.2 Use of NULL Flavors and Negation Indicators 46](#_Toc434460328)

[1.9 Meaningful Use 2014 Edition CEHRT Alignment 46](#_Toc434460329)

[1.9.1 Transitions of Care §170.314 (b)(1) & (2) 46](#_Toc434460330)

[1.9.2 MU 2014 EDITION Summary Types and Data Requirements 47](#_Toc434460331)

[1.10 Testing Tools 49](#_Toc434460332)

[1.10.1 Art décor/Gazelle Objects Checker 49](#_Toc434460333)

[1.10.2 Diameter Health 49](#_Toc434460334)

[1.10.3 MU 2014 Edition Transport Testing Tool (TTT) 49](#_Toc434460335)

[1.10.4 SITE: Standards Implementation & Testing Environment – C-CDA Sandbox 49](#_Toc434460336)

[1.10.5 Smart C-CDA Scorecard 49](#_Toc434460337)

[1.10.6 Stella Content Validation Tool 50](#_Toc434460338)

[CCD C-CDA Content Test Procedures & Test Data 51](#_Toc434460339)

**eHealth Exchange 2015 C-CDA Continuity of Care Document Content Testing Profile v0.1**

## Introduction

The eHealth Exchange continues to support the content requirements and specifications defined within the 2014 Edition Meaningful Use program. 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. In addition, this content testing documentation adds the additional content requirements from the Transitions of Care Implementation guidance published by HL7. It defines one document type know as the Continuity of Care Document (CCD) that may be exchanged by nodes among the eHealth Exchange participants to address particular use cases or business needs. The eHealth Exchange participants act as nodes on the eHealth Exchange 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.

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 Testing Workgroup will work with the specification factory to recommend an overall timeline to include the pilot phase and recommendation for when these test procedures should be considered required for all participants. The Coordinating Committee will review the recommendation and associated information gathered from the pilot testing to recommend and approve an overall timeline for these requirements. In addition, this documentation leverages the test procedures for evaluating conformance to the certification criteria defined in 45 CFR Part 170 Subpart C of the Health Information Technology, Final Rule as published in the Federal Register on September 4, 2012. It references the Testing and Test Methods for the 2014 Edition Test Methods for the following (see page 52 for full test procedure definitions):

1. [Test Procedure for §170.314 (b)(1) Transitions of care – receive, display and incorporate transition of care/referral summaries](https://www.healthit.gov/sites/default/files/170.314b1toc_rdi_2014_tp_v1.7.pdf)
2. [Test Procedure for §170.314 (b)(2) Transitions of care – create and transmit summary care records](https://www.healthit.gov/sites/default/files/170.314b2toc_createandtransmit_2014_tp_updated_v1.4.pdf)

The overall goal for mirroring the 2014 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 t**est the following:

1. Test the content and format of the C-CDA Continuity of Care Document covering the electronic exchange of health information between NHIOs, and
2. To test for the adherence to a standard set of vocabularies.

## Use Case Scenarios

### Use Case 1: Hospital Discharge

### 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. Includes provider to provider referral using DIRECT

**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

Standards and Implementation Guides Referenced

### HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial Use

<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

<http://www.hl7.org/implement/standards/product_brief.cfm?product_id=374>

**HL7, HEALTH LEVEL SEVEN and CDA, C-CDA are the registered trademarks of Health Level Seven International.**

Testing Approach

The testing Approach will include a business process and technical testing process to facilitate the streamlined onboarding process for the 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. Survey (describes the candidate’s content, data limits included in each section, terminology coding, include reports, etc. and evidence that their test environment closely emulates their production environment)
2. Testing

* Focus is on CCDA CCD r1.1
* Candidate provides their own samples or create samples based on 2014 Edition Meaningful Use Test Procedure test data

The pilot process will include a period to verify coverage and gaps for the testing tools currently available. These are referenced elsewhere in the document but at a minimum it is expected that the following combination of document compliance testing will be administered:

1. TTT (compliance with specs + MU 2014 EDITION)

OR

1. SITE (compliance with specs + MU 2014 EDITION + smart quality scoring)

OR

1. Visual inspection

* Of samples
* Of ability to display ONE fully populated sample (testing of candidate style sheet)

### eHealth Exchange Testing Plan

|  |  |
| --- | --- |
| |  | | --- | |  | |
| 1. Candidate submits content description and ‘fully populated’ content samples  a. Manual review and feedback to candidate 2. Tools analyze ‘fully populated’ content samples  a. Scores are produced reflecting richness, semantic interoperability, and data quality 3. Recommendation is made to Coordinating Committee  a. Manual inspection + scores are combined to inform a recommendation: pass, fail, pass with revisions 4. Post-production data quality surveillance  a. Certified participants measure their data quality index  b. eHealth Exchange create a dashboard showing the overall quality level |

### Pilot Timeline Plan implementation

* Publish Content Testing Documentation Available for public comment 11/2015 (Testing Workgroup and Specification Factory)
* Coordinating Committee Brief Update Approval 11/10/2015
* Coordinating Committee Meets - November 17, 2015
* Pilot Trial period – 6 months – December 2015 to May 2016
* Tooling assessment – 3 months – December 2015 – February 2016 - this will include determination of testing tools to be used and manual testing requirements that may not be met by automated tooling. It is expected feedback from pilot will help prioritize tooling improvements for use by the program in production.
* Mandatory content testing – Consideration by Coordinating Committee after Pilot concludes – Date TBD.

### Outstanding Questions

1. Do systems that do not create content but rather only pass through HIT Certified Modules for MU 2014 EDITION certified products get a waiver?
2. **SHALL** New 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?

Continuity of Care Document (CCD) Conformance Verbs

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. CCD was defined from the ASTM continuity of care record (CCR) standard. Consolidated CDA imposes constraints within templates based on conformance verbs defined in IETF RFC 2119.

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 type specification
* **SHOULD:** 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:** 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.

**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

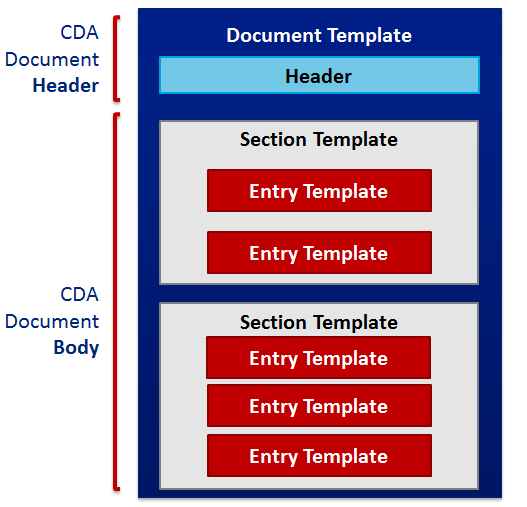
The Consolidated CDA implementation guide employs the concept of "templates." Templates are declared at the document, section, and entry level of CDA documents. The Consolidated CDA implementation guide defines an initial set of commonly used clinical documents whose contents are harmonized, thus ensuring 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. 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 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 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.

**Figure X: CDA Template Types**

****

### 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? Should a waiver be provided for systems that at currently attesting to Meaningful Use? Please provide your suggested edit/additions/deletions during the public comment to [testing@sequoiaproject.org](mailto:testing@sequoiaproject.org).

Testable Assertion 1.5.2.1; 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 1.5.2.2;** While some systems **MAY** create CCDs with only the five minimum required sections,

**Testable Assertion 1.5.2.3;** others **MAY** include additional optional CCD sections (up to all 17).

**Testable Assertion 1.5.2.4;** Still, others **MAY** include additional templates not included in the CCD document type definition.

**Testable Assertion 1.5.2.5;** The **receiving system** is not required to parse the structured entries (machine-readable fields) in the additional sections,

**Testable Assertion 1.5.2.6;** but it **SHALL** be able to display the entire CDA document, including narrative blocks, in human-readable form.

**Testable Assertion 1.5.2.7;** CDA R2 requirements affecting design[[1]](#footnote-1) 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 1.5.2.8;** 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 1.5.2.9;** 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 1.5.2.10;** 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 1.5.2.11;** 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 1.5.2.12;** Document Sources **SHALL** provide the capability to send all data for Meaningful Use,

**Testable Assertion 1.5.2.13;** 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 1.5.2.14;** The Document Source **SHALL** pass certification tests based on ONC certification criteria and NIST test procedures. When ONC describes the data required for an information exchange that meets Meaningful Use requirements, they mean that a vendor’s product must be able to produce all those data elements. The test procedures will validate the vendor’s capabilities by including test data to populate all the data elements, generally using an automated validation tool created by, or approved by, NIST. For example, NIST recommended a C32 validator for Meaningful Use Stage 1 requirements. The tool validates that all required, or SHALL, sections and data elements are present and conform to applicable syntactic and vocabulary standards.

**Testable Assertion 1.5.2.15;** No "blank" sections **MAY** exist in the tests because otherwise the test procedures would not be able validate the product. Therefore, vendor validation will use test patients who have entries for every kind of Meaningful Use data requirement.

**Testable Assertion 1.5.2.16;** 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 1.5.2.17;** 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 1.5.2.18;** 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 1.5.2.19;** 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 1.5.2.20;** 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 1.5.2.21; 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 1.5.2.22;** 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 Consolidated CDA Documents

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

The following 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 types. Please reference the CCD\_CCDA\_MU\_eHEX\_Content\_Checklist-2015-11-02.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 IG Chapters

| **MU 2014 EDITION Data Requirement** | **Consensus Recommendations** | **Consolidated CDA IG Chapter** |
| --- | --- | --- |
| Patient Name; Sex; Date of Birth; Race; Ethnicity; Preferred Language | Header element: Record Target | 2.2.1 |
| 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 |
| Provider Name & Contact Information [performing the service event]; Care Team Members [performing the service event] | Header element:  Documentation Of Service Event | 2.2.11 |
| Medication Allergies | Allergies Section | 4.2 |
| Functional Status; Cognitive Status | Functional Status Section | 4.14 |
| Discharge Instructions or Clinical Instructions | Hospital Discharge Instructions Section (inpatient settings) or Instructions Section | 4.23 or 4.28 |
| Immunizations | Immunizations Section | 4.27 |
| Medications | Medications Section (entries required) or Hospital Discharge Medications (inpatient settings) | 4.33 or 4.24 |
| 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 |
| Problems | Problems Section (entries required) | 4.44 |
| Procedures | Procedures Section (entries required) | 4.52 |
| Reason for Referral | Reason for Referral Section | 4.53 |
| Reason for Visit or Hospitalization | Reason for Visit or Chief Complaint or Chief Complaint and Reason for Visit | 4.54 and/or 4.7 |
| Laboratory Test(s); Results of Laboratory Test(s) | Results Section (entries required) | 4.55 |
| Smoking Status | Social History Section | 4.57 |
| Vital Signs | Vital Signs Section | 4.60 |

### Header Constraints Specific to CCD

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

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 Chapter 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 Chapter 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 Chapter 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 Chapters 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.

Table 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 Chapter 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 Chapter 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.

**Table 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] |

#### 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 Chapter 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.

Table 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 | CCD |
|  | Advance Directives (entries optional) | **O** |
| Medication allergies | Allergies (entries required) | **R** |
|  | Encounters (entries optional) | **O** |
|  | Family History | **O** |
| Functional Status; Cognitive Status | Functional Status | **O** |
| Discharge instructions (Inpatient setting) | Hospital Discharge Instructions |  |
| Immunizations | Immunizations (entries optional) | **O** |
| Clinical instructions; Recommended patient decision aids | Instructions |  |
|  | Medical Equipment | **O** |
| Medications | Medications (entries required) | **R** |
|  | Payers | **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 | **O** |
| Problems | Problem (entries required) | **R** |
| Procedures | Procedures (entries required) | **O** |
| 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** |
| Smoking status | Social History | **O** |
| Vital signs | Vital Signs (entries optional) | **O** |

### 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.

Table 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) |
| **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) |
| **MAY** Cognitive Status Problem Observation(2.16.840.1.113883.10.20.22.4.73) |
| **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 type for MU2 requirements is prohibited.**

### Advance Directives (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

Table X: 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) |

#### 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 (Entries Required)

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

Table XX: 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)** | * 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: Allergies Section Structure

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

#### 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)

**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.

##### Severity Observation (2.16.840.1.113883.10.20.22.4.8)

***Table XXX: 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 (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

Table XX: 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) |

#### Vocabulary

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

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

Table xx: Family History Observation Contexts

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

#### 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 (Required)

#### Structure

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 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 Chapter 4.14 of the 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, R.1 – US Realm Page **43** of **85** © 2014 Health Level Seven International. All rights reserved. October 2014 would be appropriate. 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 Chapter 4.14 of the 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 (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 (2.16.840.1.113883.10.20.22.4.73) * Cognitive Status Result Observation (2.16.840.1.113883.10.20.22.4.74) |

Table XX: Functional Status Section Structure

|  |
| --- |
| **Functional Status** |
| MAY **Assessment Scale Observation** |
| MAY **Caregiver Characteristics** |
| MAY **Cognitive Status Problem Observation** |
| MAY **Cognitive Status Result Observation** |
| MAY **Cognitive Status Result Organizer** |
| MAY **Functional Status Problem Observation** |
| 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** |

#### 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 Chapter 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-3) 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 (Entries Optional)

#### Structure

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

Table XX: 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: 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** |

##### 

#### 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

#### Structure

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

Table XX: Instructions Section Structure

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

The Instructions template 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: Clinical or Discharge Instructions MU 2014 EDITION 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)** |  |

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 Chapter 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 Chapter 4.23 of the Consolidated CDA implementation guide, consists of a narrative block and does not specify any entrie

The Hospital Discharge Instructions section records instructions at discharge.

Table XX: 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) |  |

#### 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 (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 pertinent equipment relevant to the diagnosis, care, and treatment of a patient **SHOULD** be included.

Table X: 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) |

### Medications

#### Structure

The structure of the Medications with coded entries required section is described hierarchically with corresponding entry-level constraints as specified in Chapter 4.33 of the 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: 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** |

#### 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

#### 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.

### Plan of Care or Assessment and Plan

#### Structure

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

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.

Table XX: 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: 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** |

#### 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 Chapter 4.28 of the Consolidated CDA implementation guide within the Instructions section.

Table 12: Clinical or Discharge Instructions MU2 Data Requirement in Consolidated CDA

Section(s) Instructions (2.16.840.1.113883.10.20.22.2.45)

Associated Entry(ies)

• Instructions (2.16.840.1.113883.10.20.22.4.20)

Section(s) Hospital Discharge Instructions (2.16.840.1.113883.10.20.22.2.41)

3.4.3. Instructions Section Structure

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

Table 13: Instructions Section Structure

SHOULD Instructions

3.4.4. Hospital Discharge Instructions Section Structure

The structure of the Discharge Instructions section, as specified in Chapter 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 Chapter 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

#### 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.

#### 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 Chapter 4.28 of the Consolidated CDA implementation guide within the Instructions section.

### Problem (Entries Required)

#### Structure

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

Table XX: 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: Problem Section Structure

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

#### 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 (Entries Required)

#### Structure

The structure of the Procedures with coded entries required section is described hierarchically with corresponding entry-level constraints as specified in Chapter 4.52 of the 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 may contain all procedures for the period of time being summarized, but should include notable procedures. 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: Procedures Section Structure

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

#### Vocabulary

Procedures require the combination of both HCPCS[[4]](#footnote-4) and CPT-4[[5]](#footnote-5), 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-6) or CDT[[7]](#footnote-7)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

#### Structure

The structure of the Reason for Referral, as specified in Chapter 4.53 of the 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: 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) |  |

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

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.

Table XX: Reason for Visit or Hospitalization MU 2014 Edition Data Requirement in Consolidated 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)** |  |

#### 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 (Entries Required)

#### Structure

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

The Results section contains the results of observations generated by laboratories, imaging procedures, and other procedures. 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.

Table XX: Results Section Structure

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

Table XX: 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)** | 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) | 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) |

#### 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 type in inpatient settings, the Hospital Discharge Studies Summary section **SHALL** include coded entries to capture Laboratory Results.

### Social History

#### Structure

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

This section contains data defining the patient’s occupational, personal (e.g. lifestyle), social, and environmental history and health risk factors, as well as administrative data such as marital status, race, ethnicity and religious affiliation. 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.

Table XX: 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) | 1. Smoking Status Observation (2.16.840.1.113883.10.22.4.78) |

Table XX: Social History Section Structure

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

#### 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 (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 Chapter 4.60 of the 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 type, such as blood pressure, heart rate, respiratory rate, height, weight, body mass index, head circumference, and pulse oximetry. 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: 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) | 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) |
| **Vital Signs with coded entries required**  **(2.16.840.1.113883.10.20.22.2.4.1)** | 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: Vital Signs Section Structure

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

#### 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

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.

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. An example includes the requirement of a Hospital Course section within a Discharge Summary. Typically, this section is not available at the time of a hospital discharge, but the Discharge Summary document type may still be used to meet the MU2 objective for transmitting health information within 36 hours of the hospital discharge. In this example, the incomplete Discharge Summary is sent at the time of discharge and a new Discharge Summary is sent communicating that it supersedes the previous version.

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 Chapter 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 Chapter 1.8.9 of the 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 2](#_Handling_Missing_or) of this guide and Chapters 1.8.8 and 1.8.9 of the Consolidated CDA implementation guide.

Meaningful Use 2014 Edition CEHRT Alignment

### Transitions of Care §170.314 (b)(1) & (2)

The eHealth Exchange has chosen to align with the Transitions of Care Criterion for Eligible Professionals (EP) and Eligible Hospitals (EH).

1. 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. EH/CAH Objective: The EH or CAH 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
3. 2011 Ed. Certification Equivalent(s): § 170.304(i) - Ambulatory; § 170.306(f) – Inpatient

### MU 2014 EDITION Summary Types and Data Requirements

The 2014 Ed. CEHRT specifies summary types that include MU 2014 EDITION data requirements to be formatted using Consolidated CDA for the objective. The summary types do not equate to a specific CDA document or purpose, they are simply a collection of data requirements to be included for an MU 2014 EDITION objective. The following table lists the 2014 Ed. CEHRT criterion and the corresponding summary type that is required for successful demonstration of MU 2014 EDITION.

**Table XX: MU 2014 EDITION Summary Types**

|  |  |
| --- | --- |
| 2014 CEHRT Criterion | Summary Type |
| 170.314(b)(1) & (2)- Receive, Display, Incorporate, and Create Transition of Care/Referral Summaries | Transition of Care/Referral Summary |
| 170.314(b)(7)- Data Portability | Export Summary |
| 170.314(e)(1)- View, Download, and Transmit to a 3rd Party | Ambulatory Summary or  Inpatient Summary |
| 170.314(e)(2)- Clinical Summary | Clinical Summary |

**Table XX: MU 2014 EDITION Data Requirements**

| **ToC Designated Category** | **MU 2014 EDITION Data Elements** | **Transition of Care/Referral Summary** | **Export Summary** | **Ambulatory or Inpatient Summary** | **Clinical Summary (Ambulatory)** |
| --- | --- | --- | --- | --- | --- |
| [**Encounter and Care Team Information**](#_Patient_Information) | **Care Team Members** | **X** | **X** | **X** | **X** |
| [**Patient Information**](#_Patient_Information_1) | **Date of Birth** | **X** | **X** | **X** | **X** |
| **Ethnicity** | **X** | **X** | **X** | **X** |
| **Patient Name** | **X** | **X** | **X** | **X** |
| **Preferred Language** | **X** | **X** | **X** | **X** |
| **Race** | **X** | **X** | **X** | **X** |
| **Sex** | **X** | **X** | **X** | **X** |
| [**Care Planning**](#_Encounter_Information) | **Care plan field(s), including goals and instructions** | **X** | **X** | **X** | **X** |
| [**Conditions or Concerns**](#_Conditions_or_Concerns) | **Problems** | **X** | **X** | **X** | **X** |
| [**Medications and Immunizations**](#_Medications_and_Immunizations) | **Medication Allergies** | **X** | **X** | **X** | **X** |
| **Medications** | **X** | **X** | **X** | **X** |
| [**Observations and Results**](#_Observations_and_Results) | **Laboratory Test(s)** | **X** | **X** | **X** | **X** |
| **Laboratory Value(s)/Result(s)** | **X** | **X** | **X** | **X** |
| **Smoking Status** | **X** | **X** | **X** | **X** |
| **Vital signs (height, weight, BP, BMI)** | **X** | **X** | **X** | **X** |
| [**Procedures**](#_Procedures_and_Surgeries) | **Procedures** | **X** | **X** | **X** | **X** |
| [**Encounter and Care Team Information**](#_Patient_Information) | Admission and Discharge Dates |  |  | X (Inpatient) |  |
| Admission and Discharge Location |  |  | X (Inpatient) |  |
| Date of Visit |  |  |  | X |
| Provider Name and Office Contact Information | X (Ambulatory) | X (Ambulatory) | X (Ambulatory) | X |
| Visit Location |  |  |  | X |
| [**Care Planning**](#_Encounter_Information) | Clinical Instructions |  |  |  | X |
| Diagnostic Test(s) Pending |  |  |  | X |
| Discharge Instructions | X (Inpatient) | X (Inpatient) | X (Inpatient) |  |
| Future Scheduled Appointments |  |  |  | X |
| Future Scheduled Test(s) |  |  |  | X |
| Recommended Patient Decision Aids |  |  |  | X |
| Referrals to Other Providers |  |  |  | X |
| [**Conditions or Concerns**](#_Conditions_or_Concerns) | Encounter Diagnoses | X | X |  |  |
| Reason for Hospitalization |  |  | X (Inpatient) |  |
| Reason for Referral | X (Ambulatory) | X (Ambulatory) |  |  |
| Reason for Visit |  |  |  | X |
| [**Medications and Immunizations**](#_Medications_and_Immunizations) | Immunizations | X | X |  | X |
| Medications Administered during the Visit |  |  |  | X |
| [**Observations and Results**](#_Observations_and_Results) | Cognitive Status | X | X |  |  |
| Functional Status | X | X |  |  |

Testing Tools

During the pilot phase planned for December 2015 – February 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. (<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” We’ve got 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. We focus on things that are not simple schema/schematron rules available in in the NIST TTT set. Our tool is proprietary, but I’d be happy to show how it works. Its logic is based on the many EHR vendors and 500,000+ C-CDAs our company has processed to date. ([www.diameterhealth.com)](http://www.diameterhealth.com))

### MU 2014 Edition Transport Testing Tool (TTT)

This tooling is leveraged by the Authorized Testing Labs for Meaningful Use 2014 Edition Certification. It does test for the Transitions of Care Requirements Currently. (http://transport- testing.nist.gov/ttt/)

### 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. (<http://sitenv.org/c-cda)>

### Smart C-CDA Scorecard

As part of the past work from the SMART C-CDA Collaborative, Josh Mandel wrote the code ( to which HL7 SDWG + me + others provided additional guidance) for the SMART C-CDA Scorecard. It’s open source with a limited rule set, but not actively managed to my knowledge; Josh is currently a core architect on the FHIR standard. (<http://ccda-scorecard.smartplatforms.org/static/ccdaScorecard/#/>)

### Stella Content Validation Tool

Inspector Quality Healthcare Data (IQHD) – Quality Profiler for Meaningful Clinical Data

Stella Technology IQHD, the first Clinical Data Quality tool that evaluates the “meaningfulness” of the clinical data. Healthcare organizations have a unique tool to measure the quality of clinical data in a quick, efficient and automated way. Developed in partnership with Buffalo, NY HIE HEALTHeLINK, IQHD “measures” the quality of data from various source systems based on configurable validation rules. Organizations can work collaboratively with their partners and stakeholders to improve the overall quality of the clinical healthcare data in their community, and save a substantial amount of time, resources and costs in collecting, analyzing and leveraging data for integration projects and population health management initiatives.

Benefits of IQHD:

1. Efficiently identifies data quality issues

2. Determines clinical data readiness for HIE onboarding, analytics and more

3. Validation score allows organizations to quantify and measure the relative quality of their data

4. Significant time and savings for both data providers, receivers and users

Technical Features:

1. Support for any XML-based healthcare data (e.g. HL7 v3, CCD, CCDA, FHIR XML) or data that can be converted into XML (e.g. HL7 v2, FHIR JSON, X12)

2. Configurable validation rules with adjustable weighting for specific use cases (e.g. quality improvement reporting initiatives, HIE onboarding)

3. Ability to evaluate the same data against multiple rules

4. Individual documents validation via web interface or a batch processing via API

5. Exportable reports with quality score and attribute-level issues identification, including top 10 quality issues

# CCD C-CDA Content Test Procedures & Test Data

1. [Test Procedure for §170.314 (b)(1) Transitions of care – receive, display and incorporate transition of care/referral summaries](https://www.healthit.gov/sites/default/files/170.314b1toc_rdi_2014_tp_v1.7.pdf)
   1. **Receive.** EHR technology must be able to electronically receive transition of care/referral summaries in accordance with:
      1. The standard specified in § 170.202(a).
      2. Optional. The standards specified in § 170.202(a) and (b).
      3. Optional. The standards specified in § 170.202(b) and (c).
   2. **Display.** EHR 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)(1), § 170.205(a)(2), and § 170.205(a)(3).
   3. **Incorporate.** Upon receipt of a transition of care/referral summary formatted according to the standard adopted at § 170.205(a)(3), EHR technology must be able to:
      1. Correct patient. Demonstrate that the transition of care/referral summary received is or can be properly matched to the correct patient
      2. Data incorporation. Electronically incorporate the following data expressed according to the specified standard(s):
         1. Medications. At a minimum, the version of the standard specified in
            1. § 170.207(d)(2);
         2. Problems. At a minimum, the version of the standard specified in § 170.207(a)(3);
         3. Medication allergies. At a minimum, the version of the standard specified in § 170.207(d)(2)
      3. (C) Section views. Extract and allow for individual display each additional section or sections (and the accompanying document header information) that were included in a transition of care/referral summary received and formatted in accordance with the standard adopted at § 170.205(a)
   4. **Test Data** 
      1. Please reference the test procedure reference in item #1 above and hyperlinked to pdf.
      2. Please note that this test case will leverage the same test data referenced by the 2014 Edition Meaningful Use Certification Program. There are separate patients that are to be leveraged for inpatient and Ambulatory Environments. This program will not dictate which patient to be leveraged, but the testing submission to be validated should utilize the patient data and can be found here:

https://www.healthit.gov/sites/default/files/170.314b1toc\_rdi\_2014\_td\_v1.4.pdf

1. [Test Procedure for §170.314 (b)(2) Transitions of care – create and transmit summary care records](https://www.healthit.gov/sites/default/files/170.314b2toc_createandtransmit_2014_tp_updated_v1.4.pdf)
   1. **Create.** Enable a user to electronically create a transition of care/referral summary formatted according to the standard adopted at § 170.205(a)(3) that includes, at a minimum, the Common MU Data Set and the following data expressed, where applicable, according to the specified standard(s):
      1. Encounter diagnoses. The standard specified in § 170.207(i) or, at a minimum, the version of the standard specified § 170.207(a)(3);
      2. Immunizations. The standard specified in § 170.207(e)(2);
      3. Cognitive status;
      4. Functional status; and
      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.
   2. **Transmit.** Enable a user to electronically transmit the transition of care/referral summary created in paragraph (b)(2)(i) of this section in accordance with:
      1. The standard specified in § 170.202(a).
      2. Optional. The standards specified in § 170.202(a) and (b).
      3. Optional. The standards specified in § 170.202(b) and (c).
   3. **Test Data** 
      1. Please reference the test procedure reference in item #2 above and hyperlinked to pdf.
      2. Please note that this test case will leverage the same test data referenced by the 2014 Edition Meaningful Use Certification Program. There are separate patients that are to be leveraged for inpatient and Ambulatory Environments. This program will not dictate which patient to be leveraged, but the testing submission to be validated should utilize the patient data and can be found here:

https://www.healthit.gov/sites/default/files/170.314b2toc\_create\_transmit\_2014\_td\_v1.6.pdf

The overall goal for mirroring the 2014 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. Items as referenced by the Associated Content Testing Checklist to validate content and format of the C-CDA Continuity of Care Document covering the electronic exchange of health information between eHealth Exchange Participants, and
2. To test for the adherence to a standard set of vocabularies.

1. Taken from section 1.2.3 of the CDA R2 specification available through HL7. [↑](#footnote-ref-1)
2. International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10 CM) [↑](#footnote-ref-2)
3. [http://minorityhealth.hhs.gov/templates/ content.aspx?ID=9228#4](http://minorityhealth.hhs.gov/templates/content.aspx?ID=9228#4) [↑](#footnote-ref-3)
4. Health Care Financing Administration Common Procedure Coding System [↑](#footnote-ref-4)
5. Current Procedural Terminology, Fourth Edition [↑](#footnote-ref-5)
6. International Classification of Diseases, 10th Revision, Procedure Coding System [↑](#footnote-ref-6)
7. Code on Dental Procedures and Nomenclature [↑](#footnote-ref-7)