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HL7 Implementation Guide: S&I Framework Transitions of Care Companion Guide to Consolidated-CDA for Meaningful Use Stage 2, Release 1 – US Realm

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Standards & Interoperability Framework

Companion Guide to HL7 Consolidated CDA for MU2

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Revision History

Date	Document Version	Document Revision Description
8/23/2012	1.0	Initial draft based on the proposed MU2 requirements
9/10/2012	2.0	Draft updated for the MU2 Final Rule and comments submitted by Transitions of Care Initiative participants from 08/23-09/10
10/01/2012	3.0	Draft updated with comments submitted by Transitions of Care Initiative participants from 09/13-09/24
10/25/2012	3.1	Draft approved by consensus from Transitions of Care Initiative participants
11/19/2012	3.2	INITIAL RELEASE including final resolution of comments received during consensus
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[1] Standards and Interoperability Framework Wiki contains pages capturing the work of the Transitions of Care Initiative and the Implementation Guidance Sub-Workgroup http://wiki.siframework.org/

Table of Contents

Executive Summary

The Companion Guide to Consolidated Clinical Document Architecture (CDA) for Meaningful Use Stage 2 provides supplemental guidance to the Health Level Seven (HL7)[2] Implementation Guide for CDA Release 2: Integrating Health Enterprise (IHE) Health Story Consolidation, Draft Standard for Trial Use (DSTU) Release 1.1 - US Realm, July 2012[3] in the context of the 2014 Edition Certified Electronic Health Record Technology (CEHRT) requirements. The summary types identified for Meaningful Use Stage 2 do not equate to a specific CDA document or purpose, but represent a collection of data requirements to be included for various MU2 objectives. The purpose of the guide is to supplement the Consolidated CDA implementation guide by providing additional clinical and functional context to assist implementers and offers practical guidance that is outside the scope of HL7 balloted standards.

The development of the Companion Guide is a direct result of feedback from healthcare community stakeholders believing that supplementary guidance to Consolidated CDA would foster consistent implementations. Companion Guide contents are a blend of white paper narrative and implementation "quick start" guidance for using Consolidated CDA to meet 2014 Ed. CEHRT requirements supporting the Electronic Health Record Incentive Program, Stage 2 objectives. The contents of the Companion Guide intend to:

- Promote understanding of basic CDA concepts that are important to understand prior to implementing the 2014 Ed. CEHRT requirements
- Provide guidance on the 2014 Ed. CEHRT requirements and representations in the Consolidated CDA format, including alignment to the CDA document templates currently included in the Consolidated CDA implementation guide
- Recommend an approach that satisfies the 2014 Ed. CEHRT requirements and meets the needs of clinicians performing EHR Incentive Program, Stage 2 objectives
- Highlight additional resources for CDA, 2014 Ed. CEHRT requirements, vocabularies, and implementation tools

As a companion, or a supplement, to the Consolidated CDA implementation guide, the Companion Guide is informative guidance and does not impose new constraints beyond those in the Consolidated CDA implementation guide or called for in the 2014 Ed. CEHRT requirements. The Standards & Interoperability (S&I) Framework, enabled by the Office of the National Coordinator (ONC) for Health Information Technology, Office of Science & Technology (OST) facilitated the development of the Companion Guide with leadership from the Implementation Guidance Sub-Workgroup (IG SWG), Transitions of Care (ToC) Initiative.

[2] For additional information on Health Level 7 and associated standards work, visit http://www.hl7.org/.
[3] For access the Health Level Seven (HL7) Implementation Guide for CDA Release 2: Integrating Health Enterprise (IHE) Health Story Consolidation, Draft Standard for Trial Use (DSTU) Release 1.1 - US Realm, July 2012, visit Structured Documents Workgroup, http://www.hl7.org/Special/committees/structure/index.cfm.

1. Introduction

1.1. Transitions of Care Initiative Overview

The Transitions of Care (ToC) Initiative[4] focuses on empowering patients, engaging the clinician, and enabling health information exchange in support of national health initiatives to increase patient safety and improve health care outcomes. The purpose of the ToC Initiative is to improve the electronic exchange of core clinical information among providers, patients and other authorized entities electronically in support of Meaningful Use and Institute of Medicine (IOM) identified needs for improvement in the quality of care. The ToC Initiative is supported by a wide range of health IT community members, health care providers, health IT vendors, states, federal partners, government agencies, the standards community, and the research community.

Key Functions of the Initiative

- Focus on clinical content to be exchanged in patient care transitions;
- Build on existing standards to accelerate adoption;
- Work with the HIT community to remove barriers to implementation; and
- Guide decision-making based on the requirements of Meaningful Use that are consistent with IOM-identified needs for improvement in the quality of care.

Key Outputs of the Initiative

- Unambiguous definition of the clinical elements that should be included in care transitions;
- Guidance on the exchange of information during patient care transitions;
- Agreement on a single standard (Consolidated CDA) in support of Meaningful Use requirements, which minimizes interoperability errors and streamlines patient care coordination; and
- Identification of tools and resources to lower the barrier to implementation.

1.2. Implementation Guidance Sub-Workgroup

In October 2011, select members of the ToC Initiative formed the Implementation Guidance (IG) Sub-Workgroup (SWG) in response to concerns that the Consolidated CDA implementation guide does not provide clear and unambiguous guidance to the healthcare community for implementation of regulatory requirements on care transition exchange packages. IG SWG activities focused on Rule requirements for Meaningful Use Stage 2 (MU2), comprised of the Centers for Medicare and Medicaid Services (CMS) *Electronic Health Record Incentive Program, Stage 2*[5] and Office of the National Coordinator for Health IT (ONC) *Health Information Technology: Standards*[6]*, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology* (2014 Ed. CEHRT). The IG SWG completed activities, listed below, that served as the foundation for the guidance contained in the Companion Guide.

[4] For additional information on the S&I Framework and the Transitions of Care Initiative, visit http://wiki.siframework.org/.

[5] Electronic Health Record Incentive Program, Stage 2, Final Rule http://www.gpo.gov/fdsys/pkg/FR-2012-09-04/pdf/2012-21050.pdf.

[6] Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule http://www.gpo.gov/fdsys/pkg/FR-2012-09-04/pdf/2012-21050.pdf

- **Analysis of the MU2 requirements.** The IG SWG conducted an analysis between the 2014 Ed. CEHRT requirements indicating Consolidated CDA to identify gaps or ambiguities that would hinder implementations supporting EHR Incentive Program, Stage 2 objectives. A list of recommendations to align the standard with MU2 requirements were brought to the HL7 Structured Documents Workgroup (SDWG) for the May 2012 ballot of the Consolidated CDA implementation guide. 2014 Ed. CEHRT requirements analyzed are listed below.

    - **Criterion:** Transitions of care §170.314 (b)(1) & (2)
    - **Criterion:** Data portability §170.314 (b)(7)
    - **Criterion:** View, download, & transmit to 3rd party § 170.314(e)(1)
    - **Criterion:** Clinical summary § 170.314(e)(2)

- **Analysis of the Consolidated CDA document types.** The SWG aligned the MU2 requirements to all Consolidated CDA documents in order to conduct a "goodness of fit" assessment. The assessment resulted in the recommendation of a single CDA document for MU2 requirements.

- **Research on barriers to successful implementation using the Consolidated CDA implementation guide.** The goal of the activity was to generate a list of barriers to implementation that was used to prioritize the guidance included in the Companion Guide.

1.3. HL7 Consolidated CDA

The *HL7 Implementation Guide for CDA Release 2: IHE Health Story Consolidation, DSTU Release 1.1 - US Realm*[7], or "The Consolidated CDA," is the recommended standard of the ToC Initiative for implementing regulatory requirements and exchanging key clinical information. The Consolidated CDA implementation guide contains a core set of CDA documents[8] including the CCD, Discharge Summary, and Consultation Note.

The Consolidated CDA v1.1 standard is indicated at §170.205(a)(3) of the 2014 Ed. CEHRT for criterion capturing key clinical data for exchange in certain EHR Incentive Program, Stage 2 objectives.

1.4. Audience

The audience of this Companion Guide includes, but is not limited to, software developers, vendors, and other health IT implementers pursuing CMS EHR Incentive Program, Stage 2 and ONC 2014 Edition EHR Standards and Certification requirements (CEHRT), or jointly, Meaningful Use Stage 2 (MU2). This guide also includes informative content for general audiences for educational purposes as well as resources to assist in understanding Consolidated CDA. Readers are encouraged to review the Contents of this Guide to identify sections aligned to their needs.

1.5. Requisite Knowledge

Readers of the Companion Guide are assumed to have functional knowledge of HL7 concepts including the base CDA specification and the Reference Information Model (RIM), as well as the use of terminologies and data types. Readers should also have knowledge of Extensible Markup Language

[7] For additional information on the HL7 Implementation Guide for CDA Release 2: IHE Health Story Consolidation, DSTU Release 1.1 – US Realm, visit http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258

[8] Consolidated CDA documents are listed in Section 2 of this guide

(XML)[9] and XPath[10] syntax. Additionally, readers should have an understanding of terminologies such as SNOMED CT®, LOINC®, CPT, ICD, and RxNorm. Resources for these concepts are available in section 6.

1.6. Contents of this Guide

A description of subsequent Companion Guide sections is provided below. This guide contains a range of content that may or may not be applicable to certain audiences. Readers are encouraged to review section descriptions so that applicable guidance is referenced. **Section titles** are hyperlinked for quick navigation to preferred content.

- **Section 2: General Consolidated CDA Guidance** This section contains high-level information on functional topics such as how to navigate the Consolidated CDA implementation guide, considerations for MU2, and the inclusion of clinically relevant data.
- **Section 3: Implementing MU2 Requirements** This section details all representations of MU2 Requirements in Consolidated CDA, as well as consensus recommendations for implementations. Section Structure tables are included which depict the HL7 C-CDA sectional requirements.
- **Section 4: Consolidated CDA Document Alignment** This section contains guidance on considerations for implementing MU2 requirements using the current Consolidated CDA documents and recommends a "best fit" document type.
- **Section 5: Transitions of Care Initiative Recommended Approach** This section contains a complete recommendation to meet MU2 and the needs of clinicians, building on the Continuity of Care (CCD) document type definition.
- **Section 6: Additional Guidance** This section contains suggested tools and resources to assist in understanding, implementing, and validating implementation specifications.
- **Appendix A** This appendix includes clinical workflow considerations and additional guidance on the exchange of clinical documentation using Direct.
- Appendix **B** This appendix provides recommendations beyond CCD, identifying additional clinical content that may be sent with CCD documents.
- **Appendix C** This appendix details Consolidated CDA document assessments that are the foundation of guidance in section 4.

[9] For additional information on Extensible Markup Language, visit http://www.w3.org/TR/xml/.
[10] For additional information on XPath syntax, visit http://www.w3.org/TR/xpath/.

2. Understanding the Consolidated CDA

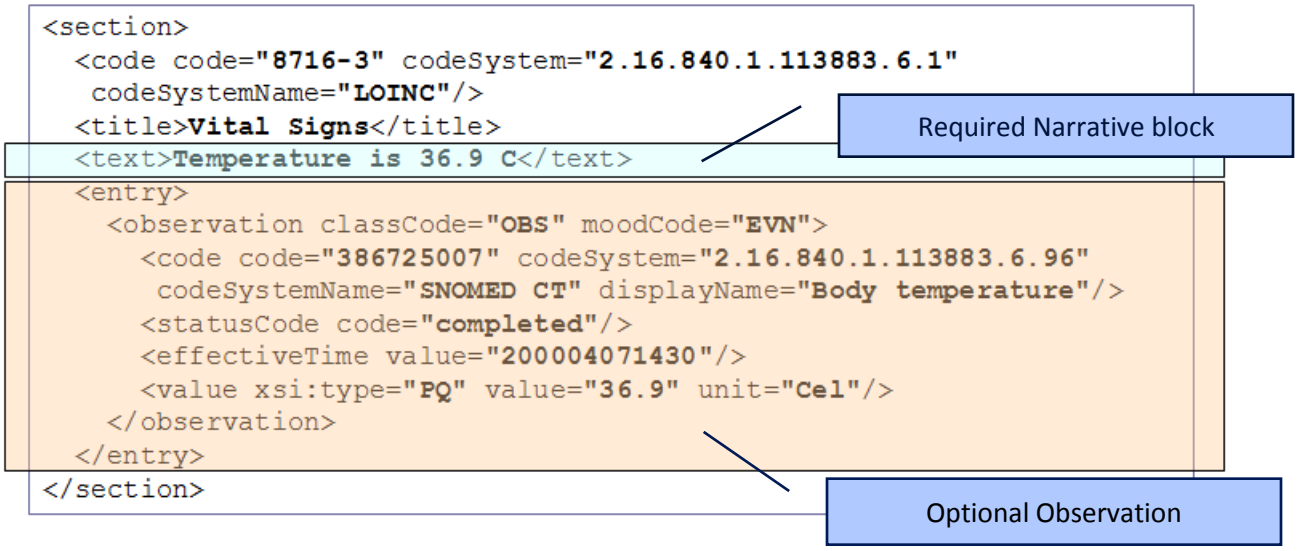
To assist in the implementation of Meaningful Use Stage 2 (MU2) requirements, this section provides guidance on navigating the Consolidated CDA implementation guide and guidance on CDA concepts that are relevant to MU2 requirements. This guidance is intended for both developers of EHR systems using CDA documents, as well as guidance for other interested parties who use those systems. The guidance is not merely about compliance to regulations and standards, but is envisioned to promote creation of highly functional and usable transition of care documents catering to the needs of clinicians. While this section provides a brief overview of the CDA concepts integral to MU2 implementations, familiarity with Health Level Seven (HL7) CDA Release 2 standard and the Consolidated CDA implementation guide is assumed. For examples on guidance applications, look for the grey call-out boxes, *Principles in Practice*.

> **Principles in Practice:** Examples of how guidance may be applied.

2.1. Clinical Document Architecture

As one of the first HL7 Version 3 (V3) specifications, the Clinical Document Architecture (CDA) is based on the HL7 Reference Information Model (RIM), which supports numerous data types, and vocabulary bindings. The CDA schema is an Extensible Markup Language (XML) schema that describes the structure of any clinical document. The CDA schema was generated from a model created from the RIM using the HL7 Version 3 Methodology. The CDA model was built from RIM classes, whose sub-elements are mapped to HL7 Version 3 data types. Those class sub-elements are used to represent various concepts: E.g. Dates, addresses, names, physical quantities or coded concepts, etc. Coded concepts can be bound to value sets (codes) drawn from either HL7 or external vocabularies, such as SNOMED® or LOINC®.

Figure 1: Simplified section example



To express context and purpose within CDA, templates constrain the CDA schema for a specific use and provide the 'architecture' for CDA documents. To help simplify clinical document implementations, commonly used templates were harmonized from existing CDA templates and "consolidated" into a single implementation guide – the Consolidated CDA. Updated template IDs and any previous template IDs are detailed in Appendix B of the Consolidated CDA implementation guide.

2.2. Template-Driven Approach

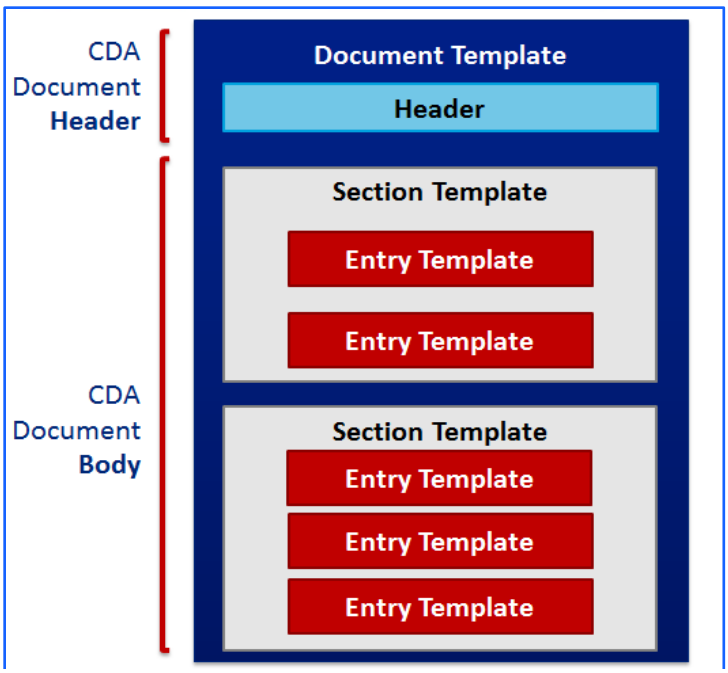
The Consolidated CDA implementation guide employs the concept of "templates." Conformance to templates is asserted at the document, section, and entry level of CDA documents. The Consolidated CDA implementation guide defines an initial set of commonly used clinical documents whose contents are harmonized, thus ensuring semantic interoperability across current and future document models.

Templates define constrains on models, thus contextualizing models for specific use cases. Templates can improve interoperability by removing optionality, defining conventions, and identifying codes or value sets that are to be used when creating conformant instances. Templates can be specified by professional society recommendations, national clinical practice guidelines, and standardized data sets. Templates support the creation of standardized clinical documents that are specifically intended to support clinical workflows in various use cases. For example, the Continuity of Care Document (CCD 1.0) template was informed by patient summary data defined by the ASTM Continuity of Care Record (CCR). 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.

Starting at the top of a document, the **header template** includes the metadata, or data about the document, 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. Referenced in the header are a number of **data type templates**, these templates define a common set of constraints that are reused within a CDA document. For example, the US Realm Date and Time (DTM.US.FIELDED) include a set of common constraints for recording time. This template is referenced several times throughout the IG in place of repeating constraints.

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. Section-level templates group or contain similar clinical concept(s), such as Procedures. 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 2: CDA Template Types



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.

> **Principles in Practice:** Vocabulary requirements imposed by MU2 increase semantic interoperability by using standardized codes for machine-readable content in entries. This means that different EHR systems can incorporate data from a CDA document based on codes that communicate the same concepts. Therefore, while a diagnosis *can* be described in various ways, a code would state what the diagnosis is, with no need for interpretation.

It is important to emphasize the reusability and flexibility of templates so that implementations support the ability to customize CDA documents specific to the patient's care needs. While templates constrain CDA schema for specific uses, additional content may augment each document as needed for a particular circumstance. Within Consolidated CDA, all but two templates are open templates, which mean they allow additional content. The two closed templates are "Estimated Date of Delivery" and "Policy Activity", which means no additional content, is allowed within those templates. Open and closed templates are detailed in Chapter 1.8.2 of the Consolidated CDA implementation guide.

Principles in Practice: Open document templates allow for the inclusion of additional sections. For example, CCD, as defined in Consolidated CDA, does not contain an Instructions section, which is required for MU2. Because CCD is an open template, Consolidated CDA allows for the addition of this section to the CCD document. If the sender wants to include the additional section, and the sender's system allows it, sending the CCD including the Instructions section is permissible.

The presence of template identifiers (templateId) assert conformance to a particular template. In an exchange, originators of CDA documents may use template IDs to signal conformance to a specific template. Likewise, recipients of CDA documents may filter content through rejecting certain template IDs. For the purpose of validation, template IDs set the rules for which the template is tested. In circumstances where additional content has been included in an *open* template, validators will ignore content beyond template requirements. Therefore, templates containing additional content are valid as long as they maintain conformance to specified template constraints.

It is necessary to include all template IDs that are required by a given CDA implementation guide. You may optionally include additional template IDs for which the instance is asserting conformance. This practice assists the receiving system in organizing information, but it is not always required. To this end, it is important to note that Consolidated CDA introduces harmonized templates that supersede previous versions employed in HL7, HITSP, and IHE specifications.

Note that all the templates in this guide refer to Consolidated CDA version 1.1, published in July 2012, as referenced in the ONC certification criteria for Stage 2. Later releases of Consolidated CDA, such as the one balloted in September 2013, have introduced new versions -- labeled "(V2)" -- and in some cases new names, for several templates. However, CDA documents produced using the templates in version 1.1 will continue to be valid for certification and meaningful use purposes.

2.3. Navigating the Consolidated CDA Implementation Guide

To make it easier to navigate the document, the Consolidated CDA implementation guide is organized into four main chapters that are dedicated to each template type. Chapters detail CDA document contents starting with broader contexts at the document-level and refines down to the clinical statements at the entry-level.

Included in the latest release of the C-CDA R1.1, "CDAR2_IG_IHE_CONSOL_DSTU_R1dot1_2012JULErrata .zip" is a spreadsheet, "C-CDA_Change_List_2012_12_21.xlsx" which details a number of technical corrections "Errata" which have been reviewed and approved by the SDWG at HL7. All implementers should download the latest IG which includes errata applied to the guide. MU2 certification is based on this errata package.

Organization of the Consolidated CDA implementation guide

- **Chapter 1:** Introduction
- **Chapter 2:** General Header Template
- **Chapter 3:** Document-Level Templates

- **Chapter 4:** Section-Level Templates
- **Chapter 5:** Entry-Level Templates

After reviewing the introductory information contained in the Consolidated CDA implementation guide, this guide recommends returning to Chapter 3: Document-Level Templates. These templates describe the purpose and rules for assembling a CDA document type, which includes specific constraints upon the US Realm Header. The header is defined for general use across all Consolidated CDA documents within Chapter 2 of the implementation guide. At the time of this publication, the Consolidated CDA implementation guide includes definitions for nine different types of commonly used CDA documents.

Table 1: Consolidated CDA Document-Level Templates

Document Template	Description
Consultation Note	According to CMS evaluation and management guidelines, a Consultation Note must be generated as a result of a physician or nonphysician practitioner's (NPP) request for an opinion or advice from another physician or NPP
Continuity of Care Document (CCD)	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.
Diagnostic Imaging Report (DIR)	A Diagnostic Imaging Report (DIR) is a document that contains a consulting specialist's interpretation of image data.
Discharge Summary	The Discharge Summary is a document that is a synopsis of a patient's admission to a hospital; it provides pertinent information for the continuation of care following discharge but also includes the hospital course and details of events that may not be pertinent to continuity of patient care. Discharge Summary template is defined to meet Joint Commission requirements for discharge summaries.
History and Physical Note (H&P)	A History and Physical (H&P) Note is a medical report that documents the current and past conditions of the patient to determine a patient's health status. The H&P Note is typically used upon admission to a hospital or prior to an operative procedure.
Operative Note	The Operative Note is created immediately following a surgical procedure and records the pre- and post-surgical diagnosis, pertinent events of the procedure, as well as the condition of the patient following the procedure.
Procedure Note	The Procedure Note is created immediately following a non-operative procedure and records the indications for the procedure and, when applicable, post-procedure diagnosis, pertinent events of the procedure, and the patient's tolerance of the procedure.
Progress Note	A Progress Note documents a patient's clinical status during a hospitalization or outpatient visit; thus, it is associated with an encounter. Note that the Progress Note is not intended to be a

Document Template	Description
	re-evaluation note for Medicare requirements.
Unstructured Document ***Use for MU2 requirements is prohibited***	Used when the patient record is captured in an unstructured format, such as a word or PDF document, that is encapsulated within an image file or as unstructured text in an electronic file

The eight structured Consolidated CDA documents define content drawn from the section templates and entry templates detailed in Chapters 4 and 5 of the implementation guide. Relationships between the template types consist of usage by or containment of another template within Consolidated CDA. Tables detailing related templates, as well as hyperlinks, are available within each individual document, section, and entry template for context. Consolidated CDA imposes constraints within templates based on conformance verbs defined in IETF RFC 2119. Constraints in guides previously employed, such as HITSP, are detailed within Appendix B of the implementation guide. A list of the conformance verbs, or keywords, defined in Chapter 1.8.3 of the Consolidated CDA implementation guide is provided below.

Consolidated CDA Conformance Verbs

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

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 3: 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
   a. **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).
   a. 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).

2.4. Guidance on Accommodating MU2 Requirements

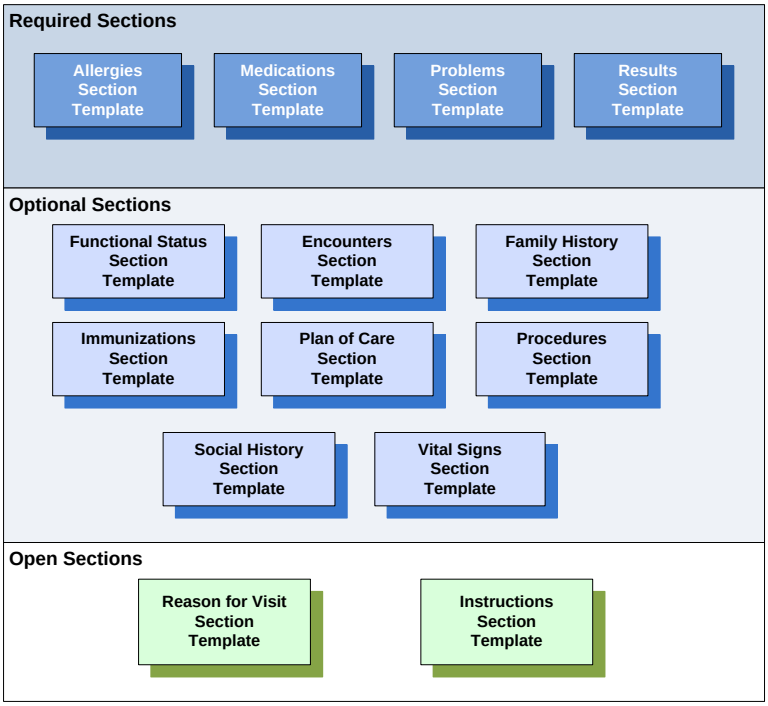
As detailed in later sections of this guide, achieving MU2 requirements does not rely on the use of a specific document-level template within Consolidated CDA. The guidance in this section provides assurance that clinical information required by MU2 is reliably and completely conveyed, even if it is not

included as part of a Consolidated CDA document template. MU2 prohibits the use of an unstructured document, so guidance in subsequent sections of this guide are focused on accommodating requirements through any of the eight structured documents currently available in Consolidated CDA.

2.4.1. Options for Systems Sending and Receiving CDA Documents

To meet the varying business needs of healthcare organizations, the ability to include additional content beyond the Consolidated CDA document template is allowable and maintains compliance with the underlying CDA R2 standard. This means that open document templates may be supplemented by additional CDA section or entry templates and remain a fully compliant CDA document, which is shown in figure 4.

Figure 4: Example CCD with open sections



Systems receiving CDA documents must be capable of rendering all human-readable content of CDA documents received. This ensures that any additional content beyond template definitions are at least displayable. As discussed in section 2.2 of this guide, inclusion of additional sections or content does not affect validation as long as conformance to the specified template is maintained. However, the validator will ignore additional content beyond the template.

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

Adherence to the CDA R2 requirement for human-readability ensures safe, effective and complete communication of pertinent patient clinical information. The CDA schema allows vendors and providers to include additional structured content (templates) beyond those called for by Meaningful Use. CDA R2 requirements affecting design are provided directly from the standard for reference below.

CDA R2 requirements affecting design:

- There must be a deterministic way for a recipient of an arbitrary CDA document to render the attested content.
- 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.
- 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.
- When structured content is derived from narrative, there must 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.
- When narrative is derived from structured content, there must be a mechanism to identify the process by which narrative was generated from structured data[13].

2.4.2. Using CDA Documents to Meet the Needs of Care Transitions

One C-CDA document type does not necessarily apply to all patient care scenarios. Transitions may include varying levels of information within a document, as well as transmission of one or more documents at different points in time. For example, upon discharge from an outpatient surgery center, a transition could include a CCD summarizing data pertinent to continuity of care, but might also include a Diagnostic Imaging Report (DIR) and/or a Pathology Report.

> **Principles in Practice:** When sending multiple C-CDA documents for a care transition, it is not necessary to include duplicate information / sections in each of the documents (assuming the information is not required by each document used).
>
> For example, if a C-CDA document includes the MU2 required sections, additional C-CDA documents being sent, should not have additional sections added beyond the requirements of their document type.

In scenarios involving multiple types of documents, each should be distinctly named for accurate identification by the receiving provider. Furthermore, including text describing the purpose of each document is recommended. This practice ensures that the recipient clearly understands the contents

[13] Additional insight into clinical workflow considerations is provided in Appendix A.

and the relationship to other content. On this same note, combining multiple documents into a single document where data does not align with the purpose of a document type is not recommended.

Even though CDA documents are recommended, the use of non-CDA document formats is permissible and even preferred where they are the best fit to the content being represented. Based on current understandings, certification will require that all required elements for MU2 conformance, be present in a single C-CDA document. There are no preclusions per say to send any additional content, in other formats. The current C-CDA standard can handle embedded images; however current EMR implementations may not have implemented that capability. Otherwise, implementations are free to send additional document / files formats as needed for care.

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 document identifier is created, which includes markup 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 later 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, null flavors or negation indicators should 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; the quote below is taken from the Transition of Care/Referral Summary requirements.

"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" in Transition of Care/Referral Summaries, but must include the section and a null value describing the unknown data.

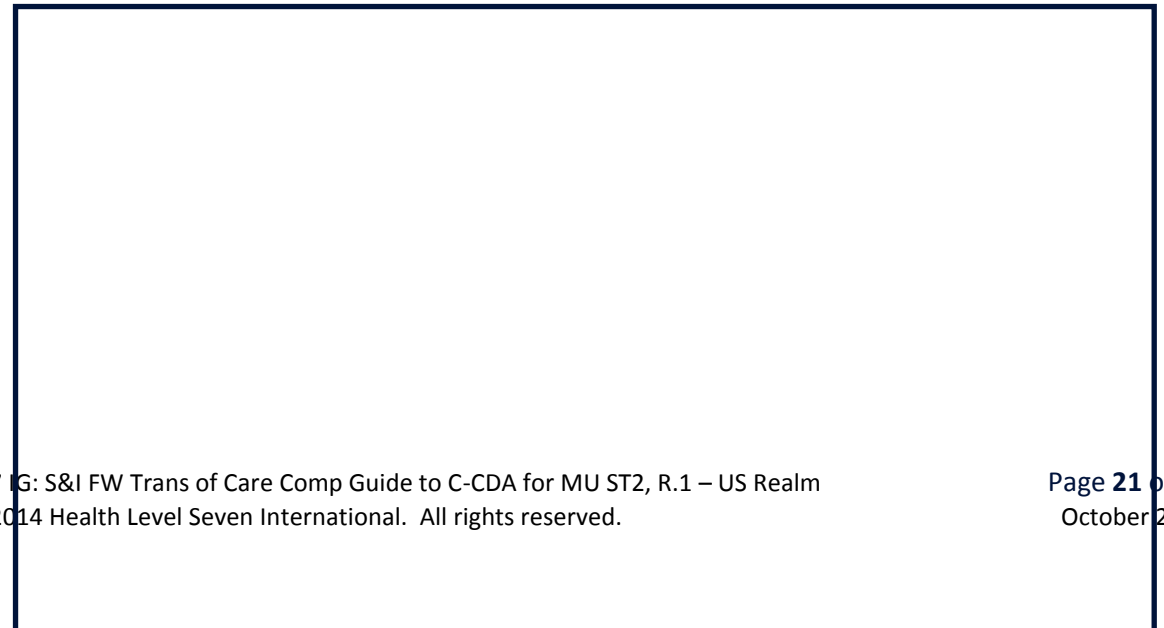
None or "no known" data

In scenarios where the data reflects a value of 'none', negation indicators should be used. The sample below shows the use of the negation indicator flag to include "no known allergies". 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 act as 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.

{Sample of no known allergies on next page.}

Figure 5: No Known Allergies



```
<!-- ************************ Allergies, Adverse Reactions, Alerts ********************** -->
<component>
  <section>
    <!-- conforms to Allergies section with entries optional -->
    <templateId root="2.16.840.1.113883.10.20.22.2.6"/>
    <!-- Allergies section with entries required -->
    <templateId root="2.16.840.1.113883.10.20.22.2.6.1"/>
    <code code="48765-2" codeSystem="2.16.840.1.113883.6.1"/>
    <title>ALLERGIES, ADVERSE REACTIONS, ALERTS</title>
    <text>No Known Allergies 10/03/2010 </text>
    <entry typeCode="DRIV">
      <!-- Allergy Concern Act -->
      <act classCode="ACT" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.22.4.30"/>
        <id root="36e3e930-7b14-11db-9fe1-0800200c9a66"/>
        <!-- SDWG supports 48765-2 or CONC in teh code element -->
        <code code="CONC" codeSystem="2.16.840.1.113883.5.6"/>
        <statusCode code="active"/>
        <!--currently tracked concerns are active concerns-->
        <effectiveTime>
          <low value="20091201"/>
          <!--show time when the concern first began being tracked-->
        </effectiveTime>
        <entryRelationship typeCode="SUBJ">
          <!-- No Known Allergies -->
          <observation classCode="OBS" moodCode="EVN" negationInd="true">
            <!-- allergy - intolerance observation template -->
            <templateId root="2.16.840.1.113883.10.20.22.4.7"/>
            <id root="4adc1020-7b14-11db-9fe1-0800200c9a66"/>
            <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
            <statusCode code="completed"/>
            <!-- N/A - author/time records when this assertion was made -->
            <effectiveTime nullFlavor="NA"/>
            <value type="CD" code="419199007" displayName="Allergy to substance (disorder)"
                   codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"/>
                   ...
```

Narrative text

Negation Indicator

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.

2.4.3. Migration Considerations (MU1 to MU2)

The Consolidated CDA implementation guide did not exist at the time Meaningful Use Stage 1 (MU1) was released, but has since defined a harmonized CCD specification to streamline MU2 implementations. As developers prepare for MU2, it is important to note considerations to ensure vendors are capable of meeting both MU1 and MU2 requirements. These migration considerations are applicable to developers who have certified according to HITSP C32 specifications (which were ONC-required constraints on CCD for MU1) and indicate enhancements to CCDs to achieve MU2 requirements.

Considerations for CCD 1.1 and MU2 requirements:

- Updated template IDs

- Additional sections, entries, or header elements
- Updated versions of vocabularies or additional vocabulary requirements
- Data elements not carried over to Consolidated CDA
- Different constraints on existing elements

For detailed guidance, please reference blog post in section 6.2.4 which contains guidance contributed by Keith Boone, Standards Architect, GE Healthcare, on moving from HITSP C32 to CCD 1.1.

3. Implementing MU2 Requirements

This section of the Companion Guide details Meaningful Use Stage 2 (MU2) required data elements and representation in Consolidated CDA.

For the purposes of this guide, MU2 data requirements are organized into logical categories to best represent guidance. Please note that these categories are designated by ToC and hold no meaning outside of organizational purposes for this section of the Companion Guide. The individual MU2 data requirements are listed in section 3.1.1 along with the corresponding category designated by ToC.

Guidance for each ToC-designated category describes considerations (details to note) for the MU2 data requirement, representation in Consolidated CDA, and a structure example of the consensus recommendations for meeting each data requirement. Resources for required vocabularies are available in section 6.2.6 of this guide. All guidance contents are listed alphabetically, with the exception of the Patient Information and Encounter Information categories, which contain data requirements represented in the header of the CDA document.

3.1. MU2 Requirements and Objectives

As part of the EHR Incentive Program, Stage 2, CMS has stipulated objectives for Eligible Professionals (EPs) or Eligible Hospitals (EHs) and Critical Access Hospitals (CAHs) that require the use of 2014 Ed. CEHRT as defined by ONC. Collectively, these Rules comprise Meaningful Use Stage 2. The ToC Initiative analyzed the following 2014 Ed. CEHRT criteria that require Consolidated CDA at §170.205(a)(3). Applicable MU2 objectives and equivalent 2011 Edition Certification criteria are provided for reference.

MU2 Requirements using Consolidated CDA:

- **2014 Ed. CEHRT Criterion:** Transitions of care §170.314 (b)(1) & (2)
  - **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
  - **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
  - **2011 Ed. Certification Equivalent(s):** § 170.304(i) - Ambulatory; § 170.306(f) - Inpatient

- **2014 Ed. CEHRT Criterion:** Data portability §170.314 (b)(7)

- **2014 Ed. CEHRT Criterion:** View, download, & transmit to 3rd party § 170.314(e)(1)
  - **EP Objective:** Provide patients the ability to view online, download and transmit their health information within four business days of the information being available to the EP
  - **EH/CAH Objective:** Provide patients the ability to view online, download and transmit their health information within 36 hours after discharge from the hospital
  - **2011 Ed. Certification Equivalent(s):** §170.304(g); §170.304(f) – Ambulatory; §170.306(d) & (e) - Inpatient
- **2014 Ed. CEHRT Criterion:** Clinical summary § 170.314(e)(2) – Ambulatory
  - **EP Objective:** Provide clinical summaries for patients for each office visit
  - **2011 Ed. Certification Equivalent(s):** § 170.304(h) –Ambulatory

3.1.1. MU2 Summary Types and Data Requirements

The 2014 Ed. CEHRT specifies summary types that include MU2 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 MU2 objective. The following table lists the 2014 Ed. CEHRT criterion and the corresponding summary type that is required for successful demonstration of MU2.

Table 2: MU2 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**

Each summary type requires a minimum set of data requirements that constitute the Common MU Data Set. In addition, each summary type includes data requirements specific to the objective. Certain data requirements are specific to the care setting (ambulatory or inpatient) using the summary type. The following table lists all MU2 data requirements and applicable summary types. All ToC-designated categories are hyperlinked to further guidance on applicable data requirements within this section of the Companion Guide.

Table 3: MU2 Data Requirements

ToC Designated Category	Common MU2 Data Elements	Transition of Care/Referral Summary	Export Summary	Ambulatory or Inpatient Summary	Clinical Summary (Ambulatory)
Encounter and Care Team Information	Care Team Members	X	X	X	X
Patient Information	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	Care plan field(s), including goals and instructions	X	X	X	X
Conditions or Concerns	Problems	X	X	X	X
Medications and Immunizations	Medication Allergies	X	X	X	X
	Medications	X	X	X	X
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

ToC Designated Category	Common MU2 Data Elements	Transition of Care/Referral Summary	Export Summary	Ambulatory or Inpatient Summary	Clinical Summary (Ambulatory)
	Vital signs (height, weight, BP, BMI)	**X**	**X**	**X**	**X**
Procedures	**Procedures**	**X**	**X**	**X**	**X**
ToC Designated Category	**Additional MU2 Data Elements**	**Transition of Care/Referral Summary**	**Export Summary**	**Ambulatory or Inpatient Summary**	**Clinical Summary (Ambulatory)**
Encounter and Care Team 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	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	Encounter Diagnoses	X	X		
	Reason for Hospitalization			X (Inpatient)	
	Reason for Referral	X (Ambulatory)	X (Ambulatory)		
	Reason for Visit				X
Medications and Immunizations	Immunizations	X	X		X
	Medications Administered during the Visit				X
Observations and Results	Cognitive Status	X	X		
	Functional Status	X	X		

Rows containing data requirements included in the Common MU Data Set are **bolded.**

3.2. Encounter and Care Team Information

This category captures MU2 requirements pertaining to encounter and care team information and the elements within the General Header template that are recommended to meet the requirement for an MU2 Objective. Consolidated CDA Header XML examples are available in the Companion Guide XML Examples file.

3.2.1. Considerations

Considerations are provided below for implementations of the Consolidated CDA General Header template to achieve MU2 requirements for encounter and care team information.

Care Team Members and Provider Names and Contact Information

Any known care team members, this could include referring providers, receiving providers, or any other provider inside or outside the originating provider's practice, that provide care to the 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. Although the Care Team Member roles have not been explicitly called, this information may be useful in aiding in the management of future information to Care Team Members. For example, care team members involved in the day to day care may need to receive all information, while a specialist such as a podiatrist may want to only receive specific type of information.

Within C-CDA, care team members are represented in the header using various participations, for example: the clinical encounter, service event, and the generic participant. 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 4: Participants in the Header

Participant	Description
author	Care team member(s) and/or devices that authored content within 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 members who should receive a copy of the document. *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.

A primary referral is when a primary care physician (PCP), or the patient's primary clinician, refers the patient to a specialist. After the specialist has evaluated the patient, the specialist may determine that the patient requires a "secondary" referral and refers the patient to another specialist or subspecialist.

As an example, a PCP finds that his/her patient has a thyroid nodule and refers the patient to an endocrinologist to perform a thyroid fine needle aspiration (FNA). The FNA result is positive for thyroid medullary carcinoma. The endocrinologist makes a secondary referral to an endocrine surgeon who evaluates the patient in the office and later admits the patient to hospital for surgery. Each of these encounters is a discrete encounter and is associated with the specific clinician.

The FNA procedure, or service event, that occurs during the office visit with the endocrinologist, is associated with that encounter and the endocrinologist is associated as the "performer" of that procedure, the endocrinologist is listed as a performer in the documentationOf/serviceEvent header element.

The hospitalization where the patient undergoes surgery for medullary thyroid cancer is a separate encounter and this procedure (or service event) is associated with the endocrine surgeon, and the endocrine surgeon is listed as a performer in the documentationOf/serviceEvent header element.

As part of the closed-loop-referral, the endocrinologist sends a Direct consultation message to the PCP, following his/her evaluation of the patient, and again copies the PCP when sending the Direct referral message to the endocrine surgeon. Ideally, the endocrine surgeon lists the PCP in his/her EHR as a member of the patient's care team and copies the PCP when sending their consultation Direct message back to the endocrinologist after their evaluation of the patient. Following the surgery, at the time of discharge, the endocrine surgeon would again send the discharge message to both the PCP and the endocrinologist.

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 5-7: 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/ performer	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/ performer	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/ responsibleParty **componentOf/ encompassingEncounter/ encounterParticipant**	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/ performer	Captures the names and contact information for any known key care team members, including the PCP
componentOf/ encompassingEncounter/ responsibleParty **componentOf/ encompassingEncounter/ encounterParticipant**	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 example participant scenarios for a procedure note in Chapter 3.7.1.5.

3.2.2. componentOf/encompassingEncounter Header Element

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

When the document is about a single visit 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.

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** MU2 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 MU2 data requirements are shaded in red.

The last column (CONF) in the following table identifies constraints attributable to the rules defined in the Federal Register. Please refer to Appendix C which contains a cross walk of these identifiers to the MU data requirements found in the Federal Register.

Table 8: componentOf/encompassingEncounter Header Element

componentOf/encompassingEncounter	CONF
SHALL **id**	
SHALL **effectiveTime** [date of visit or hospitalization]	**CG003, CG023**
low [admission date]	**CG003, CG023**
high [discharge date]	**CG003, CG023**
responsibleParty [care team member or provider responsible for the encounter]	**CG021**
assignedEntity	
addr [care team member or provider contact information]	**CG021**
telecom [care team member or provider contact information]	**CG021**
assignedPerson or representedOrganization	
name [care team member or provider name]	**CG021**
encounterParticipant [care team member or provider participating in the encounter]	**CG021, CG022**
@typeCode [type of care team member or provider]	

time [time of participation in the encounter]	
assignedEntity	
addr [care team member or provider contact information]	**CG021, CG022**
telecom [care team member or provider contact information]	**CG021, CG022**
assignedPerson or representedOrganization	
name [care team member or provider name]	**CG021, CG022**
location	
healthCareFacility	
id	
code	
location [location of visit or hospitalization]	**CG003**
name	
addr	
serviceProviderOrganization [provider's organization]	
id	
name	
telecom	
addr	
standardIndustryClassCode [type of facility]	

3.2.3. documentationOf/serviceEvent Header Element

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** MU2 data requirements. Chapter 2.2.11 of the Consolidated CDA implementation guide summaries the use of service event as follows:

> *"A serviceEvent represents the main act, such as a colonoscopy or a cardiac stress study, being documented. In a continuity of care document, CCD, the serviceEvent is a provision of healthcare over a period of time. In a provision of healthcare serviceEvent, the care providers, PCP or other longitudinal* ***providers, are recorded within the serviceEvent. If the document is about a single encounter, the providers associated can be recorded in the componentOf/encompassingEncounter."***

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. That same section provides guidance on the use of service event.

Elements without a constraint are not specified within the General Header template, but guidance maybe 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 MU2 data requirements are shaded in red.

The last column (CONF) in the following table identifies constraints attributable to the rules defined in the Federal Register. Please refer to Appendix C which contains a cross walk of these identifiers to the MU data requirements found in the Federal Register.

Table 9: documentationOf/serviceEvent Header Element

documentationOf/serviceEvent	CONF

SHOULD **performer** [care team member or provider performing the service event]	**CG002, CG021**
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]	**CG002, CG021**
telecom [care team member or provider contact information]	**CG002, CG021**
assignedPerson	
name [care team member or provider name]	**CG002, CG021**

3.3. Patient Information

This category captures MU2 requirements pertaining to patient information and elements within the General Header template that meet the requirement for an MU2 Objective. Consolidated CDA Header XML examples are available in the Companion Guide XML Examples file.

3.3.1. Considerations

Considerations for implementations of the Consolidated CDA general header template to achieve MU2 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 MU2 data requirements in the header.

Patient Preferred Language

Consolidated CDA specifies RFC 4646 for the language value set. RFC 4646, which is maintained by The Internet Society, describes the structure, content, construction, and semantics of language tags. RFC 4646 supports both ISO 639 Part 1 (Alpha-2 codes) and ISO 639 Part 2 (Alpha-3 codes).

MU2 constrains the preferred Language code to be drawn from the ISO 639 Part 2 alpha-3 codes limited to those that also have a corresponding alpha-2 code in ISO 639 Part 1. Use of codes with both alpha-3 and alpha-2 codes from the Language value set specified in Consolidated CDA meets this requirement. See the following ONC reference for more information on MU2 requirements for patient preferred language: http://forum.sitenv.org/viewtopic.php?f=16&t=36

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 MU2 summary types include null values (e.g., ASKU, UNK) and the special code MIS for languages not codified.

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. Currently for EHR certification, vendors are expected to code the "recordTarget/patientRole/Patient/raceCode" element using the following five categories:

- American Indian or Alaska Native (1002-5)
- Asian (2028-9)
- Black or African American (2054-5)
- Native Hawaiian or Other Pacific Islander (2076-8)
- White (2106-3).

Additional fine grained race codes can be reported via sdtc extension raceCode element, as described in the CCDA Implementation guide, as long as the race codes are present in the value set (2.16.840.1.113883.1.11.14914) defined for Race, in the CCDA IG.

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.

In instances where the patient declines to provide their race or ethnicity or it is unknown, HL7 null values may be used.

3.3.2. 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** MU2 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 MU2 data requirements are shaded in red.
The last column (CONF) in the following table identifies constraints attributable to the rules defined in the Federal Register. Please refer to Appendix C which contains a cross walk of these identifiers to the MU data requirements found in the Federal Register.

Table 10: recordTarget Header Element

recordTarget	CONF
SHALL **patientRole**	
SHALL **id**	
SHALL **addr**	
SHALL **telecom**	
SHALL **patient**	
SHALL **name** [patient name]	**CG001**
SHOULD **administrativeGenderCode** [sex]	**CG018**
SHALL **birthTime** [date of birth]	**CG018**
SHOULD **maritalStatusCode**	
MAY **religiousAffiliationCode**	
MAY **raceCode** [race]	**CG018**
MAY **sdtc:raceCode** [additional race]	**CG018**
MAY **ethnicGroupCode** [ethnicity]	**CG018**

MAY **guardian**	
MAY **birthPlace**	
SHOULD **languageCommunication** [preferred language]	**CG018**
SHALL **languageCode**	
MAY **preferenceInd**	
MAY **providerOrganization**	

3.4. Care Planning

This category captures MU2 requirements pertaining to care planning and the Consolidated CDA section(s) that meet the requirement for an MU2 Objective.

3.4.1. Considerations

Considerations for implementations of Consolidated CDA templates to achieve MU2 requirements for care planning are provided below.

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. In instances where the diagnostic test pending is a laboratory test, the use of LOINC® vocabulary is required for MU2 compliance. 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.

Clinical Instructions, Discharge Instructions and Recommended Patient Decision Aids

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.

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.

3.4.2. Representation in Consolidated CDA

Through analysis of Consolidated CDA, the ToC Initiative has determined the following Consolidated CDA sections and entries meet the **Care Plan, including Goals and Instructions**, **Future Scheduled Tests and Appointments**, **Laboratory Tests**, **Recommended Patient Decision Aids**, **Referrals to Other Providers**, or the **Clinical Instructions** or **Hospital Discharge Instructions** MU2 data requirements. Sections that are **bolded** are the ToC consensus recommendation to meet the requirement and are hyperlinked to further guidance in this guide. The entries are not required by MU2 or by the Consolidated CDA templates.

Table 11: Care Plan MU2 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 12: Clinical or Discharge Instructions MU2 Data Requirement in Consolidated CDA

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

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

Instructions
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. A best practice would be to include the information that the patient was given directly or reference any educational materials provided to the patient in the narrative.

3.4.5. Plan of Care 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.

Table 14: 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**

3.5. Conditions or Concerns

This category captures MU2 requirements pertaining to conditions or concerns and the Consolidated CDA section(s) that meet the requirement for an MU2 Objective.

3.5.1. Considerations

Considerations for implementations of Consolidated CDA templates to achieve MU2 requirements for conditions or concerns are provided below.

Encounter Diagnoses and Problems

Problems must be coded using SNOMED CT®[14] vocabulary and Encounter Diagnoses must be coded using either SNOMED CT® or ICD-10-CM[15] 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 Encounters with coded entries required or Hospital Discharge Diagnosis will vary depending on ambulatory or inpatient care setting.

Medication Allergies

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

Reason for Visit or Hospitalization

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

[14] IHTSDO SNOMED CT International Release July 2012 and US Extension to SNOMED CT March 2012 Release
[15] International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10 CM)

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.

Reason for Referral

Recommendation is to use the Reason for Referral section for the MU2 data requirement so that the referring provider's intentions are clear to the consulting provider.

3.5.2. Representation in Consolidated CDA

Through analysis of Consolidated CDA, the ToC Initiative has determined the following Consolidated CDA sections and entries meet the **Encounter Diagnoses**, **Problems**, **Medication Allergies**, **Reason for Referral**, or the **Reason for Visit or Hospitalization** MU2 data requirements. Sections that are **bolded** indicate the ToC consensus recommendation to meet the requirement and are hyperlinked to further guidance in this guide.

Table 15: Encounter Diagnoses MU2 Data Requirement in Consolidated CDA

Section(s)	Associated Entry(ies)
Encounters with coded entries required (2.16.840.1.113883.10.20.22.2.22.1)	• Encounter Activities (2.16.840.1.113883.10.20.22.4.49) ○ Encounter Diagnosis (2.16.840.1.113883.10.20.22.4.80)
Hospital Discharge Diagnosis (2.16.840.1.113883.10.20.22.2.24)	• Hospital Discharge Diagnosis (2.16.840.1.113883.10.20.22.4.33)
Postoperative Diagnosis (2.16.840.1.113883.10.20.22.2.35)	• Problem Observation (2.16.840.1.113883.10.20.22.4.4)
Post-procedure Diagnosis (2.16.840.1.113883.10.20.22.2.36)	• Post-procedure Diagnosis (2.16.840.1.113883.10.20.22.4.51)

Note: It is recommended that the Encounters with coded entries required be used in general; however for Hospital Discharge Summary the Hospital Discharge Diagnosis must be used. For the Operative Note and Procedure Note, the Post-operative Diagnosis and Post-procedure Diagnosis could be used respectively.

Table 16: 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 17: 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 Concern Act (2.16.840.1.113883.10.20.22.4.3) ○ Problem Observation (2.16.840.1.113883.10.20.22.4.4)

Table 18: Reason for Referral MU2 Data Requirement in Consolidated CDA

Section(s)	Associated Entry(ies)
Reason for Referral	

Section(s)	Associated Entry(ies)
(1.3.6.1.4.1.19376.1.5.3.1.3.1)	

Table 19: Reason for Visit or Hospitalization MU2 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)	

3.5.3. Allergies (entries required) Section Structure

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

Table 20: Allergies Section Structure

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

3.5.4. Reason for Visit Section Structure

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.

3.5.5. Problem (entries required) Section 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 21: Problem Section Structure

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

MAY **Health Status Observation**

3.5.6. Encounter Section (entries required) Structure

The structure of the Encounter Section, as specified in Chapter 4.11 of the Consolidated CDA implementation guide, consists of a narrative block and with a required Encounter Activities templates and may contain any number of Indication and/or Encounter Diagnosis entries as required.

Table 22: Encounter Section Structure

Encounter Section (entries required)
SHALL **Encounter Activities**
MAY **Encounter Diagnosis**
MAY **Indication**
MAY **Service Delivery Location**

3.5.7. Hospital Discharge Diagnosis Section Structure

The structure of the Hospital Discharge Diagnosis Section, as specified in Chapter 4.22 of the Consolidated CDA implementation guide, consists of a narrative block and with an optional Hospital Discharge Diagnosis Act. It shall contain one or more Problem Observation(s) which can be used to identify the Discharge Diagnosis.

Table 23: Hospital Discharge Diagnosis Section Structure

Hosptial Discharge Diagnosis Section
May **Hospital Discharge Diagnosis**
SHALL **Problem Observation**
MAY **Age Observation**
MAY **Health Status Observation**
MAY **Problem Status**

3.5.8. Reason for Referral Section Structure

The structure of the Reason for Referral, as specified in Chapter 4.53 of the Consolidated CDA

3.6. Medications and Immunizations

This category captures MU2 requirements pertaining to medications and immunizations and the Consolidated CDA section(s) that meet the requirement for an MU2 Objective.

3.6.1. Considerations

Considerations for implementations of Consolidated CDA templates to achieve MU2 requirements for medications and immunizations are provided below.

Immunizations

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

Medications

Medications and medications administered are to be coded using RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, August 6, 2012 Release. Consistent with the MU2 requirement for the inclusion of medications or medications administered during the visit, ToC describes any medication list exchanged at a care transition to include a reconciled list of the current medications, using either the "Medications Section with Coded Entries Required" or "Hospital Discharge Medications Section with Coded Entries Required" as appropriate. Inclusion of medications that have been discontinued is not recommended in these sections. See "Irrelevant (Not Pertinent) Data" in section 2.4.3.

If called for by MU2 or relevant for continuity of care medications administered during the visit or hospital stay, should be listed in the "Medications Administered Section". Note that MU2 explicitly requires medications administered during the visit for the Clinical Summary (EP only). Use of either the Medication Brand Name or the Medication Clinical Information value sets specified in Consolidated CDA meets this requirement.

3.6.2. Representation in Consolidated CDA

Through analysis of Consolidated CDA, the ToC Initiative has determined the following Consolidated CDA sections and entries meet the **Medications** and **Immunizations** MU2 data requirements. Sections that are **bolded** indicate the ToC consensus recommendation to meet the requirement and are hyperlinked to further guidance in this guide.

Table 24: Immunizations MU2 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)	• Immunization Activity (2.16.840.1.113883.10.20.22.4.52)

Table 25: Medications MU2 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) ○ 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)	• Medication Activity (2.16.840.1.113883.10.20.22.4.16) ○ 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) ▪ 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) ▪ Medication Information (2.16.840.1.113883.10.20.22.4.23)

3.6.3. Immunizations (entries required) Section 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 26: Immunizations Section 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**

3.6.4. Medications (entries required) Section 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 27: Medications Section 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**

3.7. Observations and Results

This category captures MU2 requirements pertaining to observations and results and the Consolidated CDA section(s) that meet the requirement for an MU2 Objective.

Note: CCDA results can be for ALL types of observations, including but not limited to laboratory, diagnostic imaging, EKG, procedure observations, etc. Implementers are encouraged to include all results that are relevant to the recipients of ToC documents, according to the selection principles explained in section 2.4.2 of this Companion Guide. However, it should also be noted that the XML examples only include laboratory simply because MU2 only specifically requires lab results coded in LOINC. It is silent on inclusion or exclusion of other types of results. Thus, inclusion of Lab results is the required minimum, and other (non-Lab) results may also be included in the CCDA Results Section based on clinical relevance. Lab and non-Lab results should be coded according to the vocabularies specified in CCDA.

3.7.1. Considerations

Considerations for implementations of Consolidated CDA templates to achieve MU2 requirements for observations and results are provided below.

Functional Status and Cognitive Status

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 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 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"

would be appropriate. That questionnaire is available through the Office of Minority Health[16] 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.

Smoking Status

Smoking Status must use the values and SNOMED CT® codes listed in table 26. Please note that the last two values in the table below were specified by MU2 and were not originally specified by C-CDA Implementation Guide. The values for unknown or no value smoking statuses are specified by MU2, so null values are not used for missing information.

Table 28: 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

Laboratory Tests and Values of Laboratory Results

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

Vital Signs

MU2 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 MU2 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.

3.7.2. Representation in Consolidated CDA

Through analysis of Consolidated CDA, the ToC Initiative has determined the following Consolidated CDA section(s) meet the **Functional Status**, **Cognitive Status**, **Smoking Status**, **Laboratory Tests**, **Values of Laboratory Results**, or **Vital Signs** MU2 data requirements. Sections that are **bolded** indicate the ToC consensus recommendation to meet the requirement and are hyperlinked to further guidance in this guide.

Table 29: Functional and Cognitive Status MU2 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)

[16] http://minorityhealth.hhs.gov/templates/ content.aspx?ID=9228#4

	• 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 30: Smoking Status MU2 Data Requirement in Consolidated CDA

Section(s)	Associated Entry(ies)
Social History (2.16.840.1.113883.10.20.22.2.17)	• Smoking Status Observation (MU2 Required) (2.16.840.1.113883.10.22.4.78)

Table 31: Laboratory Tests and Result Values MU2 Data Requirements in Consolidated CDA

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

Table 32: Vital Signs MU2 Data Requirements in Consolidated CDA

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

3.7.3. Functional Status Section Structure

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 33: 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**

3.7.4. Results (entries required) Section 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.

Table 34: Results Section Structure

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

3.7.5. Social History Section 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.

Table 35: Social History Section Structure

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

3.7.6. Vital Signs (entries required) Section 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.

Table 36: Vital Signs Section Structure

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

3.8. Procedures

This category captures MU2 requirements pertaining to procedures and the Consolidated CDA section(s) that may be employed to meet the requirement for an MU2 Objective.

3.8.1. Considerations

Considerations for implementations of Consolidated CDA templates to achieve MU2 requirements for procedures are provided below.

Procedures

Procedures require the combination of both HCPCS[17] and CPT-4[18], 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[19] or CDT[20]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.

3.8.2. Procedures (entries required) Section 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.

Table 37: Procedures Section Structure

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

3.9.Summary of Vocabularies

The following summarizes a number of the key MU2 requirements for vocabularies

- **Medication allergies** must use values specified in RxNorm, 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. CONF[**CG035**]

- **Immunizations** must use of codes from HL7 Standard Code Set CVX—Vaccines Administered, July30, 2009 version. Use of the Vaccine Administered value set specified in Consolidated CDA meets this requirement. CONF[**CG036**]

- **Medications** must use values specified in RxNorm, 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. CONF[**CG035**]

- **Problems** must 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. CONF[**CG032**]

- **Procedures** must use values specified in IHTSDO SNOMED CT® International Release July 2012 or later and US Extension to SNOMED CT® March 2012 or later Release or the combination of Health Care Financing Administration Common Procedure Coding System (HCPCS) and Current Procedural Terminology, Fourth Edition (CPT-4). Use of values specified in Code on Dental Procedures and Nomenclature (CDT) or International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) is optional, but SNOMED CT® or HCPCS/CPT-4 must be used as well. Use of these code systems is allowable in Consolidated CDA to meet this requirement. CONF[**CG032, CG041, CG042**]

[17] Health Care Financing Administration Common Procedure Coding System
[18] Current Procedural Terminology, Fourth Edition
[19] International Classification of Diseases, 10th Revision, Procedure Coding System
[20] Code on Dental Procedures and Nomenclature

- **Laboratory test(s) and value(s)/result(s)** must use values specified in Logical Observation Identifiers Names and Codes (LOINC®) version 2.40 or later. Use of the LOINC® code system is allowable in Consolidated CDA to meet this requirement. CONF[**CG034**]

- **Smoking status** must use the values listed in the table below from SNOMED CT®. Use of these values is allowable in Consolidated CDA to meet these requirements. CONF[**CG039**]

Table 38: Smoking Status Values from SNOMED CT®

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

3.9.1. C-CDA Value Set Resource

Value Set Authority Center (VSAC) - https://vsac.nlm.nih.gov/ The Value Set Authority Center (VSAC) is provided by the National Library of Medicine (NLM), in collaboration with the Office of the National Coordinator for Health Information Technology and the Centers for Medicare & Medicaid Services. The VSAC provides search, retrieval and download capabilities through a Web interface and APIs to all official versions of vocabulary value sets contained in the 2014 Clinical Quality Measures (CQMs) and the Consolidated CDA for Meaningful Use 2.

4. Consolidated CDA Document Alignment to MU2 Requirements

This section provides guidance for developers implementing the Meaningful Use Stage 2 (MU2) requirements using the currently available documents within Consolidated CDA. While it is recognized that there are many valid CDA documents available for use, this guidance is based on the analysis of the eight structured documents available in the Consolidated CDA 1.1 guide at the time of this publication. Please note that the use of the unstructured document type for MU2 requirements is prohibited.

Consolidated CDA Structured Document Templates:

- Continuity of Care Document (CCD)
- Consultation Note
- Diagnostic Imaging Report
- Discharge Summary
- History and Physical (H&P) Note
- Operative Note
- Procedure Note
- Progress Note

4.1. Consolidated CDA and MU2 Requirements

Consolidated CDA contains a library of section and entry templates that can be assembled in various ways to meet the requirements of MU2. It also contains several predefined structured document templates (noted above) detailed in Chapters 3.1 through 3.8 of the Consolidated CDA implementation guide. Each of these document types specify body constraints, which define the optional and required sections included in the document.

> **Principles in Practice:** ToC recommends adopting the CCD for MU2 requirements since it comes closer to meeting MU2 data requirements and is a straightforward evolutionary step in EHRs that already support CCD for MU1.

The ToC Initiative has determined that none of the document templates currently included in Consolidated CDA contains all of the MU2 data requirements. Nonetheless, each of the structured documents may be supplemented by additional sections to achieve MU2 conformance as detailed in section 2 of this guide. Please see section 3 of this guide for the complete list of Consolidated CDA representations of MU2 data requirements identified by the Initiative. The remainder of this section provides guidance to help developers conform to select Consolidated CDA documents.

4.2. Assessing Consolidated CDA Documents

In order to determine alignment of these sections for MU2 requirements to the Consolidated CDA documents, the ToC Initiative conducted a "goodness of fit" assessment based on existing document requirements and definitions. The eight Consolidated CDA structured documents were assessed for gaps based on the consensus recommendations to satisfy MU2 requirements summarized in table 34.

Table 39: Initiative Consensus Recommendations and Consolidated CDA IG Chapters

MU2 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 (ambulatory setting)	4.53
Reason for Visit or Hospitalization	Reason for Visit	4.54
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

Note: References to "Consensus Recommendations" elements in CDA are expressed in general terms, refer to C-CDA specifications for specific x-path locations.

The following sections detail the body constraints for select CDA documents and results of the assessment. CDA documents selected for in-depth analysis were determined by ToC to be the most appropriate for MU2 Objectives based on document purpose and alignment with MU2 requirements.

Detailed document assessments included the CCD, Consultation Note, Discharge Summary, and H&P Note. The US Realm Clinical Document Header is required for all document types, so it is assumed as required, but is not included in the alignment tables. A comprehensive list of all body constraints for the eight structured documents and the detailed assessment may be found in Appendix B.

4.2.1. CCD Alignment

The following table details the MU2 data requirement consensus recommendations sections and body constraints for the CCD. Section-level constraints are specified as "**O**" for optional (SHOULD or MAY) and "**R**" for required (SHALL). Rows where there is no corresponding section-level constraint indicate a potential gap for meeting MU2 requirements. See the Goodness of Fit Assessment in Appendix B for more detail.

Table 40: Consensus Recommendations for MU2 Data Requirements

MU2 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**

The Consolidated CDA guide defines the Continuity of Care Document (CCD) Release 1.1 that supersedes the previous Release 1.0 and specifies constraints in accordance with Meaningful Use Stage 1. **The ToC Initiative determined that the CCD serves as the best fit for MU2 requirements for both EPs and EHs or CAHs due to the overall alignment of requirements and purpose.** Considerations are noted in the following assessment. The CCD document template may be found in Chapter 3.1 of the Consolidated CDA implementation guide.

MU2 Goodness of Fit Assessment: CCD

Requires the addition of:

- Social History Section with structured Entry: Smoking Status Observation for Smoking Status requirement
- 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
- Hospital Discharge Instructions or Instructions Sections for Clinical Instructions or Discharge Instructions (inpatient settings) requirement
- Reason for Referral Section for Reason for Referral Requirement

Sections required by the document type definition but not required for MU2:

- None

Other Considerations:

- Entries are required by MU2 for Immunizations
- Component Of Encompassing Encounter header element for Provider and Care Team Members [participating in the encounter], and Visit or Hospitalization Information requirements
- Documentation Of Service Event header element for Provider and Care Team Members [performing the service event]
- Encounters Section for Provider and Care Team Members associated with relevant encounters summarized in the CCD
- In instances where the diagnostic test pending is a laboratory test, the use of LOINC® vocabulary is required for MU2 compliance.
- Medications and medications administered are to be coded using RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, August 6, 2012 Release.

The ToC approach for CCD implementations to meet MU2 requirements is detailed in Section 5 of this guide. Guidance for migrating from HITSP C32 to CCD 1.1 is contained in blog posting referenced in section 6.2.4

4.2.2. Consultation Note Alignment

The following table details the MU2 data requirement consensus recommendations sections and body constraints for the Consultation Note. Section-level constraints are specified as "**O**" for optional (SHOULD or MAY) and "**R**" for required (SHALL). Rows where there is no corresponding section-level constraint indicate a potential gap for meeting MU2 requirements. See the Goodness of Fit Assessment in Appendix B for more detail.

Table 41: Consultation Note Alignment

MU2 Data Requirements	Consolidated CDA Section	Consultation Note
Medication allergies	Allergies (entries optional)	**O**
	Family History	**O**
Functional status; Cognitive status	Functional Status	
	General Status	**O**
	History of Past Illness	**O**
	History of Present Illness	**R**
Discharge instructions (Inpatient setting)	Hospital Discharge Instructions	
Immunizations	Immunizations (entries optional)	**O**

MU2 Data Requirements	Consolidated CDA Section	Consultation Note
Clinical instructions; Recommended patient decision aids	Instructions	
Medications	Medications (entries optional)	**O**
	Physical Exam	**R**
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	**R**
Problems	Problem (entries optional)	**O**
Procedures	Procedures (entries optional)	**O**
Reason for Referral	Reason for Referral	**O**
Reason(s) for visit or Reason(s) for hospitalization (Inpatient setting)	Reason for Visit or Chief Complaint or Chief Complaint and Reason for Visit	**R**
Laboratory tests; Values/results of laboratory tests	Results (entries optional)	**O**
	Review of Systems	**O**
Smoking status	Social History	**O**
Vital signs	Vital Signs (entries optional)	**O**

The Consolidated CDA implementation guide defines the Consultation Note in accordance with Centers for Medicare and Medicaid Services (CMS) evaluation and management guidelines. The ToC Initiative determined that the Consultation Note is a reasonably good fit for Meaningful Use Stage 2 EP requirements due to the overall alignment of requirements, with considerations noted in the following assessment. However, it should be noted that if the transition of care does not follow a consultation, but is (for example) a referral, a Consultation Note would not be the appropriate document template to use. The Consultation Note document template may be found in Chapter 3.2 of the Consolidated CDA implementation guide.

Goodness of Fit Assessment: Consultation Note

Requires the addition of:

- Social History Section with structured Entry: Smoking Status Observation for Smoking Status requirement
- Hospital Discharge Instructions Section or Instructions Section for Clinical Instructions or Discharge Instructions (inpatient settings)
- Functional Status Section for Functional Status and Cognitive Status requirements

Sections required by the document type definition but not required for MU2:

- History of Present Illness Section

Other Considerations:

- Entries are required by MU2 for Allergies, Medications, Immunizations, Problems, Procedures, Laboratory Tests, and Values/Results of Laboratory Tests
- In instances where the diagnostic test pending is a laboratory test, the use of LOINC® vocabulary is required for MU2 compliance.
- Medications and medications administered are to be coded using RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, August 6, 2012 Release.

4.2.3. Discharge Summary Alignment

The table below details the MU2 data requirement consensus recommendations sections and body constraints for the Discharge Summary. Section-level constraints are specified as "**O**" for optional (SHOULD or MAY) and "**R**" for required (SHALL). Rows where there is no corresponding section-level constraint indicate a potential gap for meeting MU2 requirements. See the Goodness of Fit Assessment in Appendix B for more detail.

Table 42: Discharge Summary Alignment

MU2 Data Requirements	Consolidated CDA Section	Discharge Summary
Medication allergies	Allergies (entries optional)	**R**
	Discharge Diet	**O**
	Family History	**O**
Functional Status; Cognitive Status	Functional Status	**O**
	History of Past Illness	**O**
	History of Present Illness	**O**
	Hospital Admission Diagnosis	**O**
	Hospital Consultations	**O**
	Hospital Course	**R**
	Hospital Discharge Diagnosis	**R**
Discharge instructions (Inpatient setting)	Hospital Discharge Instructions	**O**
Medications	Hospital Discharge Medications	**R**
	Hospital Discharge Physical	**O**
	Hospital Discharge Studies Summary	**O**
Immunizations	Immunizations (entries optional)	**O**
Care plan, including problem, goals, and instructions to the patient. Also included: Future Appointments, Future scheduled tests; Referrals to other providers; Diagnostic test pending	Plan of Care or Assessment and Plan	**R**
Problems	Problem (entries optional)	**O**
Procedures	Procedures (entries optional)	**O**
Reason for Referral	Reason for Referral	
Reason(s) for hospitalization (Inpatient setting)	Reason for Visit or Chief Complaint or Chief Complaint and Reason for Visit	**O**
Laboratory tests; Values/results of laboratory tests	Results (entries required)	
	Review of Systems	**O**
Smoking status	Social History	**O**
Vital signs	Vital Signs (entries optional)	**O**

The ToC Initiative determined that the Discharge Summary is a reasonably good fit for Meaningful Use Stage 2 requirements for Eligible Hospitals (EHs) and Critical Access Hospitals (CAHs) due to the overall alignment of requirements, with considerations noted in the following assessment. The Discharge Summary document template may be found in Chapter 3.4 of the Consolidated CDA implementation guide.

Goodness of Fit Assessment: Discharge Summary

Requires the addition of:

- Social History Section with structured Entry: Smoking Status Observation for Smoking Status requirement
- Results with entries required Section for Laboratory Tests and Results/Values of Tests requirement
- Reason for Referral Section for Reason for Referral requirement

Sections required by the document type definition but not required for MU2:

- Hospital Course Section

Other Considerations:

- Entries are required by MU2 for Allergies, Medications, Immunizations, Problems, Procedures, Laboratory Tests, and Values/Results of Laboratory Tests
- In instances where the diagnostic test pending is a laboratory test, the use of LOINC® vocabulary is required for MU2 compliance.
- Medications and medications administered are to be coded using RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, August 6, 2012 Release.

4.2.4. H&P Note Alignment

The table below details the MU2 data requirements consensus recommendation sections and body constraints for the H&P Note. Section-level constraints are specified as "**O**" for optional (SHOULD or MAY) and "**R**" for required (SHALL). Rows where there is no corresponding section-level constraint indicate a potential gap for meeting MU2 requirements. See the Goodness of Fit Assessment in Appendix B for more detail.

Table 43: H&P Note Alignment

MU2 Data Requirements	Consolidated CDA Section	H&P Note
Medication allergies	Allergies (entries optional)	**R**
	Family History	**R**
Functional status; Cognitive status	Functional Status	
	General Status	**R**
	History of Past Illness	**R**
	History of Present Illness	**O**
Discharge instructions (Inpatient setting)	Hospital Discharge Instructions	
Immunizations	Immunizations (entries optional)	**O**
Clinical instructions; Recommended patient decision aids	Instructions	**O**
Medications	Medications (entries optional)	**R**
	Physical Exam	**R**
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	**R**
Problems	Problem (entries optional)	**O**
Procedures	Procedures (entries optional)	**O**
Reason for Referral	Reason for Referral	
Reason(s) for visit or Reason(s) for	Reason for Visit or Chief Complaint or	**R**

MU2 Data Requirements	Consolidated CDA Section	H&P Note
hospitalization (Inpatient setting)	Chief Complaint and Reason for Visit	
Laboratory tests; Values/results of laboratory tests	Results (entries optional)	**R**
	Review of Systems	**R**
Smoking status	Social History	**R**
Vital signs	Vital Signs (entries optional)	**R**

The ToC Initiative determined that the H&P Note is a reasonably good fit for Meaningful Use Stage 2 requirements due to the overall alignment of requirements, with considerations noted in the following assessment. The H&P Note document template may be found in Chapter 3.5 of the Consolidated CDA implementation guide.

Goodness of Fit Assessment: H&P Note

Requires the addition of:

- Social History Section with structured Entry: Smoking Status Observation for Smoking Status requirement
- Functional Status Section for Functional Status and Cognitive Status requirements
- Hospital Discharge Instructions Section for Discharge Instructions requirement (inpatient settings)
- Reason for Referral Section for Reason for Referral requirement

Sections required by the document type definition but not required for MU2:

- Family History Section
- General Status Section
- History of Past Illness Section
- Physical Exam Section
- Review of Systems Section

Other Considerations:

- Entries are required by MU2 for Allergies, Medications, Immunizations, Encounter Diagnoses, Problems, Procedures, Laboratory Tests, and Values/Results of Laboratory Tests
- In instances where the diagnostic test pending is a laboratory test, the use of LOINC® vocabulary is required for MU2 compliance.
- Medications and medications administered are to be coded using RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, August 6, 2012 Release.

5. Transitions of Care Initiative Recommended Approach

This section of the Companion Guide describes a specific implementation approach, developed by the Transitions of Care Initiative for the implementation of initiative-specific recommendations as well as Meaningful Use Stage 2 (MU2) requirements. **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 MU2 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.

Note: The use of serviceEvent in CCD specifically calls for the representation of the provision of healthcare over a period of time. As such, it proscribes an @classCode of "PCPR" and the duration of care to be noted in the .../serviceEvent/effectiveTime.

For other document types in C-CDA the serviceEvent is used to identify procedures performed and the code used in the @classCode element must not conflict with the ClinicalDocument/code, but be equivalent to or further specialize the value. The .../serviceEvent/effectiveTime should indicate the actual start time and stop time or duration of the procedure.

Also note that additional data elements were defined by the Transitions of Care Initiative, but have not been included in this document due to insufficient or lack of accurate representation in Consolidated CDA v1.1, though some have been proposed for Consolidated CDA v2.0. Examples include Diet and Nutrition data elements as well as medication reconciliation activity data elements. The complete list of ToC data elements and representations in Consolidated CDA may be found in the Companion Guide Requirements Mapping Spreadsheet.

5.1. Transitions of Care Initiative Priorities

To classify data elements, the Transitions of Care Initiative defined priorities which describe applicability of a data element or category of data elements to clinical transitions of care scenarios. For the purposes of the Companion Guide, these priorities were streamlined as follows:

- **"A" Priority:** Core Data Elements required for all care transitions
  - These may be automated by the edge system (EHR)
  - "A" data elements have validated data models by an SDO
  - Required indicates that every clinical document created must have core data elements
- **"B" Priority:** Core Data Elements that need to be selected
  - These data elements must be selected by the sending clinician as applicable to the specific transition of care to prevent information overload by the recipient clinician.
  - "B" data elements have validated data models or have data models that are in the process of being validated
  - Relies on clinical relevance to a specific care transition, additional detail is available in section 2 and Appendix A of this guide.

For the recommended approach, MU2 data requirements were not classified as either A or B priority elements and were treated as required for exchanges.

5.2. Recommended Conformance

Conformance is informative for the Transition of Care Initiative's recommended approach. The goal is to clearly describe the clinical data to be included in the CDA document. **This approach may tighten constraints imposed by Consolidated CDA to ensure inclusion of MU2 data requirements and ToC recommended data**.

To determine constraints for the recommended approach, applications of conformance verbs from Consolidated CDA were determined as follows:

- **SHALL:** an absolute requirement.
  - Required by MU2 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.
  - ToC priority "A" and no MU2 requirement (e.g., advance directives)
- **MAY:** truly optional; can be included or omitted as the author decides with no implications.
  - ToC priority "B" and no MU2 requirement

The above conformance definitions were copied verbatim from Chapter 1.8.3 of the Consolidated CDA implementation guide. It is important to note that this does not mean that sections or entries are clinically not relevant if they are the subject of a MAY conformance verb. The relevance is usually dependent on the clinical context for a specific patient care transition.

5.2.1. 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.

- 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.
- **SHOULD** and **MAY** conformance statement may also use a null flavor.
- 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 of this guide and Chapters 1.8.8 and 1.8.9 of the Consolidated CDA implementation guide.

5.3. Recommended Approach Preamble

The following sections detail the recommended approach for an implementation of the CCD document template to satisfy MU2 requirements. The Initiative's approach details a fully compliant CDA document to meet MU2 requirements when used in conjunction with Consolidated CDA. This approach relies on extending the CCD for summarizing patient data captured during an encounter. A similar approach may be applied to a document type better aligned to the patient care scenario, such as a Consultation Note if the encounter was a consultation. This concept is further detailed in section 2 of this guide.

5.4. Recommended Approach: Header

This section details the recommended approach for the US Realm Clinical Document Header to satisfy MU2 requirements for EPs or EHs and CAHs. This approach is limited to elements representing MU2 data requirements and ToC recommendations for patient and encounter information. The elements required by MU2 are shaded in red with the data requirement listed in [brackets] and any element included in the approach that is additional to the template, will be noted as "Added".

The last column (CONF) in the following table identifies constraints attributable to the rules defined in the Federal Register. Please refer to Appendix C which contains a cross walk of these identifiers to the MU data requirements found in the Federal Register.

Table 44: Recommended Approach: Header

recordTarget	6. Note	CONF
SHALL **patientRole**		
SHALL **id**		
SHALL **addr**		
SHALL **telecom**		
SHALL **patient**		
SHALL **name** [patient name]		**CG001**
SHALL **administrativeGenderCode** [sex]		**CG018**
SHALL **birthTime** [date of birth]		**CG018**
SHOULD **maritalStatusCode**		
SHOULD **religiousAffiliationCode**		
SHOULD **raceCode** [race]		**CG018**
MAY **sdtc:raceCode**		**CG018**
SHOULD **ethnicGroupCode** [ethnicity]		**CG018**
SHOULD **guardian**		
MAY **birthplace**		
SHALL **languageCommunication** [preferred language]		**CG018**
SHALL **languageCode**		
SHOULD **preferenceInd**		
MAY **providerOrganization**		

documentationOf/serviceEvent **if a service event is detailed in document*	Note	CONF
SHOULD **performer** [care team member or provider performing the service event]		**CG002, CG021**

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]	**Added**	**CG002, CG021**
telecom [care team member or provider contact information]	**Added**	**CG002, CG021**
assignedPerson	**Added**	
name [care team member or provider name]	**Added**	**CG002, CG021**

componentOf/encompassingEncounter	Note	CONF
SHALL **id**		
SHALL **effectiveTime** [date of visit or hospitalization]		**CG003, CG023**
low [admission date]	**Added**	**CG003, CG023**
high [discharge date]	**Added**	**CG003, CG023**
responsibleParty [care team member or provider responsible for the encounter]	**Added**	**CG021**
assignedEntity	**Added**	
addr [care team member or provider contact information]	**Added**	
telecom [care team member or provider contact information]	**Added**	
assignedPerson or representedOrganization	**Added**	
name [care team member or provider name]	**Added**	**CG021**
encounterParticipant [care team member or provider participating in the encounter]	**Added**	**CG021**
typeCode [type of care team member or provider]	**Added**	
time [time of participation in the encounter]	**Added**	
assignedEntity	**Added**	
addr [care team member or provider contact information]	**Added**	**CG021, CG022**
telecom [care team member or provider contact information]	**Added**	**CG021, CG022**
assignedPerson or representedOrganization	**Added**	
name [care team member or provider name]	**Added**	**CG021, CG022**
location	**Added**	
healthCareFacility	**Added**	
id	**Added**	
code	**Added**	
location [location of visit or hospitalization]	**Added**	**CG003**
name	**Added**	
addr	**Added**	
serviceProviderOrganization [provider's organization]	**Added**	
id	**Added**	
name	**Added**	
telecom	**Added**	
addr	**Added**	
standardIndustryClassCode [type of facility]	**Added**	

6.1.Recommended Approach: CCD

This section details the recommended approach for the implementation of a CCD to satisfy MU2 requirements. An XML example of this approach is available in the Companion Guide XML Example file.

6.1.1. Recommended Approach: CCD Body

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. Any sections included in the approach that are additional to the document template will be noted as "Added".

Table 45: CCD Body Constraints

CCD Body Constraints	Note	CONF
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)		**CG007**
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)	**Added**	**CG004**
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)		**CG025**
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)		**CG010**
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)		

CCD Body Constraints	Note	CONF
SHALL Instructions (2.16.840.1.113883.10.20.22.2.45)	**Added**	**CG013, CG027**
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)		**CG006**
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)		**CG019**
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)		**CG005**
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)		**CG008**
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)	**Added**	**CG028**
SHALL Results (entries required: 2.16.840.1.113883.10.20.22.2.3.1)		**CG009**
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)		**CG017**
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)		**CG012**
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)		

7. Additional Guidance

The following information is supplied as a starting point for information on the various tools and information one may find useful (depending on their proficiency).

- Comparison and conversion tools to migrate from the existing CDA standard to new Consolidated CDA
- CCR-Consolidated CDA conversion tool for vendors who previously implemented CCR
- Openly available data modeling tools, reference implementation code, and test suite, to aid to lower implementation time and costs
- Educational resources

7.1. Tools

The Standards & Interoperability Framework has worked to enable the availability of multiple tools needed in support of using technology to improve care transitions. These tools are designed to provide the level of automated tooling needed in support of Consolidated CDA.

7.1.1. OHT/MDHT

The implementation guidance is designed to be generated directly from Model Driven Health Tools (MDHT), which is an open-source tool available to everyone. The MDHT-generated guidance includes the appropriate level of specification and detail needed to implement a care transition information exchange, including API's, code documentation, and models needed for implementation.

MDHT allows the creation of computable models of the templates in UML. These models can be used to produce template specifications (DITA, XHTML, PDF, Other), validation tools, and model driven code generation. Thus far, the project has built models from the specifications including Consolidated CDA, HITSP C83, and IHE Patient Care Coordination Technical Framework.

- **Open Health CDA Tools:** http://cdatools.org/
- **MDHT:** https://www.projects.openhealthtools.org/sf/projects/mdht/

7.1.2. NIST Validation and Testing Resources

The National Institute of Standards and Technology (NIST) provides a list of available validation tooling sites for interoperability specifications. NIST also provides tools for testing MU2 implementations.

- **Validation:** http://xreg2.nist.gov/hit-testing/
- **Testing:** http://healthcare.nist.gov/use_testing/tools.html

7.1.3. Validation and Design Resources from the Lantana Consulting Group

The Lantana Consulting Group's Trifolia Workbench provides tooling support for HL7 members. The tool supports standards authors, developers and implementers in capturing, storing and managing HL7 Clinical Document Architecture (CDA) templates. Additionally, the Lantana Consulting Group offers free tools for validating common types of CDA documents and downloadable CDA XSL StyleSheets.

- **Trifolia Workbench:** http://www.lantanagroup.com/resources/products/

- **Validation & CDA XSL Stylesheets:** http://www.lantanagroup.com/resources/free-tools/

7.2. Educational Resources

Resources for further education on topics discussed in this guide are provided below.

7.2.1. ToC Quickstart Site

The Transitions of Care (ToC) Quickstart site is a central source to view and download Transitions of Care Initiative guides, work products and models.

- **ToC Quickstart:** http://wiki.siframework.org/Transitions+of+Care+Quickstart+Page

7.2.2. Clinical Document Architecture (CDA)

The full CDA Release 2 Normative Edition is available from www.HL7.org, this package includes additional publications such as Datatypes, HL7 Value Sets, and other detailed information required for proper implementation of CDA. The following links are provided to assist in understanding the HL7 CDA standard:

- **HL7:** Certain resources from HL7 for additional information on CDA, Consolidated CDA implementation guide, and frequently asked questions are available to non-members.
  CDA R2 Product Brief: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7
  Consolidated CDA Product Brief: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258
  HL7 FAQs: http://www.hl7.org/about/FAQs/index.cfm

- **HL7 Training & Certification:** HL7 training programs provide knowledge and support to guide the healthcare industry through successful implementation of HL7 standards. Certification testing is available for specific HL7 standards including CDA.
  - ***HL7 Training:*** http://www.hl7.org/implement/training.cfm?ref=nav

- **The HL7 Book:** This wiki is focused on providing resources for understanding and implementing HL7 standards. The HL7 CDA resources include toolkits, whitepapers, and examples.
  The HL7 Book for CDA: http://hl7book.net/index.php?title=CDA

- **The CDA Book:** Written by Keith W. Boone, *The CDA Book* provides clear and simplified guidance for the HL7 CDA standard, the foundation of Consolidated CDA. The book is available for purchase through retailers and is highly recommended to assist in understanding core concepts of the standard.
  Amazon.com: http://amzn.to/18GmHvv

7.2.3. HL7 Structured Documents Work Group

As the custodian of the Consolidated CDA implementation guide, the HL7 Structured Documents work group (SDWG) is a good resource for additional guidance with implementations. There are a number of sub-categories available from the main SDWG wiki page relative to the use of CDA, items of particular interest may be: CDA Suggested Enhancements and the associated Formal Proposals, Continuity of Care

Document and CCD Errata. Users of CDA documents are encouraged to sign up for the Structured Documents listserv to learn and share expertise with other users.

- **HL7 SDWG wiki:** http://wiki.hl7.org/index.php?title=Structured_Documents
- **HL7 Listserv registration:** http://www.hl7.org/myhl7/managelistservs.cfm

7.2.4. Blogs

Several notable healthcare IT standards blogs that frequently discuss CDA are provided for reference.

- **Graham Grieve:** http://www.healthintersections.com.au/?cat=9
- **HL7 Standards:** http://www.hl7standards.com/blog/
- **Keith W. Boone:** http://motorcycleguy.blogspot.com
  - This post series by Keith, describes how to move from the HITSP C32 required by Meaningful Use Stage 1 to Consolidated CDA required by Meaningful Use Stage 2.

7.2.5. MU2 Resources

The following links are provided for additional guidance on MU2 requirements:

- **CDC:** http://www.cdc.gov/EHRmeaningfuluse/index.html
  - ***Jurisdictional Resources:*** http://www.cdc.gov/ehrmeaningfuluse/Jurisdiction.html
- **CMS:** https://www.cms.gov/Regulations-and Guidance/Legislation/EHRIncentivePrograms/Stage_2.html
- **HRSA:** http://www.hrsa.gov/healthit/index.html
- **NIH:** http://www.nlm.nih.gov/healthit/meaningful_use.html
- **ONC:** http://www.healthit.gov/policy-researchers-implementers/meaningful-use-stage-2-0
  - ***Certification Program:*** http://www.healthit.gov/policy-researchers-implementers/about-certification
- **AHIMA:** http://www.ahima.org/advocacy/arrameaningfuluse.aspx
- **AMIA:** http://www.amia.org/public-policy/policy-priorities/meaningful-use
- **HIMSS:** http://www.himss.org/ASP/topics_meaningfuluse.asp

7.2.6. 2014 Ed. CEHRT Vocabularies

The following links are provided for vocabularies required by the 2014 Ed. CEHRT as part of MU2:

- **CDT:** http://www.ada.org/3827.aspx The American Dental Association (ADA) publishes the Code on Dental Procedures and Nomenclature (CDT) for accurately reporting dental treatment. The CDT manual may be purchased through the ADA.

- **CPT:** http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt.page The American Medical Association (AMA) Current Procedural Terminology (CPT) is available through AMA where license fees are required for access to the codes.
  AMA Bookstore: https://catalog.ama-assn.org/Catalog/cpt/cpt_home.jsp

- **HCPCS:** http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/index.html?redirect=/MedHCPCSGenInfo/ CMS provides downloadable release files updated quarterly for the Healthcare Common Procedure Coding Systems (HCPCS). This standardized procedure coding system is comprised of two levels, which include the AMA CPT at level one and products, services, and supplies at level two.
  HCPCS Quarterly Update: http://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS_Quarterly_Update.html

- **HL7 Standard Code Set CVX - Vaccines Administered:** http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cvx The HL7 Table 0292, Vaccine Administered (CVX) is developed and maintained by the Centers for Disease Control and Prevention (CDC) National Center of Immunization and Respiratory Diseases (NCIRD). Additional resources for code set mappings, technical guidance, and interoperability projects are available through CDC.

- **ICD-10:** http://www.who.int/classifications/icd/en/ The International Classification of Diseases (ICD) is the standard diagnostic tool for epidemiology, health management and clinical purposes. ICD-10-CM is the diagnosis classification system developed by the CDC for use in all U.S. health care treatment settings. ICD-10-PCS is the procedure classification system developed by CMS for use in the U.S. for inpatient settings.
  ICD-10-CM: http://www.cdc.gov/nchs/icd/icd10cm.htm
  ICD-10-PCS: https://www.cms.gov/Medicare/Coding/ICD10/index.html

- **ISO 639-2 Language Codes:** http://www.loc.gov/standards/iso639-2/langhome.html The Library of Congress has been designated as the ISO 639-2 Registration Authority for processing requests for alpha-3 language codes comprising Part 2 of the ISO-639 standard. Additionally, the Library of Congress provides search tools and downloadable code lists.

- **LOINC:** http://loinc.org/relma The Regenstrief Institute provides a Windows-based mapping utility called the Regenstrief LOINC Mapping Assistant (RELMA) to facilitate searches through the LOINC database and to assist efforts to map local codes to LOINC codes.
  LOINC Educational Resources: http://loinc.org/slideshows

- **OMB Statistical Policy Directive No. 15:** http://www.whitehouse.gov/omb/fedreg_1997standards The Office of Management and Budget Standards for maintaining, collecting, and presenting federal data on race and ethnicity provides a common language to

promote uniformity and comparability for data on race and ethnicity for the population groups. Value sets for race and ethnicity are available through CDC.
PHIN VADS: https://phinvads.cdc.gov/vads/SearchVocab.action

- **RxNorm:** https://www.nlm.nih.gov/research/umls/rxnorm/ The Unified Medical Language System (UMLS) provides downloadable release files containing RxNorm and Prescribable Content releases. In addition, release notes and technical documentation detailing topics such as scripts for loading RxNorm data into Oracle or MySQL databases are available.

- **SNOMED CT:** http://www.nlm.nih.gov/research/umls/licensedcontent/snomedctfiles.html The Unified Medical Language System (UMLS) provides downloadable release files containing SNOMED CT terminology, cross maps, and technical resources. The International Release is updated each year in January and July.

Appendix A: Clinical Best Practices

A. Introduction: ToC use of Direct

The ToC Initiative defined the scope of its use cases to be closed-loop referrals and discharges from hospitals, where the information is sent in a timely way, e.g. "near-real time" to another provider. For, example a Direct message would be sent to the PCP at discharge before the patient has even left the hospital facility. A term sometimes used for this type of exchange is "directed exchange," or the "push model." As such, the ToC Initiative assumed use of the Direct Project, which specifies a simple, secure, scalable, standards-based way for participants to send authenticated, encrypted health information directly to known, trusted recipients over the Internet. Today, communication of health information among healthcare organizations, providers, and patients is most often achieved by sending a paper through the mail or fax. The Direct Project seeks to benefit patients and providers by improving the transport of health information, making it faster, more secure, and less expensive. By facilitating direct communication patterns, the Direct Project, or "Direct," moves the community closer to advanced levels of interoperability.

Direct focuses on the technical standards and services necessary to securely push content from a sender to a receiver and not the actual content exchanged. However, when these services are used by providers and organizations to transport and share qualifying clinical content, the combination of content and Direct-specified transport standards may satisfy some Meaningful Use requirements. For example, a primary care physician who is referring a patient to a specialist can use Direct to provide a patient summary of care record to the specialist and to receive a summary of the consultation. All references to Direct in this Companion Guide encompass both the primary Direct secure email transport protocol (SMTP) described in the Applicability Statement for Secure Health Transport, or the alternative transport (SOAP-based XDR and XDM for Direct Messaging). Both methods are cited in the ONC Standards and Certification Criteria 2014 Edition Final Rule.

All the detailed guidance on Consolidated CDA sections and entries in this Companion Guide is applicable to documents sent by Direct, to documents that are viewed/downloaded by a patient, which is another Meaningful Use Stage 2 requirement, as well as to documents retrieved via the "pull model." For example, Consolidated CDA documents that are viewed and/or downloaded by a patient, or sent to an HIE repository for later query and retrieval. However, the clinical workflow guidance in this Appendix assumes that the recipient is known and that directed exchange is used. A key tenet of the guidance is selectability of information based on the needs of the recipient. If the recipient is not known in advance, such as when documents are registered in a Health Information Exchange (HIE) repository, different principles may apply and are therefore, out of scope for this Companion Guide.

More information about the Direct Project can be found via a slide presentation, a Direct Project Overview document, and ONC's website.

a. Distinction between Vendors' Certified Capabilities & Providers' Meaningful Use of Certified EHR Technology

Throughout various ONC S&I Framework initiatives and workgroups, the importance of promoting physician adoption of Direct exchange has been emphasized. To this end, two tenets have been established: (1) enhance or maintain existing clinical workflow; and (2) facilitate the ability for the clinician to select clinical content for the Direct message so that it is clinically appropriate for the transition of care circumstance for which it is being employed. This section deals with the latter tenet.

There is a subtle, but critically important, distinction of what implementation guidance means, depending on the audience. In particular, how would a vendor interpret a SHALL conformance statement on a section or data element, or how would a provider interpret a meaningful use regulation that requires certain data elements? This section seeks to address these questions.

b. EHR Development of Certified Capabilities

Guiding Principle: EHRs must provide the capability to send all data for Meaningful Use, 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

EHR developers create software products that enable providers to achieve meaningful use of certified EHR technology. The vendor must 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. No "blank" sections may exist in the tests because otherwise the test procedures would not be able validate the product. Therefore, vendor certification typically uses test patients who have entries for every kind of Meaningful Use data requirement.

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.

c. Providers (EPs, EHs and CAHs) Use of EHRs

Guiding Principle: providers should use certified EHR 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 EHR technology from vendors that is capable of providing all required Meaningful Use data. Furthermore, it assumes that the EHR 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. For example, if a PCP were requesting a consultation of a Cardiologist for a new onset arrhythmia, she would include all pertinent positive and negative histories and results relevant to the cardiologist. If the same PCP were sending the same patient to a dermatologist, she would include all pertinent positive and negative histories and results relevant to the Dermatologist. The cardiologist does not require a description or image of a pustular skin rash, and the dermatologist does not require the Family History of Myocardial Infarction prior to age 60, or the Holter Monitor, and Cardiac Stress test results. The ToC Initiative recommends that EHR vendors develop their software such that it can both pass certification testing and meet clinicians' needs, thereby promoting the adoption of this technology. 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:

- 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.

For all these instances, even data that was required for certification does not have to be included in the Consolidated CDA compliant summary of care record about the patient. In addition, it would be unnecessary and irrelevant to run this document through a validator. Even though the instance would fail the technical validation because it did not contain smoking status and vital signs, it would still be a valid and useful clinical document for its specific care transition.

d. What If the Data are Incomplete When a Document is Sent?

In "push" use cases, the Transitions of Care Initiative recommends that messages be sent from the sending provider before the patient has even left the care facility, such that the recipient provider can best support the care transition in a timely manner.

For example:

- If a "high risk" patient is being discharged to home and his Patient Centered Medical Home (PCMH) Team receives the discharge information the day of discharge, the patient's care manager can arrange for appropriate follow up, call the patient once he returns home to ensure that the patient understands his discharge instructions and new active medication list. These timely actions can prevent adverse events and re-hospitalization.

- When a specialist receives a Direct message to perform a consultation for a patient, the specialist can review the tests and studies that the patient already has had performed, determine if other tests or studies are required and arrange for the patient to have them prior to the first visit. This level of Direct communication can help eliminate duplicate testing and greatly enhance care efficiency.

The immediacy of sending Direct messages to the recipient clinician may mean that some information is not yet available to be sent. For example, most facilities do not require physicians to complete the discharge summary required by CMS for a Hospital Discharge for up to 30-days post-discharge. As a result, some of this information would not be available at the time the Direct message is sent at discharge before the patient has left the hospital. Additionally, tests or study results may be pending, which the sending clinician deems pertinent to the recipient clinician in support of the care transition. The sending clinician, therefore, needs to inform the recipient that these results are pending. Thus, the recipient clinician would be aware that these tests or studies were in process, but were not yet resulted. Once the results of the missing fields were available, if pertinent to the recipient clinician, the sending clinician could send an updated Consolidated CDA document with this information.

Some transitions of care involve sending multiple communications (e.g. CDA documents, non-CDA documents and Direct messages) at different times (e.g. immediately following the transition of care). However, there is no standardized process for linking or connecting all of the communications together to indicate that the communications are all related to the same transition of care. While the focus of the Transitions of Care Initiative was on clinical content within CDA documents, rather than the metadata that might be used to link multiple communications, the Initiative recognizes this as an important consideration that requires further analysis of requirements and standards. In July 2012, ONC launched the 360X Closed-Loop Referral Initiative, which is supported by the State Health Information Exchange Program. The 360X Closed-Loop Referral Initiative seeks to "…enable providers to exchange patient information for referrals from their EHR workflow, regardless of the EHR systems and/or HISP services used (i.e., allowing information to move point-to-point between unaffiliated organizations, differing EHRs, and differing HISPs) and with at least the same quality of workflow integration providers currently experience when referring between homogeneous EHR systems." The issue of "referral matching" or "linking" is a recognized challenge that requires further discussion. At this time, current common medical practice is that the clinician that ordered the test or study for a patient is responsible to follow up with the patient regarding these results. If Direct is broadly adopted, there will be enhanced communication between the clinicians caring for the patient during care transitions regarding results, but it is out of scope for this guidance to suggest any changes to current common medical practice regarding the responsibility of the ordering clinician to follow up with the patient.

Appendix B: Recommendations beyond CCD

The ToC Initiative also defined data elements that are typically captured in CDA sections outside the scope of the CCD document. The following guidance describes the sections that may be captured as part of additional documents sent with the CCD upon a care transition as appropriate to the clinical scenario.

ToC Recommended Sections

Specific data elements defined by ToC for the recommended sections, as well as data elements supplementing MU2 data requirements, may be found in the Companion Guide Requirements Mapping Spreadsheet.

Recommended sections with no required entries

History of Present Illness
ToC recommends this section for capturing historical details leading up to and pertaining to the patient's current complaint or reason for seeking medical care. History of Present Illness is described in Chapter 4.17 of the Consolidated CDA implementation guide.

Operative Note Surgical Procedure
ToC recommends this section for capturing a narrative of any operation(s) performed during the visit or hospitalization. Operative Note Surgical Procedure is described in Chapter 4.36 of the Consolidated CDA implementation guide.

Physical Exam
ToC recommends this section for capturing a narrative of the physical examination or clinical examination performed by the clinician. Physical Exam is described in Chapter 4.38 of the Consolidated CDA implementation guide.

Postoperative Diagnosis
ToC recommends this section for capturing the diagnosis discovered during or confirmed through the surgery performed. Postoperative Diagnosis is described in Chapter 4.43 of the Consolidated CDA implementation guide.

Review of Systems
ToC recommends this section for capturing a narrative of the relevant collection of symptoms and functions systematically gathered by a clinician. Review of Systems is described in Chapter 4.56 of the Consolidated CDA implementation guide.

Recommended sections with defined entries

History of Past Illness
ToC recommends this section for capturing all aspects of the medical history of the patient, even if not pertinent to the current encounter. History of Past Illness is described in Chapter 4.16 of the Consolidated CDA implementation guide.

Table 46: History of Past Illness Section Structure

History of Past Illness
MAY **Problem Observation**

Preoperative Diagnosis

ToC recommends this section for capturing the diagnoses assigned to the patient before the surgical procedure that is to be confirmed through the surgery. Preoperative Diagnosis is described in Chapter 4.43 of the Consolidated CDA implementation guide.

Table 47: Preoperative Diagnosis Section Structure

Preoperative Diagnosis
SHOULD **Preoperative Diagnosis**
SHALL **Problem Observation**

Appendix C: Federal Register - MU Data Requirements Citations

MU Data Requirements

The following identifiers have been provided to identify MU Data Requirements found in the Federal Register. As needed, they will be referenced to identify constraints presented in the Companion Guide where those constraints are not expressed within the C-CDA Implementation Guide or CDA standard.

The references below refer to: "Medicare and Medicaid Programs; Electronic Health Record Incentive Program--Stage 2", 77 Federal Register 171 (4 September2012), {pages}. The specific pages will be noted in the Citation Page(s) column of this table.

Identifier	Description	Citation Page(s)
CG001	Patient name	54001, 54010, 54016, 54040
CG002	Provider's name and office contact information	54001, 54010
CG003	Date and location of the visit	54001
CG004	Reason for the office visit	54001
CG005	Current and past problem list*	54001, 54010, 54016, 54040
CG006	Current medication list and medication history**	54001, 54010, 54016, 54040
CG007	Current medication allergy list and medication allergy history***	54001, 54010, 54016, 54040
CG008	Procedures	54002, 54010, 54016, 54040
CG009	Laboratory test results	54002, 54010, 54016, 54040
CG010	Immunizations or medications administered during the visit	54002
CG011	List of diagnostic tests pending	54002
CG012	Vital signs (height, weight, blood pressure, BMI, VDT only → growth charts)	54002, 54010, 54016, 54040
CG013	Clinical instructions	54002
CG014	Future appointments	54002
CG015	Referrals to other providers	54002
CG016	Future scheduled tests	54002
CG017	Smoking status	54002, 54010, 54016, 54040
CG018	Demographic information (preferred language, sex, race, ethnicity, date of birth)	54002, 54011, 54016, 54040
CG019	Care plan field(s), including goals and instructions	54002, 54011, 54016, 54040
CG020	Recommended patient decision aids (if applicable to the visit).	54002
CG021	Any known care team members including the primary care provider (PCP) of record	54011, 54040
CG022	Referring or transitioning provider's name and office contact information (EP only)	54016
CG023	Encounter diagnosis	54016
CG024	Immunizations	54016
CG025	Functional status, including activities of daily living, cognitive and disability status	54016
CG026	Any additional known care team members beyond the referring or transitioning provider and the receiving provider	54016
CG027	Discharge instructions (Hospital Only)	54016
CG028	Reason for referral (EP only)	54016
CG029	Admit and discharge date and location	54040
CG030	Reason for hospitalization	54040
CG031	Discharge instructions for patient	54040

Note: * Past problem list not required for Clinical Summaries (VDT) or Summary of Care (transitions or referrals).
Note: ** Medication history not required for Clinical Summaries (VDT) or Summary of Care (transitions or referrals).
Note: *** Medication allergy history not required for Clinical Summaries (VDT) or Summary of Care (transitions or referrals).

MU Vocabulary Requirements

The following identifiers have been provided to identify MU Vocabulary Requirements found in the Federal Register. As needed, they will be referenced to identify constraints presented in the Companion Guide where those constraints are not expressed to the same rigor within the C-CDA Implementation Guide or CDA standard.

The references below refer to: "Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology", 77 Federal Register 171 (4 September2012), {pages}. The specific pages will be noted under Citation Page(s).

Identifier	Description	Citation Page(s)
CG032	IHTSDO SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release	54284
CG033	Logical Observation Identifiers Names and Codes (LOINC®) version 2.27	54284
CG034	Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.40	54284
CG035	RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, August 6, 2012 Release	54284
CG036	HL7 Standard Code Set CVX—Vaccines Administered, July 30, 2009 version	54284
CG037	The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997	54284-54285
CG038	ISO 639–2 alpha-3 codes limited to those that also have a corresponding alpha-2 code in ISO 639–1	54285
CG039	Smoking status. Smoking status must be coded with one of eight codes provided.	54285

The references below refer to: "Title 45 - Public Welfare. SUBTITLE A - DEPARTMENT OF HEALTH AND HUMAN SERVICES. SUBCHAPTER C - ADMINISTRATIVE DATA STANDARDS AND RELATED REQUIREMENTS", 1 Code of Federal Regulations 162.1002 (1 October 2011). The specific citation will be noted under Citation Reference.

Identifier	Description	Citation Reference
CG040	Code on Dental Procedures and Nomenclature, as maintained and distributed by the American Dental Association, for dental services.	45 CFR 162.1002(a)(4)
CG041	International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) (including The Official ICD–10–CM Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following conditions: (i) Diseases. (ii) Injuries. (iii) Impairments. (iv) Other health problems and their manifestations. (v) Causes of injury, disease, impairment, or other health problems.	45 CFR 162.1002(c)(2)
CG042	International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) (including The Official ICD–10–PCS Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following procedures or other actions taken for diseases,	45 CFR 162.1002(c)(3)

injuries, and impairments on hospital inpatients reported by hospitals:
(i) Prevention.
(ii) Diagnosis.
(iii) Treatment.
(iv) Management.

Appendix D: Additional Information on Consolidated CDA Documents

Consolidated CDA Structured Document Body Constraints

The table below summarizes the body constraints for each of the eight structured documents. Required sections are indicated by an "R" and optional sections are indicated by an "O". ToC consensus recommendation sections for MU2 requirements are highlighted in blue. Please note that the list of Consolidated CDA sections is not comprehensive, but includes all sections indicated as required or optional as part of any of these eight document templates.

Consolidated CDA Section	CCD	Consult Note	Diagnostic Imaging Report	Discharge Summary	History and Physical	Operative Summary	Procedure Note	Progress Note
Advance Directives (entries optional)	O							
Allergies (entries required)	R							
Allergies (entries optional)		O		R	R		O	O
Anesthesia						R	O	
Assessment*		O			O		O	O
Assessments and Plan*		O			O		O	O
Chief Complaint and Reason for Visit**				O	O		O	
Chief Complaint**				O	O		O	O
Complications						R	R	
DICOM Object Catalog			R					
Discharge Diet				O				
Encounters (entries optional)	O							

Encounters (entries required)								
Family History	**O**	**O**		**O**	**R**		**O**	
Findings (DIR)			**R**					
Functional Status	**O**			**O**				
General Status		**O**			**R**			
History of Past Illness		**O**		**O**	**R**		**O**	
History of Present Illness		**R**		**O**	**O**		**O**	
Hospital Admission Diagnosis				**O**				
Hospital Admission Medications (entries optional)				**O**				
Hospital Consultations				**O**				
Hospital Course				**R**				
Hospital Discharge Diagnosis				**R**				
Hospital Discharge Instructions				**O**				
Hospital Discharge Medications (entries optional)				**R**				
Hospital Discharge Medications (entries required)								
Hospital Discharge Physical				**O**				
Hospital Discharge Studies				**O**				
Immunizations (entries optional)	**O**	**O**		**O**	**O**			

Immunizations (entries required)								
Instructions								
Interventions								**O**
Medical (General) History							**O**	
Medical Equipment	**O**							
Medications (entries optional)		**O**			**R**		**O**	**O**
Medications (entries required)	**R**							
Medications Administered							**O**	
Objective								**O**
Operative Note Fluids						**O**		
Operative Note Surgical Procedure						**O**		
Payers	**O**							
Physical Exam		**O**			**R**		**O**	**O**
Plan of Care*	**O**	**R**		**R**	**R**	**O**	**O**	**O**
Planned Procedure						**O**	**O**	
Postoperative Diagnosis						**R**		
Post-procedure Diagnosis							**R**	
Preoperative Diagnosis						**R**		
Problem (entries optional)		**O**		**O**	**O**			**O**

Problem (entries required)	**R**							
Procedure Description						**R**	**R***	
Procedure Disposition						**O**	**O**	
Procedure Estimated Blood Loss						**R**	**O**	
Procedure Findings						**R**	**O**	
Procedure Implants						**O**	**O**	
Procedure Indications						**O**	**R**	
Procedure Specimens Taken						**R**	**O**	
Procedures (entries optional)		**O**		**O**	**O**		**O**	
Procedures (entries required)	**O**							
Reason for Referral		**O**						
Reason for Visit**		**O**		**O**	**R**		**O**	
Results (entries optional)		**O**			**R**			**O**
Results (entries required)	**R**							
Review of Systems		**O**		**O**	**R**		**O**	**O**
Social History	**O**	**O**		**O**	**R**		**O**	
Subjective								**O**
Surgical Drains						**O**		
Vital Signs (entries optional)	**O**	**O**		**O**	**R**			**O**

Vital Signs (entries required)								

* Wherever referenced, intent is that either Assessment and Plan is present or both Assessment and Plan of Care. Only these combinations should be used. Local policy determines whether the individual sections or combined section is employed.

** Wherever referenced, intent is that either Chief Complaint/Reason for Visit Section is present or Chief Complaint Section and/or Reason for Visit unique Sections should be present. Local policy determines whether the individual sections or the combined section should be employed.

Consolidated CDA Goodness of Fit Assessment

The tables below illustrate the assessment of select Consolidated CDA document types for the goodness of fit against Meaningful Use Stage 2 (MU2) data requirements. Header constraints for elements aligned the MU2 data requirements were not included in the assessment. The goodness of fit assessment findings are used as the foundation for guidance provided in section 4 of the Companion Guide.

Assessment summary:

- For Eligible Professionals (EPs), the **CCD matched MU2 data requirements** more closely than the Consult Note or the History and Physical (H&P). This is primarily due to the carryover from MU1 to MU2 of the requirements for **structured entries** in Medications, Allergies, Problems, Procedures, and Results sections, which are required in CCD but not in the other document types.
- For Eligible Hospitals (EHs), the **CCD matched MU2 data requirements slightly** more closely than the Discharge Summary, but the differences are very narrow. CCD scored higher due to the carryover from MU1 to MU2 of the requirements for **structured entries** in Medications, Allergies, Problems, Procedures, and Results sections, which are not required in the Discharge Summary. On the other hand, Discharge Summary did better in certain areas because it requires sections aligned to MU2 that are not in CCD, such as Discharge Instructions, History of Past Illness, and Reason for Visit (Hospitalization).

Please note that the above conclusions assume that **only** MU2 required data is included in the document. Other document types' goodness of fit may improve depending on which additional data (beyond MU2) the provider wishes to transmit on a transition. Scores were totaled for each document type, and the highest score was deemed the "best fit" document type for MU2. Individual MU2 objectives are provided for reference, but do not affect scoring. The method for the assessment scores are detailed in the table below.

Goodness of Fit Assessment Scoring	
Score	**Criteria**
0	a. Required or optional only in the Document type AND no requirement for MU2 b. Required only by MU2 AND no constraint in the Document type
1	a. Required for MU2 with specified vocabulary AND section with no required entries is optional in document type
2	a. Required for MU2 AND section is optional in document type b. Required for MU2 with specified vocabulary AND section with required entries is optional in document type c. Required for MU2 with specified vocabulary AND section with no required entries is required in document type
3	a. Required for MU2 AND section is required in document type b. Required for MU2 with specified vocabulary AND section with required entries is required in document type

EPs

The table below contains the data requirements for MU2 Objectives and Consolidated CDA documents applicable to EPs for determining "goodness of fit". Not all possible Consolidated CDA sections are listed: rows are limited to sections that are listed as Required or Optional in the two specific Consolidated CDA (CCD, Discharge Summary) document types shown. Those sections that are not required in any MU2 objective are shaded gray. Sections required (SHALL) in the document definition are noted "R" and optional sections (SHOULD or MAY) are noted "O" for optional. MU2 data requirements with specified vocabularies are shaded in red.

	MU2 Objectives (EPs)			C-CDA Documents			Goodness of Fit		
C-CDA Section (inclusive of requirements)	Transitions of Care or Data Portability	VDT to 3rd Party	Clinical Summary	C-CDA CCD	C-CDA Consult Note	C-CDA H&P	CCD GOF	Consult Note GOF	H&P GOF
Advance Directives (entries optional)				O			0		
Allergies (entries required)	Medication Allergy List	Medication Allergy List	Medication Allergy List	R			3	1	2
Allergies (entries optional)					O	R			
Family History				O	O	R	0	0	0
Functional Status	Functional Status; Cognitive Status		Functional Status; Cognitive Status	O			2	0	0
General Status					O	R		0	0
History of Past Illness					O	R		0	0
History of Present Illness					R	O		0	0
Immunizations (entries optional)	Immunizations		Immunizations	O	O	O	1	1	1
Immunizations (entries required)									
Instructions	Instructions	Instructions	Instructions; Recommended Patient Decision Aids				0	0	0
Medical Equipment				O			0		
Medications (entries optional)	Medications	Medications	Medications		O	R	3	1	2
Medications (entries required)				R					
Payers				O			0		
Physical Exam					O	R		0	0
Plan of Care~	Care Plan & Goals	Care Plan & Goals	Care Plan & Goals; Future Scheduled Tests and/or Appts; Tests Pending;	O	R	R	2	3	3

C-CDA Section (inclusive of requirements)	MU2 Objectives (EPs)			C-CDA Documents			Goodness of Fit		
	Transitions of Care or Data Portability	VDT to 3rd Party	Clinical Summary	C-CDA CCD	C-CDA Consult Note	C-CDA H&P	CCD GOF	Consult Note GOF	H&P GOF
			Referrals to Other Providers						
Problem (entries optional)	Encounter Diagnoses; Problems	Encounter Diagnoses; Problems	Problems		O	O	3	1	1
Problem (entries required)				R					
Procedures (entries optional)	Procedures	Procedures	Procedures		O	O	3	1	1
Procedures (entries required)				R					
Reason for Referral*	Reason for Referral		Reason for Referral		R		0	3	0
Reason for Visit*^			Reason for Visit		R	R	0	3	3
Results (entries optional)	Laboratory Tests and Value/ Results	Laboratory Tests and Value/ Results	Laboratory Tests and Value/ Results		O	R	3	1	2
Results (entries required)				R					
Review of Systems					O	R		0	0
Social History	Smoking Status	Smoking Status	Smoking Status	O	O	R	1	1	2
Vital Signs (entries optional)	Vital Signs	Vital Signs	Vital Signs	O	O	R	2	2	3
Vital Signs (entries required)									
						Total Scores	23	18	20

* Consult Note SHALL contain Reason for Referral or Reason for Visit sections, both have been noted "R" for MU2 data requirements.

^ H&P Note and Consult Note SHALL contain Chief Complaint, Chief Complaint and Reason for Visit, or Reason for Visit, Reason for Visit has been noted "R" for MU2 data requirements.

~ H&P Note and Consult Note SHALL contain Assessment, Assessment and Plan, or Plan of Care sections, Plan of Care has been noted "R" for MU2 data requirements.

EHs and CAHs

The table below contains the data requirements for MU2 Objectives and Consolidated CDA documents applicable to EHs and CAHs for determining "goodness of fit". Not all possible Consolidated CDA sections are listed: rows are limited to sections that are listed as Required or Optional in the two specific Consolidated CDA (CCD, Discharge Summary) document types shown. Those sections that are not required in any

MU2 objective are shaded gray. Sections required (SHALL) in the document definition are noted "R" and optional sections (SHOULD or MAY) are noted "O" for optional. MU2 data requirements with specified vocabularies are shaded in red.

	MU2 Objectives		C-CDA Docs		Goodness of Fit	
C-CDA Section (inclusive of requirements/ recommendations)	**Transitions of Care or Data Portability**	**VDT to 3rd Party**	**C-CDA CCD**	**C-CDA Discharge Summary**	**CCD GOF**	**Discharge Summary GOF**
Advance Directives (entries optional)			O		0	
Allergies (entries optional)	Medication Allergy List	Medication Allergy List		R	3	1
Allergies (entries required)			R			
Discharge Diet				O		0
Family History			O	O	0	0
Functional Status	Functional Status; Cognitive Status		O	O	2	2
History of Past Illness				O		0
History of Present Illness				O		0
Hospital Admission Diagnosis				O		0
Hospital Course				R		0
Hospital Discharge Diagnosis	Encounter Diagnoses; Problems**	Problems**		R		3
Hospital Discharge Instructions	Discharge Instructions	Discharge Instructions		O	0	1
Hospital Discharge Medications	Medications~~	Medications~~		R		3
Hospital Discharge Physical				O		0
Hospital Discharge Studies	Laboratory Tests and Values/Results^^	Laboratory Tests and Values/Results^^		O		1
Immunizations (entries optional)	Immunizations		O	O	1	1
Immunizations (entries required)						
Medical Equipment			O		0	
Medications (entries required)	Medications~~	Medications~~	R		3	
Payers			O		0	
Plan of Care	Care Plan & Goals	Care Plan & Goals	O	R	2	
Problem (entries optional)	Encounter Diagnoses; Problems**	Problems**		O	3	
Problem (entries required)			R			
Procedures (entries optional)	Procedures	Procedures		O	3	1
Procedures (entries required)			R			
Reason for Visit^	Reason(s) for Hospitalization	Reason(s) for Hospitalization		O	0	2

	MU2 Objectives		C-CDA Docs		Goodness of Fit	
C-CDA Section (inclusive of requirements/ recommendations)	Transitions of Care or Data Portability	VDT to 3rd Party	C-CDA CCD	C-CDA Discharge Summary	CCD GOF	Discharge Summary GOF
Results (entries optional)	Laboratory Tests and Values/Results^^	Laboratory Tests and Values/Results^^			3	
Results (entries required)			R			
Review of Systems				O	0	
Social History	Smoking Status	Smoking Status	O	O	1	1
Vital Signs (entries optional)	Vital Signs	Vital Signs	O	O	2	2
Vital Signs (entries required)						
				Total Scores	21	18

^ Discharge Summary SHALL contain Chief Complaint, Chief Complaint and Reason for Visit, or Reason for Visit, Reason for Visit has been noted "R" for MU2 data requirement.

** Encounter Diagnoses and Problems are included in Hospital Discharge Diagnoses section for Discharge Summary and Problems section for CCD. Optional inclusion of Problems section in Discharge Summary was not calculated for the assessment.

^^ Laboratory Tests and Values/Results are included in Hospital Discharge Studies section for Discharge Summary and Results section for CCD. Hospital Discharge Studies section does not require entries.

~~ Medications are included in Hospital Discharge Medications section for Discharge Summary and Medications section for CCD.