



**HL7 CDA® R2 Implementation Guide:  
C-CDA Templates for Clinical Notes R2.1  
Companion Guide  
Release 2 (US Realm)  
Standard for Trial Use**

**October 2019  
October 2021 Errata Version**

**Sponsored by:  
Structured Documents Work Group**

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### Revision History

Release	Date	Description
Release 1	MAR 2017	Initial version with implementation guidance corresponding to use of C-CDA 1.1
Release 2	OCT 2019	Updated to revise guidance to address C-CDA 2.1
Release 2 Oct 2020 Errata	OCT 2020	Errata version to remove stylesheets from publication package to address security concerns
Release 2 Oct 2021 Errata	OCT 2021	Errata version to address various issues reported by the community. See spreadsheet in release package for details. In addition to the spreadsheet list of errata, these changes have been incorporated in the artifacts included in the publication package

The Companion Guide has been developed by MaxMD under the management of HL7 as part of a grant awarded to HL7 by the Office of the National Coordinator for Health Information Technology (ONC). The MaxMD team included Lisa Nelson and Natasha Kreisle. The guidance in the Companion Guide reflects implementation experience and input from healthcare community stakeholders, and feedback from surveys and in-person “Implementation-a-thons” conducted by HL7.

It has been developed through a detailed analysis and review of the current regulations, reviews with HL7 Working Groups, and reviews by experienced implementers and “Implementation-a-thons” participants.

The project team wishes to extend its thanks to members of the HL7 Structured Documents Work Group, HL7 C-CDA Implementation-A-Thon participants and those who contributed to the development and review of guidance noted in this document:

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# 1 Introduction

## 1.1 Purpose: Essential Guidance for Advancing Interoperability

This companion guide titled, “Companion Guide to Consolidated Clinical Document Architecture (C-CDA) R2,” provides essential implementer guidance to continuously expand interoperability for clinical information shared via structured clinical notes. The guidance supplements specifications established in the Health Level Seven (HL7) CDA® R2.1 IG: C-CDA Templates for Clinical Notes. This additional guidance is intended to make implementers aware of emerging expectations and best practices for C-CDA document exchange. The objective is to increase consistency and expand interoperability across the community of data sharing partners who utilize C-CDA for information exchange.

The guide provides additional technical clarification and practical guidance for implementers interested in supporting current best practices for interoperability and for those who wish to explore advancing guidance from stakeholders throughout the C-CDA implementer community. It is part of a larger strategy to expand the level of interoperability within the healthcare ecosystem over time. The strategy involves regularly balloting a Companion Guide via the HL7 ballot process to document rising expectations for interoperability being driven from within the C-CDA implementer community. Then, regularly incorporating the consensus conformance expectations into the base C-CDA specification through the HL7 STU Update process. Over time, this new approach provides a pathway for continuous improvement and expansion of C-CDA based information exchange.

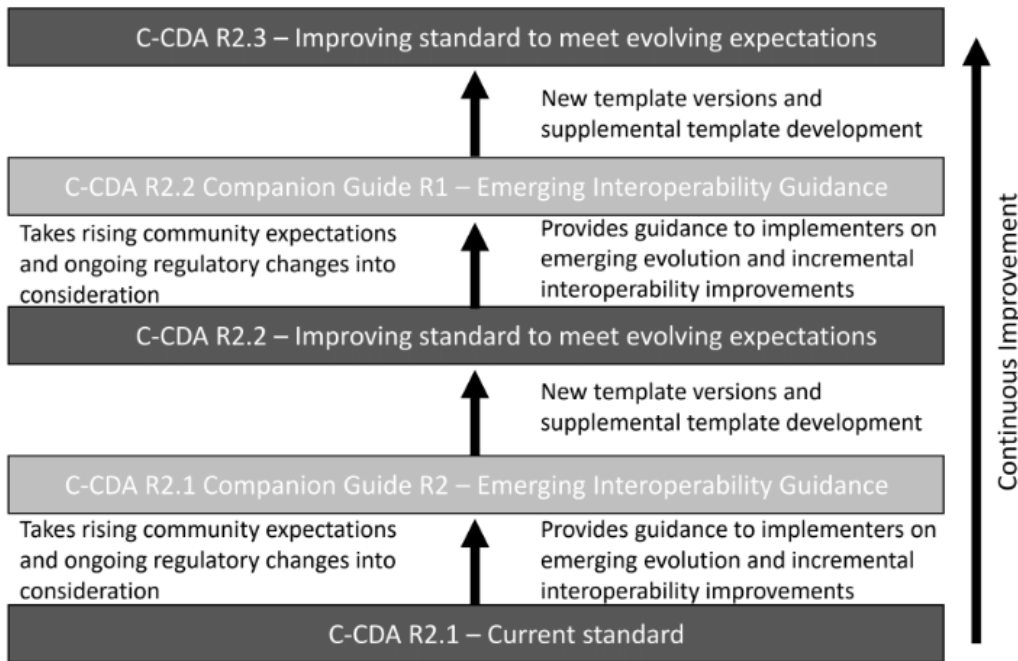


Figure 1: Continuous Improvement Strategy

The Companion Guide is intended to:

- Explain basic CDA concepts that are important to understand, when creating or consuming C-CDA documents.
- Provide guidance on best practices for consistent representation of information that is essential for interoperability across systems.
- Offer additional guidance that is relevant for implementers given emerging regulations and rising expectations for sharing information via C-CDA documents.

Guidance included in this Companion Guide is consistent with and augments the guidance and specifications defined in the Health Level Seven (HL7) CDA® R2 IG: C-CDA Templates for Clinical Notes STU Release 2.1 implementation guide. It is an integral part of the maturation process driving the growth and improvement of C-CDA and supports the shift away from using early specifications such as C32 and C-CDA 1.1.

## 1.2 The Genesis and Evolution of C-CDA

Consolidated CDA (C-CDA) is a library of CDA templates developed by HL7. It leverages prior efforts from HL7, Integrating the Healthcare Enterprise (IHE), and Health Information Technology Standards Panel (HITSP). It harmonizes that work and consolidates implementation guides developed under the HL7 Health Story Project. C-CDA was originally developed within the ONC's Standards and Interoperability (S&I) Framework to provide a definitive set of harmonized CDA templates for the US Realm. C-CDA has evolved over time as additional implementer guidance has been developed through the HL7 ballot process to contribute new templates that supplement the available template library. The C-CDA R2.1 implementation guide (IG) is the currently available version of these templates. However, additional IGs have been developed, balloted and published within the C-CDA implementer community to supplement and expand the number of available templates. This collection of work continues to evolve as major enabler of information exchange and interoperability.

### 1.2.1 The Maturation Process for C-CDA

Currently, C-CDA R2.1 is an HL7 Standard for Trial Use that is working toward Normative.<sup>1</sup> The HL7 classification of "Standard for Trial Use" (STU) classifies C-CDA R2.1 within the standards development process at HL7.<sup>2</sup> In order to be useful, standards need to evolve and mature. At the same time, the evolution of standards needs to be predictable and manageable for the implementation community. The C-CDA Companion Guide introduces an Informative standard

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<sup>1</sup> Normative HL7 standards are subject to accreditation by the American National Standards Institute (ANSI) and must comply with policies defined in HL7® Essential Requirements at:

[https://www.hl7.org/documentcenter/public/procedures/HL7\\_Essential\\_Requirements.pdf](https://www.hl7.org/documentcenter/public/procedures/HL7_Essential_Requirements.pdf)

<sup>2</sup> Policies for non-normative standards are defined in the HL7® Governance and Operations Manual (GOM) at: [https://www.hl7.org/documentcenter/public/membership/HL7\\_Governance\\_and\\_Operations\\_Manual.pdf](https://www.hl7.org/documentcenter/public/membership/HL7_Governance_and_Operations_Manual.pdf)

that contributes to the maturation of C-CDA. This section describes how HL7 develops a standard so that implementers know what to expect as the standard evolves.

HL7 has four classifications that describe the level of stability and implementation readiness associated with evolving specifications. They are summarized in the table below.

Standard Level	Description
<b>Normative</b>	This content has been subject to review and production implementation in a wide variety of environments. The content is considered to be stable and has been 'locked', subjecting it to <b>HL7® Essential Requirements</b> . While changes are possible, they are expected to be infrequent and are tightly constrained.
<b>Trial Use</b>	This content has been well reviewed and is considered by the authors to be ready for use in production systems. It has been subjected to ballot and approved as an official standard. However, it has not yet seen widespread use in production across the full spectrum of environments it is which it is intended to be used. In some cases, there may be documented known issues that require implementation experience to determine appropriate resolutions.
<b>Informative</b>	This portion of the specification is provided for implementer assistance and does not make rules that implementers are required to follow. Typical examples of this content in this specification are tables of contents, registries, examples, and implementer advice.
<b>Draft</b>	This portion of the specification is not considered to be complete enough or sufficiently reviewed to be safe for implementation. It may have known issues or still be in the "in development" stage. It is included in the publication as a place-holder, to solicit feedback from the implementation community and/or to give implementers some insight as to functionality likely to be included in future versions of the specification. Content at this level should only be implemented "at your own risk." The content that is Draft that will usually be elevated to Trial Use once review and correction is complete after it has been subjected to ballot.

*Table 1: Classifications of specifications*

Certain templates within C-CDA are more mature than others. HL7 FHIR supports a process that allows a large standard to classify component parts with different levels of maturity.<sup>3</sup> The CDA Management team is working to apply a maturity model to C-CDA templates.

Implementers are encouraged to submit comments regarding issues discovered in the published standard. Currently STU comments are posted on the HL7 website. A link to the STU comments page for C-CDA R2.1 can be found on the main product page of the HL7 standards Master Grid.<sup>4</sup>

HL7 is in the process of migrating the STU comment process to Jira during the 2019-2020 timeframe.<sup>5</sup> STU Comments are reviewed by the HL7 Structured Documents Work Group and disposed of on a regular basis. Periodic STU updates take into consideration balloted supplemental and companion guidance, emerging best practices, and implementer comments.

<sup>3</sup> HL7 FHIR. Maturity Levels. <https://www.hl7.org/fhir/versions.html#std-process>

<sup>4</sup> HL7 Standards – Master Grid [http://www.hl7.org/implement/standards/product\\_matrix.cfm](http://www.hl7.org/implement/standards/product_matrix.cfm)

<sup>5</sup> HL7 Jira. <https://confluence.hl7.org/display/HL7/Confluence+and+JIRA+Information+Updates>

### 1.2.2 C-CDA Errata Process

C-CDA R2.1 is regularly updated to include technical corrections and clarifications. These published updates are called Technical Errata Releases. They are published on the HL7.org website. Only those comments with a disposition of persuasive are considered errata. The HL7 Structured Documents Work Group reviews the STU comments on a periodic basis and publishes an errata package to report changes that have been approved as technical corrections. A C-CDA implementation SHALL incorporate all published errata applicable to the templates used. When an errata package is published, it is announced through HL7 and errata packages are published on the HL7.org website.<sup>6</sup> The errata package is published in the download kit for the standard. It includes a letter from HL7 summarizing the errata, a spreadsheet list of approved errata and the base Implementation Guide to which the errata must be applied.

Implementers should note that to maintain a current list of the approved technical errata for C-CDA R2.1 the errata packages need to be downloaded regularly from the HL7.org website.<sup>7</sup>

The errata version of the C-CDA R2.1 Implementation Guide includes text changes to implement the errata changes. However, it should be noted that the C-CDA R2.1 Schematron is not always up-to-date with C-CDA R2.1 Errata and may contain errors of its own. Issues uncovered by use of Schematron validation must be investigated to determine if they are true validation errors, Schematron errors, or unimplemented errata. These issues should be reported to the HL7 Structured Documents Work Group

**Reference:** Chapter 6 Resources

### 1.2.3 C-CDA STU Updates

HL7 supports a Review Ballot process called, STU Update, that supports updating a standard in the trial use category. The process entails several steps summarized in the table below.<sup>8</sup>

Process Step	Summary of Activity
<b>Initiate an update review</b>	The Technical Steering Committee (TSC), in compliance with its defined processes, may initiate the review of the subject matter of the proposed STU. Once initiated, the review ballot shall remain active until such time as the subject matter of the proposed STU has been approved or withdrawn from consideration. <sup>9</sup>

<sup>6</sup> For more information on errata packages, visit [http://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=408](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=408)

<sup>7</sup> Visit <http://www.hl7.org>

<sup>8</sup> HL7 Governance and Operating Procedures. April 23, 2019. [http://www.hl7.org/documentcenter/public\\_temp\\_24864365-1C23-BA17-0C7F85DECF8DE71A/membership/HL7\\_Governance\\_and\\_Operations\\_Manual.pdf](http://www.hl7.org/documentcenter/public_temp_24864365-1C23-BA17-0C7F85DECF8DE71A/membership/HL7_Governance_and_Operations_Manual.pdf)

<sup>9</sup> HL7 GOM. Page 50, Section 13.02.01. [http://www.hl7.org/documentcenter/public\\_temp\\_3BFA6E11-1C23-BA17-0CA9D4758D6F5E56/membership/HL7\\_Governance\\_and\\_Operations\\_Manual.pdf](http://www.hl7.org/documentcenter/public_temp_3BFA6E11-1C23-BA17-0CA9D4758D6F5E56/membership/HL7_Governance_and_Operations_Manual.pdf)



Process Step	Summary of Activity
<b>Form a Consensus Group</b>	All current members shall be notified of the intent to form a consensus group and ballot the content of a proposed standard for trial use. This notification shall occur via the various HL7 newsletters and member list servers and shall include the dates of enrollment in the consensus group. Members shall indicate their interest by enrolling in the appropriate consensus group via the HL7 Ballot Desktop during the enrollment period which shall end with the opening of the ballot period. <sup>10</sup> The minimum consensus group shall be ten current individual members or individuals representing at least three current organizational members. The ballot shall not commence if the minimum consensus group requirement is not met. Nonmembers who wish to participate in a STU consensus group must register their intent with HL7 Headquarters during the stated enrollment period by completing the Non-Member Enrollment process through the HL7 Ballot Desktop. Nonmembers shall be assessed a fee established by HL7 for such participation.
<b>Ballot the updated standard</b>	The ballot package shall be available to all members of the consensus group for thirty days following the opening of the ballot period. Reviewers are encouraged to provide constructive comments for improving the content or language of the subject matter under review.
<b>Handle comments</b>	At the close of the review ballot the responsible Work Group (WG) shall capture all comments using the HL7 Ballot Spreadsheet unless the WG has petitioned for and been granted a waiver of such use by the Technical Steering Committee (TSC). The responsible WG shall consider all comments with the intent of improving the quality and clarity of the proposed standard. While not on a par with a normative reconciliation package, the results of the Work Group’s consideration of the comments submitted as recorded on the Ballot Spreadsheet shall be posted to the Ballot Desktop. A negative without comment shall be considered as “no response” and shall not be factored into the numerical requirements for approval. No effort shall be made to solicit comments from the submitter of a negative without comment. The process of consideration of the comments is not as complete or rigorous as normative reconciliation. There is no requirement to resolve negative comments and seek withdrawal of the negative. Nevertheless, the responsible Work Group is expected to annotate each negative comment on the reconciliation spreadsheet with a disposition of “Persuasive”, “Not Persuasive”, “Considered for Future Use”, or “Not Related” with a recorded vote and an explanation for the Work Group’s decision in accordance with the Work Group’s Decision-making Practices (DMP) to maintain transparency on decisions made. A negative ballot withdrawn at the request of the submitter shall be recorded as an affirmative. The issue of substantive change shall not be applicable to a STU. In the instance of an approved STU with substantive change resulting from review, it is left to the discretion of the responsible Work Group to either submit to another review ballot or move forward with a request to the TSC to release the revised content as a standard for trial use.

<sup>10</sup> HL7 Governance and Operations Manual Adopted March 7, 2019 51 Last Update: April 23, 2019  
[http://www.hl7.org/documentcenter/public temp EE387793-1C23-BA17-0C0E4E265FA6688F/membership/HL7 Governance and Operations Manual.pdf](http://www.hl7.org/documentcenter/public_temp_EE387793-1C23-BA17-0C0E4E265FA6688F/membership/HL7_Governance_and_Operations_Manual.pdf)



Process Step	Summary of Activity
<b>Approve</b>	The proposed STU shall be considered approved if sixty percent (60%) of the combined affirmative and negative votes cast by the review group are affirmative. Upon approval and posting of the ballot reconciliation the responsible Work Group shall vote to submit a Publication Request Template to the TSC Project Manager, who shall include an item on the agenda of the next scheduled TSC meeting for the consideration of affirmation of release for publication. The Work Group vote shall be recorded in the minutes and reported on the Publication Request Template. If the proposed STU fails to be approved, it again falls to the discretion of the responsible Work Group, after appropriate revision if necessary, to either submit to another review ballot, withdraw the document from consideration, or repackage the content and submit it to the TSC for consideration as a normative ballot.

Table 2: Review Ballot process

### 1.3 Semantic Interoperability: C-CDA Value Set Management

Through a community consensus process, HIMSS developed the following definition for Interoperability:

Interoperability is the ability of different information systems, devices or applications to connect, in a coordinated manner, within and across organizational boundaries to access, exchange and cooperatively use data amongst stakeholders, with the goal of optimizing the health of individuals and populations that characterizes four aspects to interoperability: foundational, structural, semantic, and organizational. The table below summarizes the four concepts.<sup>11</sup>

Aspect	Relationship to Interoperability
<b>Foundational</b>	Foundation interoperability develops the building blocks of information exchange between disparate systems by establishing the inter-connectivity requirements needed for one system or application to share data with and receive data from another. It does not outline the ability for the receiving information technology system to interpret the data without interventions from the end user or other technologies.
<b>Structural</b>	Structural interoperability defines the structure or format of data exchange (i.e., the message format standards) where there is uniform movement of healthcare data from one system to another such that the clinical or operational purpose and meaning of the data is preserved and unaltered. Structural interoperability defines the syntax of the data exchange. It ensures that data exchanges between information technology systems can be interpreted at the data field level.
<b>Semantic</b>	Semantic interoperability is the ability of two or more systems to exchange information and to interpret and use that information. Semantic interoperability takes advantage of both the structuring of the data exchange and the codification of the data, including standard, publicly available vocabulary, so that the receiving information management systems can interpret the data. Semantic interoperability supports the electronic exchange of patient data and information among authorized parties via potentially disparate health information and technology systems and products to improve quality, costs, safety, efficiency, experience and efficacy of healthcare delivery.

<sup>11</sup> HIMSS. 2018. What Is Interoperability? <https://www.himss.org/library/interoperability-standards/what-is-interoperability>.

Aspect	Relationship to Interoperability
<b>Operational</b>	Operational interoperability encompasses the technical components as well as clear policy, social and organizational components. These components facilitate the secure, seamless and timely communication and use of data within and between organizations and individuals. Inclusion of these non-technical considerations enables interoperability that is integrated into end-user processes and workflows in a manner that supports efficiencies, relationships and overall health and wellness through cooperative use of shared data both across and within organizational boundaries.

*Table 3: Aspects of Interoperability*

C-CDA Templates address both structural and semantic aspects of interoperability. The Value Sets defined and used in the C-CDA templates constrain the semantic meaning associated with each defined template. The combination of meaningful coded concepts in the context of meaning data structure creates robust “clinical statement patterns” that convey the semantic meaning of the human information exchanged in the document. The HL7 Clinical Statement model is designed to be used within multiple HL7 V3 domain models. A Clinical Statement is intended to facilitate the consistent design of communications that convey clinical information to meet specific use cases. The notion is applicable across all information exchange domains. A Clinical Statement model provides a pattern that can be used by various domains to propagate commonality in the core clinical act domain space, while allowing for controlled extensions for select participations.

Value Sets used by C-CDA R2.1 play a critical role in supporting semantic interoperability.

The C-CDA implementer community works together over the course of an annual cycle to review and update the Value Sets used in C-CDA. In some cases, specific organizations with subject matter expertise in a corresponding area act as a Value Set steward and proactively manage the continual evolution of the Value Set as its definition and expansions members change over time with the changing base code systems used to define the Value Set. In other cases, HL7 acts as the steward in maintaining the Value Sets.

For ease of use they are published through the Value Set Authority Center (VSAC) maintained by the National Library of Medicine. A UMLS license is required to download the C-CDA R2.1 Value Set Release Package. The C-CDA R2.1 Value Set Release Package is updated annually and published at the end of June each year.<sup>12</sup>

Value Set stewards and implementers need to report issues with the concepts included in or missing from a Value Set used by C-CDA templates. The HL7 STU Comment process supports reporting issues regarding value set definitions. Only through on-going and regular Value Set updates can the semantic interoperability of C-CDA be maintained.

Value Set maintenance also impacts C-CDA validation.

**Reference:** 1.2.3 C-CDA STU Updates, 2.3 C-CDA Templates and Schematron Validation, 5.1.3 DisplayName Representation

<sup>12</sup> <https://vsac.nlm.nih.gov/>

### 1.4 Audience

The audience for this Companion Guide includes, but is not limited to, software developers, vendors, and other health IT implementers wishing to share information through the use of C-CDA documents. It also includes Health IT stakeholders who receive information via C-CDA documents, such as Payors, other support service providers, registries and researchers. This guide also includes educational content and resource references to assist general audiences in understanding C-CDA, the base HL7 Clinical Document Architecture (CDA) standard which C-CDA is built upon, and other implementation guidance resources available within the C-CDA community.

### 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 knowledge of value sets and data types. Readers should also have knowledge of Extensible Markup Language (XML)<sup>13</sup> and XPath<sup>14</sup> syntax. Additionally, readers should have an understanding of terminologies such as SNOMED CT®, LOINC®, CPT®, ICD®, and RxNorm®.

Readers of the Companion Guide also are assumed to have rudimentary knowledge of document workflow concepts and practices associated with the creation, transport, consumption, and registration of C-CDA documents. Many of these practices are documented by communities engaged in widespread use of C-CDA documents for information exchange such as, eHealth Exchange, Carequality, CommonWell, Integrating the Healthcare Enterprise (IHE.net)<sup>15</sup>, HIMSS Health Story Project and other HL7 Workgroup such as the Attachments Work Group and the Clinical Quality Information (CQI) Work Group. Organizations such as Integrating the Healthcare Enterprise and DirectTrust<sup>16</sup> also maintain standards that address document management, transport, and exchange, and are included in the Interoperability Standards Advisory. Prior familiarity with the growing body of specifications for C-CDA is not required. The Companion Guide introduces implementers to the expanding available guidance and explains where additional guidance may be relevant to address current interoperability challenges.

**Reference:** Chapter 6 Resources

### 1.6 Contents of this Guide

This guide is organized into six chapters and appendices as follows:

- **Chapter 1: Introduction** (this chapter)

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<sup>13</sup> For more information on Extensible Markup Language, visit <http://www.w3.org/TR/xml/>.

<sup>14</sup> For more information on XPath syntax, visit <http://www.w3.org/TR/xpath/>.

<sup>15</sup> For more information on Integrating the Healthcare Enterprise, visit <https://www.ihe.net/>

<sup>16</sup> For more information on DirectTrust, visit <https://www.directtrust.org/>

- **Chapter 2: Understanding C-CDA and the C-CDA Companion Guide.** This chapter contains high-level information on foundational topics such as the HL7 Clinical Document Architecture (CDA) standard, CDA Schema, CDA Templates, and Schematron. It explains general concepts that are relevant for C-CDA documents, like structured versus unstructured documents and what it means for a document template to be an open template. It covers select topics from the base CDA standard and other general topics that are relevant for understanding the C-CDA templates and C-CDA Document exchange. It describes the continuous improvement strategy supported by the C-CDA Companion Guide and explains how implementers can use this guidance to help expand interoperability over time.
- **Chapter 3: Document-Level Guidance.** This chapter provides guidance regarding information that is carried in the header of C-CDA documents.
- **Chapter 4: Structure Document Content.** This chapter provides general guidance pertinent to the section-level templates used to represent information in a structured C-CDA document. It also includes clarification and consensus recommendation for implementing specific types.
- **Chapter 5: Representation of Discrete Data.** This chapter covers general guidance relevant to including discrete data within the body of a structured C-CDA document. It also includes clarifications and consensus recommendations for implementing specific types of discrete data entries within C-CDA sections.
- **Chapter 6: Resources.** This section provides references to additional resources for understanding C-CDA documents and common practices associated with sharing information via this HL7 standard.
- **Appendix A: Additional C-CDA Templates.** This appendix includes template definitions that have emerged through community collaboration to enable and expand interoperability of essential information. The templates augment the set of templates defined in the current version of C-CDA. As the C-CDA implementation guide evolves and matures, templates defined in the Companion Guide will be considered for incorporation with the core C-CDA specification.
- **Appendix B: UDI Organizer Template.** This appendix includes template definitions that define an organizer structure for representing the individual Universal Device Identifier (UDI) components of a device. The templates are designed to supplement templates in C-CDA used to represent medical equipment (including implantable devices) and non-medicinal supplies.
- **Appendix C: Provenance – Author Participation.** This appendix includes the definition for basic provenance information that captures the author. The new template is a specialization of the Author Participation template defined in C-CDA.

## 2 Understanding C-CDA and the C-CDA Companion Guide

Consolidated CDA (C-CDA) is a library of CDA templates developed by HL7. It leverages prior efforts from HL7, Integrating the Healthcare Enterprise (IHE), and Health Information Technology Standards Panel (HITSP). It harmonizes that work and consolidates implementation guides developed under the HL7 Health Story Project. C-CDA was originally developed within the ONC's Standards and Interoperability (S&I) Framework to provide a definitive set of harmonized CDA templates for the US Realm. C-CDA has evolved over time as additional implementer guidance has been developed through the HL7 ballot process to contribute new templates that supplement the available template library. The C-CDA R2.1 implementation guide (IG) is the currently available version of these templates. However, additional IGs have been developed, balloted and published within the C-CDA implementer community to supplement and expand the number of available templates.

The C-CDA R2.1 Companion Guide ("Companion Guide") augments guidance provided in C-CDA R2.1 to improve and expand the exchange of clinical note information through use of HL7 Clinical Document Architecture (CDA) documents. The Companion Guide augments the C-CDA implementation guide to address emerging requirements stemming from new regulations and rising expectations within the implementer community to support interoperability. It provides implementers with additional guidance consistent with accepted best practices that help to drive adoption of additional data elements that are essential for core information exchange use cases in the US. It reinforces certain fundamental information especially relevant to the additional guidance. It exposes implementers to additional guidance and templates available to address the growing need for greater levels of interoperability.

### 2.1 Layered Constraints, Rising Expectations

We acknowledge that best practices may in time become certification requirements. Certification requirements should always be confirmed with the certifying organization.

The C-CDA Companion Guide offers a layered approach to conformance requirements. By adopting guidance provided in the C-CDA Companion Guide, implementers can increase their information exchange capabilities as expectations for interoperability expand.

The HL7 CDA R2 (Normative Web Edition 2010) forms the lowest level of conformance requirement. Implementers may reference CDA R2 if they are developing new templates or are seeking to understand a requirement. The HL7 CDA R2 standard includes extensions that have been defined to meet implementer needs.

C-CDA R2.1 adds an additional requirement layer on top of the base standard. This may include use of certain available CDA R2 extensions.

Periodically, C-CDA R2.1 is amended to adjust for technical corrections. The errata releases may introduce additional or updated requirements.

Over time, to keep pace with change, the Companion Guide is updated to keep implementers informed of emerging changes and rising expectations for consistency and greater levels of

interoperability. The C-CDA Companion Guide provides insight on emerging conformance specification so implementers can prepare for change, plan for greater consistency, and deliver higher quality C-CDA documents. Conforming to guidance provided in the Companion Guide is optional, but helps implementers prepare for coming changes.

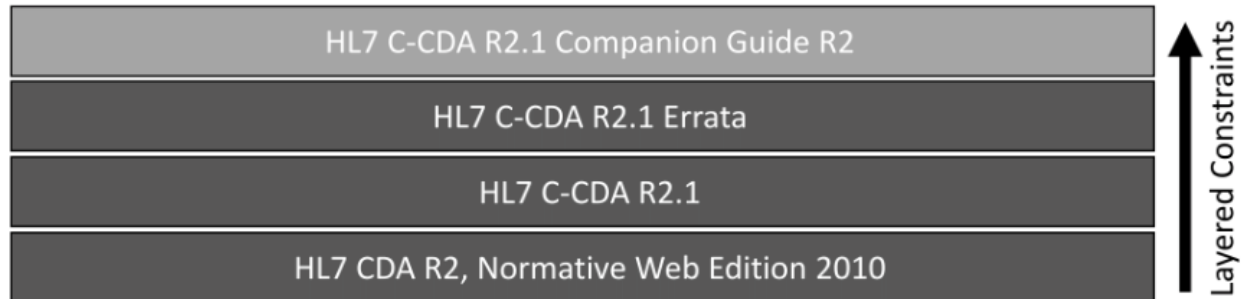




Figure 2: CDA, C-CDA, Errata and Companion Guide Relationships

For example, to determine if a C-CDA document conforms to industry best practices, the following verification steps would be confirmed:

1. Document validates under the CDA\_SDTC schema<sup>17</sup>; and
2. Document meets constraints as defined in C-CDA R2.1; and
3. Document conforms to relevant technical corrections published in the C-CDA R2.1 Errata; and
4. Document conforms to C-CDA Content Rubric based upon C-CDA Companion Guide guidance.

**Reference:** 1.2.2 C-CDA Errata Process, 2.4 C-CDA Companion Guide and C-CDA Rubric Rules

Throughout the C-CDA Companion Guide, implementer best practice guidance is summarized using a visual conformance block callout like you see below. If the implementer best practice guidance is machine testable, and therefore implementable in the rubric rules supported by validation tools such as the Scorecard tool, then the visual conformance block callout is labeled with “CONF” preceding the identifying number. Otherwise, the conformance block callout is labeled with “BP” preceding the identifying number. Readers cannot rely on the callouts alone to summarize the full range of best practice guidance provided in the Companion Guide.

	A C-CDA implementer SHOULD support the standards maturation process to advance the evolution of the C-CDA specification. <b>[BP-001]</b>
	A C-CDA implementation SHALL incorporate all published errata applicable to the templates used. <b>[CONF-002]</b>

<sup>17</sup> Available from the HL7 GitHub, <https://hl7.org/permalink/?CDAR2.0schema>



Implementers wishing to create C-CDA documents according to current industry best practices MAY conform to guidance specified in the C-CDA Companion Guide. **[BP-003]**

It is important to note that all guidance provided in the C-CDA Companion Guide is considered optional, regardless of the modal verb used.

**Reference:** 1.2.2 C-CDA Errata Process, 2.4 C-CDA Companion Guide and C-CDA Rubric Rules, 2.4.1 Best Practice Guidance for Higher Levels of Interoperability, 2.4.2 Guidance Language and Expectations

## 2.2 CDA R2 Schema and Schema Validation

CDA defines a standard schema, based on the HL7 RIM, for all CDA documents. When there is a need to communicate information where there is no suitable representation in the schema, the CDA standard permits extensions to be developed. These extensions are described in the context of the section where they are used.

The HL7 Structured Documents Work Group maintains a complete list of CDA R2 extensions that are approved for use within the `sdtc` namespace.<sup>18</sup> The base CDA R2 schema (with approved extensions) can be found on the HL7 CDA Core GitHub repository.<sup>19</sup>

To perform schema validation on a CDA document instance properly, it is necessary to use the schema that includes the CDA R2 schema extensions. All extensions will use the namespace **urn:hl7-org:sdtc**. As a document consumer, the possibility of schema extensions needs to be considered.

**Reference:** 6.6.1 CDA Schema, C-CDA Schematrons, Sample Stylesheet

### 2.2.1 CDA R2 Schema Extensions Used by C-CDA R2.1

The table below lists the extensions to CDA R2 that have been defined to support requirements in C-CDA R2.1.

Extension [Cardinality]	Definition
<code>sdtc:admissionReferralSourceCode</code> [0..1]	This element is a coded concept that represents the type of referral. Its RIM source class is PatientEncounter. Adds to: <ul style="list-style-type: none"> <li>componentOf/encompassingEncounter</li> </ul>

<sup>18</sup> For more information on CDA R2 Extensions, visit <https://confluence.hl7.org/display/SD/CDA+Extensions>

<sup>19</sup> For more information on base CDA R2 schema, visit, <https://hl7.org/permalink/?CDAR2.0schema>



Extension [Cardinality]	Definition
<b>sdct:alternateIdentification</b>	<p>The <a href="#">alternateIdentification</a> extension provides additional information about an identifier found in the linked role. The extensions augment the id information in the linked role. The id in the alternateIdentification extension SHALL match an id in the linked role. The alternateIdentification provides additional information about a particular identifier, such as its type. As an extension it needs to be safe for implementers to ignore this additional information.</p> <ul style="list-style-type: none"> <li>• identifiedBy Cardinality is [0..*]</li> <li>• identifiedBy.typeCode = REL</li> <li>• See slide 8 in <a href="#">attached ppt.</a></li> <li>• <a href="#">POCD_HD000040-alternateIdentifier.xls</a></li> </ul>
<b>sdct:asPatientRelationship</b> [0..1]	<p>Each participant role other than an informant/relatedEntity may have zero or more relationship roles with the patient. Each of these roles can be expressed with an asPatientRelationship element which further describes the type of role using a code element. The informant/relatedEntity participant role already supports specification of the relationship between the informant and the patient via the RelatedEntity classCode, and therefore should not include this extension. (CCD)</p> <p>Adds to:</p> <ul style="list-style-type: none"> <li>• Person</li> </ul>
<b>sdct:birthTime</b>	<p>The sdct:birthTime element allows for the birth date of any person to be recorded. The purpose of this extension is to allow the recording of the subscriber or member of a health plan in cases where the health plan eligibility system has different information on file than the provider does for the patient.</p>
<b>sdct:deceasedInd</b> [0..1]	<p>The deceasedInd extension is used to record that the recordTarget or subjectPerson is deceased.</p> <p>Adds to:</p> <ul style="list-style-type: none"> <li>• recordTarget/patientRole/patient</li> <li>• subject/relatedSubject/subject</li> </ul>
<b>sdct:deceasedTime</b> [0..1]	<p>The deceasedTime extension is used to record the time of death for the recordTarget or subjectPerson.</p> <p>Adds to:</p> <ul style="list-style-type: none"> <li>• recordTarget/patientRole/patient</li> <li>• subject/relatedSubject/subject</li> </ul>
<b>stdc:desc</b> [0..1]	<p>The desc extension allows multimedia depictions of patients, healthcare providers, or other individuals to be included in a CDA document. It may be used in any person (or derived) entity and appears after the entity name.</p> <p>Adds to:</p> <ul style="list-style-type: none"> <li>• recordTarget/patientRole/patient</li> <li>• subject/relatedSubject/subject</li> <li>• person</li> </ul>
<b>sdct:dischargeDispositionCode</b>	<p>The sdct:dischargeDispositionCode element allows the discharge disposition to be recorded for an encounter act.</p>



Extension [Cardinality]	Definition
<b>sdct:ethnicGroupCode</b> [0..*]	<p>This ethnicGroupCode extension is used to record additional ethnicity groups for the recordTarget or subjectPerson.</p> <p>Adds to:</p> <ul style="list-style-type: none"> <li>recordTarget/patientRole/patient</li> <li>subject/relatedSubject/subject</li> </ul>
<b>sdct:functionCode</b> [0..1]	<p>The sdct:functionCode extension element allows the function that the participant is doing to be recorded.</p> <p>Adds to:</p> <ul style="list-style-type: none"> <li>performer and participant for entries. It currently is available for these data elements in the header and just needs to be added for entry representation.</li> </ul>
<b>sdct:id</b> [0..*]	<p>This id extension is used to record the subject's medical record number or other id.</p> <p>The id extension in the family history organizer on the related subject allows for unique identification of the family member(s). (C-CDA) CDA Release 2.0 does not provide a mechanism to determine when two participants in different roles are in fact the same entity (i.e., an entity can be a person, organization or device). A CDA Document identifies each participant through the application of a role identifier. This identifier can be used to trace the participation of an entity in a given role but cannot necessarily be used to determine that two entities are the same. While more role identities could be provided whose intended use is to unify the entities, this is better modeled through the use of an entity identifier. Therefore, to facilitate this capability, this guide defines an extension to CDA Release 2.0 that allows the person or organization playing the role to be uniquely identified, by the inclusion of an identifier on the entity.</p> <p>Adds to:</p> <ul style="list-style-type: none"> <li>subject/relatedSubject</li> </ul>
<b>sdct:inFulfillmentOf1</b> [0..1]	<p>This is an actRelationship called inFulfillmentOf1 that represents the Fulfills General Relationship Operator in QDM 4.1.x in QDM-Base QRDA Category 1, R3 (uses FLFS actRelationship type which is not an allowed actRelationship (entryRelationship) type in CDA). Also create ActReference to contain the pointer to already existing class.</p> <p>Adds to:</p> <ul style="list-style-type: none"> <li>Observation</li> <li>Substance Administration</li> <li>Supply</li> <li>Procedure</li> <li>Encounter</li> <li>Act</li> </ul> <p>Extension will be a pointer (reference) to an already existing order or recommendation. The id of the existing order or recommendation will be used to allow pointing to the already existing data without repeating it in the relationship (ActReference). InFulfillmentOf1 is the relationship between the act that is fulfilling the order/recommendation and that order/recommendation.</p>

Extension [Cardinality]	Definition
<b>sdct:multipleBirthInd</b> [0..1]	<p>The multipleBirthInd extension is used to record that the recordTarget or subjectPerson is part of a multiple birth.</p> <p>Adds to:</p> <ul style="list-style-type: none"> <li>• recordTarget/patientRole/patient</li> <li>• subject/relatedSubject/subject</li> </ul>
<b>sdct:multipleBirthOrderNumber</b> [0..1]	<p>The multipleBirthOrderNumber extension is used to record the order number within a multiple birth that the recordTarget or subjectPerson was born in.</p> <p>Adds to:</p> <ul style="list-style-type: none"> <li>• recordTarget/patientRole/patient</li> <li>• subject/relatedSubject/subject</li> </ul>
<b>sdct:negationInd</b> [0..1]	<p>The Quality Measures need to be able to state that something did not happen and the reason why that thing did not happen. This is accomplished by setting negationInd="true" and stating the reason (rationale) in a contained Reason template. This is needed for supply and encounters, however CDA has constrained the negationInd out of supply and encounter. (i.e. this device was not supplied because of reason x or this encounter did not happen because of reason y). On 4/23/2015 this proposal was withdrawn. Despite the argument for a consistent approach for negation on all act classes and acknowledgement of the issues unique to negation for observation acts, the proposal was withdrawn based on the requirement in the CDA R2 standard, Chapter 1.4 CDA Extensibility, "These extensions should not change the meaning of any of the standard data items, and receivers must be able to safely ignore these elements. Document recipients must be able to faithfully render the CDA document while ignoring extensions."</p> <p>Adds to:</p> <ul style="list-style-type: none"> <li>• Supply</li> <li>• Encounter</li> </ul>
<b>sdct:patient</b> [0..1]	<p>The sdct:patient extension element allows for the patient's identifier, used by a given provider, to be reported. The provider in their role as an assigned entity is related to the patient.</p> <p>Adds to:</p> <ul style="list-style-type: none"> <li>• AssignedEntity</li> </ul>
<b>sdct:precondition1</b> [0..*]	<p>The sdct:precondition1 extension allows for the association of a criterion with a reference range (ObservationRange), which allows the expression in a lab report that a reference range is conditional on some criterion such as patient sex or age (or a combination of criterion).</p> <p>Adds to:</p> <ul style="list-style-type: none"> <li>• ObservationRange</li> </ul>

Extension [Cardinality]	Definition
<b>sdtc:priorityNumber</b> [0..1]	The sdtc:priorityNumber extension element allows the priority order of a set of acts to be reported through the use of this element in the component actRelationship of an organizer source act that holds the set of acts being ranked. The RIM states, that priorityNumber is an integer specifying the relative preference for considering this relationship before other like-typed relationships having the same source Act. Relationships with lower priorityNumber values are considered before and above those with higher values. Adds to: <ul style="list-style-type: none"> <li>Organizer/component</li> </ul>
<b>sdtc:raceCode</b>	The raceCode extension allows for multiple races to be reported for a patient. Adds to: <ul style="list-style-type: none"> <li>recordTarget/patientRole/patient</li> </ul>
<b>sdtc:raceCode</b> [0..*]	The raceCode extension is used to record additional race codes for the subject. Adds to: <ul style="list-style-type: none"> <li>subject/relatedSubject/subject</li> </ul>
<b>sdtc:signatureText</b>	The signatureText extension adds an attribute for authenticator and legalAuthenticator to record encoded digital signature information.
<b>sdtc:statusCode</b>	The statusCode extension attribute allows the implementer to identify a ClinicalDocument that is in other than the completed state. It was created to support the Structured Form Definition IG to identify that the document itself is an unfinished product currently being completed for a patient.
<b>sdtc:text</b> [0..1]	The text extension adds the text element to the organizer act. Every other act has a text element, so this was needed to make the organizer act consistent with other acts. It also is needed to support mapping between the organizer act in CDA and the list resource in FHIR. Adds to: <ul style="list-style-type: none"> <li>organizer</li> </ul>
<b>sdtc:valueSet</b>	The valueSet extension adds an attribute for elements with a dataType which indicates the particular value set constraining the coded concept.
<b>sdtc:valueSetVersion</b>	The valueSetVersion extension adds an attribute for elements with a CD dataType which indicates the version of the particular value set constraining the coded concept.

Table 4:CDA R2 Extensions Used by C-CDA R2.1

### 2.3 C-CDA Templates and Schematron Validation

The C-CDA R2.1 IG defines templates that specify conformance statements for representing structured clinical notes. CDA templates are defined for document, section, entry, and entry relationship content. Inclusion of a template ID in a CDA document does not convey semantic meaning. A template declaration in a CDA document indicates an expectation that the associated XML conforms to the rules defined by that template.

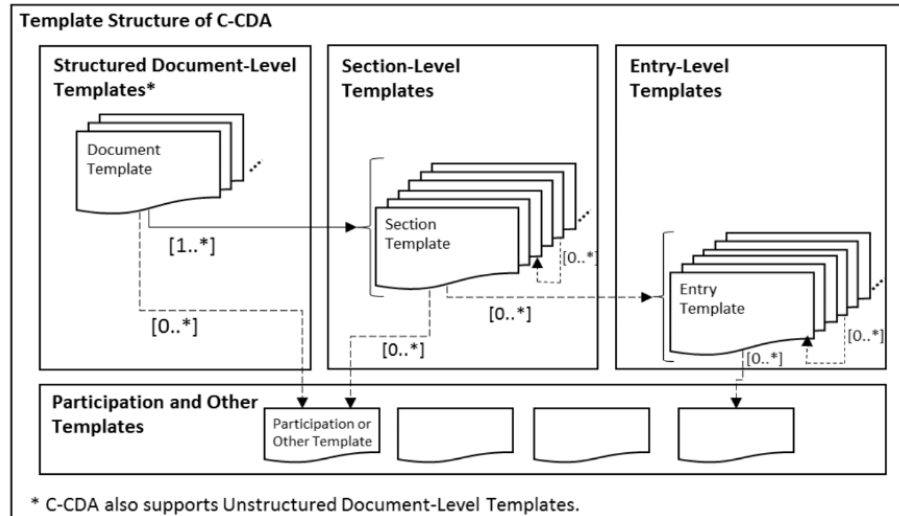


Figure 3: Template Structure of C-CDA

CDA

documents may declare template conformance at the header level to express conformance expectations for the content before the <structuredBody> tag in a structured CDA document or before the <nonXMLBody> tag in an unstructured CDA document. A CDA document also may declare template conformance at the document level to express conformance expectations for the sections that will be included within the <structuredBody> tag.

A structured CDA document additionally may declare template conformance at the section level. A template declaration at the section-level establishes conformance expectations for the section itself and for the discrete entries that may be included in the section.

Templates also may be declared at the entry level to express conformance expectations for the discrete data that is represented in the machine processable entry. Template declarations also may be nested within the structural components of an entry to convey conformance expectations about sub-parts of the entry structure.

The presence of a template declaration in a C-CDA document is to define the constraints which stipulate what may, should, or shall be populated in an instance of the document.

Conformance to a template from C-CDA R1.1 (defined prior to the practice of template versioning) is expressed by declaring the templated of the version of the template published under C-CDA R1.1 in the root attribute with no version information included in the extension attribute.

Schematron is a rule-based validation language for confirming declarations about the presence or absence of patterns in XML trees. Schematron is capable of expressing constraints above and beyond what is possible with XML Schema.

Schematron can be used to:

- Extend structural validation by testing for co-occurrence constraints, non-regular constraints, and inter-document constraints; and
- Express rules about complex structures within an XML document.

Each template in the C-CDA library of templates has a corresponding Schematron validation package based upon the conformance constraints defined in the template. This Schematron package can be used to confirm if a CDA document conforms to the constraints required by C-CDA R2.1. The C-CDA Schematron package is updated when errata releases for C-CDA are published. A Schematron package for C-CDA R2.1 is available on the HL7 International Structured Documents Work Group GitHub repository.<sup>20</sup> The C-CDA Schematron packages available at time of publication are included in the Publication Package as a convenience for users. To access the current version of an available Schematron, utilize the versions posted in the GitHub repository.

**Reference:** 3.2 Structured Header

### 2.3.1 Declaring Template Conformance

C-CDA templates are identified with a `templateId`. The `templateId` is a two-part identifier that consists of a root and an extension. The root identifies the named template and the extension identifies the version of that template. Initially C-CDA templates did not include versions. The `templateId/@root` attribute was not used. Many of those original templates are still used in C-CDA R2.1.

Chapter 3.1.2 of the Consolidated CDA Implementation Guide discusses the use of `templateIds` and what needs to be included in a C-CDA document:

- To assert conformance with C-CDA R2.1, declare the `templateId` of the version of the template defined in C-CDA R2.1.
- To assert conformance with C-CDA R1.1, declare the `templateId` of the version of the template defined in C-CDA R1.1.



C-CDA R2.1 Content Creators SHOULD NOT declare conformance to irrelevant templates **[BP-004]**

Note: Testability requires business decisions to be made regarding which templates are not relevant.

To avoid confusion and minimize inclusion of unnecessary information in C-CDA documents, implementers should avoid including duplicate or irrelevant `templateId` declarations.

It is important to note that including the 2.1 `templateId` and the 1.1 `templateId` is no duplication and is valid to describe the content as conformant to both the 1.1 and 2.1 versions of C-CDA .

<sup>20</sup> <https://github.com/HL7/cda-ccda-2.1/blob/master/schematron/Consolidation.sch>

### 2.4 C-CDA Companion Guide and C-CDA Rubric Rules

Based on emerging implementation expectations for C-CDA based interoperability, a set of criteria are compiled and balloted through HL7 to inform the C-CDA community of additional rubric rules to consider when assessing the quality of C-CDA documents.

The rubric criteria are created through an ongoing project in the HL7 Structured Documents Work Group (SDWG), originating in 2016. HL7 members continually update the rubric which is periodically balloted and then published.

Rubric criteria are created to address key problematic interoperability issues identified in real system-generated C-CDA documents where the community has determined that data is represented inconsistently or incompletely, adversely impacting interoperability. The rubric rules are designed to improve the ability of systems to reliably share and compare data. The goal is to create rubric rules above and beyond the conformance constraints required by CDA and C-CDA to promote best practices by allowing providers and health IT developers to identify and resolve issues in C-CDA documents. Implementers can use the published C-CDA rubric rules to improve data representation in their health IT systems, thereby promoting interoperability and expanding the use of clinical data exchanged in C-CDA documents.

#### 2.4.1 Best Practice Guidance for Higher Levels of Interoperability

Interoperability is an ever-expanding capability. As new use cases for information exchange emerge and expectations for data sharing rise, additional guidance is needed for implementers to maintain interoperability. Specifications such as C-CDA are published periodically and may not include the most recent developments and growing best practices determined to be needed by the community engaged in information exchange. The C-CDA Companion Guide is produced and published more frequently in order to document and share guidance that has been determined to be essential for interoperability. Best practices documented in the C-CDA Companion Guide inform the C-CDA Content Rubric available for verifying the content of C-CDA documents. The C-CDA Companion Guide also informs the update process used to advance the C-CDA specification. It provides a continuous improvement mechanism for folding essential expanding implementer guidance into the published C-CDA standard.

#### 2.4.2 Guidance Language and Expectations

The following guidance language is not specific to C-CDA templates. It is used in all CDA templates to communicate guidance that applies to creating conformant documents. Conformance statements also are used within the C-CDA Companion Guide to clearly communicate best practice implementer guidance that has emerged as essential for interoperability.

The Companion Guide does not replace, or repeat conformance requirements specified in referenced source specifications.



The Companion Guide only provides optional guidance that implementer MAY choose to follow as part of their own path toward higher levels of interoperability. **[BP-005]**

In some cases, the Companion Guide provides guidance suggesting that an optional conformance requirement in a source specification should be tightened and become the requirement in order to achieve interoperability. ***Although the additional guidance suggests a MAY or SHOULD conformance from an underlying specification be elevated to a SHALL, the Companion Guide guidance is still considered optional.***



C-CDA documents that do not conform to guidance specified in the Companion Guide SHALL NOT be deemed non-conformant with C-CDA R2.1. **[BP-006]**

### 2.4.2.1 Conformance Statements

CDA templates impose constraints based on conformance verbs defined in the HL7 Version 3 Publishing Facilitator's Guide.<sup>21</sup> Relevant conformance verbs are:

- SHALL – This word, or the term “REQUIRED”, means that the definition is an absolute requirement of the specification.
- SHALL NOT – an absolute prohibition against inclusion. No data are permitted.
- SHOULD/SHOULD NOT — best practice or recommendation. There may be valid reasons to ignore an item or include an item, but the full implications must be understood and carefully weighed before choosing a different course.
- MAY/NEED NOT: truly optional; can be included or omitted as the author decides with no implications. The mandate that there are no implications on the author decision to include or not some MAY data means that interoperability between systems shall not be affected by presence or absence of this content. Inclusion or exclusion may vary from document to document, even for documents for the same patient from the same organization.



Schematron and other C-CDA Document Validators SHALL indicate Schema and Schematron conformance errors as follows:

SHALL violation (error)

SHOULD violation (warning)

MAY violation (not checked unless present) **[CONF-007]**

<sup>21</sup> <http://www.hl7.org/v3ballot/html/help/pfg/pfg.htm>



The table below shows the relationship between conformance verb usage, minimum cardinality and permitted use of nullFlavor.

Conformance Verb	Minimum Cardinality	nullFlavor Permitted?
<b>SHALL</b>	1	Y (unless explicitly disallowed) <sup>22</sup>
<b>SHOULD</b>	0	Y
<b>MAY</b>	0	Y

*Table 5: Conformance Verbs, Cardinality and Use of nullFlavor*

### 2.4.3 Best Practice Rubric and Validation

Guidance published in the C-CDA Companion Guide is used to develop best practice Rubric which are balloted within the HL7 C-CDA community and adopted as accepted rules for validating content in C-CDA documents. Published C-CDA Rubric are implemented by document validation tools such as the ONC Scorecard to provide feedback on CDA document conformance to the layer of conformance criteria considered by the C-CDA community to be best practice and essential for interoperability.

	C-CDA Document Validators <b>MAY</b> support validation of all the layers of conformance described in Chapter 2.3.1 Declaring Template Conformance. <b>[BP-008]</b>
	C-CDA Document Validators <b>SHALL</b> indicate best practice guideline violations as follows: <div style="margin-left: 40px;">                     SHALL violation (warning)                      SHOULD violation (not checked unless present)                      MAY violation (not checked unless present) <b>[CONF-009]</b> </div>

## 2.5 Fundamental Concepts for Document-Based Exchange

The following chapters reinforce explain fundamental information especially relevant to the guidance included in the Companion Guide.

### 2.5.1 CDA and C-CDA Templates

The HL7 Clinical Document Architecture (CDA) is a document markup standard that specifies the structure and semantics of “clinical documents” for the purpose of exchange. A clinical document is documentation of clinical observations and services, with the following characteristics:

- Persistence – A clinical document continues to exist in an unaltered state, for a time period defined by local and regulatory requirements (NOTE: There is a distinct scope of persistence for a clinical document, independent of the persistence of any XML-encoded CDA document instance).

<sup>22</sup> Any SHALL, SHOULD or MAY conformance statement may use nullFlavor, unless the nullFlavor is explicitly disallowed (e.g., through another conformance statement which includes a SHALL conformance for a vocabulary binding to the @code attribute, or through an explicit SHALL NOT allow use of nullFlavor conformance).



- Stewardship – A clinical document is maintained by an organization entrusted with its care.
- Potential for authentication – A clinical document is an assemblage of information that is intended to be legally authenticated.
- Context – A clinical document establishes the default context for its contents.
- Wholeness – Authentication of a clinical document applies to the whole and does not apply to portions of the document without the full context of the document.
- Human readability – A clinical document is human readable.

A CDA document is a defined and complete information object that can include text, images, sounds, and other multimedia content.<sup>23</sup>

Key aspects of CDA include:

- CDA documents are encoded in Extensible Markup Language (XML). (NOTE: When alternate implementations are feasible, suitable conformance requirements will be issued so that in future the syntax may not be limited to XML.)
- CDA documents derive their machine processable meaning from the HL7 Reference Information Model (RIM) and use the HL7 Version 3 Data Types.

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<sup>23</sup> HL7 Clinical Document Architecture, R2.0, Normative Web Edition 2010.

- The CDA specification is richly expressive and flexible. Document-level, section-level and entry-level templates can be used to constrain the generic CDA specification.<sup>24</sup>

**Document templates** define header requirements as well as section template requirements; they specify a header template as well as section templates as needed. The header template describes the scope and intended use of the document. The header includes the metadata that details contextual information, such as who created the document, encounter information, and patient demographics.

**Section templates** revolve around a common clinical concept, such as *Procedures* or *Encounters* – i.e. the *Procedures* section template captures information relative to patient procedures.

Section templates are defined globally and may be used by more than one document template. For example, the template defining the Medications section are used in both a CCD and Referral Note. A section template may contain zero, one or many entry templates.

**Entry templates** represent individual clinical statements through structured data elements, such as a specific medication or procedure. Entry templates may also have requirements for certain data elements to be coded. Entries are very specific templates intended to capture an event, action, or observation relative to the information captured in the section or parent entry. An entry-level template may be used within multiple section-level templates.

Templates are identified using a special Object Identifier (OID). An OID is a globally unique ISO [\(International Organization for Standardization\)](#) identifier. Within the context of HL7 C-CDA, OIDs are represented in the following way: urn:oid:2.16.840.1.113883.10.20.15.3.1 (closed). Often the “urn:oid” is omitted when identifying a specific template.

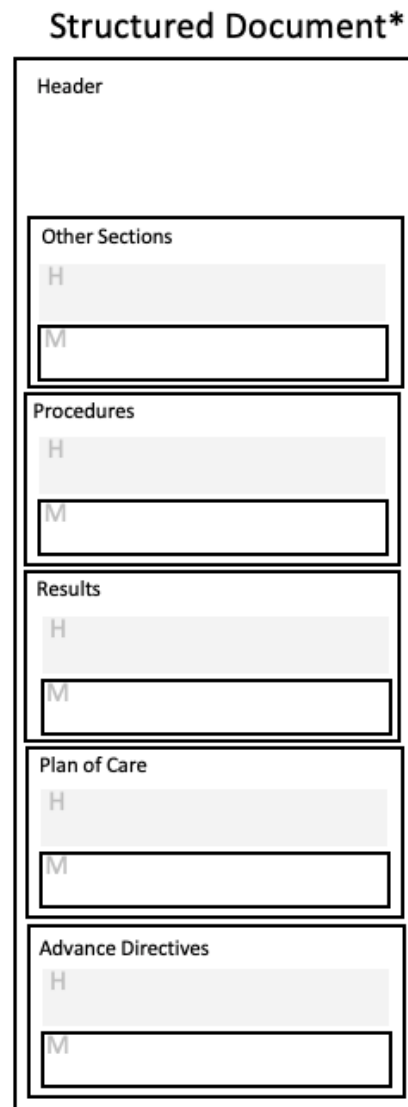


Figure 4: Structured Document

\*Includes a <structuredBody> that includes sections which carry human readable information (H) and may include corresponding machine processable data (M).

<sup>24</sup> HL7 Clinical Document Architecture, R2.0, Normative Web Edition 2010.

## 2.5.2 Structured Versus Unstructured Documents

For the purposes of this guide, a CDA document with a structured header paired with a structuredBody element will be referred to as a “structured document” and a CDA document with a structured header paired with a nonXMLBody element will be referred to as an “unstructured document”. The structured header for either type of document permits computer processing (parsing) to occur on its content.

Unstructured documents fill an important role where structured information is inappropriate, impractical, or unavailable. Use of unstructured documents facilitates exchange for information that does not yet have standardized representation specifications or when processing of structured data is not yet available at recipient systems.<sup>25</sup>

NOTE: The Unstructured Document template defined in C-CDA R2.1 does not restrict the type of content that can be represented. Thus, it may prove to be useful for systems with limited capability to create fully structured documents.<sup>26</sup>

### Unstructured Document\*

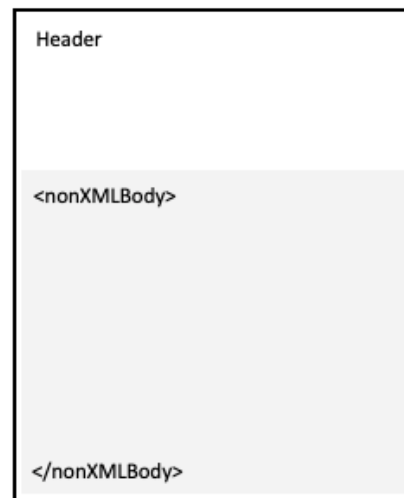


Figure 5: Unstructured Document

\* Includes a <nonXMLBody> which carries base64 encoded data that may be rendered for human readability

#### Example 1: Pathology Narrative Note

A Pathology Narrative Note represented in a minimally structured CDA document which asserts conformance to the C-CDA US Realm Header template and then uses standard LOINC codes for the document type and its narrative sections.

```
<?xml version="1.0"?>
<?xml-stylesheet type="text/xsl" href="CDA.xsl"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xmlns="urn:hl7-org:v3" xmlns:cda="urn:hl7-org:v3" xmlns:sdtc="urn:hl7-org:sdtc">
  <realmCode code="US"/>
  <typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>

  <!-- US Realm Header -->
  <templateId root="2.16.840.1.113883.10.20.22.1.1" extension="2015-08-01"/>

  <id root="2.16.840.1.113883.3.3208.101.1" extension="20130607100315-CCDA-CCD"/>
  <code code="90371-6" displayName="Clinical pathology Note"
codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
  <title>Pathology Note</title>

  ...
  The rest of the header here.
  ...

  <component>
    <structuredBody>
```

<sup>25</sup> HL7 CDA R2 Attachments IG: Exchange of C-CDA Based Documents, R1 – US Realm, pages 16-19

<sup>26</sup> HL7 CDA R2 Attachments IG: Exchange of C-CDA Based Documents, R1 – US Realm, pages 18, 25

```
<component>
  <section>
    <code code="81192-7" codeSystem="2.16.840.1.113883.6.1"/>
    <title>Clinical Pathology Consult Note</title>
    <text>
      ...
      The narrative note appears here.
      ...
    </text>
  </section>
</component>

...
Additional narrative sections appear here, if appropriate.
...
</structuredBody>
</component>
</ClinicalDocument>
```

### 2.5.3 Open Versus Closed Templates

The exchange documents defined in C-CDA R2.1 use “open templates” in that they permit additional sections to be included when needed to exchange available clinical information.

In open templates, all of the features of the CDA R2 base specification are allowed except as constrained by the templates. By contrast, a closed template specifies everything that is allowed, and nothing further may be included. Open templates allow HL7 implementers to include additional structured content not constrained by the asserted template(s).

At this time, few if any closed templates exist in the specifications reference by the C-CDA Companion Guide. In fact, the Estimated Date of Delivery template (urn:oid:2.16.840.1.113883.10.20.15.3.1 (closed)) defined in C-CDA R2.1 has been redesigned in the C-CDA R2.1 Supplemental Templates for Pregnancy Status, Release 1 – US Realm implementation guide, and the new version is an open template (2.16.840.1.113883.10.20.22.4.297:2018-04-01 (open)).<sup>27</sup>

HL7 encourages implementers to bring forward use cases that require additional data elements to be included in C-CDA templates. This practice fuels advances in interoperability and maximizes the development of shared semantics as candidate requirements become formalized in subsequent versions of the standard.

#### 2.5.3.1 Other Templates Available for Use in C-CDA Documents

As the library of available CDA templates grows and implementers become more experienced using the standard, implementers may use templates developed in other CDA implementation guides which are compatible with C-CDA. Employing additional C-CDA compatible templates will expand the range of interoperable information available for exchange and help address emerging use cases for data exchange.

<sup>27</sup> C-CDA R2.1 Supplemental Templates for Pregnancy Status, Release 1 – US Realm implementation guide, page 42



C-CDA Content Creators MAY include other C-CDA compatible templates defined in other implementation guides. [BP-010]

A C-CDA compatible template is a template that further constrains a template defined in C-CDA R2.1 or a template that does not conflict with templates defined in C-CDA. Determining if a template is C-CDA compliant may require human discernment and consensus building within the C-CDA implementer community.

### 2.5.4 Encounter Summary Versus Patient Summary

The set of twelve document templates defined in C-CDA R2.1 can be summarized in the following groupings explained in the following chapters.

#### 2.5.4.1 Encounter Summaries

An encounter summary document is primarily a clinician authored collection of information specific to a single patient interaction with a clinician, care team or hospitalization. The document may be provided to a patient immediately upon, or soon after, the conclusion of their encounter even if all the information related to that encounter is not yet available.<sup>28</sup>

Encounter summaries are used to exchange clinical information that was gathered during an encounter with the patient. The header allows information about the encompassing encounter to be included as structured data, including who was the responsible party for the rendered care and where the encounter took place. For encounter summaries, this information SHOULD be included to support emerging use cases for data from C-CDA documents to support quality measure assessment.

#### 2.5.4.2 Patient Summaries

Patient summaries are used to exchange clinical information about a patient's care over time. A patient summary is not specific to a particular encounter. The context of the document is a span of time over which care services have been provided.

#### 2.5.4.3 Other Categories of Clinical and Patient-Generated Documents

Other types of clinical information exchange documents used to share information that supports care delivery, planning, and transitions of care.

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<sup>28</sup> Concise Consolidated CDA: Deploying Encounter Summary Documents with Clinical Notes. Carequality and CommonWell Work Groups. 2017. Page 7.

Encounter Summary Documents	Patient Summary Documents	Other Categories of Clinical and Patient-Generated Documents
Consultation Note Discharge Summary History and Physical Note Progress Note	Continuity of Care Document (CCD) Transfer Summary	Care Plan Diagnostic Imaging Report Operative Note Procedure Note Referral Note Patient Generated Document
<p><b>NOTE: Unstructured Documents are classified based upon the document type associated with the LOINC code in the ClinicalDocument/code element in the header of the document.</b></p>		

Table 6: Document templates defined in C-CDA R2.1, sorted by category.

A great deal of clarity was added in the recent Carequality CommonWell Joint Document Content Work Group implementation guide to explain the difference between an Encounter Summary document and a Patient Summary document.

An Encounter Summary provides a snapshot of the patient’s condition at the time of the encounter as authored by the clinician. A Patient Summary on the other hand provides a historical view of the information available in the sending system for a span of time which may cross multiple encounters. While the workgroup primarily focused on the importance of creating Encounter Summary documents to complement Patient Summary documents, the work group acknowledged that some systems create CCD documents when requested, based on the IHE XDS Query parameters of the requestor. Systems that support this capability may continue to produce CCD documents in this manner, however, the Joint Document Content Work Group recommends that future development by systems that don’t support this capability focus on implementing Encounter Summary documents, not enhancing CCD generation to match time range parameters of the requestor.<sup>29</sup>

**Reference:** 6.3.1 The Joint Document Content Workgroup

## 2.6 General Guidance on Document-Based Exchange

The HL7 CDA standard was designed to permit information to be exchanged using a document paradigm. The scope of the CDA is the standardization of clinical documents for exchange. The data format of clinical documents outside of the exchange context (*e.g.*, the data format used to store clinical documents) is not addressed. CDA documents can be transmitted in HL7 messages designed to transfer clinical documents. While the detailed specification for such messages is outside of the scope of the CDA, this specification does impose requirements upon the packaging of CDA documents in HL7 messages. Consult the HL7 CDA standard for additional information about requirements for CDA document exchange.<sup>30</sup>

<sup>29</sup> [Concise Consolidated CDA: Deploying Encounter Summary Documents with Clinical Notes](#). Carequality and CommonWell Work Groups. 2017. Page 23.

<sup>30</sup> HL7 Clinical Document Architecture, R2.0, Normative Web Edition 2010, CDA Document Exchange in HL7 Messages, chapter 3.

HL7 CDA does not specify the creation or management of documents, only their exchange markup. Document management is critically interdependent with the CDA specifications, but the specification of document management messages is outside the scope of the CDA.<sup>31</sup>

In a chapter titled “Smart Senders and Resilient Receivers”, the Carequality CommonWell Joint Workgroup’s Concise Consolidated CDA implementation guide states:

Successful document exchange relies on layers of rules from CDA document specifications, C-CDA 2.1 specification, and the C-CDA 2.1 companion guide. Despite every effort by implementers, and the HL7 community, to document all the important topics for successful exchange, the Joint Document Content Work Group (“Joint Work Group”) discussed many other areas that would benefit from additional guidance. The Smart Senders and Resilient Receivers sections are not an exhaustive list of best practices, but instead is a list of the best practices that captured the group’s attention.

The following chapters summarize best practices identified for C-CDA document Content Creators (Senders) and C-CDA document Content Consumers (Receivers).

**Reference:** 2.7.1 LOINC Coding for Clinical Notes

### 2.6.1 Content Creator Responsibilities

Volume 1 of C-CDA R2.1 includes an explicit requirement to support narrative text linking, which states:

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

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<sup>31</sup> HL7 Clinical Document Architecture, R2.0. Normative Web Edition 2010. Scope of the CDA, chapter 1.1.2.



C-CDA Content Creators SHOULD support narrative text linking when creating documents that include sections with discrete data. The primary act of each templated entry:

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

a. The text, if present, SHOULD contain zero or one [0..1] reference/@value (CONF: XXXX).

i. This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA R2.0, section 4.3.5.1) (CONF: XXXX).

MAY contain zero or one [0..1] originalText (CONF:XXXX).

a. The originalText, if present, SHOULD contain zero or one [0..1] reference/@value (CONF:XXXX).

i. This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA R2.0, section 4.3.5.1) (CONF:XXXX).<sup>32</sup> **[CONF-011]**

The Joint Document Content Work Group identified this capability as, “extremely important for processing and validating C-CDA documents that include machine-processable entries.”<sup>33</sup> The narrative text linkages are the mechanism that associate human readable information in the narrative text of each section to the entries carrying that information for machine processing. Without proper narrative text linking, it is impossible to accurately validate if the machine-readable entries and the human-readable representation of that information accurately reflect the same semantic meaning.<sup>34</sup>

Resources for more information:

- [How to create narrative text linking in sections that contain machine-processable entries.](#)<sup>35</sup>
- See narrative reference examples in the General section of HL7 Example Task Force.<sup>36</sup>
- See sample documents provided with this Companion Guide.



C-CDA Content Creators SHOULD maintain act/observation IDs across documents. **[BP-012]**

Many entry templates in C-CDA require an identifier (ID) on an entry.

<sup>32</sup> For more information on narrative text linking conformance requirements see C-CDA R2.1 Volume 1, Chapter 3.5

<sup>33</sup> [http://www.commonwellalliance.org/wp-content/uploads/2018/07/Carequality\\_CommonWell\\_Improve\\_C-CDA\\_06-15-2018\\_V1.pdf](http://www.commonwellalliance.org/wp-content/uploads/2018/07/Carequality_CommonWell_Improve_C-CDA_06-15-2018_V1.pdf) Page 24

<sup>34</sup> [http://www.commonwellalliance.org/wp-content/uploads/2018/07/Carequality\\_CommonWell\\_Improve\\_C-CDA\\_06-15-2018\\_V1.pdf](http://www.commonwellalliance.org/wp-content/uploads/2018/07/Carequality_CommonWell_Improve_C-CDA_06-15-2018_V1.pdf) Page 25.

<sup>35</sup>CDA narrative text linking.docx

[https://docs.google.com/document/d/1r1qBuzPQNkLiNpLkTOIv4RHXQHkx7\\_N7\\_Es3MiHUek/edit](https://docs.google.com/document/d/1r1qBuzPQNkLiNpLkTOIv4RHXQHkx7_N7_Es3MiHUek/edit)

<sup>36</sup> <http://cdasearch.hl7.org/>



### Reference: 5.1.4 Use of Consistent Identifiers

The Joint Document Content Work Group implementation guide states, “Maintaining consistent IDs enables receivers who machine-process documents to de-duplicate the information and accurately identify data that has been previously reported. For any entry where an ID is required, systems SHALL maintain consistent IDs whether sending the entry in an Encounter Summary Document, a Patient Summary document or any other CDA document types.”<sup>37</sup>

The C-CDA R2.1 specification does not include a conformance requirement addressing the need for this practice of maintaining act/observation IDs. The Joint Document Content Work Group’s guidance adopts the practice as a strict requirement.<sup>38</sup> This Companion Guide recommends that implementers follow this guidance as a best practice.



C-CDA Content Creators SHOULD support document versioning. **[BP-013]**

There are many situations where a document may be updated. For example, a pending lab result or a missing note may trigger an update. The base CDA standard provides a mechanism to replace or append a previously sent document through the parentDocument relationship.<sup>39</sup> Since senders will not know what a receiver stored, it is preferable to always send a complete document that replaces the prior document, then indicate the parent document being replaced by including it with the replace relationship (typeCode=“RPLC”).<sup>40</sup>



C-CDA Content Creators SHOULD send a complete document and use the replace relationship (typeCode=“RPLC”) when sending a new version of a previously shared document. **[BP-014]**



C-CDA Content Consumers SHOULD support replacing a prior version of a document when a document is received that indicates it is a replacement for a prior document. **[BP-015]**

Chapter 7 of the HL7 CDA R2 Attachment IG: Exchange of C-CDA Based Documents, R1 – US Realm identifies conformance requirements when using C-CDA documents for attachments shared with Payers.<sup>41</sup> Chapter 7.5 establishes this conformance rule which applies to Content Consumers for handling document succession:

<sup>37</sup> [Concise Consolidated CDA: Deploying Encounter Summary Documents with Clinical Notes. Carequality and CommonWell Work Groups.](#) 2017. Page 26.

<sup>38</sup> [Concise Consolidated CDA: Deploying Encounter Summary Documents with Clinical Notes. Carequality and CommonWell Work Groups](#) Chapter 5.1.2 Maintain act/observation IDs across documents.

<sup>39</sup> [Concise Consolidated CDA: Deploying Encounter Summary Documents with Clinical Notes. Carequality and CommonWell Work Groups.](#) 2017. Page 26.

<sup>40</sup> [Concise Consolidated CDA: Deploying Encounter Summary Documents with Clinical Notes. Carequality and CommonWell Work Groups.](#) 2017. Page 27.

<sup>41</sup> [https://www.hl7.org/implement/standards/product\\_matrix.cfm](https://www.hl7.org/implement/standards/product_matrix.cfm)



Document creators SHOULD use the setId and version in the US Realm Header to identify a specific document (document type, patient and visit) the initial version and any successor documents shall use the same setId and increment the version. [AIGEX-DS1]



C-CDA Content Creators SHOULD use setId and versionNumber to identify document version succession. [CONF-016]



C-CDA Content Creators MAY indicate section content was reconciled using the Reconciliation Act Entry (1.3.6.1.4.1.19376.1.5.3.1.1.24.3.1). [BP-017]

The Joint Document Content Work Group implementation guide allows sending systems to indicate that a particular list was reconciled using the IHE Reconciliation Act Entry content module (1.3.6.1.4.1.19376.1.5.3.1.1.24.3.1). The IHE Reconciliation Act Entry defines an entry template to indicate the information in a section has been reconciled.

NOTE: IHE calls CDA templates “content modules”.

The guidance states, “While not required, systems should consider including this act, or a similar indicator, to explicitly state a list has been reconciled.” The guidance also notes, “Only include if the system is confident a user reconciled the list. This should not be included if a clinician simply reviewed the list and did not reconcile it.”<sup>42</sup>



C-CDA Content Creators SHOULD include the Section Time Range entry in a section when business logic dictates the range of information that is included. [BP-018]

**Reference:** 4.2.8 Declaring Business Rules that Limit Section Content; 5.1.8 Specifying Time Intervals for Sections with Limits

### 2.6.2 Content Consumer Responsibilities



C-CDA Content Consumers MAY validate documents prior to importing them. [BP-019]




Chapter 7 of the HL7 CDA R2 Attachment IG: Exchange of C-CDA Based Documents, R1 – US Realm identifies conformance requirements when using C-CDA documents for attachments shared with Payers.<sup>43</sup> Chapter 7.4 establishes these conformance rules which apply to Content Consumers for handling document validation:



All documents SHALL conform to the CDA R2 schema for CDA (XSD) with sdtc extensions included. [AIGEX-VR1]



<sup>42</sup> [Concise Consolidated CDA: Deploying Encounter Summary Documents with Clinical Notes](#). Carequality and CommonWell Work Groups. 2017. Page 28.

<sup>43</sup> [https://www.hl7.org/documentcenter/public\\_temp\\_E3F202CB-1C23-BA17-0C6B02F543752C9B/standards/dstu/CDAR2\\_AIG\\_CCDA\\_EXCHANGE\\_R1\\_STU\\_2017AUG.pdf](https://www.hl7.org/documentcenter/public_temp_E3F202CB-1C23-BA17-0C6B02F543752C9B/standards/dstu/CDAR2_AIG_CCDA_EXCHANGE_R1_STU_2017AUG.pdf) Page 48.


	All documents SHALL conform to the published HL7 implementation guide conformance specifications for the specific document template (including incorporated section and entry templates) as defined for the specific templateId and extension. [AIGEX-VR2]
	All documents SHALL pass defined as no errors the validation requirements in VR1 and VR2. [AIGEX-VR3]
	Documents that do not meet the validation criteria SHALL NOT be considered a valid attachment for the purpose of this Guide. [AIGEX-VR4]

Previously some implementer communities took a different stance suggesting that any C-CDA document that passed CDA Schema validation should, at a minimum, be accepted and systems SHOULD support rendering the section.text information present in the document. The position suggested Content Consumers SHOULD NOT reject documents that did not conform to the C-CDA R2.1 specification for the declared Document templates.

Content Consumers SHOULD be tolerant of accepting non-conformant C-CDA documents because rejecting documents for non-conformance may reduce or delay availability of valuable clinical data. However, Content Consumers may reject non-conformant C-CDA documents. For example, if a document cannot be rendered. Local trading partners may establish additional requirements for accepting documents.

	Consumers SHOULD be tolerant of accepting non-conformant C-CDA documents when possible. However, rejecting documents based on an entity’s validation rules or for structural issues may reduce or delay availability of valid clinical data. [BP-020]
	C-CDA Content Consumers SHOULD be able to replace a prior version of a document. [CONF-021]

Additionally, there are regulatory (Certification) requirements to support sequencing and hiding sections based on a provider’s preferences. A system must allow restricted viewing and support the ability of providers to tailor restricted views as a possible solution for large unusable documents. Use of the C-CDA CDA XSL style sheet will not be sufficient to meet the certification requirements.<sup>44</sup>

	Content Consumers SHALL support sequencing and hiding sections based on a provider’s preferences and SHALL allow restricted viewing and support the ability of providers to tailor restricted views as a possible solution for large unusable documents. [BP-022]
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<sup>44</sup> 80 FR 62634

The receiving system's ability to replace a parent document should be maintained regardless of the mechanism of exchange (*e.g.* via Direct, query, etc.). Some systems cannot link to prior versions using relatedDocument/parentDocument/id. Due to this inconsistent implementation of linking to parent documents, receiving systems may link to prior versions by using encompassingEncounter/id.<sup>45</sup>

**Reference:** 2.8 Options for Temporarily Unavailable Data



C-CDA Content Consumers SHOULD use setId and versionNumber to manage document succession. **[CONF-023]**

When using C-CDA documents for attachments shared with Payers, additional conformance requirements were set forth in HL7 CDA R2 Attachment IG: Exchange of C-CDA Based Documents, R1 – US Realm. Chapter 7.5 addresses how Content Consumers should handle document succession:



Document recipients SHOULD recognize, associate, and make available versions of documents as defined by the setId and version in the US Realm Header. **[AIGEX-DS2]**



Document recipients SHOULD apply any document retention policies to all versions of a document as defined by setId and version. **[AIGEX-DS3]**<sup>46</sup>



C-CDA Content Consumers SHOULD display useful document metadata when showing available documents for retrieval or retrieved documents. **[BP-024]**



C-CDA Content Consumers SHOULD enable display of all unrestricted sections of a valid CDA Document. **[BP-025]**

The Joint Document Content Work Group implementation guide states, “The base CDA standard is designed so that every section's section.text element is displayable in a basic browser using the base CDA stylesheet, cda.xsl. While receivers are allowed to implement complex processing to apply their own display styles to a section, a system SHALL never hide a section if it does not recognize the LOINC section code. Every properly formatted section SHALL be displayed, or an option given, to allow the user to view the full unrestricted document.”<sup>47</sup>

This guidance, combined with the guidance regarding Content Consumer capabilities to limit and customize the rendering of content in a C-CDA document, shows that implementer best practices for Content Consumers includes a wide range of rendering possibilities.

When presenting users with a list of available documents, implementer best practice includes displaying metadata based on guidance included in the Sequoia Project - [eHealth Exchange](#)

<sup>45</sup> [Concise Consolidated CDA: Deploying Encounter Summary Documents with Clinical Notes](#). Carequality and CommonWell Work Groups. 2017. Page 27.

<sup>46</sup> [https://www.hl7.org/documentcenter/public\\_temp\\_E3F202CB-1C23-BA17-0C6B02F543752C9B/standards/dstu/CDAR2\\_AIG\\_CCDA\\_EXCHANGE\\_R1\\_STU\\_2017AUG.pdf](https://www.hl7.org/documentcenter/public_temp_E3F202CB-1C23-BA17-0C6B02F543752C9B/standards/dstu/CDAR2_AIG_CCDA_EXCHANGE_R1_STU_2017AUG.pdf) Page 49

<sup>47</sup> [Concise Consolidated CDA: Deploying Encounter Summary Documents with Clinical Notes](#). Carequality and CommonWell Work Groups. 2017. Page 31.

[Content Testing Program Guide](#) with the additions of Date and Title by the Joint Document Content Work Group.

Shown below is “Figure 18 Document Information Available during the IHE Query and in the stored C-CDA from the Joint Work Group implementation guide which summarizes key data elements available in the IHE Document Query transaction (ITI-18) and in the C-CDA document header.”<sup>48</sup>

When displaying available documents for retrieval or retrieved documents, systems should display corresponding document information. This information may be obtained from the IHE query/retrieve transaction (i.e., the same as what was displayed in the “list of available documents” during the query) or may be obtained (parsed) from within the C-CDA document header<sup>49</sup>.

Document Info	Availability	Location
Date range	IHE Metadata	<code>DocumentEntry.serviceStartTime</code> <code>DocumentEntry.serviceStopTime</code>
	Encounter Summary C-CDA Header	<code>ClinicalDocument/componentOf/encompassingEncounter/effectiveTime/low</code> <code>ClinicalDocument/componentOf/encompassingEncounter/effectiveTime/high</code>
	Patient Summary C-CDA Header	<code>ClinicalDocument/documentationOf/serviceEvent/effectiveTime/low</code> <code>ClinicalDocument/documentationOf/serviceEvent/effectiveTime/high</code>
Title	IHE Metadata	<code>DocumentEntry.title</code>
	C-CDA Header	<code>ClinicalDocument/title</code>
Document Type	IHE Metadata	<code>DocumentEntry.typeCode</code>
	C-CDA Header	<code>ClinicalDocument/code</code>
Author	IHE Metadata	<code>DocumentEntry.authorPerson</code>
	C-CDA Header	<code>ClinicalDocument/author/assignedAuthor/assignedPerson</code>
Author Organization	IHE Metadata	<code>DocumentEntry.authorInstitution</code>
	C-CDA Header	<code>ClinicalDocument/author/assignedAuthor/representedOrganization/name</code>
	IHE Metadata	<code>DocumentEntry.eventCodeList</code>

<sup>48</sup> [Concise Consolidated CDA: Deploying Encounter Summary Documents with Clinical Notes](#). Carequality and CommonWell Work Groups. 2017. Page 30-31.

<sup>49</sup> While this section focuses on query/retrieve, documents received via Direct **SHOULD** follow the recommended metadata for display

List of Services	Encounter Summary C-CDA Header	ClinicalDocument/documentationOf/serviceEvent/code
	Patient Summary C-CDA Header	Not Applicable - the service event information in a patient summary is restricted to "Provision of Care". The document does not contain details about the services provided during the span of time covered by the document.
Practice Type	IHE Metadata	DocumentEntry.practiceSettingCode
	Encounter Summary C-CDA Header	ClinicalDocument/componentOf/encompassingEncounter/location/healthcareFacility
	Patient Summary C-CDA Header	Not Applicable - Patient Summary may multiple practice types
Format Code	IHE Metadata	DocumentEntry.formatCode
	C-CDA Header	Not Applicable - the formatCode is inferred by the templateIDs asserted in the Header

Table 7: from Concise Consolidated CDA: Deploying Encounter Summary Documents with Clinical Notes. Document Information Available during the IHE Query and in the stored C-CDA

The meta data mapping provides best practice guidance for use with query/retrieve operations. It also applies to best practices for display of documents received via Direct. Display of these metadata elements offer useful information when selecting documents for retrieval or review.

## 2.7 Clinical Notes

The term “clinical note” can be used to mean different things, depending on the context of use. For example, the term “clinical note” can refer to an entire C-CDA R2.1 document. A C-CDA R2.1 document is a clinical note in that it includes all the clinical information that is relevant and pertinent to a care encounter, a span of time when care services have been delivered, or a point in time when clinical information about a patient needs to be shared across systems. C-CDA, in fact, was developed to exchange clinical notes in this sense of the term.

Additionally, the term clinical note is often used to describe a document authored by a clinician to capture the health story of a patient – this may include their past and current health as well as planned next steps to improve their health. Clinical notes are a critical part of the patient record. Prior to the formation of the Joint Document Content Work Group the independent Carequality and CommonWell content work groups were discussing methods to exchange clinical notes in C-CDA. Additionally, in response to requirements within the 21<sup>st</sup> Century Cures Act, to identify a common set of data for exchange, the Office of the National Coordinator (ONC) has included Clinical Notes in the proposed the U.S. Core Data for Interoperability (USCDI). The exchange of clinical notes is also a high priority for the further development of the

Fast Healthcare Interoperability Resources (FHIR) specification as supported through the Argonaut Project.<sup>50</sup>

Within EHR systems, a clinical note may refer to narrative information that is entered by a clinician in a patient's record. This type of clinical note is clinical information that is not captured as structured data. It exists within the context of a patient's record and is part of the documentation gathered during an encounter or related to a specific care event. A clinical note of this type could be a single sentence to record an impression or it could be a paragraph of information that tells a larger story. It is part of the larger clinical note produced to tell the whole story of the encounter.

Regardless of the granularity, clinical note information can be categorized by the type of information contained in the note. Several common categories of clinical notes exist to help classify and organize much of the clinical information exchange today. The categories can apply to collections of information gathered as a whole document, a Notes Section within a larger document, or a single Note Activity entry that holds a narrative clinical note that appears within a standard structured section.

A clinical note created and managed in an EHR system may be represented for exchange with other systems using a C-CDA document template designed for that type of clinical note. The document templates defined in C-CDA 2.1 establish the section structure for several common types of structured clinical notes. Not all systems used by practitioners to generate clinical notes maintain internal information structures sufficient to classify clinical note information into the structured sections defined for C-CDA structured documents.

In order to address the challenge that clinical notes in an EHR systems have varying levels of identifiable structure, C-CDA defines clinical note templates at different levels.

Clinical note information that can be represented as a complete document using the section structures required and recommended by C-CDA document-level templates may be exchanged as a structured clinical note document.

Clinical note information which does not contain all the structure required for a C-CDA document may be represented within a section-level template in the context of a larger collection of information pulled together to complete the content required by the document-level template. A Notes Section is used when the type of clinical note information that needs to be shared isn't specifically aligned with one of the standard sections defined for the document.

An entry-level template called the Note Activity template is defined to represent narrative clinical note information from the originating system. A Note Activity entry is used to represent clinical note information within a document section in a machine processable format.

This layered approach to representing clinical notes in C-CDA enables the wide range of information gathered in EHR systems to be represented and shared via a CDA Document. Narrative note information as well as discrete data can be included and encoded in a structure way that facilitates both human readability and machine processing.

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<sup>50</sup> [Concise Consolidated CDA: Deploying Encounter Summary Documents with Clinical Notes](#). Concise Consolidated CDA: Deploying Encounter Summary Documents with Clinical Notes. Carequality and CommonWell Work Groups. 2017. Page 14.



**Reference:** 5.2.18 Clinical Note; 6.3.1 The Joint Content Document Workgroup, Appendix A.

### 2.7.1 LOINC Coding for Clinical Notes

Logical Observation Identifiers Names and Codes (LOINC) is an international standard code set developed and maintained by the Regenstrief Institute for identifying clinical information.<sup>51</sup> Since its inception, Regenstrief has developed LOINC as an open standard and is available at no cost. LOINC is used worldwide for the exchange and pooling of clinical results for care delivery, outcomes management, public health reporting, document management, and research. Used in conjunction with standards for messages, documents, and APIs, LOINC supports efficient processing and storage of data from disparate sources. When exchanging clinical information between providers and with payers, attachment requests and attachment submissions use LOINC codes to identify the type of information desired and the information provided.<sup>52</sup>

The LOINC terminology includes thousands of different clinical note types.<sup>53</sup> These codes can be used at the document, section, or entry level to categorize the type of clinical note information being shared. To focus the industry, the Argonaut participants and the Department of Veterans Affairs contributed their most commonly used note types to develop the following list of most frequently created clinical note documents.<sup>54</sup> The table below includes the clinical note type, the most general LOINC code available for this type of document, and the value set listing the full range of LOINC codes available for the clinical notes of that type.

The clinical note type value sets are established by the HL7 Payer/Provider Information Exchange Work Group. The value sets use LOINC document codes, are maintained by Regenstrief Institute, and are published through the US National Library of Medicine Value Set Authority Center (VSAC).<sup>55</sup> Each value set is identified by a unique object identifier (OID). These value sets are included in the C-CDA 2.1 value set expansion package available as a VSAC downloadable resource.<sup>56</sup>

Clinical Note Type	Most General LOINC Code	LOINC Long Name	Complete Note Type Value Set
<b>Discharge Summary Note</b>	18842-5	Discharge summary	DischargeSummaryDocumentType 2.16.840.1.113883.11.20.4.1
<b>Consultation Note</b>	11488-4	Consult Note	ConsultDocumentType 2.16.840.1.113883.11.20.9.31

<sup>51</sup> For more information on LOINC, visit <https://loinc.org>

<sup>52</sup> [HL7 CDA R2 Attachments IG: Exchange of C-CDA Based Documents, R1](#) – US Realm, Page 22.

<sup>53</sup> LOINC website Regenstrief administers: <https://loinc.org/>

<sup>54</sup> Concise Consolidated CDA: Deploying Encounter Summary Documents with Clinical Notes. Carequality and CommonWell Work Groups. 2017. Page 14.

<sup>55</sup> <https://vsac.nlm.nih.gov/>


<sup>56</sup> <https://vsac.nlm.nih.gov/valueset/expansions?pr=ccda>



Clinical Note Type	Most General LOINC Code	LOINC Long Name	Complete Note Type Value Set
<b>Imaging Narrative Note</b>	18748-4	Used for query for all Imaging reports. Not an actual clinical note document type.	CompleteNoteType 1.3.6.1.4.1.12009.10.2.5
<b>Laboratory Narrative Note</b>	11502-2	Laboratory report	Note Types 2.16.840.1.113883.11.20.9.68
<b>Pathology Narrative Note</b>	11526-1	Pathology study	Note Types 2.16.840.1.113883.11.20.9.68
<b>History &amp; Physical Note</b>	34117-2	History and physical note	HPDocumentType 2.16.840.1.113883.1.11.20.22
<b>Progress Note</b>	11506-3	Progress note	ProgressNoteDocumentType 2.16.840.1.113883.11.20.8.1
<b>Procedures Note</b>	28570-0	Procedure note	ProcedureNoteDocumentType 2.16.840.1.113883.11.20.6.1

Table 8: LOINC Coding for Document Level clinical note types

The list was not provided in a priority order, nor was it intended to represent the exclusive list of what systems can and will support. Guidance from the Joint Document Content Work Group encouraged support for C-CDA document templates of these clinical note types.


C-CDA Content Creators SHOULD support creation of C-CDA documents for multiple clinical note types. [BP-002]


Guidance from the Joint Content Document Work Group also encouraged support for the Notes Section template which covers the standardized clinical note sections for use in C-CDA structured documents shown below.

The table below includes common categories of clinical note information. These LOINC codes are used to identify a section that includes narrative clinical notes of this type. These LOINC codes also are used to identify an individual clinical note when it is included as a machine processable entry within a standard C-CDA section. The Note Types value set (2.16.840.1.113883.11.20.9.68) identifies the full set of LOINC Codes that can be used with the Notes Section and the Note Activity entry.

Type of Narrative Clinical Note Information	LOINC Code for Note Section and/or Note Activity Entry
<b>Consultation Note</b>	11488-4
<b>Discharge Summary Note</b>	18842-5
<b>History &amp; Physical Note</b>	34117-2

Type of Narrative Clinical Note Information	LOINC Code for Note Section and/or Note Activity Entry
<b>Imaging Narrative Note</b>	Appropriate LOINC Code with Scale = DOC
<b>Laboratory Narrative Note</b>	11502-2
<b>Note</b>	34109-9
<b>Nurse Note</b>	34746-8
<b>Pathology Narrative Note</b>	11526-1
<b>Patient Note</b>	51855-5
<b>Procedures Note</b>	28570-0
<b>Progress Note</b>	11506-3
<b>Referral Note</b>	57133-1
<b>Surgical Operation Note</b>	11504-8
<b>Transfer Summary Note</b>	18761-7

Table 9: LOINC Codes for section- and entry- level clinical notes

 C-CDA Content Creators SHOULD support inclusion of narrative clinical note information in structured sections of C-CDA documents. **[BP-027]**

**Reference:** 4.3 Sections Defined in C-CDA (ordered using SOAP framework), 5.2.18 Clinical Note

## 2.8 Options for Temporarily Unavailable Data

There may be situations when information is not available at the time a CDA document is created. In these cases, a document containing available information may be sent. If the document type being sent requires a section for which the information is not yet available, the required section should be coded at the section-level to indicate the information for that section is “not available” using the “null” Flavor=“NAV” attribute. If the document type being sent indicates the section for which information is not yet available is an optional section, then inclusion of that section is not needed.

At a later point in time, when the information becomes available to complete the document, a new version of the document may be created and marked to communicate that it supersedes the previous version of the document. Specifically, the new document is identified with a globally unique identifier in the clinicalDocument.id field. The relatedDocument/typeCode=“RPLC” and the relatedDocument/typeCode=“RPLC”/parentDocument/id element will be set to reference the prior document’s clinicalDocument.id.

The setId and versionNumber fields are only used to indicate that the new document is not considered a new document, but rather is considered a new version of a prior document. One use case for using issuing a new version of an existing document would be when correcting an error in the content of the document. Another example might be when distributing the same

document to more or different information recipients. Business rules determine the circumstances when a document instance is a new document or a new version of an existing 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. However, but the Discharge Summary document type may still be used to meet the objective for transmitting health information within 36 hours of the hospital discharge. In this example, the incomplete Discharge Summary may be sent at the time of discharge and a new Discharge Summary may be sent later to communicate the updated information.

*Example 2: Discharge Summary with no Hospital Course information (see replacement document below).*

```
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns:sdtc="urn:h17-org:sdtc" classCode="DOCCLIN" moodCode="EVN" xmlns="urn:h17-org:v3">
  <realmCode code="US" />
  <typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040" />
  <templateId root="2.16.840.1.113883.10.20.22.1.1" extension="2015-08-01" />
  <templateId root="2.16.840.1.113883.10.20.22.1.8" extension="2015-08-01" />
  <id root="2.16.840.1.113883.19.5.99999.1" extension="20160414014447" />
  <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" code="18842-5"
  displayName="Discharge Summary" />
  <title>Health Summary</title>
  <effectiveTime value="20160414014447-0500" />
  <confidentialityCode codeSystem="2.16.840.1.113883.5.25" code="N" />
  <languageCode code="en-US" />
  <setId extension="20160414014447" root="2.16.840.1.113883.19.5.99999.19" />
  <versionNumber value="1" />
  ...
  <section nullFlavor="NAV">
    <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.5"/>
    <code code="8648-8"
      displayName="HOSPITAL COURSE"
      codeSystem="2.16.840.1.113883.6.1"
      codeSystemName="LOINC"/>
    <title>Hospital Course</title>
    <text>Information Not Available</text>
  </section>
  ...
</ClinicalDocument>
```

*Example 3: Replacement Discharge Summary document with Hospital Course information.*

The addition of Hospital Course information is not an errata correction, so it does not generate a new version of the document. The new document is indicated to wholly replace the prior document.

```
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns:sdtc="urn:h17-org:sdtc" classCode="DOCCLIN" moodCode="EVN" xmlns="urn:h17-org:v3">
  <realmCode code="US" />
  <typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040" />
  <templateId root="2.16.840.1.113883.10.20.22.1.1" extension="2015-08-01" />
  <templateId root="2.16.840.1.113883.10.20.22.1.8" extension="2015-08-01" />
  <id root="2.16.840.1.113883.19.5.99999.1" extension="20160414145050" />
  <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" code="18842-5"
  displayName="Discharge Summary" />
  <title>Health Summary</title>
  <effectiveTime value="20160414145050-0500" />
  <confidentialityCode codeSystem="2.16.840.1.113883.5.25" code="N" />
  <languageCode code="en-US" />
  <setId extension="20160414014447" root="2.16.840.1.113883.19.5.99999.19" />
  <versionNumber value="2" />
  <relatedDocument typeCode="RPLC">
```

```

<parentDocument>
  <id root="2.16.840.1.113883.19.5.99999.1" extension="20160414014447" />
  <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" code="18842-5"
displayName="Discharge Summary" />
  <setId extension="20160414014447" root="2.16.840.1.113883.19.5.99999.19" />
  <versionNumber value="1" />
</parentDocument>
</relatedDocument>
...
<section>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.5"/>
  <code code="8648-8"
    displayName="HOSPITAL COURSE"
    codeSystem="2.16.840.1.113883.6.1"
    codeSystemName="LOINC"/>
  <title>Hospital Course</title>
  <text>The patient was admitted and started on Lovenox and nitroglycerin paste. ...</text>
</section>
...
</ClinicalDocument>

```

### 3 Document Level Guidance

The C-CDA R2.1 Companion Guide provides additional guidance aimed at increasing consistency in the way data in C-CDA document templates are represented and used across all implementations. The goal is to increase awareness about how to use the HL7 CDA and C-CDA standards to meet rising expectations and emerging regulations focused on expanding interoperability.

This chapter provides generalized document header guidance and additional guidance for specific types of C-CDA documents.

#### 3.1 Reusable, Nesting Templates

C-CDA R2.1 establishes two document header templates. These header templates establish consistent rules for populating the data elements in a C-CDA document header. Document header elements create context for the information contained in the body of the document.

The US Realm General Header is used for documents that are authored by clinicians and systems supporting clinicians, and the US Realm Patient Generated Header is used for documents that are authored by patients and systems supporting patients



Each document template defined in C-CDA R2.1 indicates the header template that the document is expected to conform to, and each MAY include additional header constraints that are relevant to the type of clinical note being represented in the document. **[BP-028]**

Additionally, document templates define the sections of content that SHALL, SHOULD, or MAY be present for exchanging clinical notes. Each section is identified with a code that tells the computer the type of information in the section.

Further, the sections define entry templates which SHALL, SHOULD, or MAY be used to represent the information in each section using even more discrete representations that aid further computer processing of the clinical information in the section.

### 3.1.1 Nested Content and Context Conduction

CDA context is set in the CDA header and applies to the entire document. Context can be overridden at the level of the section, and/or CDA entry. A document, in a sense, is a contextual wrapper for its contents. Assertions in the document header are typically applicable to statements made in the body of the document, unless overridden. For instance, the patient identified in the header is assumed to be the subject of observations described in the body of the document, unless a different subject is explicitly stated. The author identified in the header is assumed to be the author of the information in the sections and entries of the document, unless a different author is explicitly identified on a section or on individual entries. The objective of the CDA context rule is to make these practices explicit with relationship to the RIM, such that a computer will understand the context of a portion of a document the same way that a human interprets it.<sup>57</sup>

CDA's approach to context, and the propagation of that context to nested document components, follows these design principles<sup>58</sup>:

- The CDA Header sets context for the entire document. A propagating value specified in the document header holds true throughout the document, unless explicitly overridden. This principal applies only to designated participations and attributes of the CDA Header that support propagating context conduction. Contextual header components (i.e., those that have propagating values) include:
  - Author
  - Confidentiality
  - Data enterer
  - Human language
  - Informant
  - Legal authenticator
  - Participant
  - Record target
- Context components that can be overridden at the level of the document body include:
  - Confidentiality
  - Human language
- Context components that can be overridden at the level of a document section include:

---

<sup>57</sup> HL7 CDA Web Edition 2010. Chapter 4.4.

<sup>58</sup> HL7 CDA Web Edition 2010. Chapter 4.4

- Author
  - Confidentiality
  - Human language
  - Informant
  - Subject
- Context components that can be overridden at the level of a CDA entry include:
    - Author
    - Confidentiality
    - Human language
    - Informant
    - Participant
    - Subject
  - Context propagates from outer context to nested context. Context that is specified on an outer tag holds true for all nested tags, unless overridden on a nested tag. Context specified on a tag within the CDA body always overrides context propagated from an outer tag. For instance, the specification of authorship at a document section level overrides all authorship propagated from the header. The outer context for an entryRelationship component in an entry is the outer entry act. The outer context for an entry is the encompassing section. The outer context for a section is the document header.
  - Context is sometimes known precisely, and is sometimes unknown, such as in the case where a document is comprised of a large unparsed narrative block that potentially includes statements that contradict outer context. Because CDA context always propagates unless overridden, the representation of unknown context is achieved by overriding with a null value.
  - To override the Confidentiality at the entry level, an implementation must use Confidentiality Security Observation [Observation: templateId 2.16.840.1.113883.3.445.12] defined in "HL7 CDA® R2 Implementation Guide: Privacy Consent Directives, Release 1."<sup>59</sup>

*Example 4: Section with narrative text and a nullFlavor for the author*

This example explains that the author of the section is not known. Thus the author in the header does not conduct to be the author of the unparsed narrative information contained in the section.

```
<section>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.13.2.1"/>
  <code code="10154-3" displayName="Chief complaint Reported"
    codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
  <title>Chief Complaint Section</title>
  <text><content>No complaints, annual wellness exam</content>
  <content>Author of this section not known.</content>
</text>
  <author nullFlavor="UNK">
    <time/>
  <assignedAuthor>
```

<sup>59</sup> [http://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=280](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=280)

```

        <id/>
      </assignedAuthor>
    </author>
  </section>

```

**Reference:** For additional information on Context Conduction mechanisms in CDA documents, consult the HL7 CDA R2.0 specification.

**Reference:** The HL7 Data Security for Privacy<sup>60</sup> and HL7 Privacy Consent Directives<sup>61</sup> implementation guides define how to override confidentiality context at the entry level.

**Reference:** 5.2.1 Provenance, 5.1.6 Unknown Data in Sections

### 3.2 Structured Header

All CDA documents include a structured header regardless if the document is CDA document with a structured structuredBody element (a “structured document”) or a CDA document with a nonXMLBody element (an “unstructured document”). The structured header permits computer processing (parsing) to occur on its content.

#### 3.2.1 Patient

The recordTarget represents the medical record that this document belongs to. In the uncommon case where a clinical document (such as a group encounter note) is placed into more than one patient chart, more than one recordTarget participants can be stated.<sup>62</sup> The recordTarget records the administrative and demographic data of the patient whose health information is described by the clinical document; each recordTarget must contain at least one patientRole element.<sup>63</sup>

The recordTarget contains many elements that hold core data for interoperability. The table below summarizes data elements present in the recordTarget.

Patient matching continues to be one of the major challenges for interoperability due to the lack of a universal patient identifier, similar to a Social Security Number, but used for healthcare.

Data Element	Data element xPath
<b>First Name</b>	/ClinicalDocument/recordTarget/patientRole/patient/name/given[1]
<b>Last Name</b>	/ClinicalDocument/recordTarget/patientRole/patient/name/family
<b>Previous Name</b>	/ClinicalDocument/recordTarget/patientRole/patient/name/family/@qualifier
<b>Middle Name</b>	/ClinicalDocument/recordTarget/patientRole/patient/name/given[2]

<sup>60</sup> [http://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=354](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=354) page 46




<sup>61</sup> [http://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=280](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=280) page 38

<sup>62</sup> HL7 CDA Web Edition 2010. Chapter 4.2.2.11.

<sup>63</sup> HL7 Consolidated CDA R2.1. Chapter 1.1.1.2.

Data Element	Data element XPath
Suffix	/ClinicalDocument/recordTarget/patientRole/patient/name/suffix
Administrative Gender	/ClinicalDocument/recordTarget/patientRole/patient/administrativeGenderCode
Birth Sex	Reference: 5.2.10.3 Birth Sex
Date of Birth	/ClinicalDocument/recordTarget/patientRole/patient/birthTime
Race	/ClinicalDocument/recordTarget/patientRole/patient/raceCode
Ethnicity	/ClinicalDocument/recordTarget/patientRole/patient/ethnicGroupCode
Preferred Language (requires preferenceInd = "true")	/ClinicalDocument/recordTarget/patientRole/patient/languageCommunication /ClinicalDocument/recordTarget/patientRole/patient/languageCommunication/preferenceInd
Address	/ClinicalDocument/recordTarget/patientRole/addr
Phone Number	/ClinicalDocument/recordTarget/patientRole/telecom

Table 10: Patient Data Elements

- 
**C-CDA Content Creators SHOULD include identifiers that improve the accuracy of automated patient matching mechanisms. [BP-029]**  
 Note: Testability would require business decisions to be made about what type of identifiers improve automated matching.
- 
**C-CDA Content Creators SHALL include the patient’s administrative gender in the demographic information of the recordTarget. [CONF-030]**
- 
**C-CDA Content Creators SHALL include the patient’s birth sex as a Social History Observation in the Social History Section. [CONF-031]**

Example 5: recordTarget with demographic data

```

<recordTarget>
  <patientRole>
    <!-- Here is a public id that has an external meaning based on a root OID that is
publically identifiable. -->
    <!-- root="1.3.6.1.4.1.41179.2.4" is the assigningAuthorityName for
DirectTrust's Patient/Consumer addresses "DT.org PATIENT" -->
    <id root="1.3.6.1.4.1.41179.2.4" extension="lisarnelson@direct.myphd.us"
assigningAuthorityName="DT.org PATIENT"/>
    <!-- More ids may be used. -->
    <!-- Here is the patient's MRN at RVHS -->
    <id root="2.16.840.1.113883.1.111.12345" extension="12345-0828"
assigningAuthorityName="River Valley Health Services local patient Medical
Record Number" />
    <addr>
      <streetAddressLine>1 Happy Valley Road</streetAddressLine>
      <city>Westerly</city>
      <state>RI</state>
      <postalCode>02891</postalCode>
      <country nullFlavor="UNK"/>
    </addr>
    <telecom use="WP" value="tel:+1-4013482345"/>
    <telecom use="HP" value="tel:+1-4016412345"/>
    <telecom value="mailto:lisarnelson@gmail.com"/>
    <telecom value="mailto:lisarnelson@direct.myphd.us"/>
  </patient>
  
```



```

        <name use="L">
          <family>Nelson</family>
          <given qualifier="CL">Lisa</given>
        </name>
        <administrativeGenderCode code="F" displayName="Female"
          codeSystem="2.16.840.1.113883.5.1" codeSystemName="HL7
AdministrativeGender"/>
        <birthTime value="19620828"/>
        <maritalStatusCode code="M" displayName="Married"
          codeSystem="2.16.840.1.113883.5.2"
          codeSystemName="HL7 MaritalStatus"/>
        <raceCode code="2106-3" displayName="White"
codeSystem="2.16.840.1.113883.6.238"
          codeSystemName="CDC Race and Ethnicity"/>
        <ethnicGroupCode code="2186-5" displayName="Not Hispanic or Latino"
codeSystem="2.16.840.1.113883.6.238" codeSystemName="CDC Race and
Ethnicity"/>
        <languageCommunication>
          <templateId root="2.16.840.1.113883.3.88.11.32.2"/>
          <languageCode code="eng"/>
          <preferenceInd value="true"/>
        </languageCommunication>
      </patient>
      <providerOrganization>
        <!-- This is a public id where the root is registered to indicate the
National Provider ID -->
        <id root="2.16.840.1.113883.4.6" extension="1417947383"
          assigningAuthorityName="National Provider ID"/>

```

*Example 6: recordTarget including the provider organization context for the clinical documentation*

```

<recordTarget>
  <patientRole>
    <!-- Here is a public id that has an external meaning based on a root OID that is
publicly identifiable. -->
    <!-- root="1.3.6.1.4.1.41179.2.4" is the assigningAuthorityName for
DirectTrust's Patient/Consumer addresses "DT.org PATIENT" -->
    <id root="1.3.6.1.4.1.41179.2.4" extension="lisarnelson@direct.myphd.us"
      assigningAuthorityName="DT.org PATIENT"/>
    <!-- More ids may be used. -->
    <!-- Here is the patient's MRN at RVHS -->
    <id root="2.16.840.1.113883.1.111.12345" extension="12345-0828"
      assigningAuthorityName="River Valley Health Services local patient
Medical Record Number" />
    <addr>
      <streetAddressLine>1 Happy Valley Road</streetAddressLine>
      <city>Westerly</city>
      <state>RI</state>
      <postalCode>02891</postalCode>
      <country nullFlavor="UNK"/>
    </addr>
    <telecom use="WP" value="tel:+1-4013482345"/>
    <telecom use="HP" value="tel:+1-4016412345"/>
    <telecom value="mailto:lisanelson@gmail.com"/>
    <telecom value="mailto:lisarnelson@direct.myphd.us"/>
  </patient>
  <name use="L">
    <family>Nelson</family>
    <given qualifier="CL">Lisa</given>
  </name>
  <administrativeGenderCode code="F" displayName="Female"
codeSystem="2.16.840.1.113883.5.1" codeSystemName="HL7
AdministrativeGender"/>
  <birthTime value="19620828"/>
  <maritalStatusCode code="M" displayName="Married"
codeSystem="2.16.840.1.113883.5.2"
codeSystemName="HL7 MaritalStatus"/>

```

```

    <raceCode code="2106-3" displayName="White"
codeSystem="2.16.840.1.113883.6.238"
    codeSystemName="CDC Race and Ethnicity"/>
    <ethnicGroupCode code="2186-5" displayName="Not Hispanic or Latino"
codeSystem="2.16.840.1.113883.6.238" codeSystemName="CDC Race
and Ethnicity"/>
    <languageCommunication>
    <templateId root="2.16.840.1.113883.3.88.11.32.2"/>
    <languageCode code="eng"/>
    <preferenceInd value="true"/>
    </languageCommunication>
  </patient>
  <providerOrganization>
    <!-- This is a public id where the root is registered to indicate
the National Provider ID -->
    <id root="2.16.840.1.113883.4.6" extension="1417947383"
assigningAuthorityName="National Provider ID"/>
    <!-- This is a public id where the root indicates this is a
Provider Direct Address. -->
    <!-- root="1.3.6.1.4.1.41179.2.1" is the assigningAuthorityName for
DirectTrust's Covered Entity addresses "DT.org CE" -->
    <id root="1.3.6.1.4.1.41179.2.1" extension="rvhs@rvhs.direct.md"
assigningAuthorityName="DT.org CE (Covered Entity)"/>
    <!-- By including a root OID attribute for a healthcare
organization, you can use this information to
indicate a patient's MRN id at that organization.-->
    <id root="2.16.840.1.113883.1.111.12345"
assigningAuthorityName="River Valley Health Services local
patient Medical Record Number" />
    <name>River Valley Health Services</name>
    <telecom use="WP" value="tel:+1-4015394321"/>
    <telecom use="WP" value="mailto:rvhs@rvhs.direct.md"/>
    <addr>
    <streetAddressLine>823 Main Street</streetAddressLine>
    <city>River Valley</city>
    <state>RI</state>
    <postalCode>028321</postalCode>
    <country>US</country>
    </addr>
  </providerOrganization>
</patientRole>
</recordTarget>
</patientRole>
</recordTarget>

```

The CDA Examples Search tool provides useful examples showing the Patient Demographic data elements represented in a C-CDA document. The examples below show how to include information about a patient's prior name or prior address in a C-CDA document. The relevance and pertinence of including this type of information in an exchange document remains a business decision to be made by organizations engaged in sharing information.

*Example 7: How to represent Patient demographic Information<sup>64</sup>*

```

<recordTarget>
  <patientRole>
    <!-- The @root OID below (which is fictional) would be specific to an institution's
record identifier system. -->
    <id root="2.16.840.1.113883.3.6132" extension="345678912-0154"/>
    <!-- HP is "primary home" from valueSet 2.16.840.1.113883.1.11.10637 -->
    <addr use="HP">
      <!-- You can have multiple [1..4] streetAddressLine elements. Single shown below --
    >

```

<sup>64</sup> <http://cdasearch.hl7.org/examples/view/de1f429a35879e80f3df21b5fb1522809fdb736>

```

<streetAddressLine>1436 Jennyhill Ln.</streetAddressLine>
<city>Hollywood</city>
<!-- 5 or 9 digit zip codes from valueSet 2.16.840.1.113883.3.88.12.80.2-->
<!-- PostalCode is required if the country is US. If country is not specified, it's
assumed to be US. If country -->
<!-- is something other than US, the postalCode MAY be present but MAY be bound to
different vocabularies -->
<postalCode>90068</postalCode>
<!-- State is required if the country is US. If country is not specified, it's
assumed to be US. -->
<!-- If country is something other than US, the state MAY be present but MAY be
bound to different vocabularies -->
<!-- OR is "Oregon" from valueSet 2.16.840.1.113883.3.88.12.80.1 -->
<state>CA</state>
<!-- US is the two digit code for "United States" -->
<country>US</country>
</addr>
<!-- MC is "mobile contact" from HL7 AddressUse 2.16.840.1.113883.5.1119 -->
<telecom value="tel:+1(565)867-5309" use="MC"/>
<!-- Multiple telecoms are possible -->
<telecom value="mailto://adam@diameterhealth.com" use="WP"/>
<patient>
  <name use="L">
    <given>Adam</given>
    <family>Everyman</family>
  </name>
  <!-- From CDA R2 on administrativeGender Code: This attribute does not include
terms related to clinical gender.
      Gender is a complex physiological, genetic and sociological
concept that requires multiple observations in order to be
comprehensively described. The purpose of this attribute is to
provide a high level classification that can additionally
be used for the appropriate allocation of inpatient bed
assignment.-->
  <!-- Sex at birth and gender identity may be specified in social history -->
  <administrativeGenderCode code="M" codeSystem="2.16.840.1.113883.5.1"
displayName="Male" codeSystemName="AdministrativeGender"/>
  <birthTime value="19621022"/>
  <maritalStatusCode code="M" displayName="Married"
codeSystem="2.16.840.1.113883.5.2" codeSystemName="MaritalStatus"/>
  <religiousAffiliationCode code="1013" displayName="Christian (non-Catholic, non-
specific)" codeSystem="2.16.840.1.113883.5.1076" codeSystemName="HL7 Religious Affiliation"/>
  <!-- CDC Race and Ethnicity code set contains the five minimum race and ethnicity
categories defined by OMB Standards -->
  <raceCode code="2106-3" displayName="White" codeSystem="2.16.840.1.113883.6.238"
codeSystemName="OMB Standards for Race and Ethnicity"/>
  <ethnicGroupCode code="2186-5" displayName="Not Hispanic or Latino"
codeSystem="2.16.840.1.113883.6.238" codeSystemName="OMB Standards for Race and Ethnicity"/>
  <languageCommunication>
    <languageCode code="eng"/>
    <!-- "eng" is ISO 639-2 alpha-3 code for "English" -->
    <modeCode code="ESP" displayName="Expressed spoken"
codeSystem="2.16.840.1.113883.5.60" codeSystemName="LanguageAbilityMode"/>
    <proficiencyLevelCode code="E" displayName="Excellent"
codeSystem="2.16.840.1.113883.5.61" codeSystemName="LanguageAbilityProficiency"/>
    <preferenceInd value="true"/>
  </languageCommunication>
  <!-- Multiple languages are permitted. Only one should have a preferenceInd = true
-->
  <languageCommunication>
    <languageCode code="ita"/>
    <!-- "ita" is ISO 639-2 alpha-3 code for "Italian" -->
    <modeCode code="ESP" displayName="Expressed spoken"
codeSystem="2.16.840.1.113883.5.60" codeSystemName="LanguageAbilityMode"/>
    <proficiencyLevelCode code="G" displayName="Good"
codeSystem="2.16.840.1.113883.5.61" codeSystemName="LanguageAbilityProficiency"/>
    <!-- Patient's preferred language -->
    <preferenceInd value="false"/>
  </languageCommunication>
</patient>
</patientRole>

```

```
</recordTarget>
```

*Example 8: How to represent Patient with Previous Name<sup>65</sup>*

```
<recordTarget>
  <!-- Note: several other data elements (telecom, address, etc.) are required to meet C-CDA
  R2.1 requirements -->
  <patientRole>
    <id extension="444222222" root="2.16.840.1.113883.4.1"/>
    <patient>
      <!-- SDWG reviewed and approved approach for recording a birth name and legal name
      -->
      <name use="L">
        <given>Alice</given>
        <given>Jones</given>
        <family>Newman</family>
      </name>
      <name>
        <given qualifier="BR">Alicia</given> <!-- BR = Birth name-->
        <given>Jones</given>
        <family qualifier="BR">Newman</family> <!-- BR = Birth name-->
        <!-- Optional valid time - best practice -->
        <validTime>
          <low value="20010505"/>
          <high value="20010510"/>
        </validTime>
      </name>
    </patient>
  </patientRole>
</recordTarget>
```

*Example 9: How to represent Patient with Prior Address<sup>66</sup>*

```
<!-- recordTarget example from C-CDA-Examples/Header/Patient Demographic Information
added multiple home addresses
-->
<recordTarget>
  <patientRole>
    <id root="2.16.840.1.113883.3.6132" extension="345678912-0154"/>
    <!-- HP is "primary home" from valueSet 2.16.840.1.113883.1.11.10637
    and in this instance represents patient's current address -->
    <addr use="HP">
      <streetAddressLine>152 Creek Lane</streetAddressLine>
      <city>Shelburne</city>
      <state>VT</state>
      <postalCode>05455</postalCode>
      <country>US</country>
      <useablePeriod xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xsi:type="IVL_TS">
        <low value="20110822"/>
      </useablePeriod>
      <!-- It is permissible to omit a low element to indicate current residence -->
      <!-- It is permissible to omit a high element or use nullFlavor='NA' -->
    </addr>
    <addr use="H">
      <streetAddressLine>191 S OAK AVE</streetAddressLine>
      <city>BURLINGTON</city>
      <state>VT</state>
      <postalCode>05422</postalCode>
      <country>US</country>
      <useablePeriod xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xsi:type="IVL_TS">
        <low value="20110131"/>
        <high value="20110821"/>
      </useablePeriod>
    </addr>
  </patientRole>
</recordTarget>
```

<sup>65</sup> <http://hl7-c-cda-examples.herokuapp.com/examples/view/Header/Patient%20Previous%20Name>

<sup>66</sup> <http://hl7-c-cda-examples.herokuapp.com/examples/view/Header/Patient%20With%20Prior%20Addresses>

```

</addr>
<addr use="H">
  <streetAddressLine>1141 W MAIN AVE</streetAddressLine>
  <city>CHICAGO</city>
  <state>IL</state>
  <postalCode>60613</postalCode>
  <country>US</country>
  <useablePeriod xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xsi:type="IVL_TS">
    <low value="20070513"/>
    <high value="20110130"/>
  </useablePeriod>
</addr>
<telecom value="tel:+1(565)867-5309" use="MC"/>
<telecom value="mailto://adam@diameterhealth.com" use="WP"/>
<patient>
  <name use="I">
    <given>Adam</given>
    <family>Everyman</family>
  </name>
  <administrativeGenderCode code="M" codeSystem="2.16.840.1.113883.5.1"
displayName="Male" codeSystemName="AdministrativeGender"/>
  <birthTime value="19621022"/>
  <maritalStatusCode code="M" displayName="Married"
codeSystem="2.16.840.1.113883.5.2" codeSystemName="MaritalStatus"/>
  <religiousAffiliationCode code="1013" displayName="Christian (non-Catholic, non-
specific)" codeSystem="2.16.840.1.113883.5.1076" codeSystemName="HL7 Religious Affiliation"/>
  <raceCode code="2106-3" displayName="White" codeSystem="2.16.840.1.113883.6.238"
codeSystemName="OMB Standards for Race and Ethnicity"/>
  <ethnicGroupCode code="2186-5" displayName="Not Hispanic or Latino"
codeSystem="2.16.840.1.113883.6.238" codeSystemName="OMB Standards for Race and Ethnicity"/>
  <languageCommunication>
    <languageCode code="eng"/>
    <modeCode code="ESP" displayName="Expressed spoken"
codeSystem="2.16.840.1.113883.5.60" codeSystemName="LanguageAbilityMode"/>
    <proficiencyLevelCode code="E" displayName="Excellent"
codeSystem="2.16.840.1.113883.5.61" codeSystemName="LanguageAbilityProficiency"/>
    <preferenceInd value="true"/>
  </languageCommunication>
  <languageCommunication>
    <languageCode code="ita"/>
    <modeCode code="ESP" displayName="Expressed spoken"
codeSystem="2.16.840.1.113883.5.60" codeSystemName="LanguageAbilityMode"/>
    <proficiencyLevelCode code="G" displayName="Good"
codeSystem="2.16.840.1.113883.5.61" codeSystemName="LanguageAbilityProficiency"/>
    <preferenceInd value="false"/>
  </languageCommunication>
</patient>
</patientRole>
</recordTarget>

```

### 3.2.1.1 @use and @qualifier attributes for Patient name

The US Realm Patient Name template (2.16.840.1.113883.10.20.22.5.1) supports the @use attribute on the name tag. This template also supports the @qualifier attribute on the given and family tags.

These value sets are available in the C-CDA R2.1 Value Set Release Package available from the Downloads page of the Value Set Authority Center.<sup>67</sup>

<sup>67</sup> For more information on Value Set Release Package, visit <https://vsac.nlm.nih.gov/download/ccda>



Concepts available for use with the @use attribute of the name element SHALL be selected from the EntityNameUse value set (2.16.840.1.113883.1.11.15913 ). **[CONF-032]**



Concepts available for use with the @qualifier attribute of the name element SHALL be selected from the EntityPersonNamePartQualifier value set (2.16.840.1.113883.11.20.9.26 ). **[CONF-033]**

*Example 10: Logical display order of name pieces*

*(i.e. such that a receiver which only extracts the text and ignores the markup around <given>, <family>, etc. would still display the name in a way a human would interpret correctly).*

```
<recordTarget>
  <!-- Examples of how systems send names and logical display order -->
  <!-- Note: This snippet omits other data elements required to meet C-CDA R2.1 requirements
  (telecom, address, etc.) -->
  <patientRole>
    <id nullFlavor="NI" />
    <patient>
      <!-- This is okay; "Robin Taylor" is a logical display order -->
      <name>
        <given>Robin</given>
        <family>Taylor</family>
      </name>
      <!-- This is okay; "Taylor, Robin" implies Lastname, Firstname ordering in the US -->
      <name>
        <family>Taylor</family>
        <delimiter>, </delimiter>
        <given>Robin</given>
      </name>
      <!-- This is okay; "Dr. Robin Taylor" is a logical display order -->
      <name>
        <prefix qualifier="AC TITLE">Dr. </prefix><!-- Space in element is intentional
  (see CDA R2.0 Section 2.23.4) -->
        <given>Robin</given>
        <family>Taylor</family>
      </name>
      <!-- This is okay; "Robin Taylor MD" is a logical display order -->
      <name>
        <given>Robin</given>
        <family>Taylor</family>
        <suffix qualifier="AC TITLE"> MD</suffix><!-- Space in element is intentional
  (see CDA R2.0 Section 2.23.4) -->
      </name>
      <!-- Don't do this; "Robin Taylor Dr." isn't a logical display order -->
      <name>
        <given>Robin</given>
        <family>Taylor</family>
        <prefix qualifier="AC TITLE">Dr. </prefix><!-- Space in element is intentional --
    >
      </name>
      <!-- Don't do this; "Taylor Robin" is confusing (is Taylor the given name?) -->
      <name>
        <family>Taylor</family>
        <given>Robin</given>
      </name>
    </patient>
  </patientRole>
</recordTarget>
```

Some systems may collect a patient's Social Security number but organizational business rules prohibit distribution of the full number and require that all but the final four digits of the identifier to be masked when distributing this information to data sharing partners.



Content Consumers SHALL NOT treat id elements that include a nullFlavor attribute and globally unique identifiers. [BP-034]

*Example 11: How to represent a social security number (SSN) that has been masked to show only the last four digits.*

```
<?xml version="1.0" encoding="UTF-8"?>
<recordTarget>
  <patientRole>
    <!-- Example Social Security Number using the root for the Social Security Administration
    assigningAuthority. -->
    <id assigningAuthorityName="US Social Security Administration"
      root="2.16.840.1.113883.4.1" extension="414122222"/>
    <!-- SSN provided, but masked to include only the last 4 characters. -->
    <!-- Note: both examples are shows for comparison. It would not make sense to use both of
    these options in a real C-CDA Document. -->
    <!-- When recording SSN in the extension dashes (-) are permitted but not required" -->
    <!-- Receiving systems may decide whether to store the last 4 or discard -->
    <!-- an id with a nullFlavor SHALL NOT be used for matching or indexing -->
    <id assigningAuthorityName="US Social Security Administration"
      root="2.16.840.1.113883.4.1" extension="***-**-2222" nullFlavor="MSK"/>
    <addr use="HP">
      <!-- HP is "primary home" from codeSystem 2.16.840.1.113883.5.1119 -->
      <streetAddressLine>1357 Amber Dr</streetAddressLine>
      <city>Beaverton</city>
      <state>OR</state>
      <postalCode>97006</postalCode>
      <country>US</country>
      <!-- US is "United States" from ISO 3166-1 Country Codes: 1.0.3166.1 -->
    </addr>
    <telecom value="tel:+1(555)-777-1234" use="MC"/>
    <telecom value="tel:+1(555)-723-1544" use="HP"/>
    <!-- HP is "primary home" from HL7 AddressUse 2.16.840.1.113883.5.1119 -->
    <patient>
    ...
    </patient>
    <providerOrganization>
    ...
    </providerOrganization>
  </patientRole>
</recordTarget>
```

### 3.2.1.2 Representing Multiple Races or Multiple Ethnicities




The recordTarget utilizes two CDA R2 extensions for representing multiple races and multiple ethnicities.

The following guidance is available in Chapter 1.1 of the HL7 C-CDA R2.1 Implementation Guide<sup>68</sup>:



This patient **SHALL** contain exactly one [1..1] **raceCode**, which **SHALL** be selected from ValueSet **Race Category Excluding Nulls** urn:oid:2.16.840.1.113883.3.2074.1.1.3 **DYNAMIC** [CONF:1198-5322].

<sup>68</sup> HL7 C-CDA R2.1 Implementation Guide. Chapter 1.1 US Realm Header. Page 52.

	This patient <b>MAY</b> contain zero or more [0..*] <b>sdct:raceCode</b> , which <b>SHALL</b> be selected from ValueSet <b>Race</b> urn:oid:2.16.840.1.113883.1.11.14914 <b>DYNAMIC</b> (CONF:1198-7263). Note: The sdct:raceCode is only used to record additional values when the patient has indicated multiple races or additional race detail beyond the five categories required for Meaningful Use Stage 2. The prefix sdct: SHALL be bound to the namespace “urn:hl7-org:sdct”. The use of the namespace provides a necessary extension to CDA R2 for the use of the additional raceCode elements. a. If sdct:raceCode is present, then the patient <b>SHALL</b> contain [1..1] raceCode [CONF:1198-31347].
	This patient <b>SHALL</b> contain exactly one [1..1] <b>ethnicGroupCode</b> , which <b>SHALL</b> be selected from ValueSet <b>Ethnicity</b> urn:oid:2.16.840.1.114222.4.11.837 <b>DYNAMIC</b> [CONF:1198-5323].
	This patient <b>MAY</b> contain zero or more [0..*] sdct:ethnicGroupCode, which <b>SHALL</b> be selected from ValueSet Detailed Ethnicity urn:oid:2.16.840.1.114222.4.11.877 <b>DYNAMIC</b> (CONF:1198-32901).

### 3.2.1.3 Patient Identifiers

Patient identifiers are included in a C-CDA within the patientRole structure of the recordTarget. The @extension attribute of the id tag holds the identifier. The @root attribute holds an OID associated with the assigning authority of the identifier. The @assigningAuthorityName attribute holds the name of the assigning authority. Many organizations that assign trusted identifiers exist today and have registered OIDs to support exchange of the identifiers they assign. The table below includes some examples.

Assigning Authority Name	Assigning Authority OID identifier
<b>U.S. Social Security Administration</b>	2.16.840.1.113883.4.1
<b>Driver’s license issuing authority</b>	2.16.840.1.113883.12.333
<b>DT.org PATIENT (DirectTrust assigned identity for Consumer entity)</b>	1.3.6.1.4.1.41179.2.4

Table 11: Patient Identifiers

*Example 12: How to represent a patient's social security number*

```

<recordTarget>
  <patientRole>
    <id assigningAuthorityName="EPI"
      extension="700000305" root="1.2.840.114350.1.13.6289.1.7.5.737384.14"/>
    <id assigningAuthorityName="US Social Security Administration"
      root="2.16.840.1.113883.4.1" extension="999-99-9999"/>
    <id assigningAuthorityName="Driver’s license issuing authority"
      extension="43721-643" root="2.16.840.1.113883.4.3.24"/>
    <patient>
      <name use="L"><given>Barbara</given><family>Epic</family></name>
      . . .
    </patient>
  </patientRole>
</recordTarget>

```



```

. . .
  </patientRole>
</recordTarget>

```

### 3.2.1.4 recordTarget Provider Organization

While the recordTarget represents the medical record that this document belongs to, the providerOrganization within the recordTarget represents the provider organization to which the medical record belongs.



C-CDA Content Creators SHOULD populate the providerOrganization within the recordTarget when the document represents information from a provider's medical record system. **[CONF-035]**



C-CDA Content Creators SHOULD include an identifier for the provider organization in the id/@extension attribute and SHOULD identify the assigning authority for the identifier using a globally unique identifier (GUID or OID) in the id/@root attribute. **[CONF-036]**

**Reference:** Example 5: recordTarget with demographic data, Example 6: recordTarget including the provider organization context for the clinical documentation

### 3.2.2 Authors Versus Performers

CDA includes structures to record the author of information, and separately, the performer of a service. It is important for implementers to avoid recording a performer as an author, if that performer was not the individual who authored content.

A performer participant represents a clinician who actually and principally carried out a service. A performer participation indicated at one location in a document does not conduct throughout the document and must be repeated at each entry to indicate involvement. For example, the performer indicated in the serviceEvent in the CDA header is not automatically implied to be the performer in procedures or medication activities represented by the entries in the document. An author represents the human or machine that authored content. Authors listed in the header are responsible for all content in the document, while authors recorded in a section or entry are only responsible for content within that structure and override the author in the header. Section authorship applies to the full content of a section, including both the narrative block and any entries. Entry authorship applies only to the specific entry.

One example where confusion between these roles might arise for implementers is related to quality measurement use cases, which require clinical documentation to indicate who diagnosed a patient's condition and when a clinician made or re-confirmed the diagnosis. The provider who documents the diagnosis (data enterer or author) may not be the provider who makes the diagnosis (performer).

The Author Participation template (2.16.840.1.113883.10.20.22.4.119) is used to explicitly indicate an Author in a section or entry. The template provides conformance rules for representing the author and author.time elements associated with individual entries. The HL7

Basic Provenance project<sup>69</sup> is developing additional guidance sharing the Author in the new—  
Provenance - Author Participation template in Appendix C.

The C-CDA R2.1 specification requires the following:



1. **SHALL** contain exactly one [1..1] **templateId** (CONF:1098-32017) such that it

- a. **SHALL** contain exactly one [1..1]  
**@root="2.16.840.1.113883.10"20.22.4.119"** (CONF:1098-32018).

2. **SHALL** contain exactly one [1..1] **time** (CONF:1098-31471).

3. **SHALL** contain exactly one [1..1] **assignedAuthor** (CONF:1098-31472).

- a. This assignedAuthor **SHALL** contain at least one [1..\*] **id** (CONF:1098-31473).

Note: This id may be set equal to (a pointer to) an id on a participant elsewhere in the document (header or entries) or a new author participant can be described here. If the id is pointing to a participant already described elsewhere in the document, assignedAuthor/id is sufficient to identify this participant and none of the remaining details of assignedAuthor are required to be set. Application Software must be responsible for resolving the identifier back to its original object and then rendering the information in the correct place in the containing section's narrative text. This id must be a pointer to another author participant.

If the ID isn't referencing an author described elsewhere in the document, then the author components required in US Realm Header are required here as well (CONF:1098-32628).

- b. This assignedAuthor **SHOULD** contain zero or one [0..1] **code**, which **SHOULD** be selected from ValueSet **Healthcare Provider Taxonomy (HIPAA)** urn:oid:2.16.840.1.114222.4.11.1066 **DYNAMIC** (CONF:1098-31671). i. If the content is patient authored the code **SHOULD** be selected from Personal And Legal Relationship Role Type (2.16.840.1.113883.11.20.12.1) (CONF:1098-32315).

- c. This assignedAuthor **MAY** contain zero or one [0..1] **assignedPerson** (CONF:1098-31474). i. The assignedPerson, if present, **MAY** contain zero or more [0..\*] **name** (CONF:1098-31475).

- d. This assignedAuthor **MAY** contain zero or one [0..1] **representedOrganization** (CONF:1098-31476).

i. The representedOrganization, if present, **MAY** contain zero or more [0..\*] **id** (CONF:1098-31478).

ii. The representedOrganization, if present, **MAY** contain zero or more [0..\*] **name** (CONF:1098-31479).

iii. The representedOrganization, if present, **MAY** contain zero or more [0..\*] **telecom** (CONF:1098-31480).

<sup>69</sup> <https://confluence.hl7.org/display/SEC/Basic+Provenance+Implementation+Guide>

iv. The representedOrganization, if present, **MAY** contain zero or more [0..\*] **addr** (CONF:1098-31481).

Figure 6: Author Participation

Inclusion of an entry-level author is allowed in open entry templates in C-CDA R2.1 where use of entry-level authors has not explicitly been prohibited. Its use is required on only one entry template, the Handoff Communication Participants template (2.16.840.1.113883.10.20.22.4.141).<sup>70</sup>



C-CDA Content Creators **MAY** explicitly indicate the performer for observations and acts, not just the author who documents those activities. **[BP-038]**

### 3.2.2.1 Identifying Practitioners

The example below shows how to identify a practitioner playing the role of author, performer or other roles such as authenticator, legal authenticator. It shows how to represent the provider's NPI number and his or her Direct Address. It also shows how to represent a provider Organization's NPI number and Direct Address. It includes how to indicate the preferred telecom addresses for various forms of communication.

*Example 13: How to represent a provider and the provider's organization in the role of author.*

This representation pattern is applicable for other roles such as performer, authenticator, legal authenticator, etc. The example shows how to represent NPI information for the provider and for the provider organization. It also shows how to represent Direct address information and how to indicate the preferred telecom address to use.

```
<!-- an appropriate participation such as author/assignedAuthor -->
<author>
  <time value="20180801095245-0400"/>
  <assignedAuthor>
    <!-- This is a public id where the root is registered to indicate the National Provider ID
-->
    <id root="2.16.840.1.113883.4.6" extension="1417947383"
      assigningAuthorityName="National Provider ID"/>
    <!-- This is a public id where the root indicates this is a Provider Direct Address. -->
    <!-- root="1.3.6.1.4.1.41179.2.1" is the assigningAuthorityName for
      Direct Trust's Covered Entity addresses "DT.org CE" -->
    <id root="1.3.6.1.4.1.41179.2.1" extension="rvhs@rvhs.direct.md"
      assigningAuthorityName="DT.org CE (Covered Entity)"/>
    <addr>
      <streetAddressLine>823 Main Street</streetAddressLine>
      <city>River Valley</city>
      <state>RI</state>
      <postalCode>028321</postalCode>
      <country>US</country>
    </addr>
    <telecom use="WP" value="tel:+1-(401)539-4321"/>
    <!-- The provider's preferred Direct Address is the address identified with his practice.
See below.-->
    <telecom use="WP" value="mailto:rvhs@rvhs.direct.md"/>
    <assignedPerson>
      <name>
        <given>Terry</given>
        <given>A</given>
        <family>Manning</family>
        <delimiter>, </delimiter>
```

<sup>70</sup> HL7 C-CDA R2.1. Author Participation Template. Pages 930-931.

```

        <suffix>MD</suffix>
    </name>
</assignedPerson>
<representedOrganization>
    <id extension="334" root="1.3.6.1.4.1.22812.4.222.334"/>
    <!-- This is a public id where the root is registered to indicate the National Provider
ID -->
    <!-- Based on context, this is the NPI of the organization -->
    <id root="2.16.840.1.113883.4.6" extension="9999999999"
        assigningAuthorityName="National Provider ID"/>
    <!-- This is a public id where the root indicates this is a Provider Direct Address. --
>
    <!-- root="1.3.6.1.4.1.41179.2.1" is the assigningAuthorityName for
    Direct Trust's Covered Entity addresses "DT.org CE" -->
    <id root="1.3.6.1.4.1.41179.2.1" extension="rvhs@rvhs.direct.md"
assigningAuthorityName="DT.org CE (Covered Entity)"/>
    <name>River View Health Services</name>
    <telecom use="WP" value="tel:+1-(401)539-4321"/>
    <telecom use="WP" value="mailto:rvhs@rvhs.direct.md"/>
    <addr>
        <streetAddressLine>823 Main Street</streetAddressLine>
        <city>River Valley</city>
        <state>RI</state>
        <postalCode>028321</postalCode>
        <country>US</country>
    </addr>
</representedOrganization>
</assignedAuthor>
</author>
<!-- end of the appropriate role block -->

```

If a provider's NPI number is not known, it can be represented using a nullFlavor of UNK. However, is it important to note the id's populated with a nullFlavor cannot be used as a globally unique identifier.

*Example 14: Provider with an unknown NPI number.*

```

<assignedAuthor>
    <!-- This is a public id where the root is registered to indicate the National Provider ID
-->
    <!--Use nullFlavor UNK if the provider's NPI number is not known. -->
    <id root="2.16.840.1.113883.4.6" nullFlavor="UNK"
        assigningAuthorityName="National Provider ID"/>
    <!-- This is a public id where the root indicates this is a Provider Direct Address. -->
    <!-- root="1.3.6.1.4.1.41179.2.1" is the assigningAuthorityName for
    Direct Trust's Covered Entity addresses "DT.org CE" -->
    <id root="1.3.6.1.4.1.41179.2.1" extension="rvhs@rvhs.direct.md"
assigningAuthorityName="DT.org CE (Covered Entity)"/>
    <addr>
        <streetAddressLine>823 Main Street</streetAddressLine>
        <city>River Valley</city>
        <state>RI</state>
        <postalCode>028321</postalCode>
        <country>US</country>
    </addr>
    <telecom use="WP" value="tel:+1-(401)539-4321"/>
    <!-- The provider's preferred Direct Address is the address identified with his practice.
See below.-->
    <telecom use="WP" value="mailto:rvhs@rvhs.direct.md"/>
<assignedPerson>
    <name>
        <given>Terry</given>
        <given>A</given>
        <family>Manning</family>
        <delimiter>,</delimiter>
        <suffix>MD</suffix>
    </name>

```

```
</assignedPerson>  
...  
</assignedAuthor>
```

### 3.2.3 Custodian

Every CDA document has exactly one custodian. The custodian represents the organization who is in charge of maintaining the document. The custodian is the steward that is entrusted with the care of the document. The custodian participation satisfies the CDA definition of Stewardship.

### 3.2.4 Care Team Members

Recommendations for care team member representation in the header of documents are included below. This guidance aims to explain the options available for representation of care team members and clarify which care team members belong in the available header structures. Industry consensus has not been reached in this area. However, implementers can help reduce variability in the representation of care team members by adopting these recommendations.

This guide also includes representation of care team members in a care team section template with structured entries. The care team section documents care team members involved in support of care provision and coordination for the patient. Business rules are used to determine which care team members are involved in the encounter or services represented and documented in the header. Care team members established in the header should be included in the care team section template as well as any others who are relevant to the patient's care.

#### Reference: 5.2.3 Care Team

Because of the variability of how care team members are represented in the header, and because there is a lack of normative guidance on which header items must be rendered, it is recommended that receiving systems should render ALL the participants in the header, rather than only rendering participants of a particular type. The CDA R2.1 Stylesheet supports complete participant rendering.<sup>71</sup>

The term “care team member” encompasses any participant in the care of a patient. A patient's care team may include individuals providing support to the patient, such as family members or caregivers, as well as physician providers and non-physician providers, including nurses, social workers, behavioral health specialists, community-based providers, technicians, and assistants. In fact, a patient may have more than one care team. Different care teams exist for different purposes and at different times.

When exchanging information about a care team member, it is recommended to capture the name, identification number, and contact information, along with codes to indicate the type of

---

<sup>71</sup> HL7 CDA R2.1 Stylesheet. <https://hl7.org/permalink/?CDASheet>  
GitHub Project Folder.

provider and the role he or she plays on the patient’s care team. These details help to distinguish care team members from different care settings and helps clarify who is involved in the patient’s care and in what ways.

Within CDA, care team members are represented as participants in elements of the document header and may be associated with the patient (i.e. guardian), the clinical encounter, and/or service event(s) detailed in the document, and the document itself. Applicable header elements for documenting care team members from Chapter 1.1 of the C-CDA Implementation Guide are described in the following table.

Participant	Description
<b>documentationOf/ serviceEvent/ performer</b>	Care team member who performs the service event detailed in the document. Examples: PCP, surgeon, consulting physician
<b>encompassingEncounter/ responsibleParty</b>	Care team member who is responsible for the patient encounter described in the document. Examples: PCP, surgeon, consulting physician, home health nurse
<b>recordTarget</b>	The patient, his or herself, is considered a member of the Care team.
<b>author</b>	Care team member who documents events included in the documentation of the encounter or documentation of the provision of care over time. Example: PCP, surgeon, consulting physician, home health nurse
<b>custodian</b>	The steward of the document is likely an organization with a role on the patient’s care team, although not necessarily. Example: PCP practice, Hospital, home health agency, HIE
<b>legalAuthenticator</b>	Care team member who authenticates content contained in the document and accepts legal responsibility. Examples: PCP, consulting physician, attending physician
<b>authenticator</b>	Care team member who authenticates content contained in the document. Examples: PCP, consulting physician, attending physician
<b>informationRecipient</b>	Care team member who the document is intended for. Examples: PCP, caregiver, consulting physician
<b>participant</b>	Other supporting care team members associated with the patient. Examples: Caregiver, family member, emergency contact

Table 12: Header Elements for Care Team Members

In the header of an Encounter Summary, a care team member may be documented as fulfilling more than one responsibility. For example, a consulting physician who sees a patient in a clinical encounter may be:




1. the author of the Consultation Note,
2. the responsible party for the Encounter (rendering physician), or
3. the authenticator (physician attesting to the human readable content in the document).

The physician also may be the person who legally authenticates the information contained in the document. In this example, the consulting physician is participating as the

encompassingEncounter/responsibleParty, the author, the authenticator and the legalAuthenticator.

In the header of a Patient Summary, it is most common to see care team members identified in the documentationOf/serviceEvent as performers who were involved in the provision of care for the patient during the range of time covered by the summary. Again, depending on the use case behind how the Patient Summary is generated, care team members also may be documented in other roles such as the author, the authenticator and the legalAuthenticator.

Semantically, the actRelationships hold the key data elements for documenting Care Team members in the header. These are the data elements that tell who was responsible for the patient encounter and who was responsible for performing care services.

	For Encounter Summary documents, C-CDA Content Creators SHALL document the provider who is responsible for the encounter in the componentOf/encompassingEncounter/responsibleParty. <b>[BP-039]</b>
	For Patient Summary documents, C-CDA Content Creators SHALL document providers who played the role of Primary Care Provider for the patient during the range of time covered in the summary using the documentationOf/serviceEvent/performer. <b>[BP-040]</b>
	C-CDA Content Creators SHALL populate the functionCode element with the provider's or person's role on the patient's care team. Coded concepts for the functionCode SHALL be selected from the Care Team Member Function value set (2.16.840.1.113762.1.4.1099.30). <b>[BP-041]</b>

**Reference:** 5.2.3 Care Team

### 3.2.5 sdct:signatureText in Authenticator and legalAuthenticator



Sharing clinical documents with payers is an emerging use case for C-CDA. To meet the needs of this use case, document authentication and signing of C-CDA documents needs to be addressed.

The HL7 CDA R2 Attachment IG: Exchange of C-CDA Based Documents, R1 – US Realm explains, “The legalAuthenticator is recorded in ClinicalDocument.legalAuthenticator, and represents a participant who has legally authenticated the document. Authenticators are recorded in ClinicalDocument.authenticator, and each authenticator represents a participant who has attested to the accuracy of the document, but who does not have privileges to legally authenticate the document. An example would be a resident physician who sees a patient and dictates a note, then later signs it.”<sup>72</sup>



It further includes these conformance requirements<sup>73</sup>:

<sup>72</sup> The HL7 CDA R2 Attachment IG: Exchange of C-CDA Based Documents, R1 – US Realm, page 46.

<sup>73</sup> The HL7 CDA R2 Attachment IG: Exchange of C-CDA Based Documents, R1 – US Realm, page 46.

	<p>All documents SHALL have a <i>legalAuthenticator</i>. In the case of generated summary documents, institutions may meet the requirement for a Legal Authenticator by extending the practice of maintaining a “Signature on File”. The person/entity indicated is responsible for the contents of the note where it is understood that this Legal Authenticator is not an author of the document. Policy for determining who is responsible for legal authentication of the summary document rests with the originating organization. [AIGEX-HD4]</p>
	<p>All documents that contain <i>sdhc:signatureText</i>, SHALL conform to the HL7 Digital Signatures and Delegation of Rights Implementation Guide R1. [AIGEX-HD7]</p>

The HL7 Digital Signatures and Delegation of Rights Implementation Guide R1 defines the standards for digitally signing C-CDA documents.<sup>74</sup>


	<p>C-CDA Content Creators MAY include the <i>sdhc:signatureText</i> extension for Authenticators and LegalAuthenticators. [BP-042]</p>
	<p>C-CDA Content Consumers MAY render certificate information associated with digital signed C-CDA Documents when rendering the document. [BP-043]</p>

### 3.2.6 Context of Care


As focus has shifted from using C-CDA to exchange Patient Summary documents to using C-CDA to exchange Encounter Summaries, new guidance is needed to clarify expectations for populating the *actRelationships* present in the header. In a Patient Summary, the *documentationOf/serviceEvent* holds the key information about the range of time covered by the document and the key providers involved in the provision of the summarized care.

In an Encounter Summary, the header needs to capture the context of care for a particular encounter.

#### 3.2.6.1 Encompassing Encounter

	<p>In an Encounter Summary, C-CDA Content Creators SHALL populate the <i>encompassingEncounter/effectiveTime</i> and the <i>encompassingEncounter/location/healthCareFacility/serviceProviderOrganization</i> and the <i>encompassingEncounter/responsibleParty/assignedEntity</i>. [CONF-044]</p>
---	--

#### 3.2.6.2 Service Events

	<p>In an Encounter Summary, C-CDA Content Creators MAY populate the <i>documentationOf/serviceEvent</i>, including the <i>serviceEvent/effectiveTime</i>, <i>serviceEvent/code</i>, and <i>serviceEvent/performer(s)</i>. [BP-045]</p>
---	--

<sup>74</sup> HL7 Digital Signatures and Delegation of Rights Implementation Guide R1, [http://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=375](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=375)





In a Patient Summary, C-CDA Content Creators SHALL populate the documentationOf/serviceEvent based on conformance requirements of the C-CDA R2.1 specification for CCD documents. **[CONF-046]**

### 3.2.6.3 Orders Fulfilled

If an Encounter occurred as a result of a previously placed order (e.g., a visit to perform an MRI), the id of that order should be provided as context for the Encounter.



In an Encounter Summary, C-CDA Content Creators SHOULD populate the infulfillmentOf/order and the infulfillmentOf/order/id element where the order/id references the id of a previously placed order. **[BP-047]**



The Order Fulfilled area of the header MAY carry information about fulfilled orders, rereferrals or other requests that have been fulfilled. **[BP-048]**

### 3.2.7 Related Parent Document

The ParentDocument represents the source of a document revision, addendum, or transformation.<sup>75</sup> The relatedDocument/parentDocument/id element is a mechanism used to link a revised, addendum, or transformed document to its original source document. There are many situations where a document may be updated. For example, a pending lab result or a missing note may trigger an update. The base CDA standard provides this mechanism to replace or append a previously sent document through the parentDocument relationship.

C-CDA Content Creators cannot know with certainty what documents a Content Consumer has previously stored. Therefore, it always is preferable for Content Creators to send a complete document that replaces a prior document rather than sending an addendum to a prior document. Indicate the parent document is being replaced by using a replace relationship (typeCode="RPLC").<sup>76</sup>



C-CDA Content Creators SHOULD populate the ClinicalDocument/relatedDocument using @typeCode="RPLC" when a document replaces a prior document. **[BP-049]**

*Example 15: Replacement Discharge Summary Document with Hospital Course Added*

```
<ClinicalDocument> <realmCode code="US">
  <typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
  <templateId root="2.16.840.1.113883.10.20.22.1.1" extension="2015-08-01">
  <templateId root="2.16.840.1.113883.10.20.22.1.8" extension="2015-08-01">
  <id root="2.16.840.1.113883.19.5.99999.1" extension="20160414145050">
  <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" code="18842-5"
    displayName="Discharge Summary" />
  <title>Health Summary</title>
  <effectiveTime value="20160414145050-0500">
```

<sup>75</sup> HL7 CDA R2. 4.2.3.1 ParentDocument

<sup>76</sup> <https://www.commonwellalliance.org/wp-content/uploads/2019/01/Improve-Joint-Documents-Whitepaper.pdf>  
Section 5.1.3 Document Versioning, P26

```

<confidentialityCode codeSystem="2.16.840.1.113883.5.25" code="N">
<languageCode code="en-US">
<setId extension="20160414014447" root="2.16.840.1.113883.19.5.99999.19" I>
<versionNumber value="2">
<relatedDocument typeCode="RPLC">
  <parentDocument> <id root="2.16.840.1.113883.19.5.99999.1" extension="20160414014447">
    <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" code="18842-5"
      displayName="Discharge Summary" I>
    <setId extension="20160414014447" root="2.16.840.1.113883.19.5.99999.19">
    <versionNumber value="1"> </parentDocument>
  </relatedDocument>
  ...
<section>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.5"/>
  <code code="8648-8" displayName="HOSPITAL COURSE" codeSystem="2.16.840.1.113883.6.1"
    codeSystemName="LOINC"/>
  <title>Hospital Course</title>
  <text>The patient was admitted
  ...
</text>

```

**Reference:** 2.6.1 Content Creator Responsibilities

### 3.2.8 C-CDA R2.1 Document Templates

While all C-CDA documents share a common US Realm Header template, the C-CDA R2.1 implementation guide defines distinct types of document templates for exchanging different types of clinical notes.

Document-level templates describe the purpose and rules for constructing a conforming CDA document. Document templates include constraints on the CDA header and indicate contained section-level templates.

Each document-level template contains the following information:

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

Templates for structured documents (those that include a structuredBody) also define required and optional section-level templates.

All section-level templates include human readable narrative that conveys the information in that section. CDA calls this the Narrative Block. Each section-level template also includes:

- Scope and intended use within a document.
- Description and explanatory narrative.
- Template metadata (*e.g.*, templateId).

The section may also define required and optional entry-level templates. Entry-level templates are structures for representing the information in the Narrative Block using machine representations that facilitates computerized information processing.

The table below describes the various document types defined by C-CDA R2.1 for use in representing clinical notes as structured documents that facilitate digital information exchange.

Document-Level Templates for Representing Clinical Notes as Structured Documents <sup>77</sup>	Description
<b>Care Plan</b>	<p>A Care Plan (including Home Health Plan of Care (HHPoC)) is a consensus-driven dynamic plan that represents a patient's and Care Team Members' prioritized concerns, goals, and planned interventions.</p> <p>The CDA Care Plan represents an instance of this dynamic Care Plan at a point in time. The CDA document itself is NOT dynamic.</p>
<b>Consultation Note</b>	The Consultation Note is generated by a request from a clinician for an opinion or advice from another clinician.
<b>Continuity of Care Document (CCD)</b>	The Continuity of Care Document (CCD) represents a core data set of the most relevant administrative, demographic, and clinical information facts about a patient's healthcare, covering one or more healthcare encounters. It provides a means for one healthcare practitioner, system, or setting to aggregate all of the pertinent data about a patient and forward it to another to support the continuity of care.
<b>Diagnostic Imaging Report</b>	A Diagnostic Imaging Report (DIR) is a document that contains a consulting specialist's interpretation of image data. It conveys the interpretation to the referring (ordering) physician and becomes part of the patient's medical record. It is for use in Radiology, Endoscopy, Cardiology, and other imaging specialties.
<b>Discharge Summary</b>	The Discharge Summary is a document which synthesizes a patient's admission to a hospital, LTPAC provider, or other setting. It provides information for the continuation of care following discharge.
<b>History and Physical</b>	A History and Physical (H&P) Note is a medical report that documents the current and past conditions of the patient. It contains essential information that helps determine an individual's health status.
<b>Operative Note</b>	The Operative Note is a frequently used type of procedure note with specific requirements set forth by regulatory agencies. The Operative Note is created immediately following a surgical or other high-risk procedure. It records the pre- and post-surgical diagnosis, pertinent events of the procedure, as well as the condition of the patient following the procedure.
<b>Progress Note</b>	This template represents a patient's clinical status during a hospitalization, outpatient visit, treatment with a LTPAC provider, or other healthcare encounter.

<sup>77</sup>C-CDA R2.1 Volume 2. Document-Level Templates.

Document-Level Templates for Representing Clinical Notes as Structured Documents <sup>77</sup>	Description
<b>Procedure Note</b>	This template encompasses many types of non-operative procedures including interventional cardiology, gastrointestinal endoscopy, osteopathic manipulation, and many other specialty fields. Procedure Notes are differentiated from Operative Notes because they do not involve incision or excision as the primary act.
<b>Referral Note</b>	A Referral Note communicates pertinent information from a provider who is requesting services of another provider of clinical or non-clinical services.
<b>Transfer Summary</b>	The Transfer Summary standardizes critical information for exchange of information between providers of care when a patient moves between health care settings.

Table 13: C-CDA R2.1 Document-Level Templates for Representing Clinical Notes as Structured Documents

**Reference:** Chapter 4 Section Level Guidance and Chapter 5 Representation of Discrete Data


The table below describes the document template defined by C-CDA R2.1 for use in representing clinical notes as an unstructured document that facilitates digital information exchange.

Document Templates for Unstructured Clinical Notes	Description
<b>Unstructured Document</b>	An Unstructured Document (UD) document type can (1) include unstructured content, such as a graphic, directly in a text element with a mediaType attribute, or (2) reference a single document file, such as a word-processing document using a text/reference element.

Table 14: Document Templates of Unstructured Clinical Notes

The C-CDA R2.1 Unstructured Document template defines a C-CDA document with a structured header and a non-XML body. This template is used to convey information as an embedded object or referenced file. It may be appropriate for use cases where the exchange of clinical information does not require structured representation of the content. Simply having the structured header information may be beneficial for information exchange.

When the content to be exchanged does not have structured document templates defined in C-CDA, such as for Laboratory Report Narrative or Pathology Report Narrative, the Unstructured Document template can be used to represent the clinical note information.

 C-CDA Content Creators MAY support the Unstructured Document template for representing clinical note types when the type of clinical note to be exchanged does not have an appropriate structured document template or when it is not possible for

the C-CDA Content Creator to represent the clinical note information using a structured document template. **[BP-050]**

### 3.2.9 Further Constraints on C-CDA Documents

#### 3.2.9.1 Payer-focused Constraints on C-CDA Documents

Other stakeholders in the C-CDA Community have further constrained the document templates established by C-CDA in order to address specific use cases for information exchange. For example, the Payer Community further constrains many of the C-CDA document templates to reduce optionality and clarify required information needed for their use cases. Implementers interested in sharing clinical information with payers via C-CDA documents should consult the following specifications to determine where additional requirements exist.

The table below provides a list of document templates that include additional content requirements when C-CDA Documents are used to exchange clinical information with Payers.<sup>78</sup> This list does not include every IG that further constrains C-CDA templates. The HL7 product page for C-CDA contains a list of IGs that are registered as further constraints on C-CDA. Although the HL7 CDA Release 2 Implementation Guide: Additional CDA R2 Templates – Clinical Documents for Payers Set 1, Release 1 – US Realm conforms to C-CDA R2, the material provides best practice guidance when exchanging clinical information with Payers.

Encounter Summary Documents	Description
<b>Enhanced Discharge Document (CDP1)</b> 2.16.840.1.113883.10.20.35.1.2	A comprehensive record of the patient’s hospitalization may include a combination of the Enhanced Discharge Document, Enhanced Operative Notes Document(s), Enhanced Procedure Document(s), and Interval Documents. Document (CDP1) template conforms to the C-CDA R2 Discharge Summary (V2) template but replaces many of the optional MAY section conformance statements with SHALL.  Any section for which data is not available (not collected, not relevant, not supported by the EHR technology, etc.) SHALL have the appropriate nullFlavor.
<b>Enhanced Encounter Document (CDP1)</b> 2.16.840.1.113883.10.20.35.1.1	An Enhanced Encounter Document includes all sections relevant to a single Office, Consult, or Home Health visit, except for details concerning procedures, operations or imaging performed during the encounter, which are included in different document types. Enhanced encounters may involve face-to-face time with the patient or may fall under the auspices of tele-medicine visits.  Enhanced Encounter Document requires support by the EHR for a broader range of templates related to a patient visit for the administrative or clinical exchange with a third party. The Consult Note, History and Physical and/or Progress Note defined in the C-CDA R2 should be used when a summary record is appropriate or when it is specifically requested.

<sup>78</sup> HL7 CDA Release 2 Implementation Guide: Additional CDA R2 Templates – Clinical Documents for Payers Set 1, Release 1 – US Realm

Encounter Summary Documents	Description
<b>Enhanced Operative Note Document (CDP1)</b> 2.16.840.1.113883.10.20.35.1.3	The Enhanced Operative Note Document is created immediately following a surgical or other high-risk procedure. It records the pre- and post-surgical diagnosis, pertinent events of the procedure, as well as the condition of the patient following the procedure. The report should be sufficiently detailed to support the diagnoses, justify the treatment, document the course of the procedure, and provide for continuity of care.
<b>Enhanced Procedure Note Document (CDP1)</b> 2.16.840.1.113883.10.20.35.1.4	The Enhanced Procedure Document is created immediately following a non-operative procedure. It records the indications for the procedure and, when applicable, post-procedure diagnosis, pertinent events of the procedure, and the patient’s tolerance for the procedure. It should be detailed enough to justify the procedure, describe the course of the procedure, and provide continuity of care.
Patient Summary Documents	
<b>Interval Document (CDP1)</b> 2.16.840.1.113883.10.20.35.1.5	<p>The Interval Document is generated by a provider at the end of a fixed period of time (shift, day, etc.) either:</p> <ol style="list-style-type: none"> <li>1) within the context of a single encounter with a patient (e.g. Hospitalization) or</li> <li>2) spanning multiple encounters (e.g. a home health skilled service that is provided over several visits).</li> </ol> <p>The serviceEvent time shall specify the start (effectiveTime/low element) and end (effectiveTime/high element) of the period covered by the Interval Document. If the Interval Document is used to describe activity within an encompassingEncounter, then the start and end date/time shall be contained within the date/time range of the encompassingEncounter unless the encompassingEncounter is not completed; in which case, the start time for the Interval shall be equal to or greater than the start of the encounter. If the Interval Document spans multiple encounters (e.g. for specific home health services), then there shall be no encompassingEncounter and the contributing encounter(s) shall be listed in the Encounters Section. The effectiveTime for all encounters should be within the low/high time for the Interval Document.</p>

Table 15: Payer additional content requirements

The documents types defined by Payors mirror several of the document types defined in Consolidated CDA. The document types defined by Payors further constrain the base C-CDA document, in some cases tightening existing constraints or in other places adding additional constraints.

### 3.2.9.2 Nutrition-focused Constraints on C-CDA Documents

The table below identifies a supplemental document template defined to further constrain the C-CDA Care Plan document template when exchanging nutrition care plan information.<sup>79</sup>


<sup>79</sup> HL7 CDA® R2 Implementation Guide: C-CDA R2.1 Supplemental Templates for Nutrition, Release 1 - US Realm

Care Plan Summary Documents	Description
<b>Care Plan (Nutrition)</b> 2.16.840.1.113883.10.20.22.1.16:2017-12-01	This template is for supplemental use in a C-CDA Care Plan document.  The Care Plan (Nutrition) standardizes documentation of information gathered and developed through the process of the Nutrition Care Process (NCP). The four steps in the NCP align with sections in a Care Plan (Nutrition) document. This template further constrains the C-CDA R2.1 Care Plan document-level template.

Table 16: Care Plan (Nutrition)

### 3.3 Section Structure by Document Type

The following tables describe the required and optional section templates for each document type defined in C-CDA.<sup>80</sup> They include sections that support best practices for representing emerging data for exchange such as Patient Goals and Health Concerns.

 Transition of Care C-CDA Documents SHALL include a Health Concerns section and a Goals Section. **[CONF-051]**

#### 3.3.1 Care Plan: Document Template

A Care Plan (including Home Health Plan of Care (HHPoC)) is a consensus-driven dynamic plan that represents a patient’s and Care Team Members’ prioritized concerns, goals, and planned interventions. It serves as a blueprint shared by all Care Team Members (including the patient, their caregivers and providers), to guide the patient’s care. A Care Plan integrates multiple interventions proposed by multiple providers and disciplines for multiple conditions.

A Care Plan represents one or more Plan(s) of Care and serves to reconcile and resolve conflicts between the various Plans of Care developed for a specific patient by different providers. While both a plan of care and a care plan include the patient’s life goals and require Care Team Members (including patients) to prioritize goals and interventions, the reconciliation process becomes more complex as the number of plans of care increases. The Care Plan also serves to enable longitudinal coordination of care.

The CDA Care Plan represents an instance of this dynamic Care Plan at a point in time. The CDA document itself is NOT dynamic.

This document template enables Care Plan information to be shared in a way that includes:

- The ability to identify patient and provider priorities with each act.
- A header participant to indicate occurrences of Care Plan review.

<sup>80</sup> C-CDA R2.1 Document-Level Templates. Volume 2. Pages 34-40.

A Care Plan document can include entry references from the information in these sections to the information (entries) in other sections. Volume 1 of the C-CDA R2.1 implementation guide includes of a Care Plan Relationship diagram and a story board to explain its use.

### 3.3.1.1 Structured Sections

The table below describes the required and optional sections in a Care Plan document template: Care Plan (V2) [ClinicalDocument: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.1.15:2015-08-01 (open)]

Document Type	Required Sections	Optional Sections
<b>Care Plan</b>	Health Concerns Section (V2) Goals Section	Interventions Section (V3) Health Status Evaluations and Outcomes Section
<b>Sample</b>	CarePlan.xml Sample	Included with this Companion Guide

Table 17: Care Plan: Document Template.

### 3.3.2 Consultation Note: Document Template

The Consultation Note is generated by a request from a clinician for an opinion or advice from another clinician. Consultations may involve face-to-face time with the patient or may fall under the auspices of telemedicine visits. Consultations may occur while the patient is inpatient or ambulatory. The Consultation Note should also be used to summarize an Emergency Room or Urgent Care encounter. A Consultation Note includes the reason for the referral, history of present illness, physical examination, and decision-making components (Assessment and Plan).

#### 3.3.2.1 Structured Sections

The table below describes the required and optional sections in a Consultation Note document template: Consultation Note (V3)[ClinicalDocument: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.1.4:2015-08-01 (open)]

Document Type	Required Sections	Optional Sections
<b>Consultation Note</b>	History of Present Illness Section Allergies and Intolerances Section (entries required) (V3) Problem Section (entries required) (V3)	Assessment Section Assessment and Plan Section (V2) Plan of Treatment Section (V2) Reason for Visit Section Physical Exam Section (V3) Chief Complaint Section Chief Complaint and Reason for Visit Section Family History Section (V3) General Status Section Past Medical History (V3)



Document Type	Required Sections	Optional Sections
		Immunizations Section (entries optional) (V3) Medications Section (entries required) (V2) Procedures Section (entries optional) (V2) Results Section (entries required) (V3) Social History Section (V3) Vital Signs Section (entries required) (V3) Functional Status Section (V2) Review of Systems Section Medical Equipment Section

Table 18: Consultation Note: Document Template.

### 3.3.3 Continuity of Care Document (CCD): Document Template

The Continuity of Care Document (CCD) was originally based on the Continuity of Care Document (CCD) Release 1.1 which itself was derived from HITSP C32 and CCD Release 1.0. The Continuity of Care Document (CCD) represents a core data set of the most relevant administrative, demographic, and clinical information facts about a patient's healthcare, covering one or more healthcare encounters. It provides a means for one healthcare practitioner, system, or setting to aggregate all of the pertinent data about a patient and forward it to another to support the continuity of care. The primary use case for the CCD is to provide a snapshot in time containing the germane clinical, demographic, and administrative data for a specific patient. The key characteristic of a CCD is that the ServiceEvent is constrained to "PCPR" "care provision." This means that the contents of the document reflect the care that was actually provided within the time range indicated in serviceEvent.effectiveTime range. It reports on care that has already been provided. The CCD provides a historical tally of the care over a range of time and is not a record of new services delivered. More specific use cases, such as a Discharge Summary, Transfer Summary, Referral Note, Consultation Note, or Progress Note, are available as alternative documents in this guide.

#### 3.3.3.1 Structured Sections

The table below describes the required and optional sections in a Continuity of Care Document document template: Continuity of Care Document (CCD) (V3) [ClinicalDocument: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.1.2:2015-08-01 (open)]

Document Type	Required Sections	Optional Sections
<b>Continuity of Care Document (CCD)</b>	Allergies and Intolerances Section (entries required) (V3) Medications Section (entries required) (V2) Problem Section (entries required) (V3) Results Section (entries required) (V3) Social History Section (V3) Vital Signs Section (entries required) (V3)	Procedures Section (entries required) (V2) Encounters Section (entries optional) (V3) Family History Section (V3) Functional Status Section (V2) Immunizations Section (entries required) (V3) Medical Equipment Section (V2) Payers Section (V3) Plan of Treatment Section (V2) Mental Status Section (V2)

Document Type	Required Sections	Optional Sections
		Nutrition Section Advance Directives Section (entries optional) (V3) Goals Section Health Concerns Section (V2)
<b>Example</b>	CCD-Sample.xml Sample	Included with this Companion Guide

Table 19: Continuity of Care Document: Document Template.

### 3.3.4 Diagnostic Imaging Report: Document Template

A Diagnostic Imaging Report (DIR) is a document that contains a consulting specialist’s interpretation of image data. It conveys the interpretation to the referring (ordering) physician and becomes part of the patient’s medical record. It is for use in Radiology, Endoscopy, Cardiology, and other imaging specialties.

#### 3.3.4.1 Structured Sections

The table below describes the required and optional sections in a Diagnostic Imaging Report document template: Diagnostic Imaging Report (V3)[ClinicalDocument: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.1.5:2015-08-01 (open)]

Document Type	Required Sections	Optional Sections
<b>Diagnostic Imaging Report</b>	Finding Sections (DIR)	DICOM Object Catalog Section – DCM 121181

Table 20: Diagnostic Imaging Report: Document Template.

### 3.3.5 Discharge Summary: Document Template

The Discharge Summary is a document which synthesizes a patient's admission to a hospital, LTPAC provider, or other setting. It provides information for the continuation of care following discharge. The Joint Commission<sup>81</sup> requires the following information to be included in the Discharge Summary:

- Reason for hospitalization (the admission)
- Procedures performed, as applicable
- Care, treatment, and services provided
- Patient’s condition and disposition at discharge
- Information provided to the patient and family
- Provisions for follow-up care

The best practice for a Discharge Summary is to include the discharge disposition in the display of the header.

<sup>81</sup> For more information on The Joint Commission, visit <http://www.jointcommission.org/>

### 3.3.5.1 Structured Sections

The table below describes the required and optional sections in a Discharge Summary document template: Discharge Summary (V3)[ClinicalDocument: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.1.8:2015-08-01 (open)]

Document Type	Required Sections	Optional Sections
<b>Discharge Summary</b>	Allergies and Intolerances Section (entries optional) (V3) Hospital Course Section Discharge Diagnosis Section (V3) Plan of Treatment Section (V2)	Discharge Medications Section (entries optional) (V3) Chief Complaint Section Chief Complaint and Reason for Visit Section Nutrition Section Family History Section (V3) Functional Status Section (V2) Past Medical History (V3) History of Present Illness Section Admission Diagnosis Section (V3) Admission Medications Section (entries optional) (V3) Hospital Consultations Section Hospital Discharge Instructions Section Hospital Discharge Studies Summary Section Immunizations Section (entries optional) (V3) Procedures Section (entries optional) (V2) Reason for Visit Section Review of Systems Section Social History Section (V3) Vital Signs Section (entries optional) (V3) Discharge Medications Section (entries required) (V3) Goals Section Health Concerns Section (V2)
<b>Example</b>	DischargeSummary.xml Sample	Included with this Companion Guide

Table 21: Discharge Summary: Document Template.

### 3.3.6 History and Physical: Document Template

A History and Physical (H&P) Note is a medical report that documents the current and past conditions of the patient. It contains essential information that helps determine an individual's health status. The first portion of the report is a current collection of organized information unique to an individual. This is typically supplied by the patient or the caregiver, concerning the current medical problem or the reason for the patient encounter. This information is followed by a description of any past or ongoing medical issues, including current medications and allergies. Information is also obtained about the patient's lifestyle, habits, and diseases among family members. The next portion of the report contains information obtained by physically examining the patient and gathering diagnostic information in the form of laboratory tests, imaging, or other diagnostic procedures. The report ends with the clinician's assessment of the patient's situation and the intended plan to address those issues. A History and Physical

Examination is required upon hospital admission as well as before operative procedures. An initial evaluation in an ambulatory setting is often documented in the form of an H&P Note.

**3.3.6.1 Structured Sections**

The table below describes the required and optional sections in a History and Physical document template: History and Physical (V3)[ClinicalDocument: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.1.3:2015-08-01 (open)]

Document Type	Required Sections	Optional Sections
<b>History and Physical</b>	Allergies and Intolerances Section (entries optional) (V3) Family History Section (V3) General Status Section Past Medical History (V3) Medications Section (entries optional) (V2) Physical Exam Section (V3) Results Section (entries optional) (V3) Review of Systems Section Social History Section (V3) Vital Signs Section (entries optional) (V3)	Assessment Section Plan of Treatment Section (V2) Assessment and Plan Section (V2) Chief Complaint Section Chief Complaint and Reason for Visit Section History of Present Illness Section Immunizations Section (entries optional) (V3) Instructions Section (V2) Problem Section (entries optional) (V3) Procedures Section (entries optional) (V2) Reason for Visit Section

Table 22: History and Physical: Document Template.

**3.3.7 Operative Note: Document Template**

The Operative Note is a frequently used type of procedure note with specific requirements set forth by regulatory agencies. The Operative Note is created immediately following a surgical or other high-risk procedure. It records the pre- and post-surgical diagnosis, pertinent events of the procedure, as well as the condition of the patient following the procedure. The report should be sufficiently detailed to support the diagnoses, justify the treatment, document the course of the procedure, and provide continuity of care.

**3.3.7.1 Structured Sections**

The table below describes the required and optional sections in an Operative Note document template: Operative Note (V3)[ClinicalDocument: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.1.7:2015-08-01 (open)]

Document Type	Required Sections	Optional Sections
<b>Operative Note</b>	Anesthesia Section (V2) Complications Section (V3) Preoperative Diagnosis Section (V3) Procedure Estimated Blood Loss Section Procedure Findings Section (V3) Procedure Specimens Taken Section Procedure Description Section Postoperative Diagnosis Section	Procedure Implants Section Operative Note Fluids Section Operative Note Surgical Procedure Section Plan of Treatment Section (V2) Planned Procedure Section (V2) Procedure Disposition Section Procedure Indications Section (V2) Surgical Drains Section

Table 23: Operative Note: Document Template.

### 3.3.8 Procedure Note: Document Template

A Procedure Note encompasses many types of non-operative procedures including interventional cardiology, gastrointestinal endoscopy, osteopathic manipulation, and many other specialty fields. Procedure Notes are differentiated from Operative Notes because they do not involve incision or excision as the primary act. The Procedure Note is created immediately following a non-operative procedure. It records the indications for the procedure and, when applicable, post-procedure diagnosis, pertinent events of the procedure, and the patient’s tolerance for the procedure. It should be detailed enough to justify the procedure, describe the course of the procedure, and provide continuity of care.

#### 3.3.8.1 Structured Sections

The table below describes the required and optional sections in a Procedure Note document template: Procedure Note (V3)[ClinicalDocument: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.1.6:2015-08-01 (open)]

Document Type	Required Sections	Optional Sections
<b>Procedure Note</b>	Complications Section (V3) Procedure Description Section Procedure Indications Section (V2) Postprocedure Diagnosis Section (V3)	Assessment Section Assessment and Plan Section (V2) Plan of Treatment Section (V2) Allergies and Intolerances Section (entries optional) (V3) Anesthesia Section (V2) Chief Complaint Section Chief Complaint and Reason for Visit Section Family History Section (V3) Past Medical History (V3) History of Present Illness Section Medical (General) History Section Medications Section (entries optional) (V2) Medications Administered Section (V2) Physical Exam Section (V3)

Document Type	Required Sections	Optional Sections
		Planned Procedure Section (V2) Procedure Disposition Section Procedure Estimated Blood Loss Section Procedure Findings Section (V3) Procedure Implants Section Procedure Specimens Taken Section Procedures Section (entries optional) (V2) Reason for Visit Section Review of Systems Section Social History Section (V3)

Table 24: Procedure Note: Document Template.

### 3.3.9 Progress Note: Document Template

The Progress Note represents a patient’s clinical status during a hospitalization, outpatient visit, treatment with a LTPAC provider, or other healthcare encounter. Taber’s medical dictionary defines a Progress Note as “An ongoing record of a patient’s illness and treatment. Physicians, nurses, consultants, and therapists record their notes concerning the progress or lack of progress made by the patient between the time of the previous note and the most recent note.”<sup>82</sup> Mosby’s medical dictionary defines a Progress Note as “Notes made by a nurse, physician, social worker, physical therapist, and other health care professionals that describe the patient’s condition and the treatment given or planned.”<sup>83</sup> A Progress Note is not a re-evaluation note. A Progress Note is not intended to be a Progress Report for Medicare. Medicare B Section 1833(e) defines the requirements of a Medicare Progress Report.

#### 3.3.9.1 Structured Sections

The table below describes the required and optional sections in a Progress Note document template: Progress Note (V3)[ClinicalDocument: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.1.9:2015-08-01 (open)]

Document Type	Required Sections	Optional Sections
Progress Note		Assessment Section Plan of Treatment Section (V2) Assessment and Plan Section (V2) Allergies and Intolerances Section (entries optional) (V3) Chief Complaint Section Interventions Section (V3) Instructions Section (V2) Medications Section (entries optional) (V2)

<sup>82</sup> <https://www.tabers.com/tabersonline/>

<sup>83</sup> Mosby’s Medical Dictionary. 9th ed. St. Louis, MO: Mosby Elsevier, 2013. Print.

Document Type	Required Sections	Optional Sections
		Objective Section Physical Exam Section (V3) Problem Section (entries optional) (V3) Results Section (entries optional) (V3) Review of Systems Section Subjective Section Vital Signs Section (entries optional) (V3) Nutrition Section
<b>Example</b>	ProgressNote.xml Sample	Included with this Companion Guide

Table 25: Progress Note: Document Template.

### 3.3.10 Referral Note: Document Template

A Referral Note communicates pertinent information from a provider who is requesting services of another provider of clinical or non-clinical services which includes the reason for the referral and additional information that would augment decision making and care delivery.

Examples of referral situations include when a patient is:

- Referred from a family physician to a cardiologist for cardiac evaluation.
- Sent by a cardiologist to an emergency department for angina.
- Referred by a nurse practitioner to an audiologist for hearing screening.
- Referred by a hospitalist to social services.

#### 3.3.10.1 Structured Sections

The table below describes the required and optional sections in a Referral Note document template: Referral Note (V2)[ClinicalDocument: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.1.14:2015-08-01 (open)]

Document Type	Required Sections	Optional Sections
<b>Referral Note</b>	Problem Section (entries required) (V3) Allergies and Intolerances Section (entries required) (V3) Medications Section (entries required) (V2) Reason for Referral Section (V2)	Plan of Treatment Section (V2) History of Present Illness Section Family History Section (V3) Immunizations Section (entries required) (V3) Procedures Section (entries optional) (V2) Results Section (entries required) (V3) Review of Systems Section Social History Section (V3) Vital Signs Section (entries required) (V3) Functional Status Section (V2) Physical Exam Section (V3) Nutrition Section Mental Status Section (V2) Medical Equipment Section (V2) Assessment Section

Document Type	Required Sections	Optional Sections
		Assessment and Plan Section (V2) Past Medical History (V3) General Status Section Advance Directives Section Health Concerns Section (V2) Goals Section
<b>Example</b>	ReferralNote.xml Sample	Included with this Companion Guide

Table 26: Referral Note: Document Template.

### 3.3.11 Transfer Summary: Document Template

The Transfer Summary template describes constraints on the Clinical Document Architecture (CDA) header and body elements for a Transfer Summary. The Transfer Summary standardizes critical information for exchange of information between providers of care when a patient moves between health care settings. Standardization of information used in this form will promote interoperability; create information suitable for reuse in quality measurement, public health, research, and for reimbursement.

#### 3.3.11.1 Structured Sections

The table below describes the required and optional sections in a Transfer Summary document template Transfer Summary (V2)[ClinicalDocument: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.1.13:2015-08-01 (open)]

Document Type	Required Sections	Optional Sections
<b>Transfer Summary</b>	Allergies and Intolerances Section (entries required) (V3) Medications Section (entries required) (V2) Problem Section (entries required) (V3) Results Section (entries required) (V3) Vital Signs Section (entries required) (V3) Reason for Referral Section (V2)	Physical Exam Section (V3) Encounters Section (entries required) (V3) Family History Section (V3) Functional Status Section (V2) Discharge Diagnosis Section (V3) Immunizations Section (entries optional) (V3) Medical Equipment Section (V2) Payers Section (V3) Plan of Treatment Section (V2) Procedures Section (entries required) (V2) Social History Section (V3) Mental Status Section (V2) General Status Section Review of Systems Section Nutrition Section Past Medical History (V3) History of Present Illness Section Assessment and Plan Section (V2) Assessment Section




Document Type	Required Sections	Optional Sections
		Admission Medications Section (entries optional) (V3) Admission Diagnosis Section (V3) Course of Care Section Advance Directives Section (entries required) (V3)

Table 27: Transfer Summary: Document Template.

### 3.3.12 Other Section-Level Templates Available for Use in C-CDA Documents

As the library of available CDA templates grows and implementers become more experienced using the standard, implementers may use templates developed in other CDA implementation guides which are compatible with C-CDA. Employing additional C-CDA compatible templates within existing document types will expand the range of interoperable information available for exchange and help address emerging use cases for data exchange.


 C-CDA Content Creators MAY include in existing C-CDA documents, other C-CDA compatible section-level templates defined in other implementation guides. **[BP-052]**

A C-CDA compatible template is a template that further constrains a template defined in C-CDA R2.1 or a template that does not conflict with templates defined in C-CDA. Determining if a template is C-CDA compliant may require human discernment and consensus building within the C-CDA implementer community.

The Joint Document Content Work Group recommends all sections include the Section Time Range Observation to describe the range of time used to limit the range of information contained in a section.<sup>84</sup>

**Reference:** Chapter 4.2.8 Declaring Business Rules that Limit Section Content; 5.1.8 Specifying Time Intervals for Sections with Limits

The Joint Document Content Work Group also recommends use of the Progress Note document template to represent an encounter summary for a non-inpatient setting.<sup>85</sup> The Progress Note document template does not include any required sections and the open nature of the template enables Content Creators to include the right sections to express the source data or the needed sections to satisfy the requirements of Content Consumers.

 C-CDA Content Creators MAY support further constraints on the document templates defined in C-CDA R2.1. **[BP-053]**

<sup>84</sup> Joint Content Workgroup IG. Chapter 2.1.1 Section Time Range Observation.

<sup>85</sup> Joint Content Workgroup IG. Chapter 2.2 Outpatient/Ambulatory Summary (Progress Note Document)

## 4 Section Level Guidance

The C-CDA Companion Guide provides additional guidance aimed at increasing consistency in the way content in structured C-CDA documents is represented and used across all implementations. The goal is to raise awareness about why and how to use the section templates defined in C-CDA, and in other standards that supplement and complement C-CDA, to meet rising expectations and emerging regulations focused on expanding interoperability.

This chapter provides general guidance relevant when representing clinical information as structured C-CDA documents. It explains the purpose of structured sections and supplies background on how the section templates in C-CDA were originally developed. It summarizes the set of sections defined by Consolidate CDA and explains how each type of document template uses different section templates to represent—in human readable form—the information commonly contained in each specific type of clinical note. It introduces the section templates which require machine processable “discrete data” to accompany the human readable narrative. Finally, it summarizes several section templates that are new for Consolidated C-CDA or defined in implementation guides published elsewhere in the C-CDA implementer community and provides guidance on their use in C-CDA documents.

### 4.1 Understanding Content Sections in Structured Documents

The idea of improving the communication of information contained in clinical notes has been around for decades. Long before C-CDA, a documentation methodology called “SOAP (Subjective, Objective, Assessment, and Plan) notes” was invented. The birth of the problem-oriented medical record (POMR) and SOAP note marked an epoch in the history of health care. Dr. Lawrence Weed, developer of the SOAP note and professor of medicine and pharmacology at Yale University, challenged conventional medical documentation and advocated for a scientific structure to frame clinical reasoning in the 1950s.<sup>86</sup> Today, the SOAP note is the most common method of documentation used by providers to input notes into patients’ medical records. They allow providers to record and share information in a universal, systematic and easy to read format.<sup>87</sup> Ineffective communication contributes to the top causes of sentinel events and continues to be an unremitting area for refinement.<sup>88</sup>

After the development of the HL7 Clinical Document Architecture R2 standard in 2005, an alliance of healthcare vendors, providers and associations pooled resources in a rapid-development initiative. In a span of three years, the Health Story Project produced eight Health Level Seven (HL7) data standards for the flow of information using common types of healthcare documents.<sup>89</sup> The alliance examined thousands of common clinical notes generated by a variety of medical transcription solutions and identified what structured sections were needed to

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<sup>86</sup> Wright A, Sittig DF, McGowan J, Ash JS, Weed LL. Bringing science to medicine: An interview with Larry Weed, inventor of the problem-oriented medical record. *J Am Med Inform Assoc.* 2014;21:964–968.

<sup>87</sup> Continuum. How SOAP Notes Paved the Way for Modern Medical Documentation.

<https://www.carecloud.com/continuum/how-soap-notes-paved-the-way-for-modern-medical-documentation/>

<sup>88</sup> *Academic Medicine.* January 2019 - Volume 94 - Issue 1 - p 11

<sup>89</sup> <https://www.himss.org/library/health-story-project>

represent the SOAP notes commonly generated by current-day clinicians. The “Health Story Guides,” as they were originally named, defined the initial set of section templates based on this analysis.<sup>90</sup> Every section template includes a section.text element designed to hold the human readable narrative of that section of the structured document.

The HIMSS Health Story Project continues to provide education to the health IT community on tools and resources to aid in the creation of comprehensive electronic records that tell a patient's *complete health story*. The quarterly roundtable presentations are recorded and posted for public access on the HIMSS Health Story website.<sup>91</sup> Many of these presentations provide general background information that helps implementers understand the vision for the use of the C-CDA standard. Some especially educational Roundtables include are summarized in the following chapters.

### 4.1.1 The Storytelling Power of C-CDA<sup>92</sup>

This Roundtable presentation explains the twelve common clinical document types that are defined in Consolidated CDA (C-CDA) and describes how each can be leveraged for information exchange in different care settings and for different encounter types. When should each C-CDA clinical document type be leveraged? What sections are used in C-CDA clinical documents and how do they differ from a Continuity of Care Document (CCD)? The Roundtable shows how to apply the SOAP framework to reveal the storytelling power of C-CDA by thinking of the section templates in terms of the subjective, objective, assessment, and plan information each contains. In some cases, the information in one section may be classified in multiple SOAP categories. The categorization is an approximation designed to improve understanding of the full collection of C-CDA section templates.

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<sup>90</sup> HIMSS Health Story Project. Our History. <https://www.himss.org/library/health-story-project>

<sup>91</sup> HIMSS Health Story Project. Roundtable Archives. <https://www.himss.org/health-story-project/roundtable-archives>

<sup>92</sup> HIMSS Health Story Project. Storytelling Power of C-CDA <https://www.himss.org/library/storytelling-power-c-cda>

C-CDA R2.1 Templates								
Reorganized Using a SOAP Framework								
Subjective	Reason for Visit	Reason for Referral	Chief Complaint Reason for Visit	Chief Complaint	Health Concerns	Allergies & Intolerances	Review of Systems	History Present Illness
History Past Illness	Social History	Family History	Objective	Problem	Medical (Gen) History	Medications	Immunizations	Implants
Medical Equipment	Procedures	Results	Vital Signs	Admission Diagnosis	Admission Meds	Course of Care	Hospital Course	Hospital Consultations
Medications Administered	Anesthesia	Procedure Indications	Procedure Description	Procedure Specimens	Procedure Est. Blood Loss	Procedure Findings	Procedure Implants	Procedure Disposition
Preoperative Diagnosis	Surgery Description	Op Note Surgical Procedure	Operative Note Fluids	Surgical Drains	Complications	Hospital Discharge Studies Sum	Hospital Discharge Physical	Advance Directives
Payers	Encounters	Physical Exam	Findings	Health Status Eval/Outcomes	General Status	Functional Status	Mental Status	Nutrition
Assessment	Postprocedure Diagnosis	Postoperative Diagnosis	Discharge Diagnosis	Assessment & Plan	Plan of Treatment	Goals	Planned Procedure	Instructions
			Hospital Discharge Instructions	Discharge Medications	Discharge Diet			

Figure 7: Visualizing C-CDA section templates by applying the SOAP framework

#### 4.1.2 A More Meaningful Patient Story Using C-CDA: Tell it. Use it. Share it.<sup>93</sup>

This presentation explains how documentation-based exchange via Consolidated Clinical Document Architecture (C-CDA), when implemented correctly, has the power to capture and share a more comprehensive electronic record that can be used to improve care.

By 2011, when C-CDA R1.0 was first published, a larger industry effort brought together CDA templates for clinical SOAP notes that had been defined by several organizations including Integrating the Healthcare Enterprise (IHE), HITSP, and HL7. The harmonized work included not only definitions for section templates needed to structure common clinical note types, but also included entry templates that defined how to represent the human readable section information using machine processable “clinical statements”. Clinical statements were templated using the syntax and data structures supported by the HL7 CDA R2 standard which derived its data types and modeling from an early version of the HL7 Reference Information Model (RIM). The HL7 RIM is the cornerstone of all HL7 Version 3 standards. It is a shared model between all domains and, as such, forms a common basis from which all domains can create information exchange artifacts and messages.<sup>94</sup>

<sup>93</sup> HIMSS Health Story Project. A More Meaningful Patient Story Using C-CDA: Tell it. Use it. Share it. <https://www.himss.org/library/more-meaningful-patient-story-using-c-cda-tell-it-use-it-share-it>

<sup>94</sup> HL7 Reference Information Model. <http://www.hl7.org/implement/standards/rim.cfm>

Today in C-CDA R2.1 and in other supplemental implementation guides, the C-CDA standards development community has defined and published a wide array of section templates to represent clinical information in the context of structured documents. It is important to note that the purpose of each section template is dependent on the context of its intended use within a larger document structure. While some templates have been defined generically and are suitable for reuse in multiple structured documents, others due to the nature of their definitions may not be appropriate for re-use across other documents. For this reason, it is important for the context of the overarching document to be considered when determining if it is appropriate to include a particular type of section template in a particular type of document template.



C-CDA Content Creators **SHOULD** use section templates that are appropriate within the context of a document based on the defined purpose of the section template. **[BP-054]**

## 4.2 General Section-Level Guidance

The following guidance elements are not specific to any one C-CDA template but rather are overarching guidance elements that apply to an entire C-CDA document.

### 4.2.1 Data Provenance for a Section

The author role is key to understanding the provenance of the information.

The roles populated in the header of the document apply to each section of content as well, unless explicitly indicated otherwise. If the author information for a section is not explicitly declared, then the author of the information in that section can be assumed to be the author contained in the document header. This behavior within a CDA document is called context conduction.

This assumption extends to entries contained in the section as well. If the author information for an entry is not explicitly declared, then the author of the information in that entry can be assumed to be the author contained in the encompassing section.

While it is generally preferred that provenance be conveyed either at the document level, or at the entry level, it is possible for provenance to be conveyed at the section level when the default context conduction does not apply.

When representing a clinical note using structured sections, each section of information receives its context from the document's header. If author information for a section is not explicitly declared, then the author of that section of information can be assumed to be the same as the author information contained in the document header.

The recordTarget, author, and informant roles populated in the header of the document apply to each section of content as well, unless explicitly indicated otherwise. The author role is key to understanding the provenance of the information in the document. If the author information for a section is not explicitly declared, then the author of that section of information can be assumed to be the same as the author information contained in the header.

This assumption extends to entries contained in the section as well, unless the author information is explicitly declared at the entry level. While it is generally preferred that provenance be conveyed at the entry level, provenance information included at the document or section level conducts to the entry when provenance at the entry level is not stated explicitly.

### 4.2.2 Declaring Section Template Conformance

As explained in Chapter 2.3.1 Declaring Template Conformance, template conformance may be declared at any level of a C-CDA document—header, section, entry, or within an entry at a sub-structural level.

A template declaration in a C-CDA section asserts the constraints applicable for that section of XML. The template declaration tells validators and Content Consumers what to expect in terms of the information that, may, should, or shall be populated within this section of the document.

C-CDA templates are identified with a templateId. The templateId is a two-part identifier that consists of a root and an extension. The root identifies the named template and the extension identifies the version of that template. Initially C-CDA templates did not include versions. The templateId/@extension attribute was not used. Many of those original template versions are still used in C-CDA R2.1.

Chapter 3.1.2 of the Consolidated CDA Implementation Guide discusses the use of templateIds and what needs to be included in a C-CDA document:

- To assert conformance with C-CDA R2.1, declare the templateId of the version of the template defined in C-CDA R2.1.
- To assert conformance with C-CDA R1.1, declare the templateId of the version of the template defined in C-CDA R1.1.

Over time, many implementations have added template declarations without regard for the overhead they place on validation services or the confusion they may create for Content Consumers. The volume of templateId declarations adds to the size and complexity of C-CDA documents. This is beginning to have a negative impact for the C-CDA implementer community and has resulted in the realization that templateId declarations need regular maintenance and pruning over time.



C-CDA R2.1 Content Creators SHOULD NOT declare conformance to irrelevant templates. [BP-066]



C-CDA R2.1 Content Creators SHALL NOT include duplicate templateId declarations. **[CONF-067]**

A duplicate templateId declaration is a template declaration for the same structural part of a C-CDA document (i.e. document, section, entry, entry-part) with identical @root and @extension information. The order of the @root and @extension attributes does not matter when determining duplication.

To avoid confusion and minimize inclusion of unnecessary information in C-CDA documents, implementers should avoid including duplicate or irrelevant templateId declarations.

It is important to note that including the 2.1 templateid and the 1.1 template id is no duplication and is valid to describe the content as conformant to both the 1.1 and 2.1 versions of C-CDA.

As standards evolve an implementer community may decide to deprecate a version of a template or a collected of templates published in a version of an implementation guide. It should be anticipated that implementer communities may determine that certain version of a template should not be used going forward.



C-CDA Content Creators and C-CDA Content Consumers SHOULD NOT attribute semantic meaning to templateId declarations in C-CDA documents. **[BP-057]**



C-CDA Content Creators SHOULD support template deprecation requiring discontinued use of all versions of a templateId or a specific version of a templateId. **[BP-058]**

*Example 16: Declaring template conformance at the section level.*

```
<!-- Allergies and Intolerances Section-->
<component>
  <section>
    <!-- Conformant to C-CDA R2.1 Allergies and Intolerances Section (entries optional)-->
    <templateId root="2.16.840.1.113883.10.20.22.2.6" extension="2015-08-01"/>
    <!-- Conformant to C-CDA R1.1 Allergies and Intolerances Section (entries optional) -->
    <templateId root="2.16.840.1.113883.10.20.22.2.6"/>
    <id root="0937FF9A-00CE-11E6-B4C5-0050568B000B"/>
    <code code="48765-2" displayName="Allergies &or adverse reactions Doc"
      codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
    <title>Allergies</title>
    <text>
      ...
    </text>
  </section>
</component>
```

*Example 17: Declaring conformance to multiple templates.*

```
<!--Substance or Device Allergy -->
<templateId root="2.16.840.1.113883.10.20.24.3.90" extension="2014-06-09" />
<templateId root="2.16.840.1.113883.10.20.24.3.90"/>
<!--Allergy - Intolerance Observation -->
<templateId root="2.16.840.1.113883.10.20.22.4.7" extension="2014-06-09" />
<templateId root="2.16.840.1.113883.10.20.22.4.7"/>
```



*Example 18: (Wrong) Duplicate template declarations at the section level.*

```

<!-- Allergies and Intolerances Section-->
<component>
  <section>
    <templateId root="2.16.840.1.113883.10.20.22.2.6"/>
    <templateId root="2.16.840.1.113883.10.20.22.2.6" extension="2015-08-01"/>
    <templateId root="2.16.840.1.113883.10.20.22.2.6"/>
    <templateId extension="2015-08-01" root="2.16.840.1.113883.10.20.22.2.6.1" />
    <id root="0937FF9A-00CE-11E6-B4C5-0050568B000B"/>
    <code code="48765-2" displayName="Allergies &amp;or adverse reactions Doc"
          codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
    <title>Allergies</title>
    <text>
    ...
  </text>
</section>
</component>

```

### 4.2.3 Narrative Block Formatting

The CDA requirement for human readability guarantees that a receiver of a CDA document can algorithmically display the clinical content of the note on a standard Web browser.<sup>95</sup> This requirement impacts C-CDA in the following ways:

- 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.
- 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.

These principles and requirements have led to the current approach, where the material to be rendered is placed into the section.text field. In some cases, the data design of the entry templates required in the section heavily influence what clinical information can be expected to be present in the Narrative Block. In other cases, where entry templates are optional or not defined at all, the content in the Narrative Block may reflect information gathered in source systems as text and human crafted notes.

If the CDA Body is structured, the Content Creator includes the attested narrative content in the appropriate section.text field, regardless of whether information is also conveyed in CDA entries. An originator of a CDA document is not required to fully encode all narrative into CDA entries within the CDA body. Within specific implementations, trading partners may ascribe

<sup>95</sup> HL7 CDA. 1.2.3 Human Readability and Rendering CDA Documents.



additional originator responsibilities to create various entries that meet certain conformance requirements or meet the conformance requirements described by defined templates.

*Example 19: Sample Narrative Block in a Section*

```

<section>
. . .
  <text>
    <table>
      <colgroup>
        <col width="25%"/>
        <col width="25%"/>
        <col width="25%"/>
        <col width="25%"/>
      </colgroup>
      <thead>
        <tr>
          <th>Information Type</th>
          <th>Date</th>
          <th>Relevant Information</th>
          <th>Documented By</th>
        </tr>
      </thead>
      <tbody>
        <tr ID="SocialHistory_1">
          <td>Tobacco smoking status:</td>
          <td><content>(04/12/2016)</content></td>
          <td><content>Never smoked</content></td>
          <td><content>M.Smith</content> <content>(04/12/2016)</content></td>
        </tr>
      </tbody>
    </table>
  </text>
  ...
  <entry typeCode="DRIV">
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.22.4.78"/>
      <templateId root="2.16.840.1.113883.10.20.22.4.78"
        extension="2014-06-09"/>
      <id extension="64020-Z9301" root="1.2.840.114350.1.13.6289.1.7.1.1040.1"/>
      <code code="72166-2" codeSystem="2.16.840.1.113883.6.1"
        codeSystemName="LOINC" displayName="Tobacco smoking status NHIS"/>
      <text><reference value="#SocialHistory_1"></reference></text>
      <statusCode code="completed"/>
      <effectiveTime value="20160412"/>
      <value xsi:type="CD" code="266919005" codeSystem="2.16.840.1.113883.6.96"
        displayName="Never smoked tobacco" />
      <author>
        <time value="20160412"/>
        <assignedAuthor>
          <id extension="10.1" root="1.2.840.114350.1.1"/>
        </assignedAuthor>
      </author>
    </observation>
  </entry>
  ...
</section>

```

CDA permits additional information conveyed in the document that is there primarily for machine processing that is not authenticated and need not be rendered. However, the requirement that all attested content be present in the section.text field, suggests best practice is for all clinical content to be rendered through section.text.



C-CDA Content Creators SHOULD include all clinical content conveyed by a document in the section.text field. [BP-059]

**Reference:** Chapter 5 Representation of Discrete Data

#### 4.2.3.1 HTML tags for formatting Narrative Text

The content model of the CDA Narrative Block schema is specially hand crafted to meet the requirements outlined above. Chapter 4.3.5 of the HL7 CDA standard provides a detailed explanation of the section Narrative Block and its representation to support ubiquitous rendering.<sup>96</sup> The table below provides information on some of the formatting tags commonly used to organize and render the human readable information in the Narrative Block.

Tag Description	Description
<b>&lt;content&gt;</b>	The CDA <content> element is used to wrap a string of text so that it can be explicitly referenced, or so that it can suggest rendering characteristics. The <content> element contains an optional identifier, that can serve as the target of a reference. All values of attributes of type XML ID must be unique within the document (per the <a href="#">W3C XML specification</a> ). The originalText component of a RIM attribute present in any CDA entry can make explicit reference to the identifier, thereby indicating the original text associated with the attribute in the CDA entry.
<b>&lt;br&gt;</b>	The CDA   element is used to indicate a hard line break. It differs from the CDA <paragraph> element in that the   element has no content. Receivers are required to interpret this element when rendering so as to represent a line break.
<b>&lt;list&gt;</b>	A CDA <list> is similar to the HTML list. A CDA <list> has an optional caption and contains one or more <item> elements. A CDA <item> element contains an optional caption, which if present must come first before any other character data. The required listType attribute specifies whether the <list> is ordered or unordered (with unordered being the default). Unordered lists are typically rendered with bullets, whereas ordered lists are typically rendered with numbers, although this is not a requirement.
<b>&lt;table&gt;</b>	The CDA <table> is similar to the HTML table. The table markup is for presentation purposes only and, unlike a database table, does not possess meaningful field names.
<b>&lt;linkHtml&gt;</b>	The CDA <linkHtml> is a generic referencing mechanism, similar, but not identical, to the HTML anchor tag. It can be used to reference identifiers that are either internal or external to the document.
<b>styleCode attribute</b>	The styleCode attribute is used within the CDA Narrative Block to give the instance author the ability to suggest rendering characteristics of the nested character data (e.g. Bold, Underline, Italics). Receivers are not required to render documents using the style hints provided and can present stylized text in accordance with their local style conventions. <b>Reference:</b> HL7 CDA Chapter 4.3.5.11 for information on additional stylecodes.

Table 28: HTML tags for formatting Narrative Text

<sup>96</sup> HL7 CDA, Chapter 4.3.5 Section Narrative Block.

### 4.2.4 Multiple Views and styleCode

Experience sharing documents has proven that different users expect, even demand, different views. Patients and providers have different needs; specialists and general practice providers have different needs. The HL7 Relevant and Pertinent Survey identified the need to improve rendering capabilities for the information contained in CDA documents.

CDA documents support a technique for using multiple XML stylesheet processing instructions and a controlled vocabulary for the @styleCode attribute has been established by IHE.<sup>97</sup> For more information on the use of styleCodes, reference the IHE Multiple Content Views (MCV) Profile - Published 2014-08-28. The profile includes examples to show how these styleCodes can be used to improve rendering options.

To promote a more consistent user experience for the viewing of the human readable content, implementers are encouraged to use the set of @styleCode values established by the MCV Profile. These @styleCode values establish a common way to tag text as a code, a date, a dateTime, an alert, and many other generally useful concepts.

These styleCode values can be used to facilitate multiple clinical content rendering features. Systems that create CDA documents can use values from this table to improve the processing and rendering options for the information. Systems that render CDA document content with these styleCodes shall not omit or hide or otherwise obstructed from view information that uses these styleCodes unless they are using a specific rendering view that calls for such behavior.

### 4.2.5 Date/Time Guidance

Temporal information is often included as relevant and pertinent information to be exchanged. However, implementers need to be diligent when representing date/time information to make sure irrelevant or inaccurate levels of precision are not introduced when representing this type of information.

**Reference:** 5.1.10 Detailed Date/Time Guidance

### 4.2.6 Irrelevant Data (Not Pertinent)

Sharing irrelevant data, or omitting relevant data, can have an undesirable impact on clinician satisfaction and/or patient care. Developers of software to create, render, or incorporate C-CDA documents are encouraged to review recommendations in the HL7 CDA® R2 IG: Clinical Summary Relevant and Pertinent Data, Release 1 (PI ID: 1183) that underwent ballot during the HL7 January 2017 ballot cycle.

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<sup>97</sup> For more information on the use of styleCodes, reference the IHE Multiple Content Views (MCV) Profile - Published 2014-08-28. The profile includes examples to show how these styleCodes can be used to improve rendering options.

#### 4.2.7 Use of Open Templates for Sections

Again, it is important to emphasize the reusability and flexibility of templates so that implementations support the ability to tailor the content in CDA sections specific to the patient’s care, provider, or setting needs. Within C-CDA, nearly all templates allow additional content and are described as *open* templates.

While section templates define the content to be included in that structural component of the document, additional content may augment each document as needed for a particular circumstance, so long as the content is relevant to the defined purpose of the section.

For example, the Social History Section is defined as, “This section contains social history data that influence a patient’s physical, psychological or emotional health (e.g., smoking status, pregnancy). Demographic data, such as marital status, race, ethnicity, and religious affiliation, is captured in the header.”<sup>98</sup>

Therefore, information about the person’s level of education, housing instability, food insecurity or transportation access challenges could be included in this section, provided the document did not contain another section defined to more appropriately include this information.

Existing templates defined in C-CDA can be used to represent additional data elements defined in the Vocabulary section of the Interoperability Standards Advisory (ISA).<sup>99</sup> Table 29 below shows the social, psychological and behavioral data elements defined in the 2019 version of the ISA.

Data Element Concept	LOINC Code	LOINC Long common name
Alcohol Use	72109-2	Alcohol Use Disorder Identification Test - Consumption [AUDIT-C]
Depression	55757-9	Patient Health Questionnaire 2 item (PHQ-2) [Reported]
Exposure to Violence (Intimate Partner Violence)	76499-3	Humiliation, Afraid, Rape, and Kick questionnaire [HARK]
Financial Resource Strain	76513-1	How hard is it for you to pay for the very basics like food, housing, medical care, and heating [CARDIA]
Level of Education	63504-5	What is the highest grade or level of school you have completed or the highest degree you have received [NHANES]
Physical Activity	68515-6	How many days of moderate to strenuous exercise, like a brisk walk, did you do in the last 7 days [SAMHSA]
Social Connection and Isolation	76506-5	Social connection and isolation panel
Stress	76542-0	Do you feel stress - tense, restless, nervous, or anxious, or unable to sleep at night because your mind is troubled all the time - these days [OSQ]

Table 29: List of social, psychological, and behavioral data elements defined in the 2019 ISA

<sup>98</sup> HL7 C-CDA R2.1 Chapter 2.66 Social History Section.

<sup>99</sup> <https://www.healthit.gov/isa/sites/isa/files/inline-files/2019ISARefereceEdition.pdf>

When using available templates to represent a data element defined in the ISA, it is important to represent the concept with coded values from the associated value set included for that data element in the ISA. For example, in the Sex at Birth, Sexual Orientation and Gender Identity section of the Vocabulary Section of the ISA the data element for Gender Identity is defined using LOINC Code 76691-5 with a possible range of values shown in the table below.<sup>100</sup> The data element definition formed by this information is what should be used in the appropriate available template.

Answer Concept	Code	Code System Meaning
Male	446151000124109 SNOMED CT (US)	Male gender identity
Female	446141000124107 SNOMED CT (US)	Female gender identity
Female-to-Male	407377005 SNOMED CT (US)	FTM-female to male transsexual
Male-to-Female	407376011 SNOMED CT (US)	MTF- male to female transsexual
Identifies as non-conforming gender	446131000124102 SNOMED CT (US)	Identifies as non-conforming gender. Synonyms include: Genderqueer; Identifies as neither exclusively male nor female, Non-binary gender)
Additional	OTH HL7 Version 3 NullFlavor	Other
Choose not to disclose	ASKU HL7 Version 3 NullFlavor	Asked but unknown

Table 30: Coded concepts defined in the Interoperability Standards Advisory for the “Patient Gender Identity” data element defined by coded concept 76691-5 from LOINC<sup>101</sup>

Example 20: How to represent the data element for Gender Identity using the code and value set supplied in the Interoperability Standards Advisory<sup>102</sup>

```

<component>
  <!-- This sample is undergoing significant review. Please be aware that there may be
  significant changes -->
  <!-- Developed by Emma Jones -->
  <section>
    <templateId root="2.16.840.1.113883.10.20.22.2.17" extension="2015-08-01"/>
    <templateId root="2.16.840.1.113883.10.20.22.2.17"/>
    <code code="29762-2" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
    <title>Social History</title>
    <text>
      <table>
        <thead>
          <tr>
            <th>Social History</th>
            <th>Observation</th>
            <th>Date</th>
          </tr>
        </thead>
      </table>
    </text>
  </section>

```

<sup>100</sup> <https://www.healthit.gov/isa/representing-patient-gender-identity>

<sup>101</sup> <https://www.healthit.gov/isa/representing-patient-gender-identity>

<sup>102</sup> <http://hl7-c-cda-examples.herokuapp.com/examples/view/Social%20History/Sexual%20Orientation%20Gender%20Identity>

```

        <tbody styleCode="xRowGroup">
          <tr ID="_a1305452-cddd-4654-980f-bba6745588c8">
            <td>
              <content ID="_3b8a5051-3968-4cfe-ab70-8b69f84bd378">Sexual
orientation</content>
            </td>
            <td>
              <content ID="_12d30bb3-f589-4d3b-a011-
4b463aafa093">bisexual</content>
            </td>
            <td>
              <content>2001 - </content>
            </td>
          </tr>
        </tbody>
      </table>
      <tbody styleCode="xRowGroup">
        <tr ID="_6e185602-f807-40c6-8003-41c589ae62af">
          <td>
            <content ID="_4503c511-8e06-41a0-8f6b-3f5d23b131e2">Gender
identity</content>
          </td>
          <td>
            <content ID="_71d1b8e1-b3dd-483f-80f3-49656e518994">Female-to-male
transsexual</content>
          </td>
          <td>
            <content>2001 - </content>
          </td>
        </tr>
      </tbody>
    </table>
  </text>
  <entry>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.22.4.38" extension="2015-08-01"/>
      <templateId root="2.16.840.1.113883.10.20.22.4.38"/>
      <id root="2.16.840.1.113883.19" extension="123456789"/>
      <!-- Per the C-CDA 2.1 IG - (CONF:1198-8558) - social history type value set is
a SHOULD - therefore this value is not in the value set however, it is allowed-->
      <code code="76690-7" codeSystem="2.16.840.1.113883.6.1" displayName="Sexual
orientation" codeSystemName="LOINC">
        <originalText>
          <reference value="#_3b8a5051-3968-4cfe-ab70-8b69f84bd378"/>
        </originalText>
      </code>
      <text>
        <reference value="#_a1305452-cddd-4654-980f-bba6745588c8"/>
      </text>
      <statusCode code="completed"/>
      <!-- interval start with no end to indicate from 2001 -->
      <effectiveTime xsi:type="IVL_TS">
        <low value="2001"/>
      </effectiveTime>
      <value xsi:type="CD" code="42035005" codeSystem="2.16.840.1.113883.6.96"
displayName="Bisexual" codeSystemName="SNOMED CT">
        <originalText>
          <reference value="#_12d30bb3-f589-4d3b-a011-4b463aafa093"/>
        </originalText>
      </value>
      <author>
        <templateId root="2.16.840.1.113883.10.20.22.4.119"/>
        <time value="20140606"/>
        <assignedAuthor>
          <id extension="99999999" root="2.16.840.1.113883.4.6"/>
          <code code="200000000X" codeSystem="2.16.840.1.113883.6.101"
displayName="Allopathic and Osteopathic Physicians" codeSystemName="Healthcare Provider
Taxonomy (HIPAA)"/>
          <telecom use="WP" value="tel:+1(555)555-1002"/>
          <assignedPerson>
            <name>
              <given>Henry</given>
            </name>
          </assignedPerson>
        </assignedAuthor>
      </author>
    </observation>
  </entry>

```

```

        <family>Seven</family>
        </name>
    </assignedPerson>
</assignedAuthor>
</author>
</observation>
</entry>
<entry>
    <observation classCode="OBS" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.22.4.38" extension="2015-08-01"/>
        <templateId root="2.16.840.1.113883.10.20.22.4.38"/>
        <id root="2.16.840.1.113883.19" extension="123456789"/>
        <!-- Per the C-CDA 2.1 IG - (CONF:1198-8558) - social history type value set is
a SHOULD - therefore this value is not in the value set however, it is allowed-->
        <code code="76691-5" codeSystem="2.16.840.1.113883.6.1" displayName="Gender
identity" codeSystemName="LOINC">
            <originalText>
                <reference value="#_4503c511-8e06-41a0-8f6b-3f5d23b131e2"/>
            </originalText>
        </code>
        <text>
            <reference value="#_6e185602-f807-40c6-8003-41c589ae62af"/>
        </text>
        <statusCode code="completed"/>
        <!-- interval start with no end to indicate from 2001 -->
        <effectiveTime xsi:type="IVL_TS">
            <low value="2001"/>
        </effectiveTime>
        <!-- Selected from this value set -
https://phinvads.cdc.gov/vads/ViewValueSet.action?id=B0155EA6-45BB-E711-ACE2-0017A477041A -->
        <value xsi:type="CD" code="407377005" codeSystem="2.16.840.1.113883.6.96"
displayName="Female-to-male transsexual" codeSystemName="SNOMED CT">
            <originalText>
                <reference value="#_71d1b8e1-b3dd-483f-80f3-49656e518994"/>
            </originalText>
        </value>
        <author>
            <templateId root="2.16.840.1.113883.10.20.22.4.119"/>
            <time value="201406061032-0500"/>
            <assignedAuthor>
                <id extension="99999999" root="2.16.840.1.113883.4.6"/>
                <code code="200000000X" codeSystem="2.16.840.1.113883.6.101"
displayName="Allopathic and Osteopathic Physicians" codeSystemName="Healthcare Provider
Taxonomy (HIPAA)"/>
                <telecom use="WP" value="tel:+1(555)555-1002"/>
                <assignedPerson>
                    <name>
                        <given>Henry</given>
                        <family>Seven</family>
                    </name>
                </assignedPerson>
            </assignedAuthor>
        </author>
    </observation>
</entry>
</section>
</component>

```

#### 4.2.8 Declaring Business Rules that Limit Section Content

In order to communicate that business rules have been applied to constrain the amount of information represented in the section of a document C-CDA Content Creators should explicitly clarify the time range of the included information in the human readable text for the section.

For example, the Vital Signs Section is defined as, "The Vital Signs Section contains relevant vital signs for the context and use case of the document type, such as blood pressure, heart rate, respiratory rate, height, weight, body mass index, head circumference, pulse oximetry, temperature, and body surface area. The section should include notable vital signs such as the most recent, maximum and/or minimum, baseline, or relevant trends. Vital signs are represented in the same way as other results but are aggregated into their own section to follow clinical conventions."<sup>103</sup>

A C-CDA Content Creator may have a business rule that limits the amount of vital sign information included in a Patient Summary to only the most recent vital signs for the patient in the requested period of time. This may be determined based on the effectiveTime/high for the time interval of the request. Business rules that further constrain the standard purpose of the defined section template should be explicitly documented in the section content.

**Reference:** 5.1.8 Specifying Time Intervals for Sections with Limits on the Included Discrete Data

The Section Time Range Observation is a newly defined template to describe the business rule used to limit the information contained in the section. It is an optional entry and may be used in any section.

The Section Time Range Observation template (urn:hl7ii:2.16.840.1.113883.10.20.22.4.201:2016-06-01) may be useful when a query for a C-CDA document may request a large amount of data—potentially years—and the system that creates the document supplied in a response, limits the data they return to a specific range of time. This template enables the system creating the document to state the business logic used to constrain the amount of data provided in a section.

The Section Time Range template is used to communicate the 'business logic' used to limit the information contained in the section to a specific range of time. For example, if a CCD document is requested for the last 5 years and the Content Creator system has business rules that creates documents on demand but only returns one-year of past lab results, the Section Time Range template can be used to indicate the lab section only contains 12 months of data from the requested effectiveTime/low or at most 12 months of data prior to the effectiveTime/high in the request. The business logic used to limit the data is stated in the value element of the Section Time Range template using a datatype of IVL\_TS. The template does not include an effectiveTime element.

*Example 21: Example of Section Time Range Observation*

```
<section>
...
  <title>Procedures</title>
  <text>
    <content ID="Proc_STR">Procedures performed between 08/15/2012 and 08/15/2015.</content>
  ...
</text>
<entry>
```

<sup>103</sup> HL7 C-CDA R2.1. Chapter 2.70 Vital Signs Section.



```

<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.22.4.201" extension="2016-06-01"/>
  <code code="82607-3" codeSystem="2.16.840.1.113883.6.1"
    displayName="Section Date and Time Range"/>
  <text>
    <reference value="#Proc_STR"/>
  </text>
  <statusCode code="completed"/>
  <value xsi:type="IVL_TS">
    <low value="20120815"/>
    <high value="20150815"/>
  </value>
</observation>
</entry>
</section>


```

Reference: Appendix A.2

### 4.3 Sections Defined in C-CDA (ordered using SOAP framework)

As explained in the Health Story Roundtable presentation titled “The Storytelling Power of C-CDA”, understanding the purpose of the C-CDA section templates is not facilitated by considering them in alphabetical order.<sup>104</sup> The C-CDA Implementation Guide presents them in alphabetical order to speed access for readers. Considering the C-CDA section templates using the SOAP framework makes it easier to see how these sections can be used in a structured document to express the content of a clinical SOAP note.

The application of the SOAP framework does not produce a perfect classification result. Some sections don’t fit well into the SOAP framework. They have been classified as “other types of sections”. Some sections are defined to contain “heterogeneous” information, meaning the section’s content spans the boundaries of the SOAP framework. For example, the Assessment and Plan Section contains both assessment (A) and plan (P) information. Section structures that contain “homogeneous” information, all of the same type with the same purpose, improves information processing.



C-CDA Content Creators SHOULD use section templates containing “homogeneous” information with regards to not mixing subjective, objective, assessment, and plan types of information together in a single section. **[BP-060]**

#### 4.3.1 Subjective Information

Section Name	Purpose Description
LONIC OID <b>Subjective Section</b> 61150-9 2.16.840.1.113883.10.20.21.2.2	This section describes in a narrative format the patient’s current condition and/or interval changes as reported by the patient or by the patient’s guardian or another informant.

<sup>104</sup> <https://www.himss.org/library/storytelling-power-c-cda>

Section Name	Purpose Description
LONIC OID	
<b>Reason for Visit</b> 29299-5 2.16.840.1.113883.10.20.22.2.12	This section records the patient’s reason for the patients’ visit (as documented by the provider). Local policy determines whether Reason for Visit and Chief Complaint are in separate or combined sections.
<b>Reason for Referral</b> 42349-1 1.3.6.1.4.1.19376.1.5.3.1.3.1:2014-06-09	This section describes the clinical reason why a provider is sending a patient to another provider for care. The reason for referral may become the reason for visit documented by the receiving provider.
<b>Chief Complaint</b> 10154-3 2.16.840.1.113883.10.20.22.2.13	This section records the patient’s chief complaint (the patient’s own description).
<b>Chief Complain and Reason for Visit</b> 46239-0 2.16.840.1.113883.10.20.22.2.13	This section records the patient’s chief complaint (the patient’s own description) and/or the reason for the patient’s visit (the provider’s description of the reason for visit). Local policy determines whether the information is divided into two sections or recorded in one section serving both purposes. <b>Reference:</b> Chapter 4.3 Sections Defined in C-CDA
<b>Health Concerns Section</b> 75310-3 2.16.840.1.113883.10.20.22.2.58:2015-08-01	This section contains data describing an interest or worry about a health state or process that could possibly require attention, intervention, or management. A Health Concern is a health-related matter that is of interest, importance or worry to someone, who may be the patient, patient’s family or patient’s health care provider. Health concerns are derived from a variety of sources within IEHR.  Health concerns can be medical, surgical, nursing, allied health or patient-reported concerns. “Transportation difficulties” for someone who doesn't drive and has trouble getting to appointments, or “Underinsured” for someone who doesn't have sufficient insurance to properly cover their medical needs such as medications. Problem Concerns are a subset of Health Concerns that have risen to the level of importance that they typically would be described in the Problems Section.
<b>Allergies and Intolerances Section</b> 48765-2 Entries optional: 2.16.840.1.113883.10.20.22.2.6:2015-08-01 Entries required: 2.16.840.1.113883.10.20.22.2.6.1:2015-08-01	This section lists and describes any medication allergies, adverse reactions, idiosyncratic reactions, anaphylaxis/anaphylactoid reactions to food items, and metabolic variations or adverse reactions/allergies to other substances (such as latex, iodine, tape adhesives). At a minimum, it should list currently active and any relevant historical allergies and adverse reactions.
<b>Review of Systems Section</b> 10187-3 1.3.6.1.4.1.19376.1.5.3.1.3.18	This section contains a relevant collection of symptoms and functions systematically gathered by a clinician. It includes symptoms the patient is currently experiencing, some of which were not elicited during the history of present illness, as well as a potentially large number of pertinent negatives, for example, symptoms that the patient denied experiencing.
<b>History of Present Illness</b> 10164-2 1.3.6.1.4.1.19376.1.5.3.1.3.4	This section describes the history related to the reason for the encounter. It contains the historical details leading up to and pertaining to the patient’s current complaint or reason for seeking medical care.

Section Name	Purpose Description
LONIC OID	
<b>Past Medical History</b> 11348-0 2.16.840.1.113883.10.20.22.2.20:2015-08-01	This section contains a record of the patient’s past complaints, problems, and diagnoses. It contains data from the patient’s past, up to the patient’s current complaint or reason for seeking medical care.
<b>Social History Section</b> 29762-2 2.16.840.1.113883.10.20.22.2.17:2015-08-01	This section contains social history data that influence a patient’s physical, psychological or emotional health (e.g., smoking status, pregnancy). Demographic data, such as marital status, race, ethnicity, and religious affiliation, is captured in the header.
<b>Family History Section</b> 10157-6 2.16.840.1.113883.10.20.22.2.15:2015-08-01	This section contains data defining the patient’s genetic relatives in terms of possible or relevant health risk factors that have a potential impact on the patient’s healthcare risk profile.

Table 31: Subjective Information

#### 4.3.2 Objective Information

Sections defined in C-CDA R2.1	Purpose Description
LONIC OID	
<b>Objective Section</b> 61149-1 2.16.840.1.113883.10.20.21.2.1	This section contains data about the patient gathered through tests, measures, or observations that produce a quantified or categorized result. It includes important and relevant positive and negative test results, physical findings, review of systems, and other measurements and observations.
<b>Problems Section</b> 11450-4 Entries optional: 2.16.840.1.113883.10.20.22.2.5:2015-08-01 Entries required: 2.16.840.1.113883.10.20.22.2.5.1:2015-08-01	This section lists and describes all relevant clinical problems at the time the document is generated. At a minimum, all pertinent current and historical problems should be listed. Overall health status may be represented in this section.
<b>Medical (General) History Section</b> 11329-0 2.16.840.1.113883.10.20.22.2.39	This section describes all aspects of the medical history of the patient even if not pertinent to the current procedure, and may include chief complaint, past medical history, social history, family history, surgical or procedure history, medication history, and other history information. The history may be limited to information pertinent to the current procedure or may be more comprehensive. The history may be reported as a collection of random clinical statements or it may be reported categorically. Categorical report formats may be divided into multiple subsections including Past Medical History, Social History.
<b>Medications Section</b> 10160-0 Entries optional: 2.16.840.1.113883.10.20.22.2.1:2014-06-09 Entries required: 2.16.840.1.113883.10.20.22.2.1.1:2014-06-09	This section contains a patient’s current medications and pertinent medication history. At a minimum, the currently active medications are listed. An entire medication history is an option. The section can describe a patient’s prescription and dispense history and information about intended drug monitoring.

Sections defined in C-CDA R2.1 LONIC OID	Purpose Description
<p><b>Immunizations Section</b> 11369-6 Entries optional: 2.16.840.1.113883.10.20.22.2.2:2015-08-01 Entries required: 2.16.840.1.113883.10.20.22.2.1:2015-08-01</p>	<p>This section defines a patient’s current immunization status and pertinent immunization history. The primary use case for the Immunization Section is to enable communication of a patient’s immunization status. The section should include current immunization status and may contain the entire immunization history that is relevant to the period of time being summarized.</p>
<p><b>Medical Equipment Section</b> 46264-8 2.16.840.1.113883.10.20.22.2.23:2014-06-09</p>	<p>This section defines a patient’s implanted and external health and medical devices and equipment. This section lists any pertinent durable medical equipment (DME) used to help maintain the patient’s health status. All equipment relevant to the diagnosis, care, or treatment of a patient should be included. Devices applied to, or placed in, the patient are represented with the Procedure Activity Procedure (V2) template. Equipment supplied to the patient (e.g., pumps, inhalers, wheelchairs) is represented by the Non-Medicinal Supply Activity V2 template. These devices may be grouped together within a Medical Equipment Organizer.</p>
<p><b>Procedures Section</b> 47519-4 Entries optional: 2.16.840.1.113883.10.20.22.2.7:2014-06-09 Entries required: 2.16.840.1.113883.10.20.22.2.7.1:2014-06-09</p>	<p>This section describes all interventional, surgical, diagnostic, or therapeutic procedures or treatments pertinent to the patient historically at the time the document is generated. The section should include notable procedures.</p>
<p><b>Results Section</b> 30954-2 Entries optional: 2.16.840.1.113883.10.20.22.2.3:2015-08-01 Entries required: 2.16.840.1.113883.10.20.22.2.3.1:2015-08-01</p>	<p>This section contains the results of observations generated by laboratories, imaging and other procedures. The scope includes observations of hematology, chemistry, serology, virology, toxicology, microbiology, plain x-ray, ultrasound, CT, MRI, angiography, echocardiography, nuclear medicine, pathology, and procedure observations. This section often includes notable results such as abnormal values or relevant trends.</p>
<p><b>Vital Signs Section</b> 8716-3 Entries optional: 2.16.840.1.113883.10.20.22.2.4:2015-08-01 Entries required: 2.16.840.1.113883.10.20.22.2.4.1:2015-08-01</p>	<p>This section contains relevant vital signs for the context and use case of the document type, such as blood pressure, heart rate, respiratory rate, height, weight, body mass index, head circumference, pulse oximetry, temperature, and body surface area. The section should include notable vital signs such as the most recent, maximum and/or minimum, baseline, or relevant trends. Vital signs are represented in the same way as other results. However, they are represented in their own section to follow clinical conventions.</p>
<p><b>Course of Care Section</b> 8648-8 2.16.840.1.113883.10.20.22.2.64</p>	<p>This section describes what happened during the course of an encounter.</p>
<p><b>General Status Section</b> 10210-3 2.16.840.1.113883.10.20.2.5</p>	<p>This section describes general observations and readily observable attributes of the patient, including affect and demeanor, apparent age compared to actual age, gender, ethnicity, nutritional status based on appearance, body build and habitus (e.g., muscular, cachectic, obese), developmental or other deformities, gait and mobility, personal hygiene, evidence of distress, and voice quality and speech.</p>

Sections defined in C-CDA R2.1 LONIC OID	Purpose Description
<b>Functional Status Section</b> 47420-5 2.16.840.1.113883.10.20.22.2.14:2014-06-09	This section contains observations and assessments of a patient’s physical abilities. A patient’s functional status may include information regarding the patient’s ability to perform Activities of Daily Living (ADLs) in areas such as Mobility (e.g., ambulation), Self-Care (e.g., bathing, dressing, feeding, grooming) or Instrumental Activities of Daily Living (IADLs) (e.g., shopping, using a telephone, balancing a check book). Problems that impact function (e.g., dyspnea, dysphagia) can be contained in the section.
<b>Mental Status Section</b> 10190-7 2.16.840.1.113883.10.20.22.2.56:2015-08-01	This section contains observations and evaluations related to a patient’s psychological and mental competency and deficits including, but not limited to any of the following types of information: • Appearance (e.g., unusual grooming, clothing or body modifications) • Attitude (e.g., cooperative, guarded, hostile) • Behavior/psychomotor (e.g., abnormal movements, eye contact, tics) • Mood and affect (e.g., anxious, angry, euphoric) • Speech and Language (e.g., pressured speech, perseveration) • Thought process (e.g., logic, coherence) • Thought content (e.g., delusions, phobias) • Perception (e.g., voices, hallucinations) • Cognition (e.g., memory, alertness/consciousness, attention, orientation) – which were included in Cognitive Status Observation in earlier publications of C-CDA. • Insight and judgment (e.g., understanding of condition, decision making)
<b>Nutrition Section</b> 61144-2 2.16.840.1.113883.10.20.22.2.57	This section represents diet and nutrition information including special diet requirements and restrictions (e.g., texture modified diet, liquids only, enteral feeding). It also represents the overall nutritional status of the patient and nutrition assessment findings.
<b><i>Specific to Inpatient Encounter Notes:</i></b>	
<b>Admission Diagnosis Section</b> 46241-6 2.16.840.1.113883.10.20.22.2.43:2015-08-01	This section contains a narrative description of the problems or diagnoses identified by the clinician at the time of the patient’s admission. This section may contain a coded entry which represents the admitting diagnoses.
<b>Admission Medications Section</b> 42346-7 2.16.840.1.113883.10.20.22.2.44:2015-08-01	This section contains the medications taken by the patient prior to and at the time of admission to the facility.
<b>Hospital Course Section</b> 8648-8 1.3.6.1.4.1.19376.1.5.3.1.3.5	This section describes the sequence of events from admission to discharge in a hospital facility.
<b>Hospital Consultations Section</b> 18841-7 2.16.840.1.113883.10.20.22.2.42	This section records consultations that occurred during the admission.

Sections defined in C-CDA R2.1	Purpose Description
LONIC OID	
<b>Hospital Discharge Studies Summary Section</b> 11493-4 2.16.840.1.113883.10.20.22.2.16	This section records the results of observations generated by laboratories, imaging procedures, and other procedures. The scope includes hematology, chemistry, serology, virology, toxicology, microbiology, plain x-ray, ultrasound, CT, MRI, angiography, echocardiography, nuclear medicine, pathology, and procedure observations. This section often includes notable results such as abnormal values or relevant trends and could record all results for the period of time being documented.
<b>Hospital Discharge Physical Section</b> 10184-0 1.3.6.1.4.1.19376.1.5.3.1.3.2	This section records a narrative description of the patient's physical findings generated by the discharge physician at the time of discharge.
<b>Discharge Medications Section</b> 10183-2 Entries optional: 2.16.840.1.113883.10.20.22.2.11:2015-08-01 Entries required: 2.16.840.1.113883.10.20.22.2.11.1:2015-08-01	This section contains the medications the patient is intended to take or stop after discharge. Current, active medications must be listed. The section may also include a patient's prescription history and indicate the source of the medication list.
<i>Specific to Procedure and Operative Notes:</i>	
<b>Medications Administered Section</b> 29549-3 2.16.840.1.113883.10.20.22.2.38:2014-06-09	This section usually resides inside a Procedure Note describing a procedure. This section defines medications and fluids administered during the procedure, its related encounter, or other procedure related activity excluding anesthetic medications.
<b>Anesthesia Section</b> 59774-0 2.16.840.1.113883.10.20.22.2.25:2014-06-09	This section records the type of anesthesia (e.g., general or local) and may state the actual agent used. This may be a subsection of the Procedure Description Section. The full details of anesthesia are usually found in a separate Anesthesia Note.
<b>Procedure Indications Section</b> 59768-2 2.16.840.1.113883.10.20.22.2.29:2014-06-09	This section contains the reason(s) for the procedure or surgery. This section may include the pre-procedure diagnoses as well as symptoms contributing to the reason for the procedure.
<b>Medical Equipment Section</b> 46264-8 urn:hl7ii:2.16.840.1.113883.10.20.22.2.23:2014-06-09	This section contains devices that have been placed in a patient. This section is also relevant for recording information about non-implanted medical equipment and non-medicinal supplied equipment (e.g. wheelchair, hearing aid, walker). <b>Reference:</b> 5.2.8 Medical Equipment
<b>Complications Section</b> 55109-3 2.16.840.1.113883.10.20.22.2.37:2015-08-01	This section contains problems that occurred during or around the time of a procedure. The complications may be known risks or unanticipated problems.
<b>DICOM Object Catalog Section</b> DCM: 121181 2.16.840.1.113883.10.20.6.1.1	DICOM Object Catalog lists all referenced objects and their parent Series and Studies, plus other DICOM attributes required for retrieving the objects. DICOM Object Catalog sections are not intended for viewing and contain empty section text.

Sections defined in C-CDA R2.1 LONIC OID	Purpose Description
<b>Findings Section (DIR)</b> DCM: 11070 2.16.840.1.113883.10.20.6.1.2	This section contains the main narrative body of the report. While not an absolute requirement for transformed DICOM SR reports, it is suggested that Diagnostic Imaging Reports authored in CDA follow Term Info guidelines for the codes in the various observations and procedures recorded in this section.

Table 32: Objective Information

### 4.3.3 Assessment Information

Sections defined in C-CDA R2.1 LONIC OID	Purpose Description
<b>Assessment Section</b> 51848-0 2.16.840.1.113883.10.20.22.2.8	This section (also referred to as “impression” or “diagnoses” outside of the context of CDA) represents the clinician’s conclusions and working assumptions that will guide treatment of the patient. The assessment may be a list of specific disease entities or a narrative block.
<b>Assessment and Plan Section</b> 51847-2 2.16.840.1.113883.10.20.22.2.9:2014-06-09	This section represents the clinician’s conclusions and working assumptions that will guide treatment of the patient. The Assessment and Plan Section may be combined or separated to meet local policy requirements. Best practice is to separate these distinct types of information by using the Assessment Section: templated 2.16.840.1.113883.10.20.22.2.8 and the Plan of Treatment Section (V2): templated 2.16.840.1.113883.10.20.22.2.10:2014-06-09 <b>Reference:</b> Chapter 4.3 Sections Defined in C-CDA
<b>Specific to Inpatient Encounter Notes:</b>	
<b>Discharge Diagnosis Section</b> 11535-2 2.16.840.1.113883.10.20.22.2.24:2015-08-01	This section represents problems or diagnoses present at the time of discharge which occurred during the hospitalization. This section includes an optional entry to record patient diagnoses specific to this visit. Problems that need ongoing tracking should also be included in the Problem Section.
<b>Specific to Procedure and Operative Notes:</b>	
<b>Postprocedure Diagnosis Section</b> 59769-0 2.16.840.1.113883.10.20.22.2.36:2015-08-01	This section records the diagnosis or diagnoses discovered or confirmed during the procedure. Often it is the same as the preprocedure diagnosis or indication.
<b>Postoperative Diagnosis Section</b> 10219-4 2.16.840.1.113883.10.20.22.2.35	This section records the diagnosis or diagnoses discovered or confirmed during the surgery. Often it is the same as the preoperative diagnosis.

Table 33: Assessment Information

4.3.4 Plan/Planning Information

Sections defined in C-CDA R2.1 LONIC OID	Purpose Description
<b>Goals Section</b> 61146-7 2.16.840.1.113883.10.20.22.2.60	This section represents patient Goals. A goal is a defined outcome or condition to be achieved in the process of patient care. Goals include patient-defined over-arching goals and health concern-specific or intervention-specific goals to achieve desired outcomes.
<b>Advance Directives Section</b> 42348-3 Entries optional: 2.16.840.1.113883.10.20.22.2.21:2015-08-01 Entries required: 2.16.840.1.113883.10.20.22.2.21.1:2015-08-01	This section contains data defining the patient’s advance directives and any reference to supporting documentation, including living wills, healthcare proxies, and CPR and resuscitation status. If the referenced documents are available, they can be included in the exchange package.
<b>Assessment and Plan Section</b> 51847-2 2.16.840.1.113883.10.20.22.2.9:2014-06-09	This section represents the clinician’s conclusions and working assumptions that will guide treatment of the patient. The Assessment and Plan Section may be combined or separated to meet local policy requirements. Best practice is to separate these distinct types of information by using the Assessment Section: templated 2.16.840.1.113883.10.20.22.2.8 and the Plan of Treatment Section (V2): templated 2.16.840.1.113883.10.20.22.2.10:2014-06-09  <b>Reference:</b> 4.3 Sections Defined in C-CDA
<b>Plan of Treatment Section</b> 18776-5 2.16.840.1.113883.10.20.22.2.10:2014-06-09	This section, formerly known as "Plan of Care", contains data that define pending orders, interventions, encounters, services, and procedures for the patient. It is limited to prospective, unfulfilled, or incomplete orders and requests only. All active, incomplete, or pending orders, appointments, referrals, procedures, services, or any other pending event of clinical significance to the current care of the patient should be listed.
<b>Instructions Sections</b> 69730-0 2.16.840.1.113883.10.20.22.4.20:2014-06-09	This section can be used in several ways, such as to record patient instructions within a Medication Activity or to record fill instructions within a supply order.
<b>Specific to Procedure and Operative Notes:</b>	
<b>Planned Procedures Section</b> 59772-4 2.16.840.1.113883.10.20.22.2.30:2014-06-09	This section contains the procedure(s) that a clinician planned based on the preoperative assessment.
<b>Specific to Inpatient Encounter Notes:</b>	
<b>Hospital Discharge Instructions Section</b> 8653-8 2.16.840.1.113883.10.20.22.2.41	This section records instructions at discharge.

Table 34: Plan/Planning Information



4.3.5 Other Information

Sections defined in C-CDA R2.1 LONIC OID	Purpose Description
<p><b>Encounters Section</b> 46240-8 Entries optional: 2.16.840.1.113883.10.20.22.2.22:2015-08-01 Entries required: 2.16.840.1.113883.10.20.22.2.22.1:2015-08-01 2.16.840.1.113883.10.20.22.2.18:2015-08-01</p>	<p>This section is relevant in nearly all documents. It lists and describes any healthcare encounters pertinent to the patient’s current health status or historical health history. An encounter is an interaction, regardless of the setting, between a patient and a practitioner who is vested with primary responsibility for diagnosing, evaluating, or treating the patient’s condition. It may include visits, appointments, or non-face-to-face interactions. An encounter also may be a contact between a patient and a practitioner who has primary responsibility (exercising independent judgment) for assessing and treating the patient at a given contact. This section may include a single encounter in an Encounter Summary. It contains relevant encounters for the time period being summarized in a Patient Summary Document.</p>
<p><b>Payers Section</b> 48768-6 2.16.840.1.113883.10.20.22.2.18:2015-08-01</p>	<p>This section contains data on the patient’s payers, "third party" insurance, self-pay, other payer or guarantor, or some combination of payers, and is used to define which entity is the responsible fiduciary for the financial aspects of a patient’s care. Each unique instance of a payer and all the pertinent data needed to contact, bill to, and collect from that payer should be included. Authorization information that can be used to define pertinent referral, authorization tracking number, procedure, therapy, intervention, device, or similar authorizations for the patient or provider, or both should be included. At a minimum, the patient’s pertinent current payment sources should be listed.</p>

Table 35: Other Information

4.4 Supplemental C-CDA Section Templates

The following table defines section templates that supplement C-CDA. They are defined within the context of C-CDA Supplemental Guides that have been balloted and reconciled separately from C-CDA but with the intention of eventually replacing earlier version of the templates in C-CDA or eventually being added to be set of templates considered a part of the C-CDA set of templates.

Sections defined in this C-CDA Companion Guide LONIC OID	Purpose Description
<i>Specific to Documenting a Person’s Pregnancy Status:</i>	

Sections defined in this C-CDA Companion Guide LONIC OID	Purpose Description
<b>Pregnancy Section</b> 90767-5 2.16.840.1.113883.10.20.22.2.80:2018-04-01	This section is a supplemental C-CDA template contains a patient’s current and past pregnancy history information. This template and any of its contained templates are available for use in any of the existing C-CDA document types and any other related document types that need to record pregnancy information, for example, C-CDA transition of care document types such as CCD, Transfer Summary, Discharge Summary, and Consultation Note as well as non-C-CDA documents such as the Public Health Case Report, Release 2 - US Realm - the Electronic Initial Case Report (eICR).
<i>Specific to Documenting a Person’s Advance Directives:</i>	
<b>Advance Directives Section</b> 42348-3 Entries Optional: 2.16.840.1.113883.10.20.22.2.21:2017-05-01 Entries required: 2.16.840.1.113883.10.20.22.2.21.1:2017-05-01	This section is a New Version of an existing C-CDA Section. It is backward compatible and meets the conformance required by the existing C-CDA Section (Advance Directives section 2.16.840.1.113883.10.20.22.2.21:2015-08-01, and 2.16.840.1.113883.10.20.22.2.21.1:2015-08-01)  This section contains information describing the patient’s advance directives. The description includes the kind of advance directive source documents and the type of advance directive content included in each kind of advance directive source document. The section includes information about who verified the content available in each advance directive source document, if applicable. It also includes information about who was the acting healthcare agent, if someone was acting on behalf of the patient during the encounter or during certain periods of time during the provision of care covered by the document. It provides references to the supporting documentation, including all kinds of advance directive source documents.
<i>Specific to Nutrition Care Plan Documents:</i>	
<b>Assessments, Evaluations, and Outcomes Section (Nutrition)</b> 11383-7 2.16.840.1.113883.10.20.22.2.68:2017-12-01	This section is a supplemental C-CDA template. In addition to its defined use in the Care Plan (Nutrition) hierarchy (see Contexts table above), this template is for supplemental use in a C-CDA Care Plan document.  This section contains a specialized outcome observation for nutrition.
<b>Health Concerns Section (Nutrition)</b> 75310-3 2.16.840.1.113883.10.20.22.2.67:2017-12-01	This section is a supplemental C-CDA template. In addition to its defined use in the Care Plan (Nutrition) hierarchy (see Contexts table above), this template is for supplemental use in a C-CDA Care Plan document.  The Nutrition Diagnosis is expressed using nutrition diagnostic terms and the etiologies, signs, and references symptoms recorded in the Assessments, Evaluations, and

Sections defined in this C-CDA Companion Guide LONIC OID	Purpose Description
	Outcomes section identified during the nutrition assessment.
<b>Interventions Section (Nutrition)</b> 62387-6 2.16.840.1.113883.10.20.22.2.69:2017-12-01	This template is a supplemental C-CDA template. In addition to its defined use in the Care Plan (Nutrition) hierarchy (see Contexts table above), this template is for supplemental use in a C-CDA Care Plan document.  Nutrition Intervention consists of two interrelated components: planned and completed interventions. The Nutrition Intervention is typically directed toward resolving the nutrition diagnosis or the nutrition etiology less often, it is directed at relieving signs and symptoms and attaining health goals.

Table 36: Supplemental C-CDA Sections

## 4.5 New and Additional C-CDA Section Templates (Defined in this Companion Guide)

The following table defines new section templates defined within the context of this Companion Guide.

Section Name LONIC OID	Purpose Description
<b>Care Teams Section</b> 85847-2 Entries optional: 2.16.840.1.113883.10.20.22.2.500:2019-07-01	This section is used to share historical and current Care Team information.  The Care Team Section may be included in any type of C-CDA structured document that is an open template.  An individual can have more than one Care Team. A Care Team can exist over time such as a longitudinal care team which includes historical members that may be active or inactive on the care team as needed. Or a Care Team, such as a rehabilitation team, may exist to address a person’s needs associated with a particular care event, or a team can be based on addressing a specific condition.  The Care Team Organizer entry template used in the C-CDA Care Teams Section is meant to support foundational Care Team and Care Team member information that forms the basis for effective communication, interaction channels and maintenance of current

Section Name LONIC OID	Purpose Description
	clinical context awareness for the patient, caregivers and care providers to promote care coordination.
<b>Notes Section</b> 86744-0 Entries required: 2.16.840.1.113883.10.20.22.2.65:2016-11-01	This section allows for inclusion of clinical documentation which does not fit precisely within any other C-CDA section. Multiple Notes sections may be included in a document provided they each include different types of note content as indicated by a different section.code. The Notes Section is not used in place of a more specific a C-CDA section. For example, notes about procedure should be placed within the Procedures Section, not a Notes Section.  When a Notes Section is present, Note Activity entries contain structured information about the note information allowing it to be more machine processable.

Table 37: New and Additional C-CDA Sections

## 4.6 Sections Defined in Other Implementation Guides

The table below summaries other section templates available by reference from C-CDA Supplemental IGs and CDA R2 IGs developed by other stakeholders in the C-CDA implementer community.

NOTE: The HL7 CDA Release 2 Implementation Guide: Additional CDA R2 Templates – Clinical Documents for Payers Set 1, Release 1 – US Realm<sup>105</sup> specification indicates which document types SHALL include the more tightly constrained or additional templates required for exchanging information with payers using C-CDA documents.<sup>106</sup> The table also summarizes any tighter expectations for requiring other C-CDA sections to be included in the structured documents.<sup>107</sup>

Implementation guides developed within the Payer C-CDA implementer community tighten the constrains on four existing sections and defines three new sections.

Implementers with the Payer and broader HIT C-CDA implementer community have started utilizing section templates defined by the Quality C-CDA implementer community to express and exchange information about care gaps that exist for individual patients. The templates used for this use case are re-used from the QRDA Cat I implementation guide.

<sup>105</sup> [http://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=410](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=410)

<sup>106</sup>HL7 CDA® Release 2 Implementation Guide: Additional CDA R2 Templates -- Clinical Documents for Payers – Set 1, Release 1 – US Realm. Page 123.

<sup>107</sup>HL7 CDA® Release 2 Implementation Guide: Additional CDA R2 Templates -- Clinical Documents for Payers – Set 1, Release 1 – US Realm, Table 24. page 125

Section Name	Purpose Description
<p>LONIC OID</p> <p><b>Measure Section QDM<sup>108</sup></b> 55186-1 2.16.840.1.113883.10.20.24.2.3</p>	<p>This section template contains information about the measure or measures being reported. This section references the measure through reference to an externalDocument. The externalDocument/ids and version numbers are used to reference the measure. The measure section must contain a reference to at least one externalDocument id of all the measures being reported in the QRDA instance.</p> <p>NOTE: Only measure information is included in this section. The clinical data that support quality calculation could be included in other sections (e.g. problems, procedures, results, vital signs, etc.)<sup>109</sup></p>
<p><b>Functional Status Section (CDP1)<sup>110</sup></b> 47420-5 2.16.840.1.113883.10.20.22.2.14:2014-06-09</p>	<p>The Functional Status Section contains observations and assessments of a patient's physical abilities. A patient's functional status may include information regarding the patient's ability to perform Activities of Daily Living (ADLs) in areas such as Mobility (e.g., ambulation), Self-Care (e.g., bathing, dressing, feeding, grooming) or Instrumental Activities of Daily Living (IADLs) (e.g., shopping, using a telephone, balancing a check book). Problems that impact function (e.g., dyspnea, dysphagia) can be contained in the section.</p>
<p><b>Plan of Treatment Section (CDP1)<sup>111</sup></b> 18776-5 2.16.840.1.113883.10.20.35.2.6</p>	<p>This section, formerly known as "Plan of Care", contains data that define pending orders, interventions, encounters, services, and procedures for the patient. It is limited to prospective, unfulfilled, or incomplete orders and requests only.</p> <p>This Plan of Treatment Section (CDP1) requires a response for all entry templates. It requires explicitly recording when information is not available in the source system to populate a required entry template.</p>
<p><b>Social History Section (CDP1)<sup>112</sup></b> 29762-2 2.16.840.1.113883.10.20.35.2.7</p>	<p>This section contains social history data that influences a patient's physical, psychological or emotional health (e.g. smoking status, pregnancy). Demographic data, such as marital status, race, ethnicity, and religious affiliation, is captured in the header.</p> <p>This Social History Section (CDP1) requires a response for all entry templates. It requires explicitly recording when information is not available in the source system to populate a required entry template.</p>

<sup>108</sup> HL7 QRDA Cat 1, Measure Section QDM

<sup>109</sup> HL7 CDA Examples Search. Quality Care Compliance in C-CDA. <http://hl7-c-cda-examples.herokuapp.com/sections/Quality>

<sup>110</sup> HL7 CDA® Release 2 Implementation Guide: Additional CDA R2 Templates -- Clinical Documents for Payers – Set 1, Release 1 – US Realm. Page 132.

<sup>111</sup> HL7 CDA® Release 2 Implementation Guide: Additional CDA R2 Templates -- Clinical Documents for Payers – Set 1, Release 1 – US Realm. Page 141.

<sup>112</sup> HL7 CDA® Release 2 Implementation Guide: Additional CDA R2 Templates -- Clinical Documents for Payers – Set 1, Release 1 – US Realm. Page 147.

Section Name	Purpose Description
LONIC OID	
<b>Additional Documentation Section (CDP1)<sup>113</sup></b> 77599-9 2.16.840.1.113883.10.20.35.4.11	The Additional Documentation Section (CDP1) contains additional documentation captured by the provider related to administrative requirements or care provided/planned for the patient, that is not supported in any other section of the document. (example: statement of no financial relationship with a service supplier). <sup>114</sup>
<b>Externally Defined CDE Section (CDP1)<sup>115</sup></b> 77598-1 2.16.840.1.113883.10.20.35.2.2	The Externally Defined CDE Section (CDP1) contains externally defined Clinical Data Elements (CDEs) that have been created through the interaction of the provider with externally defined templates (or questionnaires) that define name-value pairs and a reference to the externally defined information/content model. <sup>116</sup>
<b>Orders Placed Section (CDP1)<sup>117</sup></b> 77597-3 2.16.840.1.113883.10.20.35.2.3	The Orders Placed Section (CDP1) contains active and completed (not planned) orders for observations, interventions, encounters, services, and procedures for the patient. The entries in this section represent the details of the orders and not the acts involved in the processing and fulfilment of the order. This section includes order information in order to validate that clinical activities performed by other providers and suppliers are authorized by the responsible provider. <sup>118</sup>  Implementers may want to consider utilizing the Section Time Range template and apply business rules to limit the amount of information that would be included in this section.

Table 38: Sections defined in other Implantation Guides

<sup>113</sup> HL7 CDA® Release 2 Implementation Guide: Additional CDA R2 Templates -- Clinical Documents for Payers – Set 1, Release 1 – US Realm. Page 161.

<sup>114</sup> HL7 CDA® Release 2 Implementation Guide: Additional CDA R2 Templates -- Clinical Documents for Payers – Set 1, Release 1 – US Realm. Page 129

<sup>115</sup> HL7 CDA® Release 2 Implementation Guide: Additional CDA R2 Templates -- Clinical Documents for Payers – Set 1, Release 1 – US Realm. Page 131.

<sup>116</sup> HL7 CDA® Release 2 Implementation Guide: Additional CDA R2 Templates -- Clinical Documents for Payers – Set 1, Release 1 – US Realm. Page 131.

<sup>117</sup>HL7 CDA® Release 2 Implementation Guide: Additional CDA R2 Templates -- Clinical Documents for Payers – Set 1, Release 1 – US Realm. Page 137.

<sup>118</sup> HL7 CDA® Release 2 Implementation Guide: Additional CDA R2 Templates -- Clinical Documents for Payers – Set 1, Release 1 – US Realm. Page 137.

## 5 Representation of Discrete Data

The full potential of our Health IT infrastructure can only be realized when the health information being shared includes the corresponding discrete data that makes modern computing opportunities possible. Computer aided processing and analysis is only possible when the information in clinical notes conveyed by standardized structured data documents also includes machine processable representation of the data. Discrete data drives data analytics and data analytics holds the potential to revolutionize care delivery while accelerating the shift toward value-based care and innovations that improve the healthcare experience.

### 5.1 General Entry-Level Guidance

The guidance below pertains when document sections include machine processable discrete data to aid processing of information contained in the section. The following general entry-level guidance is applicable to all C-CDA entry templates.

#### 5.1.1 Narrative Text Linking (Referencing)

Best practice for CDA creation is to represent all human readable text in the section, then reference the text from the discrete entries that represent the human readable information as machine processable data. To include narrative text linking, the text element of the primary (outer-most) act in an entry should point, by reference, to the portion of the narrative text corresponding to the meaning of the entire clinical statement expressed in the discrete entry.

#### *Example 22: Narrative Text with Links to Machine Processable Data*

```

<section>
  <templateId root="2.16.840.1.113883.10.20.22.2.7.1" extension="2014-06-09"
  assigningAuthorityName="HL7 CCD" />
  <code code="47519-4" displayName="Procedures" codeSystem="2.16.840.1.113883.6.1"
  codeSystemName="LOINC" />
  <title>Procedures</title>
  <text>
    <table border="1" width="100%">
      <thead>
        <tr>
          <th>Procedure Name</th>
          <th>Code</th>
          <th>CodeSystem</th>
          <th>Target Site</th>
          <th>Date of Procedure</th>
        </tr>
      </thead>
      <tbody>
        <tr id=PROCEDURESUMMARY_1>
          <td id=PROCEDURE_1>Skin care: graft site</td>
          <td >406177009</td>
          <td >SNOMED CT</td>
          <td >11207009 (Structure of right thigh)<thigh) </td>
          <td >2015-06-23</td>
        </tr>
      </tbody>
    </table>
  </text>
  <entry typeCode="DRIV">
    <procedure classCode="PROC" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.22.4.14" extension="2014-06-09" />

```

```

<id root="93ad269d-40a6-4d71-bcc6-6978598820d9" />
<code code="406177009" displayName="Skin care: graft site"
codeSystem="2.16.840.1.113883.6.96">
  <originalText>
    <reference value="#PROCEDURE_1" />
  </originalText>
</code>
<text><reference value="#PROCEDURESUMMARY_1" /></text>
<statusCode code="completed" />
<effectiveTime value="20150623" />
<methodCode nullFlavor="UNK" />
<targetSiteCode code="11207009" displayName="Structure of right thigh"
codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" />
<author>
  <templateId root="2.16.840.1.113883.10.20.22.4.119" />
  <time value="20150623" />
  <assignedAuthor>
    <id extension="db659e09-b0b0-4e51-a6e9-7eb5abdae4e4" />
    <code nullFlavor="UNK" />
    <assignedPerson>
      <name nullFlavor="NI"/>
    </assignedPerson>
  </assignedAuthor>
</author>
</procedure>
</entry>

```

In accordance with general CDA principles for human readability, every CDA shall be viewable through the use of a CDA stylesheet. Since many vendors and document sources wish to distinguish their expertise by using specific stylesheets, it is important to test early and often to make sure that the text has not become overly complicated, to the point where only the producing system can render the text with the specific stylesheet. Obviously, document sources cannot test with all other CDA stylesheets, but it is recommended to regularly test using the HL7 CDA stylesheet approved by SDWG and managed in the HL7 GitHub.<sup>119</sup>

### 5.1.2 OriginalText

When a CDA document section contains coded discrete entries (such as allergy, medication, problem, etc. to support machine processing of the available human readable information), coded data within the discrete entry MAY include an originalText element to link the coded information back to the original human readable information represented by that code. The use of code/originalText/reference and value/originalText/reference should be used where it is useful to point to the human readable information associated with more specific areas within the narrative related to a specific coded element within a discrete entry.

Narrative text linking from the text element in the entry (for the entire discrete entry, meaning the entire machine processable clinical statement) and from the originalText element (for a specific part of the clinical statement) referencing from coded concepts in the entry can be used together to provide very tight correspondences between human readable and machine processable information.

<sup>119</sup> <https://hl7.org/permalink/?CDAStyleSheet>





Coded entries MAY include an originalText element to link the coded data back to the associated human readable information represented by that code. **[CONF-061]**

It should be noted there is no requirement that CDA entries must reference into the CDA Narrative Block. The referencing mechanism can be used where it is important to represent the original text component of a coded CDA entry.<sup>120</sup>

It should be noted that sometimes the original text will be repeated in the originalText element rather than using a reference link into the narrative text. This is not incorrect and should not be flagged as an error. In this case, the originalText element, allows the human readable information to include a quality check. However, the HL7 CDA standard recommends use of narrative text linking to minimize mismatch errors where the human readable narrative information is not identical to the original text.

*Example 23: originalText used to record the term actually selected from the EHR*

```
<code code="9999123"
  displayName="Obsessional thoughts of augmented reality video
games" codeSystem="2.16.840.1.113883.6.96">
  <originalText><reference value="#Obsessive thoughts related to video
games"/></originalText>
</code>
```

*Example 24: originalText linking the coded concept used in the machine entry to the narrative*

originalText linking the coded concept used in the machine entry to the narrative that was actually stated by the clinician or what was actually in the EHR when this problem was entered by the clinician. Narrative text linking is the preferred method of representation because it eliminates the possibility for mismatch between the attested content in the section.text and what was actually seen or said by the clinician.

```
<code code="9999123"
  displayName="Obsessional thoughts of augmented reality video
games" codeSystem="2.16.840.1.113883.6.96">
  <originalText><reference value="#Problem_1"/></originalText>
</code>
```

The originalText contains what the human stated or the terms selected from the EHR user interface.

NOTE: The C-CDA specification does not currently include an explicit coded indicator to define whether the narrative text contains additional information beyond the coded data or not. Narrative text and user selected terms may routinely have more robust content than the structured entries. The narrative text may contain additional nuances and should never be ignored by receiving systems.



The originalText attribute SHOULD reference text in the Narrative Block which mirrors what the clinician saw or selected in the user interface of the system that created the source data. **[BP-062]**

Consequently, it is also valuable to send the local code that represents the originalText as

<sup>120</sup> HL7 CDA. Chapter 4.2.5.1 Content.

a translation, along with one or more translations to publicly defined code systems. This practice is encouraged in FHIR when using data elements of type `CodableConcept`<sup>121</sup>. In CDA this can be accomplished through `translationCode`.

The following best practices were agreed upon by HL7 SD Work Group and the HL7 Vocabulary Work Group in January of 2017<sup>122</sup>:

- The `@code` attribute for a data element of type Coded Data (CD) SHALL use a code from a nationally recognized code system as identified in the ONC Interoperability Standards Advisory.<sup>123</sup>
- The `originalText` property MAY capture the text that the clinician captured or selected in the user interface of the system used in creating the data element instance
- A code that represents the meaning for the `originalText` drawn from custom interface terminologies or another (local) code system according to agreement of the trading partners MAY be populated in `translation.Code`
- When a code is populated in `translation.Code`, it SHALL be more specific than the best available standard code system code
- A code populated in `translation.Code` SHALL NOT be broader than the code populated in the `Code` property

*Example 25 TranslationCode, with originalText and local coded term*

```
<value xsi:type="CD" code="254838004" displayName="Carcinoma of Breast"
codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" >
  <originalText>
    <reference value="#problem1"></reference>Carcinoma of right breast, stage 2, estrogen
receptor
    positive</originalText>
    <!-- User Selected Term Coding -->
    <translation code="40780512" displayName="Carcinoma of right breast, stage 2, estrogen
receptor
    positive" codeSystem="2.16.840.1.113883.3.247.1.1"
codeSystemName="EHRorInterfaceTerminologyCodeSystem"/>
    <!-- "Secondary" Codes -->
    <translation code="174.9" codeSystem="2.16.840.1.113883.6.103" codeSystemName="ICD-9CM"
displayName="Malignant neoplasm of breast (female), unspecified site"/>
    <translation code="C50.911" codeSystem="2.16.840.1.113883.6.90" codeSystemName="ICD-10-CM"
displayName="Malignant neoplasm of unspecified site of right female breast"/>
    <translation code="416053008" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED
CT"
    displayName="Estrogen receptor positive tumor"/>
  </value>
```

### 5.1.3 DisplayName Representation

When sending coded information, the CD datatype (most commonly used in `<code>` and `<value>` elements) has a `displayName` element. This element is intended to be a valid human

<sup>121</sup> <https://www.hl7.org/fhir/datatypes.html#CodeableConcept>

<sup>122</sup> <https://confluence.hl7.org/display/VOC/Vocabulary+WG+Policy+on+Use+of+translationCode+in+the+V3+%28and+CDA%29+D+atatypes>

<sup>123</sup> <https://www.healthit.gov/isa/>

readable representation of the concept defined by the code system and associated with the 'code' element at the time of data entry. As an example, for LOINC codes, the 'displayName' element should convey either the short name or long name in LOINC for the code used in the associated code element.



The displayName attribute SHALL NOT modify the meaning of the code. **[BP-063]**  
Note: Testability requires fuzzy match capabilities.

The guidance for the use of the 'displayName' element are:

- display name is included as a courtesy to an unaided human interpreter of a coded value.
- display name adds no semantic meaning to the coded information, and it SHALL never exist without an associated code.
- display name may not be present if the code is an expression for which no display name has been assigned or can be derived in the associated code system.
- display name element must accurately represent the concept associated with the @code attribute of the associated code or value element.



The displayName attribute MAY be included where syntactically allowed. **[BP-064]**



The displayName attribute SHALL never exist without an associated code. **[CONF-065]**

When a CDA document includes coded data in discrete entries (such as allergen, medication, problem, etc.) to support machine processing, every discrete entry SHOULD include a text element that references the human readable representation of the information discretely represented by a code.

For example, say a new version of SNOMED is released with a new problem code of 99999123 and a display name of "Obsessional thoughts of augmented reality video games" and this code is used in a Problem Observation. If neither originalText nor display were included in the xml entry, the human readable narrative for the entry could only say, "Problem 99999123 began on July 6, 2016 as noted by Dr. Ishihara." This would violate the core CDA principal of human readability.



C-CDA Content Creators SHOULD include a human readable representation of the concept associated with the code as defined by the code system in the @displayName attribute of a code element. **[BP-066]**



C-CDA Content Validators MAY require a fuzzy match between the @displayName attribute of a code element and the preferred concept description for the code as defined by the associated code system. **[CONF-067]**

*Example 26: Code Display Name Representation*

```

<code code="9999123"
  displayName="Obsessional thoughts of augmented reality video
games" codeSystem="2.16.840.1.113883.6.96">
  <originalText><reference value="#PROBLEM1"/></originalText>
</code>

```

**5.1.4 Use of Consistent Identifiers**

The id element represents a globally unique identifier for a collection of data, be it a document, section, entry, or sub-entry (such as an author).

Within a document ids should be used consistently, for example, every instance of the same provider throughout a document should have the same id.

Within different document instances generated by the same system, the identifiers would also be the same when representing the same source information. If the information in the source system is not treated as “the same information”, then a different identifier would be used.

When to treat information as “the same” or “different” is a system design issue and may vary from source system to source system under certain scenarios when the data is changing. However, use of consistent ids is a best practice that should be expected when information has not changed.

For example, if a CCD is created for a patient with an allergy to penicillin, the next time a C-CDA document is generated by that same system for that same patient, the id associated with the penicillin allergy in the generated document and the id associated with the penicillin allergy in the previously generated document should be the same.

If the allergy has changed (such as adding a new comment or changing the severity of a reaction), but it is still internally treated by the system as the same piece of data, it should keep the same identifier. However, if the entry has changed and the source system represents the changed information as a new instance of data, then the information should contain a new id. For example, if a patient’s prescription for medication X changes in such a way that the source system considers this a new prescription, it will have a new id, even if the new prescription may still be for medication X. The new id helps the recipient system differentiate the new prescription from the previous prescription.

Using consistent identifiers helps with reconciliation of discrete data. If the penicillin allergy cited before was received and incorporated into a recipient system, then use of a consistent id makes it easier for the previously received information to be identified. If, however, a newly generated id is sent with each new document reporting on this allergy, then the allergy information appears to the recipient system as a brand-new allergy each time. More complex decision logic must be performed to identify a match to an existing allergy. Consistent ids can increase the accuracy of this complex matching step. The use of consistent ids for a specific instance of a problem, medication statement or allergy, etc., improves the possibility that a recipient system can identify and relate newly received information to an instance of the data that may already be in the recipient system.

One approach for implementing consistent unique ids is to maintain multiple Globally Unique Identifiers (GUIDs) for each object in the database. When a recipient system stores multiple GUIDs in its database, it can use its full set of GUIDs to help match incoming information with information that has been received previously. Also, when content is imported from another system and the identifiers are maintained, these identifiers can be used to improve communication back to the other system. For example, if system A imports information from system B, and then subsequently sends information back to system B, system A can include system B's identifiers to help system B identify information that has been updated by system A.

Another consideration is to use Object Identifiers (OIDs) to identify the assigning authority for each GUID. This requires some management to make sure the OID is globally unique. A vendor or specific implementation of software typically owns a unique OID that forms the root of all their ids. Unique branches can then be created for each implementation, server, data type, and record.

CDA id elements contain two elemental parts: a root (which must be a GUID or an OID) and an optional extension (which can be any string of characters). If the extension is present, the combination of root + extension must be globally unique. This can allow a hybrid approach for either using GUIDs or OIDs. For example, a GUID or OID may be created for a local instance of an entire allergy database and sent as the root, and then the local identifier (such as a database row number, a filename, or any other string) of the allergy can be sent as the extension.

A vendor may use any approach for generating valid GUIDs.



Content Creators SHOULD include ids to identify pieces of information and use consistent ids for the same piece of information **[BP-068]**

### 5.1.5 Use of nullFlavor and Handling Missing Information

Chapter 3.6 of the C-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 reason 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 is encouraged to convey the reason that required or expected data is missing. The null flavor vocabulary domain within the CDA R2 standard details the complete hierarchy of null flavor values.

The @nullFlavor attribute conveys significant information, especially when used with intervals. For example, in a Tobacco Use observation, where the effectiveTime represents the clinically relevant time a code applies, an effectiveTime/high/@nullFlavor="UNK" indicates that the patient no longer uses whatever tobacco product is represented by value but that the exact time when the patient stopped using the product is unknown. If the nullFlavor were NA (not applicable), then the end time is not applicable which means the patient is still a user (however,

since high effectiveTime is an optional field, the preferred way to communicate this is to omit the element entirely). Most other nullFlavors in this example (NI – no information, NAV – not available, NASK – not asked) convey the uncertainty of whether the patient is still a user of the substance.

*Example 27: Tobacco Use – Current Smoker with an unknown stop date*

```
<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.22.4.78"/>
  <templateId root="2.16.840.1.113883.10.20.22.4.78" extension="2014-06-09"/>
  <id extension="64020-Z9301" root="1.2.840.114350.1.13.6289.1.7.1.1040.1"/>
  <code code="72166-2" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
  displayName="Tobacco smoking status NHIS"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="20100412"/>
    <high nullFlavor="UNK"/>
  </effectiveTime>
  <value code="77176002" codeSystem="2.16.840.1.113883.6.96" displayName="Smoker"
  xsi:type="CD" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"/>
</observation>
```

*Example 28: Tobacco Use – Smoker where cessation date was not asked*

```
<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.22.4.78"/>
  <templateId root="2.16.840.1.113883.10.20.22.4.78" extension="2014-06-09"/>
  <id extension="64020-Z9301" root="1.2.840.114350.1.13.6289.1.7.1.1040.1"/>
  <code code="72166-2" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
  displayName="Tobacco smoking status NHIS"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="20100412"/>
    <high nullFlavor="NASK"/>
  </effectiveTime>
  <value code="77176002" codeSystem="2.16.840.1.113883.6.96" displayName="Smoker"
  xsi:type="CD" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"/>
</observation>
```

This is also conveyed in Chapter 3.3 of volume one of C-CDA 2.1. If the resolution to a problem is not known, its effectiveTime/high should contain a value or nullFlavor=UNK. If the nullFlavor=NA, then the problem is definitely *not* resolved. And if the nullFlavor is anything else, then it is unclear as to whether the problem is still active or if it has been resolved.

The @nullFlavor attribute also conveys when information is unknown. However, a nullFlavor SHALL NOT be used to bypass IG requirements for convenience (*e.g.* you may send a nullFlavor=UNK for a patient's birthTime when it is not recorded in a chart, but you must not send it simply because it is too difficult to convert the method your system uses to record birth dates to an HL7 timestamp). NullFlavor attributes need not be included for non-required elements, such as religiousAffiliationCode. If an element is optional and unknown, it may simply be omitted.

### 5.1.6 Unknown Data in Sections That Require Entries

The following guidelines clarify the use of the “No Information” nullflavor=“NI” pattern for a section with no information:



If a document template requires a section to be present and the source system contains no information to populate the section:

- The section SHALL be included in the xml and SHALL be declared as having no information.
- If the source system contains no information to populate a section that is not required (with a SHALL conformance statement) in the document template:
- The section MAY be omitted, or the section MAY be included and declared as having no information. **[BP-069]**

The machine-readable data required within these sections are specified for clinical best practice and should not be completely omitted unless the entire section contains no information (section/@nullFlavor=NI). In these instances, unknown information may be used on the specific act, such as a Procedure Activity. Additionally, text describing the reason for the unknown information and a code indicating the nature of the 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 3.6 of the C-CDA Implementation Guide. The 2015 Edition Certification Criteria also reinforce this concept:

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.” The applicable document must include the section and a null value. For these sections, the narrative text must explicitly indicate that the information is unknown.

*Example 29: No Information Problems Section*

```
<!-- ***** PROBLEM LIST ***** -->
<component>
  <!-- nullFlavor of NI indicates No Information.-->
  <section nullFlavor="NI">
    <!-- conforms to Problems section with entries optional -->
    <templateId root="2.16.840.1.113883.10.20.22.2.5" extension="2015-08-01"/>
    <code code="11450-4" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
      displayName="PROBLEM LIST"/>
    <title>PROBLEMS</title>
    <text>No Information</text>
  </section>
</component>
```

### 5.1.7 Representing “no known” Information Versus “no information”

There is a distinction to be made between representing “no information” and representing “no known information.” In the case of “no known information,” the author is not explicitly asserting the presence or absence of information for the data element. “No information” is an explicit assertion that there is no information for that data element in the system.



It is the difference between these statements: “I don’t know if the patient has any allergies” (no information) and “The patient states that he is not allergic to anything” (no known).

In cases where “no known” information is being asserted, negation indicators should be used. A negation indicator (negationInd) is used to flag the act as described in the third example within Chapter 3.6 of the C-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.

When representing the concept of “no known” information, ambiguity for the use of negationInd within the observation acts resulting from limitations of the earlier RIM version used by CDA R2 is acknowledged. Specific examples have been adopted for frequently needed negation semantics such as “no known problems” and “no known allergies”. In the future observation templates need to expressly define if the default actionNegationInd behavior is intended or if negationInd is intended to function as a valueNegationInd. This will need to be addressed in a future version of C-CDA.

*Example 30: Allergy List*

```

<!-- ***** ALLERGY LIST ***** -->
<component>
  <section>
    <!-- conforms to Allergies section with entries optional -->
    <templateId root="2.16.840.1.113883.10.20.22.2.6" extension="2015-08-01"/>
    <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"/>
    <templateId root="2.16.840.1.113883.10.20.22.2.6.1" extension="2015-08-01"/>
    <code code="48765-2" codeSystem="2.16.840.1.113883.6.1"/>
    <title>ALLERGIES, ADVERSE REACTIONS, ALERTS</title>
    <text>No Known Allergies</text>
    <entry typeCode="DRIV">
      <!-- Allergy Concern Act -->
      <act classCode="ACT" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.22.4.30" extension="2015-08-01"/>
        <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 the 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 -->
          <!-- The negationInd = true negates the observation/value -->
          <!-- The use of negationInd corresponds with the newer Observation.valueNegationInd -->
          <!--
          <observation classCode="OBS" moodCode="EVN" negationInd="true">
            <!-- allergy - intolerance observation template -->
            <templateId root="2.16.840.1.113883.10.20.22.4.7" extension="2014-06-09"/>
            <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>
              <low nullFlavor="NA" />
            </effectiveTime>
            <value xsi:type="CD" code="419199007"
              displayName="Allergy to substance (disorder)"
              codeSystem="2.16.840.1.113883.6.96"
              codeSystemName="SNOMED CT"/>
          </observation>
        </entryRelationship>
      </act>
    </entry>
  </section>
</component>

```



```

    <author>
      <time value="20100103"/>
      <assignedAuthor>
        <id extension="99999999" root="2.16.840.1.113883.4.6"/>
        <code code="200000000X" codeSystem="2.16.840.1.113883.6.101"
          displayName="Allopathic & Osteopathic Physicians"/>
        <telecom use="WP" value="tel:555-555-1002"/>
        <assignedPerson>
          <name>
            <given>Henry</given>
            <family>Seven</family>
          </name>
        </assignedPerson>
      </assignedAuthor>
    </author>
    <!-- In C-CDA R2.1 the participant is required. -->
    <participant typeCode="CSM">
      <participantRole classCode="MANU">
        <playingEntity classCode="MMAT">
          <code nullFlavor="NA"/>
        </playingEntity>
      </participantRole>
    </participant>
  </observation>
</entryRelationship>
</act>
</entry>

```

To represent that a section has “no information”, the section should be included, and a null value of NI used to convey that there is no information in the source system for this section. To represent that a section has information in the source system but it has been excluded from the exchange document, the section should be included and a null value of MSK used to convey that the information in the source system for this section has not been provided by the sender due to security, privacy, or other reasons. The exact wording to be included in the narrative text for the notions of “no information” and “masked information” can be determined locally.

*Example 31: Allergies Section with No Information*

```

<!-- ***** ALLERGY LIST ***** -->
<component>
  <!-- nullFlavor of NI indicates No Information.-->
  <section nullFlavor="NI">
    <!-- conforms to Allergies section with entries optional -->
    <templateId root="2.16.840.1.113883.10.20.22.2.6" extension="2015-08-01"/>
    <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"/>
    <templateId root="2.16.840.1.113883.10.20.22.2.6.1" extension="2015-08-01"/>
    <code code="48765-2" codeSystem="2.16.840.1.113883.6.1"/>
    <title>ALLERGIES, ADVERSE REACTIONS, ALERTS</title>
    <text>No Information</text>
  </section>

```

If an organization has business rules that support not providing information from the patient’s record due to security, privacy, or other reasons, nullFlavor codes can be used to represent this information in a C-CDA document. The nullFlavor code used to indicate that information is not present due to security, privacy or other reason is MSK for “masked”. The nullFlavor code for “not applicable” is NA When information is not present for these reasons, the text in the section.text element explains why. The exact meaning of the nullFlavor code can be used, or localized text that has the same semantic meaning can be used.

*Example 32: Excluding section due to business rules.*

Entire section excluded because business rules of the author determine the section of information is not present due to security, privacy, or other reasons

```
< section nullFlavor="MSK">
  <templateId root="2.16.840.1.113883.10.20.22.2.7"/>
  <templateId root="2.16.840.1.113883.10.20.22.2.7" extension="2014-06-09"/>
  <templateId root="2.16.840.1.113883.10.20.22.2.7.1"/>
  <templateId root="2.16.840.1.113883.10.20.22.2.7.1" extension="2014-06-09"/>
  <id root="4536582C-018F-11E6-9EF4-0050568B1D1B"/>
  <code code="47519-4" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
  displayName="History of procedures"/>
  <title>Procedures - from Last 3 Months</title>
  <text>
    Information has not been provided by the sender due to security, privacy, or other reasons.
    There may be an alternate mechanism for gaining access to this information.
  </text>
</section>
```

*Example 33: Procedures Section with Excluded Information, example of locally selected wording*

```
<section nullFlavor="MSK">
  <templateId root="2.16.840.1.113883.10.20.22.2.7"/>
  <templateId root="2.16.840.1.113883.10.20.22.2.7" extension="2014-06-09"/>
  <templateId root="2.16.840.1.113883.10.20.22.2.7.1"/>
  <templateId root="2.16.840.1.113883.10.20.22.2.7.1" extension="2014-06-09"/>
  <id root="4536582C-018F-11E6-9EF4-0050568B1D1B"/>
  <code code="47519-4" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
  displayName="History of procedures"/>
  <title>Procedures - from Last 3 Months</title>
  <text>
    Information not provided due to security, privacy, or other reasons.
  </text>
</section>
```

### 5.1.8 Specifying Time Intervals for Sections with Limits on the Included Discrete Data

In order to communicate that business rules have been applied to constrain the amount of information represented in the section of a document, a new template has been defined that allows C-CDA Content Creators to explicitly clarify the time range of the included information. The Section Time Range Observation entry describes the business rule used to limit the information contained in the section to a specific interval of time using a machine-readable format that facilitates computer processing. It is an optional entry and may be used in any section where the included information has been limited to prevent the section from becoming overwhelming or irrelevant. This entry links to the human readable text asserted in the section narrative disclosing the business rules applied to limit the included information.

The Section Time Range Observation template

(urn:hl7ii:2.16.840.1.113883.10.20.22.4.201:2016-06-01) may be useful when a query for a C-CDA document may request a large amount of data--potentially years—and the system that creates the document supplied in a response, limits the data they return to a relevant range of time. This template enables the system creating the document to assert the range of time constraining the data provided in a section.

**Reference:** 4.2.8 Declaring Business Rules that Limit Section Content; 5.2 Essential Entry-Level Guidance; Appendix A

### 5.1.9 Use of Open Templates for Entries

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, provider, or setting needs. Within C-CDA, nearly all templates allow additional content and are described as *open* templates.

While templates constrain the CDA schema for specific uses, additional content may augment each document as needed for a particular circumstance. For example, if the Payer section needs to be shared in a Care Plan Document, this section could be added because the Care Plan Document template is an open template. The Estimated Date of Delivery and the Medication Free Text Sig entry-level templates are the only closed templates in the C-CDA IG. Other HL7 CDA implementation guides make greater use of closed templates.

**Reference:** Chapter 4.2.3 of the C-CDA IG.

### 5.1.10 Detailed Date/Time Guidance

A recent study by members of the Association for Healthcare Documentation Integrity presented during the HIMSS Health Story Project Roundtable on March 5, 2019 demonstrated how the consistent use of style in the healthcare record promotes clear communication, contributes to patient safety, and improves information exchange, integration, and aggregation. The presentation also provided insight into the importance of applying style standards to human-readable text to reduce physician burden. Many of the examples of poor styles and confusing or irrelevant information focused on representation of the temporal date/time information contained in the narrative text. While temporal information is critical for making clinical sense of the information contained in a patient's record, too much date/time information can be overwhelming or misleading. The Roundtable recommendations challenged C-CDA creators to do more to ensure date/time information presented in the Narrative Block is relevant and pertinent and styled appropriately to reduce physician burden.<sup>124</sup>



C-CDA Content Creators **SHOULD** apply a consistent style to date/time information reported in the Narrative Blocks **[BP-070]**



C-CDA Content Creators **SHOULD** render date/time information using a level of precision that is relevant and pertinent to the intended purpose of the section within the context of the document. **[BP-071]**

#### 5.1.10.1 Timestamp Data Representation

The value of a point in time is represented using the ISO 8601 compliant form traditionally in use with HL7. This is the form that has no decorating dashes, colons and no "T" between the date and time. In short, the syntax is "YYYYMMDDHHMMSS.UUUU[+|-ZZzz]" where digits can

<sup>124</sup> HIMSS Health Story Project Roundtable. Style Standards to Improve Health IT Usability and Reduce Physician Burden. March 5, 2019. <https://www.himss.org/library/style-standards-improve-health-it-usability-and-reduce-physician-burden>

be omitted from the right side to express less precision<sup>125</sup>. Common forms are "YYYYMMDD" and "YYYYMMDDHHMM", but the ability to truncate on the right side is not limited to these two variants. The ".UUUU" part of the expression supports up to tenths of a millisecond and is used to represent time precision greater than 1 second. For example, ".001" represents a thousandth of a second. This representation also allows for timezone information to be specified using offsets from UTC. As an example of specifying time zone information, Eastern Standard Time (EST) is represented as -0500, while Eastern Daylight Saving Time (EDT) is represented as -0400. UTC Time is represented as -0000.

If no time zone offset is provided, you can make no assumption about time, unless you have made a local exchange agreement. When timezone is NULL (unknown), "local time" is assumed. However, "local time" is always local to some place, and without knowledge of that place, the time zone is unknown. Hence, a local time cannot be converted into UTC. timezone should be specified for all TS values in order to avoid a significant loss of precision when TSs are compared.

In administrative data context, sometimes values do not carry a time zone. For a date of birth in administrative data, for example, it would be incorrect to specify timezone, since this may effectively change the date of birth when converted into other time zones. For such administrative data the time zone is NULL (not applicable.)<sup>126</sup>



When populating any effectiveTime or time element in a document, C-CDA Content Creators:

1. **SHALL** be precise to the day.
2. **SHOULD** be precise to the minute.
3. **MAY** be precise to the second.
4. If more precise than day, **SHALL** include time-zone offset.

[CONF-072]

**Note: This conformance does not apply to the birthTime element because use of a timezone offset could have an unintended negative effect when doing patient matching. It also does not apply to the effectiveTime element of the Birth Sex Observation (2.16.840.1.113883.10.20.22.4.200:2016-06-01) template.**



When populating a birthTime metadata element in the header or section of a document, C-CDA Content Creators:

1. **SHALL** be precise to the day.
2. **SHOULD** be precise to the minute.
3. **MAY** be precise to the second.
4. **SHALL NOT** include time or time-zone offset.


[CONF-073]

<sup>125</sup> CDA R2 Datatypes Abstract Specification.

<sup>126</sup> Ibid.

### 5.1.10.2 Date/Time Precision


When specifying dates and times, care should be taken to only capture data with as much precision as is known. The timestamp format allows for partial dates and partial times to be specified.

 Dates and Times SHOULD NOT be padded with zeroes as this implies a precision that is probably not true. **[CONF-074]**

A date/time of “20160101000000.0000” is explicitly representing the exact first tenth of a millisecond on January 1<sup>st</sup>, 2016. Unless this is the exact tenth of a millisecond that is intended to be represented, this date/time should be sent as “20160101” which is stating “sometime on January 1<sup>st</sup>, 2016.” Similarly, “2016010109” is stating “sometime after 09:00am on January 1<sup>st</sup>, 2016, but before 10:00am.”

When documenting an interval of date/times, care must also be taken in the interpretation of the high point of the interval. Chapter 3.8.2 of the HL7 Abstract Data Types Specification reads:

The precision of a stated interval boundary is irrelevant for the interval. One might wrongly assume that the interval "[19870901;19870930]" stands for the entire month, from the 1<sup>st</sup> of September 1987 until end of the day on September 30th. However, this is not so! The proper way to denote an entire calendar cycle (e.g., hour, day, month, year, etc.) in the interval notation is to use an open high boundary. For example, all of September 1987 is denoted as "[198709;198710[".<sup>127</sup>

 For purposes of an interval, when a partial date/time is encountered, it SHOULD be acted upon as if the rest of the date/time was padded with “01” for months or days, and “0s” for hours, minutes, seconds, and fractions of a second. **[BP-075]**

Thus, the first interval above should be considered as [19870901000000.0000;19870930000000.0000], which then shows that it stands for the interval from September 1st, 1987 until the first instant of September 30th. It thus does not actually include the rest of the instants of September 30th. The second interval is considered as [19870901000000.0000;19871001000000.0000]. It includes all of September 30th but does not include the first instant of October 1st because the interval is marked open.

Date / Time Expression	Representation
<b>November 27, 1970</b>	<code>&lt;effectiveDate value="19701127"/&gt;</code>
<b>11:30:52.3333 on November 27, 1970 in EST</b>	<code>&lt;effectiveDate value="19701127113052.3333-0500"/&gt;</code>
<b>The entire year of 1970</b>	<code>&lt;effectiveDate&gt; &lt;low value="1970"/&gt; &lt;high inclusive="false" value="1971"/&gt; &lt;/effectiveDate&gt;</code>
<b>The entire month of September 1987</b>	<code>&lt;effectiveDate&gt; &lt;low value="198709"/&gt;</code>

<sup>127</sup> Chapter 3.8.2 of the HL7 Abstract Data Types Specification

Date / Time Expression	Representation
	<pre>&lt;high inclusive="false" value="198710"/&gt; &lt;/effectiveDate&gt;</pre>

Table 39: Date/Time Examples



### 5.1.11 Referencing Information Within a Document

The Entry Reference template represents the act of referencing another entry in the same CDA document instance. Its purpose is to remove the need to repeat the complete XML representation of the referred entry when relating one entry to another. This template can be used to reference many types of Act class derivations, such as encounters, observations, procedures etc., as it is often necessary when authoring CDA documents to repeatedly reference other Acts of these types. For example, in a Care Plan it is necessary to repeatedly relate Health Concerns, Goals, Interventions and Outcomes.

The ID is required and must be the same ID as the entry/id it is referencing. The ID cannot be a null value. Act/Code is set to nullFlavor="NP" (Not Present). This means the value is not present in the message (in act/Code).



The <linkHtml> tag, is a generic referencing mechanism that can be used to reference identifiers that are internal to a document. Note that security considerations need to be given to support for linking mechanisms. Not all stylesheets enable the linking features of the <linkHtml> tag to be operationalized.

#### Reference: 4.2.3.1 HTML tags for formatting Narrative Text

	C-CDA Content Creators MAY use id-based linking mechanisms within a C-CDA document. <b>[BP-076]</b>
	C-CDA Consumer SHOULD support stylesheets that facilitate the use of internal linking mechanisms, because linking within a single file does not pose security risks, facilitates readability and. Improves user experience when viewing C-CDA documents. <b>[BP-077]</b>

### 5.1.12 Referencing Information in an External Document

The base HL7 CDA standard supports four act classes that enable information in one document to reference information in an external document, external procedure, external observation, or external act. To date the C-CDA implementer community has not explored the use of these mechanisms. However, as progress evolves on the use of unique IDs that persist and are used consistently and meaningfully across systems, exploration may expand in this area.

	C-CDA Content Creators MAY explore the use of linking mechanisms to external C-CDA documents, observations, or acts, depending on business decisions and the assessment of risk associated with this functionality. <b>[BP-078]</b>
	C-CDA Content Consumers MAY support stylesheets that support or prohibit the use of external linking mechanisms, depending on business decisions and the assessment of risk associated with this functionality. <b>[BP-079]</b>

### 5.1.13 Understanding the ActStatus Model in C-CDA

Volume 1 of the HL7 C-CDA R2.1 specification includes a detailed explanation of how to determine the status of the clinical statement included in a C-CDA document when that clinical statement is expressed in a C-CDA entry template.<sup>128</sup> The chapter explains how a C-CDA Content Creator can indicate and a C-CDA Content Consumer can understand if clinical statement is active, completed, or in some other state. Most clinical statements designed for C-CDA have a completed status, but a select few include a state model expressed using the Act.statusCode. Examples include the Problem Concern Entry and the Medication Activity. Templates of this sort include a value set binding on the Act.statusCode element where the value set includes concepts from the HL7ActStatus code system. The HL7ActStatus code system includes a set of concepts defined in the RIM state model. The value set used with the Act.statusCode vary depending on the needs of the particular clinical statement but are static for each clinical statement pattern definition (i.e. each entry template definition).

Determination of the Act.statusCode depends on the interplay between an act's various components including effectiveTime and other clinical status observations that may be pertinent for determining the status of the act within the available Act.statusCode state model.

The guidance in Chapter 3.3 of Volume 1 of the HL7 C-CDA R2.1 specification is thorough and helpful. However, when an EMR system does not support state models that align with the clinical statement models defined in C-CDA, this guidance to be challenging for implementers. For additional information about how to address challenges associated with a C-CDA Act.statusCode state model, consult the ActStatus row of the guidance table for each entry templates listed below.

### 5.1.14 How Negation Works in C-CDA Templates

C-CDA entry templates include a negationInd attribute on all Act classes (act, procedure, encounter, substanceAdministration, supply, and observation). Act.negationInd, when set to "true", is a positive assertion that the Act as a whole is negated. Some properties such as Act.id, Act.moodCode, and the participations are not affected. These properties always have the same meaning: i.e., the author remains the author of the negative Act. An act statement with negationInd is still a statement about the specific fact described by the Act. For instance, a negated "finding of wheezing on July 1" means that the author positively denies that there was wheezing on July 1, and that he takes the same responsibility for such statement and the same requirement to have evidence for such statement than if he had not used negation.<sup>129</sup>

In the case of an observation, the entry template may provide additional guidance, or this Companion Guide may provide additional guidance, to clarify if the observation.negationInd



---

<sup>128</sup> HL7 C-CDA R2.1. Chapter 3.3 Determining the Status of Clinical Statement.

<sup>129</sup> HL7 CDA. Chapter 4.3.6.1 Act.



attribute applied to the act as a whole, or just to the observation.value element. In later versions of the RIM, multiple more specific negationInd attributes were implemented to communicate this design intention more clearly. In CDA, the template definitions or companion guidance needs to describe the intention explicitly.

	C-CDA Content Creators SHALL follow template conformance and additional companion guidance regarding the use of negationInd when representing discrete data in C-CDA documents. <b>[BP-080]</b>
	C-CDA Content Consumers SHALL follow template conformance and additional companion guidance regarding the use of negationInd when processing discrete data represented in C-CDA documents. <b>[BP-081]</b>

**Reference:** 5.1.7 Representing “no known” Information Versus “no information”

## 5.2 Essential Entry-Level Guidance

The following guidance is specific for individual entry templates. It has been gathered from C-CDA implementer community through other published implementation guides, C-CDA Implementation-A-Thons that HL7 and ONC jointly hold, HL7 cross-workgroup collaboration sessions to review C-CDA templates, insight from the SOA workgroup working on mappings between C-CDA and FHIR, and work produced by the HL7 C-CDA Examples Task Force.

Each entry template described below includes the description of the purpose for the template. It also includes detailed information about any state model associated with the design, issues related to the representation of negated information, and special considerations to note such as idioms supported or other nuanced guidance that has emerged through experience within the C-CDA implementer community.

The data classes listed below include guidance for relevant entry templates used to represent types of information associated with that class of data.

### 5.2.1 Provenance

As demand increases for higher quality, more trusted clinical data in C-CDA documents, new efforts have emerged to clarify basic information requirements for representing data “provenance.” Provenance provides traceability of information and supports clinical information reconciliation and incorporation.

Entry Template	Provenance Author Participation <small>[author: identifier urn:oid:2.16.840.1.113883.10.20.22.5.6:2019-10-01 (open)]</small>
<b>Reference Source</b>	HL7 C-CDA R2.1 Companion Guide R2
<b>Purpose</b>	This template provides a mechanism to record basic Provenance in an Author Participation.
<b>ActStatus</b>	Not applicable
<b>Negation</b>	Not applicable
<b>Idioms Supported</b>	Not applicable



Entry Template	Provenance Author Participation [author: identifier urn:oid:2.16.840.1.113883.10.20.22.5.6:2019-10-01 (open)]
<b>Other Considerations</b>	This template constrains the CDA Author Participation and is appropriate at the Header, Section, or Entry level. The conformance criteria specializes the C-CDA Author Participation (2.16.840.1.113883.10.20.22.4.119) but does not require generators to include this additional templateId.
<b>Reference</b>	Appendix C. Provenance – Author Participation for the full definition of this new template.
<b>Example</b>	Example 34: Use of the Provenance Author Participation

Table 40: Provenance Author Participation Template

## Example 34: Use of the Provenance Author Participation

```

<section>
  <!-- *** Allergies and Intolerances Section (entries required) (V3) *** ->
  <templateId ro"t="2.16.840.1.113883.10.20.22.2."1"/>
  <templateId ro"t="2.16.840.1.113883.10.20.22.2."1" extensi"n="2015-08"01"/>
  <code co"e="4876"-2" codeSyst"m="2.16.840.1.113883."1" codeSystemNa"e="LO"NC"/>
  <title>ALLERGIES AND ADVERSE REACTIONS</title>
  <text "D="allergiesNoKn"wn">No Known Allergies</text>
  <entry typeCo"e="D"IV">
    --- Allergy Concern Act ---
    <act classCo"e="CT" moodCo"e="VN">
      <templateId ro"t="2.16.840.1.113883.10.20.22.4"30"/>
      <templateId ro"t="2.16.840.1.113883.10.20.22.4"30" extensi"n="2015-08"01"/>
      <id ro"t="36e3e930-7b14-11db-9fe1-0800200c9"66"/>
      --- SDWG supports 48765-2 or CONC in the code element ---
      <code co"e="C"NC" codeSyst"m="2.16.840.1.113883."6"/>
      <text>
        <reference val"e="#allergiesNoKn"wn"/>
      </text>
      <statusCode co"e="act"ve"/>
      -!--currently tracked concerns are active concerns-->
      <effectiveTime>
        <low val"e="20100"03"/>
        -!--show time when the concern first began being tracked-->
      </effectiveTime>
      <entryRelationship typeCo"e="S"BJ">
        --- No Known Allergies ---
        --- The negationInd = true negates the observation/value ---
        --- The use of negationInd corresponds with the newer
            Observation.valueNegationInd ---
        <observation classCo"e="BS" moodCo"e="VN" negationI"d="t"ue">
          --- aller-y - intolerance observation template ---
          <templateId ro"t="2.16.840.1.113883.10.20.22."7"/>
          <templateId ro"t="2.16.840.1.113883.10.20.22."7" extensi"n="2014-06"09"/>
          <id ro"t="4adc1020-7b14-11db-9fe1-0800200c9"66"/>
          <code co"e="ASSERT"ON" codeSyst"m="2.16.840.1.113883."4"/>
          <text>
            <reference val"e="#allergiesNoKn"wn"/>
          </text>
          <statusCode co"e="comple"ed"/>
          --- N-A - author/time records when this assertion was made ---
          <effectiveTime>
            <low nullFlav"r="NA"/>
          </effectiveTime>
          <value xsi:ty"e="CD" co"e="419199"07"
            displayNa"e="Allergy to substance (disord"r)"
            codeSyst"m="2.16.840.1.113883.6"96" codeSystemNa"e="SNOMED"CT"/>
        </observation>
      </entryRelationship>
    </act>
  </entry>
</section>
<author>
  --- Provenan-e - Author Participation ---
  <templateId ro"t="2.16.840.1.113883.10.20.22."6" extension="2019-10-01"/>
  <time val"e="201308011235-0"00"/>
  <assignedAuthor>
    --- NPI of Author (example) ---
    <id ro"t="2.16.840.1.113883."6" extensi"n="1234"67"/>
    <assignedPerson>

```

```

        <name>
            <given>Nurse</given>
            <family>Nightingale</family>
            <suffix>RN</suffix>
        </name>
    </assignedPerson>
    <representedOrganization>
        --- Tax Identifier of Organization is Unknown -->
        <id root="2.16.840.1.113883.5.1"08" nullFlav="r="NK"/>
        --- NPI of Organization -->
        <id root="2.16.840.1.113883."6" extension="1104145"38"/>
        <name>Good Health Hospital</name>
        <telecom value="tel:+1(555)867-5"09"/>
    </representedOrganization>
</assignedAuthor>
</author>
    --- In C-CDA R2.1 the participant is required. -->
    <participant typeCode="SM">
        <participantRole classCode="M"NU">
            <playingEntity classCode="M"AT">
                <code nullFlav="r="NA"/>
            </playingEntity>
        </participantRole>
    </participant>
</observation>
</entryRelationship>
</act>
</entry>
</section>

```

**Reference:** 6.4.1 Active HL7 Projects Pertinent to the C-CDA Implementer Community

## 5.2.2 Section Time Range

The Section Time Range Observation entry describes the business rule used to limit the information contained in the section to a specific interval of time using a machine-readable format that facilitates computer processing of the information. It is an optional entry and may be used in any section to prevent the amount of information included in the section from becoming overwhelming or irrelevant. This entry references the human readable information disclosing the applied business rules stated in the asserted in the narrative text of the section.

### 5.2.2.1 Section Time Range Observation

Entry Template	Section Time Range Observation
	[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.201:2016-06-01 (open)]
<b>Reference Source</b>	HL7 C-CDA R2.1
<b>Purpose</b>	This observation describes a date/time range applied by the document creator to limit the range of information contained in a section.
<b>ActStatus</b>	This is a discrete observation that has been made in order for it to be documented. Therefore, it always has a statusCode of "completed". This template does not include an effectiveTime element. See other considerations below.
<b>Negation</b>	Not specified.
<b>Idioms Supported</b>	None specified.

Entry Template	Section Time Range Observation [observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.201:2016-06-01 (open)]
<b>Other Considerations</b>	Narrative text linking applies for this entry. The human readable information describing the date/time range used to limit the information SHOULD be reported in the Narrative Block and SHOULD NOT be implied by the section.title only. The specified date/time range of the content limit is specified in the observation.value element.
<b>Reference</b>	Appendix A for template definition
<b>Example</b>	Example 35: Section Time Range Template Example

Table 41: Section Time Range Observation Template

Example 35: Section Time Range Template Example

```

<section>
...
  <title>Procedures</title>
  <text>
    <content ID="Proc_STR">Procedures performed between 08/15/2012 and 08/15/2015.</content>
  ...
</text>
<entry>
  <observation classCode="BS" moodCode="VN">
    <templateId root="2.16.840.1.113883.10.20.22.4."01" extension="2016-06"01"/>
    <code code="8260"-3" codeSystem="2.16.840.1.113883."1"
      displayName="Section Date and Time Range"/>
    <text>
      <reference value="#Proc_TR"/>
    </text>
    <statusCode code="completed"/>
    <value xsi:type="IVL-TS">
      <low value="20120"15"/>
      <high value="20150"15"/>
    </value>
  </observation>
</entry>
</section>

```

### 5.2.3 Care Team

The header of a C-CDA document includes roles which are populated by providers and individuals who have been engaged in delivering clinical care or documenting care the patient has received. Their role on the patient's care team is implicit. The Care Teams Section and corresponding Care Team Organizer templates enable care team information to be documented explicitly. These templates also support a wider range of expressiveness provide background on the type of care team and include more details about the members of the team and the roles played by each member.

#### 5.2.3.1 Care Team Organizer

Entry Template	Care Team Organizer [organizer: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.500:2019-07-01 (open)]
<b>Reference Source</b>	HL7 C-CDA R2.1 Companion Guide R2

Entry Template	Care Team Organizer [organizer: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.500:2019-07-01 (open)]
<b>Purpose</b>	<p>This organizer template contains information about a single care team.</p> <p>The author of the organizer is the person who documented the care team information.</p> <p>The participants of the organizer are the care team lead(s) and the care team organization.</p> <p>The components of the organizer contain the following information:</p> <ul style="list-style-type: none"> <li>• The encounter that caused the care team to be formed</li> <li>• Narrative information about the care team</li> <li>• The care team members</li> <li>• Reasons for the care team</li> <li>• The care team type(s) - a care team can have multiple care team types</li> </ul>
<b>ActStatus</b>	<p>The actStatus of this entry is statically bound to ValueSet ActStatus urn:oid:2.16.840.1.113883.1.11.15933. Implementers need to be prepared to address the specified state model. Possible states include: active, completed, cancelled, held, suspended, new, normal, nullified, obsolete, and aborted.</p>
<b>Negation</b>	<p>Not explicitly specified.</p>
<b>Idioms Supported</b>	<p>None.</p>
<b>Other Considerations</b>	<p>Implementers are encouraged to take guidance from the structure of this entry, even if only populating the Narrative Block of the Care Teams Section.</p> <p>Implementers should note the functionCode element vocabulary binding extends the set of concepts for a Care Team member’s role on the Care Team. A new value set called “Care Team Member Function” is grouped with the original value set called “ParticipationFunction.” In cases where a concept overlaps between these two value sets, implementers should use the concept from the ParticipationFunction value set.</p>
<b>Reference</b>	<p>Appendix A for template definitions.</p>
<b>Example</b>	<p>Example 36: Care Teams Section with Care Team Member Organizer for discrete data representation.</p>

Table 42: Care Team Organizer Template

## 5.2.3.2 Care Team Organizer Template Design

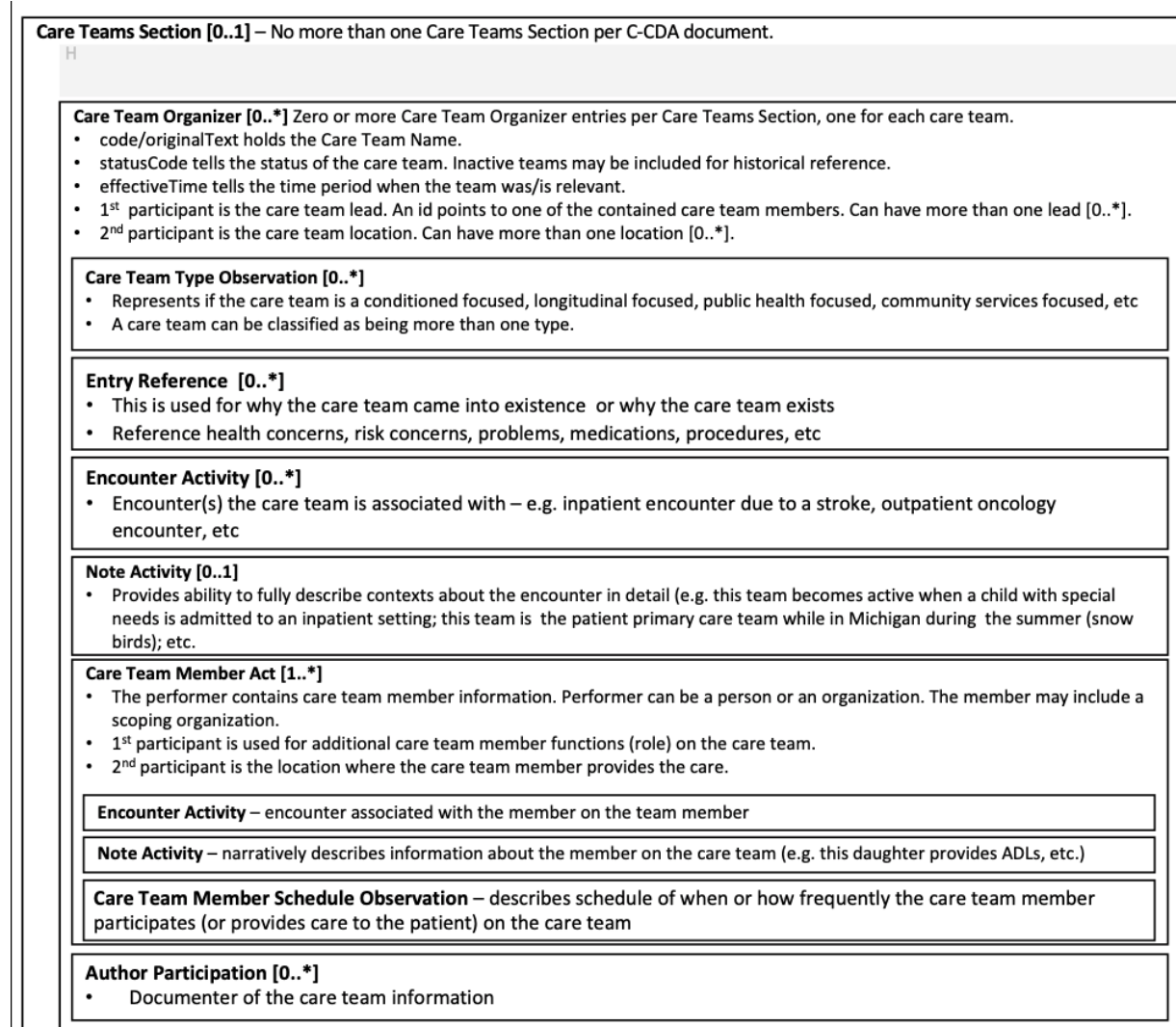


Figure 8: Logical design for Care Team Organizer Template

Example 36: Care Teams Section with Care Team Member Organizer for discrete data representation.

```

<section>
  <!--NEW Care Teams Section Template ID and extension-->
  <templateId root="2.16.840.1.113883.10.20.22.2.500" extension="2019-07-01"/>
  <code code="85847-2" codeSystem="2.16.840.1.113883.6.1"/>
  <title>Care Teams</title>
  <text>
    <!-- -->
    <list>
      <item>
        <content ID= "CareTeamName1">Inpatient Diabetes Care Team</content>
        (<content>Active</content>)
        <table>
          <thead>
            <tr>
              <th>Member</th>
              <th>Role on Team</th>
              <th>Status</th>
              <th>Date</th>
            </tr>
          </thead>
        </table>
      </item>
    </list>
  </text>

```

```

        </thead>
        <tbody>
        <tr>
            <td>Dr. Henry Seven </td>
            <td ID="CT1_M01">PCP</td>
            <td>(Active)</td>
            <td>10/18/2019</td>
        </tr>
        </tbody>
    </table>
</item>
</list>

</text>
<!--Care Team Organizer-->
<entry>
    <organizer classCode="CLUSTER" moodCode="EVN">
        <!--NEW Care Team Organizer Entry Template ID and extension-->
        <templateId root="2.16.840.1.113883.10.20.22.4.500" extension="2019-07-01"/>
        <id root="1.1.1.1.1.1"/>
        <code code="86744-0" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
displayName="Care Team">
            <originalText><reference value="#CareTeamName1"></reference></originalText>
        </code>
        <!--Care Team Status -
https://vsac.nlm.nih.gov/valueset/2.16.840.1.113883.1.11.15933/expansion-->
        <statusCode code="active"/>
        <!-- This participant is the Care Team Lead (1.1)-->
        <!-- Care Team Lead is one of the contained care team members in the list of
care team members-->
        <!--<participant typeCode="PPRF">
            <!--\-<This id matches at least one of the member's id in the Care Team Member
act template>->
            <participantRole>
                <id root="1.5.5.5.5.5"/>
            </participantRole>
        </participant-->
        <!-- #1 Care Team Member Act - This component is a care team member who is a
provider -->
        <component>
            <act classCode="PCPR" moodCode="EVN">
                <templateId root="2.16.840.1.113883.10.20.22.4.500.1" extension="2019-07-
01"/>
                <id root="1.5.5.5.5.5"/>
                <code code="85847-2" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Care Team Information"/>
                <!--Care Team Member Status -
https://vsac.nlm.nih.gov/valueset/2.16.840.1.113883.1.11.15933/expansion-->
                <statusCode code="active"/>
                <effectiveTime xsi:type="IVL_TS">
                    <low value="201810081426-0500"/>
                </effectiveTime>
                <!--Attributes about the provider member - name-->
                <performer typeCode="PRF">
                    <functionCode xmlns="urn:hl7-org:sdtc" code="PCP" displayName="primary
care physician"
                        codeSystem="2.16.840.1.113883.5.88"
codeSystemName="ParticipationFunction">
                        <originalText xmlns="urn:hl7-org:v3">
                            <reference value="#CT1_M01"></reference>
                        </originalText>
                    </functionCode> <!-- A care team member role -->
                    <assignedEntity>
                        <id root="B00B14E8-CDE4-48EA-8A09-01BC4945122A" extension="1"/>
                        <id root="1.5.5.5.5.5"/>
                    <assignedPerson>
                        <name><given>John</given><given>D</given><family>Smith</family><suffix>MD</suffix> </name>
                    </assignedPerson>
                </assignedEntity>
            </performer>

```


```

        </act>
      </component>
    </organizer>
  </entry>
</section>

```

### 5.2.4 Encounter

The Encounters Section includes relevant and pertinent encounters which have already occurred for the patient, including the encounter that instigated creation of the document. Future appointments and requested encounters should be communicated in the Plan of Treatment Section.



When the document pertains to a single encounter, the Encounter section SHALL contain information about that encounter, but MAY also contain additional encounters. **[CONF-082]**

The Encounter Activity entry with an ID matching the encompassingEncounter header element represents the primary encounter being documented.

**Reference:** 3.2.4 Care Team Members

The Encounter Diagnosis is always represented as an entryRelationship to an Encounter Activity, even when the document is about a single encounter. Historical encounters would each be documented as an Encounter Activity and information about that encounter would be recorded using an entryRelationship within that corresponding Encounter Activity. Additional information, such as free-text notes may also be communicated using extra entryRelationships within the associated Encounter Activity.

A new entry template has been defined for recording clinical notes. It is called the Note Activity entry. To provide a note on the Encounter, the entryRelationship should link to this new Note Activity entry template.

**Reference:** 4.5 New and Additional C-CDA Section Templates (Defined in this Companion Guide), Appendix A.1.2

#### 5.2.4.1 Encounter Activity

Entry Template	Encounter Activity (V3)
<b>Reference Source</b>	[encounter: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.49:2015-08-01 (open)] HL7 C-CDA R2.1
<b>Purpose</b>	This clinical statement describes an interaction between a patient and clinician. Interactions may include in-person encounters, telephone conversations, and email exchanges.
<b>ActStatus</b>	No constraint specified.
<b>Negation</b>	Not explicitly specified.
<b>Idioms Supported</b>	None.
<b>Other Considerations</b>	This template the sdtc:dischargeDispositionCode extension which may be used to record information about the disposition of the patient at the time of discharge. It

<b>Entry Template</b>	<b>Encounter Activity (V3)</b> [encounter: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.49:2015-08-01 (open)]
	also may include information about the practitioners involved in performing services, the location or locations where the encounter took place, the reason(s) that were the indication for the encounter, and any number of encounter diagnoses.
<b>Reference</b>	Visit <a href="#">HL7 CDA Example Search</a>
<b>Example</b>	How to represent " <a href="#">Outpatient Encounter with Diagnoses</a> "

Table 43: Encounter Activity Template

### 5.2.4.2 Encounter Diagnosis

<b>Entry Template</b>	<b>Encounter Diagnosis (V3)</b> [act: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.80:2015-08-01 (open)]
<b>Reference Source</b>	HL7 C-CDA R2.1
<b>Purpose</b>	This template wraps relevant problems or diagnoses at the close of a visit or that need to be followed after the visit.
<b>ActStatus</b>	No constraint specified.
<b>Negation</b>	Not explicitly specified.
<b>Idioms Supported</b>	None.
<b>Other Considerations</b>	This template requires at least one contained Problem Observation template.
<b>Reference</b>	Visit <a href="#">HL7 CDA Example Search</a>
<b>Example</b>	How to represent " <a href="#">Outpatient Encounter with Diagnoses</a> "

Table 44: Encounter Diagnosis Template

### 5.2.4.3 Hospital Admission Diagnosis

<b>Entry Template</b>	<b>Hospital Admission Diagnosis (V3)</b> [act: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.34:2015-08-01 (open)]
<b>Reference Source</b>	HL7 C-CDA R2.1
<b>Purpose</b>	This template represents problems or diagnoses identified by the clinician at the time of the patient’s admission.
<b>ActStatus</b>	No constraint specified.
<b>Negation</b>	Not explicitly specified.
<b>Idioms Supported</b>	None.
<b>Other Considerations</b>	This Hospital Admission Diagnosis act may contain more than one Problem Observation to represent multiple diagnoses for a Hospital Admission. The only difference between a Hospital Admission Diagnosis and a Hospital Discharge Diagnosis is the LOINC code used in the Act.code element of the act wrapper. Hospital Admission Diagnosis uses LOINC code 46241-6 (Hospital admission diagnosis Narrative - Reported), while Hospital Discharge Diagnosis uses LOINC code 11535-2 (Hospital discharge Dx Narrative)
<b>Example</b>	Example 37: Hospital Admission Diagnosis

Table 45: Hospital Admission Diagnosis Template



Example 37: Hospital Admission Diagnosis

```
<act classCode="ACT" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.22.4.34" extension="2015-08-01" />
  <id root="5a784260-6856-4f38-9638-80c751aff2fb" />
  <code code="46241-6" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
  displayName="Hospital Admission Diagnosis" />
  <statusCode code="active" />
  <effectiveTime>
    <low value="20090303" />
  </effectiveTime>
  <entryRelationship typeCode="SUBJ" inversionInd="false">
    <observation classCode="OBS" moodCode="EVN">
      <!-- Problem observation template -->
      <templateId root="2.16.840.1.113883.10.20.22.4.4" extension="2015-08-01" />
      ...
    </observation>
  </entryRelationship>
</act>
```



5.2.4.4 Hospital Discharge Diagnosis

Entry Template	Hospital Discharge Diagnosis (V3) [act: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.33:2015-08-01 (open)]
Reference Source	HL7 C-CDA R2.1
Purpose	This template represents problems or diagnoses present at the time of discharge which occurred during the hospitalization or need to be monitored after hospitalization.
ActStatus	No constraint specified.
Negation	Not explicitly specified.
Idioms Supported	None.
Other Considerations	This template requires at least one contained Problem Observation template. The primary difference between a Discharge Diagnosis and a Hospital Discharge Diagnosis is the LOINC code used in the Act.code element of the act wrapper. Encounter Diagnosis uses LOINC code 29308-4 (Diagnosis), while Hospital Discharge Diagnosis uses LOINC code 11535-2 (Hospital discharge Dx Narrative)
Reference	Visit <a href="#">HL7 CDA Example Search</a>
Example	How to reference " <a href="#">Hospital Discharge Encounter with Billable Diagnoses</a> "

Table 46: Hospital Discharge Diagnosis Template

5.2.5 Order

The inFulfillmentOf/order information in the document header represents documentation of orders that are fulfilled (in whole or in part) in the context of the encompassing encounter or within the context of the provided service event. For example, a provider orders an X-Ray. The X-Ray is performed. A radiologist reads the X-Ray and generates a report. The X-Ray order identifier is transmitted in the inFulfillmentOf/order class, and the performed X-Ray procedure is transmitted in the documentationOf/ServiceEvent. In the body of the document, the service activities performed to fulfill the order are represented using templates designed to represent a performed test (observation), procedure, substanceAdministration, supply, encounter or other type of act.

	C-CDA Content Creators SHALL represent completed orders in the inFulfillmentOf area of the header for orders completed in the context established for the document. <b>[BP-083]</b>
	C-CDA Content Consumers SHALL render information about completed orders documented in the inFulfillmentOf area of the header for orders completed in the context established for the document. For example, a consumer might opt to render any inFulfillmentOf/order/id elements where @displayable="true", the inFulfillmentOf/order/code/originalText or @displayName, or both. <b>[BP-084]</b>

The document header does not include structures for indexing orders that have been placed within the context of the encounter or services delivered. The HL7 CDA Release 2 Implementation Guide: Additional CDA R2 Templates – Clinical Documents for Payers – Set 1, Release 1 – US Realm implementation guide defines a section templates for this purpose.

### 5.2.5.1 Fulfilled Order

See Chapter 5.2.13 Medication and Chapter 5.2.15 Procedure of this document for more information about entry templates defined to represent performed service acts such as Intervention Act (V2), Procedure Activity Procedure (V2), Procedure Activity Observation (V2), Procedure Activity Act (V2), Immunization Activity(V3), Encounter Activity (V3), Medication Activity (V2), Non-Medicinal Supply Activity (V2), etc. Templates types are discussed in the context of the data class used to categorize the type of service act.

**Reference:** 5.2.13 Medication and 5.2.15 Procedure

### 5.2.5.2 Placed Order

See Chapter 5.2.17 for more information about entry templates defined to represent ordered service acts such as Planned Encounter (V2), Planned Medication Activity (V2), Planned Observation (V2), Planned Procedure (V2), Planned Supply (V2), Planned Act (V2), etc.

**Reference:** 5.2.17 Plan of Treatment

Templates of these types are discussed in the context of the data class used to categorize the type of service activity. The key distinction for representing a placed order is to utilize the moodCode attribute with a value of RQO. RQO in comes from the HL7ActMood code system and conceptually means “requested”. It is used to represent an ordered service activity.

The HL7 CDA® Release 2 Implementation Guide: Additional CDA R2 Templates – Clinical Documents for Payers – Set 1, Release 1 – US Realm implementation guide also include a set of entry level templates designed to represent order information for use within the Orders Placed Section (2.16.840.1.113883.10.20.35.2.3).<sup>130</sup> They include: Act Order (CDP1), Encounter Order (CDP1), Immunization Activity Order (CDP1), Medication Activity Order (CDP1), Observation Order (CDP1), Procedure Order (CDP1), and Supply Order (CDP1).

<sup>130</sup> HL7 CDA® Release 2 Implementation Guide: Additional CDA R2 Templates – Clinical Documents for Payers – Set 1, Release 1 – US Realm. Table 31, page 137.

The two sets of templates are consistent with each other. The set defined by the Payer community are more constrained about the expectations for the allowable Act.statusCode, and more specific about the guidance on what to indicate in the Act.effectiveTime.

**Reference:** 4.2.2 Declaring Section Template Conformance

### 5.2.6 Problem

Problem information includes health concerns, problem concerns and problem observations including statements about no known allergies.

A patient problem is represented using a combination of templates designed to represent health concerns. Health concerns contain data describing an interest or worry about a health state or process that could possibly require attention, intervention, or management. It is a health-related matter that is of interest, importance or worry to someone, who may be the patient, patient's family or patient's health care provider. Health concerns are derived from a variety of sources within an EHR (such as Problem List, Family History, Social History, Social Worker Note, etc.). Health concerns can be medical, surgical, nursing, allied health or patient-reported concerns.

Problem Concerns are a subset of health concerns that have risen to the level of importance that they typically would belong on a classic "Problem List", such as "Diabetes Mellitus" or "Family History of Melanoma" or "Tobacco abuse". These are of broad interest to multiple members of the care team. Examples of other Health Concerns that might not typically be considered a Problem Concern include "Transportation difficulties" for someone who doesn't drive and has trouble getting to appointments, or "Under-insured" for someone who doesn't have sufficient insurance to properly cover their medical needs such as medications. Another related clinical statement involves identifying risks. An example of a risk concern is, "Risk of Hyperkalemia" for a patient taking an ACE-inhibitor medication.

The design of these concern templates enables multiple observations or multiple concerns to be tracked together as a single concern. They act as a "wrapper" for the underlying Problem Observations.

Currently the Problem Section uses the Problem Concern template to record concerns commonly identified as being "on the patient's problem list". The Health Concerns section uses Health Concern and Risk Concern templates to record broader concerns, concerns that are not typically recorded on the patient's problem list, and risks that have not risen to the level of being a health concern.

When the designed clinical statement patterns do not match with the source information to be exchanged, it creates challenges for implementers. The concern pattern has been a challenge for implementers because many EHR systems do not organize the source problem data within the patient's medical record in this way.

## 5.2.6.1 Problem Concern

Entry Template	Problem Concern Act (V3) [act: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.3:2015-08-01 (open)]
Reference Source	HL7 C-CDA R2.1
Purpose	This template reflects an ongoing concern on behalf of the provider who is managing the patient's condition.
ActStatus	<p>So long as the underlying condition is of ongoing concern and interest to the provider, the statusCode of the concern is "active", regardless if the condition is active or resolved. Only when the underlying condition is no longer of concern is the statusCode of the Problem Concern Act set to "completed".</p> <p>The effectiveTime reflects the time that the underlying condition was felt to be a concern; it may or may not correspond to the effectiveTime of the condition (e.g., even five years later, the clinician may remain concerned about a prior heart attack).</p> <p>The statusCode of the Problem Concern Act is the status of the concern, whereas the effectiveTime of the nested Problem Observation tells when the problem was experienced by the patient. The effectiveTime/low of the Problem Concern Act asserts when the concern became active. The effectiveTime/high asserts when the concern was completed (e.g., when the clinician deemed there is no longer any need to track the underlying condition).</p>
Negation	Not explicitly specified.
Idioms Supported	Visit <a href="#">HL7 CDA Example Search</a> for representing the expression "No Known Problems" <sup>131</sup> Reference: 5.2.6.2 Problem Observation
Other Considerations	A Problem Concern Act can contain one or more Problem Observations (templateId 2.16.840.1.113883.10.20.22.4.4). In practice, most EHRs do not support this template design. See best practice guidance below for implementers who do not support problem concern tracking at this time.
Example	Example 38: Problem Concern containing a Problem Observation

Table 47: Problem Concern Template

The design and guidance regarding the Problem Concern Act and Problem Observation templates are undergoing a cross-workgroup collaborative review with participation from the HL7 Structured Documents and Patient Care workgroups. This analysis has resulted in recommendations for improved guidance to help implementers with challenges previously encountered when using the Problem Concern Act and Problem Observation templates to exchange information about a patient's conditions.

Based on guidance resulting from the HL7 cross-workgroup collaborative review project where the HL7 Patient Care and Structured Documents workgroups jointly assessed issues with the Problem Concern Act template, the following guidance was developed<sup>132</sup>.

<sup>131</sup> HL7 C-CDA Examples Search. Problems. No Known Problems.

<http://cdasearch.hl7.org/examples/view/7353a215efda8dfe3fbacb19abb90756ce14bab>

<sup>132</sup> HL7 Cross-Workgroup C-CDA Template Review Project.



C-CDA Content Creators who do not natively support organizing a patient's problem observations into collections associated with a tracked concern SHOULD use the following guidance:

1. Populate the Act.statusCode of the Problem Concern Act to reflect the status of the clinical statement about the problem stored within the source system.
2. Use nullFlavor="NI" for the effectiveTime of the outer concern act wrapper.
3. Do not populate the author participation template associated with the outer concern act wrapper.
4. Include a single Problem Observation within the act wrapper.
5. Populate the effectiveTime of the Problem Observation with the biologically relevant time period associated with problem.
6. Include the author participation template associated with the Problem Observation to record the person who documented the problem.
7. Use the performer associated with the Problem Observation to record the person who made the diagnosis or observed the problem if that person is not also the author.
8. Use the Problem Status Observation template to record the clinical status assigned to the problem. Note that clinical status is a judgement assigned by the performer of the observation. **[BP-085]**

*Example 38: Problem Concern containing a Problem Observation*

```
<section>
  <!-- PLEASE REFER TO THE EXAMPLE TASK FORCE <http://hl7-c-cda-
  examples.herokuapp.com/sections/Problems> PAGE FOR EXAMPLES TO COMMON CHALLENGES WITH ENTRIES
  IN THIS SECTION -->
  <templateId root="2.16.840.1.113883.10.20.22.2.5"/>
  <templateId root="2.16.840.1.113883.10.20.22.2.5" extension="2015-08-01"/>
  <templateId root="2.16.840.1.113883.10.20.22.2.5.1"/>
  <templateId root="2.16.840.1.113883.10.20.22.2.5.1" extension="2015-08-01"/>
  <id root="093A5380-00CE-11E6-B4C5-0050568B000B"/>
  <code code="11450-4" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
  displayName="PROBLEM LIST"/>
  <title>ACTIVE PROBLEMS</title>
  <text>
  <table width="100%">
    <thead>
      <tr>
        <th>Problem Concern Information | Tracked By</th>
        <th>Condition(s)</th>
      </tr>
    </thead>
    <tbody>
      <tr styleCode="normRow">
        <td ID="ProblemConcern_1"><content>Active Problem</content> | <content/></td>
        <td>
          <list>
            <item>
              <table>
                <thead>
                  <tr>
                    <th>Problem Type | Problem<br/></th>
                    <th>Time Frame</th>
                    <th>Clinical Status</th>
                    <th>Documented By</th>
                  </tr>
                </thead>
              </table>
            </item>
          </list>
        </td>
      </tr>
    </tbody>
  </table>
  </text>
  </section>
```

```

        <tbody>
          <tr ID="ProblemObs1">
            <td>
              <content ID="ProblemObs_1_PT1">Problem</content> | <content
styleCode="Bold"                                ID="ProblemObs_1_P1">Osteoarthritis</content>
              </td>
            <td><content>(09/09/2014 - )</content></td>
            <td><content ID="ProblemObs_1_PS1">Active</content></td>
            <td><content>W.Colon</content> <content>(06/18/2015)</content></td>
          </tr>
        </tbody>
      </table>
    </item>
  </list>
</td>
</tr>
</tbody>
</table>
</text>
<entry>
  <act classCode="ACT" moodCode="EVN">
    <!-- Problem Concern -->
    <templateId root="2.16.840.1.113883.10.20.22.4.3"/>
    <templateId root="2.16.840.1.113883.10.20.22.4.3" extension="2015-08-01"/>
    <id extension="68993" root="1.2.840.114350.1.13.6289.1.7.2.768076"/>
    <id root="093A5380-00CE-11E6-B4C5-0050568B000B" extension="1"/>
    <code code="CONC" codeSystem="2.16.840.1.113883.5.6"
codeSystemName="HL7ActClass" displayName="Concern"></code>
    <!-- This shows what to do when the source system does not track problem concerns. -->
    <text>
      <reference value="#ProblemConcern_1"></reference>
    </text>
    <statusCode code="active"/>
    <effectiveTime nullFlavor="NI"/>
    <!-- A System that supports Concern tracking MAY include the author(s) of the Concern
in addition to
          author(s) for the contained Problem Observation(s). -->
    <entryRelationship inversionInd="false" typeCode="SUBJ">
      <!-- Problem Observation -->
      <observation classCode="OBS" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.22.4.4"/>
        <templateId root="2.16.840.1.113883.10.20.22.4.4" extension="2015-08-01"/>
        <id extension="68993" root="1.2.840.114350.1.13.6289.1.7.2.768076"/>
        <id root="093A5380-00CE-11E6-B4C5-0050568B000B" extension="1.1"/>
        <code code="55607006" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"
displayName="Problem">
          <originalText>
            <reference value="#ProblemObs_1_PT1"/>
          </originalText>
          <translation code="75326-9" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Problem"/>
        </code>
        <text>
          <reference value="#ProblemObs1"/>
        </text>
        <statusCode code="completed"/>
        <effectiveTime>
          <low value="20140909"/>
        </effectiveTime>
        <value code="396275006" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED
CT" displayName="Osteoarthritis"
xsi:type="CD" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
          <originalText>
            <reference value="#ProblemObs_1_P1"/>
          </originalText>
          <translation code="715.90" codeSystem="2.16.840.1.113883.6.103" codeSystemName="ICD-
9CM" displayName="Osteoarthritis"/>
          <translation code="M19.90" codeSystem="2.16.840.1.113883.6.90" codeSystemName="ICD-
10-CM" displayName="Osteoarthritis"/>
        </value>
        <author>

```

```

    <time value="20150618"/>
    <assignedAuthor>
    <id nullFlavor="UNK"/>
    <addr>
      <streetAddressLine>8333 Clairemont Mesa Blvd.</streetAddressLine>
      <city>Bel Air</city>
      <state>MD</state>
      <postalCode>21014</postalCode>
    </addr>
    <telecom use="WP" value="tel:+1-410-555-5544"/>
    <assignedPerson>
      <name>
        <given>Wilma</given>
        <family>Colon</family>
      </name>
    </assignedPerson>
    <representedOrganization>
      <name>Good Health Hospital</name>
      <telecom use="WP" value="tel:+1-410-555-5544"/>
      <addr>
        <streetAddressLine>8333 Clairemont Mesa Blvd.</streetAddressLine>
        <city>Bel Air</city>
        <state>MD</state>
        <postalCode>21014</postalCode>
      </addr>
    </representedOrganization>
  </assignedAuthor>
</author>
<entryRelationship typeCode="REFR">
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.22.4.6"/>
    <code code="33999-4" codeSystem="2.16.840.1.113883.6.1" displayName="Status"/>
    <text>
      <reference value="#ProblemObs_1_PS1"></reference>
    </text>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="20140909"/>
    </effectiveTime>
    <value code="55561003" codeSystem="2.16.840.1.113883.6.96" displayName="Active"
xsi:type="CD"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"/>
    </observation>
  </entryRelationship>
</observation>
</entryRelationship>
</act>
</entry>
</section>

```

### 5.2.6.2 Problem Observation

Entry Template	Problem Observation (V3) [observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.4:2015-08-01 (open)]
Reference Source	HL7 C-CDA R2.1
Purpose	This template reflects a discrete observation about a patient's problem.

Entry Template	Problem Observation (V3) [observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.4:2015-08-01 (open)]
<b>ActStatus</b>	This is a discrete observation that has been made in order for it to be documented. Therefore, it always has a statusCode of "completed".  The effectiveTime, also referred to as the "biologically relevant time" is the time at which the observation holds true for the patient. For a provider seeing a patient in the clinic today, observing a history of heart attack that occurred five years ago, the effectiveTime is five years ago. The effectiveTime of the Problem Observation is the definitive indication of when the problem occurred. If the problem is known to be resolved, then an effectiveTime/high would be present. If the date of resolution is not known, then effectiveTime/high will be present with a nullFlavor of "UNK". <sup>133</sup>
<b>Negation</b>	In this template, the negationInd attribute is used to indicate the absence of the condition in observation/value (Observation.ValueNegationInd).
<b>Idioms Supported</b>	A negationInd of "true" coupled with an observation/value of SNOMED code 55607006 "Problem" indicates that the patient has no known conditions. <sup>134</sup>
<b>Other Considerations</b>	The optional Problem Status Observation template (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.6) represents a clinical judgement of the status of the problem.
<b>Example</b>	Example 38: Problem Concern containing a Problem Observation
<b>Example</b>	Example 39: No Known Problems

Table 48: Problem Observation Template

## Example 39: No Known Problems

```

<section>
  <templateId root="2.16.840.1.113883.10.20.22.2.5.1"/>
  <!-- Problem Section with Coded Entries Required -->
  <templateId root="2.16.840.1.113883.10.20.22.2.5.1" extension="2015-08-01"/>
  <!-- Problem Section with Coded Entries Required -->
  <code code="11450-4" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
    displayName="Problem List"/>
  <title>PROBLEMS</title>
  <text ID="Concern_1"> Problem Concern:<br/> Concern Tracker Start Date: 06/07/2013
16:05:06<br/>
    Concern Tracker End Date: <br/> Concern Status: Active<br/>
    <content ID="problems1">No known <content
ID="problemType1">problems.</content></content>
  </text>
  <entry typeCode="DRIV">
    <!-- Problem Concern Act -->
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.22.4.3"/>
      <templateId root="2.16.840.1.113883.10.20.22.4.3" extension="2015-08-01"/>
      <id root="36e3e930-7b14-11db-9fe1-0800200c9a66"/>
      <!-- SDWG supports 48765-2 or CONC in the code element -->
      <code code="CONC" codeSystem="2.16.840.1.113883.5.6"/>
      <text>
        <reference value="#Concern_1"/>
      </text>
      <statusCode code="active"/>
      <!-- So long as the underlying condition is of concern to the provider (i.e., as
long as the condition,
        whether active or resolved, is of ongoing concern and interest to the
provider), the statusCode is "active".
    </act>
  </entry>
</section>

```

<sup>133</sup> HL7 C-CDA R2.1 2018Dec with errata. Problem Observation (V3). Page 21.<sup>134</sup> HL7 C-CDA Examples Search. Problems. No Known Problems.<http://cdasearch.hl7.org/examples/view/7353a215efda8dfe3fbacb19abbb90756ce14bab>



```

        Only when the underlying condition is no longer of concern is the
statusCode set to "completed". -->
        <effectiveTime>
            <low value="20130607160506"/>
            <!-- The effectiveTime reflects the time that the underlying condition was felt
to be a concern;
                it may or may not correspond to the effectiveTime of the condition
(e.g., even five years later, the clinician may remain concerned about a prior heart attack).--
>
            </effectiveTime>
            <!-- status is active so high is not applicable. If high is present it should have
nullFlavor of NA-->

        <author>
            <templateId root="2.16.840.1.113883.10.20.22.4.119"/>
            <time value="20130607160506"/>
            <assignedAuthor>
                <id extension="66666" root="2.16.840.1.113883.4.6"/>
                <code code="207RC0000X" codeSystem="2.16.840.1.113883.6.101"
                    codeSystemName="NUCC" displayName="Cardiovascular Disease"/>
                <addr>
                    <streetAddressLine>6666 StreetName St.</streetAddressLine>
                    <city>Silver Spring</city>
                    <state>MD</state>
                    <postalCode>20901</postalCode>
                    <country>US</country>
                </addr>
                <telecom value="tel:+1(301)666-6666" use="WP"/>
                <assignedPerson>
                    <name>
                        <given>Heartly</given>
                        <family>Sixer</family>
                        <suffix>MD</suffix>
                    </name>
                </assignedPerson>
            </assignedAuthor>
        </author>
        <entryRelationship typeCode="SUBJ">
            <observation classCode="OBS" moodCode="EVN" negationInd="true">
                <!-- The negationInd is used to indicate the absence of the condition in
observation/value (Observation.ValueNegationInd).
                    A negationInd of "true" coupled with an observation/value of SNOMED
code 55607006 "Problem"
                        indicates that the patient has no known conditions. -->
                <!-- problem observation template -->
                <templateId root="2.16.840.1.113883.10.20.22.4.4"/>
                <templateId root="2.16.840.1.113883.10.20.22.4.4" extension="2015-08-01"/>
                <id root="4adc1021-7b14-11db-9fe1-0800200c9a67"/>
                <code code="64572001" displayName="Disease"
codeSystem="2.16.840.1.113883.6.96"
                    codeSystemName="SNOMED CT">
                    <translation code="75323-6" codeSystem="2.16.840.1.113883.6.1"
                        codeSystemName="LOINC" displayName="Condition"/>
                </code>
                <text>
                    <reference value="#problems1"/>
                </text>
                <statusCode code="completed"/>
                <effectiveTime>
                    <low value="20130607160506"/>
                </effectiveTime>
                <!-- The time when this was biologically relevant ie True for the patient.
-->
                <!-- As a minimum time interval over which this is true, populate the
effectiveTime/low with the current time. -->
                <!-- It would be equally valid to have a longer range of time over which
this statement was represented as being true. -->
                <!-- As a maximum, you would never indicate an effectiveTime/high that was
greater than the current point in time. -->

```

```

value set, or--> <!-- This idea assumes that the value element could come from the Problem
value set (and code would be ASSERTION). -->
  <!-- when negationInd was true, is could also come from the ProblemType
  <value xsi:type="CD" code="55607006" displayName="Problem"
    codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT">
    <originalText>
      <reference value="#problemType1"/>
    </originalText>
  </value>
</observation>
</entryRelationship>
</act>
</entry>
</section>

```

### 5.2.6.3 Health Concern, Risk Concern

A health concern describes an interest or worry about a health state or process that could possibly require attention, intervention, or management. A Health Concern is a health-related matter that is of interest, importance or worry to someone, who may be the patient, patient's family or patient's health care provider. It is a wrapper for a single health concern which may be derived from a variety of sources within an EHR (such as Problem List, Family History, Social History, Social Worker Note, etc.). Problem Concerns are a subset of the set of Health Concerns. Problem Concerns are more specifically the set of concerns a care provider has indicated as being on the patient's "Problem List".

A Health Concern Act is used to track non-optimal physical or psychological situations drawing the patient to the healthcare system. These may be from the perspective of the care team or from the perspective of the patient. When the underlying condition is of concern (i.e., as long as the condition, whether active or resolved, is of ongoing concern and interest), the statusCode is "active". Only when the underlying condition is no longer of concern is the statusCode set to "completed". The effectiveTime reflects the time that the underlying condition was felt to be a concern; it may or may not correspond to the effectiveTime of the condition (e.g., even five years later, a prior heart attack may remain a concern). Health concerns require intervention(s) to increase the likelihood of achieving the goals of care for the patient and they specify the condition-oriented reasons for creating the plan.

A Risk Concern Act represents a health concern that is at risk of occurring but has not yet manifested for the patient. A risk is a clinical or socioeconomic condition that the patient does not currently have, but the probability of developing that condition rises to the level of concern such that an intervention and/or monitoring is needed. It is a wrapper for a single concern which may be derived from a variety of sources within an EHR (such as Problem List, Family History, Social History, Social Worker Note, etc.). The design of this template is identical to the design of a Health Concern template. The only difference is the semantics associated with the Act.code element. The Act.code of a Risk Concern template carries the SNOMED CT concept 281694009 (Finding of at risk (finding)) whereas the Act.code of a Health Concern template carries the LOINC concept 75310-3 (Health Concerns Document). The two templates are otherwise identical. Implementer best practice guidelines for the Health Concern template should be applied to the Risk Concern template as well.

Entry Template	Health Concern (V2) [act: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.132:2015-08-01 (open)]
Reference Source	HL7 C-CDA R2.1
Purpose	This template represents a single health concern which may be derived from a variety of sources within an EHR (such as Problem List, Family History, Social History, Social Worker Note, etc.). A Health Concern is used to track non-optimal physical or psychological situations drawing the patient to the healthcare system. These may be from the perspective of the care team or from the perspective of the patient.
ActStatus	When the underlying condition is of concern (i.e., as long as the condition, whether active or resolved, is of ongoing concern and interest), the statusCode is "active". Only when the underlying condition is no longer of concern is the statusCode set to "completed". The effectiveTime reflects the time that the underlying condition was felt to be a concern; it may or may not correspond to the effectiveTime of the condition (e.g., even five years later, a prior heart attack may remain a concern).
Negation	Not explicitly specified.
Idioms Supported	None.
Other Considerations	In its simplest form, a Health Concern template can be used to wrap a Problem Observation template. Also, best practice guidance associated with the Problem Concern Act template can be applied similarly to the Health Concern template.  Examples of a Health Concern that might not be considered a Problem Concern include: "Risk of Hyperkalemia" for a patient taking an ACE-inhibitor medication, "Transportation difficulties" for a patient who doesn't drive and has trouble getting to appointments, or "Under-insured" for a patient who doesn't have sufficient insurance to cover their medical needs such as medications. Problem Concerns are a subset of Health Concerns. Problem Concerns are problems and diagnoses typically found on a classic "Problem List", such as "Diabetes Mellitus" or "Family History of Melanoma" or "Multi-vessel Coronary Artery Disease".
Example	Example 40: Health Concern narrative entry

Table 49: Health Concern Template

## Example 40: Health Concern narrative entry

```
<?xml version="1.0" encoding="UTF-8"?>
<component>
  <section>
    <!-- Health Concerns Section -->
    <templateId root="2.16.840.1.113883.10.20.22.2.58" extension="2015-08-01"/>
    <code code="75310-3" displayName="Health Concerns Document"
codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
    <title>Health Concerns</title>
    <text><paragraph ID="Concern">On March 1, 2014, the patient expressed concern about
spreading their Community Acquired Pneumonia.</paragraph></text>
    <entry>
      <!-- Health Concern Act -->
      <act classCode="ACT" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.22.4.132" extension="2015-08-01"/>
        <id nullFlavor="UNK"/>
        <!-- Fixed act/code in C-CDA -->
        <code code="75310-3" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
displayName="Health Concern"/>
        <text><reference value="#Concern"></reference></text>
        <statusCode code="active"/>
      </act>
    </entry>
  </section>
</component>
```

## 5.2.7 Allergy

Allergy information includes medication and non-medication allergy concerns and observations including statements about no known allergies.

### 5.2.7.1 Allergy Concern

The Allergy Concern template enables multiple allergy intolerance observations to be tracked together as a single concern. An allergy concern contains data describing a patient allergy or intolerance that could possibly require attention, intervention, or management. The Allergy Concern Act template is used to record concerns commonly identified as being “on the patient’s allergy list.” The Allergy Concern Act acts as a “wrapper” for the underlying Allergy - Intolerance Observations.


Entry Template	Allergy Concern Act (V3) [act: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.30:2015-08-01 (open)]
Reference Source	HL7 C-CDA R2.1
Purpose	This template reflects an ongoing concern on behalf of the provider who is managing the patient’s care.
ActStatus	<p>So long as the underlying allergy or intolerance is of ongoing concern and interest to the provider, the statusCode of the concern is “active”. Only when the underlying allergy or intolerance is no longer of concern is the statusCode of the Allergy Concern Act set to “completed.”</p> <p>The effectiveTime reflects the time that the underlying allergy or intolerance was felt to be a concern; it may or may not correspond to the effectiveTime of the observation associated with the actual allergic reaction experienced by the patient.</p> <p>The statusCode of the Allergy Concern Act is the status of the concern, whereas the effectiveTime of the nested Allergy - Intolerance Observation tells when the allergy or intolerance was experienced by the patient. The effectiveTime/low of the Allergy Concern Act asserts when the concern became active. The effectiveTime/high asserts when the concern was completed (e.g., when the clinician deemed there is no longer any need to track the underlying allergy or intolerance).</p>
Negation	Not explicitly specified.
Idioms Supported	<p>Visit <a href="#">HL7 CDA Example Search</a> for representing the expression “No Known Allergies”, “No Known Medication Allergies”.<sup>135</sup></p> <p><b>Reference:</b> Example 42: No known allergies</p>
Other Considerations	An Allergy Concern Act can contain one or more Allergy - Intolerance Observations (templateId .16.840.1.113883.10.20.22.4.7). In practice, most EHRs do not support this template design. See best practice guidance below for implementers who do not support allergy concern tracking at this time.
Example	Example 41: Allergy concern for food allergy to eggs
Example	Example 42: No known allergies

<sup>135</sup> HL7 C-CDA Examples Search. Problems. No Known Problems.  
<http://cdasearch.hl7.org/examples/view/7353a215efda8dfe3fbacb19abbb90756ce14bab>

<b>Entry Template</b>	<b>Allergy Concern Act (V3)</b> [act: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.30:2015-08-01 (open)]
<b>Example</b>	Visit <a href="#">HL7 CDA Example Search</a> for additional examples showing allergies to specific medication.

Table 50: Allergy Concern Template

When the designed clinical statement patterns do not match with the source information to be exchanged, it creates challenges for implementers. The concern pattern has been a challenge for implementers because many EHR systems do not organize the source allergy data within the patient’s medical record in this way. Based on guidance resulting from the HL7 cross-workgroup collaborative review project where the HL7 Patient Care and Structured Documents workgroups jointly assessed issues with the Allergy Concern Act template, the following guidance was developed.<sup>136</sup>



C-CDA Content Creators who do not natively support organizing a patient’s allergy/intolerance observations into collections associated with a tracked concern SHOULD use the following guidance:

1. Populate the Act.statusCode of the Allergy Concern Act to reflect the status of the clinical statement about the allergy/intolerance stored within the source system.
2. Use nullFlavor="NI" for the effectiveTime of the outer concern act wrapper.
3. Do not populate the author participation template associated with the outer concern act wrapper.
4. Include a single Allergy-Intolerance Observation within the act wrapper.
5. Populate the effectiveTime of the Allergy-Intolerance Observation with the biologically relevant time period associated with allergy/intolerance.
6. Include the author participation template associated with the Allergy-Intolerance Observation to record the person who documented the problem.
7. Use the performer associated with the Allergy-Intolerance Observation to record the person who identified or observed the allergy/intolerance.
8. Use the Allergy Status Observation template to record the clinical status assigned to the allergy-intolerance. Note that clinical status is a judgement assigned by the performer of the observation. **[BP-086]**

Example 41: Allergy concern for food allergy to eggs

```
<section>
  <!-- PLEASE REFER TO THE EXAMPLE TASK FORCE <http://hl7-c-cda-
examples.herokuapp.com/sections/Allergies> PAGE FOR EXAMPLES TO COMMON CHALLENGES WITH
ENTRIES IN THIS SECTION →
  <templateId ro"t="2.16.840.1.113883.10.20.22."6"/>
  <templateId ro"t="2.16.840.1.113883.10.20.22."6" extensi"n="2015-08"01"/>
  <templateId ro"t="2.16.840.1.113883.10.20.22.2."1"/>
  <templateId ro"t="2.16.840.1.113883.10.20.22.2."1" extensi"n="2015-08"01"/>
  <id ro"t="0937FF9A-00CE-11E6-B4C5-0050568B0"0B"/>
  <code co"e="4876"-2" displayNa"e="Allergies &amp;or adverse reactions "oc"
codeSyst"m="2.16.840.1.113883."1" codeSystemNa"e="LO"NC"/>
  <title>ALLERGIES</title>
  <text>
```

<sup>136</sup> HL7 Cross-Workgroup C-CDA Template Review Project.

```

<table width="100%">
  <thead>
    <tr>
      <th>Concern Information | Tracked By</th>
      <th>Allergy - Intolerance Information</th>
    </tr>
  </thead>
  <tbody>
    <tr "D="AllergyConcern_1" styleColor="normal">
      <td>
        <content>Active (01/04/2014 - )</content> |
        <content>(01/04/2019) H.Seven</content>
      </td>
      <td>
        <list>
          <item>
            <table>
              <thead>
                <tr>
                  <th>Allergy Type | Allergen<br/></th>
                  <th>Criticality</th>
                  <th>Reaction | Severity<br/></th>
                  <th>Time Frame</th>
                  <th>Clinical Status</th>
                  <th>Documented By</th>
                </tr>
              </thead>
              <tbody>
                <tr "D="AllergyConcern_1_Allerg_1">
                  <td><content>Food allergy</content> |
                    <content styleColor="Bold"
"D="AllergyConcern_1_Allerge_1">Egg</content>
                  <td>
                    <content "D="AllergyConcern_1_Criticalit_1">High
Criticality</content>
                  </td>
                  <td>
                    <content "D="AllergyConcern_1_Reactio_1">Hives</content> |
                    <content "D="AllergyConcern_1_ReacSeverit_1">Moderate</content>
                  </td>
                  <td>
                    <content>(1998)</content>
                  </td>
                  <td>
                    <content>Active</content>
                  </td>
                  <td>
                    <content>H.Provider</content>
                    <content>(01/04/2014)</content>
                  </td>
                </tr>
              </tbody>
            </table>
          </item>
        </list>
      </td>
    </tr>
  </tbody>
</table>
</text>
<entry typeCode="DIV">
  <act classCode="CT" moodCode="VN">
    <!-- ** Allergy Concern act ** -->
    <templateId root="2.16.840.1.113883.10.20.22.4"30"/>
    <templateId root="2.16.840.1.113883.10.20.22.4"30" extension="2015-08"01"/>
    <id root="0ffffb34f-c1e0-47c2-92af-c414a3ff2"ec"/>
    <code code="C"NC" codeSystem="2.16.840.1.113883."6"/>
    <text>
      <reference value="#AllergyConcern_1"/>
    </text>
  </act>

```

```

<statusCode co"e="act"ve"/>
--- This is the time stamp for when the allergy was first documented as a concern-->
<effectiveTime>
  <low val"e="20140104123506-0"00"/>
</effectiveTime>
<author>
  <templateId ro"t="2.16.840.1.113883.10.20.22.4."19"/>
  <time val"e="20140"04"/>
  <assignedAuthor>
    <id extensi"n="99999"99" ro"t="2.16.840.1.113883."6"/>
    <code co"e="207Q000"0X" codeSyst"m="2.16.840.1.113883.6."01"
codeSystemNa"e="Health Care Provider Taxon"my" displayNa"e="Family medic"ne"/>
    <telecom u"e="WP" val"e="tel:555-555-1"02"/>
    <assignedPerson>
      <name>
        <given>Henry</given>
        <family>Seven</family>
      </name>
    </assignedPerson>
  </assignedAuthor>
</author>
<entryRelationship typeCo"e="S"BJ">
<observation classCo"e="BS" moodCo"e="VN">
--- allergy observation template -->
  <templateId ro"t="2.16.840.1.113883.10.20.22."7"/>
  <templateId ro"t="2.16.840.1.113883.10.20.22."7" extensi"n="2014-06"09"/>
  <id ro"t="0fffb34f-c1e0-47c2-92af-c414a3ff2"ec"/>
  <code co"e="ASSERT"ON" codeSyst"m="2.16.840.1.113883."4"/>
  <text>
    <reference val"e="#AllergyConcern_1_Allerg"1"/>
  </text>
  <statusCode co"e="comple"ed"/>
  --- This is the time stamp for the biological onset of the allergy. -->
  --- Just the year is shown since a specific month and date was not reported -->
  <effectiveTime>
    <low val"e="1"98"/>
  </effectiveTime>
  --- This specifies that the allergy is to a food in contrast to other allergies
  (drug) -->
    <value xsi:ty"e="CD" co"e="414285"01" displayNa"e="Food allergy (disord"r)"
codeSyst"m="2.16.840.1.113883.6"96" codeSystemNa"e="SNOMED"CT"/>
    <author>
      <templateId ro"t="2.16.840.1.113883.10.20.22.4."19"/>
      <time val"e="20140"04"/>
      <assignedAuthor>
        <id extensi"n="99999"99" ro"t="2.16.840.1.113883."6"/>
        <code co"e="207Q000"0X" codeSyst"m="2.16.840.1.113883.6."01"
codeSystemNa"e="Health Care Provider Taxon"my" displayNa"e="Family Medic"ne"/>
        <telecom u"e="WP" val"e="tel:555-555-1"02"/>
        <assignedPerson>
          <name>
            <given>Henry</given>
            <family>Seven</family>
          </name>
        </assignedPerson>
      </assignedAuthor>
    </author>
    --- In C-CDA R2.1 the participant is required. -->
    <participant typeCo"e="SM">
      <participantRole classCo"e="M"NU">
        <playingEntity classCo"e="M"AT">
          --- The agent responsible for an allergy or adverse reaction is not always a
          manufactured material (for example, food allergies),
          nor is it necessarily consumed. The following constraints reflect limitations in the base CDA
          R2 specification,
          and should be used to represent any type of responsible agent, i.e., use playingEntity
          classCode="M"AT" for all agents,
          manufactured or not. -->---
          ... the expectation for use is that the chosen concept identifier for a substance should be
          appropriately specific and drawn from the available code systems in the following priority

```

```

order: NDFRT, then RXNORM, then SNOMEDCT. UNII was in an earlier version of this grouping value
set but has been removed due to lack of industry use
-->
      <code co"e="102263"04" displayNa"e="Eggs (edib"e)"
codeSyst"m="2.16.840.1.113883.6"96" codeSystemNa"e="SNOMED"CT">
      <originalText>
      <reference val"e="#AllergyConcern_1_Allerge"_"1"/>
      </originalText>
      </code>
      </playingEntity>
    </participantRole>
  </participant>
  <entryRelationship typeCo"e="S"BJ" inversionI"d="t"ue">
    <observation classCo"e=""BS" moodCo"e=""VN">
      <templateId ro"t="2.16.840.1.113883.10.20.22.4."45"/>
      <code co"e="8260"-5" codeSyst"m="2.16.840.1.113883."1"
displayNa"e="Critical"ty" />
      <text>
      <reference val"e="#AllergyConcern_1_Criticalit"_"1"/>
      </text>
      <statusCode co"e="comple"ed"/>
      <value xsi:ty"e="CD" co"e="CR"TH" displayNa"e="High Critical"ty"
codeSyst"m="2.16.840.1.113883.5.1"63"
codeSystemNa"e="HL7ObservationVa"ue"/>
    </observation>
  </entryRelationship>
  <entryRelationship typeCo"e="M"ST" inversionI"d="t"ue">
    <observation classCo"e=""BS" moodCo"e=""VN">
      --- Reaction Observation template -->
      <templateId ro"t="2.16.840.1.113883.10.20.22."9"/>
      <templateId ro"t="2.16.840.1.113883.10.20.22."9" extensi"n="2014-06"09"/>
      <id ro"t="d89ce431-e0f1-4f8d-a81f-489b6ed91"09"/>
      <code co"e="ASSERT"ON" codeSyst"m="2.16.840.1.113883."4"/>
      <text>
      <reference val"e="#AllergyConcern_1_Reactio"_"1"/>
      </text>
      <statusCode co"e="comple"ed"/>
      <effectiveTime>
      <low val"e="1"98"/>
      <high nullFlav"r=""NK"/>
      </effectiveTime>
      <value xsi:ty"e="CD" co"e="247472"04" codeSyst"m="2.16.840.1.113883.6"96"
codeSystemNa"e="SNOMED"CT" displayNa"e="Hi"es"/>
    <entryRelationship typeCo"e="S"BJ" inversionI"d="t"ue">
      <observation classCo"e=""BS" moodCo"e=""VN">
        --- Severity Observation template -->
        <templateId ro"t="2.16.840.1.113883.10.20.22."8"/>
        <templateId ro"t="2.16.840.1.113883.10.20.22."8" extensi"n="2014-06"09"/>
        <code co"e=""EV" codeSyst"m="2.16.840.1.113883."4"
codeSystemNa"e="ActC"de"/>
        <text>
        <reference val"e="#AllergyConcern_1_ReacSeverit"_"1"/>
        </text>
        <statusCode co"e="comple"ed"/>
        <value xsi:ty"e="CD" co"e="6736"07" codeSyst"m="2.16.840.1.113883.6"96"
codeSystemNa"e="SNOMED"CT" displayNa"e="moder"te"/>
      </observation>
    </entryRelationship>
  </observation>
</entryRelationship>
</observation>
</entryRelationship>
</act>
</entry>
</section>

```



## Example 42: No known allergies

```

<section>
  <!-- *** Allergies and Intolerances Section (entries required) (V3) *** ->
  <templateId ro"t="2.16.840.1.113883.10.20.22.2."1"/>
  <templateId ro"t="2.16.840.1.113883.10.20.22.2."1" extensi"n="2015-08"01"/>
  <code co"e="4876"-2" codeSyst"m="2.16.840.1.113883."1" codeSystemNa"e="LO"NC"/>
  <title>ALLERGIES AND ADVERSE REACTIONS</title>
  <text "D="allergiesNoKn"wn">No Known Allergies</text>
  <entry typeCo"e="D"IV">
    --- Allergy Concern Act ---
    <act classCo"e="CT" moodCo"e="VN">
      <templateId ro"t="2.16.840.1.113883.10.20.22.4"30"/>
      <templateId ro"t="2.16.840.1.113883.10.20.22.4"30" extensi"n="2015-08"01"/>
      <id ro"t="36e3e930-7b14-11db-9fe1-0800200c9"66"/>
      --- SDWG supports 48765-2 or CONC in the code element ---
      <code co"e="C"NC" codeSyst"m="2.16.840.1.113883."6"/>
      <text>
        <reference val"e="#allergiesNoKn"wn"/>
      </text>
      <statusCode co"e="act"ve"/>
    -!--currently tracked concerns are active concerns-->
    <effectiveTime>
      <low val"e="20100"03"/>
      -!--show time when the concern first began being tracked-->
    </effectiveTime>
    <author>
      <templateId ro"t="2.16.840.1.113883.10.20.22.4."19"/>
      <time val"e="20100"03"/>
      <assignedAuthor>
        <id extensi"n="99999"99" ro"t="2.16.840.1.113883."6"/>
        <code co"e="207Q000"0X" codeSyst"m="2.16.840.1.113883.6."01"
          codeSystemNa"e="Health Care Provider Taxon"my" displayNa"e="Family Medic
        <telecom u"e="WP" val"e="tel:555-555-1"02"/>
        <assignedPerson>
          <name>
            <given>Henry</given>
            <family>Seven</family>
          </name>
        </assignedPerson>
      </assignedAuthor>
    </author>
    <entryRelationship typeCo"e="S"BJ">
      --- No Known Allergies ---
      --- The negationInd = true negates the observation/value ---
      --- The use of negationInd corresponds with the newer Observation.valueNegationIn
      <observation classCo"e="BS" moodCo"e="VN" negationI"d="t"ue">
        --- aller-y - intolerance observation template ---
        <templateId ro"t="2.16.840.1.113883.10.20.22."7"/>
        <templateId ro"t="2.16.840.1.113883.10.20.22."7" extensi"n="2014-06"09"/>
        <id ro"t="4adc1020-7b14-11db-9fe1-0800200c9"66"/>
        <code co"e="ASSERT"ON" codeSyst"m="2.16.840.1.113883."4"/>
        <text>
          <reference val"e="#allergiesNoKn"wn"/>
        </text>
        <statusCode co"e="comple"ed"/>
        --- N-A - author/time records when this assertion was made ---
        <effectiveTime>
          <low nullFlav"r="NA"/>
        </effectiveTime>
        <value xsi:ty"e="CD" co"e="419199"07"
          displayNa"e="Allergy to substance (disord"r)"
          codeSyst"m="2.16.840.1.113883.6"96" codeSystemNa"e="SNOMED"CT"/>
        <author>
          <templateId ro"t="2.16.840.1.113883.10.20.22.4."19"/>
          <time val"e="20100"03"/>
          <assignedAuthor>
            <id extensi"n="99999"99" ro"t="2.16.840.1.113883."6"/>
            <code co"e="207Q000"0X" codeSyst"m="2.16.840.1.113883.6."01"
              codeSystemNa"e="Health Care Provider Taxon"my"
              displayNa"e="Family Medic"ne"/>
            <telecom u"e="WP" val"e="tel:555-555-1"02"/>
          </assignedAuthor>
        </author>
      </entryRelationship>
    </act>
  </entry>
</section>

```

```

        <assignedPerson>
            <name>
                <given>Henry</given>
                <family>Seven</family>
            </name>
        </assignedPerson>
    </assignedAuthor>
</author>
--- In C-CDA R2.1 the participant is required. -->
    <participant typeCode="SM">
        <participantRole classCode="MNU">
            <playingEntity classCode="MAT">
                <code nullFlavor="NA"/>
            </playingEntity>
        </participantRole>
    </participant>
</observation>
</entryRelationship>
</act>
</entry>
</section>

```

### 5.2.7.2 Allergy – Intolerance

The design and guidance regarding the Allergy Concern Act and Allergy – Intolerance Observation templates are undergoing a cross-workgroup collaborative review with participation from the HL7 Structured Documents and Patient Care workgroups. This analysis has resulted in recommendations for improved guidance to help implementers with challenges previously encountered when using the Allergy Concern Act and Allergy-Intolerance Observation templates to exchange information about a patient’s allergies.

Entry Template	Aller-y - Intolerance Observation (V2) [observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.7:2014-06-09 (open)]
<b>Reference Source</b>	HL7 C-CDA R2.1
<b>Purpose</b>	This template reflects a discrete observation about a pati’nt's allergy or intolerance.
<b>ActStatus</b>	<p>This is a discrete observation that has been made in order for it to be documented. Therefore, it always has a statusCode of “completed.”</p> <p>The effectiveTime, also referred to as the “biologically relevant time” is the time at which the observation holds true for the patient. For a provider seeing a patient in the clinic today, observing a history of penicillin allergy that developed five years ago, the effectiveTime is five years ago. The effectiveTime of the Problem Observation is the definitive indication of when the allergy-intolerance occurred. If the allergy/intolerance is known to be resolved, then an effectiveTime/high would be present. If allergy-intolerance in ongoing, then effectiveTime/high will not be present.<sup>137</sup></p>
<b>Negation</b>	In this template, the negationInd attribute is used to indicate the absence of the allergy in observation/value (Observation.ValueNegationInd).

<sup>137</sup> HL7 C-CDA R2.1 2018Dec with errata. Problem Observation (V3). Page 21.

<b>Entry Template</b>	<b>Allergy - Intolerance Observation (V2)</b> [observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.7:2014-06-09 (open)]
<b>Idioms Supported</b>	Visit <a href="#">HL7 CDA Example Search</a> for representing the expression “No Known Problems.” <sup>138</sup> A negationInd of "true" coupled with an observation/value of SNOMED code 41919907.  "Allergy to substance (disorder)" indicates that the patient has no known allergies.
<b>Other Considerations</b>	The optional Allergy Status Observation template (identifier: urn:oid: 2.16.840.1.113883.10.20.22.4.28 ) represents a clinical judgement of the status of the allergy-intolerance.  The Allergy-Intolerance Observation includes a Reaction Observation that tells what sort of reaction was associated with the event. The Reaction Observation includes a Severity Observation to indicate how severe that reaction was. The Allergy-Intolerance Observation also includes a Criticality Observations that indicates how serious a health issue this allergy-intolerance is. The possible values for the Criticality Observation include: high criticality, low criticality, or unable to assess criticality.
<b>Example</b>	Example 43: Recording an allergy that started in January of 2009, but became a tracked concern as of January 4, 2014
<b>Example</b>	Example 44: Updating an allergy that is no longer a concern
<b>Example</b>	Visit <a href="#">HL7 CDA Example Search</a> for additional examples for allergies

Table 51: Allergy - Intolerance Observation Template

Example 43: Recording an allergy that started in January of 2009, but became a tracked concern as of January 4, 2014

```
<entry typeCode="DRIV">
  <act classCode="ACT" moodCode="EVN">
    <!-- ** Allergy problem act ** -->
    <templateId root="2.16.840.1.113883.10.20.22.4.30" extension="2015-08-01"/>
    <templateId root="2.16.840.1.113883.10.20.22.4.30"/>
    <id root="4a2ac5fc-0c85-4223-baee-c2e254803974" />
    <code code="CONC" codeSystem="2.16.840.1.113883.5.6"/>
    <statusCode code="active"/>
    <!-- This is the time stamp for when the allergy was first documented as a concern-->
    <effectiveTime>
      <low value="20140104123506-0500"/>
    </effectiveTime>
    <author>
      <time value="20140104123506-0500"/>
      ...information identifying the author of the concern...
    </author>
    <entryRelationship typeCode="SUBJ">
      <observation classCode="OBS" moodCode="EVN">
        <!-- allergy observation template -->
        <templateId root="2.16.840.1.113883.10.20.22.4.7"/>
        <id root="4a2ac5fc-0c85-4223-baee-c2e254803974"/>
        <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
        <statusCode code="completed"/>
        <!-- This is the time stamp for the biological onset of the allergy. -->
        <effectiveTime>
          <low value="200901"/>
        </effectiveTime>
      </observation>
    </entryRelationship>
  </act>
</entry>
```

<sup>138</sup> HL7 C-CDA Examples Search. Problems. No Known Problems.  
<http://cdasearch.hl7.org/examples/view/7353a215efda8dfe3fbacb19abbb90756ce14bab>

```

    </observation>
  </entryRelationship>
</act>
</entry>

```

During an encounter, if a patient's record was updated to indicate that an allergy concern recorded one month ago about a penicillin allergy/intolerance that occurred five years ago was no longer a concern, the information recorded in the CDA document would be as follows:

- act/statusCode - completed
- act/effectiveTime/low – a month ago
- act/effectiveTime/high – today (no longer a concern)
- act/author/time – today
- act/entryRelationship/observation/effectiveTime/low – five years ago
- act/entryRelationship/observation/effectiveTime/high - not present (allergy still ongoing)

*Example 44: Updating an allergy that is no longer a concern*

```

<entry typeCode="DRIV">
  <act classCode="ACT" moodCode="EVN">
    <!-- ** Allergy problem act ** -->
    <templateId root="2.16.840.1.113883.10.20.22.4.30" extension="2015-08-01"/>
    <templateId root="2.16.840.1.113883.10.20.22.4.30"/>
    <id root="4a2ac5fc-0c85-4223-baee-c2e254803974" />
    <code code="CONC" codeSystem="2.16.840.1.113883.5.6"/>
    <statusCode code="completed"/>
    <!-- This is the time stamp for when the allergy was first documented as a concern-->
    <effectiveTime>
      <low value="20160104123506-0500"/>
      <high value="20160204123506-0500"/>
    </effectiveTime>
    <author>
      <time value="20160204123506-0500"/>
      ...information identifying the author of the concern...
    </author>
    <entryRelationship typeCode="SUBJ">
      <observation classCode="OBS" moodCode="EVN">
        <!-- allergy observation template -->
        <templateId root="2.16.840.1.113883.10.20.22.4.7"/>
        <id root="4a2ac5fc-0c85-4223-baee-c2e254803974"/>
        <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
        <statusCode code="completed"/>
        <!-- This is the time stamp for the biological onset of the allergy. -->
        <effectiveTime>
          <low value="200901"/>
        </effectiveTime>
      </observation>
    </entryRelationship>
  </act>
</entry>

```

... Add representation of the Allergy Status Observation ...

## 5.2.8 Medical Equipment

Medical Equipment includes devices implanted within the patient and devices the patient has or uses.

### 5.2.8.1 Implanted Device

Each implanted device can be represented in an Individual Procedure Activity Procedure template. If information about the procedure that applied or placed the device is known, it should be included, otherwise as much information as is known should be specified.

An implanted device (or groups of implanted devices) also can be represented within a Medical Equipment Organizer template. Including information about a device in the procedure details does not remove the need to list the device in the Medical Equipment section. Each component of the Medical Equipment Organizer contains a Procedure Activity Procedure template.

UDI information is considered core data for interoperability. Content Creators should support population of an UDI Organizer within a Procedure Activity Procedure to represent the parsed universal identifier information for an implanted device. Content Consumers should support processing of this information when it is received.

Entry Template	Procedure Activity Procedure (V2)
<b>Reference Source</b>	HL7 C-CDA R2.1 [procedure: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.14:2014-06-09 (open)]
<b>Purpose</b>	This template is used to represent procedures whose immediate and primary outcome (post-condition) is the alteration of the physical condition of the patient. It also is used with a contained Product Instance template to represent a device implanted in or on a patient. In this case, targetSiteCode is used to record the location of the device in or on the patient's body.
<b>ActStatus</b>	This template includes a state model that includes: active, completed, aborted, and cancelled. When documenting an implanted medical device, the statusCode = "completed".  The effectiveTime, also referred to as the "biologically relevant time" is the time at which the procedure was performed which implies the data the device was implanted. Best practice is to use the TS data type and record a single point in time to represent when the device was implanted. For implementers who must populate a time interval, effectiveTime/low MAY be populated. effectiveTime/high SHOULD NOT be populated.
<b>Negation</b>	In this template, the negationInd attribute is used to indicate the procedure was not performed.
<b>Idioms Supported</b>	See example below for the representation of "No Implanted Devices". The idiom clinical statement pattern uses a combination of negation and nullFlavor to semantically represent "the patient has not had any procedures to implant any devices."

Entry Template	Procedure Activity Procedure (V2) [procedure: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.14:2014-06-09 (open)]
<b>Other Considerations</b>	<p>The contained Product Instance template is used to represent a particular device that was placed in a patient or used as part of a procedure or other act.</p> <p>To record the removal of an implanted device, use a separate Procedure Activity Procedure template with an appropriate code for the device removal procedure. Again, use the TS data type and record a single point in time to represent when the device was removed. Best practice includes linking the device removal procedure to the original implant procedure using the entry reference template. [act: identifier urn:oid:2.16.840.1.113883.10.20.22.4.122 (open)]</p> <p>When representing that a procedure was not performed, the Indication (V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.19:2014-06-09) template MAY be used to represent the rationale for not performing the procedure. More than one indication template may be contained within a Procedure template.</p>
<b>Example</b>	Example 45: Implanted Device – known procedure details
<b>Example</b>	Example 46: Implanted Device - Procedure unknown
<b>Example</b>	Example 47: No Implanted Devices
<b>Example</b>	Example 48: Non-Medicinal Supply – Cane and Eyeglasses

Table 52: Procedure Activity Template

Example 45: Implanted Device – known procedure details

```

<component>
  <section>
    <templateId root="2.16.840.1.113883.10.20.22.2.23"/>
    <templateId root="2.16.840.1.113883.10.20.22.2.23" extension="2014-06-09"/>
    <code code="46264-8" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
    displayName="Medical Equipment"/>
    <title>Implants</title>
    <text>
      <!-- table omitted for space -->
    </text>
    <entry>
      <procedure classCode="PROC" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.22.4.14" extension="2014-06-09"/>
        <id extension="2744" root="1.2.840.114350.1.13.5552.1.7.2.737780"/>
        <code code="609588000" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"
        displayName="Total knee replacement (procedure)"/>
        <!-- Procedure is completed, even though the implant is still active -->
        <statusCode code="completed"/>
        <effectiveTime>
          <!-- Placed Date -->
          <low value="20160413"/>
        </effectiveTime>
        <targetSiteCode code="72696002" codeSystem="2.16.840.1.113883.6.96"
        codeSystemName="SNOMED CT" displayName="Knee region structure">
          <qualifier>
            <name code="272741003" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED
            CT" displayName="laterality" />
            <value code="7771000" codeSystem="2.16.840.1.113883.9.96" codeSystemName="SNOMED
            CT" displayName="left" />
          </qualifier>
        </targetSiteCode>
        <participant typeCode="DEV">
          <participantRole classCode="MANU">
            <templateId root="2.16.840.1.113883.10.20.22.4.37"/>
            <id assigningAuthorityName="FDA"
            extension="(01)00848486000400(11)160330(10)ABC634(21)123777" root="2.16.840.1.113883.3.3719"/>
            <playingDevice>

```

```

        <code nullFlavor="UNK">
            <originalText>
                <reference value="#implant1"/>
            </originalText>
        </code>
    </playingDevice>
    <!-- From Product Instance template:
        The scopingEntity/id should correspond to FDA or the appropriate issuing
agency. -->
    <scopingEntity>
        <id root="2.16.840.1.113883.3.3719"/>
    </scopingEntity>
</participantRole>
</participant>
</procedure>
</entry>
<entry>
    <!-- example without qualifier omitted for space -->
</entry>
<entry>
    <!-- example where targetSiteCode not mapped omitted for space -->
</entry>
</section>
</component>

```

*Example 46: Implanted Device - Procedure unknown<sup>139</sup>*

```

<component>
  <section>
    <templateId root="2.16.840.1.113883.10.20.22.2.23"/>
    <templateId root="2.16.840.1.113883.10.20.22.2.23" extension="2014-06-09"/>
    <code code="46264-8" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
displayName="Medical Equipment"/>
    <title>Implants</title>
    <text>
      <!-- table omitted for space -->
    </text>
    <entry>
      <procedure classCode="PROC" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.22.4.14" extension="2014-06-09"/>
        <id extension="2744" root="1.2.840.114350.1.13.5552.1.7.2.737780"/>
        <code nullFlavor="UNK"/>
        <!-- Procedure is completed, even though the implant is still active -->
        <statusCode code="completed"/>
        <effectiveTime>
          <!-- Placed Date -->
          <low value="20160413"/>
        </effectiveTime>
        <participant typeCode="DEV">
          <participantRole classCode="MANU">
            <templateId root="2.16.840.1.113883.10.20.22.4.37"/>
            <id assigningAuthorityName="FDA"
extension="(01)00848486000400(11)160330(10)ABC634(21)123777" root="2.16.840.1.113883.3.3719"/>
            <playingDevice>
              <code nullFlavor="UNK">
                <originalText>
                  <reference value="#implant1"/>
                </originalText>
              </code>
            </playingDevice>
            <!-- From Product Instance template:
                The scopingEntity/id should correspond to FDA or the appropriate issuing
agency. -->
            <scopingEntity>
              <id root="2.16.840.1.113883.3.3719"/>
            </scopingEntity>
            </participantRole>
          </participant>

```

<sup>139</sup> Source: [https://github.com/benjaminflessner/HL7-C-CDA-Task-Force-Examples/blob/master/Implant Without Procedure.xml](https://github.com/benjaminflessner/HL7-C-CDA-Task-Force-Examples/blob/master/Implant%20Without%20Procedure.xml)

```

    </procedure>
  </entry>
</entry>
  <!-- example without qualifier omitted for space -->
</entry>
<entry>
  <!-- example where targetSiteCode not mapped omitted for space -->
</entry>
</section>
</component>

```

To declare that a patient has no implanted devices, the Medical Equipment section should be used that has a Procedure Activity Procedure entry with an effectiveTime that has a nullFlavor of 'NA' and a participantRole that has an ID with a nullFlavor of 'NA' and a code of 40388003 – Implant. This combination states that the patient has not had a procedure to implant anything.

*Example 47: No Implanted Devices<sup>140</sup>*

```

<component>
  <section>
    <!-- Medical equipment section -->
    <templateId root="2.16.840.1.113883.10.20.22.2.23"/>
    <templateId root="2.16.840.1.113883.10.20.22.2.23" extension="2014-06-09"/>
    <code code="46264-8" codeSystem="2.16.840.1.113883.6.1" />
    <title>MEDICAL EQUIPMENT</title>
    <!-- Alternative text: Patient has no history of procedures with implantable devices'-
->
    <!-- Alternative text: Patient has no implanted devices'-->
    <text><paragraph ID="Proc">Patient has no history of implantable
devices</paragraph></text>
    <entry>
      <procedure classCode="PROC" moodCode="EVN" negationInd="true">
        <!-- Procedure Activity Procedure V2-->
        <templateId root="2.16.840.1.113883.10.20.22.4.14"/>
        <templateId root="2.16.840.1.113883.10.20.22.4.14" extension="2014-06-09"/>
        <id root="d5b614bd-01ce-410d-8726-elfd01dcc72a" />
        <code code="71388002" codeSystem="2.16.840.1.113883.6.96"
          displayName="Procedure"/>
        <text>
          <reference value="#Proc"/>
        </text>
        <statusCode code="completed" />
        <effectiveTime nullFlavor="NA" />
        <participant typeCode="DEV">
          <participantRole classCode="MANU">
            <templateId root="2.16.840.1.113883.10.20.22.4.37"/>
            <!-- UDI is 'not applicable' since no procedure -->
            <id nullFlavor="NA" root="2.16.840.1.113883.3.3719"/>
            <playingDevice>
              <code code="40388003" codeSystem="2.16.840.1.113883.6.96"
                displayName="Implant"/>
            </playingDevice>
            <scopingEntity>
              <id root="2.16.840.1.113883.3.3719"/>
            </scopingEntity>
          </participantRole>
        </participant>
      </procedure>
    </entry>
  </section>
</component>

```

<sup>140</sup> [https://github.com/brettmarquard/HL7-C-CDA-Task-Force-Examples/blob/master/No\\_Implanted\\_Devices.xml](https://github.com/brettmarquard/HL7-C-CDA-Task-Force-Examples/blob/master/No_Implanted_Devices.xml)



### 5.2.8.2 Non-Implanted Device

Non-implanted devices are represented with the Non-Medicinal Supply Activity template. This template is used to represent devices the patient has such as eyeglasses or a cane.

Entry Template	Non-Medicinal Supply [organizer: identifier urn: : hl7ii:2.16.840.1.113883.10.20.22.4.50:2014-06-09 (open)] ]]
<b>Reference Source</b>	HL7 C-CDA R2.1
<b>Purpose</b>	This template represents equipment supplied to the patient (e.g., pump, inhaler, wheelchair, cane, eyeglasses, hearing aid).
<b>ActStatus</b>	This template uses a state model that includes the full range of status values defined in the ActStatus value set (2.16.840.1.113883.1.11.15933). The effectiveTime/low of the Non-Medicinal Supply act asserts when the person was first supplied with the indicated device. The effectiveTime/high asserts when the patient stopped using the supplied device. If the clinical statement is not about a specific non-medicinal device, it may be interpreted to generally describe when, for example, the patient first began wearing glasses or using a cane. If the clinical statement is about a specifically identified device, it may be interpreted to describe when the patient was supplied with that specific device.
<b>Negation</b>	Not specified.
<b>Idioms Supported</b>	None.
<b>Other Considerations</b>	This template is not used when represented devices that are implanted within the patient. For information about how to represent implanted devices see the Procedure Activity Procedure template.
<b>Example</b>	Example 48: Non-Medicinal Supply – Cane and Eyeglasses

Table 53: Non-Implanted Device Template

#### Example 48: Non-Medicinal Supply – Cane and Eyeglasses

```
<section>
  <templateId root="2.16.840.1.113883.10.20.22.4.50" extension="2014-06-09"/>
  <code code="46264-8" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
  displayName="Medical Equipment"/>
  <title>Medical Equipment</title>
  <text>
    <table>
      <thead>
        <tr>
          <th>Medical Equipment</th>
          <th>Device Identifier (if applicable)</th>
          <th>Model / Serial / Lot (if applicable)</th>
          <th>Date</th>
        </tr>
      </thead>
      <tbody>
        <tr ID="equipment1">
          <td><content ID="equipment1item" styleCode="header">Eye Glasses</content></td>
          <td>n/a</td>
          <td>n/a</td>
          <td>(01/13/2000 - )</td>
        </tr>
        <tr ID="equipment2">
          <td><content ID="equipment2item" styleCode="header">Cane</content></td>
```

```

        <td>n/a</td>
        <td>n/a</td>
        <td>(04/13/2016 - )</td>
    </tr>
</tbody>
</table>
</text>
<entry>
    <supply classCode="SPLY" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.22.4.50"/>
        <templateId root="2.16.840.1.113883.10.20.22.4.50" extension="2014-06-09"/>
        <id extension="2744999" root="1.2.840.999.1.13.5552.1.7.2.99999"/>
        <text><reference value="#equipment1"></reference></text>
        <statusCode code="active"/>
        <!-- low represents when person first received supply -->
        <effectiveTime xsi:type="IVL_TS">
            <low value="20000113"/>
            <high nullFlavor="NI"/> <!-- patient use of supply is ongoing, could be omitted for the
same semantics. -->
        </effectiveTime>
        <!--<quantity value="1" /> -->
        <participant typeCode="PRD">
            <participantRole classCode="MANU">
                <templateId root="2.16.840.1.113883.10.20.22.4.37"/>
                <!-- id of supply is unknown; An FDA identifier is not required since this is a non-
implantable device -->
                <id root="1.2.840.999.1.13.5552.1.7.2.999991" nullFlavor="UNK"/>
                <playingDevice>
                    <code code="50121007" codeSystem="2.16.840.1.113883.6.96"
displayName="Eyeglasses">
                        <originalText>
                            <reference value="#equipment1item"/>
                        </originalText>
                    </code>
                </playingDevice>
                <!-- Required by Product Instance Template -->
                <scopingEntity>
                    <id nullFlavor="NA"/>
                </scopingEntity>
            </participantRole>
        </participant>
    </supply>
</entry>
<entry>
    <supply classCode="SPLY" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.22.4.50"/>
        <templateId root="2.16.840.1.113883.10.20.22.4.50" extension="2014-06-09"/>
        <id extension="2744999" root="1.2.840.999.1.13.5552.1.7.2.99999"/>
        <!-- Template does not require a code, but best practice is to include a meaningful
code for the type of entry. -->
        <code code="425399007" codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMEDCT" displayName="Durable medical equipment (physical object)">
            </code>
        <text>
            <reference value="#equipment2"></reference>
        </text>
        <statusCode code="active"/>
        <!-- low represents when person first received supply -->
        <effectiveTime xsi:type="IVL_TS">
            <low value="20160413"/>
            <high nullFlavor="NI"/> <!-- patient use of supply is ongoing -->
        </effectiveTime>
        <participant typeCode="PRD">
            <participantRole classCode="MANU">
                <templateId root="2.16.840.1.113883.10.20.22.4.37"/>
                <!-- id of supply is unknown; An FDA identifier is not required since this is a
non-implantable device -->
                <id root="1.2.840.999.1.13.5552.1.7.2.999991" nullFlavor="UNK"/>
                <playingDevice>
                    <code code="87405001" codeSystem="2.16.840.1.113883.6.96" displayName="Cane">
                        <originalText>

```

```

        <reference value="#equipment2item"/>
    </originalText>
</code>
</playingDevice>
    <!-- Required by Product Instance Template -->
    <scopingEntity>
        <id nullFlavor="NA"/>
    </scopingEntity>
</participantRole>
</participant>
</supply>
</entry>
</section>

```

### 5.2.8.3 Product Instance

The Product Instance template is used to represent a particular device that was placed in a patient or used as part of a procedure or other act.

Entry Template	Product Instance [participantRole: identifier urn:oid:2.16.840.1.113883.10.20.22.4.37]
Reference Source	HL7 C-CDA R2.1
Purpose	This template is used to record the identifier and other details about the given product that was used. For example, it is important to have a record that indicates not just that a hip prostheses was placed in a patient but that it was a particular hip prostheses number with a unique identifier.
ActStatus	Not applicable.
Negation	Not applicable.
Idioms Supported	Not applicable.
Other Considerations	The FDA Amendments Act specifies the creation of a Unique Device Identification (UDI) System that requires the label of devices to bear a unique identifier that will standardize device identification and identify the device through distribution and use.
Example	Example 45: Implanted Device – known procedure details
Example	Example 48: Non-Medicinal Supply – Cane and Eyeglasses

Table 54: Product Instance Template

### 5.2.8.4 Unique Device Identifiers

A Unique Device Identifier (UDI) is used to identify a device.

Entry Template	UDI Organizer [organizer: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.312:2019-06-21 (open)]
Reference Source	HL7 C-CDA R2.1 Companion Guide – Appendix B

Entry Template	UDI Organizer
<b>Purpose</b>	[organizer: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.312:2019-06-21 (open)] This template is used to manage all the UDI-related templates to exchange the parsed UDI data elements and associated metadata including: device manufacturer, lot or batch number, serial number, manufacturing date, expiration date, distinct identification code, brand name, and model number, catalog number, company name, MRI safety, latex safety, and implantable device status.
<b>ActStatus</b>	The statusCode for the organizer is not specified. The effectiveTime element for the organizer is not specified. This template only conveys information about the UDI identifiers associated with a device.
<b>Negation</b>	Not specified.
<b>Idioms Supported</b>	None specified.
<b>Other Considerations</b>	Only the device manufacturer information is required in this template. All other component observations are optional.  If the implantable device status information is included, it SHALL contain one of following values from the NCI Thesaurus Code System (2.16.840.1.113883.3.26.1.1): Active (C45329) Inactive (C154407) Malfunctioning (C122711) Reduced Function (C160942)  From the value set identified with OID 2.16.840.1.113762.1.4.1021.48
<b>Reference</b>	Chapter 3.85 Product Instance in the HL7 <a href="#">C-CDA Implementation Guide</a> for information on how to encode the UDI.
<b>Reference</b>	See Appendix B for guidance on how to include an entryRelationship (typeCode="COMP") to reference a UDI Organizer containing the parsed components of the UDI identifier. The parsed components in the UDI Organizer shall align with the full UDI in the Product Instance.
<b>Example</b>	New Sections.xml Sample

Table 55: Unique Device Identifiers Template

### 5.2.9 Goal

Previously, to satisfy the 2015 Edition Certification Criteria, guidance recommended for Transition of Care documents (CCD, Discharge Summary, or Referral Note documents) should include the Goals Section. As the role played by C-CDA continues to expand to support use cases focused on care planning and assessing quality care, the need to gather and share goal information grows. Within goal information, it is impossible to measure the outcome of interventions performed to effect progress toward a desired health outcome.

The C-CDA Goal Observation entry template is designed to represent three different types of goals: patient goals, provider goals, and shared goals. The semantics to indicate if a goal is a patient, provider, or shared goal is represented in the author structure of the entry.

5.2.9.1 Goal Observation

Entry Template	Goal Observation [observation: identifier urn:oid:2.16.840.1.113883.10.20.22.4.121 (open)]
Reference Source	HL7 C-CDA R2.1
Purpose	<p>This template represents a patient health goal. A Goal Observation template may have related components that are acts, encounters, observations, procedures, substance administrations, or supplies.</p> <p>A goal may be a patient or provider goal. If the author is set to the recordTarget (patient), this is a patient goal. If the author is set to a provider, this is a provider goal. If both patient and provider are set as authors, this is a negotiated goal.</p> <p>A goal usually has a related health concern and/or risk.</p> <p>A goal may have components consisting of other goals (milestones). These milestones are related to the overall goal through entryRelationships.</p>
ActStatus	Currently bound to the single concept of “active”. This has been reported as a limitation that needs to be addressed. <sup>141</sup>
Negation	Not explicitly specified.
Idioms Supported	None.
Other Considerations	<p>This template current provides no guidance on what should be populated in the value element. A comment has been made against the design to request greater guidance be provided regarding the use of the value element in the design of the template.<sup>142</sup></p> <p>This template allows for multiple author participations ([0..*]).</p> <p>If the author is the recordTarget (patient), this is a patient goal. If the author is a provider, this is a provider goal. If both patient and provider are authors, this is a negotiated goal. If no author is present, it is assumed the document or section author(s) is the author of this goal.</p>
Example	C-CDA R2.1 Figure 154 Goal Observation Example (Page 234)

Table 56: Goal Observation Template

<sup>141</sup> HL7 C-CDA R2.1 STU Comments #1773, #1279, #1278. <http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=168>

<sup>142</sup> HL7 C-CDA R2.1 STU Comments #1429. <http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=168>

## Example 49: Goal Observation narrative


```

<section>
  <!-- PLEASE REFER TO THE EXAMPLE TASK FORCE <http://hl7-c-cda-
examples.herokuapp.com/sections/Goals> PAGE FOR EXAMPLES TO COMMON
  CHALLENGES WITH ENTRIES IN
  THIS SECTION -->
  <templateId root="2.16.840.1.113883.10.20.22.2.60"/>
  <code code="61146-7" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
  displayName="Goals"/>
  <title>ACTIVE GOALS</title>
  <text>
  <table>
    <thead>
      <tr>
        <th>Patient Goal Type</th>
        <th>Goal</th>
        <th>Patient-Stated?</th>
        <th>Author</th>
      </tr>
    </thead>
    <tbody>
      <tr>
        <td>Blood Pressure</td>
        <td>
          <paragraph ID="goal1" styleCode="Bold">Get BP to normal (i.e. 120/80)</paragraph>
        </td>
        <td>No</td>
        <td>Moreland, Andrew</td>
      </tr>
      ...
    </tbody>
  </table>
</text>
<entry>
  <observation classCode="OBS" moodCode="GOL">
    <templateId root="2.16.840.1.113883.10.20.22.4.121"/>
    <id extension="3241" root="1.2.840.114350.1.13.6289.1.7.2.737179"/>
    <code nullFlavor="UNK">
      <originalText>
        <reference value="#goal2"/>
      </originalText>
    </code>
    <statusCode code="active"/>
    <effectiveTime>
      <low value="20160412113717-0500"/>
    </effectiveTime>
    <author>
      <templateId root="2.16.840.1.113883.10.20.22.4.119"/>
      <time value="20160412113717-0500"/>
      <assignedAuthor>
        <id extension="1" root="1.2.840.114350.1.13.6289.1.7.2.697780"/>
        <assignedPerson>
          <name>
            <given>Andrew</given>
            <family>Moreland</family>
          </name>
        </assignedPerson>
      </assignedAuthor>
    </author>
  </observation>
</entry>
  ...
</section>

```

### 5.2.10 Social History Observation

The Social History Observation template is a general template designed to represent a full range of social history observations.

 C-CDA Content Creators SHOULD use specific templates over general templates when an appropriate specific template has been defined. **[BP-087]**

Entry Template	Social History Observation (V3) <small>[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.38:2015-08-01 (open)]</small>
<b>Reference Source</b>	HL7 C-CDA R2.1
<b>Purpose</b>	This template represents a patient's occupations, lifestyle, and environmental health risk factors. Demographic data (e.g., marital status, race, ethnicity, religious affiliation) are captured in the header.
<b>ActStatus</b>	This is a discrete observation that has been made in order for it to be documented. Therefore, it always has a statusCode of "completed." This template does not include specific guidance about the meaning of the effectiveTime element. As an observation, the effectiveTime is the time at which the observation holds true for the patient.
<b>Negation</b>	Not explicitly specified.
<b>Idioms Supported</b>	None.
<b>Other Considerations</b>	Additional more specific social history observation templates also exist. They constrain the Social History Observation in specific ways to represent key social history data elements that are essential for interoperable data exchange. Though tobacco use and exposure may be represented with a general Social History Observation template, it is recommended to use the Current Smoking Status template or the Tobacco Use template instead to aid in their exchange.
<b>Example</b>	Example 50: Social History Observation without a more specific template (Sexual Orientation)
<b>Example</b>	Example 20: How to represent the data element for Gender Identity using the code and value set supplied in the Interoperability Standards Advisory

Table 57: Entry Template

As additional social history observation data elements gain standardized definitions, the general Social History Observation template enables additional observations to be records and shared across systems. For example, the 2019 Interoperability Standards Advisory references the following value set for sexual orientation.<sup>143</sup> Codes from (i) through (iii) are SNOMED CT® and (iv) through (vi) are from HL7 Version 3:

- (i) Lesbian, gay or homosexual.38628009
- (ii) Straight or heterosexual. 20430005
- (iii) Bisexual. 42035005
- (iv) Something else, please describe. nullFlavor OTH

<sup>143</sup> 2019 Interoperability Standards Advisory. Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications. Gender Identity. <https://www.healthit.gov/isa/sites/isa/files/inline-files/2019ISAResponseEdition.pdf>

- (v) Don't know. nullFlavor UNK
- (vi) Choose not to disclose. nullFlavor

Standardized definitions such as these can be used with the social history observation template as shown in the Example below.

*Example 50: Social History Observation without a more specific template (Sexual Orientation)*


```

<section>
  <templateId root="2.16.840.1.113883.10.20.22.2.17"/>
  <templateId root="2.16.840.1.113883.10.20.22.2.17" extension="2015-08-01"/>
  <code code="29762-2" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
    displayName="Social history"/>
  <title>Social History</title>
  <text>
    <table>
      <thead>
        <tr>
          <th>Information Type</th>
          <th>Date</th>
          <th>Relevant Information</th>
          <th>Documented By</th>
        </tr>
      </thead>
      <tbody>
        <tr ID="SocialHistory_3">
          <td>Sexual Orientation</td>
          <td><content>(04/12/2016)</content></td>
          <td><content ID="SH3_SO"> Heterosexual</content></td>
          <td><content>M.Smith</content> <content>(04/12/2016)</content></td>
        </tr>
      </tbody>
    </table>
  </text>
  <entry>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.22.4.38"/>
      <templateId root="2.16.840.1.113883.10.20.22.4.38" extension="2015-08-01"/>
      <id extension="64020-Z9311" root="1.2.840.114350.1.13.6289.1.7.1.1040.1"/>
      <code code="76690-7" codeSystem="2.16.840.1.113883.6.1"
        codeSystemName="LOINC" displayName="Sexual orientation"/>
      <text><reference value="#SocialHistory_3"></reference></text>
      <statusCode code="completed"/>
      <effectiveTime value="20160412"/>
      <value xsi:type="CD" code="20430005" displayName="Heterosexual (finding)"
        codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMEDCT">
        <originalText>
          <reference value="#SH3_SO"></reference>
        </originalText>
      </value>
      <author>
        <time value="20160412"/>
        <assignedAuthor>
          <id extension="10.1" root="1.2.840.114350.1.1"/>
        </assignedAuthor>
      </author>
    </observation>
  </entry>
  ...
</section>

```



5.2.10.1 Smoking Status

 C-CDA Content Creators SHALL NOT use the Smoking Status– Meaningful Use (V2) template to represent when the current smoking status started. **[BP-088]**

Entry Template	Smoking Status – Meaningful Use (V2)
<b>Reference Source</b>	[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.78:2014-06-09 (open)] HL7 C-CDA R2.1
<b>Purpose</b>	This template represents the current smoking status of the patient as specified in Meaningful Use (MU) Stage 2 requirements.
<b>ActStatus</b>	This is a discrete observation that has been made in order for it to be documented. Therefore, it always has a statusCode of “completed.” This template represents a “snapshot in time” observation. It reflects the patient’s smoking status at the time the observation is made. As a result, the effectiveTime is constrained to a time stamp that approximately corresponds with the author/time.
<b>Negation</b>	Not explicitly specified.
<b>Idioms Supported</b>	None.
<b>Other Considerations</b>	The 2019 ISA removes the value set requirements expected for this data elements. <sup>144</sup> Presently this template requires use of the following range of possible answers: <ul style="list-style-type: none"> <li>• Never smoked tobacco</li> <li>• Occasional tobacco smoker</li> <li>• Ex-smoker</li> <li>• Heavy tobacco smoker</li> <li>• Smokes tobacco daily</li> <li>• Smoker</li> <li>• Light tobacco smoker</li> <li>• Tobacco smoking consumption unknown</li> </ul> Best practice implementation guidance allows alternate answers to be used.  Within the Social History Section of a document there can be more than one Smoking Status observation recorded. The person’s “current” smoking status may have been recorded at several different points in time.
<b>Example</b>	Example 51: Unknown Smoking Status
<b>Example</b>	HL7 C-CDA R2.1 Figure 220 Smoking Status – Meaningful Use (V2) Example (Page 881)

Table 58: Smoking Status

Example 51: Unknown Smoking Status<sup>145</sup>

```
<section>
  <templateId root="2.16.840.1.113883.10.20.22.2.17"/>
  <code code="29762-2" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
displayName="Social History"/>
  <title>Social History</title>
  <text>
    <list>
      <caption>Smoking Status</caption>
      <item>
        <content>Unknown if ever smoked</content>
      </item>
    </list>
  </text>
</section>
```

<sup>144</sup> <https://www.healthit.gov/isa/representing-patient-tobacco-use-smoking-status>

<sup>145</sup> [https://github.com/jddamore/HL7-Task-Force-Examples/blob/master/SMOKING\\_Unknown\\_Smoker.xml](https://github.com/jddamore/HL7-Task-Force-Examples/blob/master/SMOKING_Unknown_Smoker.xml)

```


                <content>As of: unknown</content>
                <content>Recorded June 6, 2014 10:32am</content>
            </item>
        </list>
    </text>
    <entry>
        <observation classCode="OBS" moodCode="EVN">
            <templateId root="2.16.840.1.113883.10.20.22.4.78"/>
            <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
            <statusCode code="completed"/>
            <effectiveTime>
                <low nullFlavor="UNK"/>

                <value xsi:type="CD" codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMED CT" code="266927001" displayName="Tobacco smoking consumption
unknown"/>

                <author>
                    <time value="201406061032+0500"/>
                    <assignedAuthor>
                        <id root="2.16.840.1.113883.4.6" extension="99999999"/>
                        <code code="200000000X"
codeSystem="2.16.840.1.113883.6.101"
                        displayName="Allopathic and Osteopathic Physicians"/>
                        <telecom use="WP" value="tel:+1(555)555-1002"/>
                        <assignedPerson>
                            <name>
                                <given>Henry</given>
                                <family>Seven</family>
                            </name>
                        </assignedPerson>
                    </assignedAuthor>
                </author>
            </observation>
        </entry>
    </section>

```

### 5.2.10.2 Tobacco Use

 C-CDA Content Creators SHALL use the Tobacco Use (V2) template to describe dates associated with the patient's tobacco use over time. [BP-089]

Entry Template	Tobacco Use (V2) [observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.85:2014-06-09 (open)]
<b>Reference Source</b>	HL7 C-CDA R2.1
<b>Purpose</b>	This template contains information that describes a patient's tobacco use over time.
<b>ActStatus</b>	This is a discrete observation that has been made in order for it to be documented. Therefore, it always has a statusCode of "completed." The effectiveTime element is used to describe dates associated with the patient's tobacco use. It represents the biologically relevant time of the observation about the patient's tobacco use.
<b>Negation</b>	Not explicitly specified.
<b>Idioms Supported</b>	None.
<b>Other Considerations</b>	All the types of tobacco use from the tobacco use and exposure-finding hierarchy in SNOMED CT, including codes required for recording smoking status in Meaningful Use Stage 2 are used by this template.
<b>Example</b>	Example 52: Tobacco Use –Light Tobacco Smoker between 4/12/2010 and 4/12/2016.


Table 59: Tobacco Use

Example 52: Tobacco Use –Light Tobacco Smoker between 4/12/2010 and 4/12/2016.

```
<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.22.4.78"/>
  <templateId root="2.16.840.1.113883.10.20.22.4.78" extension="2014-06-09"/>
  <id extension="64020-Z9301" root="1.2.840.114350.1.13.6289.1.7.1.1040.1"/>
  <code code="11367-0" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
  displayName="History of Tobacco Use"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="20100412"/>
    <high value="20160412"/>
  </effectiveTime>
  <value xsi:type="CD" code="77176002" codeSystem="2.16.840.1.113883.6.96"
  codeSystemName="SNOMEDCT" displayName="Light tobacco smoker (finding)"/>
</observation>
```

### 5.2.10.3 Birth Sex

This observation represents the biological sex assigned to the patient at birth. Although several states permit residents to alter their birth certificate, this observation records the biological sex that is entered on the person's birth certificate at time of birth. Birth sex information is relevant in a clinical setting. For example, laboratory reference range results may differ based on a patient's biological sex. Birth sex information would be needed for accurate result reporting.

 C-CDA Content Creators SHALL populate the effectiveTime/value of the Birth Sex Observation template with the patient's birthdate. The effectiveTime/low and effectiveTime/high elements SHALL NOT be used in the Birth Sex Observation template. Conformance SHALL be identical to the conformance of the birthTime metadata element. **[CONF-090]**

Entry Template	Birth Sex Observation [observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.200:2016-06-01 (open)]
Reference Source	HL7 C-CDA R2.1 Companion Guide R1
Purpose	This observation represents the sex of the patient at birth. It is the sex that is entered on the person's birth certificate at time of birth.
ActStatus	This is a discrete observation that has been made in order for it to be documented. Therefore, it always has a statusCode of "completed."  The template does not provide guidance on the use of the effectiveTime element. It represents the biologically relevant time of the observation about the patient's birth sex.
Negation	Not explicitly specified.
Idioms Supported	None.
Other Considerations	This observation is intended to be used in the Social History section.  This observation is not appropriate for recording patient gender (administrativeGender). The patient's administrative gender is recorded in the header of the document using the recordTarget.administrativeGender element.

<b>Entry Template</b>	<b>Birth Sex Observation</b> [observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.200:2016-06-01 (open)]
<b>Example</b>	Example 53: Birth Sex

Table 60: Birth Sex Template

Example 53: Birth Sex

```

<!-- Birth Sex Entry - Approved in C-CDA R2.1 Companion Guide -->
<observation classCode="OBS" moodCode="EVN">
  <!-- New templateId for Birth Sex -->
  <!-- Not planning to assert conformance to Social History Observation due to
different vocab -->
  <templateId root="2.16.840.1.113883.10.20.22.4.200" extension="2016-06-01"/>
  <code code="76689-9" codeSystem="2.16.840.1.113883.6.1"
    displayName="Sex Assigned At Birth"/>
  <text>
    <reference value="#BSex_Narrative1"/>
  </text>
  <statusCode code="completed"/>
  <!-- effectiveTime if present should match birthTime -->
  <!-- Request name change to QRDA value set (2.16.840.1.113762.1.4.1) - ONC Birth Sex
-->
  <value xsi:type="CD" codeSystem="2.16.840.1.113883.5.1"
codeSystemName="AdministrativeGender"
  code="F" displayName="Female">
    <originalText>
      <reference value="#BSex_value"/>
    </originalText>
  </value>
</observation>

```

5.2.10.4 Pregnancy Status

The Pregnancy Observation is used to represent a person’s pregnancy status over time. It is a type of social history observation and can included in the Social History Section. The supplemental Pregnancy Section template is designed to contain more detailed pregnancy information. It includes more detailed Pregnancy Observation templates that represents current and/or prior pregnancy statuses and their date ranges, enabling investigators to determine if a patient was pregnant, possibly pregnant, not pregnant or whether the pregnancy status was unknown during a particular date range.<sup>146</sup>

<b>Entry Template</b>	<b>Pregnancy Observation</b> [observation: identifier urn:oid:2.16.840.1.113883.10.20.15.3.8 (open)]
<b>Reference Source</b>	HL7 CDA® R2 Implementation Guide: C-CDA R2.1 Supplemental Templates for Pregnancy Status, Release 1 - US Realm
<b>Purpose</b>	This template contains information that describes a patient's pregnancy status over time.
<b>ActStatus</b>	This is a discrete observation that has been made in order for it to be documented. Therefore, it always has a statusCode of “completed.” The effectiveTime element is used to describe dates associated with the patient's different pregnancy statuses over time. It represents the biologically relevant time of the observation about the patient’s pregnancy status.

<sup>146</sup> HL7 CDA® R2 Implementation Guide: C-CDA R2.1 Supplemental Templates for Pregnancy Status, Release 1 - US Realm

Entry Template	Pregnancy Observation [observation: identifier urn:oid:2.16.840.1.113883.10.20.15.3.8 (open)]
<b>Negation</b>	Not explicitly specified.
<b>Idioms Supported</b>	None.
<b>Other Considerations</b>	The value element of this template holds the patient's pregnancy status. Possible coded concepts for this data element include: <ul style="list-style-type: none"> <li>• Possible pregnancy (finding)</li> <li>• Not pregnant (finding)</li> <li>• Pregnant (finding)</li> </ul>
<b>Example</b>	Example 54: Patient was pregnant from 4/10/2011 to 1/12/2012
<b>Example</b>	Example 55: Patient was not pregnant
<b>Example</b>	Example 56: Unknown if the patient was pregnant or not

Table 61: Pregnancy Observation

*Example 54: Patient was pregnant from 4/10/2011 to 1/12/2012*

```

observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.15.3.8"/>
  <id extension="123456789" root="2.16.840.1.113883.19"/>
  <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="20110410"/>
    <high value="20120112"/>
  </effectiveTime>
  <value xsi:type="CD" code="77386006"
    displayName="pregnant"
    codeSystem="2.16.840.1.113883.6.96"/>
  <entryRelationship typeCode="REFR">
    <templateId root="2.16.840.1.113883.10.20.15.3.1"/>
  .. . </entryRelationship>
</observation>

```

To indicate that the patient was not pregnant during a specified date range, the Pregnancy Observation entry should also be used, but with a negationInd set to “true” to indicate that the patient was not pregnant during the date range specified by the effectiveTime element.

*Example 55: Patient was not pregnant*

```

<observation classCode="OBS" moodCode="EVN" negationInd="true">
  <templateId root="2.16.840.1.113883.10.20.15.3.8"/>
  <id extension="123456789" root="2.16.840.1.113883.19"/>
  <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="20110410"/>
    <high value="20110710"/>
  </effectiveTime>
  <value xsi:type="CD" code="77386006"
    displayName="pregnant"
    codeSystem="2.16.840.1.113883.6.96"/>
  <entryRelationship typeCode="REFR">
    <templateId root="2.16.840.1.113883.10.20.15.3.1"/>
  .. . </entryRelationship>
</observation>

```

Finally, to indicate that it was unknown if the patient was pregnant or not, then a nullFlavor should be used on the observation to indicate that the patient's pregnancy status was unknown. An effectiveTime element can be included to assert the period over which it was unknown.

*Example 56: Unknown if the patient was pregnant or not*



```
<observation classCode="OBS" moodCode="EVN" nullFlavor="UNK">
  <templateId root="2.16.840.1.113883.10.20.15.3.8"/>
  <id extension="123456789" root="2.16.840.1.113883.19"/>
  <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="20110410"/>
    <high value="20110710"/>
  </effectiveTime>
  <value xsi:type="CD" code="77386006"
    displayName="pregnant"
    codeSystem="2.16.840.1.113883.6.96"/>
  <entryRelationship typeCode="REFR">
    <templateId root="2.16.840.1.113883.10.20.15.3.1"/>
    . . . </entryRelationship>
</observation>
```

**5.2.11 Result**

Results generated by laboratories, imaging procedures, and other procedures are coded as result observations and contained within a Results Organizer. The Result Organizer.code element is used to categorize the contained results into one of several commonly accepted values (e.g., “Hematology”, “Chemistry”, “Nuclear Medicine”). This is how laboratory tests are distinguished from Pathology test or Diagnostic imaging tests.

This template provides a mechanism for grouping result observations. It contains information applicable to all of the contained result observations. If any Result Observation within the organizer has a statusCode of "active", the Result Organizer must also have a statusCode of "active."

**5.2.11.1 Result Organizer**

-  The Result Organizer.code element is used to categorize the contained results. This element SHOULD be populated with a LOINC code that defines a specific test panel (e.g., “CBC W Auto Differential panel - Blood”) or general type of testing (e.g., “Hematology”, “Chemistry”, “Nuclear Medicine”). **[BP-091]**
-  A Result Organizer SHALL contain at least one Result Observation component template. **[CONF-092]**

<b>Entry Template</b>	<b>Result Organizer (V3)</b> [organizer: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.1:2015-08-01 (open)]
<b>Reference Source</b>	HL7 C-CDA R2.1
<b>Purpose</b>	This template provides a mechanism for grouping result observations. It contains information applicable to all of the contained result observations.

Entry Template	Result Organizer (V3) [organizer: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.1:2015-08-01 (open)]
<b>ActStatus</b>	If any Result Observation within the organizer has a statusCode of "active", the Result Organizer must also have a statusCode of "active".  The range of time specified in the Result Organizer/effectiveTime element should encompass the lowest effectiveTime/low and the highest effectiveTime/high for the Result Observations within the organizer.
<b>Negation</b>	Not specified.
<b>Idioms Supported</b>	None specified.
<b>Other Considerations</b>	If the Author Participation template is specified for the Organizer, this context applies to all the component observations unless a component observation includes a different Author Participation template.
<b>Example</b>	Example 57: Result Organizer for CBC W Auto Differential panel - Blood

Table 62: Result Organizer Template

Example 57: Result Organizer for CBC W Auto Differential panel - Blood

```
<section>
  <!-- PLEASE REFER TO THE EXAMPLE TASK FORCE <http://hl7-c-cda-
  examples.herokuapp.com/sections/Results> PAGE FOR EXAMPLES TO COMMON
  CHALLENGES WITH ENTRIES IN THIS SECTION -->
  <!-- Results Section (entries required) (V3) -->
  <!-- This example shows that lab results more recent than the inpatient encounter are
  available at Good Health Hospital at the time the CCD is generated. This is a Patient
  Summary, not an Encounter Document. It covers a span of time.-->
  <templateId root="2.16.840.1.113883.10.20.22.2.3.1" extension="2015-08-01"/>
  <templateId root="2.16.840.1.113883.10.20.22.2.3.1"/>
  <code code="30954-2" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
  displayName="Relevant diagnostic tests/laboratory data Narrative"/>
  <title>RESULTS</title>
  <text>
    <content ID="Results_STR">This document includes patent laboratory results for testing
    performed within the past three months.</content> <br></br>
    <content styleCode="Bold">CBC W Auto Differential panel - Blood (04/01/2016)</content> |
  <content>Diagnostic Labs (04/02/2016)</content>
  <table>
    <thead>
      <tr>
        <th>Result Type</th>
        <th>Result Value</th>
        <th>Relevant Reference Range</th>
        <th>Interpretation</th>
        <th>Date</th>
      </tr>
    </thead>
    <tbody>
      <tr>
        <td ID="result1">Hemoglobin</td>
        <td ID="resultvalue1">13.2 g/dL</td>
        <td ID="referencerangel">Normal range for women is 12.0 to 15.5 grams per
        deciliter</td>
        <td>Normal</td>
        <td>04/01/2016</td>
      </tr>
      <tr>
        <td ID="result2">Leukocytes</td>
        <td ID="resultvalue2">6.7 103/uL</td>
        <td ID="referencerange2">Normal white blood cell count range 3.5-10.5 billion
        cells/L</td>
        <td>Normal</td>
      </tr>
    </tbody>
  </table>
</text>
</section>
```

```

        <td>04/01/2016</td>
    </tr>
    ...
</tbody>
</table>
</text>
<entry>
  <observation classCode="OBS" moodCode="EVN">
    <!-- Section Time Range Observation -->
    <templateId root="2.16.840.1.113883.10.20.22.4.201" extension="2016-06-01"/>
    <code code="82607-3" displayName="Clinical data [Date and Time Range]"
codeSystem="2.16.840.1.113883.6.1"
      codeSystemName="LOINC"/></code>
    <text><reference value="#Results_STR"></reference></text>
    <statusCode code="completed"/>
    <value xsi:type="IVL_TS">
      <low value="20160401"/>
      <high value="20160412"/>
    </value>
    <author>
      <!-- The system that generated the CCD -->
      <time value="20160412114559-0500"/>
      <assignedAuthor>
        <id extension="8.3" root="1.2.840.114350.1.1"/>
      </assignedAuthor>
    </author>
  </observation>
</entry>
<entry typeCode="DRIV">
  <organizer classCode="BATTERY" moodCode="EVN">
    <!-- ** Result organizer (V3) ** -->
    <templateId root="2.16.840.1.113883.10.20.22.4.1" extension="2015-08-01"/>
    <templateId root="2.16.840.1.113883.10.20.22.4.1"/>
    <id root="7d5a02b0-67a4-11db-bd13-0800200c9a66"/>
    <code code="57021-8"
      displayName="CBC W Auto Differential panel - Blood"
codeSystem="2.16.840.1.113883.6.1"
      codeSystemName="LOINC"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="20160401102500-0500"/>
      <high value="20160402121500-0500"/>
    </effectiveTime>
    <!-- author at the organizer-level conducts down into the component observations.-->
    <author>
      <time value="20160402121500-0500"/>
      <assignedAuthor>
        <id extension="333444444" root="2.16.840.1.113883.4.6"/>
        <code code="246Q0000X" displayName="Technician, Pathology"
codeSystem="2.16.840.1.113883.6.101"
          codeSystemName="Healthcare Provider Taxonomy
(HIPAA)"/>
        <representedOrganization>
          <name>Diagnostic Labs</name>
        </representedOrganization>
      </assignedAuthor>
    </author>
    <component>
      <observation classCode="OBS" moodCode="EVN">
        <!-- ** Result observation (V3) ** -->
        <templateId root="2.16.840.1.113883.10.20.22.4.2" extension="2015-08-01"/>
        <templateId root="2.16.840.1.113883.10.20.22.4.2"/>
        <id root="107c2dc0-67a5-11db-bd13-0800200c9a66"/>
        <code code="718-7" displayName="Hemoglobin" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC"/>
        <text>
          <reference value="#result1"/>
        </text>
        <statusCode code="completed"/>
        <effectiveTime value="20160401102500-0500"/>
        <value xsi:type="PQ" value="13.2" unit="g/dL"/>
        <interpretationCode code="N" codeSystem="2.16.840.1.113883.5.83"/>
        <referenceRange>

```



```

        <observationRange>
          <value xsi:type="IVL_PQ">
            <low value="12.0" unit="g/dL"/>
            <high value="15.5" unit="g/dL"/>
          </value>
        </observationRange>
      </referenceRange>
    </observation>
  </component>
</component>
<component>
  <observation classCode="OBS" moodCode="EVN">
    <!-- ** Result observation ** -->
    <templateId root="2.16.840.1.113883.10.20.22.4.2" extension="2015-08-01"/>
    <templateId root="2.16.840.1.113883.10.20.22.4.2"/>
    <id root="a69b3d60-2ffd-4440-958b-72b3335ff35f"/>
    <!-- This is the correct long common name display name per LOINC web and per to
2000 -->
    <code code="6690-2" displayName="Leukocytes[#/volume] in Blood by Automated count"
codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
    <text>
      <reference value="#result2"/>
    </text>
    <statusCode code="completed"/>
    <effectiveTime value="20160401102500-0500"/>
    <value xsi:type="PQ" value="6.7" unit="10*3/uL"/>
    <interpretationCode code="N" codeSystem="2.16.840.1.113883.5.83"/>
    <referenceRange>
      <observationRange>
        <value xsi:type="IVL_PQ">
          <low value="4.3" unit="10*9/L"/>
          <high value="10.8" unit="10*9/L"/>
        </value>
      </observationRange>
    </referenceRange>
  </observation>
</component>
...
  </organizer>
</entry>
</section>

```

### 5.2.11.2 Result Observation


Entry Template	Result Observation (V3)
	[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.2:2015-08-01 (open)]
<b>Reference Source</b>	HL7 C-CDA R2.1
<b>Purpose</b>	This template represents the results of a laboratory, radiology, or other study performed on a patient.
<b>ActStatus</b>	<p>The result observation includes a statusCode to allow recording the status of an observation. "Pending" results (e.g., a test has been run but results have not been reported yet) should be represented as "active" ActStatus.</p> <p>The effectiveTime element represents the biologically relevant time of the measurement (e.g., the time a blood pressure reading is obtained, the time the blood sample was obtained for a chemistry test).</p>
<b>Negation</b>	<p>Not specified. To indicate that a test was not performed use the Procedure Activity Observation template with the negationInd attribute of "true."</p> <p><b>Reference:</b> 5.2.15 Procedure</p>
<b>Idioms Supported</b>	None specified.

Entry Template	Result Observation (V3) [observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.2:2015-08-01 (open)]
<b>Other Considerations</b>	<p>If the Author Participation template is specified for the Organizer, this context applies to all the component observations unless a component observation includes a different Author Participation template.</p> <p>If any Result Observation within the organizer has a statusCode of "active," the Result Organizer must also have a statusCode of "active." The range of time specified in the Result Organizer/effectiveTime element should encompass the lowest effectiveTime/low and the highest effectiveTime/high for the Result Observations within the organizer.</p>
<b>Example</b>	Example 57: Result Organizer for CBC W Auto Differential panel - Blood

Table 63: Result Observation Template

## 5.2.12 Vital Sign

### 5.2.12.1 Vital Signs Organizer

	A Vital Signs Organizer SHALL contain at least one Vital Sign Observation component observation template. <b>[CONF-093]</b>
---	---

Entry Template	Vital Signs Organizer (V3) [organizer: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.26:2015-08-01 (open)]
<b>Reference Source</b>	HL7 C-CDA R2.1
<b>Purpose</b>	This template provides a mechanism for grouping vital signs (e.g., grouping systolic blood pressure and diastolic blood pressure, BMI, body height, body weight).
<b>ActStatus</b>	A Vital Signs Organizer SHALL have a statusCode of "completed". The effectiveTime may be a timestamp or an interval that spans the effectiveTimes of the contained vital signs observations.
<b>Negation</b>	Not specified.
<b>Idioms Supported</b>	None specified.
<b>Other Considerations</b>	<p>Compatibility support for C-CDA R1.1 and C-CDA 2.1: A vitals organizer conformant to both C-CDA 1.1 and C-CDA 2.1 would contain the SNOMED code (46680005) from R1.1 in the root code and a LOINC code in the translation. A vitals organizer conformant to only C-CDA 2.1 would only contain the LOINC code in the root code.</p> <p>If the Author Participation template is specified for the Organizer, this context applies to all the component observations unless a component observation includes a different Author Participation template.</p>
<b>Example</b>	Example 58: Vital Signs Organizer

Table 64: Vital Signs Organizer Template

#### Example 58: Vital Signs Organizer

```
<section>
  <!-- PLEASE REFER TO THE EXAMPLE TASK FORCE <http://hl7-c-cda-
examples.herokuapp.com/sections/Vital%20Signs> PAGE FOR EXAMPLES TO COMMON CHALLENGES WITH
ENTRIES IN THIS SECTION -->
  <!-- This section shows an example of rendering information in the correct local time, which
recording it in the discrete data using a UTC offset. -->
  <!-- Note that in June, UTC offset -0500 is Central time. and Eastern Timezone is the local
time for this example. -->
  <templateId root="2.16.840.1.113883.10.20.22.2.4"/>
```

```

<templateId root="2.16.840.1.113883.10.20.22.2.4" extension="2015-08-01"/>
<templateId root="2.16.840.1.113883.10.20.22.2.4.1" extension="2015-08-01"/>
<templateId root="2.16.840.1.113883.10.20.22.2.4.1" extension="2015-08-01"/>
<code code="8716-3" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
displayName="Vital Signs"/>
<title>LAST RECORDED VITAL SIGNS</title>
<text>
<table>
<thead>
<tr>
<th>Vital Sign</th>
<th>Reading</th>
<th>Time Taken</th>
</tr>
</thead>
<tbody>
<tr>
<td styleCode="cellHeader">Blood Pressure</td>
<td>
<content ID="sysBP_5523355980">140</content></content
ID="diaBP_5523355980">90</content>
</td>
<td>(06/25/2015 1:33pm EST)</td>
</tr>
<tr>
<td styleCode="cellHeader">Weight</td>
<td ID="weight_5523355980">83.9 kg (185 lb)</td>
<td>(06/25/2015 1:33pm EST)</td>
</tr>
</tbody>
</table>
</text>
<entry typeCode="DRIV">
<organizer classCode="CLUSTER" moodCode="EVN">
<templateId root="2.16.840.1.113883.10.20.22.4.26"/>
<templateId root="2.16.840.1.113883.10.20.22.4.26" extension="2015-08-01"/>
<id extension="5523355980-Z9301" root="1.2.840.114350.1.13.6289.1.7.1.2109"/>
<code code="46680005" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"
displayName="Vital signs">
<translation code="74728-7" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC"
displayName="Vital signs, weight, height, head circumference, oximetry, BMI, and BSA
panel"/>
</code>
<statusCode code="completed"/>
<effectiveTime value="20160625123300-0500"/>
<!-- Context Conduction permits the author to be included once at the organizer level.
Authorship conducts down into the component observations. -->
<author>
<time value="20160625123300-0500"/>
<assignedAuthor>
<id extension="811111111" root="2.16.840.1.113883.4.6"/>
</assignedAuthor>
</author>
<component>
<observation classCode="OBS" moodCode="EVN">
<templateId root="2.16.840.1.113883.10.20.22.4.27"/>
<templateId root="2.16.840.1.113883.10.20.22.4.27" extension="2014-06-09"/>
<id extension="5523355980-sysBP-Z9301" root="1.2.840.114350.1.13.6289.1.7.1.2109.1"/>
<code code="8480-6" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
displayName="SYSTOLIC BLOOD PRESSURE"/>
<text>
<reference value="#sysBP_5523355980"/>
</text>
<statusCode code="completed"/>
<effectiveTime value="20160625123300-0500"/>
<value xsi:type="PQ" unit="mm[Hg]" value="140"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"/>
</observation>
</component>
</component>

```

```

<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.22.4.27"/>
  <templateId root="2.16.840.1.113883.10.20.22.4.27" extension="2014-06-09"/>
  <id extension="5523355980-diaBP-Z9301" root="1.2.840.114350.1.13.6289.1.7.1.2109.1"/>
  <code code="8462-4" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
displayName="DIASTOLIC BLOOD PRESSURE"/>
  <text>
    <reference value="#diaBP_5523355980"/>
  </text>
  <statusCode code="completed"/>
  <effectiveTime value="20160625123300-0500"/>
  <value xsi:type="PQ" unit="mm[Hg]" value="90"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"/>
</observation>
</component>
<component>
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.22.4.27"/>
    <templateId root="2.16.840.1.113883.10.20.22.4.27" extension="2014-06-09"/>
    <id extension="5523355980-weightC83-Z9301"
root="1.2.840.114350.1.13.6289.1.7.1.2109.1"/>
    <code code="29463-7" codeSystem="2.16.840.1.113883.6.1" displayName="Body weight"/>
    <text>
      <reference value="#weight_5523355980"/>
    </text>
    <statusCode code="completed"/>
    <effectiveTime value="20160625123300-0500"/>
    <value xsi:type="PQ" unit="kg" value="83.915"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"/>
  </observation>
</component>
</organizer>
</entry>
</section>


```

### 5.2.12.2 Vital Sign Observation

Entry Template	Vital Sign Observation (V2)
	[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.27:2014-06-09 (open)]
<b>Reference Source</b>	HL7 C-CDA R2.1
<b>Purpose</b>	This template represents measurement of common vital signs.
<b>ActStatus</b>	<p>The result observation includes a statusCode to allow recording the status of an observation. "Pending" results (e.g., a test has been run but results have not been reported yet) should be represented as "active" ActStatus.</p> <p>The effectiveTime element represents the biologically relevant time of the measurement (e.g., the time a blood pressure reading is obtained, the time the blood sample was obtained for a chemistry test).</p>
<b>Negation</b>	<p>Not specified. To indicate that a test was not performed use the Procedure Activity Observation template with the negationInd attribute of "true."</p> <p><b>Reference:</b> 5.2.15 Procedure</p>
<b>Idioms Supported</b>	None specified.

<b>Entry Template</b>	<b>Vital Sign Observation (V2)</b> [observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.27:2014-06-09 (open)]
<b>Other Considerations</b>	<p>If the Author Participation template is specified for the Organizer, this context applies to all the component observations unless a component observation includes a different Author Participation template.</p> <p>Vital Signs Observations require standard units to be used when recording a particular value.</p> <p>The Vital Sign Result Type value set includes method-less types of vital sign observations. When method-specific vital sign measures are used, a more specific LOINC code can be used in the translation element of the vital sign observation code element.</p>
<b>Example</b>	Example 58: Vital Signs Organizer
<b>Example</b>	Example 59: Vital Sign Coding with Translation

Table 65: Vital Sign Observation Template

 C-CDA Content Creators SHALL represent vital sign observations using the vocabulary constraints and units of measure shown in the table below and MAY include more specific LOINC terms as a translation. **[CONF-094]**

Vital Sign	LOINC Code	Unit of Measure
<b>Body height</b>	8302-2	cm
<b>Head Occipital-frontal circumference</b>	9843-4	cm
<b>Body Weight</b>	29463-7	kg
<b>Body Temperature</b>	8310-5	Cel
<b>Systolic blood pressure</b>	8480-6	Mm[Hg]
<b>Diastolic blood pressure</b>	8462-4	Mm[Hg]
<b>Respiratory Rate</b>	9279-1	/min
<b>Body mass index (BMI) [Ratio]</b>	39156-5	kg/m2
<b>Body surface area Derived from formula</b>	3140-1	m2
<b>Heart Rate (synonym for Pulse)</b>	8867-4	/min
<b>Inhaled Oxygen concentration</b>	3151-8	liters/min
<b>Oxygen Saturation in Arterial blood</b>	2708-6	%
<b>Not in the value set, but often needed as a translation to a method-specific measure</b>		
<b>Oxygen saturation in Arterial blood by Pulse oximetry</b>	59408-5	%
<b>Heart Rate by Pulse oximetry</b>	8889-8	/min
<b>Inhaled Oxygen concentration by Pulse oximetry</b>	*code requested	

Table 66: Vital Sign Observation LOINC Codes and Units for Essential Vital Sign Data Elements

*Example 59: Vital Sign Coding with Translation*

```
<code code="29463-7" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
  displayName="Body weight">
  <translation code="8350-1" codeSystem="2.16.840.1.113883.6.1"
    displayName="Body weight Measured - with clothes" />
</code>
```

**5.2.13 Medication**

The Medication Activity Entry template is used to record a medication that has been administered and also is used to record statements about medications being taken. These two clinical statement patterns are identical, so the semantics is discerned through the context of use. Both are represented as a Medications with a `substanceAdministration/@moodCode="EVN"`. A statement of this type can be interpreted to represent an actual administration of the medication. It also can be used to make a statement about the medication a patient takes.

The Admission Medication and Discharge Medication entry templates include a structural context around the Medication Activity Entry template. The additional structure includes semantic coding that identifies the medication information as admission or discharge medication information.

*Example 60: Medication Administration*

```
<substanceAdministration classCode="SBADM" moodCode="EVN">
  <!-- This medication use case is a medication administered a single time in the past.-->
  <templateId root="2.16.840.1.113883.10.20.22.4.16" />
  <id root="1061a257-3b5c-4b09-9dc7-23e59b788b18"/>
  <text>
    <reference value="#Medication_7" />
  </text>
  <statusCode code="completed"/>
  <effectiveTime xsi:type="TS" value="201309111603-0700"/>
  <routeCode code="C38288" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="ORAL"
codeSystemName="National Cancer Institute Thesaurus" />
  <doseQuantity value="2" />
  <consumable>
    <manufacturedProduct classCode="MANU">
      <templateId root="2.16.840.1.113883.10.20.22.4.23" />
      <manufacturedMaterial>
        <code code="243670" codeSystem="2.16.840.1.113883.6.88"
displayName="Aspirin 81 MG Oral Tablet">
          <originalText>
            <reference value="#MedicationName_7"/>
          </originalText>
        </code>
      </manufacturedMaterial>
    </manufacturedProduct>
  </consumable>
</substanceAdministration>
```

Medication activities with `substanceAdministration/@moodCode="INT"` document what a clinician intends a patient to be taking. For example, a clinician may intend that a patient begin taking Lisinopril 20 mg PO for blood pressure control. The Planned Medication Activity entry can also be used to record a medication that the physician intends the patient to take at some time in the future.

*Example 61: Medication Plan<sup>147</sup>*

```

<substanceAdministration classCode="SBADM" moodCode="INT">
  <!-- This medication use case is a medication that is to be administered.-->
  <templateId root="2.16.840.1.113883.10.20.22.4.16" />
  <id root="1061a257-3b5c-4b09-9dc7-23e59b788b18"/>
  <text>
    <reference value="#Medication_7" />
  </text>
  <statusCode code="active"/>
  <!-- This first effectiveTime shows that medication was prescribed on January 18, 2014
(not known to have stopped)-->
  <effectiveTime>
    <low value="20140118"/>
    <high nullFlavor="NI"/>
  </effectiveTime>
  <!-- This second effectiveTime represents every 4-6 hours from medication sig. -->
  <!-- Operator "A" means that this timing information is in addition to previous
effectiveTime information provided-->
  <effectiveTime xsi:type="PIVL_TS" operator="A">
    <period xsi:type="IVL_PQ">
      <low value="4" unit="h"/>
      <high value="6" unit="h"/>
    </period>
  </effectiveTime>
  <routeCode code="C38288" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Oral"/>
  <!-- This relates directly to the code used for medication. Since it's a tablet, then
only specified needed in dose is 2x per administration-->
  <doseQuantity value="2"/>
  <consumable>
    <manufacturedProduct classCode="MANU">
      <!-- ** Medication information ** -->
      <templateId root="2.16.840.1.113883.10.20.22.4.23"/>
      <id root="0be61984-eea5-46b3-b75b-1d1ba28b5fff"/>
      <manufacturedMaterial>
        <!-- Medications should be specified at a level corresponding to prescription when
possible, such as 30mg oral tablet (branded)-->
        <code code="1049529" displayName="Sudafed 30 MG Oral Tablet"
codeSystem="2.16.840.1.113883.6.88" codeSystemName="RxNorm">
          <originalText>
            <reference value="#MedicationName_1"/>
          </originalText>
        </code>
      </manufacturedMaterial>
    </manufacturedProduct>
  </consumable>
</substanceAdministration>

```

The Medication Supply Order entry records activities associated with ordering medications. The Medication Dispense entry records when medications are dispensed to the patient.

*Example 62: Medication Dispense*

```

<supply classCode="SPLY" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.22.4.18" extension="2014-06-09" />
  <id root="1.2.3.4.56789.1" extension="cb734647-fc99-424c-a864-7e3cda82e704" />
  <statusCode code="completed" />
  <effectiveTime value="201208151450-0800" />
  <repeatNumber value="1" />
  <quantity value="75" />
  <product>
    <manufacturedProduct classCode="MANU">
      <templateId root="2.16.840.1.113883.10.20.22.4.23" extension="2014-06-09" /> ...
    </manufacturedProduct>
  </product>
  <performer>
    <assignedEntity>

```

<sup>147</sup> [https://github.com/iddamore/HL7-Task-Force-Examples/blob/master/MED\\_Med\\_Every\\_4-6\\_hrs.xml](https://github.com/iddamore/HL7-Task-Force-Examples/blob/master/MED_Med_Every_4-6_hrs.xml)

```

.. .
    </assignedEntity>
  </performer>
</supply>

```

The structure of a medication entry can be complex. It is complicated by the fact that any one of these templates may include other types of medication templates within additional entryRelationships. To support interoperability, implementers should minimize the amount of template nesting used to express medication information.

When representing medications, consideration needs to be given to the way date/time intervals are represented. See Chapter 5.1.10.2 Date/Time Precision for additional information about how to represent and interpret date ranges that use an effectiveTime/low and effectiveTime/high. The CDA Example Task Force includes a document that summarizes commonly used medication frequencies.<sup>148</sup>

**Reference:** 5.1.10.2 Date/Time Precision

## 5.2.14 Immunization

### 5.2.14.1 Recording Immunization Date

When recording an actual immunization (with moodCode = EVN), the effectiveTime represents when the immunization was given, and this will generally just be a single dateTime value. Most of the time, when recording the immunization date, the effectiveTime element should contain just a single @value. However, there is a use case for using an interval when requesting an immunization, i.e. have this immunization done between date 1 and date 2.

#### *Example 63: Influenza Vaccination<sup>149</sup>*

```

<section>
  <!-- conforms to Immunizations section with entries optional -->
  <templateId root="2.16.840.1.113883.10.20.22.2.2"/>
  <!-- Immunizations section with entries required -->
  <templateId root="2.16.840.1.113883.10.20.22.2.2.1"/>
  <code code="11369-6" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
    displayName="History of immunizations"/>
  <title>IMMUNIZATIONS</title>
  <text>
    <content ID="immunSect"/>
    <!-- table omitted for space -->
  </text>
  <entry typeCode="DRIV">
    <substanceAdministration classCode="SBADM" moodCode="EVN" negationInd="false">
      <!-- ** Immunization activity ** -->
      <templateId root="2.16.840.1.113883.10.20.22.4.52"/>
      <id root="e6f1ba43-c0ed-4b9b-9f12-f435d8ad8f92"/>
      <text>
        <reference value="#immun1"/>
      </text>
      <!-- Indicates the status of the substanceAdministartion -->
      <statusCode code="completed"/>
      <effectiveTime value="20100815"/>
      <consumable>
        <manufacturedProduct classCode="MANU">
          <!-- ** Immunization medication information ** -->

```

<sup>148</sup> Medication Frequency List: [https://docs.google.com/document/d/1Y0Z458o\\_MrR2aPnpx6EygO6hpl88Bl95esjRWZ0agtY/edit](https://docs.google.com/document/d/1Y0Z458o_MrR2aPnpx6EygO6hpl88Bl95esjRWZ0agtY/edit)

<sup>149</sup> [https://github.com/brettmarquard/HL7-C-CDA-Task-Force-Examples/blob/master/Influenza\\_Immunization\\_Complete.xml](https://github.com/brettmarquard/HL7-C-CDA-Task-Force-Examples/blob/master/Influenza_Immunization_Complete.xml)



```

<templateId root="2.16.840.1.113883.10.20.22.4.54"/>
<manufacturedMaterial>
  <code code="88" codeSystem="2.16.840.1.113883.12.292"
    displayName="Influenza virus vaccine" codeSystemName="CVX"/>
  <lotNumberText>1</lotNumberText>
</manufacturedMaterial>
<!-- Optional manufacturerOrganization
<manufacturerOrganization>
  <name>Health LS - Immuno Inc.</name>
</manufacturerOrganization-->
</manufacturedProduct>
</consumable>
<!-- Optional Performer
<performer>
  <assignedEntity>
    <id root="2.16.840.1.113883.19.5.9999.456" extension="2981824"/>
    <addr>
      <streetAddressLine>1021 Health Drive</streetAddressLine>
      <city>Ann Arbor</city>
      <state>MI</state>
      <postalCode>99099</postalCode>
      <country>US</country>
    </addr>
    <telecom nullFlavor="UNK"/>
    <assignedPerson>
      <name>
        <given>Amanda</given>
        <family>Assigned</family>
      </name>
    </assignedPerson>
    <representedOrganization>
      <id root="2.16.840.1.113883.19.5.9999.1394"/>
      <name>Good Health Clinic</name>
      <telecom nullFlavor="UNK"/>
      <addr nullFlavor="UNK"/>
    </representedOrganization>
  </assignedEntity>
</performer -->
</substanceAdministration>
</entry>
</section>

```

### 5.2.14.2 Immunization Status Code

When recording the immunization status code, the normal value would be “completed”, as this represents an immunization that has been completely given. In extremely rare circumstances, a status of “active” could be used. The use of “active” implies that a single immunization is still on-going. This would not be appropriate for one shot in a series of immunizations. Series immunizations should be represented with multiple Immunization Activity (3.41) entries, each with a status of “completed.”


### 5.2.15 Procedure

There are three templates for representing completed procedures that have been performed on or for the patient, each based on a different RIM Act class. The Procedure template based on the Procedure Act is used to represent procedures that alter the physical condition of a patient (*e.g.*, splenectomy). The Procedure template based on the Observation Act is used to represent procedures that generate information about a patient’s condition but do not cause

physical alteration (e.g., a test like an EEG). The Procedure template based on the Act is for all other types of procedures (e.g., dressing change, patient education).

**Reference:** 4.3.4 Plan/Planning Information

**5.2.15.1 Procedure, Observation, Act**



When representing that a procedure was not performed, the Indication (V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.19:2014-06-09 template MAY be used to represent the rationale for not performing the procedure. More than one indication template may be contained within a Procedure template. **[BP-095]**

The table below shows a summary of similarities and differences for available Procedure templates.

Template	Procedure Activity Procedure	Procedure Activity Observation	Procedure Activity Act
<b>Act type</b>	Procedure	Observation	Act
<b>Purpose</b>	procedures that alter the physical condition	procedures that generate information (tests)	Other procedures
<b>Service Delivery Location</b>	Location where the procedure was performed	Location where the procedure was performed	Location where the procedure was performed
<b>Medication Activity</b>	Medication that was given	Medication that was given	Medication that was given
<b>Reaction</b>	Reaction that occurred	Reaction that occurred	Not specified
<b>Indication</b>	Indication for doing the procedure	Indication for doing the procedure	Indication for doing the procedure
<b>Instruction</b>	Instructions	Instructions	Instructions
<b>Author</b>	The person who documented the procedure	The person who documented the procedure	The person who documented the procedure

*Table 67: Summary of Procedure templates*


<b>Entry Template</b>	<b>Procedure Activity Procedure (V2)</b> [procedure: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.14:2014-06-09 (open)] <b>Procedure Activity Observation (V2)</b> [observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.13:2014-06-09 (open)] <b>Procedure Activity Act (V2)</b> [act: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.12:2014-06-09 (open)]
<b>Reference Source</b>	HL7 C-CDA R2.1
<b>Purpose</b>	These templates are used to describe all interventional, surgical, diagnostic, or therapeutic procedures or treatments pertinent to the patient historically at the time the document is generated.

<b>Entry Template</b>	<b>Procedure Activity Procedure (V2)</b> [procedure: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.14:2014-06-09 (open)] <b>Procedure Activity Observation (V2)</b> [observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.13:2014-06-09 (open)] <b>Procedure Activity Act (V2)</b> [act: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.12:2014-06-09 (open)]
<b>ActStatus</b>	These templates include a state model that includes active, completed, aborted, and cancelled. The effectiveTime, also referred to as the “biologically relevant time” is the time at which the procedure was performed. If the status of a procedure was active at the time a C-CDA document was created, the effectiveTime/low would indicate the date/time the procedure was started and the effectiveTime/high SHOULD not be present. If the status of a procedure was completed, aborted or cancelled, the effectiveTime/high SHOULD be populated. Implementer best practice would be use of the TS_IVL data type. For implementers who are not able to represent a time interval, effectiveTime/value MAY be populated
<b>Negation</b>	In this template, the negationInd attribute is used to indicate the procedure was not performed.
<b>Idioms Supported</b>	None specified.
<b>Other Considerations</b>	When representing that a procedure was not performed, the Indication (V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.19:2014-06-09 template MAY be used to represent the rationale for not performing the procedure. More than one indication template may be contained within a Procedure template.
<b>Reference</b>	Visit <a href="#">HL7 CDA Example Search</a>
<b>Example</b>	How to represent <a href="#">“Procedure Observation Entry”</a>

Table 68: Procedure, Observation, Act Template

### 5.2.16 Assessment (the noun)

An assessment is a collection of observations that together yield a summary evaluation of a particular condition. Examples include the Braden Scale (assesses pressure ulcer risk), APACHE Score (estimates mortality in critically ill patients), Mini-Mental Status Exam (assesses cognitive function), APGAR Score (assesses the health of a newborn), and Glasgow Coma Scale (assesses coma and impaired consciousness). Assessments should be included in the “status section” such as the Functional Status Section, Mental Status Section, or the Health Status Evaluations and Outcomes Section. The selection should be based on the content assessed by the assessment. This template is designed to represent both the question or type of information assessed as well as the associated answer/result.

	The Assessment Scale Observation Template SHOULD be used to represent the content of the Assessment. <b>[BP-096]</b>
---	--

**5.2.16.1 Assessment Scale Observation**

Entry Template	Assessment Scale Observation [observation: identifier urn:oid:2.16.840.1.113883.10.20.22.4.69 (open)]
<b>Reference Source</b>	HL7 C-CDA R2.1
<b>Purpose</b>	An assessment scale is a collection of observations that together yield a summary evaluation of a particular condition.
<b>ActStatus</b>	This is a discrete observation that has been made in order for it to be documented. Therefore, it always has a statusCode of “completed”. The effectiveTime represents the clinically relevant time of the measurement, which may be when the assessment was performed.
<b>Negation</b>	Not specified.
<b>Idioms Supported</b>	None specified.
<b>Other Considerations</b>	The observation/value element represents the “answer” or result for the assessed “question” or measurement. The clinical statement may also include an interpretation and may include multiple reference ranges. Additionally, each assessment scale observation may contain zero or more Assessment Scale Supporting Observations. This structure allows the Assessment Scale Observation to mirror the format of many assessment tools. An Assessment Scale Supporting Observation represents the components of a scale used in an Assessment Scale Observation. The individual parts that make up the component may be a group of cognitive or functional status observations.

Table 69: Assessment Scale Observation Template

**5.2.17 Plan of Treatment**


Plan of treatment information encompasses data that define pending orders, interventions, encounters, services, and procedures for the patient. It is limited to prospective, unfulfilled, or incomplete orders and requests only. These are indicated by the @moodCode of the entries within this section. All active, incomplete, or pending orders, appointments, referrals, procedures, services, or any other pending event of clinical significance to the current care of the patient should be listed. The plan of treatment is typically developed to address a set of goals set by the patient, provider or jointly set together.

**Reference:** 3.2.8 C-CDA R2.1 Document Templates; 5.2.9 Goal

**5.2.18 Clinical Note**

Note Activity entries contain structured information about the note information contained in a Notes Section or in one of the sections defined for exchanging structured clinical note documents. A Note Activity entry allows the corresponding human readable narrative note information to be more machine processable.

**5.2.18.1 Note Activity**

 C-CDA Content Creators SHOULD NOT use the Note Activity template in place of a more specific C-CDA entry template. [BP-097]

Entry Template	Note Activity
<b>Reference Source</b>	HL7 C-CDA R2.1 Companion Guide
<b>Purpose</b>	The Note Activity represents a clinical note.
<b>ActStatus</b>	This is a discrete observation that has been made in order for it to be documented. Therefore, it always has a statusCode of “completed.”  The effectiveTime represents the clinically relevant time of note, which may be when the note was written.
<b>Negation</b>	Not specified.
<b>Idioms Supported</b>	None specified.
<b>Other Considerations</b>	<p>Similar to the Comment Activity, the Note Activity permits a more specific code to characterize the type of information available in the note. Note information included needs to be relevant and pertinent to the information being communicated in the document.</p> <p>When the note information augments data represented in a more specific entry template, the Note Activity can be used in an entryRelationship to the associated standard C-CDA entry. For example, a Note Activity template can be added as an entryRelationship to a Procedure Activity Procedure entry. Or for example, a Note Activity template can be as an entryRelationship to an Encounter Activity entry in the Encounters Section.</p> <p>The Note Activity template also can be used as a standalone entry within a standard C-CDA section (e.g. a note about various procedures which have occurred during a visit as an entry in the Procedures Section) when it does not augment another standard entry. It may also be used to provide additional data about the source of a currently narrative-only section, such as Hospital Course.</p> <p>Finally, if the type of data in the note is not known or no single C-CDA section is appropriate enough, the Note Activity should be placed in a general Notes Section. (e.g. a free-text consultation note or a note which includes subjective, objective, assessment, and plan information combined).</p> <p>The examples below show a variety of clinical note representations that can be used with the Note Activity entry template.</p> <p><b>Reference:</b> 4.3 Sections Defined in C-CDA, Table 9: LOINC Codes for section- and entry- level clinical notes</p>

Table 70: Note Activity Template

*Example 64: Note Activity as entryRelationship to C-CDA Entry.*

```
<?xml version="1.0" encoding="UTF-8"?>
<section>
  <!-- C-CDA 2.1 Procedures Section -->
  <templateId root="2.16.840.1.113883.10.20.22.2.7.1"/>
  <templateId root="2.16.840.1.113883.10.20.22.2.7.1" extension="2014-06-09"/>
  <code code="47519-4" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
  displayName="HISTORY OF PROCEDURES"/>
```

```

<title>Procedures</title>
<text>
<table>
  <thead>
    <tr>
      <th>Description</th>
      <th>Date and Time (Range)</th>
      <th>Status</th>
      <th>Notes</th>
    </tr>
  </thead>
  <tbody>
    <tr ID="Procedure1">
      <td ID="ProcedureDesc1">Laparoscopic appendectomy</td>
      <td>(03 Feb 2014 09:22am- 03 Feb 2014 11:15am)</td>
      <td>Completed</td>

      <td ID="ProcedureNote1">
        <paragraph>Dr. Physician - 03 Feb 2014</paragraph>
        <paragraph>Free-text note about the procedure.</paragraph>
      </td>
    </tr>
  </tbody>
</table>
</text>
<entry typeCode="DRIV">
  <!-- Procedures should be used for care that directly changes the patient's physical state.-->
  <procedure moodCode="EVN" classCode="PROC">
    <templateId root="2.16.840.1.113883.10.20.22.4.14" />
    <id root="64af26d5-88ef-4169-ba16-c6ef16a1824f"/>
    <code code="6025007" displayName="Laparoscopic appendectomy"
codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED-CT">
      <originalText>
        <reference value="#ProcedureDesc1" />
      </originalText>
    </code>
    <text>
      <reference value="#Procedure1" />
    </text>
    <statusCode code="completed" />
    <effectiveTime>
      <low value="20140203092205-0700" />
      <high value="20140203111514-0700" />
    </effectiveTime>
    <!-- Note Activity entry -->
    <entryRelationship typeCode="COMP">
      <act classCode="ACT" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.22.4.202" extension="2016-11-01"/>
        <code code="34109-9" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
displayName="Note">
          <translation code="28570-0" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
displayName="Procedure note" />
        </code>
        <text>
          <reference value="#ProcedureNote1" />
        </text>
        <statusCode code="completed"/>
        <!-- Clinically-relevant time of the note -->
        <effectiveTime value="20140203" />
        <!-- Author Participation -->
        <author>
          <templateId root="2.16.840.1.113883.10.20.22.4.119" />
          <!-- Time note was actually written -->
          <time value="20140204083215-0500" />
          <assignedAuthor>
            <id root="20cf14fb-b65c-4c8c-a54d-b0cca834c18c" />
            <name>Dr. Physician</name>
          </assignedAuthor>
        </author>
        <!-- Reference to encounter -->

```

```

    <entryRelationship typeCode="COMP" inversionInd="true">
      <encounter>
        <!-- Encounter ID matches an encounter in the Encounters Section -->
        <id root="1.2.3.4" />
      </encounter>
    </entryRelationship>
  </act>
</entryRelationship>
</procedure>
</entry>
</section>

```

*Example 65: Note Activity as Standalone Entry*

```

<section>
  <!-- C-CDA 2.1 Procedures Section, entries optional -->
  <templateId root="2.16.840.1.113883.10.20.22.2.7"/>
  <templateId root="2.16.840.1.113883.10.20.22.2.7" extension="2014-06-09"/>
  <code code="47519-4" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
  displayName="HISTORY OF PROCEDURES"/>
  <title>Procedures</title>
  <text>
    <list>
      <item ID="ProcedureNote1">
        <paragraph>Dr. Physician - 03 Feb 2014</paragraph>
        <paragraph>Free-text note about procedures which have occurred during this
  visit.</paragraph>
      </item>
    </list>
  </text>
  <!-- If section were entries required, an additional <entry nullFlavor="NI"> would be
  required for a Procedure Activity -->
  <!-- Note Activity entry -->
  <entry>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.22.4.202" extension="2016-11-01"/>
      <code code="34109-9" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
      displayName="Note"/>
      <translation code="28570-0" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
      displayName="Procedure note" />
    </code>
    <text>
      <reference value="#ProcedureNote1" />
    </text>
    <statusCode code="completed"/>
    <!-- Clinically-relevant time of the note -->
    <effectiveTime value="20140203" />
    <!-- Author Participation -->
    <author>
      <templateId root="2.16.840.1.113883.10.20.22.4.119" />
      <!-- Time note was actually written -->
      <time value="20140204083215-0500" />
      <assignedAuthor>
        <id root="20cf14fb-b65c-4c8c-a54d-b0cca834c18c" />
        <name>Dr. Physician</name>
      </assignedAuthor>
    </author>
    <!-- Reference to encounter -->
    <entryRelationship typeCode="COMP" inversionInd="true">
      <encounter>
        <!-- Encounter ID matches an encounter in the Encounters Section -->
        <id root="1.2.3.4" />
      </encounter>
    </entryRelationship>
  </act>
</entry>
</section>

```

Example 66: Rich Text Format (RTF) Example

```


<section>
  <!--... -->
  <text>
    <list>
      <item ID="note1">
        <caption>Nursing Note written by Nick Nurse</caption>
        <paragraph>Completed rounds; no incident</paragraph>
      </item>
    </list>
  </text>
  <!-- Note Activity (extra markup removed to focus on <text>) -->
  <entry>
    <act>
      <code>...</code>
      <text mediaType="text/rtf" representation="B64">
        <reference value="#note1"/>
      </text>
      <!--...-->
    </act>
  </entry>
  ...
</section>

```

### 5.2.19 Advance Directive

New versions of previously defined entry templates for representing advance care planning interventions and for documenting information about a person’s Advance Directives are now available for use. The templates are backward compatible with current version.

Two new entry templates have been added to represent obligation instructions and prohibition instructions a patient makes about the care her or she wants or does not want to be performed. The table below summarizes the improvements in the new version and describes the information that can be represented in these supplemental templates.

 C-CDA Content Creators MAY use the new templates and template versions for representing Advance Directive information. **[BP-098]**

Summary of C-CDA Supplemental Templates for Advance Directives	
<p><b>Advance Care Planning Intervention (V1)</b>            New Version:            [procedure: identifier            urn:hl7ii:2.16.840.1.113883.10.20.22.4.204:            2017-05-01 (open)]</p>	<p>The Advance Care Planning Intervention template is used to record a planned intervention that will involve reviewing and verifying a person’s directives or will involve educating and supporting a person on establishing or modifying his or her advance directives. It also can be used to record when the activity of reviewing and verifying a person’s directives has been completed or when educating and supporting a person to establish or update his or her advance directives has been completed.</p>



Summary of C-CDA Supplemental Templates for Advance Directives	
<p><b>Advance Directive Observation (V4)</b>                      New Version:                      [observation: identifier                      urn:hl7ii:2.16.840.1.113883.10.20.22.4.48:                      2017-05-01 (open)]</p>	<p>An Advance Directive Observation template is used to record information about a document authored by the person and containing goals, preferences, and priorities for care. The observation records that the document was available and may have been reviewed (verified). It records the kind (category) of advance directive document, where the document can be accessed, who verified it, and the type of content that was determined to be present. When a person has more than one advance directive document, each document is recorded using an Advance Directive Observation template. A set of Advance Directive Observations are grouped together using an Advance Directive Organizer.</p>
<p><b>Advance Directive Organizer (V3)</b>                      New Version:                      [organizer: identifier                      urn:hl7ii:2.16.840.1.113883.10.20.22.4.108:                      2017-05-01 (open)]</p>	<p>This clinical statement groups a set of advance directive observations documented together at a single point in time, and relevant during the episode of care being documented.</p>
<p><b>Obligation Instruction</b>                      [act: identifier                      urn:hl7ii:2.16.840.1.113883.10.20.22.4.205:                      2018-01-01 (open)]</p>	<p>The Obligation Instruction template represents a statement made by a patient regarding care services he or she wants to be performed.</p>
<p><b>Prohibition Instruction</b>                      [act: identifier                      urn:hl7ii:2.16.840.1.113883.10.20.22.4.206:                      2018-01-01 (open)]</p>	<p>The Prohibition Instruction template represents a statement made by a patient regarding care services he or she does not want to be performed.</p>

Table 71: Summary of C-CDA Supplemental Templates for Advance Directives<sup>150</sup>

Refer to the C-CDA R2.1 Supplemental Implementation Guide titled HL7 Implementation Guide: C-CDA R2.1; Advance Directives Templates, Release 1 – US Realm for more information, examples, and template definitions.<sup>151</sup>

### 5.2.20 Quality Measure

As the focus on exchange of quality measure information increases, new possibilities have emerged for sharing quality care gap information in C-CDA documents. Quality reporting CDA templates, compatible with C-CDA R2.1, are defined by the Clinical Quality Information Workgroup in the HL7 Quality Reporting Document Architecture standard.<sup>152</sup> QRDA is a document format that provides a standard structure with which to report quality measure data to organizations that will analyze and interpret the data. Although the initial use case for the QRDA Cat I templates was to share information from EHR systems to organizations administering quality programs, it has recently become apparent that same templates can be used to share patient-focused quality measure information in the opposite direction. Organizations with visibility to a patient’s compliance to a set of applicable quality measures can share this information with the care deliver organizations who can help to close the gap.

<sup>150</sup> HL7 Implementation Guide: C-CDA R2.1; Advance Directives Templates, Release 1 – US Realm.

<sup>151</sup> HL7 Implementation Guide: C-CDA R2.1; Advance Directives Templates, Release 1 – US Realm.

<sup>152</sup> HL7 Quality Reporting Document Architecture (QRDA) Category 1, STU R5.1  
[http://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=35](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35)

The Measure Section (2.16.840.1.113883.10.20.24.2.2) template contains information about the measure or measures being reported.

### 5.2.20.1 Measure Reference

Entry Template	Measure Reference [organizer: identifier urn:oid:2.16.840.1.113883.10.20.24.3.98 (open)]
<b>Reference Source</b>	HL7 QRDA Cat I, STU R5.1
<b>Purpose</b>	<p>The template represents measure logic (i.e. denominators, numerators) by using negationInd in conjunction with the measure component observations to show if a patient is compliant with one or more quality measures or not.</p> <p>This example complies with QRDA1 measure section but may not suitable for formal quality reporting. Refer to QRDA1 and QRDA3 implementation guidance for more details. Per discussions with clinical quality improvement CQI workgroup, this template aligns with how the Joint Commission encourage patient level reporting in QRDA1 documents.</p>
<b>ActStatus</b>	<p>This is a discrete observation that has been made in order for it to be documented. Therefore, it always has a statusCode of “completed”.</p> <p>This template does not include an effectiveTime element. See other considerations below.</p>
<b>Negation</b>	Not specified.
<b>Idioms Supported</b>	None specified.
<b>Other Considerations</b>	<p>The template enables patient-level quality measure information (i.e. reported outcome) to be included in a C-CDA document.</p> <p>Measures are referenced through externalAct reference to an externalDocument. The externalDocument/ids and version numbers are used to reference the measure. The Reporting Parameter Act (2.16.840.1.113883.10.20.17.3.8) template is used to record the relevant reporting period for the reported quality care gap or compliance information.</p>
<b>Example</b>	Example 67: QRDA1 measure section
<b>Reference</b>	Visit <a href="#">HL7 CDA Example Search</a>
<b>Example</b>	How to represent <a href="#">“Quality Section”</a>

Table 72: Measure Reference Template

This example complies with QRDA1 measure section but may not suitable for formal quality reporting. Refer to QRDA1 and QRDA3 implementation guidance for more details. Per discussions with clinical quality improvement CQI workgroup, this template aligns with how the Joint Commission encourage patient level reporting in QRDA1 documents.

#### Example 67: QRDA1 measure section

```
<section>
  <!-- Templates use QRDA1 1.1 (current reporting standard as of 2018)-->
  <!-- This is the templateId for Measure Section -->
  <templateId root="2.16.840.1.113883.10.20.24.2.2"/>
  <!-- This is the templateId for Measure Section QDM -->
  <templateId root="2.16.840.1.113883.10.20.24.2.3"/>
  <code code="55186-1" codeSystem="2.16.840.1.113883.6.1" codeSystemName=" LOINC"
    displayName="Measure Document"/>
  <title>Measure Section</title>
  <text>
    <table border="1" width="100%">
      <thead>
        <tr>
```

```

<!-- Note that this table is an illustrative format that could be used to
show human readable measure, but others are possible -->
<!-- Each of the fields in this table will be represented in machine
readable as well as human readable -->
<!-- For each of the measures we provide a descriptive name and an
identifier -->
<!-- The machine-readable entries will have the unique GUID reference to
this measure, if available -->
<!-- An alternative option would be to include additional description of
measure logic or a link in the human-readable -->
<!-- This aligns with what may be typically included from QRDA1 document --
>
    <th>Measure</th>
    <th>Compliance Period</th>
    <th>Denominator</th>
    <th>Numerator</th>
    <th>Exclusion</th>
    <th>Outcome</th>
  </tr>
</thead>
<tbody>
  <tr>
    <td>Diabetes Hemoglobin A1c Poor Control (CMS 122v5)</td>
    <td>Jan 1 2017 - Dec 31 2017</td>
    <td>yes</td>
    <td>no</td>
    <td>no</td>
    <!-- Compliance here is based on the measure "Improvement Notation" from
the Measure Definition-->
    <!-- Since lower = better for CMS 122v5, a false numerator means
compliance-->
    <td>Compliant</td>
  </tr>
  ...
</tbody>
</table>
</text>
<entry>
  <organizer classCode="CLUSTER" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.24.3.98"/>
    <templateId root="2.16.840.1.11.3883.10.20.24.3.97"/>
    <id root="d7345481-b3b5-41e0-a8ae-03dabcd4a0cc"/>
    <!-- A code element could be added to make organizer type more specific, although
was not in the original QRDA1 template -->
    <statusCode code="completed"/>
    <!-- This reference contains the version specific identifier of the measure-->
    <reference typeCode="REFR">
      <externalDocument classCode="DOC" moodCode="EVN">
        <!-- This includes an uuid identifier of the measure logic, For this
example, -->
        <!-- see
https://ecqi.healthit.gov/system/files/ecqm/measures/CMS122v5_SimpleXML_2.xml -->
        <!-- If no GUID available, the measure would at least be described using
the text field -->
        <id root="2.16.840.1.113883.4.738"
          extension="40280381-51f0-825b-0152-229afff616ee"/>
        <code code="57024-2" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC"
          displayName="Health Quality Measure Document"/>
        <text>Diabetes: Hemoglobin A1c Poor Control</text>
        <versionNumber value="5"/>
      </externalDocument>
    </reference>
    <!-- To specify the time period, a component has been added with the appropriate
QRDA1 template (Reporting Parameters Act) -->
    <component>
      <act classCode="ACT" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.17.3.8"/>
        <id root="55a43e20-6463-46eb-81c3-9a3alad41225"/>
        <code code="252116004" codeSystem="2.16.840.1.113883.6.96"

```

```

        displayName="Observation Parameters"/>
        <effectiveTime>
        <!-- The beginning of the reporting period. -->
        <low value="20170101000000-0500"/>
        <!-- The ending of the reporting period. -->
        <high value="20171231235959-0500"/>
        </effectiveTime>
    </act>
</component>
<component>
    <!-- Set negationInd="false" to assert that the criteria are met by the
included data.
                                Set negationInd="true" to assert that the criteria are
NOT met by the included data.
                                Since this patient is in the denominator, negationInd is
set to false -->
    <observation classCode="OBS" moodCode="EVN" negationInd="false">
        <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"
        codeSystemName="ActCode" displayName="Assertion"/>
        <value xsi:type="CD" code="DENOM" codeSystem="2.16.840.1.113883.5.4"
        codeSystemName="ObservationValue" displayName="denominator"/>
        <reference typeCode="REFER">
            <externalObservation classCode="OBS" moodCode="EVN">
                <!-- This includes a version specific uuid identifier of the
specific measure component, (denominator in this example) -->
                <!-- For example, see
https://ecqi.healthit.gov/system/files/2017\_CMS\_QRDA\_III\_Eligible\_Clinicians\_and\_EP\_IG\_final\_07\_03\_508.pdf -->
                <id root="D346DA74-F16E-4159-DEDF-331BA28837FB"/>
            </externalObservation>
        </reference>
    </observation>
</component>
<component>
    <!-- Since this patient is NOT in the numerator, negationInd is set to true -->
    <!-- Note that this measure has inverted numerator logic (i.e. numerator events
are non-compliant)-->
    <observation classCode="OBS" moodCode="EVN" negationInd="true">
        <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"
        codeSystemName="ActCode" displayName="Assertion"/>
        <value xsi:type="CD" code="NUMER" codeSystem="2.16.840.1.113883.5.4"
codeSystemName="ObservationValue" displayName="numerator"/>
        <reference typeCode="REFER">
            <externalObservation classCode="OBS" moodCode="EVN">
                <id root="6D01A564-58CC-4CF5-929-F-B83583701BFE"/>
            </externalObservation>
        </reference>
    </observation>
</component>
    <!-- no denominator exclusion criteria available for this measure so omitted -->
</organizer>
</entry>
...
</section>

```

## 6 Resources

The following resources are available to the C-CDA implementer community to support the growing use of this important information exchange standard for interoperability.

### 6.1 Sample C-CDA Files

Published along with this Companion Guide, there are sample C-CDA files for a variety of Clinical Note types. Additionally, sample documents are posted in Github where they are incrementally improved by the CDA Examples Task Force. Reference the C-CDA Sample Document registry for the current version of these sample documents.<sup>153</sup>

Type	C-CDA Sample File Name and brief description
<b>CCD Patient Summary</b>	<p>CCD-Sample.xml</p> <p>This sample demonstrates sections relevant to creating a summary of essential clinical data to exchange from a patient's health record.</p>
<b>Discharge Summary</b>	<p>DischargeSummary-Sample.xml</p> <p>This sample demonstrates sections relevant to creating a summary of information that supports a transfer of care following an inpatient discharge.</p>
<b>Referral Note</b>	<p>ReferralNote-Sample.xml</p> <p>This sample demonstrates sections relevant when initiating a referral to support a transfer of care to another care provider.</p>
<b>Progress Note</b>	<p>ProgressNote-Sample.xml</p> <p>This sample demonstrates sections relevant for documenting a patient's progress during an ongoing episode of care.</p>
<b>Care Plan</b>	<p>Care Plan Summary-Sample.xml</p> <p>This sample demonstrates the organization of care plan information for exchange. It shows the relationships between health concerns, goals, interventions and health assessment and outcome evaluation information are expressed.</p>
<b>Unstructured Document</b>	<p>Unstructured Document PACP-Sample.xml</p> <p>This sample demonstrates use of the &lt;nonXMLbody&gt; option for a C-CDA document.</p>
<b>Legal Authenticator-signed</b>	<p>LegalAuthenticator-signed.xml</p> <p>This sample demonstrates use of the HL7 Digital Signature standard for digitally signing a C-CDA document as the Legal Authenticator.</p>
<b>Authenticator-signed</b>	<p>Authenticator-signed.xml</p> <p>This sample demonstrates use of the HL7 Digital Signature standard for digitally signing a C-CDA document as an Authenticator.</p>

<sup>153</sup> [https://github.com/chb/sample\\_ccdas](https://github.com/chb/sample_ccdas)

<b>New Sections</b>	<p>New Sections.xml</p> <p>This sample is not a valid C-CDA document. It simply demonstrates how to formulate information for exchange using the new Care Teams Section template and other supplemental templates defined for use with C-CDA.</p>
---------------------	---

Table 73: Sample Document Files

## 6.2 Published HL7 CDA and C-CDA Specifications

The HL7 Version 3 Clinical Document Architecture (CDA®) is a document markup standard that specifies the structure and semantics of "clinical documents" for the purpose of exchange between healthcare providers and patients. It defines a clinical document as having the following six characteristics: 1) Persistence, 2) Stewardship, 3) Potential for authentication, 4) Context, 5) Wholeness and 6) Human readability.

CDA R2.0 is the currently release normative version of the HL7 CDA standard. However, implementers are encouraged to begin educating themselves about the improvements offered by the new CDA R2.1. CDA R2.1 is a minor enhancement of the base Clinical Document Architecture standard that is backward compatible to the existing CDA R2.0 standard and provides optional improvements which natively support most previous extensions used in implementation guides world-wide.

Notable extensions have been added to the patient reference and classes in the clinical statement model used for machine process-ability. The documentation has been improved and updated to explain how CDA can be constrained using templating to support any number of use cases found in healthcare using a base schema just like CDA R2.0.

A CDA document can be used to represent any type of clinical content -- a CDA document could be used to represent a Discharge Summary, Imaging Report, Admission & Physical, Pathology Report and more. The most popular use is for inter-enterprise information exchange, such as is envisioned for a US Health Information Exchange (HIE). The HL7 C-CDA Implementation Guide constrains the base CDA standard to meet the use cases for information exchange of common types of clinical notes.

As the demand for interoperable information exchange in healthcare grows, stakeholders across the C-CDA implementer community continue to develop and publish additional templating guidance to supplement the set of templates defined in C-CDA. Supplemental C-CDA implementation guides are balloted through the HL7 consensus process and published together with C-CDA on the HL7 Master Grid of Standards. Supplemental C-CDA implementation guides define additional templates and new versions of templates in C-CDA. All templates in Supplemental C-CDA implementation guides are considered for optional use.

**Source:** HL7 CDA® Release 2

**Resource:** [https://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=7](https://www.hl7.org/implement/standards/product_brief.cfm?product_id=7)

**Description:** This package includes additional publications such as Datatypes, HL7 Value Sets, and other detailed information required for proper implementation of CDA.

**Source:** CDA Management Group Listserv for HL7 CDA® Release 2.1

**Resource:** <http://www.hl7.org/Special/committees/cdamg/index.cfm>

**Description:** At this time, there are no plans to migrate to the new version of CDA within the US. However, the CDA Management Group will begin an information gathering campaign in 2020 to allow the implementer community to explore and discuss the pros and cons of introducing CDA R2.1 into production.

**Source:** C-CDA (HL7 CDA® R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes - US Realm R2.1)

**Resource:** [http://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=492](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=492)

**Description:** The HL7 Consolidated CDA is an implementation guide which specifies a library of templates and prescribes their use for a set of specific document types. The Consolidated CDA (C-CDA) implementation guide contains a library of CDA templates, incorporating and harmonizing previous efforts from Health Level Seven (HL7), Integrating the Healthcare Enterprise (IHE), and Health Information Technology Standards Panel (HITSP). It represents harmonization of the HL7 Health Story guides, HITSP C32, related components of IHE Patient Care Coordination (IHE PCC), and Continuity of Care (CCD). C-CDA Release 1 included all required CDA templates in Final Rules for Stage 1 Meaningful Use and 45 CFR Part 170 – Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology; Final Rule. C-CDA R2.1 guide was developed and produced by the HL7 Structured Documents Workgroup. It updates the C-CDA R2 (2014) guide to support “on-the-wire” compatibility with R1.1 systems. The C-CDA Release 2.1 implementation guide, in conjunction with this Companion Guide, the published C-CDA R2.1 Supplemental Guides, and the HL7 CDA Release 2 (CDA R2) standard, are to be used for implementing the following CDA documents and header constraints for clinical notes: Care Plan including Home Health Plan of Care (HHPoC), Consultation Note, Continuity of Care Document (CCD), Diagnostic Imaging Reports (DIR), Discharge Summary, History and Physical (H&P), Operative Note, Procedure Note, Progress Note, Referral Note, Transfer Summary, as well as patient generated documents and all types of unstructured documents classified under the LOINC document ontology.

**Source:** C-CDA R2.1; Advance Directives Templates, Release 1 – US Realm

**Resource:** [https://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=473](https://www.hl7.org/implement/standards/product_brief.cfm?product_id=473)

**Description:** Advance Directive Templates are important components of the C-CDA standard, yet to date, their usage in the standard has been optional. New focus within the industry on patient-centered care plans and value-based care has raised implementer interest in care planning and advance care planning. As implementers have started to include advance directive information, it became clear that additional guidance was needed and that the template designs required refinement. Also, the new standard was developed to represent personal advance care planning information have been developed to communicate health goals and treatment preferences expressed by the patient. The older Advance Directive templates needed revisions to take the newer work into consideration.

As advance care planning information began to be shared, concern increased about the possibility that clinicians might misinterpret patient wishes in a way that would result in errors that risk patient safety or that violate patient intent. Information context is crucial when it comes to interpreting advance directives. Directives should always be maintained in their original form - not chopped up and stored as structured data. There is a very high risk that the conversion from text to structure will lose critical information. Changes were needed to the templates to clarify that these observations DO NOT convert patient wishes into structured data that acts as a decision or an order. The structured data is used to document WHAT TYPE of CONTENT is present in the source document that describes the patient's wishes, health goals, and treatment preferences. Fixing this issue was a critical need.

For these reasons, the earlier versions of the Consolidated CDA Advance Directive Templates needed to be clarified and revised, and some additional templates needed to be added.

**Source:** HL7 CDA R2 Implementation Guide: C-CDA R2.1 Supplemental Templates for Nutrition, Release 1 – US Realm

**Resource:** [http://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=478](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=478)

**Description:** The Nutrition Care Process (NCP) is used by Registered Dietitians Nutritionists (RDN) and other nutrition and dietetics professionals as a systematic approach to providing high quality nutrition care. Templates in this guide are specific to the four steps of the Nutrition Care Process: Nutrition Assessment and Reassessment, Nutrition Diagnosis, Nutrition Intervention, and Nutrition Monitoring and Evaluation. These templates are intended to promote nutrition interoperability across care settings and will create information suitable for reuse in transitions of care, quality measurement, public health reporting, research and reimbursement.

**Source:** C-CDA Supplemental Templates for Unique Device Identifier (UDI) for Implantable Medical Devices, Release 1 – US Realm

**Resource:** [http://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=478](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=478)

**Description:** This document defines the individual UDI Components for all HL7 standards except for CDA.

**Source:** HL7 CDA R2 Implementation Guide: C-CDA R2.1 Supplemental Templates for Pregnancy Status, Release 1 – US Realm

**Resource:** [http://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=494](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=494)

**Description:** This implementation guide provides consistent guidance for capturing key pregnancy status information in healthcare information technology (HIT) products and contains optional supplemental pregnancy status templates for current C-CDA document types.

**Source:** HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1

**Resource:** [http://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=280](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=280)

**Description:** This implementation guide defines constraints on the HL7 CDA standard to support Meaningful Use in provide data representation specifications that are consistent with federal and state privacy policies. The guidance enables the exchange of protected/sensitive personal health information. It supports secure



exchange of health information and privacy annotations applied to documents, messages, or atomic data elements(HIT) products and contains optional supplemental pregnancy status templates for current C-CDA document types.

**Source:** HL7 CDA® R2 Implementation Guide: Privacy Consent Directives, Release 1

**Resource:** [http://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=354](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=354)

**Description:** This implementation guide defines a CDA representation of privacy consents (e.g. authorization to disclose health information, consent for research) which enables the exchange of computable consents across EHRs. It supports the display of consents to end-users based on existing CDA infrastructure and applications. It also supports Data Use and Reciprocal Support Agreement (DURSA) opt-in and other opt-in consent agreements. This specification enhances IHE BPPC (Basic Patient Privacy Consent). This implementation guide defines constraints on the HL7 CDA standard to support Meaningful Use in provide data.

### 6.3 Published C-CDA Implementer Community Guidance

Below are brief descriptions of additional specifications relevant for C-CDA based information exchange.

#### 6.3.1 The Joint Document Content Work Group

The Joint Document Content Work Group was established in 2018 as a cooperative effort between Carequality and CommonWell initiatives.<sup>154</sup> The outcome was the white paper “Concise Consolidated CDA: Deploying Encounter Summary CDA Documents with Clinical Notes” which provides recommendations to improve content in C-CDA for document-based information exchange including the following topics: inclusion of Encounter Summary Documents, best practices for Clinical Notes, and document display guidance for Smart Senders and Resilient Receivers.

**Source:** Concise Consolidated CDA: Deploying Encounter Summary CDA Documents with Clinical Notes

**Resource:** [http://www.commonwellalliance.org/wp-content/uploads/2018/07/Carequality\\_CommonWell\\_Improve\\_C-CDA\\_06-15-2018\\_V1.pdf](http://www.commonwellalliance.org/wp-content/uploads/2018/07/Carequality_CommonWell_Improve_C-CDA_06-15-2018_V1.pdf)

**Description:** Provides recommendations to improved content in C-CDA.

#### 6.3.2 Integrating the Healthcare Enterprise (IHE)

IHE is an initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information. IHE promotes the coordinated use of established standards such as DICOM and HL7 to address specific clinical needs in support of optimal patient care.

<sup>154</sup> <https://www.commonwellalliance.org/wp-content/uploads/2019/01/Improve-Joint-Document-Content-Whitepaper.pdf>

**Source:** Integrating the Healthcare Enterprise (IHE) Patient Care Coordination Technical Framework Supplement: CDA Document Summary Sections (CDA-DSS)

**Resource:** [https://www.ihe.net/uploadedFiles/Documents/PCC/IHE\\_PCC\\_Suppl\\_CDA\\_DSS.pdf](https://www.ihe.net/uploadedFiles/Documents/PCC/IHE_PCC_Suppl_CDA_DSS.pdf)

**Description:** Provides a method to summarize and communicate specific information to the reader (*e.g.*, provider and/or patient) in a concise and useful manner. This profile can be added to any CDA document that is an open template and allows a relevant and pertinent information in a section to be available to the reader while including the large amount of data in a CDA document.

**Source:** Integrating the Healthcare Enterprise (IHE) Patient Care Coordination Technical Framework Supplement: Multiple Content Views (MCV)

**Resource:** [https://www.ihe.net/uploadedFiles/Documents/PCC/IHE\\_PCC\\_Suppl\\_MCV.pdf](https://www.ihe.net/uploadedFiles/Documents/PCC/IHE_PCC_Suppl_MCV.pdf)

**Description:** Provides guidance on how to tag text in CDA documents for rendering of the narrative for different Document Consumers and their specific viewing requirements.

**Source:** Integrating the Healthcare Enterprise (IHE) Patient Care Coordination Technical Framework Supplement: Reconciliation of Clinical Content and Care Providers (RECON)

**Resource:** [http://ihe.net/uploadedFiles/Documents/PCC/IHE\\_PCC\\_Suppl\\_RECON.pdf](http://ihe.net/uploadedFiles/Documents/PCC/IHE_PCC_Suppl_RECON.pdf)

**Description:** This profile enables Health Information Systems and Exchanges to support automation of reconciliation of tasks and clinical workflows and the ability to communicate lists of reconciled clinical data, when they were reconciled and who did the reconciliation using CDA constructs and FHIR Resource attributes.

### 6.3.3 The HIMSS Health Story Project

The HIMSS Health Story Project began in 2006 to educate the health IT community on electronic records that provide a patient's complete health story.<sup>155</sup> The Health Story Project developed eight Health Story Implementation Guides that originally specified how to constrain the HL7 CDA standard to represent common clinical note types that eventually were harmonized with other specifications from IHE and the Health Information Technology Standards Panel (HITSP) to form the original Consolidated CDA standard. Today, the HIMSS Health Story Project provides Roundtable events to advocate, educate, and engage the health IT community in the use of HL7 CDA and C-CDA.

**Source:** The storytelling Power of C-CDA

**Resource:** <https://www.himss.org/library/storytelling-power-c-cda>

<sup>155</sup> <https://www.himss.org/library/health-story-project>

**Description:** Provides explanations of the 12 C-CDA document types, their purpose, and the value of establishing a meaningful order for rendering sections.

**Source:** Style Standards to Improve Health IT Usability and Reduce Physician Burden

**Resource:** <https://www.himss.org/library/style-standards-improve-health-it-usability-and-reduce-physician-burden>

**Description:** Demonstrates how the consistent use of style in the healthcare record promotes clear communication, contributes to patient safety, and improves information exchange, integration, and aggregation.

### 6.3.4 The Payer Community

A joint effort of the HL7 Attachments Work Group, the HL7 Structured Documents Work Group, the Centers for Medicare & Medicaid Services (CMS), and the Office of the National Coordinator (ONC) Standards and Interoperability (S&I) Framework Electronic Submission of Medical Documentation (esMD) Initiative that addresses the need for additional documentation to support data required for processing claims.

**Source:** HL7 CDA® Release 2 Implementation Guide: Additional CDA R2 Templates – Clinical Documents for Payers Set 1, Release 1 – US Realm

**Resource:** [http://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=410](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=410)

**Description:** Provides guidance on structured documentation templates to exchange clinical and administrative information to support bi-lateral communication between providers and payers to expedite processing of claims.

### 6.3.5 Quality Community

The Quality Reporting Document Architecture (QRDA) project is developing a standard for communicating health care quality measurement information. It continues to be co-sponsored by the HL7 Structured Documents and Child Health Work Groups and is supported by the Centers for Medicare & Medicaid Services (CMS).

The Phase IV effort was launched in Summer 2014 to develop and ballot QRDA Category I, Release 3. It is co-sponsored by the HL7 Clinical Quality Information (CQI) WG and Structured Documents Work Groups and continues to be supported by CMS. The scope of this effort will include the following:

- Update templates to align with the QDM version 4.1.1.

- Review and triage QRDA Category I, Release 2 DSTU comments that were considered New Feature Requests and determine whether they are appropriate for inclusion in Release 3.
- Review the Consolidated CDA (C-CDA) templates that were used in the QRDA Category I, Release 2 DSTU, and where applicable, update the templates to align with the C-CDA R2 templates.

**Source:** QRDA I Release 1, STU Release 5.1, Supports QDM v5.4

**Resource:** [http://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=35](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35)

**Description:** Defines the requirements for sending and receiving standards-based electronic attachments. Defines the set of attachment documents as those that contain the minimum standard metadata to support basic document management functions including identification of patients and providers, the type of document, date of creation, encounter information, and a globally unique document identifier.

**Source:** HL7 Clinical Quality Information Workgroup

**Resource:** <https://confluence.hl7.org/display/CQIWC/Clinical+Quality+Information+WG+%28CQI%29+Home>

**Description:** The Clinical Quality Information (CQI) Work Group creates and maintains HL7 standards supporting quality measuring, evaluating, and reporting of quality data. Specific areas of interest include the measurement and reporting of quality and its dimensions including: safe, effective, patient-centered, timely, efficient, and equitable as defined by the Institute of Medicine (now the US Academy of Medicine).

## 6.4 Emerging C-CDA Implementer Community Guidance

HL7 continues to sponsor projects to maintain and improve the HL7 CDA standard and the family of implementation guides developed to facilitate the use of this standard to achieve interoperable information exchange. Several active projects are pertinent for C-CDA implementer community seeking to advance the maturation of this standard.

### 6.4.1 Active HL7 Projects Pertinent to the C-CDA Implementer Community

**Source:** [HL7 C-CDA Rubric, Release 1](#)

**Resource:** [http://www.hl7.org/documentcenter/public\\_temp\\_5B7B5781-1C23-BA17-0C35A21F345357EA/ballots/2019MAY/downloads/HL7\\_C-CDA\\_RUBRIC\\_R1\\_I1\\_2019MAY.pdf](http://www.hl7.org/documentcenter/public_temp_5B7B5781-1C23-BA17-0C35A21F345357EA/ballots/2019MAY/downloads/HL7_C-CDA_RUBRIC_R1_I1_2019MAY.pdf)

**Description:** This document contains rubric criteria created through an ongoing project in the HL7 Structured Documents Work Group (SDWG), originating in 2016. Throughout 2018 a group of HL7 members created a new set of rubrics to add to the original rubric. This project identified key problematic areas in real system generated C-CDA documents where similar data was consistently represented differently or incompletely. Variably constructed data removes the ability to reliably share and compare data, adversely impacting interoperability. The hope is that the rubric will promote best practices by allowing providers and health IT developers to identify and resolve issues of C-CDA document data representation in their health IT systems thereby promoting interoperability and use of clinical data received in C-CDA documents.

**Source:** [HL7 C-CDA on FHIR Implementation Guide](#)

**Resource:** <http://hl7.org/fhir/us/ccda/>

**Description:** This Implementation Guide defines a series of FHIR profiles on the Composition resource to represent the various document types in C-CDA. This release does not directly map every C-CDA template to FHIR profiles, rather tries to accomplish the C-CDA use case using the Composition resource profiles created under this project (the equivalent of Level 2 CDA documents). It begins by linking to the profiles created under the US Core project for any coded entries that would normally be included in C-CDA sections. The goal is to have a simpler, more streamlined standard that reuses existing work and focuses on the 80% that implementers actually need in production systems, based on US Core which represents a portion of the 80% needed for coded entries for coded entries of CCD, Care Plan & Discharge Summary.

**Source:** [HL7 Cross-Paradigm Model Transformation Service, Release 1](#)

**Resource:** <https://confluence.hl7.org/display/SOA/Project+Documents>

**Description:** This project is creating logical mappings between C-CDA templates and the FHIR US Core Profiles. The mappings will be used to create a functional specification for transformation services with exemplary mappings using storyboards developed by the SOA Working Group, the interested parties of the project, and co-sponsor Working Groups of this project. The project will create story boards that use aspects of 1) the current versions of HL7 Standards of V2, C-CDA, and FHIR, and 2) new information models such as CIMI and realm specific examples such as the FHIM.

**Source:** Basic Provenance Implementation Guide

**Resource:** <https://confluence.hl7.org/display/SEC/Basic+Provenance+Implementation+Guide>

**Description:** The Draft U.S. Core Data for Interoperability and Expansion Process, published by ONC on Jan 5, 2018 indicated 22 “data classes” in the list of Draft USCDI Version 1 Data Classes. While many of those data classes have already been defined within the C-CDA and FHIR standards, “provenance” has not been. For interoperability to be achieved with this data class, functional and technical guidance are needed regarding what details constitute “provenance”, which data elements should be used to convey provenance information, and technically how provenance information should be represented in the C-CDA and FHIR standards. The Basic Provenance project will develop an informative implementation guide in the US Realm to specify function and technical guidance on what constitutes minimal “provenance”. This guidance should inform future implementations of the data class identified in the US Core Data for Interoperability published by the Office of the National Coordinator. The implementation guide will include technical guidance for C-CDA 2.1 and US FHIR Core (based on R4). Guidance will be limited to the set of data classes identified in the US Core Data for Interoperability, and any additional information needed to convey those data classes within C-CDA and FHIR.

## 6.5 Emerging Regulation Changes and Periodic Updates

The Office of the National Coordinator for Health Information Technology (ONC) is at the forefront of the administration’s health IT efforts and is a resource to the entire health system

to support the adoption of health information technology and the promotion of nationwide health information exchange to improve health care.<sup>156</sup> ONC is organizationally located within the Office of the Secretary for the U.S. Department of Health and Human Services (HHS). ONC is the principal federal entity charged with coordination of nationwide efforts to implement and use the most advanced health information technology and the electronic exchange of health information.

**Source:** [USCDI v1 Summary of Data Classes and Data Elements](#)

**Resource:** <https://www.healthit.gov/isa/sites/isa/files/inline-files/USCDIv12019revised.pdf>

**Description:** ONC has proposed to remove the CCDS definition and its references from the 2015 Edition and replace it with the United States Core Data for Interoperability (USCDI) standard. This will increase the minimum baseline of data classes that must be commonly available for interoperable exchange. The USCDI Version 1 (USCDI v1) is proposed as a standard (§ 170.213). It reflects the same data classes referenced by the CCDS definition and includes new required data classes and data elements. If adopted, health IT developers will need to update their certified health IT to support the USCDI for all certification criteria affected by this change.

**Source:** [Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications](#)

**Resource:** <https://www.healthit.gov/isa/section-i-vocabularycode-setterminology-standards-and-implementation-specifications>

**Description:** Interoperability Standards Advisory (ISA) is a process by which ONC coordinates the identification, assessment, and public awareness of interoperability standards and implementation specifications that can be used by the healthcare industry to address specific interoperability needs including, but not limited to, interoperability for clinical, public health, research and administrative purposes.<sup>157</sup> ONC encourages all stakeholders to implement and use the standards and implementation specifications identified in the ISA as applicable to the specific interoperability needs they seek to address. Furthermore, ONC encourages further pilot testing and industry experience to be sought with respect to standards and implementation specifications identified as “emerging” in the ISA.

**Source:** [ONC Cures Act Proposed Rule](#)

**Resource:** <https://www.govinfo.gov/content/pkg/FR-2019-03-04/pdf/2019-02224.pdf>

**Description:** This proposed rule would implement certain provisions of the 21st Century Cures Act, including conditions and maintenance of certification requirements for health information technology (health IT) developers under the ONC Health IT Certification Program (Program), the voluntary certification of health IT for use by pediatric health care providers, and reasonable and necessary activities that do not constitute information blocking. The implementation of these provisions would advance interoperability and support the access, exchange, and use of electronic health information. The proposed rule would also modify the 2015 Edition health IT certification criteria and Program in additional ways to advance interoperability, enhance health IT certification, and reduce burden and costs.

<sup>156</sup> HealthIT.gov. <https://www.healthit.gov/topic/about-onc>

<sup>157</sup> <https://www.healthit.gov/isa/section-i-vocabularycode-setterminology-standards-and-implementation-specifications>

### 6.6 Tools

Below are brief descriptions of tools available to support C-CDA development.

#### 6.6.1 CDA Schema, C-CDA Schematrons, Sample Stylesheet

HL7 makes available resources that support implementers with their use of the CDA base standard and published implementation guides. The resources are currently housed in the HL7 gForge repository.

**Source:** CDA R2 Schema File

**Resource:** <https://hl7.org/permalink/?CDAR2.0schema>

**Description:** This folder contains the CDA R2 Schema file with updates that contain approved extensions.

**Source:** C-CDA Schematron Validation Files

**Resource:** <https://github.com/HL7/cda-ccda-2.1/blob/master/schematron/Consolidation.sch>

**Description:** This folder contains Schematron validation files for C-CDA templates and any C-CDA supplemental templates. Note: Schematron is an optional quality criteria at this time.

**Source:** CDA Sample Stylesheet

**Resource:** <https://hl7.org/permalink/?CDAStyleSheet>

**Description:** This folder contains a sample stylesheet developed to expose the structured header elements and attestable content (the section.text Narrative Block in each section) for a CDA document.

#### 6.6.2 ONC Validation Testing and C-CDA Scorecard Resources

The Standards Implementation & Testing Environment (SITE) is a centralized collection of testing tools and resources designed to assist health IT developers and health IT users fully evaluate specific technical standards and maximize the potential of their health IT implementations. SITE is organized in a collection of sandboxes that provide test tools, sample data, collaboration resources, and useful links.

**Source:** SITE Validation

**Resource:** <https://sitenv.org/sandbox-ccda>

**Description:** The C-CDA Sandbox contains resources and tools for the HL7 Consolidated Clinical Document Architecture (C-CDA) implementation guides. These tools will help in testing of C-CDA documents for conformance to the C-CDA IG, the ONC 2014 Edition and ONC 2015 Edition C-CDA objectives and also help with quantitative assessment of the data quality using the Scorecard.

**Source:** C-CDA Scorecard

**Resource:** <https://sitenv.org/scorecard/>

**Description:** The ONC Scorecard tool is used to compare a C-CDA R2.1 document against a rubric of best practice guidance developed by the HL7 C-CDA implementer community and vetted through the HL7 ballot process. The C-CDA Scorecard does not retain your submitted C-CDA file as the file is deleted from the server immediately after processing. However, we strongly suggest that you do not include any Protected Health Information (PHI) or Personally Identifiable Information (PII) in your C-CDA file submissions to the Scorecard.

### 6.6.3 Model Drive Health Tools (MDHT)

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.

**Source:** Java Runtime MDHT

**Resource:** <https://github.com/mdht/mdht-models>

**Description:** All MDHT projects supporting the various CDA based implementation guides including Consolidate CDA.

**Source:** ECLIPSE MDHT

**Resource:** <https://projects.eclipse.org/projects/modeling.mdht>

**Description:** Eclipse MDHT delivers a standard object-oriented alternative to proprietary development methodologies and tooling used to specify and implement most healthcare industry standards. The tool generates domain-specific Java classes for templates/profiles/archetypes.

## 6.7 Educational and Support Resources

HL7 and the C-CDA implementer community offer educational and support resources to help build essential implementer skills and production capacity for the use of C-CDA. Information on the HL7 Confluence sites for the SDWG and CDA Management group keeps the community informed about all aspects of the management and methodology associated with the CDA standard and its associated product families such as C-CDA.



**Source:** HL7 Training

**Resource:** <http://www.hl7.org/implement/training.cfm?ref=nav>

**Description:** 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.

**Source:** The CDA Book

**Resource:** [http://www.amazon.com/The-CDA-book-Keith-Boone/dp/0857293354/ref=sr\\_1\\_1?ie=UTF8&qid=1337020821&sr=8-1](http://www.amazon.com/The-CDA-book-Keith-Boone/dp/0857293354/ref=sr_1_1?ie=UTF8&qid=1337020821&sr=8-1)

**Description:** 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.

**Source:** HL7 CDA Management Group Confluence Space

**Resource:** <https://confluence.hl7.org/display/CDA/CDA+Management+Group>

**Description:** The HL7 CDA Management Group (CMG) is responsible for the management of the CDA standard and its derivative product families. This website is the primary repository for their projects and meetings.

**Source:** HL7 SDWG Confluence Space

**Resource:** <https://confluence.hl7.org/display/SD/Structured+Documents>

**Description:** The HL7 Structured Documents Work Group (SDWG) is responsible for the methodology used to develop and sustain the CDA standard and its derivative product families. This website is the primary repository for their projects and meetings.

**Source:** HL7 Listserv registration

**Resource:** <http://www.hl7.org/myhl7/managelistservs.cfm>

**Description:** Stakeholders within the CDA and C-CDA implementer community are encouraged to sign up for the Structured Documents and CDA Management Group listservs to stay apprised of topics relevant to the management and maintenance of these HL7 standards.

**Source:** HL7 CDA Example Search

**Resource:** <https://cdasearch.hl7.org/>

**Description:** The CDA Examples Task Force has created a large number of examples showing how to convey information accurately in a C-CDA document. The CDA Example search tool allows users to find examples based on keywords.

## Appendix A: Templates Defined in C-CDA R2.1 Companion Guide

**Reference:** See the file named CCD\_A\_COMPANION\_R2.1\_STU\_2019SEP\_Appendix.A included in this Companion Guide package for Templates that are defined in this Companion Guide.

## Appendix B: UDI Organizer Template from C-CDA Supplemental Templates for Unique Device Identifier (UDI)

**Reference:** See the file named CCD\_A\_COMPANION\_R2.1\_STU\_2019SEP\_Appendix.B included in this Companion Guide package for the UDI Organizer template defined in HL7 CDA® R2 Implementation Guide: C-CDA Supplemental Templates for Unique Device Identifier (UDI) for Implantable Medical Devices, Release 1 - US Realm

## Appendix C: Provenance – Author Participation

**Reference:** See the file named CCD\_A\_COMPANION\_R2.1\_STU\_2019SEP\_Appendix.C included in this Companion Guide package for a new template defined in the Companion Guide for representing basic provenance information.