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HL7 CDA® R2 IG: C-CDA Templates for Clinical Notes R1 Companion Guide, Release 1

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It has been developed through a detailed analysis and review of the 2015 Edition Certification Criteria, reviews with HL7 Working Groups, and reviews by experienced implementers and "Implementation-a-thons" participants.

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1 Introduction

1.1 Purpose

The Companion Guide to Consolidated Clinical Document Architecture (C-CDA) provides supplemental guidance to the Health Level Seven (HL7) CDA® R2 IG: C-CDA Templates for Clinical Notes STU Release 2.1 in support of the ONC 2015 Edition Certification Criteria (2015 Edition) Certified Electronic Health Record Technology requirements.

This guide provides additional technical clarification and practical guidance to assist implementers to support best practice implementations of the 2015 Edition Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification. The guide is intended to:

- Explain basic CDA concepts that are important to understand, prior to implementing the 2015 Edition Certification Criteria.
- Provide guidance on the 2015 Edition Certification Criteria and data representation in the C-CDA format, including the mapping of Common Clinical Data Set (CCDS) data definitions (170.102) and the "additional data" defined in 170.315(g)(6) to the CDA templates included in the C-CDA Implementation Guide.
- Highlight where guidance is optional in context of the certification program.
- Highlight additional guidance and resources relevant to the 2015 Edition Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification.

1.2 Audience

The audience of this Companion Guide includes, but is not limited to, software developers, vendors, and other health IT implementers wishing to participate in the 2015 Edition Certification Criteria for certified electronic health record technology. This guide also includes educational content and resource references to assist general audiences in understanding C-CDA

1.3 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)[1] and XPath[2] syntax. Additionally, readers should have an understanding of terminologies such as SNOMED CT®, LOINC®, CPT®, ICD®, and RxNorm®.

[1] For additional information on Extensible Markup Language, visit http://www.w3.org/TR/xml/.

[2] For additional information on XPath syntax, visit http://www.w3.org/TR/xpath/.

1.4 Contents of this Guide

This guide is organized into five sections as follows:

- Section 1: Introduction (this section)
- Section 2: Understanding C-CDA and the C-CDA Companion Guide. This section contains high-level information on functional topics such as CDA Templates, CDA Schema and Schematron.
- Section 3: Guidance for Implementing Standards for Certification. This section details the C-CDA representations for the ONC 2015 Edition Common Clinical Data Set (CCDS).
- Section 4: Recommended Approaches for Certification Requirements. This section includes specific guidance and clarifications on how to implement the certification requirements including consensus recommendations for implementations.
- Section 5: Resources. This section provides some further resources for understanding C-CDA.

Guidance Items specific to Certification requirements will be identified by the following icon:  Certification Guidance

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

The C-CDA implementation guide (IG) is a library of CDA templates developed by HL7, IHE and the Health Story Project. It 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 companion guides augment guidance in C-CDA implementation guides to address requirements specified by regulations from ONC for Certified EHR Technologies. The C-CDA R1.1 Companion Guide addresses ONC 2014 Edition Certified Electronic Health Record Technology requirements. The C-CDA R2.1 Companion guide addresses ONC 2015 Edition Certified Electronic Health Record Technology (CEHRT) requirements.

2.1 CDA and Layered Constraints

Implementers wishing to certify creation of a C-CDA document according to the 2015 Edition Certification Criteria should view conformance as meeting the requirements of four sets of constraints:

- CDA R2 (Normative Web Edition 2010)
- C-CDA R2.1
- C-CDA R2.1 Errata (see Section 2.5)
- 2015 Edition CEHRT Requirements including CCDS 170.102 and 170.315(g)(6) CCDA creation performance

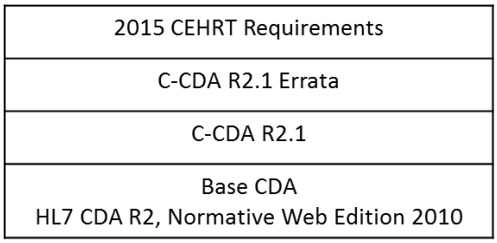

Figure 1: CDA, C-CDA, Errata and Certification Criteria Constraint Relationships

This Companion Guide, where it deviates from the items listed above is an optional set of best practices aimed at improving consistency of implementation.

C-CDA R2.1 includes all CDA R2 requirements in the constrained templates. Implementers may reference CDA R2 if they are developing new templates or are seeking to understand a requirement.

Three of these four layers are fixed. The C-CDA R2.1 Errata is subject to change as new issues are identified and resolved. Section 2.5 describes the Errata process.

For example, to conform to CCDS requirements for Medications, an implementer must conform to:

1. Validates under the CDA_SDTC schema (Available from the HL7 GForge SVN, http://gforge.hl7.org/gf/project/strucdoc/frs/)
2. Medications Section constraints as defined in C-CDA R2.1; and
3. Relevant technical corrections published in the C-CDA R2.1 Errata (See Section 2.5); and
4. Any additional Health IT Certification Criteria for Medications.

2.2 Templates

The C-CDA R2.1 IG defines templates that specify conformance statements for content in C-CDA documents. Templates exist for document, section, entry, and entry relationship content in CDA. Reference C-CDA R2.1 Volume 1, section 2.1 for a detailed description of CDA templates.

A CDA Document includes a header, which is the content before the <structuredBody> tag in a structured CDA Document or the content before the <nonXMLBody> tag in an unstructured CDA Document. A structured CDA Document additionally includes one or more sections. Each section includes a single narrative text component that holds the human readable information in that section. A section may include structured entries, called “entries”, which represent the section’s information in a machine processable and human readable format. Entry templates may also be nested, one included inside another, using an entryRelationship element. Templates define the constraints which stipulate what may, should, or shall be populated in an instance of the document.

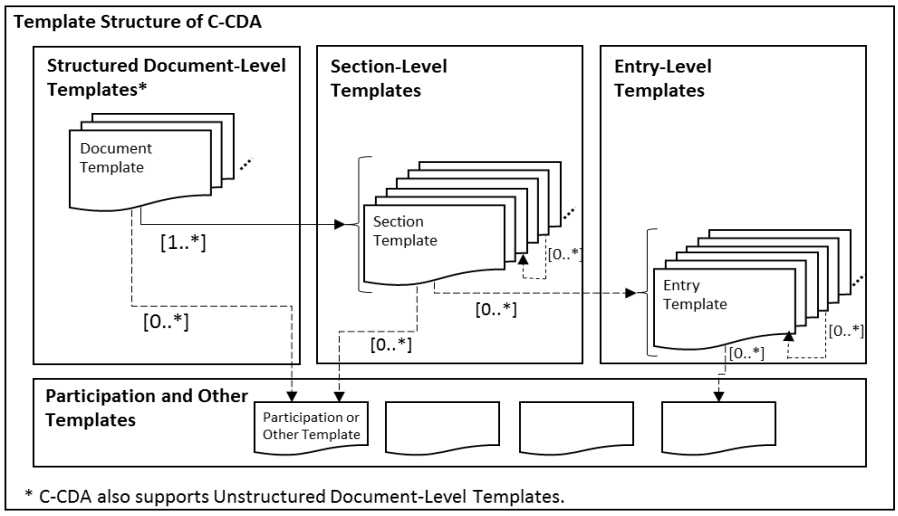

Figure 2: Templates Structure of C-CDA

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.

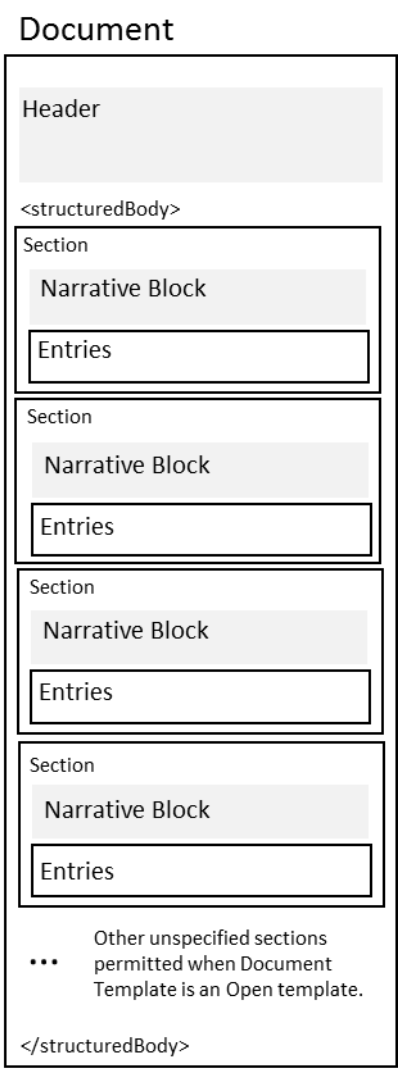

Figure 3: CDA Template Relationships

2.2.1 C-CDA 2.1 Document Templates

Document templates defined in the C-CDA R2.1 Implementation Guide – along with those referenced by the 2015 Edition Certification Criteria - are listed in Table 1 below.

Table 1: C-CDA R2.1 Document-Level Templates with 2015 Edition Certification Criteria Requirements

Document Template	Description	2015 Edition Certification Criteria
Care Plan [3]	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. The CDA Care Plan represents an instance of this dynamic Care Plan at a point in time. The CDA document itself is NOT dynamic.	Yes, if certifying to 170.315(b)(9); otherwise, No.
Consultation Note	The Consultation Note is generated by a request from a clinician for an opinion or advice from another clinician.	No
Continuity of Care Document (CCD)	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.	Yes – as per 170.315(b)(1)
Diagnostic Imaging Report	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.	No
Discharge Summary	The Discharge Summary is a document which synopsizes a patient's admission to a hospital, LTPAC provider, or other setting. It provides information for the continuation of care following discharge.	Yes, if certifying to the inpatient setting as per 170.315(b)(1)
History and Physical	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.	No
Operative Note	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.	No
Progress Note	This template represents a patient's clinical status during a hospitalization, outpatient visit, treatment with a LTPAC provider, or other healthcare encounter.	No

Document Template	Description	2015 Edition Certification Criteria
Procedure Note	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.	No
Referral Note	A Referral Note communicates pertinent information from a provider who is requesting services of another provider of clinical or non-clinical services.	Yes, if certifying to the ambulatory setting as per 170.315(b)(1).
Transfer Summary	The Transfer Summary standardizes critical information for exchange of information between providers of care when a patient moves between health care settings.	No
Unstructured Document	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.	No

Although the 2015 rule[4] does not permit the use of unstructured CDA documents (a CDA document with a structured header and a non-xml body conveying information as an embedded object or referenced file) for the purposes of certification, there are many valid use cases where the exchange of information as an unstructured CDA may be appropriate and beneficial.

Section templates referenced by the above document templates along with a mapping to Common Clinical Data Set (CCDS) data elements are noted in Section 3 - Guidance for Implementing Standards for Certification.

2.3 CDA Schema Extensions

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[5] of CDA R2 extensions that are approved for use within the sdtc namespace. The base CDA R2 schema (with approved extensions) can be found on the HL7 International Structured Documents Work Group svn repository[6].

[4] 170.315(b)(1)

[5] http://wiki.hl7.org/index.php?title=CDA_R2_Extensions

[6] http://gforge.hl7.org/gf/project/strucdoc/scmsvn/

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.

2.3.1 CDA R2 Schema Extensions Used by C-CDA R2.1

Table 2 lists the extensions to CDA R2 that have been defined to support requirements in C-CDA R2.1.

Table 2: CDA R2 Extensions Used by C-CDA R2.1

Extension	Description
sdtc:raceCode	The raceCode extension allows for multiple races to be reported for a patient. Refer to section Race and Ethnicity for additional guidance.
sdtc:ethnicGroupCode	The ethnicGroupCode extension allows for additional ethnicity groups for the recordTarget or subjectPerson.
sdtc:id	The id extension in the family history organizer on the related subject allows for unique identification of the family member(s).
sdtc:deceasedInd	The deceasedInd extension (= “true” or “false”) in the family history organizer on the related subject is used inside to indicate if a family member is deceased.
sdtc:deceasedTime	The deceasedTime extension in the family history organizer on the related subject allows for reporting the date and time a family member died.
sdtc:birthTime	The birthTime extension 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.
sdtc:dischargeDispositionCode	The dischargeDispositionCode extension allows the provider to record a discharge disposition in an encounter activity.
sdtc:signatureText	The signatureText extension provides a location in CDA for a textual or multimedia depiction of the signature by which the participant endorses and accepts responsibility for his or her participation in the Act as specified in the Participation.typeCode.

2.4 C-CDA R2.1 Schematron

Schematron is a rule-based validation language for making assertions 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.

A Schematron for C-CDA R2.1 is available on the HL7 International Structured Documents Work Group svn repository[7]. This Schematron can be used to confirm if a CDA document conforms to the constraints required by C-CDA R2.1.

2.5 C-CDA R2.1 Errata

C-CDA R2.1 is considered a *Standard for Trial Use* and has a set of suggested corrections and clarifications that is 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 (http://www.hl7.org/implement/standards/product_brief.cfm?product_id=408). 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.

Actual text changes are not made to the Implementation Guide. It is recommended that some regular process be used to retrieve the Implementation Guide and to annotate the published PDF files of the Implementation Guide with information on each and every approved balloted change from the errata package. Due to the periodic process of preparing errata, there may be approved STU changes that are not in the most recent errata package.

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 (see chapter 5.3.2.)

2.6 Responsibilities of Content Consumers

Upon receiving content in a CDA format, assuming valid xml, the primary responsibility of a Content Consumer is to show the human readable text to providers. There is sometimes a temptation to perform document validation, but that step should be performed if and only if some content is to be discretely imported from the received document.

Validation issues must never be used as a reason to reject content and prevent providers from seeing the human readable text. Follow Postel's Law[8], aka the Robustness Principle: Be stringent upon output and forgiving upon input.

[7] http://gforge.hl7.org/gf/project/strucdoc/scmsvn/?action=browse&path=%2Ftrunk%2FC-CDAR2.1%2FSchematron%2F

[8] Source: https://en.wikipedia.org/wiki/Jon_Postel#Postel.27s_law

3 Guidance for Implementing Standards for Certification

The purpose of the 2015 Edition Certification Criteria is to improve interoperability by adopting new and updated vocabulary and content standards for the structured recording and exchange of health information. As with the 2014 Edition, certain criteria specify the implementation of the C-CDA standard as the basis for content exchange.

The 2015 Certification Criteria will facilitate the accessibility and exchange of data by including enhanced data export, transitions of care, and application programming interface (API) capabilities in the 2015 Edition Base Electronic Health Record (EHR) definition;

The following section describes the 2015 Edition Certification Criteria exchange objectives and common clinical data set and maps them to the C-CDA Header and Document, Section and Entry templates.

3.1 Common Clinical Data Set Requirements

The term “Common Clinical Data Set” (CDDS) is used to refer to a minimum set of elements that are required in certain 2015 Edition Certification Criteria. A similar data set was previously referred to as the ‘‘Common MU Data Set’’ in the 2014 Edition.

In the 2015 Edition Certification Criteria, this data set was revised to support new and updated standards and code sets. Additionally, the list was augmented to support patient safety and improve care through clearly referenced data elements (‘‘care plan data’’) and the inclusion of new patient data.

Table 3: Common Clinical Data Set Requirements

CCDS Data Item	Standards Requirements	2015 Changes
Patient Name	No associated standard.	No change
Sex	The standard specified in § 170.207(n)(1) – Birth sex must be coded in accordance with HL7 Version 3 (V3) Standard. A new Birth Sex Observation entry has been added to the Social History Section to address this requirement. The Birth Sex Observation uses the ONC Administrative Sex value set (2.16.840.1.113762.1.4.1) which contains only two concepts: Male (M) and Female (F). If the value/@code of the Birth Sex data element is not populated with a concept from this value set then it shall contain a nullFlavor of "UNK".	Addition of vocabulary requirements Refer to: Birth Sex Observation template (2.16.840.1.113883.10.20.22.4.200:2016-06-01)
Date of Birth	No associated standard.	No change
Race	The standard specified in § 170.207(f)(2) - CDC Race and Ethnicity Code Set Version 1.0 (March 2000); and The standard specified in § 170.207(f)(1) for each race identified in accordance § 170.207(f)(2).	Change of vocabulary requirements.
Ethnicity	The standard specified in § 170.207(f)(2) - CDC Race and Ethnicity Code Set Version 1.0 (March 2000); and	Change of vocabulary requirements.

CCDS Data Item	Standards Requirements	2015 Changes
	The standard specified in § 170.207(f)(1) for each ethnicity identified in accordance § 170.207(f)(2).	
Preferred Language	The standard specified in § 170.207(g)(2) – Request for Comments (RFC) 5646.	Change of vocabulary requirements.
Smoking Status	The standard specified in § 170.207(h) – Smoking status must be coded in one of the following SNOMED CT® codes: • Current every day smoker. 449868002 • Current some day smoker. 428041000124106 • Former smoker. 8517006 • Never smoker. 266919005 • Smoker, current status unknown. 77176002 • Unknown if ever smoked. 266927001 • Heavy tobacco smoker. 428071000124103 • Light tobacco smoker. 428061000124105	No change
Problems	At a minimum, the standard specified in § 170.207(a)(4) - IHTSDO SNOMED CT®, U.S. Edition, September 2015 Release.	Update to vocabulary standard release.
Medications	At a minimum, the standard specified in § 170.207(d)(3) – RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, September 8, 2015 Release.	Update to vocabulary standard release.
Medication Allergies	At a minimum, the standard specified in § 170.207(d)(3) – RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, September 8, 2015 Release.	Update to vocabulary standard release.
Laboratory Test(s)	At a minimum, the standard specified in § 170.207(c)(3) – Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.52.	Update to vocabulary standard release.
Laboratory Value(s)/ Result(s)	No associated standard.	No Change
Vital Signs	The patient's diastolic blood pressure, systolic blood pressure, body height, body weight, heart rate, respiratory rate, body temperature, pulse oximetry, and inhaled oxygen concentration must be exchanged in numerical values only; and in accordance with the standard specified in § 170.207(c)(3) and with the associated applicable unit of measure for the vital sign measurement in the standard specified in § 170.207(m)(1).	Addition of vocabulary requirements.

CCDS Data Item	Standards Requirements	2015 Changes
	• § 170.207(c)(3) – Logical Observation Identifiers Names and Codes (LOINC®) version 2.52. • § 170.207(m)(1) – The Unified Code of Units of Measure, Revision 1.9, October 23, 2013. Optional. The patient's BMI percentile per age and sex for youth 2-20 years of age, weight for age per length and sex for children less than 3 years of age, and head occipital-frontal circumference for children less than 3 years of age must be recorded in numerical values only in accordance with the standard specified in § 170.207(c)(3) and with the associated applicable unit of measure for the vital sign measurement in the standard specified in § 170.207(m)(1). For BMI percentile per age and sex for youth 2-20 years of age and weight for age per length and sex for children less than 3 years of age, the reference range/scale or growth curve should be included as appropriate.	
Care Plan Field(s), including Goals and Instructions	Not applicable (replaced with Assessment and Plan of Treatment, Goals, and Health Concerns – see below).	
Assessment and Plan of Treatment	§ 170.205(a)(4) - HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.1.	New Data Set item added in 2015.
Goals	In accordance with the "Goals Section" of the standard specified in § 170.205(a)(4). • § 170.205(a)(4) - HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.1.	New Data Set item added in 2015.
Health Concerns	In accordance with the "Health Concerns Section" of the standard specified in § 170.205(a)(4). • § 170.205(a)(4) - HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.1.	New Data Set item added in 2015.
Procedures	At a minimum, the version of the standard specified in § 170.207(a)(4), or § 170.207(b)(2). • § 170.207(a)(4) - IHTSDO SNOMED CT®, U.S. Edition, September 2015 Release • § 170.207(b)(2) – The code set specified in 45 CFR 162.1002(a)(5) – The combination of Health Care Financing Administration Common Procedure	Update to vocabulary standard release.

CCDS Data Item	Standards Requirements	2015 Changes
	Coding System (HCPCS), as maintained and distributed by HHS, and Current Procedural Terminology, Fourth Edition (CPT-4), as maintained and distributed by the American Medical Association, for physician services and other health care services. These services include, but are not limited to, the following: ○ Physician services. ○ Physical and occupational therapy services. ○ Radiologic procedures. ○ Clinical laboratory tests. ○ Other medical diagnostic procedures. ○ Hearing and vision services. ○ Transportation services including ambulance. For technology primarily developed to record dental procedures, the standard specified in § 170.207(b)(3) - The code set specified in 45 CFR 162.1002(a)(4) – Code on Dental Procedures and Nomenclature, as maintained and distributed by the American Dental Association, for dental services.	
Care Team Member(s)	No associated standard.	No Change
Immunizations	In accordance with, at a minimum, the standards specified in § 170.207(e)(3) and (4). • § 170.207(e)(3) - HL7 Standard Code Set CVX—Vaccines Administered, updates through August 17, 2015 • § 170.207(e)(4) - National Drug Code Directory (NDC) – Vaccine NDC Linker, updates through August 17, 2015	New Data Set item added in 2015.
Unique Device Identifier(s) (UDIs) for a Patient's Implantable Device(s)	In accordance with the "Product Instance" in the "Procedure Activity Procedure Section" of the standard specified in § 170.205(a)(4). • § 170.205(a)(4) - HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.1. Unique device identifier is defined as it is in 21 CFR 801.3 - means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of 830.20 of this chapter. A unique device identifier is composed of: 1) A device identifier --a mandatory, fixed portion of a UDI that identifies the specific	New Data Set element added in 2015.

CCDS Data Item	Standards Requirements	2015 Changes
	version or model of a device and the labeler of that device; and 2) A production identifier --a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device: i. The lot or batch within which a device was manufactured; ii. The serial number of a specific device; iii. The expiration date of a specific device; iv. The date a specific device was manufactured; v. For an HCT/P regulated as a device, the distinct identification code required by 1271.290(c) of this chapter. Implantable device is defined as it is in 21 CFR 801.3 – means a device that is intended to be placed in a surgically or naturally formed cavity of the human body. A device is regarded as an implantable device for the purpose of this part only if it is intended to remain implanted continuously for a period of 30 days or more, unless the Commissioner of Food and Drugs determines otherwise in order to protect human health.	

3.1.1 CCDS Mapping to C-CDA

The following mapping has been made between the Common Clinical Data Set and the recommended C-CDA Data Element locations:

Table 4: CCDS Mapping to C-CDA Header

CCDS Item	C-CDA Header Elements	
Patient name	recordTarget/patientRole	patient/name
Race		patient/raceCode patient/sdtc:raceCode
Ethnicity		patient/ethnicGroupCode patient/sdtc:ethnicGroupCode
Language		patient/languageCommunication/languageCode
Date of birth		patient/birthTime
Care team members (performer)	documentationOf/ serviceEvent	performer/assigned/Entity
Care team members (responsibleParty)	componentOf/ encompassingEncounter[9]	responsibleParty /assignedEntity
Care team members (encounterParticipant)		encounterParticipant /assignedEntity
Care team members (participant)	participant	associatedEntity

[9] See also Care Team Representation in Section 4.

Table 5: CCDS Mapping to C-CDA Sections

CCDS Item	C-CDA Section Template (Name, OID and Chapter)		C-CDA Entry Template(s) (Name, OID and Chapter)	
Smoking status	Social History (V3) (2.16.840.1.113883.10.20.22.2.17:2015-08-01)	2.66	Smoking Status - Meaningful Use (V2) (2.16.840.1.113883.10.20.22.4.78:2014-06-09)	3.100
Birth Sex[10]	Social History (V3) (2.16.840.1.113883.10.20.22.2.17:2015-08-01)		Birth Sex Observation (2.16.840.1.113883.10.20.22.4.200:2016-06-01)	
Health Concerns	Health Concerns (2.16.840.1.113883.10.20.22.2.58:2015-08-01)	2.23	Health Concern Act (V2) (2.16.840.1.113883.10.20.22.4.132:2015-08-01)	3.36
Goals	Goals (2.16.840.1.113883.10.20.22.2.60)	2.22	Goal Observation (2.16.840.1.113883.10.20.22.4.121)	3.34
Assessment and Plan of Treatment[11]	Assessment (entries not supported) (2.16.840.1.113883.10.20.22.2.8)	2.7		
	Plan of Treatment (V2) (2.16.840.1.113883.10.20.22.2.10:2014-06-09)	2.48	Planned Act (V2)[12] (2.16.840.1.113883.10.20.22.4.39:2014-06-09)	3.62
	Assessment and Plan (V2) (2.16.840.1.113883.10.20.22.2.9:2014-06-09)	2.6	Planned Act (V2) (2.16.840.1.113883.10.20.22.4.39:2014-06-09)	3.62
Medication allergies	Allergies and Intolerances (entries required) (V3) 2.16.840.1.113883.10.20.22.2.6.1:2015-08-01)	2.41	Allergy Concern Act (V3) (2.16.840.1.113883.10.20.22.4.30:2015-08-01)	3.5
			Allergy - Intolerance Observation (V2) (2.16.840.1.113883.10.20.22.4.7:2014-06-09)	3.105.1
Problems	Problem (entries required) (V3) (2.16.840.1.113883.10.20.22.2.5.1:2015-08-01)	2.53.1	Problem Concern Act (V3) (2.16.840.1.113883.10.20.22.4.3:2015-08-01)	3.78
			Problem Observation (V3) (2.16.840.1.113883.10.20.22.4.4:2015-08-01)	3.79
Immunizations	Immunizations (entries required) (V3) (2.16.840.1.113883.10.20.22.2.2.1)	2.32.1	Immunization Activity (V3) (2.16.840.1.113883.10.20.22.4.52:2015-08-01)	3.41
			Immunization Medication Information (V2) (2.16.840.1.113883.10.20.22.4.54:2014-06-09)	3.42

[10] See also Birth Sex and Administrative Gender in Section 4.

[11] Plan of Treatment section with Assessment section (optionally) OR Assessment and Plan section

[12] The Assessment and Plan (V2) section includes several additional entry templates for more specific types of planned activities. See C-CDA Volume 2 Section 2.6 for a listing of the available set of entry templates for planned activities.

CCDS Item	C-CDA Section Template (Name, OID and Chapter)		C-CDA Entry Template(s) (Name, OID and Chapter)	
Medications	Medications (entries required) (V2) 2.16.840.1.113883.10.20.22.2.1.1:2014-06-09)	2.39.1	Medication Activity (V2) (2.16.840.1.113883.10.20.22.4.16:2014-06-09)	3.48
			Medication Information (V2) (2.16.840.1.113883.10.20.22.4.23:2014-06-09)	3.51
Laboratory Tests [13]	Results (entries required) (V3) (2.16.840.1.113883.10.20.22.2.3.1:2015-08-01)	2.64.1	Results Organizer (V3) (2.16.840.1.113883.10.20.22.4.1:2015-08-01)	3.93
Laboratory Values / Results			Results Observation (V3) (2.16.840.1.113883.10.20.22.4.2:2015-08-01)	3.92
Vital signs	Vital Signs (entries required) (V3) (2.16.840.1.113883.10.20.22.2.4.1:2015-08-01)	2.70.1	Vital Signs Organizer (V3) (2.16.840.1.113883.10.20.22.4.26:2015-08-01)	3.109
			Vital Sign Observation (V2) (2.16.840.1.113883.10.20.22.4.27:2014-06-09)	3.108
Procedures	Procedures (entries required) (V2) (2.16.840.1.113883.10.20.22.2.7.1:2014-06-09)	2.61.1	Procedure Activity Act (V2) (2.16.840.1.113883.10.20.22.4.12:2014-06-09)	3.81
			Procedure Activity Observation(V2) (2.16.840.1.113883.10.20.22.4.13:2014-06-09)	3.82
			Procedure Activity Procedure (V2) (2.16.840.1.113883.10.20.22.4.14:2014-06-09)	3.83
Unique Device Identifier(s) (UDIs) for a Patient's Implantable Device(s)[14]	Medical Equipment (V2) (2.16.840.1.113883.10.20.22.2.23:2014-06-09)	2.61.1	Procedure Activity Procedure (V2) (2.16.840.1.113883.10.20.22.4.14:2014-06-09))	3.83
			Product Instance (2.16.840.1.113883.10.20.22.4.37)	3.85

3.2 Document Template Requirements

The 2015 Edition Certification Criteria requires the support of four C-CDA Document Types to support five certification criteria. Support for the CCDS is not required when generating a Care Plan Document. Support of the CCDS is only required for documents generated as part of the patient engagement (View online, download and transmit and access via API) and transition / referral of care processes. The 2015 Edition

[13] See also Laboratory Tests with and without Results in Section 4

[14] See also Implanted Devices in Section 4.4.1

Certification Criteria also requires additional data which are not part of the CCDS. The third column in the table below summarizes the additional data requirements for documents in scope for the 2015 Edition Certification Criteria.

Table 6: Document Template Requirements

2015 Edition Certificatoin Criteria	C-CDA Document Type(s)	Section or Data Element Requirements
Common Clinical Data Set Summary Record §170.315(b)(4) & (5)	• CCD • Referral Note • Discharge Summary (Inpatient setting only)	• Common Clinical Data Set, • Encounter Diagnoses, • Mental status, • Functional status, • Reason for referral (ambulatory only), • Referring or transitioning provider's name and office contact information (ambulatory only), and • Discharge instructions (inpatient only)
Transitions of care §170.315(b)(1) & (2)	• CCD • Referral Note • Discharge Summary (Inpatient setting only)	
Data Export §170.315 (b)(6)	• CCD	
View, download, & transmit to 3rd party § 170.315(e)(1)	• CCD	• Common Clinical Data Set, and • Results (Diagnostic imaging report)
Care Plan §170.315 (b)(9)	• Care Plan	• Health Concerns (V2), • Goals, • Interventions Section (V2), and • Health Status Evaluations and Outcomes Section

3.2.1 C-CDA Document Templates

As discussed in Section 2, C-CDA is a library of section and entry templates with predefined structured document templates. Although none of the C-CDA Document Templates equate to the 2015 Edition Certification Criteria, they may be supplemented by additional sections to achieve 2015 Edition certification conformance.

The following table provides additional information on the C-CDA Document Templates identified as required to support the 2015 Criteria:

Table 7: C-CDA Document Templates

Document Template	Version	Template OID	LOINC Code	C-CDA Vol. 2 Section
Continuity of Care Document	V3	2.16.840.1.113883.10.20.22.1.2:2014-06-09	34133-9	1.1.5
Discharge Summary	V3	2.16.840.1.113883.10.20.22.1.8:2014-06-09	18842-5	1.1.9
Referral Note	V2	57133-1 2.16.840.1.113883.10.20.22.1.14	57133-1 (Note[15])	1.1.19
Care Plan	V2	2.16.840.1.113883.10.20.22.1.15	18776-5	1.1.2

The Referral Note recommends use of the document type code 57133-1 "Referral Note", with further specification provided by author or performer, setting, or specialty. When pre-coordinated codes are used, any coded values describing the author or performer of the service act or the practice setting must be consistent with the LOINC document type. For example, an Obstetrics and Gynecology Referral note would not be authored by a Pediatric Cardiologist. The type of referral and the target of the referral are specified via the participant (and not via the author).

3.2.2 CCDS, Additional Data and Section Requirements for Document Templates

Columns 3-6 show the requirements based on C-CDA, while columns 7-10 show 2015 Ed. Health IT Certification Criteria. When using a C-CDA document to meet 2015 Ed. Health IT Certification Criteria, you will need to modify your C-CDA document creation to meet the specified 2015 Ed. Health IT Certification Criteria. For example Language, which is optional in C-CDA, needs to be included because it is required for certification.

Regarding FormatCode values – from IHE: The formatCode shall be sufficiently specific to ensure processing/display by identifying a document encoding, structure and template (e.g., for a CDA Document, the fact that it complies with a CDA schema, possibly a template and the choice of a content-specific style sheet). Consensus is still being sought in this area, but initial reviewers of this document felt it was important to direct readers to the HL7 Structured Documents Work Group wiki for reference: http://wiki.hl7.org/index.php?title=CDA_Format_Codes_for_IHE_XDS

[15] Required to use a LOINC code from Value Set: ReferralDocumentType urn:oid:2.16.840.1.113883.1.11.20.2.3

Table Legend:

R	Required
RE	Required, but may be empty
C-R	Conditionally Required
NA	Not Allowed
O	Optional
Blank	Not specified
(IP)	Inpatient Setting Only
(OP)	Outpatient / Ambulatory Setting Only)

Table 8: CCDS Header Requirements for Document Templates

CCDS	Header Elements	C-CDA Document Requirements				2015 Ed. Health IT Certification Criteria			
		CCD	Referral Note	Discharge Summary	Care Plan	Transition of Care	CCDS Summary Record	Data Export	View Download Transmit
Yes	Patient name	R	R	R	R	R	R	R	R
Yes	Race	R	R	R	R	R	R	R	R
Yes	Ethnicity	R	R	R	R	R	R	R	R
Yes	Language	R	R	R	R	R	R	R	R
Yes	Date of birth	R	R	R	R	R	R	R	R
Yes	Care team members (performer)	O	O	O	R	R	R	R	R
Yes	Care team members (responsibleParty)			O		O	O	O	O
Yes	Care team members (encounterParticipant)			O		R	R	R	R
No	Date of Visit	O	O	O	O		R		
No	Admission Date	O	O	O	O				R (IP)
No	Discharge Date	O	O	O	O				R (IP)
No	Admission and Discharge Location								R (IP)
No	Visit Location						R		
Yes	Care team members (participant)		O		O	R	R	R	R

Table 9: CCDS Section Requirements for Document Templates

CCDS	Concept	Section Entry		C-CDA Document Requirements				2015 Ed. Health IT Certification Criteria			
				CCD	Referral Note	Discharge Summary	Care Plan	Transition of Care	CCDS Summary Record	Data Export	View Download Transmit
Yes	Birth Sex	Social History	Birth Sex Observation	R	R	R	O	R	R	R	R
Yes	Smoking status	Social History	Smoking Status - Meaningful Use	R	O	O		RE	RE	RE	RE
Yes	Health Concerns	Health Concerns	Health Concern Act				R	RE	RE	RE	RE
Yes	Goals	Goals	Goal Observation				R	RE	RE	RE	RE
Yes	Assessment and Plan of Treatment	Assessment (entries not supported)			O			C-R	C-R	C-R	C-R
Yes	Assessment and Plan of Treatment	Assessment and Plan	Planned Act		O	C-R		C-R	C-R	C-R	C-R
Yes	Assessment and Plan of Treatment	Plan of Treatment					NA				
No	Referrals to Other Providers		Planned Act				NA		RE		
No	Future Scheduled Tests		Planned Observation				NA		RE		
No	Diagnostic Tests Pending (if test has not been started)		Planned Observation								RE
Yes	Medication allergies	Allergies and Intolerances (Entries Optional)	[Entries not supported]			R					
Yes		Allergies and Intolerances	Allergy Concern Act	R	R			R	R	R	R
Yes	Problems	Problem	Problem Concern Act	R	R	O		R	R	R	R

CCDS	Concept	Section Entry		CCD	Referral Note	Discharge Summary	Care Plan	Transition of Care	CCDS Summary Record	Data Export	View Download Transmit
Yes	Immunizations	Immunizations	Immunization Activity	O	O			RE	RE	RE	RE
No	Medications Administered During Visit	Medications	Medication Activity	O	O				R		
Yes	Medications	Medications	Medication Activity	R	R			R	R	R	R
No		Admission Medications Inpatient Setting Only	Admission Medication			O		R (IP)		R (IP)	R (IP)
No		Discharge Medications Inpatient Setting Only	Discharge Medication			R		R (IP)		R (IP)	R (IP)
Yes	Laboratory Tests	Results	Results Organizer	R	O			RE	RE	RE	RE
No	Diagnostic Tests Pending (If test has been started and there are any results)		Results Observation					RE	RE		RE
Yes	Laboratory Values/Results										
Yes	Vital signs	Vital Signs	Vital Signs Organizer	R	O			RE	RE	RE	RE
Yes	Procedures	Procedures	Procedure Activity Act	O				C-R	C-R	C-R	C-R
No			Procedure Activity Observation					C-R	C-R	C-R	C-R
No			Procedure Activity Procedure					C-R	C-R	C-R	C-R
No		Interventions	Intervention Act				O	RE	RE	RE	RE
Yes	Unique Device Identifier(s) (UDIs) for a Patient's Implantable Device(s)	Medical Equipment	Procedure Activity Procedure	O	O			RE	RE	RE	RE

CCDS	Concept	Section Entry		CCD	Referral Note	Discharge Summary	Care Plan	Transition of Care	CCDS Summary Record	Data Export	View Download Transmit
	(See Implanted Devices in Section 4.4.1)										
No	Cognitive Status	Mental Status Section	Mental Status Observation	O	O			RE		RE	
No	Functional Status	Functional Status Section	Functional Status	O	O	O		RE		RE	
No	Reason for Referral	Reason for Referral Section	Patient Referral Act		R			RE		RE	
No	Reason for Visit	Reason for Visit Section				O		RE (OP)	RE	RE (OP)	RE (OP)
No	Reason for Hospitalization	Reason for Visit Section				O		RE (IP)	RE	RE (IP)	RE (IP)
No	Provider Name and Office Contact Information	Encounters Section	Encounter Activity					RE	RE	RE	RE
No	Encounter Diagnosis		Encounter Diagnosis		R			RE			RE
No	Reason for Visit or Reason for Hospitalization		Indication								RE
No	Visit Location		Service Delivery Location								RE
No	Clinical Instructions	Instructions Section	Instruction						RE		
No	Patient Decision Aids							R	R		
No	Discharge Instructions							RE (IP)		RE (IP)	RE (IP)

4 Recommended Approaches for Implementing Certification Requirements

In this section, whenever a section from the C-CDA 2.1 IG is mentioned, the appropriate section number from the guide will be specified. Where possible, examples were taken from the HL7 CDA Example Repository and linked to the source example on GitHub.

Whenever examples from the HL7 CDA Example Repository are listed, it should be clear that these examples are possible representations of the data but may not be the ONLY proper representation of the data. (Over time, we would expect that the library could expand to include alternate examples of acceptable representations and negative examples of unacceptable representations).

4.1 General 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.

4.1.1 Conformance Statements

C-CDA R2.1 imposes constraints within templates based on conformance verbs defined in the HL7 Version 3 Publishing Facilitator's Guide[16]. 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.

[16] http://www.hl7.org/v3ballot/html/help/pfg/pfg.htm

Note:
Schematron and other C-CDA validators will typically indicate conformance errors as:

- SHALL violations (error)
- SHOULD violations (warning)
- MAY violations (not checked unless present)

Best practice guideline violations are treated as warnings.

Table 10 shows the relationship between conformance verb usage, minimum cardinality and permitted use of nullFlavor.

Table 10: Conformance Verbs, Cardinality and Use of nullFlavor

Conformance Verb	Minimum Cardinality	nullFlavor Permitted?
SHALL	1	Y (unless explicitly disallowed)[17]
SHOULD	0	Y
MAY	0	Y

4.1.2 Use of Open Templates

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. 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. Within C-CDA, nearly all templates allow additional content and are described as *open* templates. 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. Open and closed templates are detailed in Section 4.2.3 of the C-CDA IG.

4.1.3 Declaring Section Template Conformance

Section 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:

- The C-CDA R2.1 templateID
- The C-CDA R1.1 templateID must also be included when the C-CDA R2.1 templateID includes an extension and where there is an equivalent 1.1 template.

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

[17] 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).

Example 1 Declaring Section Template Conformance

```
<templateId root="2.16.840.1.113883.10.20.22.4.3" extension="2014-06-09"/>
<!--For backwards compatibility-->
<templateId root="2.16.840.1.113883.10.20.22.4.3"/>
```

The US Realm Header conformance requirement CONF:32936 details this:

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

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

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

Section 3.1.2 offers several different examples at the document, section, and entry template-levels.

Also note, when a template conforms to another template—for example, the Allergy – Intolerance Observation (V2) Conforms to Substance or Device Allergy – Intolerance Observation (V2)—implementers should include both templateIds:

Example 2 Declaring Multiple Conformant 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"/>
```

4.1.4 Use of nullFlavor and Handling Missing Information

Section 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 3 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 4 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 section 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.

4.1.4.1 Options for data that is temporarily unavailable

There may be instances where information is not currently available at the time a CDA document is created. In these cases, the incomplete documents containing all other 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 needs to be included and the section-level "Not Available" pattern using nullFlavor="NAV" should be used. 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 includes a new object identifier (OID) for the

documentId. The relatedDocument/typeCode="RPLC" and the relatedDocument/typeCode="RPLC"/parentDocument/id element will be set to reference the prior document's documentId.

An example includes the requirement of a Hospital Course section within a Discharge Summary. Typically, this section is not available at the time of a hospital discharge, but the Discharge Summary document type may still be used to meet the 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 communicating updated information.

Example 5 Discharge Summary with no Hospital Course information (see replacement document below).

```
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns:sdtc="urn:hl7-
org:sdtc" classCode="DOCCLIN" moodCode="EVN" xmlns="urn:hl7-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="NI">
    <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>No Information</text>
</section>
…
```


Example 6 Replacement Discharge Summary document with Hospital Course Information

```
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns:sdtc="urn:hl7-
org:sdtc" classCode="DOCCLIN" moodCode="EVN" xmlns="urn:hl7-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>
…
```

4.1.4.2 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 the document template requires a section to be present:
    - Either the section must contain data or the section should be declared as having no information.
- If the document template does not require a section to be present:
    - If the section is present, it must contain data or be declared as having no information
    - It is reasonable to omit the section if there is no data for that section.

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, as quoted below.

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

In other words, problems, medications, and medication allergies cannot simply be "left blank". 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 7 No Information Problems Section[18]

```
<!-- ************************ 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>
```

4.1.5 Representing "No-Known" Information vs. "No Information"

There is a distinction to be made between representing "No Information" (i.e., missing or unknown information – see 4.1.4), in the case where the author of the relevant CDA element cannot explicitly declare the presence or absence of some information, versus the case where the author is explicitly stating that there is "No Known" information. 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).

[18] https://github.com/brettmarquard/HL7-C-CDA-Task-Force-Examples/blob/master/No_Information_Problems_Section_R2.xml

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.

To represent “No information” about a section, the section should be included and a null value used to convey that there is no information about this section. See section 4.1.4.2 of this guide for further 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 8 No Information Allergies vs No Known Allergies

```
<!-- ************************ 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>
```

```
<!-- ************************ 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"/>
                <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 &amp; 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>
 </section>
```

4.1.5.1 Irrelevant (Not Pertinent) Data

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.

4.1.6 Narrative Text Representation

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. The use of code/originalText/reference and value/originalText/reference should be used where appropriate to point to the human readable information associated with the discrete entries. The text element of the primary (outer-most) act in an entry should point, by reference, to the portion of tne narrative text corresponding to the meaning of the entire entry.

Example 9 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)</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[19] approved by SDWG and managed in the HL7 GForge SVN (http://gforge.hl7.org/gf/project/strucdoc/frs/).

4.1.6.1 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. For more information on the use of styleCodes, reference the IHE Multiple Content Views (MCV) Profile - Published 2014-08-28[20]. 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

[19] http://gforge.hl7.org/gf/project/strucdoc/scmsvn/?action=browse&path=%2Ftrunk%2FCDA%2Fprocessable%2FCDA.xsl&view=log

[20] http://ihe.net/uploadedFiles/Documents/PCC/IHE_PCC_Suppl_MCV.pdf

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.

4.1.7 Date/Time Guidance

4.1.7.1 Timestamp 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 be omitted from the right side to express less precision. Common forms are "YYYYMMDD" and "YYYYMMDDHHMM", but the ability to truncate on the right side is not limited to these two variants.
This representation allows up to four decimals for specifying milliseconds and it 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 Time (EDT) is represented as -0400.

4.1.7.2 Date/Time Precision

When specifying dates and times, care should be taken to only specify 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. A date/time of "20160101000000.0000" is explicitly representing the exact first millisecond on January 1st, 2016. Unless this is the exact millisecond that is intended to be represented, this date/time should be sent as "20160101" which is stating "sometime on January 1st, 2016". Similarly, "2016010109" is stating "sometime after 09:00am on January 1st, 2016, but before 10:00am".

When representing an interval of date/times, care must also be taken in the interpretation of the high point of the interval. Section 3.8.2 of the HL7 Abstract Data Types Specification reads:

> NOTE: 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 1st 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["

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 milliseconds. 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.

Table 11 Date/Time Examples

Date / Time Expression	Representation
November 27, 1970	`<effectiveDate value="19701127"/>`
11:30:52.3333 on November 27, 1970	`<effectiveDate value="19701127113052.3333"/>`

The entire year of 1970	`<effectiveDate>`
	`  <low value="1970"/>`
	`  <high inclusive="false" value="1971"/>`
	`</effectiveDate>`

The entire month of September 1987	`<effectiveDate>`
	`  <low value="198709"/>`
	`  <high inclusive="false" value="198710"/>`
	`</effectiveDate>`

4.1.8 Care Team Representation

Recommendations for care team representation are included below to show some of the possible options that implementers may be using to address representation of care team members. Industry consensus has not been reached in this area. Consequently, implementers should assume to see variability in the representation of care team members in the header and body of any given CDA document. 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.

Care team members, including providers, are participants in the care of a patient. A patient's care team may include individuals providing support to the patient, such as family members or caregivers, as well as physician providers and non-physician providers, including nurses, social workers, behavioral health specialists, community-based providers, technicians, and assistants.

When capturing care team member information, it is recommended to capture the name, identification number, and contact information along with codes to indicate the type of provider and role in the patient's care. Detailing the type of provider and role helps to distinguish care team members across care settings so that participants in the patient's care are clear to recipients of the document.

Within CDA, care team members are represented as participants in elements of the document header 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 capturing care team members from Chapter 1.1 of the C-CDA Implementation Guide are described in the following table.

Participants and Act Relationships for Recording Care Team Members in the Header

Table 12: Participants and Act Relationships – Care Team Members

Participant	Description
informationRecipient	Care team member who the document is intended for. *Examples: PCP, caregiver, consulting physician*
legalAuthenticator	Care team member who authenticates content contained in the document and accepts legal responsibility. *Examples: PCP, consulting physician, attending physician*
authenticator	Care team member who authenticates content contained in the document. *Examples: PCP, consulting physician, attending physician*
documentationOf/ serviceEvent/ performer	Care team member who performs the service event detailed in the document. *Examples: PCP, surgeon, consulting physician*
participant	Other supporting care team members associated with the patient. *Examples: Caregiver, family member, emergency contact*

Table 13: Participants and Act Relationships – Other Participants Members

Participant	Description
author	Participant who generates content contained in the document. *Examples: PCP, nurse practitioner, admitting physician*
dataEnterer	Participant who enters information into the document by transferring content from another source, such as a paper chart. *Examples: transcriptionist, technician*
informant	Participant providing information about a patient contained in the document. *Examples: PCP, family member, caregiver, patient*

In most cases, a care team member may be fulfilling more than one responsibility recorded in the header. For example, a consulting physician who sees a patient in a clinical encounter may author a progress note, and authenticate it. Depending on the business environment, the physician may also be the legal authenticator of the document. In this example, the consulting physician is participating as the author, authenticator and legalAuthenticator.

4.1.9 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 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 rules around the use of the 'displayName' element are:

- The display name is included as a courtesy to an unaided human interpreter of a coded value.
- The display name adds no semantic meaning to the coded information and it SHALL never exist without an associated code.
- A display name may not be present if the code is an expression for which no display name has been assigned or can be derived.
- The display name SHALL never modify the meaning of the code, which is to say the 'displayName' element must accurately represent the concept associated with the @code associated with a code or a value element.
- Some CDA validation applications check to ensure the display name in the 'displayName' element is associated with the coded concept in the code element as specified by the code system.

The display name helps when reviewing the raw XML of a CDA document. In some cases, inclusion of the display name improves the readability of the discrete data in the XML. It also can aid implementation debugging and content validation.

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 Concern entry. If display name and originalText were not available/used, the human readable text could only say, "Problem 99999123 began on July 6, 2016 as noted by Dr. Ishihara." A processing system that does not recognize the SNOMED CT code 99999123 and was provided no originalText can still present to an end user in a structured way, a human readable representation of the coded problem concern by using the display name, date of onset, author, etc. in the narrative text. By using the displayName element, the processing system could generate human readable information that conveyed, "Obsessional thoughts of augmented reality video games, began on July 6, 2016, as noted by Dr. Ishihara."

Example 10 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>
```

4.1.9.1 OriginalText Representation

When a CDA document includes human readable information and contains coded discrete entries (such as allergen, medication, problem, etc.) to support machine processing of the available human readable

information, then every discrete entry SHOULD include an originalText element to link the coded information back to the original human readable information represented by that code. 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. Using the above example, if the Problem Section dictated by Dr. Ishihara indicated, "The patient has obsessional thoughts of augmented reality video games. The obsession began on July 6, 2016". In this case, the validation could confirm the original text in the originalText element is associated with the coded concept in the code element as specified by the code system. Human confirmation or natural language processing could be used to confirm the coded concept correctly represented by the originalText element. The confirmation for originalText would be that it was what the human saw or said.

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 may routinely have more robust content than the structured entries or additional nuances in meaning because of clinical charting and should never be ignored by receiving systems.

4.1.10 Generating Unique Identifiers

The id element represents a globally unique identifier for a piece of data, be it document, section, entry, or sub-entry (such as an author). It should be unique within a document (for example, every instance of the same provider throughout a document should have the same id). Within different document instances, the identifier should also be the same wherever possible if it is representing the same entity, concept, instance, or version of data. If a CCD is created for a patient with an allergy to penicillin, the next time a CCD is generated for the same patient, the penicillin allergy should have the same id. If the allergy has changed slightly (such as adding a new comment or changing the severity of a reaction), it is still the same piece of data and should keep the same identifier. If the entry represents a new instance, however, such as a new prescription for the same medication, it should contain a new id to differentiate the new prescription from the previous prescription, but the medication id would remain the same if the medication had not changed.

Consistent ids help with reconciliation of discrete data. If the penicillin allergy cited before was received and incorporated into a system, then a subsequent update can be immediately associated with the previously incorporated allergy to update it without requiring additional reconciliation steps. If, however, a nullFlavor or newly-generated random id is sent with each new document, the allergy continues to appear as a brand new piece of data and decision logic must be performed (either automatic or manually reviewed by a clinician) to decide whether it should match to an existing allergy, be discarded as out of date, or be added as a brand new piece of data. Consistent ids eliminate this extra step by ensuring every time a specific piece of data is referenced, it is tied to previous instances of the same piece of data.

When content is imported from another system, the identifiers need to be maintained and output whenever that content is output into a subsequent CDA document. This will help prevent the revolving

door problem: If system A imports from system B, and then subsequently sends to system B it is very useful for system B to discover its own identifiers in the list for an item that system A imported from system B's original document.

One example approach to unique ids is to create Globally Unique Identifiers (GUIDs) for each object in the database. It is important to actually store the GUID in the database, so when the record is sent again in the future its id is consistent. Another approach is to use Object Identifiers (OIDs). 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 OIDs. Unique branches can then be created for each implementation, server, data type, and record.

HL7 id elements contain two elemental parts: a root (which must be a GUID or an OID[21]) 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 as long as it is consistent and sends the same unique identifier for an entry each time it is included in a CDA document.

4.1.11 Specifying Time Intervals for Sections

In order to communicate that information represented in the section of a document is limited to information from a specific time interval, a new entry template has been defined called a Section Time Range Observation. The Section Time Range Observation entry represents the date and time range of the information contained in a 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 assert the range of time constraining the data provided in a section. See Appendix A.2 for the template and an example.

4.2 Document-Specific Guidance

The following guidance elements are organized into the document template that they refer to.

[21] The root element may also be any string containing only letters and numbers without spaces or other punctuation, but it is more difficult to ensure uniqueness when this option is used than when a GUID or OID is used.

4.2.1 US Realm Header

4.2.1.1 Language Code

RFC 5646[22] is the preferred language standard for capturing a patient's preferred language. Other language standards such as ISO 639-1, ISO 639-2 and ISO 639-3 can be mapped to it.

Since the value set for Language Codes within RFC 5646 includes both 2-character codes (ISO 639-1) and 3-character codes (ISO 639-2) for most languages, the following guidance should be followed:

- Use the 2-character code from ISO 639-1 if one exists (English = 'en')
- Use the 3-character code from ISO 639-2 if a 2-character code does not exist (Hawaiian = 'haw')
- Country extensions to the language codes are allowed (ISO 3166-1) (US english = 'en-US')

4.2.1.2 Race and Ethnicity

Race and Ethnicity are required elements in the Common Clinical Data Set (CCDS) and must be included in C-CDA exchanges if known, or they may be marked with a nullFlavor of UNK null if not known.

For both Race and Ethnicity, there are the singular data elements along with an extension element. The standard elements tend to have codes from a small value set while the extension elements allow for more detailed (granular) representation of either race or ethnicity, or for additional race(s). SDWG created extensions because the base CDA standard only allows one Race, and one Ethnicity code. CDA also allows translations on code elements to convey the same concept in an alternate coding system or to convey a more precise code in the same coding system.

The five minimum race categories defined by OMB Standards recorded in the code should be treated equally. The granular race and ethnicity codes should be treated equally.

For Race, the raceCode data element uses a value set (Race Category Excluding Nulls 2.16.840.1.113883.3.207.4.1.1.3) that has five race categories:

- American Indian or Alaska Native
- Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander
- White

If race category is not known, the raceCode data element may be populated with a nullFlavor of "UNK".

If a more detailed race code is known, it should be conveyed in a translation element. There is no required value set for this element. Race (2.16.840.1.113883.1.11.14914) includes additional more detailed race concepts beyond the five categories.

Example 11 More Detailed Race Code

```
<patient>
<!-- CDC Race and Ethnicity code set contains the five minimum race and ethnicity categories
defined by OMB Standards -->
```

[22] https://tools.ietf.org/html/rfc5646


```
<raceCode code="2106-3" displayName="White" codeSystem="2.16.840.1.113883.6.238"
codeSystemName="OMB Standards for Race and Ethnicity">
    <translation code="2108-9" displayName=”White-European”
codeSystem=”2.16.840.1.113883.6.238”/>
</raceCode>
```

The extension sdtc:raceCode also uses the Race value that should be used to indicate additional races for a multi-racial patient..

Example 11a Multi-Racial Representation

```
<patient>
<!-- 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">
    <translation code="2112-1" displayName="German" codeSystem=”2.16.840.1.113883.6.238”/>
</raceCode>
<sdtc:raceCode code="2054-5" displayName="Black or African American"
codeSystem="2.16.840.1.113883.6.238" codeSystemName="OMB Standards for Race and Ethnicity">
    <translation code="2062-8" displayName="Ethiopian" codeSystem="2.16.840.1.113883.6.238"/>
</raceCode>
```

Prior recommendations regarding sdtc:raceCode suggested its use for either additional races or more granular races. This is not prohibited, and receivers must expect to receive documents formatted this way, but senders are encouraged to follow one of the prior examples to clarify the distinction between single-detailed-race and multiracial and to avoid sending ambiguous race code information.

Example 11b Ambiguous Race Code

```
<patient>
<!-- 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"/>
       <sdtc:raceCode code="2108-9" displayName=”White-European”
codeSystem=”2.16.840.1.113883.6.238”/>
```

The value set for ethnicGroupCode (Ethnicity 2.16.840.1.114222.4.11.837) includes only two concepts: Hispanic or Latino, and Not Hispanic or Latino. If ethnicity is not known, the ethnicGroupCode data element may be populated with a nullFlavor of “UNK”.
If a more detailed ethnicGroupCode is known, it should be conveyed in a translation element. There is no required value set for this element. Detailed Ethnicity (2.16.840.1.114222.4.11.877) includes more detailed ethnicities. The extension sdtc:ethnicGroupCode can be used to represent multiple ethnicities. Since the base code is a binary decision (Hispanic or Not Hispanic), extension elements need not repeat the high-level code.

Example 12 More Detailed Ethnicity Code

```
<patient>
<!-- CDC Race and Ethnicity code set contains the five minimum race and ethnicity categories
defined by OMB Standards -->
    <ethnicGroupCode code="2186-5" displayName="Not Hispanic or Latino"
codeSystem="2.16.840.1.113883.6.238" codeSystemName="OMB Standards for Race and Ethnicity">
```



```
        <translation code="2137-8" displayName="Spaniard" codeSystem="2.16.840.1.113883.6.238"/>
    </ethnicGroupCode>

    <sdtc:ethnicGroupCode code="2146-9" displayName="Spanish Basque"
codeSystem="2.16.840.1.113883.6.238"/>
```

Like the raceCode, the above example could also be represented with no translation and two sdtc:ethnicGroupCode elements. Receivers should expect both possible representations. However, senders are encouraged to use the translation approach shown above.

4.2.1.3 Encompassing Encounter and Service Events

A CCD may include information that spans across multiple encounters or it may include information constrained to a single encounter. When a CCD is generated for a specified date range to serve as a summary across multiple encounters, the document header does not include an encompassing encounter. Instead, the header includes a service event for provision of care during the specified range of time. The provision of care may include key care team members like the PCP and consulting physicians who may have provided care over the range of time. In this case, individual clinical encounter information is captured in the body of the document in the Encounters section along with associated care team members. Key dates associated with the encounters such as an admission or discharge date from an inpatient encounter, the start and completion of an ambulatory visit, or the admission and discharge from an Emergency Department visit are recorded in the effectiveTime/low and effectiveTime/high of the Encounter Activity entry in the Encounters Section.

The CCD may also be used to detail the provision of care within a single encounter. The Discharge Summary Document is associated with a single encompassing encounter. The Referral Note may be stimulated by an individual encounter. Data contained in a document associated with a single encounter may or may not be constrained by that encounter.

A document summarizes the entire scope of an encounter when it contains both an encompassingEncounter AND a provision-of-care serviceEvent (@classCode=PCPR) with the same ID and/or effectiveTimes. Note that in CCD, serviceEvent IS required, must be a provision-of-care, and no additional serviceEvents are allowed. In other types of documents, additional documentationOf/serviceEvents MAY be present if allowed by the document template.

Table 14: Single Episode Transition of Care Document – example 1: CCD

The consulting physician in an ambulatory setting generates a CCD detailing an encounter to provide to the patient and the patient's caregiver (*Clinical Summary Objective*).	
componentOf/encompassingEncounter	Captures information about the encompassing encounter including the admission and discharge date and time, the location information for the health care facility such as the organization and the location of the facility. Also captures the names and contact information of the consulting provider as the responsible party for the clinical encounter and the nurse practitioner as an encounterParticipant
documentationOf/serviceEvent	Captures the names and contact information for any known key care team members, such as the PCP, who may not be participating in the encounter, where @classCode="PCPR". Other serviceEvents may include additional care team members.
participant	Captures the names and contact information of supporting participants, including the patient's caregiver(s)

Table 15: Single Episode Transition of Care Document – example 2: Discharge Summary

The discharging physician in an inpatient setting generates a CCD to detail the hospitalization to send to the patient's PCP (*Transition of Care Objective*).	
componentOf/encompassingEncounter	Captures information about the encompassing encounter including the admission and discharge date and time, the location information for the health care facility such as the organization and the location of the facility. Also captures the names and contact information of the attending physician as the responsible party for the clinical encounter and the discharging physician and rounding physician as encounterParticipants. (see also 4.1.8 Care Team Member Representation).
documentationOf/serviceEvent	Captures a list of services performed during the encounter with the date and time they occured. Also captures the names and contact information for any known key care team members involved in performing the service(s). (see also 4.1.8 Care Team Member Representation). Use @classCode="PCPR" for recording care team members who may not have participated in the encompassingEncounter

Table 16 : Multiple Encounter CCD

The PCP in an ambulatory setting generates a CCD to summarize a patient's healthcare for transmission to the PHR (*View/Download/Transmit Objective*).	
This type of CCD does not contain a componentOf/encompassingEncounter	The cardinality of componentOf/encompassingEncounter in a CDA Document is [0..1], so in the header of a CCD about multiple encounters, this element of the header is not present.
documentationOf/serviceEvent	Captures the general service event for "Provision of Care" for the range of time indicated in the serviceEvent/effectiveTime/low and /high. The names and contact information for key care team members including the PCP and other active care providers, such as the patient's physical therapist or dietician, would also be included (see also 4.1.8 Care Team Member Representation).
Encounters section	In the body of the document, the Encounters Section captures relevant encounters. Each Encounter Activity entry can include associated care team members. (See 4.3.2 Encounter Section)

4.3 Section-Specific Guidance

The following guidance elements have been grouped by the C-CDA section that they deal with. Examples leveraged from the HL7 Example Task Force include a link in an accompanying footnote.

4.3.1 Allergies

There are three distinct dates associated with an Allergy Concern Act (3.5). Two of them are found on the Allergy Concern Act itself. The third is in the encompassed Allergy – Intolerance Observation:

- The effectiveTime of the Allergy Concern Act asserts the time range the allergy concern was tracked. The low value asserts when the allergy began being tracked as a concern. The high value, when included, indicates when the allergy stopped being tracked as a concern.
- The latest author/time on the allergy Concern Act indicates when the allergy concern was last modified.
- The Allergy - Intolerance Observation (3.105.1) information encompassed within the Allergy Concern Act also includes effectiveTime information. The effectiveTime information for an Allergy - Intolerance Observation indicates the actual date/time or date/time range when the patient experienced the allergy or intolerance.

The Allergy – Intolerance Observation (3.105.1) encompassed within the allergy concern information also has an effectiveTime. The effectiveTime of the Allergy-Intolerance Observation indicates the actual date/time or date/time range when the allergy was experienced by the patient. The low value is the time of the onset of the allergy and the high value is used to assert the point in time when the patient stopped experiencing the allergy. As long as no effectiveTime high value is present, the statusCode of the Allergy-Intolerance Observation remains “active”. When the effectiveTime high of the the Allergy-Intolerance Observation is populated, then the statusCode should be “completed”.The value of the statusCode for the Allergy Concern Act operates independently from the statusCode of the Allergy-Intolerance Observation. Even if a patient’s allergy is considered “completed”, the issue may still be being tracked as an “active” concern.

For a provider seeing a patient in the clinic today, recording a new penicillin allergy that developed five years ago, those dates would have the following values:

- act/effectiveTime/low – today
- act/effectiveTime/high – not present
- act/author/time – today
- act/entryRelationship/observation/effectiveTime/low – five years ago
- act/entryRelationship/observation/effectiveTime/high – not present (allergy still ongoing)

Example 13 Recording an allergy that started in January of 2009, but became a tracked concern as of January 4th, 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”/>
      …other author elements not included for sake of example…
    </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>
```

If during an encounter a patient’s record was updated to indicate that an allergy concern recorded a 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/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 14 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="active"/>
    <!-- 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”/>
      …other author elements not included for sake of example…
    </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>
```

The Allergy Status Observation (3.6) template was deprecated in November, 2014 with the release of C-CDA R2.0. It remains a deprecated template in C-CDA R2.1. Use of this template is not recommended.

4.3.2 Encounters

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, this section SHALL contain information about that encounter but MAY also contain additional encounters. The Encounter Activity entry with an ID matching the encompassingEncounter header element represents the primary encounter being documented.

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. See Appendix A.3 for the template definition and an example.

4.3.3 Immunizations

4.3.3.1 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 15 Influenza Vaccination[23]

```
<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 ** -->
                    <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>
```

[23] source: https://github.com/brettmarquard/HL7-C-CDA-Task-Force-Examples/blob/master/Influenza_Immunization_Complete.xml


```
            <!-- 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>
```

4.3.3.2 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’.

4.3.3.3 Documenting Refusals

For documenting when an immunization was not given, due to a refusal, an Immunization Activity entry should be recorded with a negationInd equal to ‘true’ to indicate that the specific immunization was not given. There would then be an entryRelationship with the reason why the immunization was refused.

Example 16 Immunization Refusal[24]

```
<component>
    <section>
        <!-- Immunizations section with entries required -->
        <templateId root="2.16.840.1.113883.10.20.22.2.2.1"/>
        <templateId root="2.16.840.1.113883.10.20.22.2.2.1" extension="2015-08-01"/>
        <code code="11369-6" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
            displayName="History of Immunizations"/>
        <title>Immunizations</title>
        <text><paragraph ID="immun1">Patient objected to <content
ID="ImmunizationProduct_1">influenza, intradermal, quadrivalent</content> on
11/15/2015</paragraph></text>
        <entry typeCode="COMP">
            <!-- negationInd=true indicates substance was NOT given at this date-->
            <substanceAdministration classCode="SBADM" moodCode="EVN"
                negationInd="true">
                <!-- ** Immunization activity ** -->
                <templateId root="2.16.840.1.113883.10.20.22.4.52"/>
                <templateId root="2.16.840.1.113883.10.20.22.4.52" extension="2015-08-01"/>
                <id root="e6f1ba43-c0ed-4b9b-9f12-f435d8ad8f92"/>
                <text>
                    <reference value="#immun1"/>
                </text>
                <!-- Indicates the status of the substanceAdministartion -->
                <statusCode code="completed"/>
                <effectiveTime value="20151115"/>
                <consumable>
                    <manufacturedProduct classCode="MANU">
                        <!-- ** Immunization medication information ** -->
                        <templateId root="2.16.840.1.113883.10.20.22.4.54"/>
                        <manufacturedMaterial>
                            <code code="166" codeSystem="2.16.840.1.113883.12.292"
                                displayName="influenza, intradermal, quadrivalent, preservative
free"
                                codeSystemName="CVX">
                                <originalText>
                                    <reference value="#ImmunizationProduct_1"/>
                                </originalText>
                            </code>
                            <!-- STU comment relaxing lotNumber requirement -->
                            <!--
http://www.hl7.org/dstucomments/showdetail_comment.cfm?commentid=995 -->
                            <!-- <lotNumberText>1</lotNumberText> -->
                        </manufacturedMaterial>
                        <!-- Optional manufacturerOrganization
                                        <manufacturerOrganization>
                                           <name>Health LS - Immuno Inc.</name>
                                                </manufacturerOrganization>-->
                    </manufacturedProduct>
                </consumable>
                <entryRelationship typeCode="RSON">
                    <observation classCode="OBS" moodCode="EVN">
                        <!-- Immunization Refusal Reason  -->
                        <!-- Included the reason since it may be relevant to a future clinician
or quality measurement -->
                        <templateId root="2.16.840.1.113883.10.20.22.4.53"/>
                        <id root="c1296315-9a6d-45a2-aac0-ee225d375409"/>
```

[24] source: https://github.com/brettmarquard/HL7-C-CDA-Task-Force-Examples/blob/master/Immunization_Not_Given_Patient_Refusal.xml


```
                        <code displayName="Patient Objection" code="PATOBJ"
                            codeSystemName="HL7 ActNoImmunizationReason"
codeSystem="2.16.840.1.113883.5.8"/>
                        <statusCode code="completed"/>
                    </observation>
                </entryRelationship>
            </substanceAdministration>
        </entry>
    </section>
</component>
```

4.3.4 Medications

C-CDA R2.1 defines several different section templates for representing medication information. They each have a distinct purpose. Some require machine readable entries to be included and some do not. For example, the Medication Section templates are used to record the patient's current medications and pertinent medication history. C-CDA R2.1 defines one version of this section template that requires a Medication Activity Entry to be used to record the medication information in this section. It also defines a version of this section template that does not specify that a specific entry template must be used. The Medication Section templates, like most templates defined in C-CDA, are open templates. Open section templates permit additional entry content to be included and open document templates permit additional section content to be included.

The following table lists the set of medication related section templates defined in C-CDA R2.1 and the associated entry templates.

Section Template	**Brief Summary of Purpose**	**Contained Entry Templates**
Medications Section (entries optional) (V2)	A patient's current medications and pertinent medication history	Medication Activity (V2)
Medications Section (entries required) (V2)	A patient's current medications and pertinent medication history This section requires either an entry indicating the subject is not known to be on any medications or entries summarizing the subject's medications.	Medication Activity (V2)
Admission Medications Section (entries optional)	The medications taken by the patient prior to and at the time of admission to the facility.	Admission Medication V2
Medications Administered Section (V2)	Medications and fluids administered during the procedure, its related encounter, or other procedure related activity excluding anesthetic medications.	Medication Activity (V2)
Discharge Medications Section (entries option) (V3)	The medications the patient is intended to take or stop after discharge. Current, active medications must be listed.	Discharge Medication (V2)
Discharge Medications Section (entries required) (V3)	The medications the patient is intended to take or stop after discharge. Current, active medications must be listed.	Discharge Medication (V2)

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.

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.

Example 17 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 18 Medication Plan[25]

```
<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-eaa5-46b3-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.

[25] source: https://github.com/jddamore/HL7-Task-Force-Examples/blob/master/MED_Med_Every_4-6_hrs.xml

Example 19 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>
.. .
        </assignedEntity>
    </performer>
</supply>
```

The structure for medication information is complicated by the fact that any one of these templates may include other type of medication templates within an entryRelationship. Thus, the structure of a medication entry can be complex. 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 section 4.1.7.2 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[26].

4.3.5 Problems

There are three distinct dates associated with an Problem Concern Act (3.78). Two of them are found on the Problem Concern Act itself. The third is in the encompassed Problem Observation:

- The effectiveTime of the Problem Concern Act asserts the time period over which the problem concern was being tracked. The low value asserts when the problem began being tracked as a concern The high, when included, indicates the problem stopped being tracked as a concern.
- The latest author/time on the Problem Concern Act indicates when the problem concern was last modified.
- The Problem Observation (3.79) information encompassed within the Problem Concern Act also includes effectiveTime information. The effectiveTime information for a Problem Observation indicates the actual date/time or date/time range when the patient experienced the problem.

[26] Medication Frequency List:[https://docs.google.com/document/d/1Y0Z458o_MrR2aPnpx6EygO6hpI88Bl95esjRWZ0agtY/edit]

For a provider seeing a patient in the clinic today, recording that the patient had a heart attack five years ago, the documentation of the physician's concern about the patient's history of heart attack would be represented as follows:

- act/effectiveTime/low – today
- act/effectiveTime/high – not present (currently a concern)
- act/author/time – today
- act/entryRelationship/observation/effectiveTime/low – five years ago
- act/entryRelationship/observation/effectiveTime/high – five years ago (heart attack is over)

See

Example 13 for how the dates would be represented.

If during an encounter the physician notes that the patient's history of heart attack noted as a concern a month ago, now was no longer a concern, the information would be represented as follows::

- 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 – five years ago (heart attack is over)

See

Example 14 for how the dates would be represented.

The Problem Status (3.8) template was deprecated in November, 2014 with the release of C-CDA R2.0. It remains a deprecated template in C-CDA R2.1. Use of this template is not recommended.

4.3.6 Vital Signs

The 2015 Edition Final Rule clarified that the CCDS element is Body Weight and does not need to be precisely Body Weight measured. Note that the 2015 Certification Requirements tighten the value set binding specification to a SHALL, thus the vital sign observation concepts in the specified value set must be used (Vital Sign Result urn:oid:2.16.840.1.113883.3.88.12.80.62). If a more specific LOINC code is applicable (such as 8350-1 – body weight with clothes), it may be sent as a translation to the corresponding more general concept from the Vital Sign Result value set, i.e. LOINC code 29463-7 (Body Weight)). Coded data should reflect what is charted.

Other types of observations that yield other types of results can be represented using the Result Observation entry template in the Results Section.

Example 20 Vital Sign Coding with Translation

```
<code code="3141-9" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
       displayName="Body weight measured">
  <translation code="8350-1" codeSystem="2.16.840.1.113883.6.1"
       displayName="Body weight^with clothes" />
</code>
```

4.3.7 Representing “Pregnant”, “Not Pregnant” and “Unknown”

To assert that a patient was pregnant during a specified date range, the Pregnancy Observation entry (3.74) may be used. The effectiveTime element will indicate the date range during which the patient was pregnant.

Example 21 Patient is pregnant

```
<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 22 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 23 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>
```


4.4 Certification-Specific Guidance

The following guidance was determined from the two Implementation-A-Thons that HL7 and ONC jointly held in Orlando in January 2016 and Chicago in April 2016. The implementers and ONC jointly discussed these issues and came up with the following guidance.

4.4.1 Implanted Devices

When recording devices that have been placed in a patient, they should all be documented in the Medical Equipment Section (2.37). If the CDA document is also documenting a procedure that applied or placed the device, then the device could also be enumerated under the details of that procedure in the Procedures Section. Detailing the device in the procedure details does not remove the need to list it in the Medical Equipment section.

Each implanted device can be represented in an Individual Procedure Activity Procedure template or groups of implanted devices can be represented within a Medical Equipment Organizer 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.

Example 24 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 25 Implanted Device - Procedure Unknown[27]

```
<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"/>
```

[27] source: https://github.com/benjaminflessner/HL7-C-CDA-Task-Force-Examples/blob/master/Implant Without Procedure.xml


```
                </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>
```

When specifying the device, the UDI of the device must be used to identify the device. See Section 3.85 Product Instance in the C-CDA Implementation Guide for information on how to encode the UDI.

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 26 No Implanted Devices[28]

```
<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-e1fd01dcc72a" />
                <code code="71388002" codeSystem="2.16.840.1.113883.6.96"
                    displayName="Procedure"/>
                <text>
                    <reference value="#Proc"/>
                </text>
                <statusCode code="completed" />
                <effectiveTime nullFlavor="NA" />
```

[28] source: https://github.com/brettmarquard/HL7-C-CDA-Task-Force-Examples/blob/master/No_Implanted_Devices.xml


```
                <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>
```

4.4.2 Health Concerns vs. Problems

Certification Guidance

To satisfy the 2015 Edition Certification Criteria, Transition of Care (ToC) documents[29] include both the Problem Section (2.53) and the Health Concerns Section (2.23), with content distinguished as described below. Please note, if certifying to 170.315(b)(9) which includes the Care Plan Document, the Problem List is part of the Health Concerns Section.

4.4.2.1 Problem Section

Certification Guidance

The Problem Section contains the Problem List which is reviewed, actioned on, and updated by the responsible clinician at/during an encounter.

The list only includes problems that the author deems pertinent. If there are historical problems that the author deems pertinent and chooses to include, these should clearly be indicated as not active.

Refrain from using the word “Concerns” in the title of the section, to avoid confusion, since this information has been titled the Problem List in 2011 Edition and 2014 Edition Certification Criteria.

4.4.2.2 Health Concerns Section (in a ToC Document)

Certification Guidance

The Health Concerns Section contains, when available, concerns as expressed by the patient and/or the patient’s agent(s), and/or by the patient or other care team members.

When the Problem Section and Health Concerns Section both appear in a single document, then the Health Concerns section is titled “**Additional Health Concerns”** to distinguish it from the Problem List (the author’s concerns). If it were simply titled Health Concerns, some would think that it contains all

[29] “Transition of Care Documents” collectively refers to the three document types that 2015 Edition Certification requires that EHRs be able to send for transitions of care. These are the Continuity of Care Document (CCD), Discharge Summary, and Referral Note.

concerns, including the Problem List, which could cause confusion. Also, the Health Concerns Section appears after the Problem Section in the documents.

The Health Concerns Section does not duplicate the entries from the Problem List. However, it may include some of the same concerns in the Problem List.

It may be formatted as a "list" but may also be free form narrative not in any particular format. Whereas the Problems Section must contain both structured entries and narrative, the 2015 Edition Certification Criteria for Health Concerns section is only narrative. C-CDA conformance requires structured entries which may be populated with relevant data or the appropriate nullFlavor.

Example 27 Health Concerns with Narrative[30]

```
<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 nullFlavor="active"/>
            </act>
        </entry>
    </section>
</component>
```

Patient concerns may be specific to an encounter, or overarching concerns not specific to an encounter. Patient concerns are not limited to medical problems. For example, they can include things like barriers (lack of transportation, lack of finances, difficulty communicating with provider) or anything else relevant to the document/care. .

Also, the Additional Health Concerns section may contain concerns from members of the care team other than the author/attester of the document. The author/owner of each concern or group of concerns within the Additional Health Concerns section should be clearly labeled (e.g. Patient, Nurse, Therapist).

[30] source: https://github.com/brettmarquard/HL7-C-CDA-Task-Force-Examples/blob/master/Health_Concern_Narrative_Example.xml

4.4.3 Plan of Treatment and Goals (in a ToC Document) Certification Guidance

To satisfy the 2015 Edition Certification Criteria, Transition of Care documents should include the Assessment Section (2.7) and the Plan of Treatment Section[31] (2.48), or the Assessment and Plan Section (2.6). They also should include the Goals Section (2.22). Content should be distinguished as described below when **the Goals Section, and the Plan of Treatment Section or Assessment and Plan of Treatment Section, are both included within the same Transition of Care document**. This guidance does **not** apply to the Goals Section within a Care Plan document. There is no additional guidance for the **Assessment Section** beyond what is already in Consolidated CDA.

4.4.3.1 Plan of Treatment Section

The Plan of Treatment Section, may contain, but is not limited to, the treatment activities related to the encounter or service(s) being documented in the ToC document.

It may contain goals, as well as many other types of data including pending orders, interventions, encounters, services, and procedures for the patient. It is limited to prospective, unfulfilled orders and requests only. When the Plan of Treatment Section is used in a ToC document that also includes a Goals Section, **all** the goals (whether narrative only, or structured Goal Observation entries) from the patient or other care team members, should be recorded in the Goals Section, rather than in the Plan of Treatment Section, to avoid confusion as to "which/whose goals should be in which section?"

The Plan of Treatment Section shall always contain a narrative and may contain structured entries. If it contains structured entries, it may contain any allowable C-CDA entries (except for Goal Observation entries in a document that also includes a Goals Section).

While guidance has been provided to put all goals in the Goals section, it is not possible to prohibit words in the Plan of Treatment *narrative text* that sound like goals, intentions, desired outcomes, etc. The Plan of Treatment narrative should read as the author intends.

4.4.3.2 Goals Section

The Goals Section should contain, when available, all goals as expressed by the authoring provider, the patient, or any other members of the care team. Patient goals may be specific to an intervention or encounter, or overarching goals not specific to an intervention/encounter.

The Goals Section is only required by ONC to contain narrative.[32] It may also contain structured entries or may contain no entries (except for the appropriate nullFlavor entries to satisfy C-CDA conformance for the Goals section).

---

[31] For simplicity, Plan of Treatment Section is used in this proposal. Per the ONC rule, alternatively there can be an Assessment and Plan Section (2.6). If the Assessment and Plan Section were used instead, the guidance still applies to the "Plan" aspect of that section.

[32] 45 CFR Part 170, RIN 0991–AB93, 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications; Corrections and Clarifications. See Federal Register page 78760, Section III.A: Clarifications, *Common Clinical Data Set*.

Example 28 Goals with Narrative[33]

```
<component>
    <section>
        <!-- Goals Section -->
        <templateId root="2.16.840.1.113883.10.20.22.2.60"/>
        <code code="61146-7" displayName="Goals" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC"/>
        <title>Goals Section</title>
        <text><paragraph ID="Goals">Patient is targeting a pulse oximetry of 92% and a weight of
195 lbs</paragraph></text>
        <entry>
            <!-- Goal Observation -->
            <observation classCode="OBS" moodCode="GOL">
                <!-- Goal Observation -->
                <templateId root="2.16.840.1.113883.10.20.22.4.121"/>
                <!-- If you have an id for your goal, include here -->
                <id nullFlavor="UNK"/>
                <code nullFlavor="UNK"/>
                <text><reference value="#Goals"></reference></text>
                <statusCode code="active"/>
                <!-- Author could be included to indicate a patient authored goal or a provider
different than the document or section author. -->
                <!-- See HL7 DSTU comment which relaxed the requirement to include the author
(867) -->
                <!-- http://www.hl7.org/dstucomments/showdetail_comment.cfm?commentid=867 -->
            </observation>
        </entry>
    </section>
</component>
```

If there are goals from multiple sources, for each goal or group of goals the author/owner of each goal (e.g., provider-expressed, patient-expressed) should be clearly labeled for the user.

4.4.4 Birth Sex and Administrative Gender

The administrativeGenderCode element in the header is used to represent the gender with which the patient identifies, i.e., the gender/sex that a patient would say when registering.. Here is the definition of this element in the HL7 Reference Information Model:

- The gender (i.e., the behavioral, cultural, or psychological traits typically associated with one sex) of a living subject as defined for administrative purposes. 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 also be used for the appropriate allocation of inpatient bed assignment.

The 2015 Edition Certification Criteria include a requirement to collect Birth Sex. The administrativeGenderCode is not the appropriate place to specify Birth Sex. Birth Sex should be represented using the new Birth Sex Observation template (2.16.840.1.113883.10.20.22.4.200:2016-06-

[33] source: https://github.com/brettmarquard/HL7-C-CDA-Task-Force-Examples/blob/master/Goals_Narrative_Only_Example.xml

01). The Birth Sex data element uses the ONC Administrative Sex value set (2.16.840.1.113762.1.4.1) which contains only two concepts: Male (M) and Female (F).

If the value/@code of the Birth Sex data element is not populated with a concept from this value set then it shall contain a nullFlavor of "UNK".

Refer to example in the Appendix Birth Sex Observation.

4.4.5 Laboratory Tests

The placement of laboratory test information depends on whether those tests have been started or not. If a laboratory test has been ordered but no action has begun to perform the test (i.e. no specimen is drawn, no image taken, etc.) , then the test information should be placed in the Plan of Treatment section (2.48). When included in the Plan of Treatment section, the Planned Observation (3.68) is the preferred template to use for representing the information, but some implementations may use the Planned Procedure (3.69) or the Planned Act (3.62) template, depending on the specific type of test being ordered.

Example 29 below illustrates the representation of a planned EKG :

Example 29 Planned Observation[34]

```
<component>
    <!-- here is the optional Plan of Treatment -->
    <section>
        <templateId root="2.16.840.1.113883.10.20.22.2.10"
            extension="2014-06-09"/>
        <code code="18776-5" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
displayName="Plan of Care"/>
        <title>Plan of Treatment</title>
        <!-- one Planned Observation in the human readable text and as a discrete entry -->
        <text>
            <!-- table omitted for space -->
        </text>
        <!-- a planned observation entry -->
        <entry>
            <!-- observation with moodCode indicating Intent -->
            <observation classCode="OBS" moodCode="INT">
                <templateId root="2.16.840.1.113883.10.20.22.4.44"/>
                <id root="b52bee94-c34b-4e2c-8c15-5ad9d6def205" />
                <code code="34534-8"
                    codeSystem="2.16.840.1.113883.6.1"
                    codeSystemName="LOINC"
                    displayName="EKG 12 channel panel">
                    <originalText>
                        <reference value="#ID0EFAAAAACAB2"></reference>
                    </originalText>
                </code>
                <text>
                    <!-- referencing the entire text -->
                    <reference value="#ID0EFFFFFFCAB2"/>
                </text>
                <statusCode code="active" />
```

[34] Source: https://github.com/brettmarquard/HL7-C-CDA-Task-Force-Examples/blob/master/Plan_of_Treatment_EKG.xml


```
                <effectiveTime value="20150623"/>
            </observation>
        </entry>
    </section>
</component>
```

For laboratory tests that have been performed and have results or have pending results, test information should be placed in the Results Section (2.64). If the laboratory test information is included in the Results section, then the Laboratory test should not also be included in the Plan of Treatment section.

Note: the statusCode element of the Result Organizer indicates if all results for the associated laboratory test are completed or not. When all results are completed, the statusCode of the Result Organizer has a value of "completed". When any results are not yet completed, the statusCode of the Result Organizer has a value of "active". The status of each individual result is included in the statusCode associated with each Result Observation.

Example 30 Laboratory Test with All Results Completed[35]

```
<component>
    <section>
        <!-- Results Section with Coded Entries Required-->
        <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 and/or laboratory data"/>
        <title>Results CO2 Example</title>
        <text>
            <!-- table omitted for space -->
        </text>
        <entry typeCode="DRIV">
            <organizer classCode="BATTERY" moodCode="EVN">
                <templateId root="2.16.840.1.113883.10.20.22.4.1"/>
                <id root="8DFF4B72-E8FE-11E4-B48A-460231621F93"/>
                <!-- This code specifies panel type - single result so just used result code-->
                <code code="2028-9" codeSystem="2.16.840.1.113883.6.1"
                    codeSystemName="LOINC" displayName="Carbon dioxide"/>
                <statusCode code="completed"/>
                <!-- Typically more than one component would be present - only one present in
test data -->
                <component>
                    <observation classCode="OBS" moodCode="EVN">
                        <templateId root="2.16.840.1.113883.10.20.22.4.2"/>
                        <id root="503B5578-E8FF-11E4-B48A-460231621F93"/>
                        <code code="2028-9" codeSystem="2.16.840.1.113883.6.1"
                            codeSystemName="LOINC" displayName="Carbon dioxide">
                            <originalText>
                                <reference value="#ResultComp1Name"/>
                            </originalText>
                        </code>
                        <text>
                            <reference value="#ResultComp1"/>
                        </text>
                        <statusCode code="completed"/>
```

[35] source: https://github.com/benjaminflessner/HL7-C-CDA-Task-Force-Examples/blob/master/Results CO2 Example.xml


```
                        <!-- Time is not present in laboratory result although very uncommon -
added time-->
                        <effectiveTime value="201208151005-0800"/>
                        <value xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
                        xsi:type="PQ" unit="mmol/L" value="27"/>
                        <interpretationCode code="N" codeSystem="2.16.840.1.113883.5.83"/>
                        <referenceRange>
                            <observationRange>
                                <text>23-29 mmol/L</text>
                                <value xsi:type="IVL_PQ">
                                    <low value="23" unit="mmol/L" />
                                    <high value="29" unit="mmol/L" />
                                </value>
                            </observationRange>
                        </referenceRange>
                    </observation>
                </component>
            </organizer>
        </entry>
    </section>
</component>
```

The effectiveTime on the Result Organizer is an interval that spans the effectiveTimes of the contained result observations. Because all contained result observations have a required time stamp, it is not required that the effectiveTime of the Result Organizer be populated. The effectiveTime on each component Result Observation, when encoded as a single timestamp (TS), represents the time the test was started. If the result is pending, then the statusCode of the component Result Observation will be "active". The effectiveTime information contained in the Result Observation may have been provided by the laboratory providing the result information.

The example below shows a laboratory test with a pending result. Even if this laboratory test had additional completed results included in the component Result Observations, as long as there was even one pending result, the Result Organizer statusCode would be "active". The Result Organizer statusCode is represented as "completed" when all component Result Observations are "completed".

Example 31 Laboratory Test with Pending Result[36]

```
<component>
    <section>
        <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 = "RESULTS"/>
        <title>RESULTS</title>
        <text>
            <table border = "1" width = "100%">
                <thead>
                    <tr>
                        <th>Name</th>
                        <th>Actual Result</th>
                        <th>Date</th>
                    </tr>
                </thead>
                <tbody>
```

[36] source: https://github.com/donaldson-ed/taskforceExample/blob/master/Result_panel_with_pending_component.xml


```
                    <tr>
                        <td>CBC with Ordered Manual Differential panel - Blood</td>
                        <td/>
                        <td>8/6/2012</td>
                    </tr>
                    <tr>
                        <td>
                            <content ID = "result5">Leukocytes [#/volume] in Blood by Manual
count [LOINC: 804-5]</content>
                        </td>
                        <!-- Representation of the pending test in the narrative section -->
                        <td>Pending</td>
                        <td>8/6/2012</td>
                    </tr>
                </tbody>
            </table>
        </text>
        <entry typeCode = "DRIV">
            <organizer classCode = "BATTERY" moodCode = "EVN">
                <templateId root = "2.16.840.1.113883.10.20.22.4.1"/>
                <id root = "7d5a02b0-67a4-11db-bd13-0800200c9a66"/>
                <code xsi:type="CE" code="57782-5" displayName = "CBC with Ordered Manual
Differential panel - Blood" codeSystemName = "LOINC" codeSystem = "2.16.840.1.113883.6.1"/>
                        <!-- Status is active since all components are not complete -->
                <statusCode code = "active"/>
                <component>
                    <observation classCode = "OBS" moodCode = "EVN">
                        <templateId root = "2.16.840.1.113883.10.20.22.4.2"/>
                        <id root = "68762391-bfa5-4dfa-9f6f-d37109a97d19"/>
                        <code xsi:type = "CE" code = "804-5" displayName = "Leukocytes [#/volume]
in Blood by Manual count" codeSystem = "2.16.840.1.113883.6.1" codeSystemName = "LOINC"/>
                        <text>
                            <reference value = "#result5"/>
                        </text>
                        <!-- Status of this test is active -->
                        <statusCode code = "active"/>
                        <effectiveTime value = "20120806"/>
                        <!-- This should represent what the EHR or other system received from the
lab -->
                        <!-- The more common scenario is the result is not present -->
                        <!-- The task force created this example becasue it came up during
certification testing-->
                        <!-- We do not believe this is a common scenario -->
                        <value xsi:type="PQ" nullFlavor="NA"/>
                        </observation>
                </component>
            </organizer>
        </entry>
    </section>
</component>
```

4.4.6 Smoking Status vs. Tobacco Use

In the Social History Section (V3) template there are two entry templates used for specifying a patient's smoking status and overall tobacco use. The Smoking Status– Meaningful Use (V2) template is used to represent the patient's current smoking status. Within this template, the effectiveTime is the date/time when the observation of the patient's current smoking status was made. Within the Social History Section of a document there can be more than one Smoking Status observations recorded, as the person's "current" smoking status may have been recorded at different points in time. The Smoking

Status– Meaningful Use (V2) template shall not be used for identifying when the current smoking status started. That information is recorded using the Tobacco Use entry template.

To provide details of the patient's smoking and overall tobacco use, the Tobacco Use (V2) entry shall be used. Within this entry, the effectiveTime represents the biologically relevant time of the observation. Thus, an observation of "cigarette smoker" would have an effectiveTime/low that details when the patient started smoking cigarettes and an effectiveTime/high that details when the patient stopped smoking cigarettes (assuming the patient had stopped smoking). If the patient is a current smoker, then the effectiveTime/high would not be specified, thus indicating that the "cigarette smoker" observation is still ongoing.

The Tobacco Use entry is used to describe the patient's particular uses of tobacco with the associated date ranges, whereas the Smoking Status - Meaningful Use (V2) template is used to represent a "snapshot in time" observation reflecting what the patient's smoking status is at the point in time when the observation was made. Thus, when timing information is provided with 'smoking status' information, a Smoking Status entry would be used to record the current smoking status and a second Tobacco Use entry would be used to record the timing information.

The Tobacco Use observation shall not include any codes which imply timing (i.e. Former Smoker, Never smoker, Unknown if ever smoked). To communicate dating information (for example, the quit date of a Former Smoker), a proper code of current smoker (7717602) should be used with an effectiveTime/low and effectiveTime/high defining the time during which the patient was a smoker. If more detailed information is known about smoking use (such as the type of tobacco used, i.e. 65568007 - Cigarette smoker), then a more appropriate code may be used.

Example 32 Unknown Smoking Status[37]

```
<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>
                            <content>Started: </content>
                            <content>Stopped:</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"/>
```

[37] source: https://github.com/jddamore/HL7-Task-Force-Examples/blob/master/SMOKING_Unknown_Smoker.xml


```
                        <value xsi:type="CD" codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMED CT" code="266927001" displayName="Unknown if ever smoked"/>
                        <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>
```

Example 33 Tobacco Use –Smoker with a known last 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 value="20160412"/>
        </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>
```


5 Resources

The following information is supplied as a starting point for information on the various tools and information one may find useful for developing conformant C-CDA implementations.

5.1 Sample C-CDA Files

Published along with this Companion Guide, there are sample C-CDA files for each document type specified in the 2015 Edition Certification Criteria.
These samples were developed during the second HL7 C-CDA Implementation-A-Thon that was held in Chicago, IL from April 14-15, 2016. There is a PDF scenario document that details what each document was intended to convey to accompany the associated C-CDA file. Additionally, for each document type, a sample from the ONC SITE C-CDA Validator site has been included.

Table 17 Sample Scenarios and Files

Scenario File	CDA Sample File
CCD-Scenario.pdf	CCD-Sample.xml
DischageSummary-Scenario.pdf	DischargeSummary-Sample.xml
ReferralNote-Scenario.pdf	ReferralNote-Sample.xml
n/a	SITE-CCD-Sample.xml
n/a	SITE-DischargeSummary-Sample.xml
n/a	SITE-ReferralNote-Sample.xml
n/a	SITE-CarePlan-Sample.xml

5.2 Tools

Below are brief descriptions of a number of tools available to support C-CDA development.

5.2.1 ECLIPSE 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. MDHT also supplies a Java Runtime which is available here https://github.com/mdht

- **Open Health CDA Tools**: http://cdatools.org/
- **MDHT:** https://projects.eclipse.org/projects/modeling.mdht

5.2.2 SITE Validation and Testing Resources

ONC has provided a Standards Implementation & Testing Environment (SITE) which provides tools for testing C-CDA implementations.

- **Validation**: https://sitenv.org/c-cda-validator
- **C-CDA Scorecard (Beta)**: https://sitenv.org/scorecard/

5.3 Educational Resources

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

5.3.1 Clinical Document Architecture (CDA)

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

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

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

- **The CDA Book:** Written by Keith W. Boone, The CDA Book provides clear and simplified guidance for the HL7 CDA standard, the foundation of Consolidated CDA. The book is available for purchase through retailers and is highly recommended to assist in understanding core concepts of the standard.
  Amazon.com: http://www.amazon.com/The-CDA-book-Keith-Boone/dp/0857293354/ref=sr_1_1?ie=UTF8&qid=1337020821&sr=8-1

5.3.2 HL7 Structured Documents Work Group

As the custodian of the Consolidated CDA IG, the HL7 Structured Documents work group (SDWG) is a good resource for additional guidance with implementations. There are a number of sub-categories available from the main SDWG wiki page relative to the use of CDA. Users of CDA documents are encouraged to sign up for the Structured Documents listserv to learn and share expertise with other users.

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

5.3.3 CDA Examples Task Force

The CDA Examples Task Force has created a large number of examples on how to convey information accurately in a CDA document. There is a CDA Example search tool that allows users to find examples based on keywords:

- **HL7 CDA Example Task Force:** http://hl7-c-cda-examples.herokuapp.com/

A. New C-CDA Templates

The following templates are new templates that were produced as a result of discussions at the Implementation-A-Thons between implementers and the ONC. To represent Birth Sex and Section Time, these templates were created and are being presented in this Companion Guide.

A.1. Birth Sex Observation

`[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.200:2016-06-01 (open)]`

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.

This observation is not appropriate for recording patient gender (administrativeGender).

Table 18: Birth Sex Observation Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.200:2016-06-01)					
@classCode	1..1	SHALL		3250-18230	urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = OBS
@moodCode	1..1	SHALL		3250-18231	urn:oid:2.16.840.1.113883.5.1001 (ActMood) = EVN
templateId	1..1	SHALL		3250-18232	
@root	1..1	SHALL		3250-18233	2.16.840.1.113883.10.20.22.4.200
@extension	1..1	SHALL		3250-32949	2016-06-01
code	1..1	SHALL		3250-18234	
@code	1..1	SHALL		3250-18235	76689-9
@codeSystem	1..1	SHALL		3250-21163	urn:oid:2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1
statusCode	1..1	SHALL		3250-18124	
@code	1..1	SHALL		3250-18125	urn:oid:2.16.840.1.113883.5.14 (ActStatus) = completed
value	1..1	SHALL	CD	3250-32947	urn:oid:2.16.840.1.113762.1.4.1 (ONC Administrative Sex)

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6 **STATIC**) (CONF:3250-18230).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" (CodeSystem: ActMood urn:oid:2.16.840.1.113883.5.1001 **STATIC**) (CONF:3250-18231).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:3250-18232) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.200" (CONF:3250-18233).
    b. **SHALL** contain exactly one [1..1] **@extension**="2016-06-01" (CONF:3250-32949).

4. **SHALL** contain exactly one [1..1] **code** (CONF:3250-18234).
    a. This code **SHALL** contain exactly one [1..1] **@code**="76689-9" Sex Assigned At Birth (CONF:3250-18235).
    b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1 **STATIC**) (CONF:3250-21163).
5. **SHALL** contain exactly one [1..1] **statusCode** (CONF:3250-18124).
    a. This statusCode **SHALL** contain exactly one [1..1] **@code**="completed" Completed (CodeSystem: ActStatus urn:oid:2.16.840.1.113883.5.14 **STATIC**) (CONF:3250-18125).
6. **SHALL** contain exactly one [1..1] **value** with @xsi:type="CD", where the code **SHALL** be selected from ValueSet **ONC Administrative Sex** urn:oid:2.16.840.1.113762.1.4.1 **STATIC** 2016-06-01 (CONF:3250-32947).

If value/@code not from value set ONC Administrative Sex urn:oid:2.16.840.1.113762.1.4.1 STATIC 2016-06-01, then value/@nullFlavor **SHALL** be "UNK" (CONF:3250-32948).

Figure 4: Birth Sex Template Example

```
<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>
    <author>
           ...
        </author>
</observation>
```


A.2. Section Time Range Observation

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.201:2016-06-01 (open)]

This observation represents the date and time range of the information contained in a section. It is an optional entry and may be used in any section.

Table 19: Section Time Range Observation Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.201:2016-06-01)					
@classCode	1..1	SHALL		3250-32960	urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = OBS
@moodCode	1..1	SHALL		3250-32961	urn:oid:2.16.840.1.113883.5.1001 (ActMood) = EVN
templateId	1..1	SHALL		3250-32951	
@root	1..1	SHALL		3250-32955	2.16.840.1.113883.10.20.22.4.201
@extension	1..1	SHALL		3250-32956	2016-06-01
code	1..1	SHALL		3250-32952	
@code	1..1	SHALL		3250-32957	82607-3
@codeSystem	1..1	SHALL		3250-32958	urn:oid:2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1
text	1..1	SHALL		3250-32962	
reference	1..1	SHALL		3250-32963	
@value	1..1	SHALL		3250-32964	
statusCode	1..1	SHALL		3250-32950	
@code	1..1	SHALL		3250-32954	urn:oid:2.16.840.1.113883.5.14 (ActStatus) = completed
value	1..1	SHALL	IVL_TS	3250-32953	
low	1..1	SHALL		3250-32965	
high	1..1	SHALL		3250-32966	

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6 **STATIC**) (CONF:3250-32960).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" (CodeSystem: ActMood urn:oid:2.16.840.1.113883.5.1001 **STATIC**) (CONF:3250-32961).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:3250-32951) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.201" (CONF:3250-32955).

b. **SHALL** contain exactly one [1..1] **@extension**="2016-06-01" (CONF:3250-32956).

4. **SHALL** contain exactly one [1..1] **code** (CONF:3250-32952).
    a. This code **SHALL** contain exactly one [1..1] **@code**=" 82607-3" Section Time Range (CONF:3250-32957).
    b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1 **STATIC**) (CONF:3250-32958).
5. **SHALL** contain exactly one [1..1] **text** (CONF:3250-32962).
    a. This text **SHALL** contain exactly one [1..1] **reference** (CONF:3250-32963).
        i. This reference **SHALL** contain exactly one [1..1] **@value** (CONF:3250-32964).
6. **SHALL** contain exactly one [1..1] **statusCode** (CONF:3250-32950).
    a. This statusCode **SHALL** contain exactly one [1..1] **@code**="completed" Completed (CodeSystem: ActStatus urn:oid:2.16.840.1.113883.5.14 **STATIC**) (CONF:3250-32954).
7. **SHALL** contain exactly one [1..1] **value** with @xsi:type="IVL_TS" (CONF:3250-32953).
    a. This value **SHALL** contain exactly one [1..1] **low** (CONF:3250-32965).
    b. This value **SHALL** contain exactly one [1..1] **high** (CONF:3250-32966).

Figure 5: Section Time Range Template Example

```
<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="#TS_Narrative1"/>
    </text>
    <statusCode code="completed"/>
    <value xsi:type="IVL_TS">
        <low value="20120815"/>
        <high value="20150815"/>
    </value>
</observation>
```


A.3. Note Activity

[act: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.202:2016-11-01 (open)]

Table 20: Note Activity Contexts

Contained By:	Contains:
Any Open Entry-Level Template Any Open Section Notes Section (required)	Author Participation Encounter Activity

The Note Activity represents a clinical note. Notes require authorship, authentication, timing information, and references to other discrete data such as encounters. Similar to the Comment Activity, the Note Activity permits a more specific code to characterize the type of information available in the note. The Note Activity template SHOULD NOT be used in place of a more specific C-CDA entry. Note information included needs to be relevant and pertinent to the information being communicated in the document.

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 Procedure Note added as an entryRelationship to a Procedure Activity Procedure entry).

The Note Activity template 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.

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 Notes Section. (e.g. a free-text consultation note or a note which includes subjective, objective, assessment, and plan information combined).

An alternative is to place the Note Activity as an entryRelationship to an Encounter Activity entry in the Encounters Section, but implementers may wish to group notes categorically into a separate location in CDA documents rather than overloading the Encounters Section.

Table 21: Note Activity Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
act (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.202:2016-11-01)					
@classCode	1..1	SHALL		3250-16899	ACT
@moodCode	1..1	SHALL		3250-16900	EVN
templateId	1..1	SHALL		3250-16933	
@root	1..1	SHALL		3250-16934	2.16.840.1.113883.10.20.22.4.202
@extension	1..1	SHALL		3250-16937	2016-11-01

code	1..1	SHALL		3250-16895	
@code	1..1	SHALL		3250-16940	urn:oid:2.16.840.1.113883.6.1 (LOINC) = 34109-9
@codeSystem	1..1	SHALL		3250-16941	2.16.840.1.113883.6.1
translation	0..*	SHOULD		3250-16939	urn:oid:2.16.840.1.113883.11.20.9.68 (Note Types)
text	1..1	SHALL		3250-16896	
@mediaType	0..1	MAY		3250-16906	urn:oid:2.16.840.1.113883.11.20.7.1 (SupportedFileFormats)
reference	1..1	SHALL		3250-16897	
@nullFlavor	0..0	SHALL NOT		3250-16920	
@value	1..1	SHALL		3250-16898	
statusCode	1..1	SHALL		3250-16916	
effectiveTime	1..1	SHALL		3250-16903	
@value	0..1	SHOULD		3250-16917	
author	1..*	SHALL		3250-16913	Author Participation (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.119
participant	0..*	MAY		3250-16923	
@typeCode	1..1	SHALL		3250-16925	LA
time	1..1	SHALL		3250-16926	US Realm Date and Time (DT.US.FIELDED) (identifier: urn:oid:2.16.840.1.113883.10.20.22.5.3
participantRole	1..1	SHALL		3250-16924	
id	1..*	SHALL		3250-16927	
playingEntity	0..1	MAY		3250-16928	
name	0..*	SHALL		3250-16929	US Realm Person Name (PN.US.FIELDED) (identifier: urn:oid:2.16.840.1.113883.10.20.22.5.1.1
entryRelationship	0..*	SHOULD		3250-16907	
@typeCode	1..1	SHALL		3250-16921	COMP

@inversionInd	1..1	SHALL		3250-16922	true
@negationInd	0..1	MAY		3250-16931	
encounter	1..1	SHALL		3250-16908	
id	1..*	SHALL		3250-16909	
reference	0..*	MAY		3250-16910	
externalDocument	1..1	SHALL		3250-16911	
id	1..1	SHALL		3250-16915	
code	0..1	SHOULD		3250-16918	

1. **SHALL** contain exactly one [1..1] **@classCode**="ACT" Act (CONF:3250-16899).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CONF:3250-16900).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:3250-16933) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.202" (CONF:3250-16934).
    b. **SHALL** contain exactly one [1..1] **@extension**="2016-11-01" (CONF:3250-16937).
4. **SHALL** contain exactly one [1..1] **code** (CONF:3250-16895).
    a. This code **SHALL** contain exactly one [1..1] **@code**="34109-9" Note (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:3250-16940).
    b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" LOINC (CONF:3250-16941).
    c. This code **SHOULD** contain zero or more [0..*] **translation**, which **SHALL** be selected from ValueSet **Note Types** urn:oid:2.16.840.1.113883.11.20.9.68 (CONF:3250-16939) such that it

For example - a Cardiologist consult note may specialize a Consult note but not a Progress note

        i. When the Note Activity is within a Note Section, the code **SHOULD** match or specialize the section code (CONF:3250-16942).
        ii. If the Note Activity is within a typically narrative-only section, the code **MAY** match the section code (CONF:3250-16943).

5. **SHALL** contain exactly one [1..1] **text** (CONF:3250-16896).

If the note was originally in another format, such as RTF, this element may also contain the base-64-encoded raw data of the note in addition to a reference to the narrative.

    a. This text **MAY** contain zero or one [0..1] **@mediaType**, which **SHOULD** be selected from ValueSet **SupportedFileFormats** urn:oid:2.16.840.1.113883.11.20.7.1 (CONF:3250-16906).

i. If @mediaType is present, the text **SHALL** contain exactly one 1..1] @representation="B64" and mixed content corresponding to the contents of the note (CONF:3250-16912).

b. This text **SHALL** contain exactly one [1..1] **reference** (CONF:3250-16897).

The note activity must reference human-readable content in the narrative, so this reference must not be null.

i. This reference **SHALL NOT** contain [0..0] **@nullFlavor** (CONF:3250-16920).

ii. This reference **SHALL** contain exactly one [1..1] **@value** (CONF:3250-16898).

1. 1. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:3250-16902).

Indicates the status of the note. The most common statusCode is completed indicating the note is signed and finalized.

6. **SHALL** contain exactly one [1..1] **statusCode** (CONF:3250-16916).

The effectiveTime represents the clinically relevant time of the note. The precise timestamp of creation / updating should be conveyed in author/time.

7. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:3250-16903).

a. This effectiveTime **SHOULD** contain zero or one [0..1] **@value** (CONF:3250-16917).

Represents the person(s) who wrote the note.

8. **SHALL** contain at least one [1..*] Author Participation (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.119) (CONF:3250-16913).

Represents the person(s) legally responsible for the contents of the note.

9. **MAY** contain zero or more [0..*] **participant** (CONF:3250-16923) such that it

a. **SHALL** contain exactly one [1..1] **@typeCode**="LA" Legal Authenticator (CONF:3250-16925).

Indicates the time of signing the note.

b. **SHALL** contain exactly one [1..1] US Realm Date and Time (DT.US.FIELDED) (identifier: urn:oid:2.16.840.1.113883.10.20.22.5.3) (CONF:3250-16926).

c. **SHALL** contain exactly one [1..1] **participantRole** (CONF:3250-16924).

This may be the ID of the note author. If so, no additional information in this participant is required.

i. This participantRole **SHALL** contain at least one [1..*] **id** (CONF:3250-16927).

ii. This participantRole **MAY** contain zero or one [0..1] **playingEntity** (CONF:3250-16928).

1. The playingEntity, if present, **SHALL** contain zero or more [0..*] US Realm Person Name (PN.US.FIELDED) (identifier: urn:oid:2.16.840.1.113883.10.20.22.5.1.1) (CONF:3250-16929).

iii. If no id matches an author or participant elsewhere in the document, then playingEntity **SHALL** be present (CONF:3250-16930).

Links the note to an encounter. If the Note Activity is present within a document containing an encompassingEncounter, then this entryRelationship is optional and the note is associated with the encounter represented by the encompassingEncounter.

10. **SHOULD** contain zero or more [0..*] **entryRelationship** (CONF:3250-16907) such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="COMP" (CONF:3250-16921).
    b. **SHALL** contain exactly one [1..1] **@inversionInd**="true" (CONF:3250-16922).

To communicate that the note is not associated with any encounter, this entryRelationship MAY be included with @negationInd=true and encounter/id/@nullFlavor=NA. The negationInd + encounter indicate this note is not associated with any encounter.

    c. **MAY** contain zero or one [0..1] **@negationInd** (CONF:3250-16931).
    d. **SHALL** contain exactly one [1..1] **encounter** (CONF:3250-16908).
        i. This encounter **SHALL** contain at least one [1..*] **id** (CONF:3250-16909).
            1. If the id does not match an encounter/id from the Encounters Section within the same document and the id does not contain @nullFlavor=NA, then this entry **SHALL** conform to the Encounter Activity (V3) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.49:2015-08-01) (CONF:3250-16914).

Represents an unstructured C-CDA document containing the original contents of the note in the original format.

11. **MAY** contain zero or more [0..*] **reference** (CONF:3250-16910) such that it
    a. **SHALL** contain exactly one [1..1] **externalDocument** (CONF:3250-16911).
        i. This externalDocument **SHALL** contain exactly one [1..1] **id** (CONF:3250-16915).
        ii. This externalDocument **SHOULD** contain zero or one [0..1] **code** (CONF:3250-16918).

Figure 6: 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>
```

Figure 7: 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>
```


Figure 8: 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">e1xydGYxXGFuc2lcYW5zaWNwZzEyNTJcZGVmZjBcbm91aWNvbXBhdFxkZWZsYW5nMTAzM3tcZm9u
dHRibHtcZjBcZm5pbFxmY2hhcnNldDAgQ2FsaWJyaTt9fQ0Ke1wqXGdlbmVyYXRvciBSaWNoZWQyMCA2LjMuOTYwMH1cdmlld
2tpbmQ0XHVjMSANClxwYXJkXHNhMjAwXHNsMjc2XHNsbXVsdDFcZjBcZnMyMlxsYW5nOSBDb21wbGV0ZWQgcm91bmRzOyBuby
BpbmNpZGVudFxwYXINCn0NCiA=
                <reference value="#note1"/>
            </text>
            <!--...-->
        </act>
    </entry>
```


A.4. Notes Section

[section: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.2.65:2016-11-01 (open)]

Table 22: Notes Section Contexts

Contained By:	Contains:
	Note Activity

The Notes Section allow 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 SHOULD NOT be 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 23: Notes Section Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
section (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.2.65:2016-11-01)					
templateId	1..1	SHALL		3250-16935	
@root	1..1	SHALL		3250-16936	2.16.840.1.113883.10.20.22.2.65
@extension	1..1	SHALL		3250-16938	2016-11-01
code	1..1	SHALL		3250-16892	urn:oid:2.16.840.1.113883.11.20.9.68 (Note Types)
title	1..1	SHALL		3250-16891	
text	1..1	SHALL		3250-16894	
entry	1..*	SHALL		3250-16904	
act	1..1	SHALL		3250-16905	Note Activity (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.202:2016-11-01

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:3250-16935) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.2.65" (CONF:3250-16936).
   b. **SHALL** contain exactly one [1..1] **@extension**="2016-11-01" (CONF:3250-16938).
2. **SHALL** contain exactly one [1..1] **code**, which **SHOULD** be selected from ValueSet **Note Types** urn:oid:2.16.840.1.113883.11.20.9.68 (CONF:3250-16892).

This title should reflect the kind of notes included in this section, corresponding to the code.

3. **SHALL** contain exactly one [1..1] **title** (CONF:3250-16891).

The narrative SHOULD contain human-readable representations using standard CDA narrative markup of each note to ensure widest compatibility with receivers.

While allowed by CDA, the use of <renderMultiMedia> elements, which contain a referencedObject attribute pointing to an <observationMedia> or <regionOfInterest> element in the discrete entries, is discouraged in Note Sections because rendering support for these elements is not widespread.

4. **SHALL** contain exactly one [1..1] **text** (CONF:3250-16894).
5. **SHALL** contain at least one [1..*] **entry** (CONF:3250-16904) such that it
    a. **SHALL** contain exactly one [1..1] **Note Activity** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.202:2016-11-01) (CONF:3250-16905).

Figure 9: Note Section Example

```
<section>
    <!-- Notes Section -->
    <templateId root="2.16.840.1.113883.10.20.22.2.65" extension="2016-11-01"/>
    <code code="11488-4" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
displayName="Consultation note"/>
    <title>Consultation Notes</title>
    <text>
        <list>
            <item ID="ConsultNote1">
                <paragraph>Dr. Specialist - September 8, 2016</paragraph>
                <paragraph>Evaluated patient due to symptoms of...</paragraph>
            </item>
        </list>
    </text>
    <!-- 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”>
                <!-- Code must match or be equivalent to section code -->
                <translation code="11488-4" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Consultation note" />
            </code>
            <text>
                <reference value="#ConsultNote1" />
            </text>
            <statusCode code="completed"/>
            <!-- Clinically-relevant time of the note -->
            <effectiveTime value="20160908" />
            <!--...-->
        </entry>
    </section>
```


A.5. New Section and Entry Template Ids

Table 24: New Section and Entry Template Ids

Template Title	Template Type	templateId
Birth Sex Observation	entry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.200:2016-06-01
Section Time Range Observation	entry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.201:2016-06-01
Notes Activity	entry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.202:2016-11-01
Notes Section	section	urn:hl7ii:2.16.840.1.113883.10.20.22.2.65:2016-11-01

A.6. New Value Sets

Table 25: New Value Sets

Value Set: ONC Administrative Sex urn:oid:2.16.840.1.113762.1.4.1
ONC Administrative Sex.

Code	Code System	Code System OID	Print Name
F	HL7AdministrativeGender	urn:oid:2.16.840.1.113883.5.1	Female
M	HL7AdministrativeGender	urn:oid:2.16.840.1.113883.5.1	Male

Value Set: SupportedFileFormats urn:oid:2.16.840.1.113883.11.20.7.1
A value set of the file formats supported by the Unstructured Document IG.

Code	Code System	Code System OID	Print Name
application/msword	Media Type	urn:oid:2.16.840.1.113883.5.79	MSWORD
application/pdf	Media Type	urn:oid:2.16.840.1.113883.5.79	PDF
text/plain	Media Type	urn:oid:2.16.840.1.113883.5.79	Plain Text
text/rtf	Media Type	urn:oid:2.16.840.1.113883.5.79	RTF Text
text/html	Media Type	urn:oid:2.16.840.1.113883.5.79	HTML Text
image/gif	Media Type	urn:oid:2.16.840.1.113883.5.79	GIF Image
image/tiff	Media Type	urn:oid:2.16.840.1.113883.5.79	TIF Image
image/jpeg	Media Type	urn:oid:2.16.840.1.113883.5.79	JPEG Image
image/png	Media Type	urn:oid:2.16.840.1.113883.5.79	PNG Image

Value Set: NoteTypes urn:oid:2.16.840.1.113883.11.20.9.68
All LOINC codes where scale=document.

Code	Code System	Code System OID	Print Name
11506-3	LOINC	urn:oid:2.16.840.1.113883.6.1	Progress note
28570-0	LOINC	urn:oid:2.16.840.1.113883.6.1	Procedure note
34117-2	LOINC	urn:oid:2.16.840.1.113883.6.1	History and physical note
34746-8	LOINC	urn:oid:2.16.840.1.113883.6.1	Nurse Note
11504-8	LOINC	urn:oid:2.16.840.1.113883.6.1	Surgical operation note
34109-9	LOINC	urn:oid:2.16.840.1.113883.6.1	Note
11488-4	LOINC	urn:oid:2.16.840.1.113883.6.1	Consultation note
57133-1	LOINC	urn:oid:2.16.840.1.113883.6.1	Referral note
18761-7	LOINC	urn:oid:2.16.840.1.113883.6.1	Transfer note
18842-5	LOINC	urn:oid:2.16.840.1.113883.6.1	Discharge summary
…			

A.7. Code Systems Used in New Templates

Table 26: Code Systems Used in New Templates

Name	OID
HL7ActMood	urn:oid:2.16.840.1.113883.5.1001
HL7ActStatus	urn:oid:2.16.840.1.113883.5.14
HL7AdministrativeGender	urn:oid:2.16.840.1.113883.5.1
HL7ActClass	urn:oid:2.16.840.1.113883.5.6
LOINC	urn:oid:2.16.840.1.113883.6.1
Media Type	urn:oid:2.16.840.1.113883.5.79

