

Implementation Guide for CDA Release 2.0
Patient Authored Note (PAN) Document
(Universal Realm)
And
(US Realm)

Draft version: November 2012

Primary Editor: Virinder Batra
Intuit Health
virinder_batra@intuit.com

Primary Editor: Lisa Nelson
Life Over Time Solutions
LisaRNelson@cox.net

Co-Editor: Jessi Formoe
Intuit Health
jessi_formoe@intuit.com

Co-Editor: Leslie Kelly Hall
Healthwise
lkellyhall@healthwise.org

Co-Editor: Shawn Meyers
Healthwise
smyers@healthwise.org

Co-Editor: Brian Scheller
Healthwise
bscheller@healthwise.org

Co-Editor: Gordon Raup
Datuit LLC
graup@datuit.com

Co-Editor: Elaine Ayres
National Institutes of Health
Eayres@cc.nih.gov

Co-Editor: Allen Traylor
Child Health& Development
Interactive System (CHADIS)
atraylor@chadis.com

Co-Editor: Stephen Chu
National E-Health Transition
Authority (NEHTA) Australia
stephen.chu@nehta.gov.au

Co-Editor: Emma Jones
Allscripts
emma.jones@allscripts.com

Co-Chair/Co-editor: Robert H. Dolin, MD
Lantana Consulting Group
bob.dolin@lantanagroup.com

Co-Chair: Calvin Beebe
Mayo Clinic
cbeebe@mayo.edu

Co-Chair: Rob Hausam
Hausam Consulting
rrhausam@gmail.com

Co-Chair: Austin Kreisler
SAIC Consultant to CDC/NHSN
duz1@cdc.gov

Co-Chair: Brett Marquard
Lantana Consulting Group
brett.marquard@lantanagroup.co

Co-Editor: Kevin Harbauer
Healthwise
kharbauer@healthwise.org

Co-Editor: David Tao
Siemens
David.Tao@siemens.com

Co-Editor: Catherine Welsh
St Judes Research Hospital
Catherine.Welsh@stjude.org

Co-Editor: Chris Schultz
Child Health& Development
Interactive System (CHADIS)
cschultz@chadis.com

Co-Editor: Vin Sekar
National E-Health Transition
Authority (NEHTA) Australia
vin.sekar@nehta.gov.au

Table of Contents

OPEN ISSUES.....	7
1 INTRODUCTION.....	9
1.1 Audience	9
1.2 Purpose.....	9
1.3 Scope	10
1.4 Approach.....	10
1.5 Organization of This Guide	11
1.10 Content of the Package	11
2 GENERAL, UNIVERSAL REALM, PATIENT AUTHORED NOTE HEADER TEMPLATE	12
2.1 Document Type Codes	12
2.2 Patient Authored Document Header	12
2.2.1 RecordTarget.....	15
2.2.2 Author	19
2.2.3 DataEnterer	21
2.2.4 Informant.....	22
2.2.5 Custodian	23
2.2.6 InformationRecipient	24
2.2.7 LegalAuthenticator	25
2.2.8 Authenticator	26
2.2.9 Participant (Support)	27
2.2.10 InFulfillmentOf.....	29
2.2.11 DocumentationOf/serviceEvent	29
2.2.12 Authorization/consent.....	31
2.2.13 ComponentOf.....	32
2.3 Rendering Header Information for Human Presentation	32
3 GENERAL US REALM PATIENT AUTHORED NOTE HEADER TEMPLATE	35
3.1 Document Type Codes	35
3.2 US Realm Patient Authored Note Document Header	35
3.2.1 RecordTarget.....	38
3.2.2 Author	49
3.2.3 DataEnterer	51
3.2.4 Informant.....	52

3.2.5	Custodian	54
3.2.6	InformationRecipient	55
3.2.7	LegalAuthenticator	56
3.2.8	Authenticator	58
3.2.9	Participant (Support)	59
3.2.10	InFulfillmentOf.....	61
3.2.11	DocumentationOf/serviceEvent	61
3.2.12	Authorization/consent.....	64
3.2.13	ComponentOf.....	65
3.3	US Realm Address (AD.US.FIELDDED)	65
3.4	US Realm Date and Time (DT.US.FIELDDED)	66
3.5	US Realm Date and Time (DTM.US.FIELDDED)	67
3.6	US Realm Patient Name (PTN.US.FIELDDED)	67
3.7	US Realm Person Name (PN.US.FIELDDED).....	69
3.8	Rendering Header Information for Human Presentation	69
APPENDIX A. PARTICIPANT SCENARIOS.....		70

Table of Figures

Figure 1: US Realm header example	14
Figure 2: effectiveTime with time zone example	15
Figure 3: recordTarget example	18
Figure 4: Person author example	20
Figure 5: Device author example	21
Figure 6: dataEnterer example	22
Figure 7: Informant with assignedEntity example	23
Figure 8: Custodian example	24
Figure 9: informationRecipient example	25
Figure 10: legalAuthenticator example	26
Figure 11: Authenticator example	27
Figure 12: Participant example for a supporting person	28
Figure 13: DocumentationOf example	31
Figure 14: Procedure note consent example	32
Table of TablesTable 1: Content of the Package	11
Table 2: Basic Confidentiality Kind Value Set	13
Table 3: Language Value Set (excerpt)	14
Table 4: Country Value Set (excerpt)	17
Table 5: IND Role classCode Value Set	28
Table 6: Basic Confidentiality Kind Value Set	36
Table 7: Language Value Set (excerpt)	37
Table 8: Telecom Use (US Realm Header) Value Set	42
Table 9: Administrative Gender (HL7) Value Set	42
Table 10: Marital Status Value Set	43
Table 11: Religious Affiliation Value Set (excerpt)	43
Table 12: Race Value Set (excerpt)	44
Table 13: Ethnicity Value Set	44
Table 14: Personal Relationship Role Type Value Set (excerpt)	45
Table 15: State Value Set (excerpt)	45
Table 16: Postal Code Value Set (excerpt)	46
Table 17: Country Value Set (excerpt)	46
Table 18: Language Ability Value Set	46

Table 19: Language Ability Proficiency Value Set.....	47
Table 20: IND Role classCode Value Set.....	60
Table 21: PostalAddressUse Value Set	66
Table 22: EntityNameUse Value Set.....	68
Table 23: EntityPersonNamePartQualifier Value Set.....	68

OPEN ISSUES

1. A request has been made to Regenstreif through Rob Hausam to add the following description to the existing LOINC code 51855-5. This request is pending.
 - a. Rob his confirming if the method can be changed to say “Patient or Patient’s Agent” or if we will need to request a different LOINC code (the first sub-code under the 51855-5 hierarchy) for documents where the method is Patient’s Agent.

REQUESTED - DEFINITION/DESCRIPTION for 51855-5

Source: HL7 Structured Documents Working Group

A Patient Authored Note is generated by a patient or a patient agent acting in a non-clinical role to provide clinically relevant information to support planned or unplanned health care services.

This document gives healthcare providers, and others involved in a person’s care, information which the patient considers essential input during care delivery and coordination. This document enables patients and their agents to contribute to the continuity of care.

Because a Patient Authored Note is generated by a person acting as a non-clinician, this document may not be a complete medical summary and should be considered in context with other information routinely collected by clinicians during care delivery and coordination.

This general class of patient authored notes includes information that is interoperable with data defined for clinician-generated documents. Other more specific classes of patient authored notes may include more tightly defined content.

This document may be generated from a patient-, clinician-, or payer-controlled source system.

Intention to Build a Hierarchy of codes for Patient Authored Notes

It is envisioned that the 51855-5 code will be the most general class of Patient Authored Note documents, and that additional more specific types of Patient Authored Notes will be created in the future.

2. A request has been initiated through Rob Hausam to have the code “SELF” added to the PersonalRelationshipRoleType value set.
3. A question has been posed through Rob Hausam to address how to specify a binding to two value sets. Should a new combined value set be created? This affects our need to join PersonalRelationshipRoleType with ResponsibleParty value sets in many places in the guide.
 - a. Rob has suggested we consider creating a new value set using SNOMED CT. This needs to be discussed with the team and the impact on timing needs to be considered. This suggestion affects #2 and #3.
4. It should be noted that mechanisms to encode and manage consent are inadequate for addressing expected consent management requirements. This represents current standard practices, and it is outside the scope of this project to address more robust consent mechanisms.
5. If the NUCC Health Care Provider Taxonomy (CodeSystem: 2.16.840.1.113883.6.101) does not have codes for allied health professions, then an additional value set will need to be added to expand any constraints referencing the NUCC Provider Taxonomy to include this additional taxonomy of allied health professions.
6. Errata currently reported against the Consolidated CDA General Header need to be identified and the adopted resolutions need to be applied.

7. Example snippets need to be updated.
8. A sample Patient Authored Note document using the US Realm Header should be generated.
9. The question came up of added a constraint on the ClinicalDocument/code to add the constraint for the use of 51855-5, but relax conformance to SHOULD for the UV Realm.

1 INTRODUCTION

1.1 Audience

The audiences for this implementation guide are the architects and developers of healthcare information technology (HIT) systems that exchange patient clinical data and seek to use data standards that are consistent with Universal or US Realm guidance. This includes those exchanges that comply to the Health Information Technology for Economic and Clinical Health (HITECH) provisions of the American Recovery And Reinvestment Act of 2009, the Final Rules for Stage 1 Meaningful Use, and the 45 CFR Part 170 – Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology; Final Rule.¹

Business analysts and policy managers can also benefit from a basic understanding of the use of Clinical Document Architecture (CDA) templates across multiple implementation use cases.

1.2 Purpose

The integration of patient generated data (PGHD) into the HIT is an important change to the HIT ecosystem. Although patients have long been the source of information recorded in the EHR, this information has been gathered orally or in paper forms, and transcribed by the provider in a way that is assessed, interpreted and summarized, and the original patient information may not be retained. Digital integration of PGHD provides the opportunity for patients to author data in a way that is consumable within the EHR.

Based upon recent testimony received by the HITSC and HITPC PGHD hearing, the successful inclusion of PGHD incorporates the following characteristics; information is material to the patient's experience of their own condition, meaningful to the provider, contextually relevant, consumable by the EHR in a familiar way and correctly attributed to the patient or designee. The ONC HITSC and HITPC have further directed that standards already directed in MU should be reused, repurposed and harmonized.

The purpose of this implementation guide is to develop a standard way within the current framework of structured documents in the evolving health information ecosystem to capture, record and make interoperable, patient generated information. The goal is to enable patients to participate and collaborate electronically with care team members.

¹ Many aspects of this guide were designed to meet the anticipated clinical document exchange requirements of Stage 3 Meaningful Use. At the time of this publication, Stage 3 Meaningful Use has not been published.

1.3 Scope

This implementation guide is intended to provide implementation guidance on the header elements for documents authored by patients or representatives of patients acting on behalf of the patient. It is modeled on the C-CDA header with the intent of being adopted as an alternative for the header used for clinician authored documents. It is expected that the C-CDA document library will be expanded over time to include patient & non-clinician generated C-CDA documents, and the C-CDA headers defined in this implementation will be used to guide the definition of these patient generated documents.

The following will be 'in scope' for this implementation guide

- Guidance and best practices for definition of the CDA header elements for the Patient authored documents
- Guidance on use of the patient authored headers (universal realm & US realm) in a general Patient Authored Note documents
- A set of 'patient' Use Cases to inform the best practices defined in this implementation guide

The following will not be in scope for this implementation guide

- Definition of new patient generated C-CDA document types. Even though the vision is for a new set of non-clinician generated consolidated document types, the new document types are NOT in scope for this implementation guide.

Implementers of this general Patient Authored Note document should consider utilizing section and entry templates defined in the Consolidated CDA Implementation Guide to maximize data interoperability. For example, a Patient Authored Note which included the same sections as a Continuity of Care Document would be a highly interoperable document because EHR systems that already exchange CCD documents would be well positioned to consume the patient generated content.

1.4 Approach

The Patient Authored Note header defines how to implement elements of the CDA header for documents that are generated by the patient or a person acting as a non-clinician and on behalf of the patient.

Like the General Header defined for Consolidated CDA documents authored by clinicians, the Patient Authored Note Header is general and can be used with classes of documents where the information is authored by the patient or a person acting as a non-clinician as the patient's agent. The Patient Authored Note Header may be further constrained to fit narrower use cases requiring tighter constraints.

A universal realm implementation is defined to provide the most general implementation guidance. Additionally, US realm specific guidance is provided as an

alternative to the current General Header defined for clinician-generated notes defined in the Consolidated CDA IG.

Going forward, the clinician and non-clinician header templates will be maintained in a synchronized manner to ensure continued alignment over time. Based upon these considerations, this document will use Consolidated CDA structures with minimal changes to reflect the inclusion of the patient as an author (and related roles). It is expected that templates created to be used in Patient Authored Note documents will also be consistent with the Consolidated CDA structure.

1.5 Organization of This Guide

This guide includes a single template defining the header constraints for a patient authored document. It is envisioned that the document-, section- and entry-level templates associated with any type of patient generated document will be defined within the consolidated CDA template library.

[Chapter 2. General Universal Realm Patient Authored Note Header Template](#). This chapter defines a template for the header constraints that apply across all documents generated by patients or their advocates. It is a generalized version of the US Realm PAN header template.

[Chapter 3. General US Realm Patient Authored Note Header Template](#). This chapter defines a template for the header constraints that apply across all documents generated by patients or their advocates. It constrains the UV Realm PAN header template to include specific codes and value sets.

[Appendix A](#). This appendix summarizes common use case patterns for patient authored notes and provides recommendations for values of CDA header elements.

1.10 Content of the Package

The following files comprise the package:

Table 1: Content of the Package

Filename	Description	Standards Applicability
Patient_Authored_Document.docx	Implementation Guide	Normative
PGHDsample.xml	Document header	Informative

2 GENERAL, UNIVERSAL REALM, PATIENT AUTHORED NOTE HEADER TEMPLATE

This template describes constraints that apply to the header for all documents within the scope of this implementation guide. Header constraints specific to each document type are described in the appropriate document-specific section below.

2.1 Document Type Codes

CDA R2 states that LOINC is the preferred vocabulary for document type codes, which specify the type of document being exchanged (e.g., History and Physical). Each document type in this guide recommends a single preferred `clinicalDocument/code`, with further specification provided by author or performer, setting, or specialty.

Documents in the class of CDA R2 documents created by non-clinicians and known as the family of Patient Authored Notes will use a LOINC code for the `clinicalDocument/code` which comes from the LOINC document ontology and falls within the hierarchy of Patient Authored Notes which begins with the most general of Patient Authored Notes (51855-5).

2.2 Patient Authored Document Header

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.29 (open)]

1. **SHALL** contain exactly one [1..1] `realmCode` (**NEWCONF:xxxxxx**).
 - a. This `realmCode` **SHOULD** be selected from HL7 ValueSet BindingRealm [2.16.840.1.113883.1.11.20355] from codesystem hl7Realm [2.16.840.1.113883.5.1124] **STATIC** 2010-11-11 (**NEWCONF:xxxxxx**).
2. **SHALL** contain exactly one [1..1] `typeId` (CONF:5361).
 - a. This `typeId` **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.1.3"` (CONF:5250).
 - b. This `typeId` **SHALL** contain exactly one [1..1] `@extension="POCD_HD000040"` (CONF:5251).
3. **SHALL** contain exactly one [1..1] header-level `templateId` (**NEWCONF:xxxxxx**) such that it
 - a. **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.29"` (**NEWCONF:xxxxxx**).
4. **SHALL** contain exactly one [1..1] `id` (CONF:5363).
 - a. This `id` **SHALL** be a globally unique identifier for the document (CONF:9991).
5. **SHALL** contain exactly one [1..1] `code` (CONF:5253).
 - a. This `code` **SHALL** specify the particular kind of patient generated document. (**NEWCONF:xxxxxx**).
 - b. This `code` **SHALL** come from the Patient Authored Note Concept Domain (**NEWCONF:xxxxxx**). **[ROB Hausam: We need to add a Concept Domain. We**

need to know how to bind the US Patient Authored Note value set to this Concept Domain.]

6. **SHALL** contain exactly one [1..1] **title** (CONF:5254).
 - a. Can either be a locally defined name or the display name corresponding to clinicalDocument/code ([CONF:5255](#)).
 - b. Title will have the words “Patient Authored Note” (**NEWCONF:xxxxxx**)
7. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:5256).
8. **SHALL** contain exactly one [1..1] **confidentialityCode**, which **SHOULD** be selected from ValueSet HL7 BasicConfidentialityKind 2.16.840.1.113883.1.11.16926 **STATIC** 2010-04-21 (CONF:5259).
9. **SHALL** contain exactly one [1..1] **languageCode**, which **SHALL** be selected from ValueSet Language 2.16.840.1.113883.1.11.11526 **DYNAMIC** (CONF:5372).
10. **MAY** contain zero or one [0..1] **setId** (CONF:5261).
 - a. If setId is present versionNumber **SHALL** be present (CONF:6380).²
11. **MAY** contain zero or one [0..1] **versionNumber** (CONF:5264).
 - a. If versionNumber is present setId **SHALL** be present (CONF:6387).³

Table 2: Basic Confidentiality Kind Value Set

Value Set: HL7 BasicConfidentialityKind 2.16.840.1.113883.1.11.16926 STATIC 2010-04-21		
Code System(s): Confidentiality Code 2.16.840.1.113883.5.25		
Code	Code System	Print Name
N	Confidentiality Code	Normal
R	Confidentiality Code	Restricted
V	Confidentiality Code	Very Restricted

² From CDA Normative Web edition: 4.2.1.7 ClinicalDocument.setId - Represents an identifier that is common across all document revisions and “Document Identification, Revisions, and Addenda” under 4.2.3.1 ParentDocument

³ From CDA Normative Web edition: 4.2.1.8 ClinicalDocument.versionNumber An integer value used to version successive replacement documents

Table 3: Language Value Set (excerpt)

Value Set: Language 2.16.840.1.113883.1.11.11526 DYNAMIC		
Code System(s): Internet Society Language 2.16.840.1.113883.1.11.11526		
Description: A value set of codes defined by Internet RFC 4646 (replacing RFC 3066). Please see ISO 639 language code set maintained by Library of Congress for enumeration of language codes http://www.ietf.org/rfc/rfc4646.txt		
Code	Code System	Print Name
en	Internet Society Language	English
fr	Internet Society Language	French
ar	Internet Society Language	Arabic
en-US	Internet Society Language	English, US
es-US	Internet Society Language	Spanish, US
...		

Figure 1: UV Realm header example

```

<realmCode code="UV"/>
<typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
<!-- UV Realm General Patient Authored Note Header Template -->
<templateId root="2.16.840.1.113883.10.20.29"/>

<id extension="d90d3eb0-a246-4c36-9f1f-a47528b617a2" root="d90d3eb0-a246-4c36-9f1f-a47528b617a2"/>

<code codeSystem="2.16.840.1.113883.6.1"
      codeSystemName="LOINC" code="51855-5"
      displayName="Patient Note"/>

<title>Adam Everyman - Patient Authored Note</title>

<effectiveTime value="20050329171504+0500"/>
<confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25"/>
<languageCode code="en-US"
      displayName="English, US"
      codeSystem="2.16.840.1.113883.1.11.11526"
      codeSystemName="Internet Society Language"/>
<setId extension=" d90d3eb0-a246-4c36-9f1f-b12345b617a2" root="d90d3eb0-a246-4c36-9f1f-a47528b617a2"/>
<versionNumber value="1"/>

```

Figure 2: effectiveTime with time zone example

```
<!-- the syntax is "YYYYMMDDHHMMSS.UUUU[+|-ZZzz]" where digits can be omitted
      the right side to express less precision. -->
<effectiveTime value="201107061227-08"/>
<!-- July 6, 2011, 12:27, 8 hours before UTC -->
```

2.2.1 RecordTarget

The recordTarget records the patient whose health information is described by the clinical document; each recordTarget must contain at least one patientRole element.

12. **SHALL** contain at least one [1..1] recordTarget (**NEWCONF:xxxxxx**).
 - a. Such recordTargets **SHALL** contain exactly one [1..1] patientRole (CONF:5267).
 - i. This patientRole **SHALL** contain at least one [1..*] id (CONF:5268).
 - ii. This patientRole **SHALL** contain at least one [1..*] addr (CONF:5271).
 - iii. This patientRole **SHALL** contain at least one [1..*] telecom (CONF:5280).

2.2.1.1 Patient

- iv. This patientRole **SHALL** contain exactly one [1..1] patient (CONF:5283).
 1. This patient **SHALL** contain exactly one [1..1] name (CONF:5284).
 2. This patient **SHALL** contain exactly one [1..1] administrativeGenderCode. (**NEWCONF:xxxxxx**).
 3. This patient **SHALL** contain exactly one [1..1] birthTime (CONF:5298).
 - a. **SHALL** be precise to year (CONF:5299).
 - b. **SHOULD** be precise to day (CONF:5300).

2.2.1.2 Guardian

4. This patient **MAY** contain zero or more [0..*] guardian (CONF:5325).
 - a. A guardian, if present, **SHOULD** contain zero or one [0..1] code (**NEWCONF:xxxxxx**)
 - b. The id **SHOULD** utilize the combined @root and @extension attributes to record the person's identity in a secure, trusted, and unique way. (**NEWCONF:xxxxxx**).
 - c. A guardian, if present, **SHOULD** contain zero or more [0..*] addr (CONF:5359).

- d. A guardian, if present, **MAY** contain zero or more [0..*] **telecom** (CONF:5382).
- e. A guardian, if present, **SHALL** contain exactly one [1..1] **guardianPerson** (CONF:5385).
 - i. This guardianPerson **SHALL** contain at least one [1..*] **name** (CONF:5386).

2.2.1.3 Birthplace

- 5. This patient **MAY** contain zero or one [0..1] **birthplace** (CONF:5395).
 - a. The birthplace, if present, **SHALL** contain exactly one [1..1] **place** (CONF:5396).

2.2.1.4 LanguageCommunication

- 6. This patient **SHOULD** contain zero or more [0..*] **languageCommunication** (CONF:5406).
 - a. The languageCommunication, if present, **SHALL** contain exactly one [1..1] **languageCode**, which **MAY** be selected from ValueSet Language 2.16.840.1.113883.1.11.11526 **DYNAMIC** (**NEWCONF:xxxxxx**).
 - b. The languageCommunication, if present, **MAY** contain zero or one [0..1] **modeCode**, which **MAY** be selected from ValueSet HL7 LanguageAbilityMode 2.16.840.1.113883.1.11.12249 **DYNAMIC** (**NEWCONF:xxxxxx**).
 - c. The languageCommunication, if present, **MAY** contain zero or one [0..1] **proficiencyLevelCode**, which **MAY** be selected from ValueSet LanguageAbilityProficiency 2.16.840.1.113883.1.11.12199 **DYNAMIC** (**NEWCONF:xxxxxx**).
 - d. The languageCommunication, if present, **MAY** contain zero or one [0..1] **preferenceInd** to indicate a preference for communication about care delivery and treatments to be translated into this language (**NEWCONF:xxxxxx**).
 - i. If more than one languageCommunication is present, only one languageCommunication element **SHALL** a **preferenceInd** with a value of 1 (**NEWCONF:xxxxxx**).

2.2.1.5 ProviderOrganization

If present this organization represents the person's preferred/nominated provider organization.

- v. This patientRole **MAY** contain zero or one [0..1] **providerOrganization** (CONF:5416).
 - 1. The providerOrganization, if present, **SHALL** contain at least one [1..*] **id** (CONF:5417).
 - 2. The providerOrganization, if present, **SHALL** contain at least one [1..*] **name** (CONF:5419).
 - 3. The providerOrganization, if present, **SHALL** contain at least one [1..*] **telecom** (CONF:5420).
 - 4. The providerOrganization, if present, **SHALL** contain at least one [1..*] **addr** (CONF:5422).
 - a. The content of the country code used in the addr SHALL be from CountryValueSet (2.16.840.1.113883.3.88.12.80.63) DYNAMIC (**NEWCONF:xxxxxx**).

2.2.1.6 RecordTarget Value Sets

Table 4: Country Value Set (excerpt)

Value Set: CountryValueSet 2.16.840.1.113883.3.88.12.80.63 DYNAMIC		
Code System(s): ISO 3166-1 Country Codes: 1.0.3166.1		
Description: A value set of codes for the representation of names of countries, territories and areas of geographical interest. Note: This table provides the ISO 3166-1 code elements available in the alpha-2 code of ISO's country code standard http://www.iso.org/iso/country_codes/iso_3166_code_lists.htm		
Code	Code System	Print Name
AW	ISO 3166-1 Country Codes	Aruba
IL	ISO 3166-1 Country Codes	Israel
KZ	ISO 3166-1 Country Codes	Kazakhstan
US	ISO 3166-1 Country Codes	United States
...		

2.2.1.7 RecordTarget Example

Figure 3: UV Realm recordTarget example

```
<recordTarget>
  <patientRole>
    <id extension="12345" root="2.16.840.1.113883.19"/>
    <!-- Fake ID using HL7 example OID. -->
    <id extension="111-00-1234" root="2.16.840.1.113883.4.1"/>
    <!-- Fake Social Security Number using the actual SSN OID. -->
    <addr use="HP">
      <!-- HP is "primary home" from codeSystem 2.16.840.1.113883.5.1119 -->
      <streetAddressLine>17 Daws Rd.</streetAddressLine>
      <city>Blue Bell</city>
      <state>MA</state>
      <postalCode>02368</postalCode>
      <country>US</country>
      <!-- US is "United States" from ISO 3166-1 Country Codes: 1.0.3166.1 -->
    </addr>
    <telecom value="tel:(781)555-1212" use="HP"/>
    <!-- HP is "primary home" from AddressUse 2.16.840.1.113883.5.1119 -->
    <patient>
      <name use="L">
        <!-- L is "Legal" from EntityNameUse 2.16.840.1.113883.5.45 -->
        <prefix>Mr.</prefix>
        <given>Adam</given>
        <given qualifier="CL">Frankie</given>
        <!-- CL is "Call me" from EntityNamePartQualifier
              2.16.840.1.113883.5.43 -->
        <family>Everyman</family>
      </name>
      <administrativeGenderCode code="M"
        codeSystem="2.16.840.1.113883.5.1" displayName="Male"/>
      <birthTime value="19541125"/>

      <guardian>
        <code code="GRFTH" displayName="Grandfather"
          codeSystem="2.16.840.1.113883.5.111"
          codeSystemName="RoleCode"/>
        <addr use="HP">
          <streetAddressLine>17 Daws Rd.</streetAddressLine>
          <city>Blue Bell</city>
          <state>MA</state>
          <postalCode>02368</postalCode>
          <country>US</country>
        </addr>
        <telecom value="tel:(781)555-1212" use="HP"/>
        <guardianPerson>
          <name>
            <given>Ralph</given>
            <family>Relative</family>
          </name>
        </guardianPerson>
      </guardian>
    </patient>
  </patientRole>
</recordTarget>
```

```

    <birthplace>
      <place>
        <addr>
          <state>MA</state>
          <postalCode>02368</postalCode>
          <country>US</country>
        </addr>
      </place>
    </birthplace>
    <languageCommunication>
      <languageCode code="fr-CN" />
      <modeCode code="RWR" displayName="Receive Written"
        codeSystem="2.16.840.1.113883.5.60"
        codeSystemName="LanguageAbilityMode" />
      <preferenceInd value="true" />
    </languageCommunication>
  </patient>
  <providerOrganization>
    <id root="2.16.840.1.113883.19" />
    <name>Good Health Clinic</name>
    <telecom use="WP" value="tel:(781)555-1212" />
    <addr>
      <streetAddressLine>21 North Ave</streetAddressLine>
      <city>Burlington</city>
      <state>MA</state>
      <postalCode>02368</postalCode>
      <country>US</country>
    </addr>
  </providerOrganization>
</patientRole>
</recordTarget>

```

2.2.2 Author

The author element represents the creator of the clinical document. The author may be a device, or a person. The person is the patient or the patient's advocate.

13. **SHALL** contain at least one [1..*] **author** (CONF:5444) .
 - a. Such authors **SHALL** contain exactly one [1..1] **time** (CONF:5445).
 - b. Such authors **SHALL** contain exactly one [1..1] **assignedAuthor** (CONF:5448).
 - i. This assignedAuthor **SHALL** contain exactly one [1..1] **id** (CONF:5449) such that it
 1. The id **SHOULD** utilize the combined **@root** and **@extension** attributes to record the person's or the device's identity in a secure, trusted, and unique way. (**NEWCONF:xxxxxx**).
 - ii. When the author is a person, this assignedAuthor **SHALL** contain one [1..1] **code** (**NEWCONF:xxxxxx**).
 1. The code, **SHALL** contain exactly one [1..1] **@code**, which **SHOULD** be selected from the

PersonalRelationshipRoleType value set PLUS
ResponsibleParty PLUS (NEWCONF:xxxxxx)

- iii. This assignedAuthor **SHALL** contain at least one [1..*] **addr** (CONF:5452).
- iv. This assignedAuthor **SHALL** contain at least one [1..*] **telecom** (CONF:5428).
- v. There **SHALL** be exactly one assignedAuthor/assignedPerson or exactly one assignedAuthor/assignedAuthoringDevice (CONF:16790).
- vi. This assignedAuthor **SHOULD** contain zero or one [0..1] **assignedPerson** (CONF:5430).
 - 1. The assignedPerson, if present, **SHALL** contain at least one [1..*] **name** (CONF:16789).
- vii. This assignedAuthor **SHOULD** contain zero or one [0..1] **assignedAuthoringDevice** (CONF:16783).
 - 1. The assignedAuthoringDevice, if present, **SHALL** contain exactly one [1..1] **manufacturerModelName** (CONF:16784).
 - 2. The assignedAuthoringDevice, if present, **SHALL** contain exactly one [1..1] **softwareName** (CONF:16785).

Figure 4: Person author example

```
<author>
  <time value="20050329224411+0500"/>
  <assignedAuthor>
    <id extension="KP00017" root="Australia example"/>
    <code code='MTH' codeSystem='2.16.840.1.113883.5.111' />
    <addr>
      <streetAddressLine>21 North Ave.</streetAddressLine>
      <city>Burlington</city>
      <state>MA</state>
      <postalCode>02368</postalCode>
      <country>US</country>
    </addr>
    <telecom use="WP" value="tel:(555)555-1003"/>
    <assignedPerson>
      <name>
        <given>Mary</given>
        <family>Seven</family>
      </name>
    </assignedPerson>
  </assignedAuthor>
</author>
```

Figure 5: Device author example

```
<author>
  <time value="20050329224411+0500" />
  <assignedAuthor>
    <id extension="KP00017dev" root="2.16.840.1.113883.19.5" />
    <addr>
      <streetAddressLine>21 North Ave.</streetAddressLine>
      <city>Burlington</city>
      <state>MA</state>
      <postalCode>02368</postalCode>
      <country>US</country>
    </addr>
    <telecom use="WP" value="tel:(555)555-1003" />
    <assignedAuthoringDevice>
      <manufacturerModelName>Good Health Medical
        Device</manufacturerModelName >
      <softwareName>Good Health Report Generator</softwareName >
    </ assignedAuthoringDevice >
  </assignedAuthor>
</author>
```

2.2.3 DataEnterer

The `dataEnterer` element represents the person who transferred the content, written or dictated by someone else, into the clinical document. The guiding rule of thumb is that an `author` provides the content found within the header or body of the document, subject to their own interpretation, and the `dataEnterer` adds that information to the electronic system. In other words, a `dataEnterer` transfers information from one source to another (e.g., transcription from paper form to electronic system).

14. **MAY** contain zero or one [0..1] **dataEnterer** (CONF:5441).
 - a. The `dataEnterer`, if present, **SHALL** contain exactly one [1..1] **assignedEntity** (CONF:5442).
 - i. This `assignedEntity` **SHALL** contain at least one [1..*] **id** (CONF:5443).
 - ii. This `assignedEntity` **SHALL** contain at least one [1..*] **addr** (CONF:5460).
 - iii. This `assignedEntity` **SHALL** contain at least one [1..*] **telecom** (CONF:5466).
 - iv. This `assignedEntity` **SHALL** contain exactly one [1..1] **assignedPerson** (CONF:5469).
 1. This `assignedPerson` **SHALL** contain at least one [1..*] **name** (CONF:5470).
 - v. This `assignedEntity` **MAY** contain zero or one [0..1] **code** to encode the relationship of the person to the `recordTarget` (**NEWCONF:xxxxxx**).

Figure 6: dataEnterer example

```
<dataEnterer>
  <assignedEntity>
    <id root="2.16.840.1.113883.19.5" extension="43252"/>
    <addr>
      <streetAddressLine>21 North Ave.</streetAddressLine>
      <city>Burlington</city>
      <state>MA</state>
      <postalCode>02368</postalCode>
      <country>US</country>
    </addr>
    <telecom use="WP" value="tel:(555)555-1003"/>
    <assignedPerson>
      <name>
        <given>Henry</given>
        <family>Seven</family>
      </name>
    </assignedPerson>
  </assignedEntity>
</dataEnterer>
```

2.2.4 Informant

The informant element describes the source of the information in a medical document.

Assigned health care providers may be a source of information when a document is created. (e.g., a nurse's aide who provides information about a recent significant health care event that occurred within an acute care facility.) In these cases, the assignedEntity element is used.

When the informant is a personal relation, that informant is represented in the relatedEntity element. The code element of the relatedEntity describes the relationship between the informant and the patient. The relationship between the informant and the patient needs to be described to help the receiver of the clinical document understand the information in the document.

15. **MAY** contain zero or more [0..*] **informant** (CONF:8001).

- a. **SHALL** contain exactly one [1..1] assignedEntity OR exactly one [1..1] relatedEntity (CONF:8002).
 - i. **SHOULD** contain at least one [1..*] **addr** (CONF:8220).
 - ii. **SHALL** contain exactly one [1..1] assignedPerson OR exactly one [1..1] relatedPerson (CONF:8221).
 1. **SHALL** contain at least one [1..*] **name** (CONF:8222).
 - iii. This assignedEntity **MAY** contain zero or one [0..1] code (**NEWCONF:xxxx**).
 - iv. **SHOULD** contain zero or more [0..*] **id** (CONF:9945).

Figure 7: Informant with assignedEntity example

```
<informant>
  <assignedEntity>
    <id extension="KP00017" root="2.16.840.1.113883.19.5"/>
    <addr>
      <streetAddressLine>21 North Ave.</streetAddressLine>
      <city>Burlington</city>
      <state>MA</state>
      <postalCode>02368</postalCode>
      <country>US</country>
    </addr>
    <telecom value="tel:(555)555-1003"/>
    <assignedPerson>
      <name>
        <given>Henry</given>
        <family>Seven</family>
      </name>
    </assignedPerson>
  </assignedEntity>
</informant>
```

2.2.5 Custodian

The custodian element represents the organization that is in charge of maintaining the document. The custodian is the steward that is entrusted with the care of the document. Every CDA document has exactly one custodian. The custodian participation satisfies the CDA definition of Stewardship. Because CDA is an exchange standard and may not represent the original form of the authenticated document (e.g., CDA could include scanned copy of original), the custodian represents the steward of the original source document. The custodian may be the document originator, a health information exchange, or other responsible party.

16. **SHALL** contain exactly one [1..1] **custodian** (CONF:5519).

a. This custodian **SHALL** contain exactly one [1..1] **assignedCustodian** (CONF:5520).

i. This assignedCustodian **SHALL** contain exactly one [1..1] **representedCustodianOrganization** which may be the person when the document is not maintained by an organization. (**NEWCONF:xxxxx**).

1. This representedCustodianOrganization **SHALL** contain at least one [1..*] **id** (CONF:5522).

2. This representedCustodianOrganization **SHALL** contain exactly one [1..1] **name** (CONF:5524).

3. This representedCustodianOrganization **SHALL** contain exactly one [1..1] **telecom** (CONF:5525).

a. This telecom **SHOULD** contain exactly one [1..1] **@use (NEWCONF:xxxxx)**.

4. This representedCustodianOrganization **SHALL** contain at least one [1..*] **addr** (CONF:5559).

Figure 8: Custodian example

```
<custodian>
  <assignedCustodian>
    <representedCustodianOrganization>
      <id root="2.16.840.1.113883.19.5"/>
      <name>Good Health Clinic</name>
      <telecom value="tel:(555)555-1212" use="WP"/>
      <addr use="WP">
        <streetAddressLine>17 Daws Rd.</streetAddressLine>
        <city>Blue Bell</city>
        <state>MA</state>
        <postalCode>02368</postalCode>
        <country>US</country>
      </addr>
    </representedCustodianOrganization>
  </assignedCustodian>
</custodian>
```

2.2.6 InformationRecipient

The `informationRecipient` element records the intended recipient of the information at the time the document is created. For example, in cases where the intended recipient of the document is the patient's health chart, set the `receivedOrganization` to be the scoping organization for that chart.

17. **MAY** contain zero or more [0..*] **informationRecipient** (CONF:5565).
 - a. The `informationRecipient`, if present, **SHALL** contain exactly one [1..1] **intendedRecipient** (CONF:5566).
 - i. This `intendedRecipient` **SHOULD** contain at least one [1..*] **id** (**NEWCONF:xxxxxx**).
 - ii. This `intendedRecipient` **MAY** contain zero or one [0..1] **informationRecipient** (CONF:5567).
 1. The `informationRecipient`, if present, **SHALL** contain at least one [1..*] **name** (CONF:5568).
 - iii. This `intendedRecipient` **MAY** contain zero or one [0..1] **receivedOrganization** (CONF:5577).
 1. The `receivedOrganization`, if present, **SHALL** contain exactly one [1..1] **name** ([CONF:5578](#)).

Figure 9: informationRecipient example

```
<informationRecipient>
  <intendedRecipient>
    <informationRecipient>
      <name>
        <given>Henry</given>
        <family>Seven</family>
      </name>
    </informationRecipient>
    <receivedOrganization>
      <name>Good Health Clinic</name>
    </receivedOrganization>
  </intendedRecipient>
</informationRecipient>
```

2.2.7 LegalAuthenticator

In a patient authored document, the `legalAuthenticator` identifies the single person legally responsible for the document and must be present if the document has been legally authenticated. (Note that per the following section, there may also be one or more document authenticators.)

Based on local practice, patient authored documents may be provided without legal authentication. This implies that a patient authored document that does not contain this element has not been legally authenticated.

The act of legal authentication requires a certain privilege be granted to the legal authenticator depending upon local policy. All patient documents have the potential for legal authentication, given the appropriate legal authority.

Local policies **MAY** choose to delegate the function of legal authentication to a device or system that generates the document. In these cases, the legal authenticator is the person accepting responsibility for the document, not the generating device or system.

Note that the legal authenticator, if present, must be a person.

18. **SHOULD** contain zero or one [0..1] `legalAuthenticator` (CONF:5579).
 - a. The `legalAuthenticator`, if present, **SHALL** contain exactly one [1..1] `time` (CONF:5580).
 - b. The `legalAuthenticator`, if present, **SHALL** contain exactly one [1..1] `signatureCode` (CONF:5583).
 - i. This `signatureCode` **SHALL** contain exactly one [1..1] `@code="S"` (CodeSystem: Participationsignature 2.16.840.1.113883.5.89) (CONF:5584).
 - c. The `legalAuthenticator`, if present, **SHALL** contain exactly one [1..1] `assignedEntity` (CONF:5585).
 - i. This `assignedEntity` **SHALL** contain at least one [1..*] `id` (CONF:5586).
 - ii. This `assignedEntity` **MAY** contain zero or one [0..1] `code` (**NEWCONF:xxxxxx**)

- iii. This assignedEntity **SHALL** contain at least one [1..*] **addr** (CONF:5589).
- iv. This assignedEntity **SHALL** contain at least one [1..*] **telecom** (CONF:5595).
- v. This assignedEntity **SHALL** contain exactly one [1..1] **assignedPerson** (CONF:5597).
 - 1. This assignedPerson **SHALL** contain at least one [1..*] **name** (CONF:5598).

Figure 10: legalAuthenticator example

```

<legalAuthenticator>
  <time value="20050329224411+0500"/>
  <signatureCode code="S"/>
  <assignedEntity>
    <id extension="KP00017" root="2.16.840.1.113883.19"/>
    <addr>
      <streetAddressLine>21 North Ave.</streetAddressLine>
      <city>Burlington</city>
      <state>MA</state>
      <postalCode>02368</postalCode>
      <country>US</country>
    </addr>
    <telecom use="WP" value="tel:(555)555-1003"/>
    <assignedPerson>
      <name>
        <given>Henry</given>
        <family>Seven</family>
      </name>
    </assignedPerson>
  </assignedEntity>
</legalAuthenticator>

```

2.2.8 Authenticator

The authenticator identifies a participant or participants who attested to the accuracy of the information in the document.

- 19. **MAY** contain zero or more [0..*] **authenticator** (CONF:5607).
 - a. The authenticator, if present, **SHALL** contain exactly one [1..1] **time** (CONF:5608).
 - b. The authenticator, if present, **SHALL** contain exactly one [1..1] **signatureCode** (CONF:5610).
 - i. This signatureCode **SHALL** contain exactly one [1..1] **@code="S"** (CodeSystem: Participationsignature 2.16.840.1.113883.5.89) (CONF:5611).
 - c. The authenticator, if present, **SHALL** contain exactly one [1..1] **assignedEntity** (CONF:5612).
 - i. This assignedEntity **SHALL** contain at least one [1..*] **id** (CONF:5613).

- ii. This assignedEntity **MAY** contain zero or one [0..1] **code** (CONF:16825).
- iii. This assignedEntity **SHALL** contain at least one [1..*] **addr** (CONF:5616).
- iv. This assignedEntity **SHALL** contain at least one [1..*] **telecom** (CONF:5622).
 - 1. Such telecoms **SHOULD** contain exactly one [1..1] **@use** (**NEWCONF:xxxxxx**)
- v. This assignedEntity **SHALL** contain exactly one [1..1] **assignedPerson** (CONF:5624).
 - 1. This assignedPerson **SHALL** contain at least one [1..*] **name** (CONF:5625).

Figure 11: Authenticator example

```

<authenticator>
  <time value="20050329224411+0500" />
  <signatureCode code="S" />
  <assignedEntity>
    <id extension="KP00017" root="2.16.840.1.113883.19" />
    <addr>
      <streetAddressLine>21 North Ave.</streetAddressLine>
      <city>Burlington</city>
      <state>MA</state>
      <postalCode>02368</postalCode>
      <country>US</country>
    </addr>
    <telecom use="WP" value="tel:(555)555-1003" />
    <assignedPerson>
      <name>
        <given>Henry</given>
        <family>Seven</family>
      </name>
    </assignedPerson>
  </assignedEntity>
</authenticator>

```

2.2.9 Participant (Support)

The participant element identifies other supporting participants, including parents, relatives, caregivers, insurance policyholders, guarantors, and other participants related in some way to the patient.

A supporting person or organization is an individual or an organization with a relationship to the patient. A supporting person who is playing multiple roles would be recorded in multiple participants (e.g., emergency contact and next-of-kin)

- 20. **MAY** contain zero or more [0..*] **participant** (CONF:10003).
 - a. The participant, if present, **MAY** contain zero or one [0..1] **time** (CONF:10004).

- b. Such participants, if present, **SHALL** have an associatedPerson or scopingOrganization element under participant/associatedEntity (CONF:10006).
- c. Unless otherwise specified by the document specific header constraints, when participant/@typeCode is IND, associatedEntity/@classCode **SHALL** be selected from ValueSet 2.16.840.1.113883.11.20.9.33 INDRoleclassCodes **STATIC** 2011-09-30 (CONF:10007).

Table 5: IND Role classCode Value Set

Value Set: INDRoleclassCodes 2.16.840.1.113883.11.20.9.33 STATIC 2011-09-30		
Code System(s): RoleClass 2.16.840.1.113883.5.110		
Code	Code System	Print Name
PRS	RoleClass	personal relationship
NOK	RoleClass	next of kin
CAREGIVER	RoleClass	caregiver
AGNT	RoleClass	agent
GUAR	RoleClass	guarantor
ECON	RoleClass	emergency contact

Figure 12: Participant example for a supporting person

```

<participant typeCode='IND'>
  <time xsi:type="IVL_TS">
    <low value="19590101"/>
    <high value="20111025"/>
  </time>
  <associatedEntity classCode='NOK'>
    <code code='MTH' codeSystem='2.16.840.1.113883.5.111' />
    <addr>
      <streetAddressLine>17 Daws Rd.</streetAddressLine>
      <city>Blue Bell</city>
      <state>MA</state>
      <postalCode>02368</postalCode>
      <country>US</country>
    </addr>
    <telecom value='tel:(555)555-2006' use='WP' />
    <associatedPerson>
      <name>
        <prefix>Mrs.</prefix>
        <given>Martha</given>
        <family>Mum</family>
      </name>
    </associatedPerson>
  </associatedEntity>
</participant>

```

2.2.10 InFulfillmentOf

The inFulfillmentOf element represents orders that are fulfilled by this document.

21. **MAY** contain zero or more [0..*] inFulfillmentOf (CONF:9952).

- a. The inFulfillmentOf, if present, **SHALL** contain exactly one [1..1] order (CONF:9953).
 - i. This order **SHALL** contain at least one [1..*] id (CONF:9954)
 1. Such ids **MAY** represent a scheduled appointment or service event in a practice management system (**NEWCONF:xxxxxx**).

2.2.11 DocumentationOf/serviceEvent

The main activity being described by a Patient Authored Note is the person's health care, health practices and relevant health history over a period of time. This is shown by setting the value of

ClinicalDocument/documentationOf/serviceEvent/@classCode to "PCPR" (care provision). The ClinicalDocument/documentationOf/serviceEvent/effectiveTime indicates the span of time documented in the note. Additional data from outside this duration may also be included if it is relevant to care documented during the covered time range (e.g. A document covering this year may include information about a condition resolved several years ago which requires annual screening).

NOTE: Implementations originating a Patient Authored Note should take care to indicate the time span being documented. For example:

- When a patient fills out a form providing relevant health history prior to an initial visit to a new doctor, the span of time being documented might be from birth to the present.
 - When a patient is authoring a note to support an annual examination, it might cover just the prior year.
 - When a patient is going for a sick visit, the time span of the note may cover only a few days.
1. **SHALL** contain exactly one [1..1] documentationOf (CONF:8452).
 - a. This documentationOf **SHALL** contain exactly one [1..1] serviceEvent (CONF:8480).
 - i. This serviceEvent **SHALL** contain exactly one [1..1] @classCode="PCPR" Provision of Care indicating the person's health care, health practices and relevant health history (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:8453).
 - ii. This serviceEvent **MAY** contain one [1..1] code (**NEWCONF:xxxxxx**).
 1. The code, **SHOULD** contain exactly one [1..1] @code, which **SHOULD** be selected from a value set established by the document-level template for a specific type of Patient Authored Note. (**NEWCONF:xxxxxx**)
 - iii. This serviceEvent **SHALL** contain exactly one [1..1] effectiveTime (CONF:8481).
 1. This effectiveTime **SHALL** contain exactly one [1..1] low (CONF:8454).

2. This effectiveTime **SHALL** contain exactly one [1..1] **high** (CONF:8455).
- iv. This serviceEvent **SHOULD** contain zero or more [0..*] **performer** (CONF:8482).
1. serviceEvent/performer represents the healthcare providers, allied health professionals or other individuals involved in the current or pertinent historical care of the patient during the time span covered by the document **(NEWCONF:xxxxxx)**.
 2. Such performers **SHALL** contain exactly one [1..1] **@typeCode="PRF"** Participation physical performer (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90) (CONF:8458).
 3. Such performers **MAY** contain exactly one [1..1] **functionCode="PCP"** when indicating the performer was the primary care physician (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90) **(NewCONF:xxxxxx)**
 4. Such performers **MAY** contain zero or more [0..1] **assignedEntity** (CONF:8459).
 - a. This assignedEntity **SHALL** contain at least one [1..*] **id** (CONF:8460).
 - b. This assignedEntity **MAY** contain zero or one [0..1] **code** (CONF:8461).

Figure 13: DocumentationOf example

```
<documentationOf>
  <serviceEvent classCode="ACT">
    <id root="1.2.840.113619.2.62.994044785528.114289542805"/>
    <id extension="123453" root="1.2.840.113619.2.62.994044785528.26"/>
    <code code="93041"
      displayName="Rhythm ECG, one to three leads; tracing only
without interpretation and report"
      codeSystem="2.16.840.1.113883.6.12"
      codeSystemName="CPT4"/>
    <effectiveTime value="20080813222400"/>
    <performer typeCode="PRF">
      <templateId root="2.16.840.1.113883.10.20.6.2.1"/>
      <assignedEntity>
        <id extension="121008" root="2.16.840.1.113883.19.5"/>
        <code code="208D00000X" codeSystem="2.16.840.1.113883.6.101"
          codeSystemName="NUCC"
          displayName="General Practice"/>
        <addr nullFlavor="NI"/>
        <telecom nullFlavor="NI"/>
        <assignedPerson>
          <name>
            <given>Matthew</given>
            <family>Care</family>
            <suffix>MD</suffix>
          </name>
        </assignedPerson>
      </assignedEntity>
    </performer>
  </serviceEvent>
</documentationOf>
```

2.2.12 Authorization/consent

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

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

22. **MAY** contain zero or more [0..*] **authorization** (CONF:16792) such that it
- a. **SHALL** contain exactly one [1..1] **consent** (CONF:16793).
 - i. This consent **MAY** contain zero or more [0..*] **id** (CONF:16794).
 - ii. This consent **MAY** contain zero or one [0..1] **code** (CONF:16795).
 1. The type of consent (e.g., a consent to perform the related `serviceEvent`) is conveyed in `consent/code` (CONF:16796).
 - iii. This consent **SHALL** contain exactly one [1..1] **statusCode** (CONF:16797).

1. This statusCode **SHALL** contain exactly one [1..1]
@code="completed" Completed (CodeSystem: HL7ActClass
2.16.840.1.113883.5.6) (CONF:16798).

Figure 14: Procedure note consent example

```
<authorization typeCode="AUTH">
  <consent classCode="CONS" moodCode="EVN">
    <id root="629deb70-5306-11df-9879-0800200c9a66" />
    <code codeSystem=" 2.16.840.1.113883.6.1" codeSystemName="LOINC"
      code="64293-4" displayName="Procedure consent"/>
    <statusCode code="completed"/>
  </consent>
</authorization>
```

2.2.13 ComponentOf

The componentOf element contains the encompassing encounter for this document. The encompassing encounter represents the setting of the clinical encounter during which the document act(s) or ServiceEvent occurred.

In order to represent providers associated with a specific encounter, they are recorded within the encompassingEncounter as participants.

In a CCD the encompassingEncounter may be used when documenting a specific encounter and its participants. All relevant encounters in a CCD may be listed in the encounters section.

23. **MAY** contain zero or one [0..1] componentOf (CONF:9955).
 - a. The componentOf, if present, **SHALL** contain exactly one [1..1] encompassingEncounter (CONF:9956).
 - i. This encompassingEncounter **SHALL** contain at least one [1..*] id (CONF:9959).
 - ii. This encompassingEncounter **SHALL** contain exactly one [1..1] effectiveTime (CONF:9958).

2.3 Rendering Header Information for Human Presentation

Metadata carried in the header of a Patient Authored Note may not match information available in an electronic medical records (EMRs) or other sources external to the document. Information provided by the individual may be more accurate and up to date than information in the EMR, or it may be missing some of the most recent data available in the EMR. Therefore, it is a requirement to render information with represents differences between the document header information and the information stored in the EMR. When there are differences, information should be rendered directly from the document as well as the EMR so that potential changes can be made and errors can be caught. An example of this would be a doctor using an EMR that already contains the patient's name, date of birth, current address, and phone number. When a CDA document is rendered within that EMR, if the address and phone number in the

patient authored note does not match those pieces of information in the EMR, the EMR may need to be updated.

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

- Document title and document dates
- Header information which does not match information stored in the EMR
- Service and encounter types, and date ranges as appropriate
- Names of all persons along with their roles, participations, participation date ranges, identifiers, address, and telecommunications information
- Names of selected organizations along with their roles, participations, participation date ranges, identifiers, address, and telecommunications information
- Date of birth for recordTarget

3 GENERAL US REALM PATIENT AUTHORED NOTE HEADER TEMPLATE

This template describes constraints that apply to the header for all documents within the scope of this implementation guide. Header constraints specific to each document type are described in the appropriate document-specific section below.

3.1 Document Type Codes

CDA R2 states that LOINC is the preferred vocabulary for document type codes, which specify the type of document being exchanged (e.g., History and Physical). Each document type in this guide recommends a single preferred `clinicalDocument/code`, with further specification provided by author or performer, setting, or specialty.

Documents in the class of CDA R2 documents created by non-clinicians and known as the family of Patient Authored Notes will use a LOINC code for the `clinicalDocument/code` which comes from the LOINC document ontology and falls within the hierarchy of Patient Authored Notes which begins with the most general of Patient Authored Notes (51855-5).

3.2 US Realm Patient Authored Note Document Header

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.29.1 (open)]

The US Realm Patient Authored Note document header template must conform to the Universal Realm Patient Authored Note document header template.

24. **SHALL** contain exactly one [1..1] `realmCode="US"` (CONF:16791).
25. **SHALL** contain exactly one [1..1] `typeId` (CONF:5361).
 - a. This `typeId` **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.1.3"` (CONF:5250).
 - b. This `typeId` **SHALL** contain exactly one [1..1] `@extension="POCD_HD000040"` (CONF:5251).
26. **SHALL** contain exactly one [1..1] header-level `templateId (NEWCONF:xxxxxx)` such that it
 - a. **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.29.1"` (NEWCONF:xxxxxx).
27. **SHALL** contain exactly one [1..1] `id` (CONF:5363).
 - a. This `id` **SHALL** be a globally unique identifier for the document (CONF:9991).
28. **SHALL** contain exactly one [1..1] `code` (CONF:5253).
 - a. This `code` **SHALL** specify the particular kind of patient authored note document. (NEWCONF:xxxxxx).
 - b. This `code` **SHALL** be selected from a dynamic value set bound to the PAN Concept Domain. In the US, this value set is comprised of the codes in the

hierarchy for Patient Authored Notes in the LOINC Document Ontology.
(NEWCONF:xxxxxx).

- 29. **SHALL** contain exactly one [1..1] **title** (CONF:5254).
 - a. Can either be a locally defined name or the display name corresponding to clinicalDocument/code ([CONF:5255](#)).
 - b. Title will have the words “Patient Authored Note” **(NEWCONF:xxxxxx)**
- 30. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:5256).
 - a. The content **SHALL** be a conformant [US Realm Date and Time \(DTM.US.FIELDDED\)](#) (2.16.840.1.113883.10.20.22.5.4) (CONF:16865).
- 31. **SHALL** contain exactly one [1..1] **confidentialityCode**, which **SHOULD** be selected from ValueSet HL7 BasicConfidentialityKind 2.16.840.1.113883.1.11.16926 **STATIC** 2010-04-21 (CONF:5259).
- 32. **SHALL** contain exactly one [1..1] **languageCode**, which **SHALL** be selected from ValueSet Language 2.16.840.1.113883.1.11.11526 **DYNAMIC** (CONF:5372).
- 33. **MAY** contain zero or one [0..1] **setId** (CONF:5261).
 - a. If setId is present versionNumber **SHALL** be present (CONF:6380).⁴
- 34. **MAY** contain zero or one [0..1] **versionNumber** (CONF:5264).
 - a. If versionNumber is present setId **SHALL** be present (CONF:6387).⁵

Table 6: Basic Confidentiality Kind Value Set

Value Set: HL7 BasicConfidentialityKind 2.16.840.1.113883.1.11.16926 STATIC 2010-04-21		
Code System(s): Confidentiality Code 2.16.840.1.113883.5.25		
Code	Code System	Print Name
N	Confidentiality Code	Normal
R	Confidentiality Code	Restricted
V	Confidentiality Code	Very Restricted

⁴ From CDA Normative Web edition: 4.2.1.7 ClinicalDocument.setId - Represents an identifier that is common across all document revisions and “Document Identification, Revisions, and Addenda” under 4.2.3.1 ParentDocument

⁵ From CDA Normative Web edition: 4.2.1.8 ClinicalDocument.versionNumber An integer value used to version successive replacement documents

Table 7: Language Value Set (excerpt)

Value Set: Language 2.16.840.1.113883.1.11.11526 DYNAMIC		
Code System(s): Internet Society Language 2.16.840.1.113883.1.11.11526		
Description: A value set of codes defined by Internet RFC 4646 (replacing RFC 3066). Please see ISO 639 language code set maintained by Library of Congress for enumeration of language codes http://www.ietf.org/rfc/rfc4646.txt		
Code	Code System	Print Name
en	Internet Society Language	english
fr	Internet Society Language	french
ar	Internet Society Language	arabic
en-US	Internet Society Language	English, US
es-US	Internet Society Language	Spanish, US
...		

Table X: LOINC DOCUMENT ONTOLOGY FOR PATIENT AUTHORED NOTES

Code System(s): LOINC 2.16.840.1.113883.6.1		
Code	Code System	Print Name
51855-5	LOINC	Patient Note

Note: this is the most general type of Patient Authored Note. It is envisioned that additional more specific types of Patient Authored Notes will be defined in the future and the additional document codes will be managed as a hierarchy.

Figure 15: US Realm header example

```
<realmCode code="US"/>
<typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
<!-- US Realm General Patient Authored Note Header Template -->
<templateId root="2.16.840.1.113883.10.20.29.1"/>

<id extension="999021" root="2.16.840.1.113883.19"/>

<code codeSystem="2.16.840.1.113883.6.1"
      codeSystemName="LOINC" code="51855-5"
      displayName="Patient Note"/>

<title>Adam Everyman - Patient Authored Note</title>

<effectiveTime value="20050329171504+0500"/>
<confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25"/>
<languageCode code="en-US"
              displayName="English, US"
              codeSystem="2.16.840.1.113883.1.11.11526"
              codeSystemName="Internet Society Language"/>
<setId extension="111199021" root="2.16.840.1.113883.19"/>
<versionNumber value="1"/>
```

Figure 16: effectiveTime with time zone example

```
<!-- the syntax is "YYYYMMDDHHMMSS.UUUU[+|-ZZzz]" where digits can be omitted
      the right side to express less precision. -->
<effectiveTime value="201107061227-08"/>
<!-- July 6, 2011, 12:27, 8 hours before UTC -->
```

3.2.1 RecordTarget

The recordTarget records the patient whose health information is described by the clinical document; each recordTarget must contain at least one patientRole element.

35. **SHALL** contain only one [1..1] recordTarget (**NEWCONF:xxxxxx**).

- a. Such recordTargets **SHALL** contain exactly one [1..1] patientRole ([CONF:5267](#)).
 - i. This patientRole **SHALL** contain at least one [1..*] id ([CONF:5268](#)).
 1. Each id **SHOULD** utilize the combined @root and @extension attributes to record a patient's identity in a secure, trusted, and unique way. (**NEWCONF:xxxxxx**).
 - ii. This patientRole **SHALL** contain at least one [1..*] addr ([CONF:5271](#)).
 1. The content of addr **SHALL** be a conformant [US Realm Address \(AD.US.FIELDED\)](#) (2.16.840.1.113883.10.20.22.5.2) ([CONF:10412](#)).

- iii. This patientRole **SHALL** contain at least one [1..*] **telecom** (CONF:5280).
 - 1. Such telecoms **SHOULD** contain exactly one [1..1] **@use**, which **SHALL** be selected from ValueSet [Telecom Use \(US Realm Header\)](#) 2.16.840.1.113883.11.20.9.20 **DYNAMIC** (CONF:5375).

3.2.1.1 Patient

- iv. This patientRole **SHALL** contain exactly one [1..1] **patient** (CONF:5283).
 - 1. This patient **SHALL** contain exactly one [1..1] **name** (CONF:5284).
 - a. The content of name **SHALL** be a conformant [US Realm Patient Name \(PTN.US.FIELDDED\)](#) (2.16.840.1.113883.10.20.22.5.1) (CONF:10411).
 - 2. This patient **SHALL** contain exactly one [1..1] **administrativeGenderCode**, which **SHALL** be selected from ValueSet Administrative Gender (HL7 V3) 2.16.840.1.113883.1.11.1 **DYNAMIC** (CONF:6394).
 - 3. This patient **SHALL** contain exactly one [1..1] **birthTime** (CONF:5298).
 - a. **SHALL** be precise to year (CONF:5299).
 - b. **SHOULD** be precise to day (CONF:5300).
 - 4. This patient **SHOULD** contain zero or one [0..1] **maritalStatusCode**, which **SHALL** be selected from ValueSet HL7 MaritalStatus 2.16.840.1.113883.1.11.12212 **DYNAMIC** (CONF:5303).
 - 5. This patient **MAY** contain zero or one [0..1] **religiousAffiliationCode**, which **SHALL** be selected from ValueSet HL7 Religious Affiliation 2.16.840.1.113883.1.11.19185 **DYNAMIC** (CONF:5317).
 - 6. This patient **MAY** contain zero or one [0..1] **raceCode**, which **SHALL** be selected from ValueSet Race 2.16.840.1.113883.1.11.14914 **DYNAMIC** (CONF:5322).
 - 7. This patient **MAY** contain zero or more [0..*] **sdct:raceCode**, where the **@code** **SHALL** be selected from ValueSet Race 2.16.840.1.113883.1.11.14914 **DYNAMIC** (CONF:7263).
 - 8. This patient **MAY** contain zero or one [0..1] **ethnicGroupCode**, which **SHALL** be selected from ValueSet Ethnicity Value 2.16.840.1.114222.4.11.837 **DYNAMIC** (CONF:5323).

3.2.1.2 Guardian

- 9. This patient **MAY** contain zero or more [0..*] **guardian** (CONF:5325).

- a. The guardian, if present, **SHOULD** contain zero or one [0..1] **code**, which **SHALL** be selected from ValueSet PersonalRelationshipRoleType plus ResponsibleParty value set (**NEWCONF:xxxxxx**).
- b. The id **SHOULD** utilize the combined @root and @extension attributes to record the person's identity in a secure, trusted, and unique way. (**NEWCONF:xxxxxx**).
- c. The guardian, if present, **SHOULD** contain zero or more [0..*] **addr** (CONF:5359).
 - i. The content of addr **SHALL** be a conformant [US Realm Address \(AD.US.FIELDDED\)](#) (2.16.840.1.113883.10.20.22.5.2) (CONF:10413).
- d. The guardian, if present, **MAY** contain zero or more [0..*] **telecom** (CONF:5382).
 - i. The telecom, if present, **SHOULD** contain exactly one [1..1] **@use**, which **SHALL** be selected from ValueSet [Telecom Use \(US Realm Header\) 2.16.840.1.113883.11.20.9.20 DYNAMIC](#) (CONF:7993).
- e. The guardian, if present, **SHALL** contain exactly one [1..1] **guardianPerson** (CONF:5385).
 - i. This guardianPerson **SHALL** contain at least one [1..*] **name** (CONF:5386).
 - 1. The content of name **SHALL** be a conformant [US Realm Person Name \(PN.US.FIELDDED\)](#) (2.16.840.1.113883.10.20.22.5.1.1) (CONF:10414).

3.2.1.3 Birthplace

10. This patient **MAY** contain zero or one [0..1] **birthplace** (CONF:5395).
- a. The birthplace, if present, **SHALL** contain exactly one [1..1] **place** (CONF:5396).
 - i. This place **SHALL** contain exactly one [1..1] **addr** (CONF:5397).
 - 1. This addr **SHOULD** contain zero or one [0..1] **country**, where the @code **SHALL** be selected from ValueSet CountryValueSet 2.16.840.1.113883.3.88.12.80.63 **DYNAMIC** (CONF:5404).
 - 2. This addr **MAY** contain zero or one [0..1] **postalCode**, where the @code **SHALL** be selected from ValueSet PostalCodeValueSet

2.16.840.1.113883.3.88.12.80.2 **DYNAMIC**
(CONF:5403).

3. This addr **SHALL** contain exactly one [1..1] state, which **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.80.1 StateValueSet **DYNAMIC** (CONF:5402).

3.2.1.4 LanguageCommunication

11.This patient **SHOULD** contain zero or more [0..*]

languageCommunication (CONF:5406).

- a. The languageCommunication, if present, **SHALL** contain exactly one [1..1] **languageCode**, which **SHALL** be selected from ValueSet Language 2.16.840.1.113883.1.11.11526 **DYNAMIC** (CONF:5407).
- b. The languageCommunication, if present, **MAY** contain zero or one [0..1] **modeCode**, which **SHALL** be selected from ValueSet HL7 LanguageAbilityMode 2.16.840.1.113883.1.11.12249 **DYNAMIC** (CONF:5409).
- c. The languageCommunication, if present, **SHOULD** contain zero or one [0..1] **proficiencyLevelCode**, which **SHALL** be selected from ValueSet LanguageAbilityProficiency 2.16.840.1.113883.1.11.12199 **DYNAMIC** (CONF:9965).
- d. The languageCommunication, if present, **MAY** contain zero or one [0..1] **preferenceInd** to indicate a preference for communication about care delivery and treatments to be translated into this language (**NEWCONF:xxxxxx**).
 - i. If more than one languageCommunication is present, only one languageCommunication element **SHALL** a **preferenceInd** with a value of 1 (**NEWCONF:xxxxxx**).

3.2.1.5 ProviderOrganization

If present this organization represents the person's primary care provider organization.

v. This patientRole **MAY** contain zero or one [0..1] **providerOrganization** (CONF:5416).

1. The providerOrganization, if present, **SHALL** contain at least one [1..*] **id** (CONF:5417).

- a. Such ids **SHOULD** contain zero or one [0..1]
@root="2.16.840.1.113883.4.6" National Provider Identifier (CONF:16820).
2. The providerOrganization, if present, **SHALL** contain at least one [1..*] **name** (CONF:5419).
3. The providerOrganization, if present, **SHALL** contain at least one [1..*] **telecom** (CONF:5420).
 - a. Such telecoms **SHOULD** contain exactly one [1..1] **@use**, which **SHALL** be selected from ValueSet [Telecom Use \(US Realm Header\)](#) [2.16.840.1.113883.11.20.9.20 DYNAMIC](#) (CONF:7994).
4. The providerOrganization, if present, **SHALL** contain at least one [1..*] **addr** (CONF:5422).
 - a. The content of addr **SHALL** be a conformant [US Realm Address \(AD.US.FIELDDED\)](#) (2.16.840.1.113883.10.20.22.5.2) (CONF:10415).

3.2.1.6 RecordTarget Value Sets

Table 8: Telecom Use (US Realm Header) Value Set

Value Set: Telecom Use (US Realm Header) 2.16.840.1.113883.11.20.9.20 DYNAMIC		
Code System(s): AddressUse 2.16.840.1.113883.5.1119		
Code	Code System	Print Name
HP	AddressUse	primary home
WP	AddressUse	work place
MC	AddressUse	mobile contact
HV	AddressUse	vacation home

Table 9: Administrative Gender (HL7) Value Set

Value Set: Administrative Gender (HL7 V3) 2.16.840.1.113883.1.11.1 DYNAMIC		
Code System(s): AdministrativeGender 2.16.840.1.113883.5.1		
Code	Code System	Print Name
F	AdministrativeGender	Female
M	AdministrativeGender	Male
UN	AdministrativeGender	Undifferentiated

Table 10: Marital Status Value Set

Value Set: HL7 Marital Status 2.16.840.1.113883.1.11.12212 DYNAMIC		
Code System(s): MaritalStatus 2.16.840.1.113883.5.2		
Code	Code System	Print Name
A	MaritalStatus	Annulled
D	MaritalStatus	Divorced
I	MaritalStatus	Interlocutory
L	MaritalStatus	Legally Separated
M	MaritalStatus	Married
P	MaritalStatus	Polygamous
S	MaritalStatus	Never Married
T	MaritalStatus	Domestic partner
W	MaritalStatus	Widowed

Table 11: Religious Affiliation Value Set (excerpt)

Value Set: HL7 Religious Affiliation 2.16.840.1.113883.1.11.19185 DYNAMIC		
Code System(s): ReligiousAffiliation 2.16.840.1.113883.5.1076		
Description:	A value set of codes that reflect spiritual faith affiliation http://www.hl7.org/memonly/downloads/v3edition.cfm#V32008	
Code	Code System	Print Name
1026	ReligiousAffiliation	Judaism
1020	ReligiousAffiliation	Hinduism
1041	ReligiousAffiliation	Roman Catholic Church
...		

Table 12: Race Value Set (excerpt)

Value Set: Race 2.16.840.1.113883.1.11.14914 DYNAMIC		
Code System(s): Race and Ethnicity - CDC 2.16.840.1.113883.6.238		
Description: A Value Set of codes for Classifying data based upon race. Race is always reported at the discretion of the person for whom this attribute is reported, and reporting must be completed according to Federal guidelines for race reporting. Any code descending from the Race concept (1000-9) in that terminology may be used in the exchange http://phinvads.cdc.gov/vads/ViewCodeSystemConcept.action?oid=2.16.840.1.113883.6.238&code=1000-9		
Code	Code System	Print Name
1002-5	Race and Ethnicity- CDC	American Indian or Alaska Native
2028-9	Race and Ethnicity- CDC	Asian
2054-5	Race and Ethnicity- CDC	Black or African American
2076-8	Race and Ethnicity- CDC	Native Hawaiian or Other Pacific Islander
2106-3	Race and Ethnicity- CDC	White
...		

Table 13: Ethnicity Value Set

Value Set: Ethnicity Value Set 2.16.840.1.114222.4.11.837 DYNAMIC		
Code System(s): Race and Ethnicity - CDC 2.16.840.1.113883.6.238		
Code	Code System	Print Name
2135-2	Race and Ethnicity Code Sets	Hispanic or Latino
2186-5	Race and Ethnicity Code Sets	Not Hispanic or Latino

Table 14: Personal Relationship Role Type Value Set (excerpt)

Value Set: Personal Relationship Role Type 2.16.840.1.113883.1.11.19563 DYNAMIC		
Code System(s): RoleCode 2.16.840.1.113883.5.111		
Description: A Personal Relationship records the role of a person in relation to another person. This value set is to be used when recording the relationships between different people who are not necessarily related by family ties, but also includes family relationships. http://www.hl7.org/memonly/downloads/v3edition.cfm#V32008		
Code	Code System	Print Name
HUSB	RoleCode	husband
WIFE	RoleCode	wife
FRND	RoleCode	friend
SISINLAW	RoleCode	sister-in-law
...		

Table X: Responsible Party Value Set (excerpt)

Table 15: State Value Set (excerpt)

Value Set: StateValueSet 2.16.840.1.113883.3.88.12.80.1 DYNAMIC		
Code System(s): FIPS 5-2 (State) 2.16.840.1.113883.6.92		
Description: Codes for the Identification of the States, the District of Columbia and the Outlying Areas of the United States, and Associated Areas Publication # 5-2, May, 1987 http://www.itl.nist.gov/fipspubs/fip5-2.htm		
Code	Code System	Print Name
AL	FIPS 5-2 (State Alpha Codes)	Alabama
AK	FIPS 5-2 (State Alpha Codes)	Alaska
AZ	FIPS 5-2 (State Alpha Codes)	Arizona
AR	FIPS 5-2 (State Alpha Codes)	Arkansas
...		

Table 16: Postal Code Value Set (excerpt)

Value Set: PostalCodeValueSet 2.16.840.1.113883.3.88.12.80.2 DYNAMIC		
Code System(s): US Postal Codes 2.16.840.1.113883.6.231		
Description: A value set of codes postal (ZIP) Code of an address in the United States. http://zip4.usps.com/zip4/welcome.jsp		
Code	Code System	Print Name
19009	US Postal Codes	Bryn Athyn, PA
92869-1736	US Postal Codes	Orange, CA
32830-8413	US Postal Codes	Lake Buena Vista, FL
...		

Table 17: Country Value Set (excerpt)

Value Set: CountryValueSet 2.16.840.1.113883.3.88.12.80.63 DYNAMIC		
Code System(s): ISO 3166-1 Country Codes: 1.0.3166.1		
Description: A value set of codes for the representation of names of countries, territories and areas of geographical interest. Note: This table provides the ISO 3166-1 code elements available in the alpha-2 code of ISO's country code standard http://www.iso.org/iso/country_codes/iso_3166_code_lists.htm		
Code	Code System	Print Name
AW	ISO 3166-1 Country Codes	Aruba
IL	ISO 3166-1 Country Codes	Israel
KZ	ISO 3166-1 Country Codes	Kazakhstan
US	ISO 3166-1 Country Codes	United States
...		

Table 18: Language Ability Value Set

Value Set: HL7 LanguageAbilityMode 2.16.840.1.113883.1.11.12249 DYNAMIC		
Code System(s): LanguageAbilityMode 2.16.840.1.113883.5.60		
Description: A value representing the method of expression of the language.		
Code	Code System	Print Name
ESGN	LanguageAbilityMode	Expressed signed
ESP	LanguageAbilityMode	Expressed spoken
EWR	LanguageAbilityMode	Expressed written
RSGN	LanguageAbilityMode	Received signed
RSP	LanguageAbilityMode	Received spoken
RWR	LanguageAbilityMode	Received written

Table 19: Language Ability Proficiency Value Set

Value Set: LanguageAbilityProficiency 2.16.840.1.113883.1.11.12199 DYNAMIC		
Code System(s): LanguageAbilityProficiency 2.16.840.1.113883.5.61		
Description: A value representing the level of proficiency in a language.		
Code	Code System	Print Name
E	LanguageAbilityProficiency	Excellent
F	LanguageAbilityProficiency	Fair
G	LanguageAbilityProficiency	Good
P	LanguageAbilityProficiency	Poor

3.2.1.7 RecordTarget Example

Figure 17: US Realm recordTarget example

```

<recordTarget>
  <patientRole>
    <!-- Fake ID using HL7 example OID. -->
    <id extension="12345" root="2.16.840.1.113883.19"/>
    <!-- Fake Social Security Number using the actual SSN OID. -->
    <id extension="111-00-1234" root="2.16.840.1.113883.4.1"/>
    <!-- Fake MRN at preferred provider/primary care practice. See id below -->
    <id extension="9876543" root="2.16.840.1.113883.19.18123"/>
    <!-- Fake DirectTrust address. -->
    <id extension="myDirectAddr@myHISP.org" root="2.16.840.1.5.167540.12345"/>
    <addr use="HP">
      <!-- HP is "primary home" from codeSystem 2.16.840.1.113883.5.1119 -->
      <streetAddressLine>17 Daws Rd.</streetAddressLine>
      <city>Blue Bell</city>
      <state>MA</state>
      <postalCode>02368</postalCode>
      <country>US</country>
      <!-- US is "United States" from ISO 3166-1 Country Codes: 1.0.3166.1 -->
    </addr>
    <telecom value="tel:(781)555-1212" use="HP"/>
    <!-- HP is "primary home" from AddressUse 2.16.840.1.113883.5.1119 -->
  </patientRole>
  <patient>
    <name use="L">
      <!-- L is "Legal" from EntityNameUse 2.16.840.1.113883.5.45 -->
      <prefix>Mr.</prefix>
      <given>Adam</given>
      <given qualifier="CL">Frankie</given>
      <!-- CL is "Call me" from EntityNamePartQualifier
      2.16.840.1.113883.5.43 -->
      <family>Everyman</family>
    </name>
    <administrativeGenderCode code="M"
      codeSystem="2.16.840.1.113883.5.1" displayName="Male"/>
    <birthTime value="19541125"/>
    <maritalStatusCode code="M" displayName="Married"
      codeSystem="2.16.840.1.113883.5.2"
      codeSystemName="MaritalStatusCode"/>
  </patient>
</recordTarget>

```

```

<religiousAffiliationCode code="1013"
  displayName="Christian (non-Catholic, non-specific)"
  codeSystemName="Religious Affiliation "
  codeSystem="2.16.840.1.113883.5.1076"/>
<raceCode code="2106-3" displayName="White"
  codeSystem="2.16.840.1.113883.6.238"
  codeSystemName="Race & Ethnicity - CDC"/>
<ethnicGroupCode code="2186-5"
  displayName="Not Hispanic or Latino"
  codeSystem="2.16.840.1.113883.6.238"
  codeSystemName="Race & Ethnicity - CDC"/>
<guardian>
  <code code="GRFTH" displayName="Grandfather"
    codeSystem="2.16.840.1.113883.5.111"
    codeSystemName="RoleCode"/>
  <addr use="HP">
    <streetAddressLine>17 Daws Rd.</streetAddressLine>
    <city>Blue Bell</city>
    <state>MA</state>
    <postalCode>02368</postalCode>
    <country>US</country>
  </addr>
  <telecom value="tel:(781)555-1212" use="HP"/>
  <guardianPerson>
    <name>
      <given>Ralph</given>
      <family>Relative</family>
    </name>
  </guardianPerson>
</guardian>
<birthplace>
  <place>
    <addr>
      <state>MA</state>
      <postalCode>02368</postalCode>
      <country>US</country>
    </addr>
  </place>
</birthplace>
<languageCommunication>
  <languageCode code="fr-CN"/>
  <modeCode code="RWR" displayName="Receive Written"
    codeSystem="2.16.840.1.113883.5.60"
    codeSystemName="LanguageAbilityMode"/>
  <preferenceInd value="true"/>
</languageCommunication>
</patient>

```



```

<providerOrganization>
  <id root="2.16.840.1.113883.19" extension="18123"/>
  <name>Good Health Clinic</name>
  <telecom use="WP" value="tel:(781)555-1212"/>
  <addr>
    <streetAddressLine>21 North Ave</streetAddressLine>
    <city>Burlington</city>
    <state>MA</state>
    <postalCode>02368</postalCode>
    <country>US</country>
  </addr>
</providerOrganization>
</patientRole>
</recordTarget>

```

3.2.2 Author

The author element represents the creator of the clinical document. The author may be a device, or a person. The person is the patient or the patient's advocate.

36. **SHALL** contain at least one [1..*] **author** (CONF:5444).
- a. Such authors **SHALL** contain exactly one [1..1] **time** (CONF:5445).
 - i. The content **SHALL** be a conformant [US Realm Date and Time \(DTM.US.FIELDDED\)](#) (2.16.840.1.113883.10.20.22.5.4) (CONF:16866).
 - b. Such authors **SHALL** contain exactly one [1..1] **assignedAuthor** (CONF:5448).
 - i. This assignedAuthor **SHALL** contain exactly one [1..1] **id** (CONF:5449) such that it
 1. The id **SHOULD** utilize the combined **@root** and **@extension** attributes to record the person's or the device's identity in a secure, trusted, and unique way. (**NEWCONF:xxxxxx**).
 - ii. When the author is a person, this assignedAuthor **SHALL** contain one [1..1] **code** (**NEWCONF:xxxxxx**).
 1. The code, **SHALL** contain exactly one [1..1] **@code**, which **SHOULD** be selected from the PersonalRelationshipRoleType value set plus ResponsibleParty (**NEWCONF:xxxxxx**)
 - iii. This assignedAuthor **SHALL** contain at least one [1..*] **addr** (CONF:5452).
 1. The content **SHALL** be a conformant [US Realm Address \(AD.US.FIELDDED\)](#) (2.16.840.1.113883.10.20.22.5.2) (CONF:16871).
 - iv. This assignedAuthor **SHALL** contain at least one [1..*] **telecom** (CONF:5428).
 1. Such telecoms **SHOULD** contain exactly one [1..1] **@use**, which **SHALL** be selected from ValueSet [Telecom Use \(US Realm](#)

[Header](#)) [2.16.840.1.113883.11.20.9.20](#) **DYNAMIC**
(CONF:7995).

- v. There **SHALL** be exactly one assignedAuthor/assignedPerson or exactly one assignedAuthor/assignedAuthoringDevice (CONF:16790).
- vi. This assignedAuthor **SHOULD** contain zero or one [0..1] **assignedPerson** (CONF:5430).
 - 1. The assignedPerson, if present, **SHALL** contain at least one [1..*] **name** (CONF:16789).
 - a. The content **SHALL** be a conformant [US Realm Person Name \(PN.US.FIELDDED\)](#) (2.16.840.1.113883.10.20.22.5.1.1) (CONF:16872).
- vii. This assignedAuthor **SHOULD** contain zero or one [0..1] **assignedAuthoringDevice** (CONF:16783).
 - 1. The assignedAuthoringDevice, if present, **SHALL** contain exactly one [1..1] **manufacturerModelName** (CONF:16784).
 - 2. The assignedAuthoringDevice, if present, **SHALL** contain exactly one [1..1] **softwareName** (CONF:16785).

Figure 18: Person author example

```
<author>
  <time value="20050329224411+0500" />
  <assignedAuthor>
    <id extension="KP00017" root="DIRECT ADDRESS example??" />
    <code code='MTH' codeSystem='2.16.840.1.113883.5.111' />
    <addr>
      <streetAddressLine>21 North Ave.</streetAddressLine>
      <city>Burlington</city>
      <state>MA</state>
      <postalCode>02368</postalCode>
      <country>US</country>
    </addr>
    <telecom use="WP" value="tel:(555)555-1003" />
    <assignedPerson>
      <name>
        <given>Mary</given>
        <family>Seven</family>
      </name>
    </assignedPerson>
  </assignedAuthor>
</author>
```

Figure 19: Device author example

```
<author>
  <time value="20050329224411+0500" />
  <assignedAuthor>
    <id extension="KP00017dev" root="2.16.840.1.113883.19.5" />
    <addr>
      <streetAddressLine>21 North Ave.</streetAddressLine>
      <city>Burlington</city>
      <state>MA</state>
      <postalCode>02368</postalCode>
      <country>US</country>
    </addr>
    <telecom use="WP" value="tel:(555)555-1003" />
    <assignedAuthoringDevice>
      <manufacturerModelName>Good Health Medical
        Device</manufacturerModelName >
      <softwareName>Good Health Report Generator</softwareName >
    </ assignedAuthoringDevice >
  </assignedAuthor>
</author>
```

3.2.3 DataEnterer

The `dataEnterer` element represents the person who transferred the content, written or dictated by someone else, into the clinical document. The guiding rule of thumb is that an `author` provides the content found within the header or body of the document, subject to their own interpretation, and the `dataEnterer` adds that information to the electronic system. In other words, a `dataEnterer` transfers information from one source to another (e.g., transcription from paper form to electronic system).

37. **MAY** contain zero or one [0..1] **dataEnterer** (CONF:5441).

a. The `dataEnterer`, if present, **SHALL** contain exactly one [1..1] **assignedEntity** (CONF:5442).

i. This `assignedEntity` **SHALL** contain at least one [1..*] **id** (CONF:5443).

1. Each **id** **SHOULD** utilize the combined **@root** and **@extension** attributes to record a patient's identity in a secure, trusted, and unique way. **(NEWCONF:xxxxx)**.

ii. This `assignedEntity` **SHALL** contain at least one [1..*] **addr** (CONF:5460).

1. The content of **addr** **SHALL** be a conformant [US Realm Address \(AD.US.FIELDDED\)](#) (2.16.840.1.113883.10.20.22.5.2) (CONF:10417).

iii. This `assignedEntity` **SHALL** contain at least one [1..*] **telecom** (CONF:5466).

1. Such telecoms **SHOULD** contain exactly one [1..1] **@use**, which **SHALL** be selected from ValueSet [Telecom Use \(US Realm Header\) 2.16.840.1.113883.11.20.9.20 DYNAMIC](#) (CONF:7996).

- iv. This assignedEntity **SHALL** contain exactly one [1..1] assignedPerson (CONF:5469).
 - 1. This assignedPerson **SHALL** contain at least one [1..*] name (CONF:5470).
 - a. The content of name **SHALL** be a conformant [US Realm Person Name \(PN.US.FIELDDED\)](#) (2.16.840.1.113883.10.20.22.5.1.1) (CONF:10418).
- v. This assignedEntity **MAY** contain zero or one [0..1] code which **SHOULD** be selected from value set PersonalRelationshipRoleType plus ResponsibleParty value set (**NEWCONF:xxxxxx**).

Figure 20: dataEnterer example

```

<dataEnterer>
  <assignedEntity>
    <id root="2.16.840.1.113883.19.5" extension="43252"/>
    <addr>
      <streetAddressLine>21 North Ave.</streetAddressLine>
      <city>Burlington</city>
      <state>MA</state>
      <postalCode>02368</postalCode>
      <country>US</country>
    </addr>
    <telecom use="WP" value="tel:(555)555-1003"/>
    <assignedPerson>
      <name>
        <given>Mary</given>
        <family>Seven</family>
      </name>
      <code code='MTH' codeSystem='2.16.840.1.113883.5.111' />
    </assignedPerson>
  </assignedEntity>
</dataEnterer>

```

3.2.4 Informant

The informant element describes the source of the information in a medical document.

Assigned health care providers may be a source of information when a document is created. (e.g., a nurse's aide who provides information about a recent significant health care event that occurred within an acute care facility.) In these cases, the assignedEntity element is used.

When the informant is a personal relation, that informant is represented in the relatedEntity element. The code element of the relatedEntity describes the relationship between the informant and the patient. The relationship between the informant and the patient needs to be described to help the receiver of the clinical document understand the information in the document.

38. **MAY** contain zero or more [0..*] informant (CONF:8001).

- a. **SHALL** contain exactly one [1..1] assignedEntity OR exactly one [1..1] relatedEntity (CONF:8002).
 - i. **SHOULD** contain at least one [1..*] **addr** (CONF:8220).
 - 1. The content of **addr** **SHALL** be a conformant [US Realm Address \(AD.US.FIELDDED\)](#) (2.16.840.1.113883.10.20.22.5.2) (CONF:10419).
 - ii. **SHALL** contain exactly one [1..1] assignedPerson OR exactly one [1..1] relatedPerson (CONF:8221).
 - 1. **SHALL** contain at least one [1..*] **name** (CONF:8222).
 - a. The content of **name** **SHALL** be a conformant [US Realm Person Name \(PN.US.FIELDDED\)](#) (2.16.840.1.113883.10.20.22.5.1.1) (CONF:10420).
 - iii. This assignedEntity **MAY** contain zero or one [0..1] **code** which **SHOULD** be selected from coding system NUCC Health Care Provider Taxonomy 2.16.840.1.113883.6.101 for an assigned person who is a care provider or which **SHOULD** be selected from value set PersonalRelationshipRoleType plus ResponsibleParty value set for a relatedPerson (**NEWCONF:xxxxxx**).
 - iv. **SHOULD** contain zero or more [0..*] **id** (CONF:9945).
 - 1. If assignedEntity/id is for a provider then this id, **SHOULD** include zero or one [0..1] id where id/@root = "2.16.840.1.113883.4.6" National Provider Identifier ([CONF:9946](#)).
 - 2. If assignedEntity/id is for a related person then this id, **SHOULD** include zero or one [0..1] id where the id utilizes the combined **@root** and **@extension** attributes to record a patient's identity in a secure, trusted, and unique way. (**NEWCONF:xxxxxx**).

Figure 21: Informant with assignedEntity example

```
<informant>
  <assignedEntity>
    <id extension="KP00017" root="2.16.840.1.113883.19.5"/>
    <addr>
      <streetAddressLine>21 North Ave.</streetAddressLine>
      <city>Burlington</city>
      <state>MA</state>
      <postalCode>02368</postalCode>
      <country>US</country>
    </addr>
    <telecom value="tel:(555)555-1003"/>
    <assignedPerson>
      <name>
        <given>Henry</given>
        <family>Seven</family>
      </name>
    </assignedPerson>
  </assignedEntity>
</informant>
```

3.2.5 Custodian

The custodian element represents the organization that is in charge of maintaining the document. The custodian is the steward that is entrusted with the care of the document. Every CDA document has exactly one custodian. The custodian participation satisfies the CDA definition of Stewardship. Because CDA is an exchange standard and may not represent the original form of the authenticated document (e.g., CDA could include scanned copy of original), the custodian represents the steward of the original source document. The custodian may be the document originator, a health information exchange, or other responsible party.

39. **SHALL** contain exactly one [1..1] **custodian** (CONF:5519).

a. This custodian **SHALL** contain exactly one [1..1] **assignedCustodian** (CONF:5520).

i. This assignedCustodian **SHALL** contain exactly one [1..1] **representedCustodianOrganization** which may be the person when the document is not maintained by an organization. **(NEWCONF:xxxxxx)**.

1. This representedCustodianOrganization **SHALL** contain at least one [1..*] **id** (CONF:5522).

a. Such ids **SHOULD** utilize the combined **@root** and **@extension** attributes to record the custodian organization's identity in a secure, trusted, and unique way. **(NEWCONF:xxxxxx)**.

2. This representedCustodianOrganization **SHALL** contain exactly one [1..1] **name** (CONF:5524).

3. This representedCustodianOrganization **SHALL** contain exactly one [1..1] **telecom** (CONF:5525).

- a. This telecom **SHOULD** contain exactly one [1..1] @use, which **SHALL** be selected from ValueSet [Telecom Use \(US Realm Header\)](#) (2.16.840.1.113883.11.20.9.20 **DYNAMIC** (CONF:7998).
- 4. This representedCustodianOrganization **SHALL** contain at least one [1..*] addr (CONF:5559).
 - a. The content of addr **SHALL** be a conformant [US Realm Address \(AD.US.FIELDDED\)](#) (2.16.840.1.113883.10.20.22.5.2) (CONF:10421).

Figure 22: Custodian example

```

<custodian>
  <assignedCustodian>
    <representedCustodianOrganization>
      <id root="2.16.840.1.113883.19.5"/>
      <name>Good Health Clinic</name>
      <telecom value="tel:(555)555-1212" use="WP"/>
      <addr use="WP">
        <streetAddressLine>17 Daws Rd.</streetAddressLine>
        <city>Blue Bell</city>
        <state>MA</state>
        <postalCode>02368</postalCode>
        <country>US</country>
      </addr>
    </representedCustodianOrganization>
  </assignedCustodian>
</custodian>

```

3.2.6 InformationRecipient

The informationRecipient element records the intended recipient of the information at the time the document is created. For example, in cases where the intended recipient of the document is the patient's health chart, set the receivedOrganization to be the scoping organization for that chart.

- 40. **MAY** contain zero or more [0..*] informationRecipient (CONF:5565).
 - a. The informationRecipient, if present, **SHALL** contain exactly one [1..1] intendedRecipient (CONF:5566).
 - i. This intendedRecipient **SHOULD** contain atleast one [1..*] id (**NEWCONF:xxxxxx**).
 1. Such ids **SHOULD** utilize the combined @root and @extension attributes to record the information recipient's identity in a secure, trusted, and unique way. (**NEWCONF:xxxxxx**).
 2. For a provider then this id, **SHOULD** include zero or one [0..1] id where id/@root ="2.16.840.1.113883.4.6" National Provider Identifier (**NEWCONF:xxxxxx**).

- ii. This intendedRecipient **MAY** contain zero or one [0..1] **informationRecipient** (CONF:5567).
 - 1. The informationRecipient, if present, **SHALL** contain at least one [1..*] **name** (CONF:5568).
 - a. The content of name **SHALL** be a conformant [US Realm Person Name \(PN.US.FIELDDED\)](#) (2.16.840.1.113883.10.20.22.5.1.1) (CONF:10427).
- iii. This intendedRecipient **MAY** contain zero or one [0..1] **receivedOrganization** (CONF:5577).
 - 1. The receivedOrganization, if present, **SHALL** contain exactly one [1..1] **name** (CONF:5578).

Figure 23: informationRecipient example

```

<informationRecipient>
  <intendedRecipient>
    <informationRecipient>
      <name>
        <given>Henry</given>
        <family>Seven</family>
      </name>
    </informationRecipient>
    <receivedOrganization>
      <name>Good Health Clinic</name>
    </receivedOrganization>
  </intendedRecipient>
</informationRecipient>

```

3.2.7 LegalAuthenticator

In a patient authored document, the legalAuthenticator identifies the single person legally responsible for the document and must be present if the document has been legally authenticated. (Note that per the following section, there may also be one or more document authenticators.)

Based on local practice, patient authored documents may be provided without legal authentication. This implies that a patient authored document that does not contain this element has not been legally authenticated.

The act of legal authentication requires a certain privilege be granted to the legal authenticator depending upon local policy. All patient documents have the potential for legal authentication, given the appropriate legal authority.

Local policies **MAY** choose to delegate the function of legal authentication to a device or system that generates the document. In these cases, the legal authenticator is the person accepting responsibility for the document, not the generating device or system.

Note that the legal authenticator, if present, must be a person.

41. **SHOULD** contain zero or one [0..1] **legalAuthenticator** (CONF:5579).

- a. The legalAuthenticator, if present, **SHALL** contain exactly one [1..1] **time** (CONF:5580).
 - i. The content **SHALL** be a conformant [US Realm Date and Time \(DTM.US.FIELDDED\)](#) (2.16.840.1.113883.10.20.22.5.4) (CONF:16873).
- b. The legalAuthenticator, if present, **SHALL** contain exactly one [1..1] **signatureCode** (CONF:5583).
 - i. This signatureCode **SHALL** contain exactly one [1..1] **@code="S"** (CodeSystem: Participationsignature 2.16.840.1.113883.5.89) (CONF:5584).
- c. The legalAuthenticator, if present, **SHALL** contain exactly one [1..1] **assignedEntity** (CONF:5585).
 - i. This assignedEntity **SHALL** contain at least one [1..*] **id** (CONF:5586).
 - 1. Such ids **SHOULD** utilize the combined **@root** and **@extension** attributes to record the legal authenticator's identity in a secure, trusted, and unique way. (**NEWCONF:xxxxxx**).
 - ii. This assignedEntity **MAY** contain zero or one [0..1] **code**, which **SHOULD** be selected from the PersonalRelationshipRoleType plus ResponsibleParty value set (**NEWCONF:xxxxxx**).
 - iii. This assignedEntity **SHALL** contain at least one [1..*] **addr** (CONF:5589).
 - 1. The content of addr **SHALL** be a conformant [US Realm Address \(AD.US.FIELDDED\)](#) (2.16.840.1.113883.10.20.22.5.2) (CONF:10429).
 - iv. This assignedEntity **SHALL** contain at least one [1..*] **telecom** (CONF:5595).
 - 1. Such telecoms **SHOULD** contain exactly one [1..1] **@use**, which **SHALL** be selected from ValueSet [Telecom Use \(US Realm Header\) 2.16.840.1.113883.11.20.9.20 DYNAMIC](#) (CONF:7999).
 - v. This assignedEntity **SHALL** contain exactly one [1..1] **assignedPerson** (CONF:5597).
 - 1. This assignedPerson **SHALL** contain at least one [1..*] **name** (CONF:5598).
 - a. The content of name **SHALL** be a conformant [US Realm Person Name \(PN.US.FIELDDED\)](#) (2.16.840.1.113883.10.20.22.5.1.1) (CONF:10430).

Figure 24: legalAuthenticator example

```
<legalAuthenticator>
  <time value="20050329224411+0500"/>
  <signatureCode code="S"/>
  <assignedEntity>
    <id extension="KP00017" root="2.16.840.1.113883.19"/>
    <addr>
      <streetAddressLine>21 North Ave.</streetAddressLine>
      <city>Burlington</city>
      <state>MA</state>
      <postalCode>02368</postalCode>
      <country>US</country>
    </addr>
    <telecom use="WP" value="tel:(555)555-1003"/>
    <assignedPerson>
      <name>
        <given>Henry</given>
        <family>Seven</family>
      </name>
    </assignedPerson>
  </assignedEntity>
</legalAuthenticator>
```

3.2.8 Authenticator

The `authenticator` identifies a participant or participants who attested to the accuracy of the information in the document.

42. **MAY** contain zero or more [0..*] **authenticator** (CONF:5607).
- a. The authenticator, if present, **SHALL** contain exactly one [1..1] **time** (CONF:5608).
 - i. The content **SHALL** be a conformant [US Realm Date and Time \(DTM.US.FIELDDED\)](#) (2.16.840.1.113883.10.20.22.5.4) (CONF:16874).
 - b. The authenticator, if present, **SHALL** contain exactly one [1..1] **signatureCode** (CONF:5610).
 - i. This `signatureCode` **SHALL** contain exactly one [1..1] `@code="S"` (CodeSystem: Participationsignature 2.16.840.1.113883.5.89) (CONF:5611).
 - c. The authenticator, if present, **SHALL** contain exactly one [1..1] **assignedEntity** (CONF:5612).
 - i. This `assignedEntity` **SHALL** contain at least one [1..*] **id** (CONF:5613).
 1. Such `ids` **SHOULD** utilize the combined `@root` and `@extension` attributes to record the authenticator's identity in a secure, trusted, and unique way. (**NEWCONF:xxxxxx**).
 - ii. This `assignedEntity` **SHOULD** contain zero or one [0..1] **code** (**NEWCONF:xxxxxx**).
 1. The code **SHOULD** be selected from value set `PersonalRelationshipRoleType` plus `ResponsibleParty` value set (**NEWCONF:xxxxxx**).

- iii. This assignedEntity **SHALL** contain at least one [1..*] **addr** (CONF:5616).
 - 1. The content of addr **SHALL** be a conformant [US Realm Address \(AD.US.FIELDDED\)](#) (2.16.840.1.113883.10.20.22.5.2) (CONF:10425).
- iv. This assignedEntity **SHALL** contain at least one [1..*] **telecom** (CONF:5622).
 - 1. Such telecoms **SHOULD** contain exactly one [1..1] **@use**, which **SHALL** be selected from ValueSet [Telecom Use \(US Realm Header\) 2.16.840.1.113883.11.20.9.20 DYNAMIC](#) (CONF:8000).
- v. This assignedEntity **SHALL** contain exactly one [1..1] **assignedPerson** (CONF:5624).
 - 1. This assignedPerson **SHALL** contain at least one [1..*] **name** (CONF:5625).
 - a. The content of name **SHALL** be a conformant [US Realm Person Name \(PN.US.FIELDDED\)](#) (2.16.840.1.113883.10.20.22.5.1.1) (CONF:10424).

Figure 25: Authenticator example

```

<authenticator>
  <time value="20050329224411+0500" />
  <signatureCode code="S" />
  <assignedEntity>
    <id extension="KP00017" root="2.16.840.1.113883.19" />
    <addr>
      <streetAddressLine>21 North Ave.</streetAddressLine>
      <city>Burlington</city>
      <state>MA</state>
      <postalCode>02368</postalCode>
      <country>US</country>
    </addr>
    <telecom use="WP" value="tel:(555)555-1003" />
    <assignedPerson>
      <name>
        <given>Henry</given>
        <family>Seven</family>
      </name>
    </assignedPerson>
  </assignedEntity>
</authenticator>

```

3.2.9 Participant (Support)

The participant element identifies other supporting participants, including parents, relatives, caregivers, insurance policyholders, guarantors, and other participants related in some way to the patient.

A supporting person or organization is an individual or an organization with a relationship to the patient. A supporting person who is playing multiple roles would be recorded in multiple participants (e.g., emergency contact and next-of-kin)

43. **MAY** contain zero or more [0..*] **participant** (CONF:10003).
- a. The participant, if present, **MAY** contain zero or one [0..1] **time** (CONF:10004).
 - b. Such participants, if present, **SHALL** have an associatedPerson or scopingOrganization element under participant/associatedEntity (CONF:10006).
 - c. Unless otherwise specified by the document specific header constraints, when participant/@typeCode is IND, associatedEntity/@classCode **SHALL** be selected from ValueSet 2.16.840.1.113883.11.20.9.33 INDRoleclassCodes **STATIC** 2011-09-30 (CONF:10007).

Table 20: IND Role classCode Value Set

Value Set: INDRoleclassCodes 2.16.840.1.113883.11.20.9.33 STATIC 2011-09-30		
Code System(s): RoleClass 2.16.840.1.113883.5.110		
Code	Code System	Print Name
PRS	RoleClass	personal relationship
NOK	RoleClass	next of kin
CAREGIVER	RoleClass	caregiver
AGNT	RoleClass	agent
GUAR	RoleClass	guarantor
ECON	RoleClass	emergency contact

Figure 26: Participant example for a supporting person

```
<participant typeCode='IND'>
  <time xsi:type="IVL_TS">
    <low value="19590101"/>
    <high value="20111025"/>
  </time>
  <associatedEntity classCode='NOK'>
    <code code='MTH' codeSystem='2.16.840.1.113883.5.111' />
    <addr>
      <streetAddressLine>17 Daws Rd.</streetAddressLine>
      <city>Blue Bell</city>
      <state>MA</state>
      <postalCode>02368</postalCode>
      <country>US</country>
    </addr>
    <telecom value='tel:(555)555-2006' use='WP' />
    <associatedPerson>
      <name>
        <prefix>Mrs.</prefix>
        <given>Martha</given>
        <family>Mum</family>
      </name>
    </associatedPerson>
  </associatedEntity>
</participant>
```

3.2.10 InFulfillmentOf

The inFulfillmentOf element represents orders that are fulfilled by this document.

44. **MAY** contain zero or more [0..*] inFulfillmentOf (CONF:9952).

- a. The inFulfillmentOf, if present, **SHALL** contain exactly one [1..1] **order** (CONF:9953).
 - i. This order **SHALL** contain at least one [1..*] **id** (CONF:9954).
 1. Such ids **MAY** represent a scheduled appointment or service event in a practice management system (**NEWCONF:xxxxxx**).

3.2.11 DocumentationOf/serviceEvent

The main activity being described by a Patient Authored Note is the person's health care, health practices and relevant health history over a period of time. This is shown by setting the value of ClinicalDocument/documentationOf/serviceEvent/@classCode to "PCPR" (care provision). The ClinicalDocument/documentationOf/serviceEvent/effectiveTime indicates the span of time documented in the note. Additional data from outside this duration may also be included if it is relevant to care documented during the covered time range (e.g. A document covering this year may include information about a condition resolved several years ago which requires annual screening).

NOTE: Implementations originating a Patient Authored Note should take care to indicate the time span being documented. For example:

- When a patient fills out a form providing relevant health history prior to an initial visit to a new doctor, the span of time being documented might be from birth to the present.
 - When a patient is authoring a note to support an annual examination, it might cover just the prior year.
 - When a patient is going for a sick visit, the time span of the note may cover only a few days.
2. **SHALL** contain exactly one [1..1] **documentationOf** (CONF:8452).
- a. This **documentationOf** **SHALL** contain exactly one [1..1] **serviceEvent** (CONF:8480).
 - i. This **serviceEvent** **SHALL** contain exactly one [1..1] **@classCode="PCPR"** Provision of Care indicating the person's health care, health practices and relevant health history (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:8453).
 - ii. This **serviceEvent** **MAY** contain one [1..1] **code** (**NEWCONF:xxxxxx**).
 1. The code, **SHOULD** contain exactly one [1..1] **@code**, which **SHOULD** be selected from a value set established by the document-level template for a specific type of Patient Authored note. (**NEWCONF:xxxxxx**)
 - iii. This **serviceEvent** **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:8481).
 1. This **effectiveTime** **SHALL** contain exactly one [1..1] **low** (CONF:8454).
 2. This **effectiveTime** **SHALL** contain exactly one [1..1] **high** (CONF:8455).
 - iv. This **serviceEvent** **SHOULD** contain zero or more [0..*] **performer** (CONF:8482).
 1. **serviceEvent/performer** represents the healthcare providers, allied health professionals or other individuals involved in the current or pertinent historical care of the patient during the time span covered by the document (**NEWCONF:xxxxxx**).
 2. Such performers **SHALL** contain exactly one [1..1] **@typeCode="PRF"** Participation physical performer (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90) (CONF:8458).
 3. Such performers **MAY** contain exactly one [1..1] **functionCode**.
 - a. The **functionCode** **SHALL** be selected from value set ParticipationType 2.16.840.1.113883.1.11.10901 (**NEWCONF:xxxxxx**).
 - b. When indicating the performer was the primary care physician the **functionCode** shall be ="PCP" (**NewCONF:xxxxxx**)
 4. Such performers **MAY** contain zero or more [0..1] **assignedEntity** (CONF:8459).

- a. This assignedEntity **SHALL** contain at least one [1..*] **id** (CONF:8460).
 - i. **MAY** include zero or one [0..1] id where id/@root="2.16.840.1.113883.4.6" National Provider Identifier (**NEWCONF:xxxxxx**).
 - ii. **MAY** utilize the combined @root and @extension attributes to record the authenticator's identity in a secure, trusted, and unique way. (**NEWCONF:xxxxxx**).

- b. This assignedEntity **MAY** contain zero or one [0..1] **code** (CONF:8461).
 - i. If the assignedEntity is a provider, the code **SHOULD** be the NUCC Health Care Provider Taxonomy (CodeSystem: 2.16.840.1.113883.6.101). (See <http://www.nucc.org>) (**NEWCONF:xxxxxx**).
 - ii. If the assignedEntity is an individual, the code **SHOULD** be selected from value set Personal Relationship Role Type Plus ResponsibleParty value set (**NEWCONF:xxxxxx**).

Figure 27: DocumentationOf example

```
<documentationOf>
  <serviceEvent classCode="ACT">
    <id root="1.2.840.113619.2.62.994044785528.114289542805"/>
    <id extension="123453" root="1.2.840.113619.2.62.994044785528.26"/>
    <code code="93041"
      displayName="Rhythm ECG, one to three leads; tracing only
without interpretation and report"
      codeSystem="2.16.840.1.113883.6.12"
      codeSystemName="CPT4"/>
    <effectiveTime value="20080813222400"/>
    <performer typeCode="PRF">
      <templateId root="2.16.840.1.113883.10.20.6.2.1"/>
      <assignedEntity>
        <id extension="121008" root="2.16.840.1.113883.19.5"/>
        <code code="208D00000X" codeSystem="2.16.840.1.113883.6.101"
          codeSystemName="NUCC"
          displayName="General Practice"/>
        <addr nullFlavor="NI"/>
        <telecom nullFlavor="NI"/>
        <assignedPerson>
          <name>
            <given>Matthew</given>
            <family>Care</family>
            <suffix>MD</suffix>
          </name>
        </assignedPerson>
      </assignedEntity>
    </performer>
  </serviceEvent>
</documentationOf>
```

3.2.12 Authorization/consent

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

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

45. **MAY** contain zero or more [0..*] **authorization** (CONF:16792) such that it
- a. **SHALL** contain exactly one [1..1] **consent** (CONF:16793).
 - i. This consent **MAY** contain zero or more [0..*] **id** (CONF:16794).
 - ii. This consent **MAY** contain zero or one [0..1] **code** (CONF:16795).
 1. The type of consent (e.g., a consent to perform the related `serviceEvent`) is conveyed in `consent/code` (CONF:16796).
 - iii. This consent **SHALL** contain exactly one [1..1] **statusCode** (CONF:16797).

1. This `statusCode` **SHALL** contain exactly one [1..1] `@code="completed"` Completed (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:16798).

Figure 28: Procedure note consent example

```

<authorization typeCode="AUTH">
  <consent classCode="CONS" moodCode="EVN">
    <id root="629deb70-5306-11df-9879-0800200c9a66" />
    <code codeSystem=" 2.16.840.1.113883.6.1" codeSystemName="LOINC"
      code="64293-4" displayName="Procedure consent"/>
    <statusCode code="completed"/>
  </consent>
</authorization>

```

3.2.13 ComponentOf

The `componentOf` element contains the encompassing encounter for this document. The encompassing encounter represents the setting of the clinical encounter during which the document act(s) or `ServiceEvent` occurred.

In order to represent providers associated with a specific encounter, they are recorded within the `encompassingEncounter` as participants.

In a CCD the `encompassingEncounter` may be used when documenting a specific encounter and its participants. All relevant encounters in a CCD may be listed in the encounters section.

46. **MAY** contain zero or one [0..1] `componentOf` (CONF:9955).
 - a. The `componentOf`, if present, **SHALL** contain exactly one [1..1] `encompassingEncounter` (CONF:9956).
 - i. This `encompassingEncounter` **SHALL** contain at least one [1..*] `id` (CONF:9959).
 - ii. This `encompassingEncounter` **SHALL** contain exactly one [1..1] `effectiveTime` (CONF:9958).

3.3 US Realm Address (AD.US.FIELDDED)

[addr: 2.16.840.1.113883.10.20.22.5.2(open)]

Reusable "address" template, designed for use in US Realm CDA Header.

1. **SHOULD** contain exactly one [1..1] `@use`, which **SHALL** be selected from ValueSet [PostalAddressUse 2.16.840.1.113883.1.11.10637](#) **STATIC** 2005-05-01 (CONF:7290).
2. **SHOULD** contain zero or one [0..1] `country`, where the `@code` **SHALL** be selected from ValueSet [CountryValueSet 2.16.840.1.113883.3.88.12.80.63](#) **DYNAMIC** (CONF:7295).
3. **SHOULD** contain zero or one [0..1] `state` (ValueSet: [StateValueSet 2.16.840.1.113883.3.88.12.80.1](#) **DYNAMIC**) (CONF:7293).

- a. State is required if the country is US. If country is not specified, its assumed to be US. If country is something other than US, the state **MAY** be present but **MAY** be bound to different vocabularies (CONF:10024).
4. **SHALL** contain exactly one [1..1] **city** (CONF:7292).
5. **SHOULD** contain zero or one [0..1] **postalCode** (ValueSet: [PostalCodeValueSet 2.16.840.1.113883.3.88.12.80.2 DYNAMIC](#)) (CONF:7294).
 - a. PostalCode is required if the country is US. If country is not specified, its assumed to be US. If country is something other than US, the postalCode **MAY** be present but **MAY** be bound to different vocabularies (CONF:10025).
6. **SHALL** contain at least one and not more than 4 **streetAddressLine** (CONF:7291).
7. **SHALL NOT** have mixed content except for white space⁶ (CONF:7296).

Table 21: PostalAddressUse Value Set

Value Set: PostalAddressUse 2.16.840.1.113883.1.11.10637 STATIC 2005-05-01		
Code System(s): AddressUse 2.16.840.1.113883.5.1119		
Code	Code System	Print Name
BAD	AddressUse	bad address
DIR	AddressUse	direct
H	AddressUse	home address
HP	AddressUse	primary home
HV	AddressUse	vacation home
PHYS	AddressUse	physical visit address
PST	AddressUse	postal address
PUB	AddressUse	public
TMP	AddressUse	temporary
WP	AddressUse	work place

3.4 US Realm Date and Time (DT.US.FIELDDED)

[effectiveTime: 2.16.840.1.113883.10.20.22.5.3(open)]

The US Realm Clinical Document Date and Time datatype flavor records date and time information. If no time zone offset is provided, you can make no assumption about time, unless you have made a local exchange agreement.

This data type uses the same rules as [US Realm Date and Time \(DTM.US.FIELDDED\)](#), but is used with the effectiveTime element.

1. **SHALL** be precise to the day (CONF:10078).
2. **SHOULD** be precise to the minute (CONF:10079).
3. **MAY** be precise to the second (CONF:10080).
4. If more precise than day, **SHOULD** include time-zone offset (CONF:10081).

⁶ For information on mixed content see Extensible Markup Language (XML) (<http://www.w3.org/TR/2008/REC-xml-20081126/#sec-mixed-content>).

3.5 US Realm Date and Time (DTM.US.FIELDDED)

[time: 2.16.840.1.113883.10.20.22.5.4(open)]

The US Realm Clinical Document Date and Time datatype flavor records date and time information. If no time zone offset is provided, you can make no assumption about time, unless you have made a local exchange agreement.

This data type uses the same rules as [US Realm Date and Time \(DT.US.FIELDDED\)](#), but is used with the time element.

1. **SHALL** be precise to the day (CONF:10127).
2. **SHOULD** be precise to the minute (CONF:10128).
3. **MAY** be precise to the second (CONF:10129).
4. If more precise than day, **SHOULD** include time-zone offset (CONF:10130).

3.6 US Realm Patient Name (PTN.US.FIELDDED)

[PN: templateId 2.16.840.1.113883.10.20.22.5.1 (open)]

The US Realm Patient Name datatype flavor is a set of reusable constraints that can be used for the patient or any other person. It requires a first (given) and last (family) name. If a patient or person has only one name part (e.g., patient with first name only) place the name part in the field required by the organization. Use the appropriate nullFlavor, "Not Applicable" (NA), in the other field.

For information on mixed content see the Extensible Markup Language reference (<http://www.w3c.org/TR/2008/REC-xml-20081126/>).

1. **MAY** contain zero or one [0..1] @use, which **SHALL** be selected from ValueSet EntityNameUse 2.16.840.1.113883.1.11.15913 **STATIC** 2005-05-01 (CONF:7154).
2. **SHALL** contain exactly one [1..1] family (CONF:7159).
 - a. This family **MAY** contain zero or one [0..1] @qualifier, which **SHALL** be selected from ValueSet EntityPersonNamePartQualifier 2.16.840.1.113883.11.20.9.26 **STATIC** 2011-09-30 (CONF:7160).
3. **SHALL** contain at least one [1..*] given (CONF:7157).
 - a. Such givens **MAY** contain zero or one [0..1] @qualifier, which **SHALL** be selected from ValueSet EntityPersonNamePartQualifier 2.16.840.1.113883.11.20.9.26 **STATIC** 2011-09-30 (CONF:7158).
 - b. The second occurrence of given (given[2]) if provided, **SHALL** include middle name or middle initial (CONF:7163).
4. **MAY** contain zero or more [0..*] prefix (CONF:7155).
 - a. The prefix, if present, **MAY** contain zero or one [0..1] @qualifier, which **SHALL** be selected from ValueSet EntityPersonNamePartQualifier 2.16.840.1.113883.11.20.9.26 **STATIC** 2011-09-30 (CONF:7156).
5. **MAY** contain zero or one [0..1] suffix (CONF:7161).
 - a. The suffix, if present, **MAY** contain zero or one [0..1] @qualifier, which **SHALL** be selected from ValueSet EntityPersonNamePartQualifier 2.16.840.1.113883.11.20.9.26 **STATIC** 2011-09-30 (CONF:7162).

6. **SHALL NOT** have mixed content except for white space (CONF:7278).

Table 22: EntityNameUse Value Set

Value Set: EntityNameUse 2.16.840.1.113883.1.11.15913 STATIC 2005-05-01		
Code System(s): EntityNameUse 2.16.840.1.113883.5.45		
Code	Code System	Print Name
A	EntityNameUse	Artist/Stage
ABC	EntityNameUse	Alphabetic
ASGN	EntityNameUse	Assigned
C	EntityNameUse	License
I	EntityNameUse	Indigenous/Tribal
IDE	EntityNameUse	Ideographic
L	EntityNameUse	Legal
P	EntityNameUse	Pseudonym
PHON	EntityNameUse	Phonetic
R	EntityNameUse	Religious
SNDX	EntityNameUse	Soundex
SRCH	EntityNameUse	Search
SYL	EntityNameUse	Syllabic

Table 23: EntityPersonNamePartQualifier Value Set

Value Set: EntityPersonNamePartQualifier 2.16.840.1.113883.11.20.9.26 STATIC 2011-09-30		
Code System(s): EntityNamePartQualifier 2.16.840.1.113883.5.43		
Code	Code System	Print Name
AC	EntityNamePartQualifier	academic
AD	EntityNamePartQualifier	adopted
BR	EntityNamePartQualifier	birth
CL	EntityNamePartQualifier	callme
IN	EntityNamePartQualifier	initial
NB	EntityNamePartQualifier	nobility
PR	EntityNamePartQualifier	professional
SP	EntityNamePartQualifier	spouse
TITLE	EntityNamePartQualifier	title
VV	EntityNamePartQualifier	voorvoegsel

3.7 US Realm Person Name (PN.US.FIELDED)

[name: 2.16.840.1.113883.10.20.22.5.1.1(open)]

The US Realm Clinical Document Person Name datatype flavor is a set of reusable constraints that can be used for Persons.

1. **SHALL** contain exactly one [1..1] **name** (CONF:9368).
 - a. The content of name **SHALL** be either a conformant Patient Name (PTN.US.FIELDED), or a string (CONF:9371).
 - b. The string **SHALL NOT** contain name parts (CONF:9372).

3.8 Rendering Header Information for Human Presentation

[Note: This section is repeated for readability as an exact duplication of the section by the same name in the General Universal Realm Patient Authored Note chapter of this document.]

Metadata carried in the header of a Patient Authored Note may not match information available in an electronic medical records (EMRs) or other sources external to the document. Information provided by the individual may be more accurate and up to date than information in the EMR, or it may be missing some of the most recent data available in the EMR. Therefore, it is a requirement to render information which represents differences between the document header information and the information stored in the EMR. When there are differences, information should be rendered directly from the document as well as the EMR so that potential changes can be made and errors can be caught. An example of this would be a doctor using an EMR that already contains the patient's name, date of birth, current address, and phone number. When a CDA document is rendered within that EMR, if the address and phone number in the patient authored note does not match those pieces of information in the EMR, the EMR may need to be updated.

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

- Document title and document dates
- Header information which does not match information stored in the EMR
- Service and encounter types, and date ranges as appropriate
- Names of all persons along with their roles, participations, participation date ranges, identifiers, address, and telecommunications information
- Names of selected organizations along with their roles, participations, participation date ranges, identifiers, address, and telecommunications information
- Date of birth for recordTarget

APPENDIX A. PARTICIPANT SCENARIOS

Participant Scenarios have been provided as an informative appendix to augment the implementation guidance provided above. The scenarios fall into two broad categories, where the primary subject of the document (the recordTarget) authors the document for his or her self or where another individual having a personal relationship or role of responsibility for the primary subject.

In use cases where the person is authoring a note for themselves, such as:

- A individual documenting his health history
- A individual documenting her nutrition and allergy information
- A individual documenting alerts and care preferences
- A individual requesting an update to his health record to adjust for changes
- A individual completing a pre-visit “clipboard” questionnaire
- A individual completing a screening questionnaire

Header participation generally follow the pattern below.

Record Target	The individual
Author	The individual
Custodian	Could be the organization providing the PHR application that manages the document or Self if the patient manages the information on their own system.
InformationRecipient	The organization, or person(s) at an organization, intended to receive the information.
Informant	A person or people who have provided information which is represented in the document. Information not attributed to a specific informant is provided by the author.
Participant	Other parties named in or referenced by the content in the document.
DataEnterer	The person who entered the information or device which entered information to create the CDA. If the data enterer is not explicitly listed, then the author is assumed to be the DataEnterer.
Authenticator	The party attesting to the content.
Legal Authenticator	The legally responsible party attesting to the content of the document.
InFulfillmentOf/Order	A scheduled appointment or service event in a practice management system
DocumentationOf/ServiceEvent	The main activity being described by a Patient Authored Note is the person’s health care, health practices and relevant health history over a period of time. This is shown by setting the value of <code>ClinicalDocument/documentationOf/serviceEvent/@classCode</code> to “PCPR” (care provision). The <code>ClinicalDocument/documentationOf/serviceEvent/effectiveTime</code> indicates the span of time documented in the note. Additional data from outside this duration may also be included if it is

	<p>relevant to care documented during the covered time range (e.g. A document covering this year may include information about a condition resolved several years ago which requires annual screening).</p> <p>NOTE: Implementations originating a Patient Authored Note should take care to indicate the time span being documented. For example:</p> <ul style="list-style-type: none"> • When a patient fills out a form providing relevant health history prior to an initial visit to a new doctor, the span of time being documented might be from birth to the present. • When a patient is authoring a note to support an annual examination, it might cover just the prior year. • When a patient is going for a sick visit, the time span of the note may cover only a few days.
--	--

In scenarios where the subject of the document (recordTarget) is not authoring a note for themselves, and a related person or responsible party is authoring the document such as:

- A parent authoring a note for a child
- A adult child authoring a note for a parent
- A guardian authoring a note for a child
- A healthcare power of attorney authoring a note for the person they represent

Header participation follows a similar pattern to the use case where an individual is the author. The differences are documented below:

Author	The person in these roles may not be the individual who is the recordTarget of the document. Their role may be a personal relationship to the individual who is the recordTarget of the document, or they may be in a position of responsibility for the individual.
Custodian	
Authenticator	
Legal Authenticator	