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 HL7 Implementation Guide for CDA Release 2.0

Patient Generated Document Header, Release 1

(1st Informative Ballot)

(US Realm & Universal Realm)

January 2013

**HL7 Informative Ballot**

Sponsored by:
Structure Documents Work Group

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Table of Contents

Open Issues 10

1 Introduction 12

1.1 Audience 12

1.2 Purpose 12

1.3 Scope 13

1.4 Approach 14

1.5 Organization of This Guide 14

1.10 Content of the Package 15

2 General, Universal Realm, Patient Generated Document Header Template 16

2.1 Document Type Codes 16

2.2 Universal Realm Patient Authored Document Header 16

2.2.1 RecordTarget 20

2.2.2 Author 26

2.2.3 DataEnterer 29

2.2.4 Informant 31

2.2.5 Custodian 33

2.2.6 InformationRecipient 36

2.2.7 LegalAuthenticator 38

2.2.8 Authenticator 40

2.2.9 Participant (Support) 42

2.2.10 InFulfillmentOf 44

2.2.11 DocumentationOf/serviceEvent 45

2.2.12 Authorization/consent 50

2.2.13 ComponentOf 51

2.3 Rendering Header Information for Human Presentation 51

3 General US Realm Patient Generated Document Header Template 54

3.1 Document Type Codes 54

3.2 US Realm Patient Generated Document Document Header 54

3.2.1 RecordTarget 58

3.2.2 Author 70

3.2.3 DataEnterer 73

3.2.4 Informant 75

3.2.5 Custodian 77

3.2.6 InformationRecipient 80

3.2.7 LegalAuthenticator 82

3.2.8 Authenticator 84

3.2.9 Participant (Support) 86

3.2.10 InFulfillmentOf 88

3.2.11 DocumentationOf/serviceEvent 88

3.2.12 Authorization/consent 94

3.2.13 ComponentOf 95

3.3 US Realm Address (AD.US.FIELDED) 95

3.4 US Realm Date and Time (DT.US.FIELDED) 96

3.5 US Realm Date and Time (DTM.US.FIELDED) 97

3.6 US Realm Patient Name (PTN.US.FIELDED) 97

3.7 US Realm Person Name (PN.US.FIELDED) 99

3.8 Rendering Header Information for Human Presentation 99

Appendix A. Participant Scenarios 100

Table of Figures

Figure 1: US Realm header example 15

Figure 2: effectiveTime with time zone example 16

Figure 3: recordTarget example 19

Figure 4: Person author example 22

Figure 5: Device author example 23

Figure 6: dataEnterer example 24

Figure 7: Informant with assignedEntity example 25

Figure 8: Custodian example 26

Figure 9: informationRecipient example 28

Figure 10: legalAuthenticator example 30

Figure 11: Authenticator example 31

Figure 12: Participant example for a supporting person 32

Figure 13: DocumentationOf example 35

Figure 14: Procedure note consent example 38

Table of TablesTable 1: Content of the Package 12

Table 2: Basic Confidentiality Kind Value Set 14

Table 3: Language Value Set (excerpt) 15

Table 4: Country Value Set (excerpt) 18

Table 5: IND Role classCode Value Set 32

Table 6: Basic Confidentiality Kind Value Set 42

Table 7: Language Value Set (excerpt) 43

Table 8: Telecom Use (US Realm Header) Value Set 48

Table 9: Administrative Gender (HL7) Value Set 48

Table 10: Marital Status Value Set 49

Table 11: Religious Affiliation Value Set (excerpt) 49

Table 12: Race Value Set (excerpt) 50

Table 13: Ethnicity Value Set 50

Table 14: Personal Relationship Role Type Value Set (excerpt) 51

Table 15: State Value Set (excerpt) 51

Table 16: Postal Code Value Set (excerpt) 52

Table 17: Country Value Set (excerpt) 52

Table 18: Language Ability Value Set 52

Table 19: Language Ability Proficiency Value Set 53

Table 20: IND Role classCode Value Set 70

Table 21: PostalAddressUse Value Set 77

Table 22: EntityNameUse Value Set 79

Table 23: EntityPersonNamePartQualifier Value Set 80

# Open Issues

# Introduction

## 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](http://www.gpo.gov/fdsys/pkg/PLAW-111publ5/content-detail.html), the [Final Rules for Stage 1 Meaningful Use](http://edocket.access.gpo.gov/2010/pdf/2010-17207.pdf), 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](http://edocket.access.gpo.gov/2010/pdf/2010-17210.pdf).[[1]](#footnote-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.

## Purpose

The integration of patient generated health data (PGHD) into 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 Meaningful Use (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.

## Scope

This Patient Generated Document (PGD) Header Template implementation guide is intended to provide implementation guidance on the header elements for documents authored by patients,representativesacting on their behalf or their devices. It is expected that the C-CDA document library will be expanded over time to include different types of patient generated documents. The PGD Header template defined in this implementation will be used to guide the header formation of these patient generated documents.

The following will be ‘in scope’ for this implementation guide for Patient Generated Documents (PGD) and documents

* Guidance and best practices for definition of the CDA header elements
* A single PGD document template established to demonstrate the use of the PGD header and which requires one or more section(s) defined in the Consolidated CDA Implementation guide. This document templateID is 2.16.840.1.113883.10.20.29.1.1.
* Guidance on use of the patient generated document headers (Universal realm & US realm) in a patient generated document
* 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 patient generated C-CDA document types which contain specific sections. 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 Generated Document Header Template should consider utilizing section and entry templates defined in the C-CDA Implementation Guide to maximize data interoperability.  For example, a patient generated document which includes the same sections as a Continuity of Care Document would be a highly interoperable document because EHR systems that already exchange Consolidated CCD documents would be well positioned to consume thecontent generated by the patient.

## Approach

The Patient Generated Document Generated Document 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 C-CDA documents authored by clinicians, the Patient Generated DocumentGenerated Document 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 GeneratedGenerated DocumentDocument 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 to augment the current General Header defined for clinician-generated notes defined in the C-CDA IG.

Going forward, the additional conformances which guide implementers on how to encode patients into roles in the header will be maintained in a syncronized manner to ensure continued alignment within the C-CDA general header over time. Generated Document

## 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 C-CDA template library.

[Chapter 2. General Universal Realm Patient Generated Document Header Template](#_U.S._Realm_CDA). 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 Generated Document Header Template](#_U.S._Realm_CDA). 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 PGD header template to include specific codes and value sets adopted within the US.

Appendix A. This appendix summarizes common use case patterns for patient generated documents and provides recommendations for values of CDA header elements.

Samples: The package will also include samples to demonstrate the use of the best practices recommended in this IG

* 1.

## Content of the Package

The following files comprise the package:

Table 1: Content of the Package

|  |  |  |
| --- | --- | --- |
| Filename | Description | Standards Applicability |
| Patient\_Generated\_Document.docx | Implementation Guide | Informative |
| PGHDsample.xml | Document header | Informative |

# General, Universal Realm, Patient Generated Document Header Template

This template supports information exchange between patients and providers to enable shared decision making.

The purpose of the PGD template is to provide implementation guidance on the header elements for documents authored by patients or representatives acting on the patient’s behalf. The universal realm guidance is not specific for elements such as telcom, and name, etc. Specific guidance for these elements will be included in a realm specific implementation guide.

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

Shared decision making and patient empowerment are part of the vision. The integration of patient generated data (PGD) into health information technology (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 PGD provides the opportunity for patients to author data in a way that is consumable within the EHR.

The successful inclusion of patient generated health data (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. To facilitate efficient effective health information exchange that includes patient generated health data, existing standards should be reused, repurposed and harmonized.

## Document Type Codes

CDA R2 states that LOINC is the preferred vocabulary for document type codes. The document type code specifies the type of document being exchanged (e.g., History and Physical). The document can contain either a structured body or a non-xml body.

Each document template defined in the Consolidated CDA guide recommends use of a single preferred clinicalDocument/code.

CDA R2 documents created by non-clinicians create a family of documents called patient generated documents. This type of document will be identified through the use of a clinicalDocument/code. LOINC code 51855-5 is one example of a LOINC code which would indicate a patient generated document.

 Universal Realm Patient Generated Document Header

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.29 (open)]

1. SHALL contain exactly one [1..1] realmCode **(NEWCONF:xxxxx)**.
	1. 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:xxxxx)**.
2. SHALL contain exactly one [1..1] typeId (CONF:5361).
	1. This typeId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.1.3" (CONF:5250).
	2. This typeId SHALL contain exactly one [1..1] @extension="POCD\_HD000040" (CONF:5251).
3. SHALL contain exactly one [1..1] header-level templateId (**NEWCONF:xxxxx**) such that it
	1. SHALL contain exactly one [1..1] @root=”2.16.840.1.113883.10.20.29” **(NEWCONF:xxxxx).**
4. SHALL contain exactly one [1..1] id (CONF:5363).
	1. This id SHALL be a globally unique identifier for the document (CONF:9991).

5. SHALL contain exactly one [1..1] code (CONF:5253).

* 1. This code SHALL specify the particular kind of patient generated document. **(NEWCONF:xxxxx).**
1. SHALL contain exactly one [1..1] title (CONF:5254).
	1. Can either be a locally defined name or the display name corresponding to clinicalDocument/code (CONF:5255).
2. SHALL contain exactly one [1..1] effectiveTime (CONF:5256).
3. 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).
4. 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).
5. MAY contain zero or one [0..1] setId (CONF:5261).
	1. If setId is present versionNumber SHALL be present (CONF:6380).[[2]](#footnote-2)
6. MAY contain zero or one [0..1] versionNumber (CONF:5264).
	1. If versionNumber is present setId SHALL be present (CONF:6387).[[3]](#footnote-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  |

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 |
| … |  |  |

***Table 4: 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 5: 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 |

Figure 1: UV Realm header example

<realmCode code="UV"/>

<typeId root="2.16.840.1.113883.1.3" extension="POCD\_HD000040"/>

<!-- US General PAN Header Template -->

<templateId root="**2.16.840.1.113883.10.20.29**"/>

<!-- \*\*\* Note: The next templateId, code and title will differ depending on what type of document is being sent. \*\*\* -->

<!-- conforms to the document specific requirements -->

<templateId root="2.16.840.1.113883.10.20.29.1.1"/>

<id extension="999" root="2.16.840.1.113883.19"/>

<!— code should be LOINC, but could come from a different code system -->

<code codeSystem="2.16.840.1.113883.6.1"

 codeSystemName="LOINC" code="**51855-5**"

 displayName="Patient Generated Document "/>

<title>**Patient Generated Document**: My Health Summary</title>

<effectiveTime value="20121126145000-0500"/>

<confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25"/>

<languageCode code="en-US"/>

<setId extension="20121126145000" root="2.16.840.1.113883.19"/>

<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=”20121126145000-0500”/>

<!-- November 26, 2012, 2:50PM, 5 hours behind UTC -->

### RecordTarget

The recordTarget records the patient whose health information is described by the clinical document; each recordTarget must contain at least one patientRole element. If the document receiver is interested in setting up a translator for the encounter with the patient, the receiver of the document will have to infer the need for a translator, based upon the language skills identified for the patient, the patients language of preference and the predominant language used by the organization receiving the CDA.

The recordTarget records the patient whose health information is described by the clinical document; each recordTarget must contain at least one patientRole element. If the document receiver is interested in setting up a translator for the encounter with the patient, the receiver of the document will have to infer the need for a translator, based upon the language skills identified for the patient, the patients language of preference and the predominant language used by the organization receiving the CDA.

The patient MAY include [0..\*] guardian(s). When that role is present, it SHOULD include a code element. The guardian/code element encodes the relationship between the person in the role of guardian and the patient.

Does the patient/guardian role refer to legal guardian?

HL7 Vocabulary simply describes guardian as a relationship to a ward.  This need not be a formal legal relationship.

If legal guardian exists for the patient, should it be included or only if they are “present” for the generation of the PGD?

When a guardian relationship exists for the patient, it may be represented, regardless of who is present at the time the document is generated.

Examples for the use of the patient/guardian role:

A child’s parent MAY be represented in the guardian role. In this case, the guardian/code element would encode the personal relationship of “mother” for the child’s mom or “father” for the child’s dad.

An elderly person’s child MAY be represented in the guardian role. In this case, the guardian/code element would encode the personal relationship of “daughter” or “son”, or if a legal relationship existed, the relationship of “legal guardian” could be encoded.

1. SHALL contain at least one [1..1] recordTarget (**NEWCONF:xxxxx**).
	1. Such recordTargets SHALL contain exactly one [1..1] patientRole (CONF:5267).
		1. This patientRole SHALL contain at least one [1..\*] id (CONF:5268).
		2. This patientRole SHALL contain at least one [1..\*] addr (CONF:5271).
		3. This patientRole SHALL contain at least one [1..\*] telecom (CONF:5280).

#### Patient

* + 1. 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:xxxxx**).
			3. This patient SHALL contain exactly one [1..1] birthTime (CONF:5298).
				1. SHALL be precise to year (CONF:5299).
				2. SHOULD be precise to day (CONF:5300).

#### Guardian

* + - 1. This patient MAY contain zero or more [0..\*] guardian (CONF:5325).
				1. A guardian, if present, SHOULD contain zero or one [0..1] code (NEWCONF:xxxxx)
				2. The id SHOULD utilize the combined @root and @extension attributes to record the person’s identity in a secure, trusted, and unique way. **(NEWCONF:xxxxx)**.
				3. A guardian, if present, SHOULD contain zero or more [0..\*] addr (CONF:5359).
				4. A guardian, if present, MAY contain zero or more [0..\*] telecom (CONF:5382).
				5. A guardian, if present, SHALL contain exactly one [1..1] guardianPerson (CONF:5385).

This guardianPerson SHALL contain at least one [1..\*] name (CONF:5386).

#### Birthplace

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

#### LanguageCommunication

* + - 1. This patient SHOULD contain zero or more [0..\*] languageCommunication (CONF:5406).
				1. 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:xxxxx**).
				2. 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:xxxxx**).
				3. 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:xxxxx**).
				4. The languageCommunication, if present, MAY contain zero or one [0..1] preferenceInd to indicate a preference for communication about care delivery and treatements to be translated into this language **(NEWCONF:xxxxx**).

If more than one languageCommunication is present, only one languageCommunication element SHALL have a preferenceInd with a value of 1 **(NEWCONF:xxxxx**).

#### ProviderOrganization

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

* + 1. 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).
				1. 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:xxxxx**).

#### RecordTarget Value Sets

Table 6: 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 |
| … |  |  |

#### RecordTarget Example

Figure 3: UV Realm recordTarget example

<recordTarget>

 <patientRole>

 <!-- Internal id using HL7 example OID. -->

 <id extension="999.1" root="2.16.840.1.113883.19"/>

 <!-- Fake Social Security Number using the actual SSN OID. -->

 <id extension="444-33-3333" root="2.16.840.1.113883.4.1"/>

 <!-- Identifier based on the person's Direct Address which is a secure

 and trusted mechanism for identifying

 a person discretely. The root of the id is the OID of the HISP

 Assigning Authority for the Direct Address-->

 <id extension="adameveryman@direct.sampleHISP.com"

 root="2.16.123.123.12345.1234"/>

 <addr use="HP">

 <!-- HP is "primary home" from codeSystem 2.16.840.1.113883.5.1119 -->

 <streetAddressLine>2222 Home Street</streetAddressLine>

 <city>Boston</city>

 <state>MA</state>

 <postalCode>02368</postalCode>

 <!-- US is "United States" from ISO 3166-1 Country Codes: 1.0.3166.1 -->

 <country>US</country>

 </addr>

 <!-- HP is "primary home" from HL7 AddressUse 2.16.840.1.113883.5.1119 -->

 <telecom value="tel:(555)555-2004" use="HP"/>

 <!-- A secure e-mail address appropriate for healthcare communications-->

 <telecom value="mailto:adameveryman@direct.sampleHISP.com" use="H"/>

 <patient>

 <name use="L">

 <!-- L is "Legal" from HL7 EntityNameUse 2.16.840.1.113883.5.45 -->

 <prefix>Mr.</prefix>

 <given>Adam</given>

 <given>A.</given>

 <given qualifier="CL">Ace</given>

 <family>Everyman</family>

 </name>

 <administrativeGenderCode code="M"

 codeSystem="2.16.840.1.113883.5.1" displayName="Male"/>

 <birthTime value="19551125"/>

 <birthplace>

 <place>

 <addr>

 <city>Pointe-Claire</city>

 <state>QC</state>

 <postalCode>H9R 1E4</postalCode>

 <country>CAN</country>

 </addr>

 </place>

 </birthplace>

 <languageCommunication>

 <languageCode code="fr-CN"/>

 <modeCode code="RWR" displayName="Recieve Written"

 codeSystem="2.16.840.1.113883.5.60"

 codeSystemName="LanguageAbilityMode"/>

 <preferenceInd value="true"/>

 </languageCommunication>

 </patient>

 <providerOrganization>

 <!-- This is the patient's perferred provider organization. -->

 <!-- Internal id -->

 <id extension="999.2" root="2.16.840.1.113883.19"/>

 <!-- NPI for the organization -->

 <id extension="1234567890" root="2.16.840.1.113883.4.6"/>

 <name>Good Health Internal Medicine</name>

 <telecom use="WP" value="tel:(781)555-1212"/>

 <addr>

 <streetAddressLine>100 Health Drive</streetAddressLine>

 <city>Boston</city>

 <state>MA</state>

 <postalCode>02368</postalCode>

 <country>USA</country>

 </addr>

 </providerOrganization>

 </patientRole>

 </recordTarget>

### 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.

1. SHALL contain at least one [1..\*] author (CONF:5444) .
	1. Such authors SHALL contain exactly one [1..1] time (CONF:5445).
	2. Such authors SHALL contain exactly one [1..1] assignedAuthor (CONF:5448).
		1. 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:xxxxx)**.
		2. When the author is a person,this assignedAuthor SHALL contain one [1..1] code (**NEWCONF:xxxxx**).
			1. The code, SHaLL contain exactly one [1..1] @code, which SHOULD be selected from the PersonalRelationshipRoleType value set PLUS ResponsibleParty PLUS (**NEWCONF:xxxxx**)
		3. This assignedAuthor SHALL contain at least one [1..\*] addr (CONF:5452).
		4. This assignedAuthor SHALL contain at least one [1..\*] telecom (CONF:5428).
		5. There SHALL be exactly one assignedAuthor/assignedPerson or exactly one assignedAuthor/assignedAuthoringDevice (CONF:16790).
		6. 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).
		7. 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="20121126145000-0500"/>

 <assignedAuthor>

 <!-- Internal id using HL7 example OID. -->

 <id extension="999.1" root="2.16.840.1.113883.19"/>

 <!-- The PAN IG includes conformance constraints on the code element.

 This author/assignedAuthor/code/@code must be a code from one of

 two value sets:

 PersonalRelationshipRoleType or ResponsibleParty. Both of these

 value sets include codes from the HL7 RoleCode Code System.

 -->

 <code code="SELF" displayName="Self"

 codeSystem="2.16.840.1.113883.5.111"

 codeSystemName="HL7 Role code"/>

 <addr use="HP">

 <!-- HP is "primary home" from codeSystem 2.16.840.1.113883.5.1119 -->

 <streetAddressLine>2222 Home Street</streetAddressLine>

 <city>Boston</city>

 <state>MA</state>

 <postalCode>02368</postalCode>

 <!-- US is "United States" from ISO 3166-1 Country Codes: 1.0.3166.1 -->

 <country>US</country>

 </addr>

 <!-- HP is "primary home" from HL7 AddressUse 2.16.840.1.113883.5.1119 -->

 <telecom value="tel:(555)555-2004" use="HP"/>

 <assignedPerson>

 <name>

 <given>Adam</given>

 <family>Everyman</family>

 </name>

 </assignedPerson>

 </assignedAuthor>

</author>

Figure 5: Device author example

<author>

 <time value="20121126145000-0500"/>

 <assignedAuthor>

 <id extension="777.11" root="2.16.840.1.113883.19"/>

 <addr nullFlavor="NA"/>

 <telecom nullFlavor="NA"/>

 <assignedAuthoringDevice>

 <manufacturerModelName>ACME PHR</manufacturerModelName>

 <softwareName>MyPHR v1.0</softwareName>

 </assignedAuthoringDevice>

 <representedOrganization>

 <id extension="999" root="1.2.3.4.5.6.7.8.9.12345"/>

 <name>ACME PHR Solutions,Inc.</name>

 <telecom use="WP" value="tel:123-123-12345"/>

 <addr>

 <streetAddressLine>4 Future Way</streetAddressLine>

 <city>Provenance</city>

 <state>RI</state>

 <postalCode>02919</postalCode>

 </addr>

 </representedOrganization>

 </assignedAuthor>

</author>

### 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). If the DataEnterer is missing, this role is assumed to be played by the Author.

1. MAY contain zero or one [0..1] dataEnterer (CONF:5441).
	1. The dataEnterer, if present, SHALL contain exactly one [1..1] assignedEntity (CONF:5442).
		1. This assignedEntity SHALL contain at least one [1..\*] id (CONF:5443).
		2. This assignedEntity SHALL contain at least one [1..\*] addr (CONF:5460).
		3. This assignedEntity SHALL contain at least one [1..\*] telecom (CONF:5466).
		4. This assignedEntity SHALL contain exactly one [1..1] assignedPerson (CONF:5469).
			1. This assignedPerson SHALL contain at least one [1..\*] name (CONF:5470).
		5. This assignedEntity MAY contain zero or one [0..1] code to encode the relationship of the person to the recordTarget **(NEWCONF:xxxxx)**.

Figure 6: dataEnterer example

<dataEnterer>

 <assignedEntity>

 <!-- Internal id using HL7 example OID. -->

 <id extension="999.1" root="2.16.840.1.113883.19"/>

 <addr use="HP">

 <!-- HP is "primary home" from codeSystem 2.16.840.1.113883.5.1119 -->

 <streetAddressLine>2222 Home Street</streetAddressLine>

 <city>Boston</city>

 <state>MA</state>

 <postalCode>02368</postalCode>

 <!-- US is "United States" from ISO 3166-1 Country Codes: 1.0.3166.1 -->

 <country>US</country>

 </addr>

 <!-- HP is "primary home" from HL7 AddressUse 2.16.840.1.113883.5.1119 -->

 <telecom value="tel:(555)555-2004" use="HP"/>

 <assignedPerson>

 <name>

 <given>Adam</given><family>Everyman</family>

 </name>

 </assignedPerson>

 </assignedEntity>

</dataEnterer>

### 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, even if the personal relation is medical professional. 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. If the informant element is missing, the Author is presumed to be the informant.

1. MAY contain zero or more [0..\*] informant (CONF:8001).
	1. SHALL contain exactly one [1..1] assignedEntity OR exactly one [1..1] relatedEntity (CONF:8002).
		1. SHOULD contain at least one [1..\*] addr (CONF:8220).
		2. 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).
		3. This assignedEntity MAY contain zero or one [0..1] code **(NEWCONF:xxxx**).
		4. SHOULD contain zero or more [0..\*] id (CONF:9945).

Figure 7: Informant with assignedEntity example

<informant>

 <assignedEntity>

 <!-- Internal id using HL7 example OID. -->

 <id extension="999.1" root="2.16.840.1.113883.19"/>

 <addr use="HP">

 <!-- HP is "primary home" from codeSystem 2.16.840.1.113883.5.1119 -->

 <streetAddressLine>2222 Home Street</streetAddressLine>

 <city>Boston</city>

 <state>MA</state>

 <postalCode>02368</postalCode>

 <!-- US is "United States" from ISO 3166-1 Country Codes: 1.0.3166.1 -->

 <country>US</country>

 </addr>

 <!-- HP is "primary home" from HL7 AddressUse 2.16.840.1.113883.5.1119 -->

 <telecom value="tel:(555)555-2004" use="HP"/>

 <assignedPerson>

 <name>

 <given>Adam</given><family>Everyman</family>

 </name>

 </assignedPerson>

 </assignedEntity>

</informant>

### Custodian

The custodian element represents the organization or person 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. Also, the custodian may be the patient or an organization acting on behalf of the patient, such as a PHR organization.

1. SHALL contain exactly one [1..1] custodian (CONF:5519).
	1. This custodian SHALL contain exactly one [1..1] assignedCustodian (CONF:5520).
		1. 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).
				1. 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 examples

<custodian>

 <assignedCustodian>

 <representedCustodianOrganization>

 <!-- Internal id -->

 <id extension="999.3" root="2.16.840.1.113883.19"/>

 <name>MyPersonalHealthRecord.Com</name>

 <telecom value="tel:(555)555-1212" use="WP"/>

 <addr use="WP">

 <streetAddressLine>123 Boylston Street</streetAddressLine>

 <city>Blue Hill</city>

 <state>MA</state>

 <postalCode>02368</postalCode>

 <country>USA</country>

 </addr>

 </representedCustodianOrganization>

 </assignedCustodian>

</custodian>

<custodian>

 <assignedCustodian>

 <representedCustodianOrganization>

 <!-- This example assumes that Ned is using a Desktop PHR application.

 There is no larger system, just the application that Ned runs on

 his desktop.

 -->

 <!-- Internal id -->

 <id extension="999.8" root="2.16.840.1.113883.19"/>

 <name>Ned Nuclear</name>

 <telecom value="tel:(555)555-5001" use="WP"/>

 <addr use="HP">

 <!-- HP is "primary home" from codeSystem 2.16.840.1.113883.5.1119 -->

 <streetAddressLine>6666 Home Street</streetAddressLine>

 <city>Boston</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>

 </representedCustodianOrganization>

 </assignedCustodian>

</custodian>

### 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).

* 1. The informationRecipient, if present, **SHALL** contain exactly one [1..1] **intendedRecipient** (CONF:5566).
		1. This intendedRecipient **SHOULD** contain atleast one [1..\*] id (**NEWCONF:xxxxx)**.
			1. Such ids MAY reference the id of a person or organization entity specified elsewhere in the document (**NEWCONF:xxxxx**).
		2. 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).
		3. 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

<!-- The document is intended for multiple recipients,

 Adam himself and his PCP physician.

-->

<informationRecipient>

 <intendedRecipient>

 <!-- Internal id using HL7 example OID. -->

 <id extension="999.1" root="2.16.840.1.113883.19"/>

 <!-- Identifier based on the person's Direct Address which is a secure

 and trusted mechanism for identifying a person discretely.

 The root of the id is the OID of the HISP Assigning Authority

 for the Direct Address-->

 <id extension="adameveryman@direct.sampleHISP.com"

 root="2.16.123.123.12345.1234"/>

 <informationRecipient>

 <name>

 <given>Adam</given><family>Everyman</family>

 </name>

 </informationRecipient>

 <receivedOrganization>

 <!-- Internal id -->

 <id extension="999.3" root="2.16.840.1.113883.19"/>

 <name>MyPersonalHealthRecord.Com</name>

 </receivedOrganization>

 </intendedRecipient>

</informationRecipient>

<informationRecipient>

 <intendedRecipient>

 <!-- Internal id using HL7 example OID. -->

 <id extension="999.4" root="2.16.840.1.113883.19"/>

 <!-- The physician's NPI number -->

 <id extension="1122334455" root="2.16.840.1.113883.4.6"/>

 <!-- The physician's Direct Address -->

 <!-- Identifier based on the person's Direct Address which is a secure

 and trusted mechanism for identifying a person discretely.

 The root of the id is the OID of the HISP Assigning Authority for

 the Direct Address-->

 <id extension="DrP@direct.sampleHISP2.com" root="2.16.123.123.12345.4321"/>

 <telecom use="WP" value="tel:(781)555-1212"/>

 <telecom use="WP" value="mailto:DrP@direct.sampleHISP2.com"/>

 <informationRecipient>

 <name>

 <prefix>Dr.</prefix>

 <given>Patricia</given>

 <family>Primary</family>

 </name>

 </informationRecipient>

 <receivedOrganization>

 <!-- Internal id -->

 <id extension="999.2" root="2.16.840.1.113883.19"/>

 <!-- NPI for the organization -->

 <id extension="1234567890" root="2.16.840.1.113883.4.6"/>

 <name>Good Health Internal Medicine</name>

 <telecom use="WP" value="tel:(781)555-1212"/>

 <addr>

 <streetAddressLine>100 Health Drive</streetAddressLine>

 <city>Boston</city>

 <state>MA</state>

 <postalCode>02368</postalCode>

 <country>USA</country>

 </addr>

 </receivedOrganization>

 </intendedRecipient>

</informationRecipient>

### 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.

1. SHOULD contain zero or one [0..1] legalAuthenticator (CONF:5579).
	1. The legalAuthenticator, if present, SHALL contain exactly one [1..1] time (CONF:5580).
	2. The legalAuthenticator, if present, SHALL contain exactly one [1..1] signatureCode (CONF:5583).
		1. This signatureCode SHALL contain exactly one [1..1] @code="S" (CodeSystem: Participationsignature 2.16.840.1.113883.5.89) (CONF:5584).
	3. The legalAuthenticator, if present, SHALL contain exactly one [1..1] assignedEntity (CONF:5585).
		1. This assignedEntity SHALL contain at least one [1..\*] id (CONF:5586).
		2. This assignedEntity MAY contain zero or one [0..1] code (**NEWCONF:xxxxx)**
		3. This assignedEntity SHALL contain at least one [1..\*] addr (CONF:5589).
		4. This assignedEntity SHALL contain at least one [1..\*] telecom (CONF:5595).
		5. 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="20121126145000-0500"/>

 <signatureCode code="S"/>

 <assignedEntity>

 <!-- Internal id using HL7 example OID. -->

 <id extension="999.1" root="2.16.840.1.113883.19"/>

 <addr use="HP">

 <!-- HP is "primary home" from codeSystem 2.16.840.1.113883.5.1119 -->

 <streetAddressLine>2222 Home Street</streetAddressLine>

 <city>Boston</city>

 <state>MA</state>

 <postalCode>02368</postalCode>

 <!-- US is "United States" from ISO 3166-1 Country Codes: 1.0.3166.1 -->

 <country>US</country>

 </addr>

 <!-- HP is "primary home" from HL7 AddressUse 2.16.840.1.113883.5.1119 -->

 <telecom value="tel:(555)555-2004" use="HP"/>

 <assignedPerson>

 <name>

 <given>Adam</given><family>Everyman</family>

 </name>

 </assignedPerson>

 </assignedEntity>

</legalAuthenticator>

### Authenticator

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

1. MAY contain zero or more [0..\*] authenticator (CONF:5607).
	1. The authenticator, if present, SHALL contain exactly one [1..1] time (CONF:5608).
	2. The authenticator, if present, SHALL contain exactly one [1..1] signatureCode (CONF:5610).
		1. This signatureCode SHALL contain exactly one [1..1] @code="S" (CodeSystem: Participationsignature 2.16.840.1.113883.5.89) (CONF:5611).
	3. The authenticator, if present, SHALL contain exactly one [1..1] assignedEntity (CONF:5612).
		1. This assignedEntity SHALL contain at least one [1..\*] id (CONF:5613).
		2. This assignedEntity MAY contain zero or one [0..1] code (CONF:16825).
		3. This assignedEntity SHALL contain at least one [1..\*] addr (CONF:5616).
		4. This assignedEntity SHALL contain at least one [1..\*] telecom (CONF:5622).
			1. Such telecoms SHOULD contain exactly one [1..1] @use **(NEWCONF:xxxxx)**
		5. 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="20121126145000-0500"/>

 <signatureCode code="S"/>

 <assignedEntity>

 <!-- Internal id using HL7 example OID. -->

 <id extension="999.1" root="2.16.840.1.113883.19"/>

 <addr use="HP">

 <!-- HP is "primary home" from codeSystem 2.16.840.1.113883.5.1119 -->

 <streetAddressLine>2222 Home Street</streetAddressLine>

 <city>Boston</city>

 <state>MA</state>

 <postalCode>02368</postalCode>

 <!-- US is "United States" from ISO 3166-1 Country Codes: 1.0.3166.1 -->

 <country>US</country>

 </addr>

 <!-- HP is "primary home" from HL7 AddressUse 2.16.840.1.113883.5.1119 -->

 <telecom value="tel:(555)555-2004" use="HP"/>

 <assignedPerson>

 <name>

 <given>Adam</given><family>Everyman</family>

 </name>

 </assignedPerson>

 </assignedEntity>

</authenticator>

### Participant (Support)

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)

1. **MAY** contain zero or more [0..\*] **participant** (CONF:10003).
	1. The participant, if present, **MAY** contain zero or one [0..1] **time** (CONF:10004).
	2. Such participants, if present, **SHALL** have an associatedPerson or scopingOrganization element under participant/associatedEntity (CONF:10006).
	3. 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).
		1. The associatedEntity SHOULD contain exactly one [1..1] code (NEWCONF:xxxxx).

Table 7: 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="19551125"/>

 <high value="20121126"/>

 </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>

### InFulfillmentOf

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

1. MAY contain zero or more [0..\*] inFulfillmentOf (CONF:9952).
	1. The inFulfillmentOf, if present, SHALL contain exactly one [1..1] order (CONF:9953).
		1. 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:xxxxx**).

DocumentationOf/serviceEvent

The main activity being described by a Patient Generated Document 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). The performer of the service event may be the patient, family member or other individual designated by the patient.

**NOTE:** Implementations originating a Patient Generated Document 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).
	1. This documentationOf **SHALL** contain exactly one [1..1] **serviceEvent** (CONF:8480).
		1. 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).
		2. This serviceEvent **MAY** contain one [1..1] code (**NEWCONF:xxxxx**).
			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 Generated Document. (**NEWCONF:xxxxx**)
		3. 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).
		4. 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:xxxxx**).
			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:xxxxx)**
			4. Such performers **MAY** contain zero or more [0..1] **assignedEntity** (CONF:8459).
				1. This assignedEntity **SHALL** contain at least one [1..\*] **id** (CONF:8460).
				2. This assignedEntity **MAY** contain zero or one [0..1] **code** (CONF:8461).

Figure 13: DocumentationOf example

<documentationOf typeCode="DOC">

 <serviceEvent classCode="PCPR">

 <effectiveTime>

 <low value="19551125"/>

 <high value="20121126145000"/>

 </effectiveTime>

 <performer typeCode="PRF">

 <functionCode code="PCP" displayName="Primary Care Provider"

 codeSystem="2.16.840.1.113883.5.88"

 codeSystemName="Participation Function">

 <originalText>Primary Care Provider (PCP)</originalText>

 </functionCode>

 <time>

 <low value="201101"/>

 </time>

 <assignedEntity>

 <!-- Internal id using HL7 example OID. -->

 <id extension="999.4" root="2.16.840.1.113883.19"/>

 <!-- The physician's NPI number -->

 <id extension="1122334455" root="2.16.840.1.113883.4.6"/>

 <!-- Type of Physician -->

 <code code="207R00000X" displayName="Internal Medicine"

 codeSystemName="NUCC Health Care Provider Taxonomy"

 codeSystem="2.16.840.1.113883.6.101"/>

 <addr>

 <streetAddressLine>100 Health Drive</streetAddressLine>

 <city>Boston</city>

 <state>MA</state>

 <postalCode>02368</postalCode>

 <country>USA</country>

 </addr>

 <telecom use="WP" value="tel:(781)555-1212"/>

 <assignedPerson>

 <name>

 <prefix>Dr.</prefix>

 <given>Patricia</given>

 <family>Primary</family>

 </name>

 </assignedPerson>

 <representedOrganization>

 <!-- Internal id -->

 <id extension="999.2" root="2.16.840.1.113883.19"/>

 <name>Good Health Internal Medicine</name>

 <telecom use="WP" value="tel:(781)555-1212"/>

 <addr>

 <streetAddressLine>100 Health Drive</streetAddressLine>

 <city>Boston</city>

 <state>MA</state>

 <postalCode>02368</postalCode>

 <country>USA</country>

 </addr>

 </representedOrganization>

 </assignedEntity>

 </performer>

 <performer typeCode="PRF">

 <functionCode code="PCP" displayName="Primary Care Provider"

 codeSystem="2.16.840.1.113883.5.88"

 codeSystemName="Participation Function">

 <originalText>Primary Care Provider (PCP)</originalText>

 </functionCode>

 <time>

 <low value="1971"/>

 <high value="201101"/>

 </time>

 <assignedEntity>

 <!-- Internal id using HL7 example OID. -->

 <id extension="999.4" root="2.16.840.1.113883.19"/>

 <!-- The physician's NPI number -->

 <id extension="1122334466" root="2.16.840.1.113883.4.6"/>

 <!-- Type of Physician -->

 <code code="207Q00000X" displayName="Family Medicine"

 codeSystemName="NUCC Health Care Provider Taxonomy"

 codeSystem="2.16.840.1.113883.6.101">

 <originalText>General Practitioner</originalText>

 </code>

 <addr>

 <streetAddressLine>103 Rue Champlain</streetAddressLine>

 <city>Roxboro</city>

 <state>QC</state>

 <postalCode>H8Y 3S6</postalCode>

 <country>CAN</country>

 </addr>

 <telecom use="WP" value="tel:514-555-1212"/>

 <assignedPerson>

 <name>

 <prefix>Dr.</prefix>

 <given>Fay</given>

 <family>Family</family>

 </name>

 </assignedPerson>

 <representedOrganization>

 <!-- Internal id -->

 <id extension="999.5" root="2.16.840.1.113883.19"/>

 <name>Roxboro Family Practice</name>

 <telecom use="WP" value="tel:514-555-1212"/>

 <addr>

 <streetAddressLine>103 Rue Champlain</streetAddressLine>

 <city>Roxboro</city>

 <state>QC</state>

 <postalCode>H8Y 3S6</postalCode>

 <country>CAN</country>

 </addr>

 </representedOrganization>

 </assignedEntity>

 </performer>

 <performer typeCode="PRF">

 <functionCode code="PCP" displayName="Primary Care Provider"

 codeSystem="2.16.840.1.113883.5.88"

 codeSystemName="Participation Function">

 <originalText>Primary Care Provider (PCP)</originalText>

 </functionCode>

 <time>

 <low value="19551125"/>

 <high value="1971"/>

 </time>

 <assignedEntity>

 <!-- Internal id using HL7 example OID. -->

 <id extension="999.6" root="2.16.840.1.113883.19"/>

 <!-- The physician's NPI number -->

 <id extension="1122334477" root="2.16.840.1.113883.4.6"/>

 <!-- Type of Physician -->

 <code code="208000000X" displayName="Pediatrics"

 codeSystemName="NUCC Health Care Provider Taxonomy"

 codeSystem="2.16.840.1.113883.6.101">

 <originalText>Pediatrician</originalText>

 </code>

 <addr>

 <streetAddressLine>10 Rue De Seville</streetAddressLine>

 <city>Pointe-Claire</city>

 <state>QC</state>

 <postalCode>H9R 1E9</postalCode>

 <country>CAB</country>

 </addr>

 <telecom use="WP" value="tel:514-333-1234"/>

 <assignedPerson>

 <name>

 <prefix>Dr.</prefix>

 <given>Karen</given>

 <family>Kidder</family>

 </name>

 </assignedPerson>

 <representedOrganization>

 <!-- Internal id -->

 <id extension="999.7" root="2.16.840.1.113883.19"/>

 <name>Pointe-Claire Pediatrics</name>

 <telecom use="WP" value="tel:514-333-1234"/>

 <addr>

 <streetAddressLine>10 Rue De Seville</streetAddressLine>

 <city>Pointe-Claire</city>

 <state>QC</state>

 <postalCode>H9R 1E9</postalCode>

 <country>CAN</country>

 </addr>

 </representedOrganization>

 </assignedEntity>

 </performer>

 </serviceEvent>

</documentationOf>

### 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’.

1. MAY contain zero or more [0..\*] authorization (CONF:16792) such that it
	1. SHALL contain exactly one [1..1] consent (CONF:16793).
		1. This consent MAY contain zero or more [0..\*] id (CONF:16794).
		2. 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).
		3. 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>

### 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.

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

Unless specifically authored to document an encounter with a provider, the patient generated document should NOT use componentOf/encompassingEncounter.

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

## Rendering Header Information for Human Presentation

Metadata carried in the header of a Patient Generated Document 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 Generated Document 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 presented 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

# General US Realm Patient Generated Document Header Template

This template supports information exchange between patients and providers to enable shared decision making.

The purpose of the PGD template is to augment the existing C-CDA US General Header. It provides implementation guidance on the header elements for documents authored by patients or representatives acting on their behalf. PGD template is used in conjunction with the CCDA General header to add the conformances for roles played by patients.

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

Shared decision making and patient empowerment are part of the vision underlying the Health Information Technology for Economic and Clinical Health (HITECH) provisions of the [American Recovery And Reinvestment Act of 2009](http://www.gpo.gov/fdsys/pkg/PLAW-111publ5/content-detail.html), the [Final Rules for Stage 1 Meaningful Use](http://edocket.access.gpo.gov/2010/pdf/2010-17207.pdf), 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](http://edocket.access.gpo.gov/2010/pdf/2010-17210.pdf).[[4]](#footnote-4)

The integration of patient generated data (PGD) into health information technology (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 PGD provides the opportunity for patients to author data in a way that is consumable within the EHR.

Based upon recent testimony received by the Office of the National Coordinator (ONC) Health Information Technology Standards Committee (HITSC) and Health Information Technology Policy Committee (HITPC) Patient Generated Health Data (PGHD) hearing, the successful inclusion of patient generaed health data (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 HITSC and HITPC have further directed that standards already directed in Meaningful Use (MU) should be reused, repurposed and harmonized.

## Document Type Codes

CDA R2 states that LOINC is the preferred vocabulary for document type codes. The document type code specifies the type of document being exchanged (e.g., History and Physical). The document can contain either a structured body or a non-xml body.

Each document template defined in the Consolidated CDA guide recommends use of a single preferred clinicalDocument/code.

CDA R2 documents created by non-clinicians create a family of documents called patient generated documents. This type of document will be identified through the use of a clinicalDocument/code. LOINC code 51855-5 is one example of a LOINC code which would indicate a patient generated document.

US Realm Patient Generated Document Header

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.29.1 (open)]

The US Realm Patient Generated Document header template must conform to the Universal Realm Patient Generated Document header template.

1. SHALL contain exactly one [1..1] realmCode="US" (CONF:16791).
2. SHALL contain exactly one [1..1] typeId (CONF:5361).
	1. This typeId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.1.3" (CONF:5250).
	2. This typeId SHALL contain exactly one [1..1] @extension="POCD\_HD000040" (CONF:5251).
3. SHALL contain exactly one [1..1] header-level templateId (**NEWCONF:xxxxx**) such that it
	1. SHALL contain exactly one [1..1] @root=”2.16.840.1.113883.10.20.29.1” **(NEWCONF:xxxxx)**.
4. SHALL contain exactly one [1..1] id (CONF:5363).
	1. This id SHALL be a globally unique identifier for the document (CONF:9991).
5. SHALL contain exactly one [1..1] code (CONF:5253).
	1. This code **SHALL** specify the particular kind of document (e.g. History and Physical, Discharge Summary, Progress Note) (CONF:9992).
6. Generated Document SHALL contain exactly one [1..1] title (CONF:5254).
	1. Can either be a locally defined name or the display name corresponding to clinicalDocument/code (CONF:5255).
7. SHALL contain exactly one [1..1] effectiveTime (CONF:5256).
	1. The content SHALL be a conformant [US Realm Date and Time (DTM.US.FIELDED)](#U_US_Realm_Date_and_Time_DTMUSFIELDED) (2.16.840.1.113883.10.20.22.5.4) (CONF:16865).
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).
	1. If setId is present versionNumber SHALL be present (CONF:6380).[[5]](#footnote-5)
11. MAY contain zero or one [0..1] versionNumber (CONF:5264).
	1. If versionNumber is present setId SHALL be present (CONF:6387).[[6]](#footnote-6)

Table 8: 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  |

***Table 9: Language Value Set***

| 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 10: Language Ability Mode 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 11: 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 |

Table 12: LOINC Document Ontology for Patient Generated Document

| 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 Generated Document. It is envisioned that additional more specific types of Generated DocumentPatient Generated Documents 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 General PAN Header Template -->

<templateId root="**2.16.840.1.113883.10.20.29.1**"/>

<!-- \*\*\* Note: The next templateId, code and title will differ depending on what type of document is being sent. \*\*\* -->

<!-- conforms to the document specific requirements -->

<templateId root="2.16.840.1.113883.10.20.29.1.1"/>

<id extension="999" root="2.16.840.1.113883.19"/>

<code codeSystem="2.16.840.1.113883.6.1"

 codeSystemName="LOINC" code="**51855-5**"

 displayName="Patient Generated Document"/>

<title>**Patient Generated Document**: My Health Summary</title>

<effectiveTime value="20121126145000-0500"/>

<confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25"/>

<languageCode code="en-US"/>

<setId extension="20121126145000" 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=”20121126145000-0500”/>

<!-- November 26, 2012, 2:50PM, 5 hours behind UTC -->

### RecordTarget

The recordTarget records the patient whose health information is described by the clinical document; each recordTarget must contain at least one patientRole element. If the document receiver is interested in setting up a translator for the encounter with the patient, the receiver of the document will have to infer the need for a translator, based upon the language skills identified for the patient, the patients language of preference and the predominant language used by the organization receiving the CDA.

The patient MAY include [0..\*] guardian(s). When that role is present, it SHOULD include a code element. The guardian/code element encodes the relationship between the person in the role of guardian and the patient.

Does the patient/guardian role refer to legal guardian?

HL7 Vocabulary simply describes guardian as a relationship to a ward.  This need not be a formal legal relationship.

If legal guardian exists for the patient, should it be included or only if they are “present” for the generation of the PGD?

When a guardian relationship exists for the patient, it may be represented, regardless of who is present at the time the document is generated.

Examples for the use of the patient/guardian role:

A child’s parent MAY be represented in the guardian role. In this case, the guardian/code element would encode the personal relationship of “mother” for the child’s mom or “father” for the child’s dad.

An elderly person’s child MAY be represented in the guardian role. In this case, the guardian/code element would encode the personal relationship of “daughter” or “son”, or if a legal relationship existed, the relationship of “legal guardian” could be encoded.

1. SHALL contain only one [1..1] recordTarget (**NEWCONF:xxxxx**).
	1. Such recordTargets SHALL contain exactly one [1..1] patientRole (CONF:5267).
		1. 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:xxxxx)**.
		2. 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)](#U_US_Realm_Address_ADUSFIELDED) (2.16.840.1.113883.10.20.22.5.2) (CONF:10412).
		3. 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](#T_VS_TelecomeUseValueSet) DYNAMIC (CONF:5375).

#### Patient

* + 1. This patientRole SHALL contain exactly one [1..1] patient (CONF:5283).
			1. This patient SHALL contain exactly one [1..1] name (CONF:5284).
				1. The content of name SHALL be a conformant [US Realm Patient Name (PTN.US.FIELDED)](#U_US_Realm_Patient_Name_PTNUSFIELDED) (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).
				1. SHALL be precise to year (CONF:5299).
				2. 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..\*] **sdtc: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).

#### Guardian

* + - 1. This patient MAY contain zero or more [0..\*] guardian (CONF:5325).
				1. The guardian, if present, SHOULD contain zero or one [0..1] code, which SHALL be selected from ValueSet PersonalAndLegalRelationshipRoleType (**NEWCONF:xxxxx).**
				2. The id SHOULD utilize the combined @root and @extension attributes to record the person’s identity in a secure, trusted, and unique way. **(NEWCONF:xxxxx)**.
				3. The guardian, if present, SHOULD contain zero or more [0..\*] addr (CONF:5359).

The content of addr SHALL be a conformant [US Realm Address (AD.US.FIELDED)](#U_US_Realm_Address_ADUSFIELDED) (2.16.840.1.113883.10.20.22.5.2) (CONF:10413).

* + - * 1. The guardian, if present, MAY contain zero or more [0..\*] telecom (CONF:5382).

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](#T_VS_TelecomeUseValueSet) DYNAMIC (CONF:7993).

* + - * 1. The guardian, if present, SHALL contain exactly one [1..1] guardianPerson (CONF:5385).

This guardianPerson SHALL contain at least one [1..\*] name (CONF:5386).

The content of name SHALL be a conformant [US Realm Person Name (PN.US.FIELDED)](#U_US_Realm_Person_Name_PTNUSFIELDED) (2.16.840.1.113883.10.20.22.5.1.1) (CONF:10414).

#### Birthplace

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

This place SHALL contain exactly one [1..1] addr (CONF:5397).

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).

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).

If this addr is a US address it 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).

#### LanguageCommunication

* + - 1. This patient SHOULD contain zero or more [0..\*] languageCommunication (CONF:5406).
				1. 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).
				2. 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).
				3. 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).
				4. The languageCommunication, if present, MAY contain zero or one [0..1] preferenceInd to indicate a preference for communication about care delivery and treatements to be translated into this language **(NEWCONF:xxxxx**).

If more than one languageCommunication is present, only one languageCommunication element SHALL have a preferenceInd with a value of 1 **(NEWCONF:xxxxx**).

#### ProviderOrganization

If present, this organization represents the provider organization where the person is claiming to be a patient.

* + 1. 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).
				1. 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).
				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](#T_VS_TelecomeUseValueSet) DYNAMIC (CONF:7994).
			4. The providerOrganization, if present, SHALL contain at least one [1..\*] addr (CONF:5422).
				1. The content of addr SHALL be a conformant [US Realm Address (AD.US.FIELDED)](#U_US_Realm_Address_ADUSFIELDED) (2.16.840.1.113883.10.20.22.5.2) (CONF:10415).

#### RecordTarget Value Sets

Table 13: : 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 14: 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 15: : 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 16: 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 17: : 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 18: 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 19: 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 20: Responsible Party Value Set (excerpt)

Table 21: PersonalAndLegalRelationshipRoleType

Table 22: 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 23: 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 24: 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 25: 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 26: 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 |

#### RecordTarget Example

 Figure 17: US Realm recordTarget example

<recordTarget>

 <patientRole>

 <!-- Internal id using HL7 example OID. -->

 <id extension="999.1" root="2.16.840.1.113883.19"/>

 <!-- Fake Social Security Number using the actual SSN OID. -->

 <id extension="444-33-3333" root="2.16.840.1.113883.4.1"/>

 <!-- Identifier based on the person's Direct Address which is a secure

 and trusted mechanism for identifying

 a person discretely. The root of the id is the OID of the HISP

 Assigning Authority for the Direct Address-->

 <id extension="adameveryman@direct.sampleHISP.com"

 root="2.16.123.123.12345.1234"/>

 <addr use="HP">

 <!-- HP is "primary home" from codeSystem 2.16.840.1.113883.5.1119 -->

 <streetAddressLine>2222 Home Street</streetAddressLine>

 <city>Boston</city>

 <state>MA</state>

 <postalCode>02368</postalCode>

 <!-- US is "United States" from ISO 3166-1 Country Codes: 1.0.3166.1 -->

 <country>US</country>

 </addr>

 <!-- HP is "primary home" from HL7 AddressUse 2.16.840.1.113883.5.1119 -->

 <telecom value="tel:(555)555-2004" use="HP"/>

 <!-- A secure e-mail address appropriate for healthcare communications-->

 <telecom value="mailto:adameveryman@direct.sampleHISP.com" use="H"/>

 <patient>

 <name use="L">

 <!-- L is "Legal" from HL7 EntityNameUse 2.16.840.1.113883.5.45 -->

 <prefix>Mr.</prefix>

 <given>Adam</given>

 <given>A.</given>

 <given qualifier="CL">Ace</given>

 <family>Everyman</family>

 </name>

 <administrativeGenderCode code="M"

 codeSystem="2.16.840.1.113883.5.1" displayName="Male"/>

 <birthTime value="19551125"/>

 <maritalStatusCode code="M" displayName="Married"

 codeSystem="2.16.840.1.113883.5.2"

 codeSystemName="MaritalStatusCode"/>

 <religiousAffiliationCode code="1013"

 displayName="Christian (non-Catholic, non-specific)"

 codeSystemName="HL7 Religious Affiliation"

 codeSystem="2.16.840.1.113883.1.11.19185"/>

 <raceCode code="2106-3" displayName="White"

 codeSystem="2.16.840.1.113883.6.238"

 codeSystemName="Race &amp; Ethnicity - CDC"/>

 <ethnicGroupCode code="2186-5" displayName="Not Hispanic or Latino"

 codeSystem="2.16.840.1.113883.6.238"

 codeSystemName="Race &amp; Ethnicity - CDC"/>

 <birthplace>

 <place>

 <addr>

 <city>Pointe-Claire</city>

 <state>QC</state>

 <postalCode>H9R 1E4</postalCode>

 <country>CAN</country>

 </addr>

 </place>

 </birthplace>

 <languageCommunication>

 <languageCode code="fr-CN"/>

 <modeCode code="RWR" displayName="Recieve Written"

 codeSystem="2.16.840.1.113883.5.60"

 codeSystemName="LanguageAbilityMode"/>

 <preferenceInd value="true"/>

 </languageCommunication>

 </patient>

 <providerOrganization>

 <!-- This is the patient's perferred provider organization. -->

 <!-- Internal id -->

 <id extension="999.2" root="2.16.840.1.113883.19"/>

 <!-- NPI for the organization -->

 <id extension="1234567890" root="2.16.840.1.113883.4.6"/>

 <name>Good Health Internal Medicine</name>

 <telecom use="WP" value="tel:(781)555-1212"/>

 <addr>

 <streetAddressLine>100 Health Drive</streetAddressLine>

 <city>Boston</city>

 <state>MA</state>

 <postalCode>02368</postalCode>

 <country>USA</country>

 </addr>

 </providerOrganization>

 </patientRole>

 </recordTarget>

### 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.

1. SHALL contain at least one [1..\*] author (CONF:5444).
	1. Such authors SHALL contain exactly one [1..1] time (CONF:5445).
		1. The content SHALL be a conformant [US Realm Date and Time (DTM.US.FIELDED)](#U_US_Realm_Date_and_Time_DTMUSFIELDED) (2.16.840.1.113883.10.20.22.5.4) (CONF:16866).
	2. Such authors SHALL contain exactly one [1..1] assignedAuthor (CONF:5448).
		1. 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:xxxxx)**.
		2. When the author is a person,this assignedAuthor SHALL contain one [1..1] code (**NEWCONF:xxxxx**).
			1. The code, SHaLL contain exactly one [1..1] @code, which SHOULD be selected from the PersonalRelationshipRoleType value set plus ResponsibleParty (**NEWCONF:xxxxx**)
		3. This assignedAuthor SHALL contain at least one [1..\*] addr (CONF:5452).
			1. The content SHALL be a conformant [US Realm Address (AD.US.FIELDED)](#U_US_Realm_Address_ADUSFIELDED) (2.16.840.1.113883.10.20.22.5.2) (CONF:16871).
		4. 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](#T_VS_TelecomeUseValueSet) DYNAMIC (CONF:7995).
		5. There SHALL be exactly one assignedAuthor/assignedPerson or exactly one assignedAuthor/assignedAuthoringDevice (CONF:16790).
		6. 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).
				1. The content SHALL be a conformant [US Realm Person Name (PN.US.FIELDED)](#U_US_Realm_Person_Name_PTNUSFIELDED) (2.16.840.1.113883.10.20.22.5.1.1) (CONF:16872).
		7. 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="20121126145000-0500"/>

 <assignedAuthor>

 <!-- Internal id using HL7 example OID. -->

 <id extension="999.1" root="2.16.840.1.113883.19"/>

 <!-- The PAN IG includes conformance constraints on the code element.

 This author/assignedAuthor/code/@code must be a code from one of

 two value sets:

 PersonalRelationshipRoleType or ResponsibleParty. Both of these

 value sets include codes from the HL7 RoleCode Code System.

 -->

 <code code="SELF" displayName="Self"

 codeSystem="2.16.840.1.113883.5.111"

 codeSystemName="HL7 Role code"/>

 <addr use="HP">

 <!-- HP is "primary home" from codeSystem 2.16.840.1.113883.5.1119 -->

 <streetAddressLine>2222 Home Street</streetAddressLine>

 <city>Boston</city>

 <state>MA</state>

 <postalCode>02368</postalCode>

 <!-- US is "United States" from ISO 3166-1 Country Codes: 1.0.3166.1 -->

 <country>US</country>

 </addr>

 <!-- HP is "primary home" from HL7 AddressUse 2.16.840.1.113883.5.1119 -->

 <telecom value="tel:(555)555-2004" use="HP"/>

 <assignedPerson>

 <name>

 <given>Adam</given>

 <family>Everyman</family>

 </name>

 </assignedPerson>

 </assignedAuthor>

</author>

Figure 19: Device author example

<author>

 <time value="20121126145000-0500"/>

 <assignedAuthor>

 <id extension="777.11" root="2.16.840.1.113883.19"/>

 <addr nullFlavor="NA"/>

 <telecom nullFlavor="NA"/>

 <assignedAuthoringDevice>

 <manufacturerModelName>ACME PHR</manufacturerModelName>

 <softwareName>MyPHR v1.0</softwareName>

 </assignedAuthoringDevice>

 <representedOrganization>

 <id extension="999" root="1.2.3.4.5.6.7.8.9.12345"/>

 <name>ACME PHR Solutions,Inc.</name>

 <telecom use="WP" value="tel:123-123-12345"/>

 <addr>

 <streetAddressLine>4 Future Way</streetAddressLine>

 <city>Provenance</city>

 <state>RI</state>

 <postalCode>02919</postalCode>

 </addr>

 </representedOrganization>

 </assignedAuthor>

</author>

### 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). If the DataEnterer is missing, this role is assumed to be played by the Author.

1. MAY contain zero or one [0..1] dataEnterer (CONF:5441).
	1. The dataEnterer, if present, SHALL contain exactly one [1..1] assignedEntity (CONF:5442).
		1. 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)**.
		2. 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.FIELDED)](#U_US_Realm_Address_ADUSFIELDED) (2.16.840.1.113883.10.20.22.5.2) (CONF:10417).
		3. 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](#T_VS_TelecomeUseValueSet) DYNAMIC (CONF:7996).
		4. This assignedEntity SHALL contain exactly one [1..1] assignedPerson (CONF:5469).
			1. This assignedPerson SHALL contain at least one [1..\*] name (CONF:5470).
				1. The content of name SHALL be a conformant [US Realm Person Name (PN.US.FIELDED)](#U_US_Realm_Person_Name_PTNUSFIELDED) (2.16.840.1.113883.10.20.22.5.1.1) (CONF:10418).
		5. This assignedEntity MAY contain zero or one [0..1] code which SHOULD be selected from value set PersonalRelationshipRoleType plus ResponsibleParty value set (**NEWCONF:xxxxx).**

Figure 20: dataEnterer example

<dataEnterer>

 <assignedEntity>

 <!-- Internal id using HL7 example OID. -->

 <id extension="999.1" root="2.16.840.1.113883.19"/>

 <addr use="HP">

 <!-- HP is "primary home" from codeSystem 2.16.840.1.113883.5.1119 -->

 <streetAddressLine>2222 Home Street</streetAddressLine>

 <city>Boston</city>

 <state>MA</state>

 <postalCode>02368</postalCode>

 <!-- US is "United States" from ISO 3166-1 Country Codes: 1.0.3166.1 -->

 <country>US</country>

 </addr>

 <!-- HP is "primary home" from HL7 AddressUse 2.16.840.1.113883.5.1119 -->

 <telecom value="tel:(555)555-2004" use="HP"/>

 <assignedPerson>

 <name>

 <given>Adam</given><family>Everyman</family>

 </name>

 </assignedPerson>

 </assignedEntity>

</dataEnterer>

### 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, even if the personal relation is medical professional. 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.

1. MAY contain zero or more [0..\*] informant (CONF:8001).
	1. SHALL contain exactly one [1..1] assignedEntity OR exactly one [1..1] relatedEntity (CONF:8002).
		1. SHOULD contain at least one [1..\*] addr (CONF:8220).
			1. The content of addr SHALL be a conformant [US Realm Address (AD.US.FIELDED)](#U_US_Realm_Address_ADUSFIELDED) (2.16.840.1.113883.10.20.22.5.2) (CONF:10419).
		2. 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).
				1. The content of name SHALL be a conformant [US Realm Person Name (PN.US.FIELDED)](#U_US_Realm_Person_Name_PTNUSFIELDED) (2.16.840.1.113883.10.20.22.5.1.1) (CONF:10420).
		3. 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:xxxxx**).
		4. 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:xxxxx)**.

Figure 21: Informant with assignedEntity example

<informant>

 <assignedEntity>

 <!-- Internal id using HL7 example OID. -->

 <id extension="999.1" root="2.16.840.1.113883.19"/>

 <addr use="HP">

 <!-- HP is "primary home" from codeSystem 2.16.840.1.113883.5.1119 -->

 <streetAddressLine>2222 Home Street</streetAddressLine>

 <city>Boston</city>

 <state>MA</state>

 <postalCode>02368</postalCode>

 <!-- US is "United States" from ISO 3166-1 Country Codes: 1.0.3166.1 -->

 <country>US</country>

 </addr>

 <!-- HP is "primary home" from HL7 AddressUse 2.16.840.1.113883.5.1119 -->

 <telecom value="tel:(555)555-2004" use="HP"/>

 <assignedPerson>

 <name>

 <given>Adam</given><family>Everyman</family>

 </name>

 </assignedPerson>

 </assignedEntity>

</informant>

### Custodian

The custodian element represents the organization or person 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. Also, the custodian may be the patient or an organization acting on behalf of the patient, such as a PHR organization.

1. SHALL contain exactly one [1..1] custodian (CONF:5519).
	1. This custodian SHALL contain exactly one [1..1] assignedCustodian (CONF:5520).
		1. 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).
				1. 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:xxxxx)**.
			2. This representedCustodianOrganization SHALL contain exactly one [1..1] name (CONF:5524).
			3. This representedCustodianOrganization SHALL contain exactly one [1..1] telecom (CONF:5525).
				1. 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](#T_VS_TelecomeUseValueSet) DYNAMIC (CONF:7998).
			4. This representedCustodianOrganization SHALL contain at least one [1..\*] addr (CONF:5559).
				1. The content of addr SHALL be a conformant [US Realm Address (AD.US.FIELDED)](#U_US_Realm_Address_ADUSFIELDED) (2.16.840.1.113883.10.20.22.5.2) (CONF:10421).

Figure 22: Custodian examples

<custodian>

 <assignedCustodian>

 <representedCustodianOrganization>

 <!-- Internal id -->

 <id extension="999.3" root="2.16.840.1.113883.19"/>

 <name>MyPersonalHealthRecord.Com</name>

 <telecom value="tel:(555)555-1212" use="WP"/>

 <addr use="WP">

 <streetAddressLine>123 Boylston Street</streetAddressLine>

 <city>Blue Hill</city>

 <state>MA</state>

 <postalCode>02368</postalCode>

 <country>USA</country>

 </addr>

 </representedCustodianOrganization>

 </assignedCustodian>

</custodian>

<custodian>

 <assignedCustodian>

 <representedCustodianOrganization>

 <!-- This example assumes that Ned is using a Desktop PHR application.

 There is no larger system, just the application that Ned runs on

 his desktop.

 -->

 <!-- Internal id -->

 <id extension="999.8" root="2.16.840.1.113883.19"/>

 <name>Ned Nuclear</name>

 <telecom value="tel:(555)555-5001" use="WP"/>

 <addr use="HP">

 <!-- HP is "primary home" from codeSystem 2.16.840.1.113883.5.1119 -->

 <streetAddressLine>6666 Home Street</streetAddressLine>

 <city>Boston</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>

 </representedCustodianOrganization>

 </assignedCustodian>

</custodian>

### 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).

* 1. The informationRecipient, if present, SHALL contain exactly one [1..1] intendedRecipient (CONF:5566).
		1. This intendedRecipient SHOULD contain atleast one [1..\*] id (**NEWCONF:xxxxx)**.
			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:xxxxx)**.
			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:xxxxx**).
			3. The ids MAY reference the id of a person or organization entity specified elsewhere in the document (**NEWCONF:xxxxx**).
		2. 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).
				1. The content of name SHALL be a conformant [US Realm Person Name (PN.US.FIELDED)](#U_US_Realm_Person_Name_PTNUSFIELDED) (2.16.840.1.113883.10.20.22.5.1.1) (CONF:10427).
		3. 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 examples

<!-- The document is intended for multiple recipients,

 Adam himself and his PCP physician.

-->

<informationRecipient>

 <intendedRecipient>

 <!-- Internal id using HL7 example OID. -->

 <id extension="999.1" root="2.16.840.1.113883.19"/>

 <!-- Identifier based on the person's Direct Address which is a secure

 and trusted mechanism for identifying a person discretely.

 The root of the id is the OID of the HISP Assigning Authority

 for the Direct Address-->

 <id extension="adameveryman@direct.sampleHISP.com"

 root="2.16.123.123.12345.1234"/>

 <informationRecipient>

 <name>

 <given>Adam</given><family>Everyman</family>

 </name>

 </informationRecipient>

 <receivedOrganization>

 <!-- Internal id -->

 <id extension="999.3" root="2.16.840.1.113883.19"/>

 <name>MyPersonalHealthRecord.Com</name>

 </receivedOrganization>

 </intendedRecipient>

</informationRecipient>

<informationRecipient>

 <intendedRecipient>

 <!-- Internal id using HL7 example OID. -->

 <id extension="999.4" root="2.16.840.1.113883.19"/>

 <!-- The physician's NPI number -->

 <id extension="1122334455" root="2.16.840.1.113883.4.6"/>

 <!-- The physician's Direct Address -->

 <!-- Identifier based on the person's Direct Address which is a secure

 and trusted mechanism for identifying a person discretely.

 The root of the id is the OID of the HISP Assigning Authority for

 the Direct Address-->

 <id extension="DrP@direct.sampleHISP2.com" root="2.16.123.123.12345.4321"/>

 <telecom use="WP" value="tel:(781)555-1212"/>

 <telecom use="WP" value="mailto:DrP@direct.sampleHISP2.com"/>

 <informationRecipient>

 <name>

 <prefix>Dr.</prefix>

 <given>Patricia</given>

 <family>Primary</family>

 </name>

 </informationRecipient>

 <receivedOrganization>

 <!-- Internal id -->

 <id extension="999.2" root="2.16.840.1.113883.19"/>

 <!-- NPI for the organization -->

 <id extension="1234567890" root="2.16.840.1.113883.4.6"/>

 <name>Good Health Internal Medicine</name>

 <telecom use="WP" value="tel:(781)555-1212"/>

 <addr>

 <streetAddressLine>100 Health Drive</streetAddressLine>

 <city>Boston</city>

 <state>MA</state>

 <postalCode>02368</postalCode>

 <country>USA</country>

 </addr>

 </receivedOrganization>

 </intendedRecipient>

</informationRecipient>

### 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.

1. SHOULD contain zero or one [0..1] legalAuthenticator (CONF:5579).
	1. The legalAuthenticator, if present, SHALL contain exactly one [1..1] time (CONF:5580).
		1. The content SHALL be a conformant [US Realm Date and Time (DTM.US.FIELDED)](#U_US_Realm_Date_and_Time_DTMUSFIELDED) (2.16.840.1.113883.10.20.22.5.4) (CONF:16873).
	2. The legalAuthenticator, if present, SHALL contain exactly one [1..1] signatureCode (CONF:5583).
		1. This signatureCode SHALL contain exactly one [1..1] @code="S" (CodeSystem: Participationsignature 2.16.840.1.113883.5.89) (CONF:5584).
	3. The legalAuthenticator, if present, SHALL contain exactly one [1..1] assignedEntity (CONF:5585).
		1. 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:xxxxx)**.
		2. This assignedEntity MAY contain zero or one [0..1] code, which SHOULD be selected from the PersonalRelationshipRoleType plus ResponsibleParty value set (**NEWCONF:xxxxx**).
		3. 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.FIELDED)](#U_US_Realm_Address_ADUSFIELDED) (2.16.840.1.113883.10.20.22.5.2) (CONF:10429).
		4. 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](#T_VS_TelecomeUseValueSet) DYNAMIC (CONF:7999).
		5. This assignedEntity SHALL contain exactly one [1..1] assignedPerson (CONF:5597).
			1. This assignedPerson SHALL contain at least one [1..\*] name (CONF:5598).
				1. The content of name SHALL be a conformant [US Realm Person Name (PN.US.FIELDED)](#U_US_Realm_Person_Name_PTNUSFIELDED) (2.16.840.1.113883.10.20.22.5.1.1) (CONF:10430).

Figure 24: legalAuthenticator example

<legalAuthenticator>

 <time value="20121126145000-0500"/>

 <signatureCode code="S"/>

 <assignedEntity>

 <!-- Internal id using HL7 example OID. -->

 <id extension="999.1" root="2.16.840.1.113883.19"/>

 <addr use="HP">

 <!-- HP is "primary home" from codeSystem 2.16.840.1.113883.5.1119 -->

 <streetAddressLine>2222 Home Street</streetAddressLine>

 <city>Boston</city>

 <state>MA</state>

 <postalCode>02368</postalCode>

 <!-- US is "United States" from ISO 3166-1 Country Codes: 1.0.3166.1 -->

 <country>US</country>

 </addr>

 <!-- HP is "primary home" from HL7 AddressUse 2.16.840.1.113883.5.1119 -->

 <telecom value="tel:(555)555-2004" use="HP"/>

 <assignedPerson>

 <name>

 <given>Adam</given><family>Everyman</family>

 </name>

 </assignedPerson>

 </assignedEntity>

</legalAuthenticator>

### Authenticator

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

1. MAY contain zero or more [0..\*] authenticator (CONF:5607).
	1. The authenticator, if present, SHALL contain exactly one [1..1] time (CONF:5608).
		1. The content SHALL be a conformant [US Realm Date and Time (DTM.US.FIELDED)](#U_US_Realm_Date_and_Time_DTMUSFIELDED) (2.16.840.1.113883.10.20.22.5.4) (CONF:16874).
	2. The authenticator, if present, SHALL contain exactly one [1..1] signatureCode (CONF:5610).
		1. This signatureCode SHALL contain exactly one [1..1] @code="S" (CodeSystem: Participationsignature 2.16.840.1.113883.5.89) (CONF:5611).
	3. The authenticator, if present, SHALL contain exactly one [1..1] assignedEntity (CONF:5612).
		1. 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:xxxxx)**.
		2. This assignedEntity SHOULD contain zero or one [0..1] code (**NEWCONF:xxxxx**).
			1. The code SHOULD be selected from value set PersonalRelationshipRoleType plus ResponsibleParty value set (**NEWCONF:xxxxx**).
		3. 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.FIELDED)](#U_US_Realm_Address_ADUSFIELDED) (2.16.840.1.113883.10.20.22.5.2) (CONF:10425).
		4. 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](#T_VS_TelecomeUseValueSet) DYNAMIC (CONF:8000).
		5. This assignedEntity SHALL contain exactly one [1..1] assignedPerson (CONF:5624).
			1. This assignedPerson SHALL contain at least one [1..\*] name (CONF:5625).
				1. The content of name SHALL be a conformant [US Realm Person Name (PN.US.FIELDED)](#U_US_Realm_Person_Name_PTNUSFIELDED) (2.16.840.1.113883.10.20.22.5.1.1) (CONF:10424).

Figure 25: Authenticator example

<authenticator>

 <time value="20121126145000-0500"/>

 <signatureCode code="S"/>

 <assignedEntity>

 <!-- Internal id using HL7 example OID. -->

 <id extension="999.1" root="2.16.840.1.113883.19"/>

 <addr use="HP">

 <!-- HP is "primary home" from codeSystem 2.16.840.1.113883.5.1119 -->

 <streetAddressLine>2222 Home Street</streetAddressLine>

 <city>Boston</city>

 <state>MA</state>

 <postalCode>02368</postalCode>

 <!-- US is "United States" from ISO 3166-1 Country Codes: 1.0.3166.1 -->

 <country>US</country>

 </addr>

 <!-- HP is "primary home" from HL7 AddressUse 2.16.840.1.113883.5.1119 -->

 <telecom value="tel:(555)555-2004" use="HP"/>

 <assignedPerson>

 <name>

 <given>Adam</given><family>Everyman</family>

 </name>

 </assignedPerson>

 </assignedEntity>

</authenticator>

### 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)

1. MAY contain zero or more [0..\*] participant (CONF:10003).
	1. The participant, if present, MAY contain zero or one [0..1] time (CONF:10004).
	2. Such participants, if present, SHALL have an associatedPerson or scopingOrganization element under participant/associatedEntity (CONF:10006).
	3. 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).

The associatedEntity SHOULD contain exactly [1..1] code (NEWCONF:xxxxx).

* + 1. The code SHOULD be selected from value set PersonalRelationshipRoleType plus ResponsibleParty value set (NEWCONF:xxxxx).

Table 27: 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="19551125"/>

 <high value="20121126"/>

 </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>

### InFulfillmentOf

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

1. MAY contain zero or more [0..\*] inFulfillmentOf (CONF:9952).
	1. The inFulfillmentOf, if present, SHALL contain exactly one [1..1] order (CONF:9953).
		1. 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:xxxxx**).

DocumentationOf/serviceEvent

The main activity being described by a Patient Generated Document 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). The performer of the service event may be the patient, family member or other individual designated by the patient.

**NOTE:** Implementations originating a Patient Generated Document 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).
	1. This documentationOf **SHALL** contain exactly one [1..1] **serviceEvent** (CONF:8480).
		1. 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).
		2. This serviceEvent **MAY** contain one [1..1] code (**NEWCONF:xxxxx**).
			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 Generated Document. (**NEWCONF:xxxxx**)
		3. 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).
		4. 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:xxxxx**).
			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.**
				1. The **functionCode** SHall be selected from value set ParticipationType 2.16.840.1.113883.1.11.10901 (**NEWCONF:xxxxx**).
				2. When indicating the performer was the primary care physician the functionCode shall be **=**”PCP” **(NewCONF:xxxxx)**
			4. Such performers **MAY** contain zero or more [0..1] **assignedEntity** (CONF:8459).
				1. This assignedEntity **SHALL** contain at least one [1..\*] **id** (CONF:8460).

**May** include zero or one [0..1] id where id/@root ="2.16.840.1.113883.4.6" National Provider Identifier (**NEWCONF:xxxxx**).

May utilize the combined @root and @extension attributes to record the authenticator’s identity in a secure, trusted, and unique way. **(NEWCONF:xxxxx)**.

* + - * 1. This assignedEntity **MAY** contain zero or one [0..1] **code** (CONF:8461).

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:xxxxx**).

If the assignedEntity is an individual, the code **SHOULD** be selected from value set Personal Relationship Role Type Plus ResponsibleParty value set (**NEWCONF:xxxxx).**

Figure 27: DocumentationOf example

<documentationOf typeCode="DOC">

 <serviceEvent classCode="PCPR">

 <effectiveTime>

 <low value="19551125"/>

 <high value="20121126145000"/>

 </effectiveTime>

 <performer typeCode="PRF">

 <functionCode code="PCP" displayName="Primary Care Provider"

 codeSystem="2.16.840.1.113883.5.88"

 codeSystemName="Participation Function">

 <originalText>Primary Care Provider (PCP)</originalText>

 </functionCode>

 <time>

 <low value="201101"/>

 </time>

 <assignedEntity>

 <!-- Internal id using HL7 example OID. -->

 <id extension="999.4" root="2.16.840.1.113883.19"/>

 <!-- The physician's NPI number -->

 <id extension="1122334455" root="2.16.840.1.113883.4.6"/>

 <!-- Type of Physician -->

 <code code="207R00000X" displayName="Internal Medicine"

 codeSystemName="NUCC Health Care Provider Taxonomy"

 codeSystem="2.16.840.1.113883.6.101"/>

 <addr>

 <streetAddressLine>100 Health Drive</streetAddressLine>

 <city>Boston</city>

 <state>MA</state>

 <postalCode>02368</postalCode>

 <country>USA</country>

 </addr>

 <telecom use="WP" value="tel:(781)555-1212"/>

 <assignedPerson>

 <name>

 <prefix>Dr.</prefix>

 <given>Patricia</given>

 <family>Primary</family>

 </name>

 </assignedPerson>

 <representedOrganization>

 <!-- Internal id -->

 <id extension="999.2" root="2.16.840.1.113883.19"/>

 <name>Good Health Internal Medicine</name>

 <telecom use="WP" value="tel:(781)555-1212"/>

 <addr>

 <streetAddressLine>100 Health Drive</streetAddressLine>

 <city>Boston</city>

 <state>MA</state>

 <postalCode>02368</postalCode>

 <country>USA</country>

 </addr>

 </representedOrganization>

 </assignedEntity>

 </performer>

 <performer typeCode="PRF">

 <functionCode code="PCP" displayName="Primary Care Provider"

 codeSystem="2.16.840.1.113883.5.88"

 codeSystemName="Participation Function">

 <originalText>Primary Care Provider (PCP)</originalText>

 </functionCode>

 <time>

 <low value="1971"/>

 <high value="201101"/>

 </time>

 <assignedEntity>

 <!-- Internal id using HL7 example OID. -->

 <id extension="999.4" root="2.16.840.1.113883.19"/>

 <!-- The physician's NPI number -->

 <id extension="1122334466" root="2.16.840.1.113883.4.6"/>

 <!-- Type of Physician -->

 <code code="207Q00000X" displayName="Family Medicine"

 codeSystemName="NUCC Health Care Provider Taxonomy"

 codeSystem="2.16.840.1.113883.6.101">

 <originalText>General Practitioner</originalText>

 </code>

 <addr>

 <streetAddressLine>103 Rue Champlain</streetAddressLine>

 <city>Roxboro</city>

 <state>QC</state>

 <postalCode>H8Y 3S6</postalCode>

 <country>CAN</country>

 </addr>

 <telecom use="WP" value="tel:514-555-1212"/>

 <assignedPerson>

 <name>

 <prefix>Dr.</prefix>

 <given>Fay</given>

 <family>Family</family>

 </name>

 </assignedPerson>

 <representedOrganization>

 <!-- Internal id -->

 <id extension="999.5" root="2.16.840.1.113883.19"/>

 <name>Roxboro Family Practice</name>

 <telecom use="WP" value="tel:514-555-1212"/>

 <addr>

 <streetAddressLine>103 Rue Champlain</streetAddressLine>

 <city>Roxboro</city>

 <state>QC</state>

 <postalCode>H8Y 3S6</postalCode>

 <country>CAN</country>

 </addr>

 </representedOrganization>

 </assignedEntity>

 </performer>

 <performer typeCode="PRF">

 <functionCode code="PCP" displayName="Primary Care Provider"

 codeSystem="2.16.840.1.113883.5.88"

 codeSystemName="Participation Function">

 <originalText>Primary Care Provider (PCP)</originalText>

 </functionCode>

 <time>

 <low value="19551125"/>

 <high value="1971"/>

 </time>

 <assignedEntity>

 <!-- Internal id using HL7 example OID. -->

 <id extension="999.6" root="2.16.840.1.113883.19"/>

 <!-- The physician's NPI number -->

 <id extension="1122334477" root="2.16.840.1.113883.4.6"/>

 <!-- Type of Physician -->

 <code code="208000000X" displayName="Pediatrics"

 codeSystemName="NUCC Health Care Provider Taxonomy"

 codeSystem="2.16.840.1.113883.6.101">

 <originalText>Pediatrician</originalText>

 </code>

 <addr>

 <streetAddressLine>10 Rue De Seville</streetAddressLine>

 <city>Pointe-Claire</city>

 <state>QC</state>

 <postalCode>H9R 1E9</postalCode>

 <country>CAB</country>

 </addr>

 <telecom use="WP" value="tel:514-333-1234"/>

 <assignedPerson>

 <name>

 <prefix>Dr.</prefix>

 <given>Karen</given>

 <family>Kidder</family>

 </name>

 </assignedPerson>

 <representedOrganization>

 <!-- Internal id -->

 <id extension="999.7" root="2.16.840.1.113883.19"/>

 <name>Pointe-Claire Pediatrics</name>

 <telecom use="WP" value="tel:514-333-1234"/>

 <addr>

 <streetAddressLine>10 Rue De Seville</streetAddressLine>

 <city>Pointe-Claire</city>

 <state>QC</state>

 <postalCode>H9R 1E9</postalCode>

 <country>CAN</country>

 </addr>

 </representedOrganization>

 </assignedEntity>

 </performer>

 </serviceEvent>

</documentationOf>

### 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’.

1. MAY contain zero or more [0..\*] authorization (CONF:16792) such that it
	1. SHALL contain exactly one [1..1] consent (CONF:16793).
		1. This consent MAY contain zero or more [0..\*] id (CONF:16794).
		2. 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).
		3. 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>

### 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.

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

Unless specifically authored to document an encounter with a provider, the patient generated document should NOT use componentOf/encompassingEncounter.

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

US Realm Address (AD.US.FIELDED)

[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](#T_VS_PostalAddressUse) 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](#T_VS_Country) DYNAMIC (CONF:7295).
3. SHOULD contain zero or one [0..1] state (ValueSet: [StateValueSet 2.16.840.1.113883.3.88.12.80.1](#T_VS_State) DYNAMIC) (CONF:7293).
	1. 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](#T_VS_PostalCode) DYNAMIC) (CONF:7294).
	1. 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 space[[7]](#footnote-7) (CONF:7296).

Table 28: 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 |

US Realm Date and Time (DT.US.FIELDED)

[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.FIELDED)**](#O_US_Realm_Date_and_Time_(DTM.US.FIELDED)**,** 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).

US Realm Date and Time (DTM.US.FIELDED)

[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.FIELDED)**](#O_US_Realm_Date_and_Time_(DT.US.FIELDED))**,** 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).

US Realm Patient Name (PTN.US.FIELDED)

[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/>)](http://www.w3.org/%29).

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).
	1. 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).
	1. 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).
	2. 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).
	1. 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).
	1. 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 29: 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 30: 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 |

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).
	1. The content of name SHALL be either a conformant [Patient Name (PTN.US.FIELDED)](#O_US_Realm_Patient_Name_(PTN.US.FIELDED)), or a string (CONF:9371).
	2. The string SHALL NOT contain name parts (CONF:9372).

## 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 Generated Document chapter of this document.]

Metadata carried in the header of a Patient Generated Document 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 Generated Document 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 presented 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. USER STORIES

User stories have been provided as an informative appendix to augment the implementation guidance provided above. The stories 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 |
| **RecordTarget/Guardian** |  |
| **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. Assumption: If there is no informant, then 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 Generated Document 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 Generated Document 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.
 |

|  |
| --- |
| 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: |
| **RecordTarget/Guardian** |  |
| **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 legal responsibility for the individual.  |
| Informant |
| Authenticator |
| Legal Authenticator |

# Appendix B. GLOSSARY

|  |  |
| --- | --- |
| TERM | DEFINITION |
| Patient’s Representative | A person with a personal relationship to the individual who is the recordTarget of the document, or a person in a position of legal responsibility for the individual. The person is not operating in the role of a clinician (health care provider) delivering care services to the patient. A person in this role is not operating in a role covered by the NUCC Taxonomy. |
| Patient-controlled medical device | Any sort of device used by the patient to record information pertinant to their health and care. |

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. [↑](#footnote-ref-1)
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 [↑](#footnote-ref-2)
3. From CDA Normative Web edition: 4.2.1.8 ClinicalDocument.versionNumber An integer value used to version successive replacement documents [↑](#footnote-ref-3)
4. 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. [↑](#footnote-ref-4)
5. 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 [↑](#footnote-ref-5)
6. From CDA Normative Web edition: 4.2.1.8 ClinicalDocument.versionNumber An integer value used to version successive replacement documents [↑](#footnote-ref-6)
7. For information on mixed content see Extensible Markup Language (XML) ([http://www.w3.org/TR/2008/REC-xml-20081126/#sec-mixed-content)](http://www.w3.org/%29). [↑](#footnote-ref-7)