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# Acknowledgments

This guide was developed and produced through the joint efforts of Health Level Seven (HL7), and the Office of the National Coordinator (ONC) Standards and Interoperability Standards and Interoperability Framework/Data Provenance Initiative.

The editors appreciate the support and sponsorship of the HL7 Community Based Collaborative Care Work Group (CBCC), co-sponsorship by the HL7 Security Work Group, and guidance and advise from the HL7 Structured Documents Working Group (SDWG), and all the volunteers, staff, and contractors participating in the Standards and Interoperability Framework.

This implementation guide (IG) references materials developed by Data Provenance Initiative (DPROV) S&I Framework Initiative as described on the project wiki with contributions from industry stakeholders.

The template constraints in this IG refer to the following sources:

- **HL7 CDA Release 2**
- **HL7 Implementation Guide for CDA Release 2 Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2, Volume 1**
- **HL7 Implementation Guide Data Segmentation for Privacy (DS4P), Release 1 CDA R2 and Privacy Metadata Reusable Content Profile January 2014 US Realm, HL7 Normative Ballot**
- **HL7 Implementation Guide for CDA: Release 2: Privacy Consent Directives, Release 1**
- **HL7 Healthcare Privacy and Security Classification System (HCS)**
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## Revision History

**Table 1: Revision History**

Changes applied to this document during its development:

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<td>Draft - May 3rd, 2014</td>
<td>Neelima Chennamaraja</td>
<td>Created initial project</td>
</tr>
<tr>
<td>Draft - Sep 20th, 2014</td>
<td>Ioana Singureanu, Neelima Chennamaraja</td>
<td>Created templates, documentation and added content based on SME input</td>
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<tr>
<td>DSTU Release 1 - Sep 30, 2015</td>
<td>Neelima Chennamaraja, Kathleen Connor</td>
<td>Incorporated ballot comments based on SME input</td>
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Table 2: Closed Issues

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<td>Template Versioning</td>
<td>July 7th, 2014</td>
<td>Neelima Chennamaraja</td>
<td>This IG doesn't re-use existing templates, therefore all the templates in this IG are 1st version and there is no need for additional version information. This item was addressed with input from Structured Documents Work Group Co-chairs</td>
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Chapter 1

INTRODUCTION

Topics:
- Purpose
- Audience
- Scope
- Overview
- Approach
- Organization of This Guide
- Use of Templates
- Conventions Used in This Guide


The DPROV Initiative is sponsored by the Office of the Chief Privacy Officer within the ONC to develop standards and guidance by which health information technology can support clinical, organizational, and jurisdictional requirements to capture, and convey provenance about health information instances. Please visit the Initiative [http://wiki.siframework.org/Data+Provenance+Initiative](http://wiki.siframework.org/Data+Provenance+Initiative) and HL7 sources noted throughout this document for further information and current status of activities. For documentation specific to the development of this IG see the Data Provenance Tiger Team wiki [http://wiki.siframework.org/Data+Provenance+Tiger+Team](http://wiki.siframework.org/Data+Provenance+Tiger+Team).

This IG is the result of a focused effort to identify existing opportunities within CDA R2 where basic provenance information about clinical (and other care related information), who created it, when was it created, where was it created, how it was created, and why it was created, can be conveyed in a consistent and interoperable manner. Also conveyed is what action was taken - resulting in (documented by) the information captured. In particular, this IG builds upon the provenance preserving constraints in the Consolidated CDA and Data Segmentation for Privacy IGs, as well as reusing the CDA Consent Directive IG.

Also within scope, the provenance patterns established in HL7 v.2 and v.3 such as v.3 Control Acts, Medical Records Domain, and RIM State Machines as well as similar specifications in v.2 Chapter 2 Control, Chapter 5 Queries, and Chapter 9 Medical Records/Information Management were leveraged as appropriate.

In addition, a wealth of EHR Functional Model Lifecycle Events, and Records Management and Evidentiary Support functional requirements have been gleaned from the invaluable input of experts in these areas including the HL7 EHR Work Group [http://wiki.hl7.org/index.php?title=EHR_Interoperability_WG](http://wiki.hl7.org/index.php?title=EHR_Interoperability_WG), US Realm participants in ISO TC 215 [ISO/TC 215 Health Informatics], CDISC, W3C PROV, and AHIMA. Standards focused on record lifecycle and trusted information flow requirements were reviewed including: ISO 21089 Trusted End-to-End Information Flows, ISO/HL7 10781 Electronic Health Record (EHR) System Functional Model Release 2 and the HL7 EHR Lifecycle Model DSTU.

This IG represents a consensus approach to meeting the requirements for conveyance of provenance data within any CDA at the document, section and entry level.
Subsequent and related activities within the S&I Framework and HL7 have provided additional guidance for specific use case events such as:

- New provenance metadata resulting from the occurrence of record lifecycle events;
- Inheritance of provenance metadata when a portion of a CDA instance is excerpted and incorporated into another CDA instance

Any ONC Data Provenance pilots that decide to exercise this IG will hopefully provide the essential substantive input to this DSTU that may lead to revisions and enhancements for a normative ballot upon completion of the one year DSTU period that begin on publication.
Purpose

This IG provides guidance to any CDA R2 implementer on the use of CDA templates to represent data provenance. These templates may also be used as building blocks for conveying provenance using other information exchange Standards.

Audience

This guide is designed for analysts and developers who require guidance on developing CDA R2 solutions consistent with the goals and requirements of the DPROV Initiative. Users of this guide must be familiar with the details of base CDA R2 standard and those IGs that are referenced by regulation, e.g., Consolidated CDA; this guide is not intended to be a tutorial on those subjects.

Scope

The scope of this IG is the conveyance of the basic provenance facts in a CDA instance. As such, it identifies the specific CDA structures and related value sets to communicate provenance related metadata for documents, sections, and entries.

This IG strives to be agnostic as to system functionality and workflow in which such data is to be collected. The goal is to provide basic guidance that can be leveraged by or applied to existing and (future) CDA R2 IGs. Use and adoption will inform best practices within the constraints of the base standard and additional constraints of this IG to achieve consistent and reliable conveyance of provenance.

The core provenance metadata to be captured are:

• Who contributed to the generation of a CDA, e.g., the participating: authors, authenticators, legal authenticators, custodians, data enterers, performers, and other participants, including assembly and composing software, and scoping organizations at the document, section, and entry levels.
• When an information event recorded in a CDA occurred
• Where an information event recorded in a CDA occurred
• Why an information event recorded in a CDA occurred
• How an information event recorded in a CDA differs from a predecessor or successor information event, and the context surrounding that change including any privacy or security policies that influenced the manner in which the information event was changed
• What provenance metadata about the information event that a recipient system may need to evaluate its authenticity, integrity, and trustworthiness, and to establish the receiver's confidence that this information is fit for use within its enterprise

Overview

As noted, this IG is agnostic of the policies, procedures and regulations that determine the actual values to be conveyed. In the context of CDA, the facts related to provenance are supported via coding systems and generic structures author, assignedEntity, etc. This IG specifies how these structures are to be populated to meet use cases of the underlying CDA instances upon which they are applied. Constraints defined in each template are intended to ensure the presence and conveyance of these values regardless of how or when they are determined.

During analysis of current practice it became clear that the abstract use case required constraints on the base CDA in two areas, both of which concern authorship of CDA content.

Generally, a CDA author is a person or a device assigned by a scoping organization to take responsibility for generating clinical content. Every document, section and entry has an author, although these relationships may be inherited from the containing document, section, or entry.
The first was to note the distinction of documents that are authored by patients versus those that are authored by clinical staff and others who have a recognized role in the care or treatment of a patient under the auspices and fulfillment of clinical or business practices for an organization such as a hospital or home health service. This IG builds on the previous work that resulted in the Patient Generated Document Template as defined in the Consolidated CDA, Release 2 Implementation guide (publication in progress). This template provides an unambiguous means of identifying those documents (or portions thereof) as having been authored by a patient or related person who acts as the patient advocate, but is clearly not a member of the provider-related organizations.

The second is to recognize two new types of actor referred to as an Assembler or a Composer. These actors compile new artifacts (CDA instances) from existing artifacts or portions thereof but are distinctly different from the type of software or device meeting existing CDA concepts of a device author, which capture and create new information independently of a human author, such as blood pressure, glucose meters, and health applications that may be used for mHealth, which may in turn be incorporated into records captured in e.g., an EHR or PHR.

The distinction between an Assembler and/or a Composer from a CDA device author is that they provide no new content. The distinguishing characteristic of an Assembler from a Composer is that the former but simply collates and repackages existing content (with existing provenance information intact) as a CDA typically as an automated response to a query. An example is algorithmic software used by an implementer of IHE On-Demand Documents such as an HIE.

A Composer also collates and repackages existing content but always in response to an author’s selection, and may incorporate new content generated by the author in the process. An example is the record entry component of an EHR that supports the addition of pre-existing content into an entry.

While the use of such applications is new, it is important to recognize the effect of this type of activity on the subjective aspects of provenance such as trust and reliability. By clearly identifying those documents that are created algorithmically with no human intervention or oversight, or the type of EHR/PHR used by an author to generate a CDA, a recipient is able to discern that these may have a different level of trust.

A key design principle for this IG is to ensure interoperability of conforming systems by tightly constraining each template. Thus all DPROV IG conformant systems will be able to fully support the templates for which they claim conformance. However, not all senders will capture all the required provenance relevant information, so this guide permits the use of null flavors throughout.

A second driving design principle is to ensure implementers flexibility by creating a menu of document, section, and entry templates to suit business requirement. The categories are driven by author types: Provider, Patient, and Device generated content, and Assembler generated content where no author is required to be specified. For example, while an EHR use case might only require Provider and Device generated content templates, a PHR might only support Patient generated content, and an HIE might use all four categories of templated content. In order to minimize the proliferation of new templates while enhancing readability by breaking up long templates, we have used null ID templates published separately to which the reader can easily navigate back and forth using links in the Context Tables [Contained by/Contains].

Another facet of this guide is a Provenance Metadata class that enable one to link predecessor and successor entries, both within and external to the CDA instance by specifying the ProvenanceEvent that changed the former to the latter as well as the performer of the change, the author of the Provenance Metadata, any facilitating software, whether there was a signature on the predecessor prior to incorporation, the applicable provenance policies for recording this information, and Provenance Security Labels that enable recipient systems to evaluate confidence in the successors authenticity, integrity, and reliability without having to register more detail than necessary for access control and integration processing than necessary.

Finally, this IG is a constraint on the HL7 DS4P IG, which is a constraint on the C-CDA General Header, so key aspects of the constraints required by Meaningful Use are supported. Adjunct to this inheritance is the Security Label capabilities from the DS4P and references to the CDA Consent Directive, which support conveyance of policy directives that may have dictated changes to CDA content such as privacy annotations, privacy marks, limitations on content sent or sent in the clear via redaction or masking.

The HL7 DPROV CDA IG is designed to meet these emerging capabilities using templates that address these distinctions, which can be used with any CDA profiles or IGs.
Approach

Working with specifications generated from formal UML models provides the opportunity to work with the data from the perspective of the underlying model and electronic format and to explore many design issues thoroughly. Taking this as an initial step ensures that the data set developers and standards community can reach consensus prior to the larger commitment of time that would be required to bring the full data set into standard format.

Organization of This Guide

The requirements as laid out in the body of this document are subject to change per the policy on implementation guides (see section 13.02 “Draft Standard for Trial Use Documents” within the HL7 Governance and Operations Manual, http://www.hl7.org/documentcenter/public/membership/HL7_Governance_and_Operations_Manual.pdf).

Templates

Templates are organized by document (see Document Templates), by section (see Section Templates), and by clinical statements (see Clinical Statement Templates). Within a section, templates are arranged hierarchically, where a more specific template is nested under the more generic template that it conforms to. See Templates by Containment for a listing of the higher level templates by containment; the appendix Templates Used in this Guide includes a table of all of the templates organized hierarchically.

Vocabulary and Value Sets

Vocabularies recommended in this guide are from standard vocabularies. In many cases, these vocabularies are further constrained into value sets for use within this guide. Value set names and OIDs are summarized in the table Summary of Value Sets. Each named value set in this summary table is stored in a template database, which will be maintained by HL7.

Use of Templates

When valued in an instance, the template identifier (templateId) signals the imposition of a set of template-defined constraints. The value of this attribute provides a unique identifier for the templates in question.

Originator Responsibilities

An originator can apply a templateId to assert conformance with a particular template.

In the most general forms of CDA exchange, an originator need not apply a templateId for every template to which an object in an instance document conforms to. This implementation guide asserts when templateIds are required for conformance.

Recipient Responsibilities

A recipient may reject an instance that does not contain a particular templateId (e.g., a recipient looking to receive only CCD documents can reject an instance without the appropriate templateId).

A recipient may process objects instance that do not contain a templateId (e.g., a recipient can process entries that contain Observation acts within a Problems section, even if the entries do not have templateIds).
## Templates List:

Table 3: Templates Defined in this IG

<table>
<thead>
<tr>
<th>Template</th>
<th>Id</th>
</tr>
</thead>
<tbody>
<tr>
<td>AssemblerDocumentParticipant Template</td>
<td>2.16.840.1.113883.3.5019.1.1</td>
</tr>
<tr>
<td>AssemblerEntryParticipant Template</td>
<td>2.16.840.1.113883.3.5019.1.2</td>
</tr>
<tr>
<td>AssemblerGeneratedDocumentWithProvenance Template</td>
<td>2.16.840.1.113883.3.5019.1.3</td>
</tr>
<tr>
<td>CompartmentSecurityObservation Template</td>
<td>2.16.840.1.113883.3.5019.1.4</td>
</tr>
<tr>
<td>ComposerDocumentParticipant Template</td>
<td>2.16.840.1.113883.3.5019.1.5</td>
</tr>
<tr>
<td>ComposerEntryParticipant Template</td>
<td>2.16.840.1.113883.3.5019.1.6</td>
</tr>
<tr>
<td>ConfidentialitySecurityObservation Template</td>
<td>2.16.840.1.113883.3.5019.1.7</td>
</tr>
<tr>
<td>DeviceAuthorParticipant Template</td>
<td>2.16.840.1.113883.3.5019.1.8</td>
</tr>
<tr>
<td>DeviceGeneratedDocumentWithProvenance Template</td>
<td>2.16.840.1.113883.3.5019.1.9</td>
</tr>
<tr>
<td>ExternalConsentDirectiveReferenceChoice Template</td>
<td>2.16.840.1.113883.3.5019.1.10</td>
</tr>
<tr>
<td>ExternalReferenceChoice Template</td>
<td>2.16.840.1.113883.3.5019.1.11</td>
</tr>
<tr>
<td>ObligationSecurityObservation Template</td>
<td>2.16.840.1.113883.3.5019.1.12</td>
</tr>
<tr>
<td>ObservationGeneratedByAssembler Template</td>
<td>2.16.840.1.113883.3.5019.1.13</td>
</tr>
<tr>
<td>ObservationGeneratedByDevice Template</td>
<td>2.16.840.1.113883.3.5019.1.14</td>
</tr>
<tr>
<td>ObservationGeneratedByPatient Template</td>
<td>2.16.840.1.113883.3.5019.1.15</td>
</tr>
<tr>
<td>ObservationGeneratedByProvider Template</td>
<td>2.16.840.1.113883.3.5019.1.16</td>
</tr>
<tr>
<td>PatientAuthorParticipant Template</td>
<td>2.16.840.1.113883.3.5019.1.17</td>
</tr>
<tr>
<td>PatientGeneratedDocumentWithProvenance Template</td>
<td>2.16.840.1.113883.3.5019.1.18</td>
</tr>
<tr>
<td>PrivacyConsentTypeSecurityObservation Template</td>
<td>2.16.840.1.113883.3.5019.1.19</td>
</tr>
<tr>
<td>ProvenanceAuthorParticipantChoice Template</td>
<td>2.16.840.1.113883.3.5019.1.20</td>
</tr>
<tr>
<td>ProvenanceInformantParticipantChoice Template</td>
<td>2.16.840.1.113883.3.5019.1.21</td>
</tr>
<tr>
<td>ProvenanceMetadata Template</td>
<td>2.16.840.1.113883.3.5019.1.22</td>
</tr>
<tr>
<td>ProvenanceMetadataRelationship Template</td>
<td>2.16.840.1.113883.3.5019.1.23</td>
</tr>
<tr>
<td>ProvenancePolicyInformationFile Template</td>
<td>2.16.840.1.113883.3.5019.1.24</td>
</tr>
<tr>
<td>ProvenancePrivacyMarkingSection Template</td>
<td>2.16.840.1.113883.3.5019.1.25</td>
</tr>
<tr>
<td>ProvenanceScopingOrganization Template</td>
<td>2.16.840.1.113883.3.5019.1.26</td>
</tr>
<tr>
<td>ProviderGeneratedDocumentWithProvenance Template</td>
<td>2.16.840.1.113883.3.5019.1.27</td>
</tr>
<tr>
<td>PurposeOfUseSecurityObservation Template</td>
<td>2.16.840.1.113883.3.5019.1.28</td>
</tr>
<tr>
<td>RefrainPolicySecurityObservation Template</td>
<td>2.16.840.1.113883.3.5019.1.29</td>
</tr>
<tr>
<td>SectionGeneratedByDevice Template</td>
<td>2.16.840.1.113883.3.5019.1.30</td>
</tr>
<tr>
<td>SectionGeneratedByMandatoryAuthor Template</td>
<td>2.16.840.1.113883.3.5019.1.31</td>
</tr>
<tr>
<td>SectionGeneratedByPatient Template</td>
<td>2.16.840.1.113883.3.5019.1.32</td>
</tr>
<tr>
<td>SectionGeneratedByProvider Template</td>
<td>2.16.840.1.113883.3.5019.1.33</td>
</tr>
</tbody>
</table>
Conventions Used in This Guide

Conformance Requirements

Conformance statements are grouped and identified by the name of the template, along with the templateId and the context of the template (e.g., ClinicalDocument, section, observation), which specifies the element under constraint. If a template is a specialization of another template, its first constraint indicates the more general template. In all cases where a more specific template conforms to a more general template, asserting the more specific template also implies conformance to the more general template. An example is shown below.

Template name

[[type of template]: templateId <XXXX.XX.XXX.XXX>]

Description of the template will be here .....  

1. Conforms to <The template name> Template (templateId: XXXX<XX>XXX>YYY).
2. SHALL contain [1..1] @classCode = <AAA> <code display name> (CodeSystem: 123.456.789 <XXX> Class) STATIC (CONF:<number>).
3. ......

Figure 1: Template name and "conforms to" appearance

The conformance verb keyword at the start of a constraint (SHALL, SHOULD, MAY, etc.) indicates business conformance, whereas the cardinality indicator (0..1, 1..1, 1..*, etc.) specifies the allowable occurrences within an instance. Thus, "MAY contain 0..1" and "SHOULD contain 0..1" both allow for a document to omit the particular component, but the latter is a stronger recommendation that the component be included if it is known.

The following cardinality indicators may be interpreted as follows:

0..1 as zero to one present  
1..1 as one and only one present  
2..2 as two must be present  
1..* as one or more present  
0..* as zero to many present

Value set bindings adhere to HL7 Vocabulary Working Group best practices, and include both a conformance verb (SHALL, SHOULD, MAY, etc.) and an indication of DYNAMIC vs. STATIC binding. The use of SHALL requires that the component be valued with a member from the cited value set; however, in every case any HL7 "null" value such as other (OTH) or unknown (UNK) may be used.

Each constraint is uniquely identified (e.g., "CONF:605") by an identifier placed at or near the end of the constraint. These identifiers are not sequential as they are based on the order of creation of the constraint.

1. SHALL contain [1..1] component/structuredBody (CONF:4082).
a. This component/structuredBody **SHOULD** contain [0..1] component (CONF:4130) such that it
   a. **SHALL** contain [1..1] Reporting Parameters section (templateId:2.16.840.1.113883.10.20.17.2.1) (CONF:4131).

b. This component/structuredBody **SHALL** contain [1..1] component (CONF:4132) such that it
   a. **SHALL** contain [1..1] Patient data section - NCR (templateId:2.16.840.1.113883.10.20.17.2.5) (CONF:4133).

**Figure 2: Template-based conformance statements example**

CCD templates are included within this implementation guide for ease of reference. CCD templates contained within
this implementation guide are formatted WITHOUT typical **KEYWORD** and **XML** element styles. A WIKI site
is available if you would like to make a comment to be considered for the next release of CCD: http://wiki.hl7.org/
index.php?title=CCD_Suggested_Enhancements. The user name and password are: wiki/wikiwiki. You will need to
create an account to edit the page and add your suggestion.

1. The value for "Observation / @moodCode" in a problem observation **SHALL** be "EVN"
   2.16.840.1.113883.5.1001 ActMood STATIC. (CONF: 814).
3. The value for "Observation / statusCode" in a problem observation **SHALL** be "completed"
   2.16.840.1.113883.5.14 ActStatus STATIC. (CONF: 816).
4. A problem observation **SHOULD** contain exactly one Observation / effectiveTime, to indicate the biological
timing of condition (e.g. the time the condition started, the onset of the illness or symptom, the duration of a
condition). (CONF: 817).

**Figure 3: CCD conformance statements example**

**Keywords**

The keywords **SHALL**, **SHALL NOT**, **SHOULD NOT**, **MAY**, and **NEED NOT** in this document are to be
interpreted as described in the **HL7 Version 3 Publishing Facilitator's Guide**:

- **SHALL**: an absolute requirement
- **SHALL NOT**: an absolute prohibition against inclusion
- **SHOULD/SHOULD NOT**: valid reasons to include or ignore a particular item, but must be understood and
carefully weighed
- **MAY/NEED NOT**: truly optional; can be included or omitted as the author decides with no implications

**XML Examples**

XML samples appear in various figures in this document in a fixed-width font. Portions of the XML content may be
omitted from the content for brevity, marked by an ellipsis (…) as shown in the example below.

```xml
<ClinicalDocument xmlns='urn:h17-org:v3'>

...</ClinicalDocument>
```

**Figure 4: ClinicalDocument example**

XPath expressions are used in the narrative and conformance requirements to identify elements because they are
familiar to many XML implementers.
Chapter 2

DOCUMENT TEMPLATES

Topics:

• Assembler Generated Document With Provenance
• Device Generated Document With Provenance
• Patient Generated Document With Provenance
• Provider Generated Document With Provenance
• Unstructured Document With Provenance

This section contains the document level constraints for CDA documents that are compliant with this IG.
Assembler Generated Document With Provenance

[ClinicalDocument: templateId 2.16.840.1.113883.3.5019.1.3]

The Assembler Generated Document with Provenance template constrains the CDA to create a document comprised entirely of preexisting content. Such preexisting content is generated by other Authors, which may also have used assembly or composer software. The preexisting sections and entries may have informant, which however, are not permitted at the Assembler Generated Document level because, by definition, the Assembler Assigned Author is not adding new information, such as that which an informant might provide.

An Assembler Generated Document with Provenance is generated under the auspices of the Organization scoping the role of the Assembler Assigned Author, which is required to be a Provenance CDA Person, and specified if known, but may be null if unknown. The scoping Organization is required to be specified.

The Assembler Assigned Author oversees and is responsible for the automatic generation of the Document with the assistance of a participating Assembler.

An Assembler Assigned Author is scoped by the Organization to ensure that the Assembly software algorithm is accurately selecting specified preexisting content and associated provenance, and aggregating this content with provenance into the specified format for persistence in a repository or in response to an authorized request. The Author and Assembler Participation times are required to be equivalent to convey the relationship between the Assembler Assigned Author and the document generation time of the Assembler.

However, the Organization scoping the Assembler Assigned Author is ultimately responsible for ensuring that the Assembler software algorithm is accurately selecting specified preexisting content and associated provenance, and aggregating this content with provenance into the specified format for persistence in a repository or in response to an authorized request.

The participating Assembler is device software, which independently of a person author, collates and repackages selected preexisting content and its associated provenance in accordance with algorithms selected by the Assigned Author as authorized by the scoping Organization. Assembly software is required to be compatible with the formats in which the selected preexisting content is maintained by the custodian. For example, the Medical Officer of a Health Information Exchange Organization should be identified as the person playing the role of the Assembler Assigned Author. In this scenario, the Medical Officer oversees and is responsible for the Assembly software used in a device to generate documents comprised of preexisting content with associated provenance intact. For purposes of provenance, Assembly software information is mandatory.

In some circumstances, an Assembler Assigned Author may not be a specified role in an Organization that uses an Assembler to generate documents such as an HIE. While identification of a responsible person author is recommended for purposes of provenance, this template accommodates the scenario where there is no Assigned Author. In this scenario, in order to specify the mandatory Assigned Author's Scoping Organization, implementers are permitted to value the Assigned Author identifier, address, telecom, and CDA Person with nullFlavors.

If there are multiple authors of an Assembler Generated Document with Provenance, implementers must ensure that the participation times of the different Authors facilitated by one or more Assemblers are equivalent to convey this relationship.

In addition, given that an Assembler Generated Document with Provenance is comprised of preexisting content, any authors of that content are expected to be listed in the Header as Assigned Authors, which is a general expectation of the CDA standard.


1. SHALL contain exactly one [1..1] templateId (CONF-DPROV-3) such that it
a. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.3.5019.1.3"

2. SHALL conform to CONTENTPROFILE cda Privacy Segmented Document template (templateId: 2.16.840.1.113883.3.3251.1.1)

3. SHOULD contain zero or one [0..1] setid (CONF:5261)

4. SHALL contain exactly one [1..1] confidentialityCode (CONF:16827), which SHALL be selected from ValueSet HL7 BasicConfidentialityKind 2.16.840.1.113883.1.11.16926 STATIC (CONF:5259)

5. SHOULD contain zero or one [0..1] versionNumber (CONF:5264)

6. SHALL contain at least one [1..1] author, where its type is Assembler Author Participant (CONF:17064)

7. SHALL contain [1..*] participant (CONF:21)

For this type of document, the Assembler Document Header Participant must be used to identify any software used to assemble existing content as determined by the Organization scoping the Assembler Assigned Author:

a. Contains exactly one [1..1] Assembler Document Participant (templateId: 2.16.840.1.113883.3.5019.1.1)

8. SHALL contain at least one [1..*] authenticator, where its type is Authenticator (CONF:5607)

9. SHALL contain at least one [1..*] authorization, where its type is Privacy Consent Directive (CONF:16792)

10. SHALL contain exactly one [1..1] component such that it (CONF:16828)

a. MAY contain zero or one [0..1] @nullFlavor (CONF:16831)

b. SHALL contain exactly one [1..1] structuredBody such that it (CONF:16830)

  a. SHALL contain exactly one [1..1] confidentialityCode (CONF:17065), which SHALL be selected from ValueSet HL7 BasicConfidentialityKind 2.16.840.1.113883.1.11.16926 STATIC (CONF:17066)

  b. SHALL contain at least one [1..*] component such that it (CONF:17338)

    a. MAY contain zero or one [0..1] @nullFlavor (CONF:16836)

    b. SHALL contain exactly one [1..1] @typeCode="COMP" (CONF:16837)

    c. SHALL contain exactly one [1..1] section, where its type is Section Generated By Device (CONF:16838)

  c. SHALL contain at least one [1..*] component such that it (CONF:17339)

    a. MAY contain zero or one [0..1] @nullFlavor (CONF:16839)

    b. SHALL contain exactly one [1..1] @typeCode="COMP" (CONF:16840)

  d. SHALL contain at least one [1..*] component such that it (CONF:17340)

    a. MAY contain zero or one [0..1] @nullFlavor (CONF:16842)

    b. SHALL contain exactly one [1..1] @typeCode="COMP" (CONF:16843)

    c. SHALL contain exactly one [1..1] section, where its type is Section Generated By Patient (CONF:16844)

  e. SHALL contain at least one [1..*] component such that it (CONF:17341)

    a. MAY contain zero or one [0..1] @nullFlavor (CONF:16845)

    b. SHALL contain exactly one [1..1] @typeCode="COMP" (CONF:16846)

    c. SHALL contain exactly one [1..1] section, where its type is Section Generated By Provider (CONF:16847)

  f. SHALL contain at least one [1..*] component such that it (CONF:17342)

    a. MAY contain zero or one [0..1] @nullFlavor (CONF:17068)

    b. SHALL contain exactly one [1..1] @typeCode="COMP" (CONF:17069)

    c. SHALL contain exactly one [1..1] section, where its type is Provenance Privacy Marking Section (CONF:17343)

11. SHALL contain at least one [1..*] relatedDocument, where its type is Provenance Related Document (CONF:40)
12. SHALL NOT contain any [0..0] informant (CONF:17437)

A Document Generated by Assembler Assigned Author does not directly incorporate content provided by an informant. Therefore, input a content by an informant participant is precluded in the generation of this document (see explanation in this template's front matter.)

a. MAY contain zero or one [0..1] assignedEntity such that it
   a. SHOULD contain zero or more [0..*] addr (CONF:8220)
   b. MAY contain zero or one [0..1] code, which SHOULD be selected from (CodeSystem: 2.16.840.1.113883.6.101 NUCC Health Care Provider Taxonomy) (CONF:9947)
   c. SHALL contain at least one [1..*] id (CONF:9945)
   d. SHALL contain exactly one [1..1] assignedPerson such that it (CONF:8221)
      a. SHALL contain at least one [1..*] name
      b. MAY contain zero or one [0..1] relatedEntity such that it
         a. SHOULD contain zero or more [0..*] addr (CONF:8220)
         b. SHALL contain exactly one [1..1] relatedPerson such that it (CONF:8221)
            a. SHALL contain at least one [1..*] name
            c. SHALL satisfy: contain exactly one [1..1] assignedEntity OR exactly one [1..1] relatedEntity (CONF:8002)

Assembler Generated Document With Provenance example

```xml
  <realmCode code="US"/>
  <templateId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
  <!-- Assembler Generated Document with Provenance-->
  <templateId root="2.16.840.1.113883.3.5019.1.3" assigningAuthorityName="HL7 CBCC"/>
  <!--cda Privacy Segmented Document Content Profile, which inherits the Consolidated CDA General Header template.-->
  <templateId root="2.16.840.1.113883.3.3251.1.1" assigningAuthorityName="HL7 Security"/>
  <id root="db734647-fc99-424c-a864-7e3cda82e703" assigningAuthorityName="SampleProject"/>
  <code code="34133-9" displayName="Summarization of episode note" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
  <title>Example Continuity of Care Document Generated by an Assembler (e.g. HIE)</title>
  <!-- Date/time (timezone added)-->
  <effectiveTime value="20141021120500-0500"/>
  <!-- Confidentiality = "Restricted" highwater mark because this document includes a Protected Problem Entry-->
  <confidentialityCode codeSystem="2.16.840.1.113883.5.25" code="R"/>
  <languageCode code="en-US"/>
  <setId root="MDHT" extension="73453669-eff9-4f9d-8ef7-0728955611f1"/>
  <versionNumber value="3"/>
  <recordTarget>
    <patientRole>
      <id extension="f289c617-a63c-4b9a-867a-3c0d873edfaa" root="ExampleMRN" assigningAuthorityName="Example"/>
      <addr use="HP">
        <streetAddressLine>1 Mainstreetusa</streetAddressLine>
      </addr>
    </patientRole>
  </recordTarget>
</ClinicalDocument>
```
<city>Anytown</city>
<state>NH</state>
<postalCode>99999</postalCode>
</addr>
<telecom value="tel:+1-999-999-9999" use="HP"/>
<telecom value="tel:+1-888-888-8888" use="WP"/>
<telecom value="mailto:ExampleEmailAddress@DomainName"/>
<patient>
  <name>
    <!--  PatientFirstName,  PatientMiddleInitial, PatientFamilyName
    <given>Mary</given>
    <given>A</given>
    <family>Everyperson</family>
  </name>
  <!--  GenderCode  GenderDisplayName -->
  <administrativeGenderCode code="F" displayName="Female"
    codeSystemName="HL7 AdministrativeGenderCodes"
    codeSystem="2.16.840.1.113883.5.1"/>
  <birthTime xsi:type="TS" value="19430704"/>
  <maritalStatusCode code="S" displayName="Single"
    codeSystem="2.16.840.1.113883.5.2"/>
  <raceCode code="P" displayName="Pacific Islander"
    codeSystem="2.16.840.1.113883.6.238"/>
  <languageCommunication>
    <languageCode code="us-en"/>
  </languageCommunication>
</patient>
<!-- Scoping organization for patient record-->
<providerOrganization>
  <id extension="1234567890" root="2.16.840.1.113883.4.6"
    assigningAuthorityName="National Plan and Provider Enumeration System"/>
  <name>Example Organization</name>
  <telecom value="tel:+1-555-555-1212" use="WP"/>
  <addr>
    <streetAddressLine>Example Organization Address Line</streetAddressLine>
    <city>ExampleCity</city>
    <state>NH</state>
    <postalCode>99999</postalCode>
  </addr>
</providerOrganization>

[remainder part of the snippet needs to be replaced --]

<author>
  <!-- Assembler Author Participant-->
  <templateId root="null templateID" assigningAuthorityName="HL7 CBCC"/>
  <!-- Mandatory date time-->
  <time value="20141021120500-0500"/>

<assignedAuthor>
  <!-- Mandatory Assembler AssignedAuthor Identifier may be null when there is no identifiable Assigned Author overseeing the Assembler participant, and the Organization scoping the Assembler AssignedAuthor, e.g., an HIE, is accountable for the Assembler operation and algorithms, but must have Provenance Scoping Organization-->
  <templateId root="null templateID" assigningAuthorityName="HL7 CBCC"/>
  <id nullFlavor="NA"/>
  <code nullFlavor="NA"/>
  <addr nullFlavor="NA"/>
  <telecom nullFlavor="NA"/>
</assignedAuthor>

<!-- Mandatory Author's Provenance Scoping Organization -->
<representedOrganization>
<templateId root="2.16.840.1.113883.3.5019.1.26" assigningAuthorityName="HL7 CBCC"/>

<!-- Mandatory Scoping Organization Identifier - if Scoping Organization is specified, and if a HIPAA covered provider organization, then at least one identifier must be a National Provider Identifier where the id/@root ="2.16.840.1.113883.4.6" is the NPI number for the provider.-->

{id root="1881638559" assigningAuthorityName="National Plan and Provider Enumeration System"/>

<name>Example Organization</name>
<telecom value="tel:+1-555-555-1212" use="WP"/>
<addr>

<streetAddressLine>Example Organization Address Line</streetAddressLine>
<city>ExampleCity</city>
<state>NH</state>
<postalCode>99999</postalCode>
</addr>

<standardIndustryClassCode code="541513" displayName="Computer Facilities Management Services" codeSystem="2.16.840.1.113883.1.11.19298"/>

</representedOrganization>
</assignedAuthor>

<!--skipping data enter because DPROV does not further constrain-->
<!--Provenance Provider and Patient Author Authenticators with signature text-->
<authenticator>
<time value="20141021120500-0500"/>

<!-- Mandatory signatureCode/@code = "S" is defined as: "Signature has been affixed, either written on file, or electronic (incl. digital) signature in Participation.signatureText." -->

<signatureCode code="S"/>

<sdtc:signatureText mediaType="text/xml" representation="B64">omSJUEdmde9j44zmMiomSJUEdmde9j44zmMiorMDSsWdIdjsIJK3737jeu836edjzMMIjdMDSsWdIdjsIJK3737jeu83MNYD83jmMdomSJUEdmde9j44zmMior ... MNYD83jmMdomSJUEdmde9j44zmMior6edjzMMIjdMDSsWdIdjsIJK3737jeu8343mMior6edjzMMIjdMDSsWdIdjsIJK3737jeu83..."</sdtc:signatureText>
</authenticator>

<assignedEntity>

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

<!-- Dynamic value set binding to Healthcare Provider Taxonomy (NUCC-HIPAA) "2.16.840.1.114222.4.11.1066" -->
<code code="207LA0401X" displayName="Addiction Medicine" codeSystem="2.16.840.1.113883.6.101" codeSystemName="NUCC"/>
<addr>

<streetAddressLine>1004 Healthcare Drive</streetAddressLine>
<city>Portland</city>
<state>OR</state>
<postalCode>99123</postalCode>
<country>US</country>
</addr>
<telecom use="WP" value="tel:+1(555)555-1004"/>

<assignedPerson>

<name>
<given>Patricia</given>
<given qualifier="CL">Patty</given>
?family>Primary</family>
<suffix qualifier="AC">M.D.</suffix>
</name>
</assignedPerson>
</assignedEntity>
</representedOrganization>

<templateId root="2.16.840.1.113883.3.5019.1.26" assigningAuthorityName="HL7 Security CBCC"/>
<!-- NPI for the organization -->
{id root="1881638559" assigningAuthorityName="National Plan and Provider Enumeration System"/>
  <name>Example Organization</name>
  <telecom value="tel:+1-555-555-1212" use="WP"/>
  <addr>
    <streetAddressLine>Example Organization Address Line</streetAddressLine>
    <city>ExampleCity</city>
    <state>NH</state>
    <postalCode>99999</postalCode>
  </addr>
  <standardIndustryClassCode code="622210" displayName="Psychiatric and Substance Abuse Hospitals" codeSystem="2.16.840.1.113883.1.11.19298"/>
</representedOrganization>
</authenticator>

<!-- Document Authenticator 2 - Signed authentication by Patient Author of Patient Authored Section using composer software Meaningful Use 3 Provider View, Download, and Transmit Portal -->
<authenticator>
  <time value="20141021120500-0500"/>
  <!-- Mandatory signatureCode/@code = "S" is defined as: "Signature has been affixed, either written on file, or electronic (incl. digital) signature in Participation.signatureText." -->
  <signatureCode code="S"/>
  <sdtc:signatureText mediaType="text/xml" representation="B64">
    omSJUEdnde9j44zmMiromSJUEdnde9j44zmMirdMDSsWdIjdksIJR3373jeu83
    6edjhMMJjdmMDSsWdIjdksIJR3373jeu83MNYY83jmMdomSJUEdnde9j44zmMirdMDSsWdIjdksIJR3373jeu83
    4zmMirdMDSsWdIjdksIJR3373jeu83==</sdtc:signatureText>
  </authenticator>
  <assignedEntity>
    <id nullFlavor="NA"/>
    <telecom value="tel:+1-555-555-1212" use="HP"/>
    <assignedPerson>
      <name>
        <given>Mary</given>
        <given>A</given>
        <family>Everyperson</family>
      </name>
    </assignedPerson>
    <representedOrganization>
      <templateId root="2.16.840.1.113883.3.5019.1.26" assigningAuthorityName="HL7 Security CBCC"/>
    </representedOrganization>
  </assignedEntity>
</authenticator>

<!-- Assembler participation type code @typeCode="DEV"-->
<participant typeCode="DEV" codeSystem="2.16.840.1.113883.1.11.10901">
<templateId root="2.16.840.1.113883.3.5019.1.1.1"
assigningAuthorityName="HL7 CBCC"/>
<!-- Assembler functionCode from ValueSet-->
<functionCode code="ASSEMBLER"
codeSystem="2.16.840.1.113883.1.11.10267"/>
<!-- Date time (time zone added -0500)-->
<time value="20141021120500-0500"/>
<associatedEntity classCode="MANU"/>
<!-- AssemblerDocumentParticipant - Device AssociatedEntity with UDI &
SNOMED Device code. Could be GMND. templateId null.-->
<id root="2.16.840.1.113883.3.3719"
extension="(01)51022222333336(11)141231(17)150707(10)A213B1(21)1234"
assigningAuthorityName="GS1 2.51.1.1"/>
<code code="46462944003" codeSystem="2.16.840.1.113883.6.96"
displayName="Hospital-administration information system application
software"/>
</participant>
<!--There are two parent documents to this Assembler Generated Document
with Provenance. Version 1 is the Assembler's transform of one or more
parent documents into an aggregation of pre-existing content, which may be
input from a variety of syntax, e.g., other CDA instances and v.2 message
segments. Version 2 is the replacement as an aggregation of pre-existing
content into a single DPROV CDA instance with all provenance required
metadata included.-->
<relatedDocument typeCode="XFRM">
<parentDocument>
<id root="223769be-f6ee-4b04-a0ce-b56ae998c880"/>
<code code="34133-9"
codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC"
displayName="Summarization of episode note"/>
<setId root="004bb033-b948-4f4c-b5bf-a8dbd7d8dd40"/>
.VERSIONNUMBER value="1"
</parentDocument>
</relatedDocument>
<relatedDocument typeCode="RPLC">
<parentDocument>
<id root="223769be-f6ee-4b04-a0ce-b56ae998c880"/>
<code code="34133-9"
codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC"
displayName="Summarization of episode note"/>
<setId root="004bb033-b948-4f4c-b5bf-a8dbd7d8dd40"/>
.VERSIONNUMBER value="2"
</parentDocument>
</relatedDocument>
<!--Skipping documentationOf and inFullfillmentof because DPROV does not
further constrain.-->

Device Generated Document With Provenance

[ClinicalDocument: templateId 2.16.840.1.113883.3.5019.1.9]

The Device Generated Document with Provenance template constrains the CDA to create a document authored by a device, which is comprised of device generated information, and may include provider selected preexisting sections and entries authored by other persons or devices with provenance information intact. Both the new content authored by the device and any preexisting content included in the document may have been facilitated with the assistance of Assembly software, which should be conveyed if known.

A Device Generated Document with Provenance is generated under the auspices of the Organization scoping the role of the Device Assigned Author. This Organization is required to be specified. The Device Assigned Author, which is required to be specified, may generate the Document with the assistance of a participating Assembler. A participating Assembler is device software, which independently of a device author, collates and repackages selected preexisting content and its associated provenance in accordance with algorithms programmatically selected by the Device Assigned Author as authorized by the scoping Organization.

Assembly software is required to be compatible with the formats in which the selected preexisting content is maintained by the custodian. A Device Assigned Author may use preexisting content with associated provenance aggregated by participating Assembler software to augment device generated content. For example, the device author may select a preexisting report on the condition that the device is monitoring accompanied by the authors, informants and devices used to generate that list as input to the device generated document.

1. SHALL contain exactly one [1..1] templateId (CONF-DPROV-9) such that it
   a. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.3.5019.1.9"
2. SHALL conform to CONTENTPROFILE cda Privacy Segmented Document template (templateId: 2.16.840.1.113883.3.3251.1.1)
3. SHALL contain exactly one [1..1] `confidentialityCode` (CONF:16962), which SHALL be selected from ValueSet HL7 BasicConfidentialityKind 2.16.840.1.113883.1.11.16926 `STATIC` (CONF:5259)

4. SHOULD contain zero or one [0..1] `setId` (CONF:5261)

5. SHOULD contain zero or one [0..1] `versionNumber` (CONF:5264)

6. SHALL NOT contain [0..0] `informant` with `@xsi:type="Informant12"

A Device Generated Document with Provenance by definition consists entirely pre-existing content. Therefore input a content by an informant participant is precluded in the generation of this document.

7. SHALL contain [1..*] `author` (CONF:103)

Specifies provenance-related details about the Device Author participant, which is mandatory for this type of document and cannot be NULL. Author participation constrained for a document generated by a Device.

a. Contains exactly one [1..1] `Device Author Participant` (templateld: 2.16.840.1.113883.1.11.16926.1.8)

8. SHOULD contain [0..*] `participant` (CONF:39)

For this type of document, the Assembler Document Header Participant should be used to identify any software used to assemble the content generated by the Device Generated Assigned Author and selected from existing content as determined by the scoping Organization.

a. Contains exactly one [1..1] `Assembler Document Participant` (templateld: 2.16.840.1.113883.1.11.16926.1.1)

9. SHALL contain at least one [1..*] `authenticator`, where its type is `Authenticator` (CONF:5607)

10. SHALL contain at least one [1..*] `authorization`, where its type is `Privacy Consent Directive` (CONF:16792)

11. SHOULD contain [0..*] `participant` (CONF:17109)

a. Contains exactly one [1..1] `Composer Document Participant` (templateld: 2.16.840.1.113883.1.11.16926.1.5

12. SHALL contain exactly one [1..1] `component` (CONF:16963)

a. This component MAY contain zero or one [0..1] `@nullFlavor` (CONF:16831)

b. This component SHALL contain exactly one [1..1] `structuredBody` (CONF:16830)

   a. This structuredBody SHALL contain exactly one [1..1] `confidentialityCode` (CONF:17065), which SHALL be selected from ValueSet HL7 BasicConfidentialityKind 2.16.840.1.113883.1.11.16926 `STATIC` (CONF:17066)

   b. This structuredBody SHALL contain at least one [1..*] `component` (CONF:17338)

      a. Such components MAY contain zero or one [0..1] `@nullFlavor` (CONF:16836)

      b. Such components SHALL contain exactly one [1..1] `@typeCode="COMP"` (CONF:16837)

      c. Such components SHALL contain exactly one [1..1] `section`, where its type is `Section Generated By Device` (CONF:16838)

   c. This structuredBody SHALL contain at least one [1..*] `component` (CONF:17339)

      a. Such components MAY contain zero or one [0..1] `@nullFlavor` (CONF:16839)

      b. Such components SHALL contain exactly one [1..1] `@typeCode="COMP"` (CONF:16840)

      c. Such components SHALL contain exactly one [1..1] `section`, where its type is `Section Generated By Mandatory Author` (CONF:16841)

   d. This structuredBody SHALL contain at least one [1..*] `component` (CONF:17340)

      a. Such components MAY contain zero or one [0..1] `@nullFlavor` (CONF:16842)

      b. Such components SHALL contain exactly one [1..1] `@typeCode="COMP"` (CONF:16843)

      c. Such components SHALL contain exactly one [1..1] `section`, where its type is `Section Generated By Patient` (CONF:16844)

   e. This structuredBody SHALL contain at least one [1..*] `component` (CONF:17341)

      a. Such components MAY contain zero or one [0..1] `@nullFlavor` (CONF:16845)
b. Such components **SHALL** contain exactly one [1..1] @typeCode="COMP" (CONF:16846)
c. Such components **SHALL** contain exactly one [1..1] section, where its type is *Section Generated By Provider* (CONF:16847)

f. This structuredBody **SHALL** contain at least one [1..*] component (CONF:17342)
   a. Such components **MAY** contain zero or one [0..1] @nullFlavor (CONF:17068)
   b. Such components **SHALL** contain exactly one [1..1] @typeCode="COMP" (CONF:17069)
   c. Such components **SHALL** contain exactly one [1..1] section, where its type is *Provenance Privacy Marking Section* (CONF:17343)

13. **SHALL** contain at least one [1..*] relatedDocument, where its type is *Provenance Related Document* (CONF:40)

Device Generated Document With Provenance example

```xml
<ClinicalDocument xmlns="urn:hl7-org:v3" xmlns:cda="urn:hl7-org:v3"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xsi:schemaLocation="urn:hl7-org:v3 file:c32/C32_CDA.xsd"
classCode="DOCCLIN" moodCode="EVN">
  <realmCode code="US"/>
  <typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
  <!--  Device Generated Document with Provenance-->
  <templateId root="2.16.840.1.113883.3.5019.1.8"
assigningAuthorityName="HL7"/>
  <id root="db734647-fc99-424c-a864-7e3cda82e703"
assigningAuthorityName="SampleProject"/>
  <code code="34133-9" displayName="Summarization of episode note"
codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
  <title>Example Continuity of Care Document Generated by an Device or Device Manager</title>
  <!--  Date/time (timezone added)-->  
  <effectiveTime value="20141021120500-0500"/>
  <confidentialityCode codeSystem="2.16.840.1.113883.5.25" code="N"/>
  <languageCode code="en-US"/>
  <recordTarget>
    <patientRole>
      <id extension="f289c617-a63c-4b9a-867a-3c0d873edfaa" root="ExampleMRN"
assigningAuthorityName="Example"/>
      <addr use="HP">
        <streetAddressLine>1 Mainstreetusa</streetAddressLine>
        <city>Anytown</city>
        <state>NH</state>
        <postalCode>99999</postalCode>
      </addr>
      <telecom value="tel:+1-999-999-9999" use="HP"/>
      <telecom value="tel:+1-888-888-8888" use="WP"/>
      <telecom value="mailto:ExampleEmailAddress@DomainName"/>
      <patient>
        <name>
          <!--  PatientFirstName,  PatientMiddleInitial, PatientFamilyName-->
          <given>Mary</given>
          <given>A</given>
          <family>Everyperson</family>
        </name>
        <!--  GenderCode  GenderDisplayName -->
        <administrativeGenderCode code="F" displayName="Female"
codeSystemName="HL7 AdministrativeGenderCodes"
codeSystem="2.16.840.1.113883.5.1"/>
        <birthTime xsi:type="TS" value="19430704"/>
      </patient>
    </patientRole>
</recordTarget>
```

<maritalStatusCode code="S" displayName="Single" codeSystem="2.16.840.1.113883.5.20141021120500-0500"/><raceCode code="P" displayName="Pacific Islander" codeSystem="2.16.840.1.113883.6.238"/>
<languageCommunication>
  <languageCode code="us-en"/>
</languageCommunication>
</patient>

<!-- Scoping organization for patient record-->
<providerOrganization>
  <id root="96449e6d-24c8-4be7-a02c-4536f83f4423" assigningAuthorityName="Issuing Organization"/>
  <name>Example Organization</name>
  <telecom value="tel:+1-555-555-1212" use="WP"/>
  <addr>
    <streetAddressLine>Example Organization Address Line</streetAddressLine>
    <city>ExampleCity</city>
    <state>NH</state>
    <postalCode>99999</postalCode>
  </addr>
</providerOrganization>
</patientRole>

<!-- Device Author -->
<author>
  <!-- Mandatory Author Participation -->
  <templateId root="2.16.840.1.113883.3.5019.1.7" assigningAuthorityName="HL7"/>
  <!-- Mandatory date time-->
  <time value="20141021120500-0500"/>
  <assignedAuthor>
    <!-- Mandatory Assigned Author -->
    <templateId root="2.16.840.1.113883.3.5019.1.6" assigningAuthorityName="HL7"/>
  </assignedAuthor>
</author>

<!-- Scoping/Authoring Organization -->
<representedOrganization>
  <templateId root="2.16.840.1.113883.3.5019.1.19" assigningAuthorityName="HL7"/>
  <id root="96449e6d-24c8-4be7-a02c-4536f83f4423" assigningAuthorityName="Issuing Organization"/>
  <name>Example Organization</name>
  <telecom value="tel:+1-555-555-1212" use="WP"/>
  <addr>
    <streetAddressLine>Example Organization Address Line</streetAddressLine>
    <city>ExampleCity</city>
    <state>NH</state>
    <postalCode>99999</postalCode>
  </addr>
</representedOrganization>
</recordTarget>

<!-- Custodian -->
<custodian>
<assignedCustodian>
  <representedCustodianOrganization>
    <id root="96449e6d-24c8-4be7-a02c-4536f83f4423"/>
    <name>Example Organization</name>
    <telecom value="tel:+1-555-555-1212" use="WP"/>
    <addr>
      <!-- Address fields -->
      <streetAddressLine>Example Address Line</streetAddressLine>
      <city>ExampleCity</city>
      <state>NH</state>
      <postalCode>99999</postalCode>
    </addr>
  </representedCustodianOrganization>
</assignedCustodian>
</custodian>
<legalAuthenticator>
  <time value="20141021120500-0500"/>
  <signatureCode code="I"/>
  <assignedEntity>
    <id nullFlavor="NA"/>
    <addr>
      <!-- Address fields -->
      <streetAddressLine>Example Address Line</streetAddressLine>
      <city>ExampleCity</city>
      <state>NH</state>
      <postalCode>99999</postalCode>
    </addr>
    <telecom value="tel:+1-555-555-1212" use="WP"/>
    <telecom value="mailto:hh@example.org" use="EC"/>
    <assignedPerson>
      <name>
        <family>Hippocrates</family>
        <given>Harold</given>
      </name>
    </assignedPerson>
  </assignedEntity>
</legalAuthenticator>
<authenticator>
  <time value="20141021120500-0500"/>
  <signatureCode code="I"/>
  <assignedEntity>
    <id nullFlavor="NA"/>
    <telecom value="tel:+1-555-555-1212" use="WP"/>
    <assignedPerson>
      <name>
        <given>Mary</given>
        <given>A</given>
        <family>Everyperson</family>
      </name>
    </assignedPerson>
  </assignedEntity>
</authenticator>
<name>Example Organization</name>
<telecom value="tel:+1-555-555-1212" use="WP"/>
<addr>
  <streetAddressLine>Example Organization Address Line</streetAddressLine>
  <city>ExampleCity</city>
  <state>NH</state>
  <postalCode>99999</postalCode>
</addr>
</representedOrganization>
</assignedEntity>
</authenticator>

<!-- Assembler type code @typeCode="DEV"-->
<participant typeCode="DEV">
  <!-- AssemblerDocumentParticipant -->
  <templateId root="2.16.840.1.113883.3.5019.1.1" assigningAuthorityName="HL7"/>
  <!-- Assembler function code -->
  <functionCode code="ASSEMBLER" codeSystem="2.16.840.1.113883.5.88"/>
  <!--  Date time (timezone added -0500)-->
  <time value="20141021120500-0500"/>
  <!-- Assembler as DeviceAssociatedEntity -->
  <associatedEntity classCode="MANU">
    <!-- Assembler as DeviceAssociatedEntity -->
    <templateId root="2.16.840.1.113883.3.5019.1.21" assigningAuthorityName="HL7"/>
    <id root="EHR1" extension="Version2" assigningAuthorityName="Vendor"/>
    <scopingOrganization>
      <templateId root="2.16.840.1.113883.3.5019.1.19" assigningAuthorityName="HL7"/>
      <id nullFlavor="NA"/>
      <name>Vendor Organization</name>
      <telecom value="tel:+1-555-555-1212" use="WP"/>
      <addr>
        <!-- Address fields -->
        <streetAddressLine>Example Address Line</streetAddressLine>
        <city>ExampleCity</city>
        <state>NH</state>
        <postalCode>99999</postalCode>
      </addr>
    </scopingOrganization>
  </associatedEntity>
</participant>

<documentationOf>
  <!-- classCode="PCPR" -->
  <serviceEvent classCode="PCPR">
    <!-- @code= EncounterType @displayName= EncounterTypeDisplayName, @codeSystem="Example" -->
    <code code="EM" codeSystem="Example" displayName="Emergency"/>
    <effectiveTime>
      <!-- AdmissionDateTime (timezone -0500 added) -->
      <low value="20140125100000-0500"/>
      <!-- DischargeDate (timezone -0500 added) -->
      <high value="20140128180000-0500"/>
    </effectiveTime>
    <performer typeCode="PRF">
      <!-- nullFlavor="NA" -->
      <id nullFlavor="NA"/>
      <!--  AuthorTelephone,  AuthorTelephone -->
      <addr>
        <!--  AuthorAddressLine,  AuthorCity,  AuthorZipCode -->
        <streetAddressLine>Example Address Line</streetAddressLine>
        <city>ExampleCity</city>
<state>NH</state>
<postalCode>99999</postalCode>
</addr>
</ClinicalDocument>

Patient Generated Document With Provenance

The Patient Generated Document with Provenance template constrains the CDA to create a document authored by a patient or their personal representative (hereafter included in the concept of patient), which is comprised of patient generated information, and may include patient selected preexisting sections and entries authored by other persons or devices with provenance information intact. Both the new content authored by the patient and any preexisting content included in the document may have been facilitated with the assistance of informants and software devices, which are required to be conveyed.

A Patient Generated Document with Provenance does not require that the role of Patient Assigned Author be scoped by an Organization, but that is not precluded. (According to RIM Role definition usage notes: "the Role of "patient" may be played by a person and scoped by the provider organization from which the patient will receive services.")

The Patient Assigned Author, which is required to be specified, generates the Document with the assistance of one or more of the following participants, as applicable, which may be authorized by a scoping organization, e.g., a Provider's Patient Portal, or may be patient selected, in which case there is no scoping organization:

1. A participating Composer, which is the device software with which a Patient Assigned Author interacts to create new content, such as a Family History Section, and to select and structure preexisting content and its associated provenance, such as a Section containing the Chief Complaint and Reason for Visit with provenance, including the authors, informants, and participating devices used to generate that content. The Composer software is required to be compatible with the formats in which the selected preexisting content is maintained by the custodian. Examples include software used for PHR record entry and for selecting preexisting content persisted in the PHR or other databases. Any Composer software used is required to be conveyed in order to specify the software that the Patient Assigned Author necessarily used in order to generate the authored document.

2. A participating Assembler, which is device software that collates and repackages selected content in accordance with algorithms selected by the Patient Assigned Author as authorized by e.g., the patient, the patient selected mobile App, PHR or a Provider's Patient Portal acting as the scoping Organization. Assembly software is required to be compatible with the formats in which the selected preexisting content is maintained by the custodian. A Patient Assigned Author may use preexisting content with associated provenance aggregated by participating Assembler software to augment patient generated content. For example, the patient author may select a preexisting medication list accompanied by the authors, informants and devices used to generate that list, and then select that list with the Composer software as input to the composed document after reconciling that medication list with medications listed in the Patient's PHR. Any Assembler software should be conveyed if known.
3. A participating Informant, who is either an assigned provider or professional, such as a teacher or office staff, authorized by a scoping organization to provide information about the patient, or a related person, such as a patient's family member or an acquaintance, who is not scoped by an organization. Any Informant participant is required to be conveyed if known.

1. SHALL contain exactly one [1..1] templateId (CONF-DPROV-18) such that it
   a. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.3.5019.1.18"

2. SHALL conform to CONTENTPROFILE cda Privacy Segmented Document template (templateId: 2.16.840.1.113883.3.3251.1.1)

3. SHALL contain exactly one [1..1] confidentialityCode (CONF:17008), which SHALL be selected from ValueSet HL7 BasicConfidentialityKind 2.16.840.1.113883.1.11.16926 STATIC (CONF:5259)

4. SHOULD contain zero or one [0..1] setId (CONF:5261)

5. SHOULD contain zero or one [0..1] versionNumber (CONF:5264)

6. SHALL contain [1..*] author (CONF:84)

   Specifies provenance-related details about the Patient Author participant, which is mandatory for this type of document. The author participation is mandatory and specifies a person, who may be affiliated with a Patient Assigned Author scoping Organization. In most cases the author of a patient-generated is the same as the document's record target or their personal representative (i.e., a substitute decision maker). Author constrained for a document generated by a Patient.

   a. Contains exactly one [1..1] Patient Author Participant (templatedId: 2.16.840.1.113883.3.5019.1.17)

7. SHOULD contain [0..*] participant (CONF:55)

   For this type of Document, the Assembler Document Header Participant should be used to identify any software used to assemble the content generated by the Patient Author and selected from existing content as determined by the Patient authoring the Document.

   a. Contains exactly one [1..1] Assembler Document Participant (templatedId: 2.16.840.1.113883.3.5019.1.1)

8. SHALL contain at least one [1..*] authenticator, where its type is Authenticator (CONF:5607)

9. SHALL contain at least one [1..*] authorization, where its type is Privacy Consent Directive (CONF:16792)

10. SHALL contain [1..*] participant (CONF:156)

   For this type of document, the Composer Document Header Participant is required be used to identify any software used to compose existing content as determined by the Organization scoping the Assembler/Device/provider/patient Assigned Author.

   a. Contains exactly one [1..1] Composer Document Participant (templatedId: 2.16.840.1.113883.3.5019.1.5)

11. SHALL contain exactly one [1..1] component (CONF:17009)

   a. This component MAY contain zero or one [0..1] @nullFlavor (CONF:16831)

   b. This component SHALL contain exactly one [1..1] structuredBody (CONF:16830)

      a. This structuredBody SHALL contain exactly one [1..1] confidentialityCode (CONF:17065), which SHALL be selected from ValueSet HL7 BasicConfidentialityKind 2.16.840.1.113883.1.11.16926 STATIC (CONF:17066)

      b. This structuredBody SHALL contain at least one [1..*] component (CONF:17338)

         a. Such components MAY contain zero or one [0..1] @nullFlavor (CONF:16836)

         b. Such components SHALL contain exactly one [1..1] @typeCode="COMP" (CONF:16837)

         c. Such components SHALL contain exactly one [1..1] section, where its type is Section Generated By Device (CONF:16838)
c. This structuredBody SHALL contain at least one [1..*] component (CONF:17339)
   a. Such components MAY contain zero or one [0..1] @nullFlavor (CONF:16839)
   b. Such components SHALL contain exactly one [1..1] @typeCode="COMP" (CONF:16840)
   c. Such components SHALL contain exactly one [1..1] section, where its type is Section Generated By Mandatory Author (CONF:16841)

d. This structuredBody SHALL contain at least one [1..*] component (CONF:17340)
   a. Such components MAY contain zero or one [0..1] @nullFlavor (CONF:16842)
   b. Such components SHALL contain exactly one [1..1] @typeCode="COMP" (CONF:16843)
   c. Such components SHALL contain exactly one [1..1] section, where its type is Section Generated By Patient (CONF:16844)

e. This structuredBody SHALL contain at least one [1..*] component (CONF:17341)
   a. Such components MAY contain zero or one [0..1] @nullFlavor (CONF:16845)
   b. Such components SHALL contain exactly one [1..1] @typeCode="COMP" (CONF:16846)
   c. Such components SHALL contain exactly one [1..1] section, where its type is Section Generated By Provider (CONF:16847)

f. This structuredBody SHALL contain at least one [1..*] component (CONF:17342)
   a. Such components MAY contain zero or one [0..1] @nullFlavor (CONF:17068)
   b. Such components SHALL contain exactly one [1..1] @typeCode="COMP" (CONF:17069)
   c. Such components SHALL contain exactly one [1..1] section, where its type is Provenance Privacy Marking Section (CONF:17343)

12. SHALL contain [1..*] participant (CONF:190)
   a. Contains exactly one [1..1] Provenance Informant Participant Choice (templateId: 2.16.840.1.113883.3.5019.1.21)

13. SHALL contain at least one [1..*] relatedDocument, where its type is Provenance Related Document (CONF:40)

Patient Generated Document With Provenance example

```xml
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns="urn:hl7-org:v3" xmlns:cda="urn:hl7-org:v3"
 xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xsi:schemaLocation="urn:hl7-org:v3 file:c32/C32_CDA.xsd"
 classCode="DOCCLIN" moodCode="EVN">
 <realmCode code="US"/>
 <typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
 <!-- Patient Generated Document with Provenance-->
 <templateId root="2.16.840.1.113883.3.5019.1.11"
 assigningAuthorityName="HL7"/>
 <id root="db734647-fc99-424c-a864-7e3cda82e703"
 assigningAuthorityName="SampleProject"/>
 <code code="34133-9" displayName="Summarization of episode note"
 codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
 <title>Example Continuity of Care Document Generated by a Patient</title>
 <!-- Date/time (timezone added)-->
 <effectiveTime value="20141021120500-0500"/>
 <confidentialityCode codeSystem="2.16.840.1.113883.5.25" code="N"/>
 <languageCode code="en-US"/>
 <recordTarget>
  <patientRole>
   <id extension="f289c617-a63c-4b9a-867a-3c0d873edfaa" root="ExampleMRN"
    assigningAuthorityName="Example"/>
   <addr use="HP">
    <streetAddressLine>1 Mainstreetusa</streetAddressLine>
```
<city>Anytown</city>
<state>NH</state>
<postalCode>99999</postalCode>
</addr>
<telecom value="tel:+1-999-999-9999" use="HP"/>
<telecom value="tel:+1-888-888-8888" use="WP"/>
<telecom value="mailto:ExampleEmailAddress@DomainName"/>
<patient>
  <name>
    <!-- PatientFirstName, PatientMiddleInitial, PatientFamilyName -->
    <given>Mary</given>
    <given>A</given>
    <family>Everyperson</family>
  </name>
  <!-- GenderCode GenderDisplayName -->
  <administrativeGenderCode code="F" displayName="Female"
    codeSystemName="HL7 AdministrativeGenderCodes"
    codeSystem="2.16.840.1.113883.5.1"/>
  <birthTime xsi:type="TS" value="19430704"/>
  <maritalStatusCode code="S" displayName="Single"
    codeSystem="2.16.840.1.113883.5.2"/>
  <raceCode code="P" displayName="Pacific Islander"
    codeSystem="2.16.840.1.113883.6.238"/>
  <languageCommunication>
    <languageCode code="us-en"/>
  </languageCommunication>
</patient>
<!-- Scoping organization for patient record-->
<providerOrganization>
  <id root="96449e6d-24c8-4be7-a02c-4536f83f4423"
      assigningAuthorityName="Issuing Organization"/>
  <name>Example Organization</name>
  <telecom value="tel:+1-555-555-1212" use="WP"/>
  <addr>
    <streetAddressLine>Example Organization Address Line</streetAddressLine>
    <city>ExampleCity</city>
    <state>NH</state>
    <postalCode>99999</postalCode>
  </addr>
</providerOrganization>
</patientRole>
<!-- Patient Author -->
<author>
  <!-- Mandatory Author Participation -->
  <templateId root="2.16.840.1.113883.3.5019.1.10"
    assigningAuthorityName="HL7"/>
  <!-- Mandatory date time-->
  <time value="20141021120500-0500"/>
  <assignedAuthor>
    <!-- Mandatory Assigned Author -->
    <templateId root="2.16.840.1.113883.3.5019.1.9"
      assigningAuthorityName="HL7"/>
    <!-- Mandatory Author Identifier - at least one is required -->
    <id root="7bb42322-9de2-4d40-94c9-2fc23979d5fc"
        assigningAuthorityName="Example Organization"/>
    <!-- Dynamic value set binding to "2.16.840.1.113883.11.20.12.1" -->
    <code code="ONESELF" displayName="self"
        codeSystem="2.16.840.1.113883.5.111"/>
    <addr>
      <streetAddressLine>Example Address Line</streetAddressLine>
      <city>ExampleCity</city>
    </addr>
  </assignedAuthor>
</author>
Provider Generated Document With Provenance

The Provider Generated Document with Provenance template constrains the CDA to create a document authored by a provider, which is comprised of provider generated information, and may include provider selected preexisting sections and entries authored by other persons or devices with provenance information intact. Both the new content authored by the provider and any preexisting content included in the document may have been facilitated with the assistance of informants and software devices, which are required to be conveyed.

A Provider Generated Document with Provenance is generated under the auspices of the Organization scoping the role of the Provider Assigned Author. This Organization is required to be specified.

A Provider Assigned Author, which is required to be specified, generates the Document with the assistance of one or more of the following participants, as applicable and authorized by the scoping organization:

A participating Composer, which is device software with which a Provider Assigned Author interacts to create new content, such as the Service Event, and to select and structure preexisting content and its associated provenance such as a Section containing the Chief Complaint and Reason for Visit with provenance, including the authors, informants, and participating devices used to generate that content. The Composer software is required to be compatible with the formats in which the selected preexisting content is maintained by the custodian. Examples include software used for EHR record entry and for selecting preexisting content persisted in the EHR or other databases. Any Composer software used is required to be conveyed in order to specify the software that the Provider Assigned Author necessarily used in order to generate the authored document.

A participating Assembler is device software, which independently of a person author, collates and repackages selected preexisting content and its associated provenance in accordance with algorithm selected by the Provider Assigned Author as authorized by the scoping Organization. Assembly software is required to be compatible with the formats in which the selected preexisting content is maintained by the custodian. A Provider Assigned Author may use preexisting content with associated provenance aggregated by participating Assembler software to augment provider generated content. For example, the author may select a preexisting medication list accompanied by the authors, informants and devices used to generate that list, and then select that list with the Composer software as part of the input to the composed document after reconciling that medication list with medications listed in the Provider's EHR. Any Assembler software should be conveyed if known.

A participating Informant, who is either an assigned provider or professional, such as a teacher or office staff, authorized by a scoping organization to provide information about the patient, or a related person, such as a patient's
family member or an acquaintance, who is not scoped by an organization. Any Informant participant is required to be conveyed if known.

1. SHALL contain exactly one [1..1] `templateId` (CONF-DPROV-27) such that it
   a. SHALL contain exactly one [1..1] `@root`="2.16.840.1.113883.3.5019.1.27"
2. SHALL conform to `CONTENTPROFILE cda Privacy Segmented Document` template (templateId: 2.16.840.1.113883.3.3251.1.1)
3. SHALL contain exactly one [1..1] `confidentialityCode` (CONF:16983), which SHALL be selected from ValueSet HL7 BasicConfidentialityKind 2.16.840.1.113883.1.11.16926 STATIC (CONF:5259)
4. SHOULD contain zero or one [0..1] `setId` (CONF:5261)
5. SHOULD contain zero or one [0..1] `versionNumber` (CONF:5264)
6. SHALL contain [1..1] `participant` (CONF:42)

For purposes of establishing provenance and accountability for content, Assembler Document Header Participant should be used to specify any device software used to assemble the content generated by the Provider Generated Assigned Author and selected from existing content as determined by the scoping Organization's specified algorithm.

   a. Contains exactly one [1..1] `Assembler Document Participant` (templateId: 2.16.840.1.113883.3.5019.1.1)
7. SHALL contain at least one [1..*] `authenticator`, where its type is `Authenticator` (CONF:5607)
8. SHALL contain at least one [1..*] `authorization`, where its type is `Privacy Consent Directive` (CONF:16792)
9. SHALL contain [1..1] `participant` (CONF:155)

For purposes of establishing provenance and accountability for content, Composer Document Header Participant is required to be conveyed to specify any device software used to compose new and preexisting content.

   a. Contains exactly one [1..1] `Composer Document Participant` (templateId: 2.16.840.1.113883.3.5019.1.5)
10. SHALL contain exactly one [1..1] `component` (CONF:16985)
   a. This component MAY contain zero or one [0..1] `@nullFlavor` (CONF:16831)
   b. This component SHALL contain exactly one [1..1] `structuredBody` (CONF:16830)
      a. This structuredBody SHALL contain exactly one [1..1] `confidentialityCode` (CONF:17065), which SHALL be selected from ValueSet HL7 BasicConfidentialityKind 2.16.840.1.113883.1.11.16926 STATIC (CONF:17066)
      b. This structuredBody SHALL contain at least one [1..*] `component` (CONF:17338)
         a. Such components MAY contain zero or one [0..1] `@nullFlavor` (CONF:16836)
         b. Such components SHALL contain exactly one [1..1] `@typeCode`="COMP" (CONF:16837)
         c. Such components SHALL contain exactly one [1..1] `section`, where its type is `Section Generated By Device` (CONF:16838)
      c. This structuredBody SHALL contain at least one [1..*] `component` (CONF:17339)
         a. Such components MAY contain zero or one [0..1] `@nullFlavor` (CONF:16839)
         b. Such components SHALL contain exactly one [1..1] `@typeCode`="COMP" (CONF:16840)
         c. Such components SHALL contain exactly one [1..1] `section`, where its type is `Section Generated By Mandatory Author` (CONF:16841)
      d. This structuredBody SHALL contain at least one [1..*] `component` (CONF:17340)
         a. Such components MAY contain zero or one [0..1] `@nullFlavor` (CONF:16842)
         b. Such components SHALL contain exactly one [1..1] `@typeCode`="COMP" (CONF:16843)
         c. Such components SHALL contain exactly one [1..1] `section`, where its type is `Section Generated By Patient` (CONF:16844)
e. This structuredBody SHALL contain at least one [1..*] component (CONF:17341)
   a. Such components MAY contain zero or one [0..1] @nullFlavor (CONF:16845)
   b. Such components SHALL contain exactly one [1..1] @typeCode="COMP" (CONF:16846)
   c. Such components SHALL contain exactly one [1..1] section, where its type is Section Generated By Provider (CONF:16847)

f. This structuredBody SHALL contain at least one [1..*] component (CONF:17342)
   a. Such components MAY contain zero or one [0..1] @nullFlavor (CONF:17068)
   b. Such components SHALL contain exactly one [1..1] @typeCode="COMP" (CONF:17069)
   c. Such components SHALL contain exactly one [1..1] section, where its type is Provenance Privacy Marking Section (CONF:17343)

11. SHALL contain [1..*] author (CONF:83)
   a. Contains exactly one [1..1] Provider Author Participant (templateId: 2.16.840.1.113883.3.5019.1.40)

12. SHALL contain [1..1] participant (CONF:188)
   a. Contains exactly one [1..1] Provenance Informant Participant Choice (templateId: 2.16.840.1.113883.3.5019.1.21)

13. SHALL contain at least one [1..*] relatedDocument, where its type is Provenance Related Document (CONF:40)

Provider Generated Document With Provenance example

```xml
  <realmCode code="US"/>
  <typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
  <!--  Provider Generated Document with Provenance-->
  <templateId root="2.16.840.1.113883.3.5019.1.15" assigningAuthorityName="HL7"/>
  <id root="db734647-fc99-424c-a864-7e3cda82e703" assigningAuthorityName="SampleProject"/>
  <code code="34133-9" displayName="Summarization of episode note" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
  <title>Example Continuity of Care Document Authored by a Provider</title>
  <!--  Date/time (timezone added)-->
  <effectiveTime value="20141021120500-0500"/>
  <confidentialityCode codeSystem="2.16.840.1.113883.5.25" code="N"/>
  <languageCode code="en-US"/>
  <recordTarget>
    <patientRole>
      <id extension="f289c617-a63c-4b9a-867a-3c0d873edfba" root="ExampleMRN" assigningAuthorityName="Example"/>
      <addr use="HP">
        <streetAddressLine>1 Mainstreetusa</streetAddressLine>
        <city>Anytown</city>
        <state>NH</state>
        <postalCode>99999</postalCode>
      </addr>
      <telecom value="tel:+1-999-999-9999" use="HP"/>
      <telecom value="tel:+1-888-888-8888" use="WP"/>
      <telecom value="mailto:ExampleEmailAddress@DomainName"/>
      <name/>
    </patientRole>
  </recordTarget>
</ClinicalDocument>
```
<given>Mary</given>
<given>A</given>
<family>Everyperson</family>
</name>
<!--  GenderCode  GenderDisplayName -->
<administrativeGenderCode code="F" displayName="Female"
codeSystemName="HL7 AdministrativeGenderCodes"
codeSystem="2.16.840.1.113883.5.1"/>
<birthTime xsi:type="TS" value="19430704"/>
<maritalStatusCode code="S" displayName="Single"
codeSystem="2.16.840.1.113883.5.2"/>
<raceCode code="P" displayName="Pacific Islander"
codeSystem="2.16.840.1.113883.6.238"/>
<languageCommunication>
<languageCode code="us-en"/>
</languageCommunication>
</patient>
<!-- Scoping organization for patient record-->
<providerOrganization>
<id root="96449e6d-24c8-4be7-a02c-4536f83f4423"
assigningAuthorityName="Issuing Organization"/>
</providerOrganization>
</patientRole>
</recordTarget>
<!-- Provider Author -->
<author>
<!-- Mandatory Author Participation -->
<templateId root="2.16.840.1.113883.3.5019.1.14"
assigningAuthorityName="HL7"/>
<!-- Mandatory date time-->
<time value="20141021120500-0500"/>
<assignedAuthor>
<!-- Mandatory Assigned Author -->
<templateId root="2.16.840.1.113883.3.5019.1.13"
assigningAuthorityName="HL7"/>
<!-- Mandatory Author Identifier - at least one is required -->
<id root="4d0c8e77-ea1d-4f41-9858-88806852e774"
assigningAuthorityName="Example Organization"/>
<!-- Root means NPI and the @extension specifies the value of the NPI -->
<id root="2.16.840.1.113883.4.6" extension="99999999"/>
<!-- Dynamic value set binding to "2.16.840.1.114222.4.11.1066" -->
<code code="1223G0001X" displayName="General Practice"
codeSystem="2.16.840.1.113883.6.101"/>
</assignedAuthor>
</author>
<streetAddressLine>Example Address Line</streetAddressLine>
<city>ExampleCity</city>
<state>NH</state>
<postalCode>99999</postalCode>
</addr>
</providerOrganization>
</patientRole>
</recordTarget>
<!-- Mandatory Name -->
<name>
  <prefix>Dr.</prefix>
  <family>Hippocrates</family>
  <given>Harold</given>
</name>

<!-- Scoping Organization -->
<representedOrganization>
  <templateId root="2.16.840.1.113883.3.5019.1.19"
    assigningAuthorityName="HL7"/>
  <id root="96449e6d-24c8-4be7-a02c-4536f83f4423"
    assigningAuthorityName="Issuing Organization"/>
  <name>Example Organization</name>
  <telecom value="tel:+1-555-555-1212" use="WP"/>
  <addr>
    <streetAddressLine>Example Organization Address Line</streetAddressLine>
    <city>ExampleCity</city>
    <state>NH</state>
    <postalCode>99999</postalCode>
  </addr>
</representedOrganization>

<!-- Provider Informant Assigned Entity -->
<informant>
  <templateId root="2.16.840.1.113883.3.5019.1.21"
    assigningAuthorityName="HL7 CBCC"/>
  <!-- Mandatory date time-->
  <time value="20151021120500-0500"/>
  <assignedEntity>
    <!--Provenance Informant Assigned Entity Occupation ID-->
    <id extension="1234567890" root="2.16.840.1.113883.3.4784"
      assigningAuthorityName="State of Maine Health and Human Services Department"/>
    <!--Provenance Informant Assigned Entity Occupation code-->
    <code code="21-109X" displayName="Miscellaneous community and social service specialists, including health educators and community health workers" codeSystem="2.16.840.1.113883.6.240" codeSystemName="US Census Occupation Code "/>
    <addr>
      <streetAddressLine>1004 Healthcare Drive </streetAddressLine>
      <city>Portland</city>
      <state>ME</state>
      <postalCode>04102</postalCode>
      <country>US</country>
    </addr>
    <telecom use="WP" value="tel:+1(555)555-1004"/>
    <assignedPerson>
      <name>
        <given>Sarah</given>
        <given qualifier="CL">Sally</given>
        <family>Social</family>
        <suffix qualifier="AC">CSWE</suffix>
      </name>
    </assignedPerson>
  </assignedEntity>
</informant>

<!-- Informant Assigned Entity's Mandatory Provenance Scoping Organization -->
<representedOrganization>
  <templateId root="2.16.840.1.113883.3.5019.1.26"
    assigningAuthorityName="HL7 Security CBCC"/>
<!-- NPI for the organization -->
{id root="1881638559" assigningAuthorityName="National Plan and Provider Enumeration System"/>
<name>Portland Health and Social Services Clinic</name>
<telecom value="tel:+1-555-555-1212" use="WP"/>
<addr>
  <streetAddressLine>Example Organization Address Line</streetAddressLine>
  <city>ExampleCity</city>
  <state>ME</state>
  <postalCode>04102</postalCode>
</addr>
<NorthAmericanIndustryClassificationSystemNAICS code="8093"
displayName="Specialty Outpatient Facilities, Not Elsewhere Classified"
codeSystem="2.16.840.1.113883.6.85"/>
</representedOrganization>
</informant>
<custodian>
  <assignedCustodian>
    <representedCustodianOrganization>
      <id root="96449e6d-24c8-4be7-a02c-4536f83f4423"/>
      <name>Example Organization</name>
      <telecom value="tel:+1-555-555-1212" use="WP"/>
      <addr>
        <!-- Address fields -->
        <streetAddressLine>Example Address Line</streetAddressLine>
        <city>ExampleCity</city>
        <state>NH</state>
        <postalCode>99999</postalCode>
      </addr>
    </representedCustodianOrganization>
  </assignedCustodian>
</custodian>
<legalAuthenticator>
  <time value="20141021120500-0500"/>
  <signatureCode code="I"/>
  <assignedEntity>
    <id nullFlavor="NA"/>
    <addr>
      <!-- Address fields -->
      <streetAddressLine>Example Address Line</streetAddressLine>
      <city>ExampleCity</city>
      <state>NH</state>
      <postalCode>99999</postalCode>
    </addr>
  </assignedEntity>
  <assignedPerson>
    <name>
      <family>Hippocrates</family>
      <given>Harold</given>
    </name>
  </assignedPerson>
  <representedOrganization>
    <id root="96449e6d-24c8-4be7-a02c-4536f83f4423"/>
    <name>Example Organization</name>
    <telecom value="tel:+1-555-555-1212" use="WP"/>
    <addr>
      <!-- Address fields -->
      <streetAddressLine>Example Address Line</streetAddressLine>
      <city>ExampleCity</city>
      <state>NH</state>
      <postalCode>99999</postalCode>
    </addr>
  </representedOrganization>
<assignedEntity>
</legalAuthenticator>
<authenticator>
<time value="20141021120500-0500"/>
<signatureCode code="I"/>
<assignedEntity>
<id nullFlavor="NA"/>
<telecom value="tel:+1-555-555-1212" use="HP"/>
<assignedPerson>
<given>Mary</given>
<given>A</given>
<family>Everyperson</family>
</name>
</assignedPerson>
<representedOrganization>
<id root="96449e6d-24c8-4be7-a02c-4536f83f4423" assigningAuthorityName="Issuing Organization"/>
</representedOrganization>
</assignedEntity>
</authenticator>
<!-- Composer type code @typeCode="DEV"-->
<participant typeCode="DEV">
<!-- ComposerDocumentParticipant -->
<templateId root="2.16.840.1.113883.3.5019.1.5" assigningAuthorityName="HL7"/>
<!-- Composer function code -->
<functionCode code="COMPOSER" codeSystem="2.16.840.1.113883.5.88"/>
<!--  Date time (timezone added -0500)--> 
<time value="20141021120500-0500"/>
<associatedEntity classCode="MANU">
<!-- COMPOSER Document participating DeviceAssociatedEntity -->
<templateId root="2.16.840.1.113883.3.5019.1.26" assigningAuthorityName="HL7"/>
</associatedEntity>
</participant>
</documentationOf>
<!-- classCode="PCPR" -->
<serviceEvent classCode="PCPR">
<!DOCTYPE html>
<html lang="en">
<head>
    <meta charset="UTF-8">
    <title>Unstructured Document With Provenance</title>
</head>
<body>

[ClinicalDocument: templateId 2.16.840.1.113883.3.5019.1.38]

</body>
</html>
The Unstructured Document with Provenance template constrains the CDA to create a document that is comprised entirely of preexisting unstructured content such as a graphic, directly in a text element with a mediaType attribute, or reference a single document file, such as word-processing document, using a text or a reference element with associated provenance information intact.

The Unstructured Document with Provenance template differs from other Unstructured Document templates by specifying that devices such as scanners, which must be operated by a data enterer, are considered as a facilitating participant of an Assigned Author in the same manner that composer or assembler software is considered a facilitating device. By matching the facilitating device's participation time with that of the author participant time provides a means on persisting the association of any Assigned Author with a facilitating device participant. Implementers of XDS scanned Documents will need to adjust their maps of CDA content to XDS-SC metadata accordingly. Another template difference is that unlike the C-CDA Unstructured Document, the Unstructured Document with Provenance template permits multiple authors because of the multitude of use cases involving unstructured content wrapped in a CDA header. [Note: This may be an error that could be corrected in a C-CDA errata].

An authoring device could generate the Unstructured content in this template's component (the nonXMLBody) and generates the template header based on that content without human intervention is treated as a Device AssignedAuthor. An example of authoring device of the nonXMLBody and Unstructured CDA Header would be a patient home health monitoring device that reports patient activity via video surveillance, and wraps that nonXMLBody with header information related to its activity. A authoring device may also be the original content author while a Person Assigned Author takes responsibility for wrapping that device's unstructured content facilitated by composing software. Unfortunately, a facilitating device entity attributes cannot be conveyed with the current CDA unless there's an extension developed for this use case.

In addition, because the Unstructured Document with Provenance template inherits the C-CDA General Header constraints via its basis in the DS4P IG, the ClinicalDocument.effectiveTime is the time at which the content was originally created as stipulated in the General Header, and not the scan or transform time. Facilitating device effective time is conveyed by the participation, which is how the scanner time must be conveyed per this IG.

Another important distinction from other Unstructured Document and C-CDA Document templates is that the Unstructured Document with Provenance Template uses codes from the HL7 LOINC Document Ontology value set OID:2.16.840.1.13883.1.11.20507 to convey provenance information that is not computably available in the unstructured body. The LOINC Document Ontology value set codes represent a pre-coordinated set of other LOINC codes included: the kind of document e.g.; a Consent or a more detailed type of Consent such as a Release of information Consent [LP173400-5], a Type of Service such as VA C and P exam. HIV-related illness [LP173165-4], the Setting such as Outpatient office [LP173054-0], the Subject Matter Domain, such as HIV [LP183500-0], and the Role (training or professional level of the document author), such as Physician [LP173084-7]. Their purpose is to be used in conjunction with local document type codes in exchange to enable trading partners to communicate document types interoperably. In addition, use of LOINC Document Ontology value set codes enhances the utility of unstructured content for purposes of conveying structured provenance metadata, evaluating the reliability of the content, and applying additional metadata such as security labels for data segmentation.

Note that it is crucial for senders to consider whether these more detailed document type codes reveal sensitive information, and if so whether there are additional privacy protections required under law. For example, if there were a LOINC Document Ontology code for the Consent to release Title 38 Section 7332 protected information described above, then the sender would need to ensure that only authorized entities had access to this code. Use of these codes is required only if an appropriate code is available in this value set. If not, then use of the most descriptive LOINC Document Type code available, and consider submitting a request for a more precise precoordinated code for inclusion in the LOINC Document Ontology value set. See LOINC Process for Submitting New Term Requests http://loinc.org/submissions/new-terms.

Assembly software is required to be compatible with the formats in which the selected preexisting content is maintained by the custodian. For example, the Medical Officer of a Health Information Exchange Organization should be identified as the person playing the role of the Assembler Assigned Author. The Medical officer oversees and is responsible for the Assembly software used in a device to generate documents comprised of preexisting content.
with associated provenance intact. The Assembler Assigned Author is required to ensure that the Assembly software algorithm is accurately selecting specified preexisting content and associated provenance, and aggregating this content with provenance into the specified format for persistence in a repository or in response to an authorized request. Assembly software is mandatory and must be conveyed.

With respect to use of Privacy related Authorizations in Unstructured Document with Provenance: Other DPROV Document Templates support a Privacy Marking Section by which a sender can relay to a receiver and end users the Privacy and Security parameters of the content. However, because an Unstructured Document supports only one NonXML body, the only means for conveying metadata comparable to the DPROV Privacy Marking Section is to add auxiliary Authorizations, which can be used to augment the Privacy Consent Directive with one or more Consent Category Directive and Consent Security Directive Authorizations, as surrogates for the DPROV Privacy Marking Section Security Labels. The Consent Category Directive and Consent Security Directive Authorizations can also be used without a Privacy Consent Directive to convey jurisdictional privacy laws e.g., minors' privacy protections or organizational privacy policies e.g., marking a VIP's records.

Keeping the association among these Unstructured Document Authorizations may present some difficulties in the unlikely case that more than one Privacy Consent Directive is applicable to the unstructured content, each of which may govern different sensitive information types and have different handling caveats. For example, three Privacy Consent Directives could apply to an Unstructured Document e.g., HIPAA Notice of Privacy Practices, HIPAA Self-pay, and 42 CFR Part 2. A HIPAA Notice of Privacy Practices permits disclosure of covered information for treatment, payment, and operation purposes of use. HIPAA Self-pay permits disclosure of services for which the patient paid in full only for treatment purposes. 42 CFR Part 2, which is the most stringent of the consent directives, requires a consent for disclosure of covered condition information for any purpose other than an emergency. Given the limited attributes available in the CDA R2 Authorization Class, the only way to link these would be via Directive identifiers e.g., by adding a suffix to the same identifier.

More importantly, because the unstructured content is authenticated as a whole document and cannot be segmented, the most stringent Privacy Consent Directive applies to the Unstructured Document, preempting the less stringent. Nevertheless, if the Consent Category Directive for sensitive information type or governing law is specific enough, the end users of the unstructured content may be able to discern the information to which each Privacy Consent Directive applies and treat that information accordingly. In a hypothetical Unstructured Document with the three Privacy Consent Directives above, if the HIPAA Self-pay Directive has an associated Consent Category Directive for Mental Health, then the end-user would know which information is not to be shared with the patient's payer. If substance abuse is the sensitivity category associated with the 42 CFR Part 2 Privacy Consent Directive, then end user would know which information may not be further disclosed without consent.

<table>
<thead>
<tr>
<th>Contained By</th>
<th>Contains</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assembler Document Participant</td>
<td></td>
</tr>
<tr>
<td>Composer Document Participant</td>
<td></td>
</tr>
<tr>
<td>Provenance Author Participant Choice</td>
<td></td>
</tr>
<tr>
<td>Provenance Informant Participant Choice</td>
<td></td>
</tr>
</tbody>
</table>

1. SHALL contain exactly one [1..1] `templateId` (CONF-DPROV-38) such that it
   a. SHALL contain exactly one [1..1] `@root"=2.16.840.1.113883.3.5019.1.38"
2. SHALL conform to `CONTENTPROFILE cda Privacy Segmented Document` template (templateId: 2.16.840.1.113883.3.3251.1.1)
3. SHALL contain exactly one [1..1] `confidentialityCode` (CONF:17055), which SHALL be selected from ValueSet HL7 BasicConfidentialityKind 2.16.840.1.113883.1.11.16926 STATIC (CONF:5259)
4. SHOULD contain zero or one [0..1] `setId` (CONF:5261)
5. SHALL contain exactly one [1..1] `code` (CONF:5253), which SHALL be selected from ValueSet LoincDocumentOntologyInternational 2.16.840.1.113883.1.11.20507 DYNAMIC (CONF:17056)
6. SHOULD contain zero or one [0..1] versionNumber (CONF:5264)
7. SHALL contain [1..1] participant (CONF:17060)

For purposes of establishing provenance and accountability for content, Assembler Document Header Participant should be used to specify any device software used to assemble the content generated by the Provider Generated Assigned Author and selected from existing content as determined by the scoping Organization’s specified algorithm.

a. Contains exactly one [1..1] Assembler Document Participant (templated:
   2.16.840.1.113883.3.5019.1.1)
8. SHALL contain at least one [1..*] authenticator, where its type is Authenticator (CONF:17187)
9. SHALL contain at least one [1..*] authorization, where its type is Privacy Consent Directive (CONF:17186)
10. SHOULD contain zero or more [0..*] authorization, where its type is Consent Category Directive (CONF:17405)
11. SHALL contain [1..1] participant (CONF:17062)

For purposes of establishing provenance and accountability for content, Composer Document Header Participant is required to be conveyed to specify any device software used to compose new and preexisting content.

a. Contains exactly one [1..1] Composer Document Participant (templated:
   2.16.840.1.113883.3.5019.1.5)
12. SHALL contain [1..*] author (CONF:17059)

Specifies provenance-related details about the Provider Author participant, which is mandatory for this type of document. The provider author must specify an assigned author id and a person name.

a. Contains exactly one [1..1] Provenance Author Participant Choice (templated:
   2.16.840.1.113883.3.5019.1.20)
13. SHALL contain [1..1] participant (CONF:17063)

a. Contains exactly one [1..1] Provenance Informant Participant Choice (templated:
   2.16.840.1.113883.3.5019.1.21)
14. SHALL contain at least one [1..*] relatedDocument, where its type is Provenance Related Document (CONF:17061)
15. SHOULD contain zero or more [0..*] authorization, where its type is Consent Security Directive (CONF:17406)

Unstructured Document With Provenance example

```xml
<?xml version="1.0" encoding="UTF-8"?>
<!DOCTYPE topic PUBLIC "-//OASIS//DTD DITA Topic//EN" "topic.dtd">
<title id="classId" xml:lang="en-us">
<shortdesc conref="generated/_UnstructuredDocumentWithProvenance.dita#classId/shortdesc"></shortdesc>
<prolog conref="generated/_UnstructuredDocumentWithProvenance.dita#classId/prolog"></prolog>
<body>
<section conref="generated/_UnstructuredDocumentWithProvenance.dita#classId/knownSubclasses">
</section>
<!-- TODO: insert non-model class description markup here -->
<section conref="generated/_UnstructuredDocumentWithProvenance.dita#classId/description">
</section>
<section audience="contextTable" conref="generated/_UnstructuredDocumentWithProvenance.dita#classId/contextTable">
```
Unstructured Document With Provenance example

Example Unstructured Document Generated by a provider Assigned Author using a Composer

This is the Unstructured Document original content effectiveTime-->
<effectiveTime value="20101021120500-0500"/>

Restricted content based on HL7 BasicConfidentialityKind value set because HIV related information is protected under Title 38 Section 7332-->
<confidentialityCode codeSystem="2.16.840.1.113883.5.25" code="R" displayName="restricted"/>

Provenance related to the XDS Submission Set indicating that this Unstructured Document has been registered with an XDS Registry-->
<setId root="MDHT" extension="2df40cd2-6e68-4a46-a530-b9688b28e2e4"/>
<versionNumber value="2"/>
<languageCode code="en-US"/>

Veterans Health Administration veteran patient information-->

PatientName-->
<name>
    <!-- PatientFirstName, PatientMiddleInitial, PatientFamilyName-->
    <given>Mary</given>
    <given>A</given>
    <family>Everyperson</family>
</name>

GenderCode GenderDisplayName -->
<administrativeGenderCode code="F" display="Female"/>
<author>
  <time value="20141021120500-0500"/>
  <assignedAuthor>
    <!-- Mandatory Author Identifier - if Provider Author is specified, then at least one identifier must be a National Provider Identifier where the id/@root = "2.16.840.1.113883.4.6" is the NPI number for the provider. -->
    <id extension="1234567890" root="2.16.840.1.113883.4.6" assigningAuthorityName="National Plan and Provider Enumeration System"/>
    <!-- Dynamic value set binding to Healthcare Provider Taxonomy (NUCC-HIPAA) "2.16.840.1.114222.4.11.1066" -->
    <code code="207LA0401X" displayName="Addiction Medicine" codeSystem="2.16.840.1.113883.6.101" codeSystemName="NUCC"/>
    <addr>
      <streetAddressLine>1004 Healthcare Drive</streetAddressLine>
      <city>Portland</city>
      <state>OR</state>
      <postalCode>99123</postalCode>
      <country>US</country>
    </addr>
    <telecom use="WP" value="tel:+1(555)555-1004"/>
  </assignedAuthor>
  <representedOrganization>
    <templateId root="2.16.840.1.113883.3.5019.1.26" assigningAuthorityName="HL7 Security CBCC"/>
    <!-- NPI for the organization -->
    <id root="1881638559" assigningAuthorityName="National Plan and Provider Enumeration System"/>
    <name>Example Organization</name>
    <telecom value="tel:+1-555-555-1212" use="WP"/>
    <addr>
      <streetAddressLine>Example Organization Address Line</streetAddressLine>
      <city>ExampleCity</city>
      <state>NH</state>
      <postalCode>99999</postalCode>
    </addr>
    <standardIndustryClassCode code="622210" displayName="Psychiatric and Substance Abuse Hospitals" codeSystem="2.16.840.1.113883.1.11.19298"/>
  </representedOrganization>
</author>
<authenticator>
  <time value="20141021120500-0500"/>
  <!-- Mandatory signatureCode/@code ="S" is defined as:"Signature has been affixed, either written on file, or electronic (incl. digital) signature in Participation.signatureText." -->
  <signatureCode code="S"/>
  <sdtc:signatureText mediaType="text/xml" representation="B64">
<omSJUEmdme9j44zmMiromSJUEmdme9j44zmMirdMDSsWdlJdkslJR3373jeu836edjzMMIjdmDSsWdlJdkslJR3373jeu833MNYD83jmMdomSJUEmdme9j44zmMir ... MNYD83jmMdomSJUEmdme9j44zmMir6edjzMMIjdmDSsWdlJdkslJR3373jeu834zmMlr86dzjMMIjdmDSsWdlJdkslJR3373jeu83==</sdtc:signatureText>
  <assignedEntity>
    <id extension="1234567890" root="2.16.840.1.113883.4.6"/>
    <!-- Dynamic value set binding to Healthcare Provider Taxonomy (NUCC-HIPAA) "2.16.840.1.114222.4.11.1066" -->
    <code code="207LA0401X" displayName="Addiction Medicine" codeSystem="2.16.840.1.113883.6.101" codeSystemName="NUCC"/>
    <addr>
      <streetAddressLine>1004 Healthcare Drive</streetAddressLine>
      <city>Portland</city>
      <state>OR</state>
      <postalCode>99123</postalCode>
      <country>US</country>
    </addr>
    <telecom use="WP" value="tel:+1(555)555-1004"/>
    <assignedPerson>
      <name>
        <given>Patricia</given>
        <given qualifier="CL">Patty</given>
        <family>Primary</family>
        <suffix qualifier="AC">M.D.</suffix>
      </name>
    </assignedPerson>
  </assignedEntity>
  <representedOrganization>
    <templateId root="2.16.840.1.113883.3.5019.1.26" assigningAuthorityName="HL7 Security CBCC"/>
    <!-- NPI for the organization -->
    <id root="1881638559" assigningAuthorityName="National Plan and Provider Enumeration System"/>
    <name>Example Organization</name>
    <telecom value="tel:+1-555-555-1212" use="WP"/>
    <addr>
      <streetAddressLine>Example Organization Address Line</streetAddressLine>
      <city>ExampleCity</city>
      <state>NH</state>
      <postalCode>99999</postalCode>
    </addr>
    <standardIndustryClassCode code="622210" displayName="Psychiatric and Substance Abuse Hospitals" codeSystem="2.16.840.1.113883.1.11.19298"/>
  </representedOrganization>
</authenticator>
<!-- Composer participation type code @typeCode="DEV"-->
<!-- Date time (time zone added -0500)-->  
<time value="20141021120500-0500"/>

<associatedEntity classCode="MANU">
  <!-- ComposerDocumentHeaderParticipant - Device AssociatedEntity with UDI & SNOMED Device code. Could be GMDN. templateId null.-->
  <id root="2.16.840.1.113883.3.3719"
    extension="(01)51022222233336(11)141231(17)150707(10)A213B1(21)1234">
    <assigningAuthorityName="GS1 2.51.1.1"/>
    <code code="46462944003" codeSystem="2.16.840.1.113883.6.96" display="Hospital-administration information system application software"/>
  </id>
  <scopingOrganization>
    <templateId root="2.16.840.1.113883.3.5019.1.26"
      assigningAuthorityName="HL7 CBCC"/>
    <id nullFlavor="NA"/>
    <name>Vendor Organization</name>
    <telecom value="tel:+1-555-555-1212" use="WP"/>
    <addr>
      <!-- Address fields -->
      <streetAddressLine>Example Address Line</streetAddressLine>
      <city>ExampleCity</city>
      <state>NH</state>
      <postalCode>99999</postalCode>
    </addr>
  </scopingOrganization>
  <relatedDocument typeCode="APND">
    <parentDocument>
      <id root="223769be-f6ee-4b04-a0ce-b56ae998c879"/>
      <code codeSystem="LP72988-6" codeSystemName="LOINC" display="Substance Abuse Note"/>
      <setId root="004bb033-b948-4f4c-b5bf-a8dbd7d8dd40"/>
      <versionNumber value="1"/>
    </parentDocument>
    <authorization typeCode="AUTH">
      <consent classCode="CONS" moodCode="EVN">
        <id root="629deb70-5306-11df-9879-0800200c9a66"/>
        <code codeSystem="2.16.840.1.113883.1.20425" codeSystemName="ActConsentDirectiveType" code="IDSCL" display="information disclosure consent"/>
        <statusCode code="completed"/>
      </consent>
    </authorization>
    <custodian>
      <assignedCustodian>
        <!-- NPI for a HIPAA covered Custodian Organization -->
        <id root="1234567890" assigningAuthorityName="National Plan and Provider Enumeration System"/>
        <name>Example Organization</name>
        <telecom value="tel:+1-555-555-1212" use="WP"/>
        <addr>
          <streetAddressLine>Example Organization Address Line</streetAddressLine>
          <city>ExampleCity</city>
          <state>NH</state>
          <postalCode>99999</postalCode>
        </addr>
      </assignedCustodian>
      <representedCustodianOrganization/>
    </custodian>
  </relatedDocument>
</participant>
</sourceOrganization>
</associatedEntity>
The Privacy Consent Directive governing the content about which the patient has consented to disclose.-->

The "ActConsentDirectiveType" value set enables conveyance of one or more Privacy Consent Directive Type codes to indicate the governing privacy restrictions to which a patient has consented.-->

<authorization typeCode="AUTH">
  <consent classCode="CONS" moodCode="EVN">
    <id root="629deb70-5306-11df-9879-0800200c9a67"/>
    <code codeSystem="2.16.840.1.113883.1.11.20425" codeSystemName="ActConsentDirectiveType" code="OPTIN" displayName="Opt-in to disclosure of health information"/>
    <statusCode code="completed"/>
  </consent>
</authorization>

<authorization typeCode="AUTH">
  <consent classCode="CONS" moodCode="EVN">
    <id root="629deb70-5306-11df-9879-0800200c9a66"/>
    <code codeSystem="2.16.840.1.113883.1.11.20425" codeSystemName="ActConsentDirectiveType" code="IDSCL" displayName="Consent to disclose information."/>
    <statusCode code="completed"/>
  </consent>
</authorization>

<authorization typeCode="AUTH">
  <consent classCode="CONS" moodCode="EVN">
    <id root="629deb70-5306-11df-9879-0800200c9a65"/>
    <code codeSystem="2.16.840.1.113883.1.11.20470" codeSystemName="USPrivacyLaw" code= "Title38Section7332" displayName="Title 38 Section 7332 governed health information"/>
    <statusCode code="completed"/>
  </consent>
</authorization>

The Security Category Sensitivity content type, which may be the basis for compliance with privacy policies or laws governing the content.-->

<authorization typeCode="AUTH">
  <consent classCode="CONS" moodCode="EVN">
    <id root="629deb70-5306-11df-9879-0800200c9a64"/>
    <code codeSystem="2.16.840.1.113883.1.11.20470" codeSystemName="ActInformationSensitivityPolicy" code="ETH" displayName="substance abuse information sensitivity"/>
    <statusCode code="completed"/>
  </consent>
</authorization>

The Security Control Observation Value conveys the purpose of use, obligations [mandates], and Refrains [prohibitions] that follow from the patient's Consent Directive, jurisdictional law, or organizational policy.-->
<consent classCode="CONS" moodCode="EVN">
  <id root="629deb70-5306-11df-9879-0800200c9a61"/>
  <code codeSystem="2.16.840.1.113883.1.11.20471" codeSystemName "SecurityControlObservationValue" code="NORDSCLCD" displayName="No redisclosure without information subject's consent directive")">
    <statusCode code="completed"/>
  </code>
</consent>
</authorization>
</component>
</nonXMLBody>
</text>
This section of the IG describes templates applied to sections of CDA Clinical Document.

The following Section level templates constrain the templates of a CDA document to accommodate the additional requirements introduced by the Data Provenance Project.

These templates are the constraints applied to a CDA section to ensure that the provenance information is correctly assigned.

The Section Templates in DPROV are not separate sections in themselves, and are used as overlays or further constraints on other CDA Section Templates. For example, a CDA would not have a section titled "Section Authored By Provider." Rather, conformant DPROV CDA documents must select the appropriate DPROV Section template for any Section Author that overrides a Document level Author. Generally, Section with Mandatory Author may be used where any type of Section Author could override a Document level Author, and insert it within an existing CDA section (e.g., Problems). Where a DPROV conformant Document only permits Provider, Device, or Patient Authors, the template for a Section Authored by one of these actors should be selected.

If one of these Section templates is used, then the author is expected to be included at the section level to override authors at the document level.

To support modularity, these templates may be reused in any CDA document regardless of its document template, i.e. the use of this template does not require use of document templates as defined in this IG.
Provenance Privacy Marking Section

[Section: templateId 2.16.840.1.113883.3.5019.1.25]

The Provenance Privacy Marking Section is the Document level Security Label, and contains any privacy markings that this document is required to display to end users.

When rendering the document, the Provenance Privacy Marking Section should be displayed before other sections to provide a visual indicator of the Document's Security Label values, and any instructions or warnings that are required to be presented to authorized end users, including:

1. The Document's Confidentiality code, which must match the Confidentiality code required on the Clinical Document header, indicating required clearance for access to the entire Document, which must be the high water mark or most restrictive Confidentiality code of any portion of the Document for which a user has clearance. All other Sections within the Document will also have a high water Confidentiality code for component Entries. If there is more than one level of Confidentiality in Entry level Security Labels, then users will only have access to those that match their clearance.

2. Sensitivity of the Document's information, which must include the list of all sensitivity codes for all entries within the Document for which a user's clearance permits access. If a user is only authorized to access HIPAA governed information, then the sensitivity codes, if any, must be constrained to those that are not sensitive under more stringent privacy policy and laws, such as employee or VIP sensitivity codes. If a user is authorized to access both Title 38 Section 7332 and HIPAA governed information, that user will see both sets of sensitivity codes. The user's clearance will also dictate the Entry level information for which the user will be permitted access.

3. Compartment(s), e.g., project or workflow to which authorized users of this Document must belong. Some users may be authorized to access or use only subsets of the Sections and Entries within this Document depending upon the compartment label in their clearance.

4. All applicable Privacy Consent Directive Type, which are the security policies stipulated by a patient's consent directive, the provisions of which may be limited by organizational or jurisdictional policies. The patient's consent directive may restrict access by user or organization identifier or role.

Note: The Privacy Consent Directive Type Security Observation Value value set is a specialization of the abstract ActPrivacyPolicy using the DPROV value set, which combines the HL7 ActConsentDirective and ActConsentType in anticipation of a restructuring of both in an upcoming HL7 Harmonization meeting.

5. All applicable US Privacy Law, which may be stipulated by any US Privacy Laws, including national, state, and other jurisdictional statutes and regulations. The Provenance Privacy Marking Section Security Label must include the applicable codes for all applicable US Privacy Law(2.16.840.1.113883.1.11.20427), which must only be rendered to authorized users. NOTE that this value set is extensible to accommodate the inclusion of other US Privacy Laws. In addition, if the applicable policy is related to a patient consent directive, then the ActConsentDirective and ActContentType codes must be included, and must match the External Consent Directive Choice code from the DPROV ConsentDirectiveTypeValueSet 2.16.840.1.113883.1.11.20425

6. Handling instructions, which must include only those pertinent to the information a user is authorized to access:
   a. Purpose of use limitations
   b. Obligations, e.g., restricting access and disclosure to the minimum necessary and to render privacy markings such as warnings about redisclosure
   c. Refrain policies such as the 42 CFR Part 2 prohibition on redisclosure of the content of the document to which this template is applied without patient consent.

Note that if Sensitivity, Privacy Policies, Privacy Laws, and Compartment codes are included in the Document Security Label, which are indicative of protected information, then the StructuredBody Confidentiality code must be rendered appropriately to ensure that only authorized users can access the Provenance Privacy Marking Section.
and other content contained in this portion of the CDA as well as limiting access to portions of the CDA to which the user is authorized. This feature enables custodians and receivers to permit users with lower clearances to access the Provenance Privacy Marking Section and portions of the CDA to which they are authorized without disclosing protected information that requires higher clearance. This feature also enables custodians and receivers to indicate in the text field whether the document had any information redacted or masked in accordance with trading partner policies as captured in a trust policy. The trading partner trust policy, which permits inclusion of a flag indicating that the receiver or a receiver’s end user is not authorized to view all of the document content, can be discovered via the location conveyed in the Security Policy Information File [Act: templateId 2.16.840.1.113883.3.5019.1.36].

<table>
<thead>
<tr>
<th>Contained By</th>
<th>Contains</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Provenance Author Participant Choice</td>
</tr>
<tr>
<td></td>
<td>Provenance Metadata Relationship</td>
</tr>
</tbody>
</table>

1. **SHALL** contain exactly one [1..1] **templateId** (CONF-DPROV-25) such that it
   a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.3.5019.1.25"

2. **SHALL** contain exactly one [1..1] **code** (CONF:17269)/@code="57017-6" Privacy Policy (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:17270)

   The section code is specified using LOINC to indicate that the section is intended. The code indicates that the section reflects the privacy policies of the sending organization.

3. **SHALL** contain exactly one [1..1] **text** (CONF:17271)

   Note: In C-CDA, this section is required if applicable, but is mandatory to any document containing information protected by specific privacy policies. For example, 42 CFR Part 2 requires that covered patient information is accompanied by an explicit notice to the provider receiving the disclosed information. Other privacy policies may include a similar recommended text or "redisclosure notice" to the end-users viewing protected information.

4. **SHALL** contain [1..*] **author** (CONF:17366)
   a. Contains exactly one [1..1] Provenance Author Participant Choice (templateId: 2.16.840.1.113883.3.5019.1.20)

5. **SHALL** contain exactly one [1..1] **entry**, where its type is Privacy Marking Entry (CONF:17272)

6. **SHOULD** contain zero or more [0..*] **entryRelationship**, where its type is Provenance Metadata Relationship (CONF:17273)

Provenance Privacy Marking Section example

```xml
<templateId root="2.16.840.1.113883.3.5019.1.7" assigningAuthorityName="HL7 CBCC"/>
<code code="57017-6" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" displayName="Privacy Policy"/>
<title>Title 38 Section 1.476 Prohibition on redisclosure</title>
<text>PROHIBITION ON REDISCLOSURE OF Title 38 Section 7332 CONFIDENTIAL INFORMATION</text>
```
1.476 Prohibition on redisclosure: Each disclosure under 1.460 through 1.499 of this part made with the patient's written consent must be accompanied by a written statement similar to the following:
This information has been disclosed to you from records protected by Federal confidentiality rules (38 CFR Part 1). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 38 CFR Part 1. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient or patient with sickle cell anemia or HIV infection. <text>

<!-- Restricted content based on HL7 BasicConfidentialityKind value set -->
<confidentialityCode code="R" displayName="restricted" codeSystem="2.16.840.1.113883.5.25" codeSystemName="HL7 Confidentiality"/>
<!-- Privacy Marking Section Assigned Author -->
<author>
<templateId root="2.16.840.1.113883.3.5019.1.28" assigningAuthorityName="HL7 CBCC"/>
<!-- Mandatory DateTime Created (timezone added -0500)-->
<time value="20131021120500-0500"/>
<assignedAuthor>
<!-- Provider Assigned Author [Null Template] -->
<!-- The Authoring Provider NPI number -->
<id extension="1122334455" root="2.16.840.1.113883.4.6"/>
<!-- The Author's Role Code = Healthcare Provider Taxonomy (NUCC- HIPAA) -->
<code code="208D00000X" codeSystem="2.16.840.1.113883.6.101" codeSystemName="NUCC" displayName="General Practice"/>
<addr>
<!-- AuthorAddressLine, AuthorCity, AuthorState, AuthorZipCode -->
<streetAddressLine>ExampleProviderAddressLine</streetAddressLine>
<city>ExampleCity</city>
<state>NH</state>
<postalCode>99999</postalCode>
</addr>
<!-- AuthorTelephone preceded by "tel:" with @use="WP"-->
<telecom value="tel:+1-301-555-1212" telecom use="WP"/>
<assignedPerson>
<!-- AuthorProviderName -->
<name>
<prefix>Dr.</prefix>
<family>Hippocrates</family>
<given>Harold</given>
</name>
<assignedAuthor/>
</author>
<!-- Provenance Scoping Organization for Provider Assigned Author-->
<ProvenanceScopingOrganization>
<templateId root="2.16.840.1.113883.3.5019.1.33" assigningAuthorityName="HL7 Security CBCC"/>
<!-- NPI for the organization -->
<id extension="1234567890" root="2.16.840.1.113883.4.6" assigningAuthorityName="Issuing Organization"/>
<name>Example Organization</name>
<telecom value="tel:+1-555-555-1212" use="WP"/>
<addr>
<streetAddressLine>Example Organization Address Line</streetAddressLine>
<city>ExampleCity</city>
<state>NH</state>
<postalCode>99999</postalCode>
</address>
Section Generated By Device

[Section: templateId 2.16.840.1.113883.3.5019.1.30]

The Section Generated by Device template constrains the CDA to create a section authored by a device, which is comprised of device generated information, and may include device selected information reported by informants with provenance information intact.

A Section Generated by Device is generated under the auspices of the Organization scoping the role of the Device Assigned Author. This Organization is required to be specified. The Device Assigned Author, which is required to be specified, may generate the Section with the assistance of one or more informant participants as applicable and authorized by the scoping Organization.

A participating Informant is not included in the Section Generated by Device because there was no use case found to cover that association. Implementers who have a use case in which an Informant contributes to the content of a Section Generated by Device are encouraged to provide this as a comment during the DSTU period.

Note: The composer and assembler is not supported on the section.

<table>
<thead>
<tr>
<th>Contained By</th>
<th>Contains</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Device Author Participant</td>
</tr>
</tbody>
</table>

1. SHALL contain exactly one [1..1] templateId (CONF-DPROV-30) such that it
   a. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.3.5019.1.30"
2. SHALL contain exactly one [1..1] confidentialityCode (CONF:17039)
3. SHALL NOT contain [0..0] informant with @xsi:type="Informant12"
   An Section Generated by Device by definition consists entirely pre-existing content. Therefore input a content by an informant participant is precluded in the generation of this section.
4. SHALL contain [1..*] author (CONF:100)
   Author participation constrained for a section generated by a Device. Specifies provenance-related details about the Device Author participant, which is mandatory for this type of section.
   a. Contains exactly one [1..1] Device Author Participant (templateId: 2.16.840.1.113883.3.5019.1.8)
5. SHALL contain exactly one [1..1] entry (CONF:17082)
   a. This entry SHOULD contain zero or one [0..1] @nullFlavor (CONF:17150)
   b. This entry SHALL contain at least one [1..*] @typeCode (CONF:17151), which SHALL be selected from ValueSet x_ActRelationshipEntry 2.16.840.1.113883.1.11.19446 STATIC (CONF:17152)
   c. This entry SHALL contain exactly one [1..1] act, where its type is CDA Clinical Statement (CONF:17383)

Section Generated By Device example

```xml
<section>
  ...
</section>
```
<templateId root="2.16.840.1.113883.3.5019.1.29"/>
<code code="8716-3" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" displayName="Vital Signs"/>
<title>Vital Signs (Last Filed)</title>
<table>
<thead>
<tr>
<th>Date</th>
<th>Blood Pressure</th>
<th>Pulse</th>
<th>Temperature</th>
<th>Respiratory Rate</th>
<th>Height</th>
<th>Weight</th>
<th>BMI</th>
<th>SpO2</th>
</tr>
</thead>
<tbody>
<tr>
<td>05/20/2014 7:36pm</td>
<td>120/80 mm[Hg] </td>
<td>80 /min</td>
<td>37.2 C</td>
<td>18 /min</td>
<td>170.2 cm</td>
<td>108.8 kg</td>
<td>37.58 kg/m2</td>
<td>98%</td>
</tr>
</tbody>
</table>
Section Generated By Mandatory Author

[Section: templateId 2.16.840.1.113883.3.5019.1.31]

Author participation constrained for a section generated by a provider, a patient, or a device. The following are the constraints applied to a CDA document section to ensure that the provenance information is correctly assigned. If this template is used, then the author is expected to be included at the section level. This template may be reused in any CDA document regardless of its document template or type. i.e. doesn’t require use of document templates as defined in this IG.

The Section Generated by Mandatory Author template constrains the CDA to create a section authored by a provider, a patient, or a device, which is comprised of provider, patient, or device generated information, and may include provider, patient, or device selected information reported by informants with provenance information intact.

If a provider or a device generates a Section Generates content constraint by the section generated by the Mandatory Author template then the content is generated under the auspices of the Organization scoping the role of the Provider or Device Assigned Author. This Organization is required to be specified. The Provider, Patient or Device Assigned Author, which is required to be specified, may generate the Section with the assistance of one or more informant participants.

A participating Informant, who is either an assigned provider or professional, such as a teacher or office staff, authorized by a scoping organization to provide information about the patient, or a related person, such as a patient's family member or an acquaintance, who is not scoped by an organization. Any Informant participant is required to be conveyed if known.

Note: The composer and assembler or any other type of participant other than an author or an informant is not supported on the section.

<table>
<thead>
<tr>
<th>Contained By</th>
<th>Contains</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Provenance Author Participant Choice</td>
</tr>
<tr>
<td></td>
<td>Provenance Informant Participant Choice</td>
</tr>
</tbody>
</table>

1. SHALL contain exactly one [1..1] `templateId` (CONF-DPROV-31) such that it
   a. SHALL contain exactly one [1..1] `@root="2.16.840.1.113883.3.5019.1.31"`
2. SHALL contain exactly one [1..1] `confidentialityCode` (CONF:16858)
3. **SHALL** contain [1..*] `author` (CONF:56)

Specifies provenance-related details about the Author participant, which is mandatory for this type of section. Author participation constrained for a section generated by a Provider, a Patient, or a Device.

   a. Contains exactly one [1..1] `Provenance Author Participant Choice` (templateId: 2.16.840.1.113883.3.5019.1.20)

4. **SHALL** contain [1..*] `provenanceInformantParticipant` (CONF:187)

   a. Contains exactly one [1..1] `Provenance Informant Participant Choice` (templateId: 2.16.840.1.113883.3.5019.1.21)

5. **SHALL** contain exactly one [1..1] `entry` (CONF:17082)

   a. This entry **SHOULD** contain zero or one [0..1] `@nullFlavor` (CONF:17150)

   b. This entry **SHALL** contain at least one [1..*] `@typeCode` (CONF:17151), which **SHALL** be selected from ValueSet `x_ActRelationshipEntry` 2.16.840.1.113883.1.11.19446 STATIC (CONF:17152)

   c. This entry **SHALL** contain exactly one [1..1] `act`, where its type is CDA Clinical Statement (CONF:17383)

Section Generated By Mandatory Author example

```xml
<section>
  <!-- Section with mandatory author -->
  <templateId root="2.16.840.1.113883.3.5019.1.18"/>
  <code code="47519-4" displayName="History of procedures"
         codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
  <title>Procedures</title>
  <text>
    <table>
      <thead>
        <tr>
          <th>Procedure</th>
          <th>Date</th>
        </tr>
      </thead>
      <tbody>
        <tr>
          <td>Knee Replacement</td>
          <td>10/06/2008</td>
        </tr>
      </tbody>
    </table>
  </text>

  <!-- Mandatory provenance if different than specified in the header -->
  <author>
    <!-- Mandatory Section Author Participation -->
    <templateId root="2.16.840.1.113883.3.5019.1.17"
                assigningAuthorityName="HL7 CBCC"/>
    <!-- Mandatory date time-->
    <time value="20141021120500-0500"/>
    <assignedAuthor>
      <!-- Mandatory Assigned Author -->
      <templateId root="2.16.840.1.113883.3.5019.1.16"
                  assigningAuthorityName="HL7 CBCC"/>
    </assignedAuthor>
    <!-- Mandatory Author Identifier - at least one is required -->
    <id root="4d0c8e77-ea1d-4f41-9858-88806852e774"
        assigningAuthorityName="Example Organization"/>
  </author>
</section>
```

<!-- Root means NPI and the @extension specifies the value of... -->
the NPI -->
<!-- Dynamic value set binding to
"2.16.840.1.114222.4.11.1066" -->
<code code="1223G0001X" displayName="General Practice"
codeSystem="2.16.840.1.113883.6.101"/>
<addr>
<streetAddressLine>Example Address Line</streetAddressLine>
<city>ExampleCity</city><name>
<prefix>Dr.</prefix>
<family>Hippocrates</family>
<given>Harold</given>
</name>
</assignedPerson>
<!-- Scoping Organization -->
<representedOrganization>
<templateId root="2.16.840.1.113883.3.5019.1.19"
assigningAuthorityName="HL7 CBCC"/>
<id root="96449e6d-24c8-4be7-a02c-4536f83f4423"
assigningAuthorityName="Issuing Organization"/>
<name>Example Organization</name>
<telecom value="tel:+1-555-555-1212" use="WP"/>
<addr>
<state>NH</state>
<postalCode>99999</postalCode>
</addr>
<telecom value="tel:+1-555-555-1212" use="WP"/>
<telecom value="mailto:Hippocrates@Clinic.org" use="EC"/>
<assignedPerson>
<!-- Assigned Authoring Person -->
<templateId root="2.16.840.1.113883.3.5019.1.5"
assigningAuthorityName="HL7 CBCC"/>
<!-- Mandatory Name -->
<name>
<prefix>Dr.</prefix>
<family>Hippocrates</family>
<given>Harold</given>
</name>
</assignedPerson>
<!-- Scoping Organization -->
<representedOrganization>
<templateId root="2.16.840.1.113883.3.5019.1.19"
assigningAuthorityName="HL7 CBCC"/>
<id root="96449e6d-24c8-4be7-a02c-4536f83f4423"
assigningAuthorityName="Issuing Organization"/>
<name>Example Organization</name>
<telecom value="tel:+1-555-555-1212" use="WP"/>
<addr>
<streetAddressLine>Example Organization Address Line</streetAddressLine>
<city>ExampleCity</city>
<state>NH</state>
<postalCode>99999</postalCode>
</addr>
</representedOrganization>
</assignedAuthor>
</author>
<entry>
<procedure classCode="PROC" moodCode="EVN">
<templateId root="2.16.840.1.113883.10.20.1.29"
assigningAuthorityName="CCD"/>
<id nullFlavor="NI"/>
<!-- ProcedureCode, ProcedureDisplayName, ProcedureDateTime -->
<code code="ProcedureCode" codeSystemName="CPT"
Section Generated By Patient

[Section: templateId 2.16.840.1.113883.3.5019.1.32]

The Section Generated by Patient template constrains the CDA to create a section authored by a patient, which is comprised of patient generated information, and may include patient selected information reported by informants with provenance information intact.

Note: By patient we mean both the patient and/or their representatives.

A Section Generated by Patient does not require that the role of Patient Assigned Author be scoped by an Organization, but that is not precluded. (According to RIM Role definition usage notes: "the Role of "patient" may be played by a person and scoped by the provider organization from which the patient will receive services."). The Patient Assigned Author, which is required to be specified, may generate the Section with the assistance of one or more informant participants.

A participating Informant, who is either an assigned provider or professional, such as a teacher or office staff, authorized by a scoping organization to provide information about the patient, or a related person, such as a patient's family member or an acquaintance, who is not scoped by an organization. Any Informant participant is required to be conveyed if known.

Note: The composer and assembler or any other type of participant other than an author or an informant is not supported on the section.

<table>
<thead>
<tr>
<th>Contained By</th>
<th>Contains</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Patient Author Participant</td>
</tr>
<tr>
<td></td>
<td>Provenance Informant Participant Choice</td>
</tr>
</tbody>
</table>

1. SHALL contain exactly one [1..1] `templateId` (CONF-DPROV-32) such that it
   a. SHALL contain exactly one [1..1] `@root`="2.16.840.1.113883.3.5019.1.32"

2. SHALL contain exactly one [1..1] `confidentialityCode` (CONF:17042)

3. SHALL contain [1..*] `author` (CONF:101)
   a. Contains exactly one [1..1] `Patient Author Participant` (templatedId: 2.16.840.1.113883.3.5019.1.17)

4. SHALL contain [1..*] `provenanceInformantParticipant` (CONF:196)
   a. Contains exactly one [1..1] `Provenance Informant Participant Choice` (templatedId: 2.16.840.1.113883.3.5019.1.21)

5. SHALL contain exactly one [1..1] `entry` (CONF:17159)
   a. This entry SHOULD contain zero or one [0..1] `@nullFlavor` (CONF:17150)
   b. This entry SHALL contain at least one [1..*] `@typeCode` (CONF:17151), which SHALL be selected from ValueSet `x_ActRelationshipEntry` 2.16.840.1.113883.1.11.19446 STATIC (CONF:17152)
c. This entry **SHALL** contain exactly one [1..1] act, where its type is CDA Clinical Statement (CONF:17383)

**Section Generated By Patient example**

```xml
<templateId root="2.16.840.1.113883.3.5019.1.30"
assigningAuthorityName="HL7"/>
<templateId root="2.16.840.1.113883.10.20.1.2"
assigningAuthorityName="CCD"/>
<code code="10160-0" displayName="Alerts"
codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC"/>
<!-- AllergySectionTitle = Allergies and Alert Problems-->
<title>Allergies and Alert Problems</title>
<text>
<table>
<thead>
<tr>
<!-- AllergySubstanceHeading -->
<th>Substance</th>
<!-- AllergyReactionHeading -->
<th>Reactions</th>
<!-- AllergySeverityHeading -->
<th>Severity</th>
<!-- AllergyOnsetHeading -->
<th>Date of onset</th>
<!-- AllergyCommentHeading -->
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<!-- AllergySubstanceDisplayName -->
<td>IVP dye</td>
<!-- AllergyReactionDisplayName -->
<td>anaphylaxis</td>
<!-- AllergySeverityDisplayName -->
<td>High</td>
<!-- AllergyOnsetDate -->
<td>2014</td>
<!-- AllergyComment -->
<td>Allergy is very severe...</td>
</tr>
</tbody>
</table>
</text>
<confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25"
codeSystemName="HL7 Confidentiality"/>
<!-- Patient Author -->
<author>
<!-- Mandatory Author Participation -->
</author>
</section>
```

<time value="20141021120500-0500"/>
<assignedAuthor>
  <!-- Mandatory Assigned Author -->
  <templateId root="2.16.840.1.113883.3.5019.1.9"
    assigningAuthorityName="HL7"/>
  <!-- Dynamic value set binding to
  "2.16.840.1.113883.11.20.12.1" -->
  <id root="7bb4232-9de2-4d40-94c9-2fc23979d5fc"
    assigningAuthorityName="Example Organization"/>
  <code code="ONESELF" displayName="self"
    codeSystem="2.16.840.1.113883.5.111"/>
  <addr>
    <streetAddressLine>Example Address Line</streetAddressLine>
    <city>ExampleCity</city>
    <state>NH</state>
    <postalCode>99999</postalCode>
  </addr>
  <telecom value="tel:+1-555-555-1212" use="WP"/>
  <telecom value="mailto:Hippocrates@Clinic.org" use="EC"/>
  <assignedPerson>
    <!-- Assigned Authoring Person -->
    <templateId root="2.16.840.1.113883.3.5019.1.5"
      assigningAuthorityName="HL7"/>
  </assignedPerson>
</assignedAuthor>
</author>
</section>

### Section Generated By Provider

[Section: templateId 2.16.840.1.113883.3.5019.1.33]

The Section Generated by Provider template constrains the CDA to create a section authored by a provider, which is comprised of provider generated information, and may include provider selected information reported by informants with provenance information intact.

A Section Generated by Provider is generated under the auspices of the Organization scoping the role of the Provider Assigned Author. This Organization is required to be specified. The Provider Assigned Author, which is required to be specified, may generate the Section with the assistance of one or more informant participants as applicable and authorized by the scoping Organization.

A participating Informant, who is either an assigned provider or professional, such as a teacher or office staff, authorized by a scoping organization to provide information about the patient, or a related person, such as a patient's family member or an acquaintance, who is not scoped by an organization. Any Informant participant is required to be conveyed if known.

Note: The composer and assembler or any other type of participant other than an author or an informant is not supported on the section.
1. **SHALL** contain exactly one [1..1] **templateId** (CONF-DPROV-33) such that it
   a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.3.5019.1.33"
2. **SHALL** contain exactly one [1..1] **confidentialityCode** (CONF:17036)
3. **SHALL** contain [1..*] **author** (CONF:99)
   a. Contains exactly one [1..1] **Provider Author Participant** (templateId:
      2.16.840.1.113883.3.5019.1.40)
4. **SHALL** contain [1..*] **provenanceInformantParticipant** (CONF:195)
   a. Contains exactly one [1..1] **Provenance Informant Participant Choice** (templateId:
      2.16.840.1.113883.3.5019.1.21)
5. **SHALL** contain exactly one [1..1] **entry** (CONF:17159)
   a. This entry **SHOULD** contain zero or one [0..1] @nullFlavor (CONF:17150)
   b. This entry **SHALL** contain at least one [1..*] @typeCode (CONF:17151), which **SHALL** be selected
      from ValueSet x_ActRelationshipEntry 2.16.840.1.113883.1.11.19446 STATIC (CONF:17152)
   c. This entry **SHALL** contain exactly one [1..1] **act**, where its type is CDA Clinical Statement (CONF:17383)

### Section Generated By Provider example

```xml
<!!-- Section Generated by Provider with Conditions or Problems -->
<section>
  <!-- root="2.16.840.1.113883.10.20.1.11" assigningAuthorityName="CCD" -->
  <templateId root="2.16.840.1.113883.10.20.1.11"
    assigningAuthorityName="CCD"/>
  <!-- Provenance Problem section authored by a provider-->
  <templateId root="2.16.840.1.113883.3.5019.1.33"
    assigningAuthorityName="HL7"/>
  <code code="11450-4" displayName="Problems"
    codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
  <title>Conditions or Problems</title>
  <text>
    <table>
      <thead>
        <!-- ConditionHeading='Condition' -->
        <th>Condition</th>
        <!-- ConditionCodeSystemHeading='Code System' -->
        <th>Code System</th>
        <!-- ConditionCodeHeading='Code' -->
        <th>Code</th>
        <!-- ConditionOnsetHeading='Date of onset' -->
        <th>Date of onset</th>
        <!-- ConditionOnsetAuthor='Author' -->
        <th>Author</th>
      </tr>
      <tbody>
        <!-- DiagnosisDisplayName -->
      </thead>
    </table>
  </text>
</section>
```
<td>Cannabis dependence, unspecified</td>
<!-- DiagnosisCodeSystem -->
<td>ICD-9</td>
<!-- DiagnosisCode -->
<td>304.30</td>
<!-- ProblemOnsetDate -->
<td>January 2009</td>
<!-- ProblemAuthor, ProblemAuthorOrganization, ProblemAuthorDateTime -->
<td>Dr. Patricia Psych, <br/> Example Organization<br/> Oct. 21, 2014</td>
</tr>
<tr>
<td>Headache</td>
<!-- DiagnosisCodeSystem -->
<td>ICD-9</td>
<!-- DiagnosisCode -->
<td>784.0</td>
<!-- ProblemOnsetDate -->
<td>October 10, 2014</td>
<!-- ProblemAuthor, ProblemAuthorOrganization, ProblemAuthorDateTime -->
<td>Dr. Harold Hippocrates, <br/> Example Organization<br/> Oct 21, 2014</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Accident Type</th>
<th>Accident Description</th>
<th>Date of onset</th>
</tr>
</thead>
<tbody>
<tr>
<td>Car Accident</td>
<td>Trauma...</td>
<td>October 10, 2014</td>
</tr>
</tbody>
</table>
<templateId root="2.16.840.1.113883.3.3251.1.8" assigningAuthorityName="HL7"/>
<code code="64572001" displayName="Condition" codeSystemName="SNOMED CT"
codeSystem="2.16.840.1.113883.6.96"/>
<statusCode code="completed"/>
<effectiveTime value="200901"/>
<value xsi:type="CD" codeSystemName="ICD-9"
displayName="Cannabis dependence, unspecified"/>
</observation>
</entryRelationship>
</act>
</entry>
</act>
</entry>
</representedOrganization>
<author>
</author>
</entry>
</templateId>
<id nullFlavor="NA"/>
</code nullFlavor="NA"/>
</act>
</entry>
</act>
</templateId>
<id nullFlavor="NA"/>
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<id nullFlavor="NA"/>
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<code code="207LA0401X" displayName="Addiction Medicine" codeSystem="2.16.840.1.113883.6.101" codeSystemName="NUCC"/>
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<state>OR</state>
<postalCode>99123</postalCode>
<country>US</country>
</addr>
<telecom use="WP" value="tel:+1(555)555-1004"/>
<assignedPerson>
<name>
<given>Patricia</given>
<given qualifier="CL">Patty</given>
<family>Psych</family>
<suffix qualifier="AC">M.D.</suffix>
</name>
</assignedPerson>
</assignedAuthor>
</author>
<!-- This relationship is used to specify entry-level Security Labels-->
<entryRelationship typeCode="COMP">
<templateId root="2.16.840.1.113883.3.3251.1.11" assigningAuthorityName="HL7 Security CBCC"/>
</templateId>
</entryRelationship>
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</assignedAuthor>
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</component>
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</entryRelationship>

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<code code="SECCNOBSS" codeSystem="2.16.840.1.113883.1.11.20457" displayName="Security Classification" codeSystemName="HL7ObservationTypeCodeSystem"/>

<!-- value set constrained to "2.16.840.1.113883.1.11.16926" -->
<value xsi:type="CE" code="R" codeSystem="2.16.840.1.113883.5.1063" codeSystemName="SecurityObservationValueCodeSystem" display="Restricted">
<originalText>Restricted Confidentiality</originalText>
</value>
</observation>
</component>

<component typeCode="COMP">
<observation classCode="OBS" moodCode="EVN">
<!-- Security Observation -->
<templateId root="2.16.840.1.113883.3.445.21" assigningAuthorityName="HL7"/>
<!-- Obligation Policy Code template -->
<templateId root="2.16.840.1.113883.3.445.14" assigningAuthorityName="HL7"/>
<code code="SECCNOBSS" codeSystem="2.16.840.1.113883.1.11.20457" displayName="Security Classification" codeSystemName="HL7ObservationTypeCodeSystem"/>
<!-- Value set constraint "2.16.840.1.113883.1.11.20445" -->
<value xsi:type="CE" code="ENCRYPT" codeSystem="2.16.840.1.113883.5.1063" codeSystemName="SecurityObservationValueCodeSystem" display="Encrypt information">
<originalText>Information must be encrypted</originalText>
</value>
</observation>
</component>

<component typeCode="COMP">
<observation classCode="OBS" moodCode="EVN">
<!-- Security Observation -->
<templateId root="2.16.840.1.113883.3.445.21" assigningAuthorityName="HL7"/>
<!-- Refrain Policy Code template -->
<templateId root="2.16.840.1.113883.3.445.23" assigningAuthorityName="HL7"/>
<code code="SECCNOBSS" codeSystem="2.16.840.1.113883.1.11.20457" displayName="Security Classification" codeSystemName="HL7ObservationTypeCodeSystem"/>
<!-- Value set constraint "2.16.840.1.113883.1.11.20446" -->
<value xsi:type="CE" code="NORDSLCD" codeSystem="2.16.840.1.113883.5.1063" codeSystemName="SecurityObservationValueCodeSystem" display="Prohibition on redisclosure without patient consent directive">
<originalText>Prohibition on redisclosure without patient consent directive</originalText>
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</observation>
</component>

<component typeCode="COMP">
<observation classCode="OBS" moodCode="EVN">
<!-- Security Observation -->
<templateId root="2.16.840.1.113883.3.445.21" assigningAuthorityName="HL7"/>
<!-- Purpose Of Use Code template -->
<templateId root="2.16.840.1.113883.3.445.22" assigningAuthorityName="HL7"/>
<code code="SECCNOBSS" codeSystem="2.16.840.1.113883.1.11.20457" displayName="Security Classification" codeSystemName="HL7ObservationTypeCodeSystem"/>
<!-- Value set constraint "2.16.840.1.113883.1.11.20448" -->
<value xsi:type="CE" code="TREAT" codeSystem="2.16.840.1.113883.5.1063" codeSystemName="SecurityObservationValueCodeSystem" display="Treatment">
<originalText>Information intended for treatment</originalText>
</value>
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</section>
This section of the IG details the DPROV Entry templates for clinical statements that may be referenced in the DPROV document and section templates. These templates are arranged alphabetically.

DPROV Entry templates are constraints applied to a CDA clinical statement entry to ensure that provenance information is correctly assigned to support the additional requirements introduced by the Data Provenance Project.

If DPROV Entry templates are used, then the author is expected to be included at the entry level to override authors at the document and/or section levels.

A conformant DPROV CDA Document, which contains an Entry generated by an Author overriding a Document or Section level Author, must apply one of the following DPROV Entry level author participation templates: Assembler, Device, Patient, or Provider Author Participant templates.

Summary of the four Observation Exemplar Entry Templates with Provenance:

- The Observation Generated By Assembler template constrains the CDA to create an exemplar Entry authored entirely of preexisting content. An assembler generated entry is comprised of preexisting content authored by other persons, who may have used assembly or composer software or included informant reported information, or authored by devices with any associated provenance information intact.

- The Observation Generated by Device template constrains the CDA to create an exemplar Entry authored by a device. A device generated entry is comprised of device generated information, and may be associated with entries generated by an assembler. Any associated assembler generated entries are comprised of preexisting content authored by other persons, who may have used assembly or composer software or included informant reported information, or devices with any associated provenance information intact.

- The Observation Generated by Patient template constrains the CDA to create an exemplar Entry authored by a patient or their personal representative (hereafter included in the concept of patient). A patient generated entry is comprised of patient generated information, and may be associated with entries comprised of preexisting content that the patient selected with assistance of composing software or was automatically associated by assembly software. The composer or assembly software facilitated content is comprised of preexisting entries authored by other persons, who may have used assembly or composer software or have incorporated informant reported information, or by devices with associated provenance information intact.
• The Observation Generated by Provider template constrains the CDA to create an exemplar Entry authored by a provider. A provider generated entry is comprised of provider generated information, and may be associated with entries comprised of preexisting content that the provider selected with assistance of composing software or was automatically associated by assembly software. The composer or assembly software facilitated content is comprised of preexisting entries authored by other persons, who may have used assembly or composer software to incorporate informant reported information, or by devices with associated provenance information intact.

While each of the Exemplar Entry Templates have unique differences due to the types of authors and whether they are facilitated in the generation of the entry content by types of software devices or informants, they all share the common ability to be associated with predecessor entries of different sorts.

There are several ways in which these entries may be related to predecessors that are of interest to provenance. These entries with provenance may be directly related as successor entry using inherent CDA R2 associations with other entries in a section via an appropriate entry relationship such as being an extract of, a reference to, a component of a predecessor entry.

These entries with provenance may be directly related as successor entry content using CDA R2 associations with external acts, observations, procedures or documents via an appropriate external reference relationship such as an extract of, a reference to, a component of, or a replacement of a successor externally referenced artifact.

The entries with provenance can, in addition, be related both to other entries in the document or with externally referenced artifacts via a Provenance Metadata entry template developed for this IG, to enable conveyance of lifecycle relationships.

This pattern has been used in various HL7, version 2 and 3 Control Act, as well as CDA R2, FHIR Provenance Resource, and potentially more comprehensively in CDA R2.1 models, and may be based on the EHR Lifecycle Functional Model.

It enables an entry to be associated with predecessor entries for which it is a successor artifact in a later stage of the lifecycle of content as it proceeds through the clinical and administrative workflow so as to track the permutations and the agents involved in those workflow processes that resulted in those permutations. The additional capability is enabled via the Provenance Metadata’s “ProvenanceCurrentEventState” act code, which supports specification of the state change, e.g., update, legal authentication, completion etc.

Currently, the HL7 ProvenanceCurrentEventState value set is an adequate starter set, but not comprehensive; it is acknowledged as a placeholder for a more comprehensive one.
more robust value set, which the HL7 CBCC WG’s Data Provenance Project is tasked to take through the HL7 Vocabulary Harmonization process once the ONC Data Provenance Initiative has completed its gap analysis to determine the state changes that need to be added to that vocabulary.

The following summarizes the current Provenance Metadata capabilities to convey additional provenance information as enabled by the base CDA R2

- Where applicable, associations to predecessor Entries within a section should be specified per CDA using entryRelationship values denoting the type of transition that transitioned the predecessor to the subject Entry. For example, the x_ActRelationshipEntryRelationship code XCRPT could be used to indicate that one Entry is excerpted from another Entry.
- In addition, associations to predecessor External Acts should be specified using x_ActRelationshipExternalReference codes such as RPLC, which can be used to indicate that the Entry is a replacement for an External Act.
- The transition of an Observation or other Entry from its previous state as a predecessor Act to its current state should be specified using the x_ActRelationshipEntryRelationship code COMP to associate a subject Entry with its Provenance Metadata.

The ONC Data Provenance Initiative, HL7 CBCC WG’s Data Provenance Project, and the HL7 EHR WG are collaboratively analyzing the business requirement and use case gaps in the current, placeholder ProvenanceEventCurrentState vocabulary for recommended addition that may be submitted to the H7 Vocabulary Harmonization process during this IG’s DSTU comment period, and welcomes suggested additions from reviewers.

Any DPROV conformant Entry using an Assembler participant to compose or in some way prepare (e.g., translate, aggregate, re-structure) an author’s pre-existing content must include an Assembler by applying constraints in the manner used in the relevant Observation Authored by Device/Patient/Provider Entry template. In this case (i.e., where the Entry author is a device, patient, or provider), the Author playing the Assigned Author takes responsibility for the manner in which the assembly software composes pre-existing content authored by themselves or another author.

When a DPROV conformant Entry applies an Assembler Generated Author template, an Assembler participant must, by definition, be applied because the Entry is the product of an Assembler Assigned Author scoping Organization, which utilized and takes responsibility for the assembly software to compose an Entry comprised of pre-existing content that was NOT authored by any Assigned Author scoped by that Organization.

Where applicable, associations to predecessor Entries within a section should be specified per CDA using entryRelationship values denoting the type of transition that took place from the predecessor to the subject Entry. For example, the x_ActRelationshipEntryRelationship code XCRPT can be used to indicate that one Entry is excerpted from another Entry.

In addition, associations to predecessor External Acts should be specified per CDA using x_ActRelationshipExternalReference codes such as RPLC, which can be used to indicate that the Entry is a replacement for an External Act.

The transition of an Observation or other Entry from its previous state as a predecessor Act to its current state should be specified using the x_ActRelationshipEntryRelationship code SUBJ to associate a subject Entry with its Provenance Metadata.
This IG specifies DPROV Observation Entry Templates as an exemplar to situate the DPROV Author Generated Entry Templates within the CDA structure, and to provide associations to these templates.

DPROV Observation Entry Templates provides the pattern that all DPROV conformant Entries must follow, thereby providing this IG’s implicit constraints.

To support modularity, these templates may be reused in any CDA document or section regardless of its document or section template, i.e. the use of this template does not require use of document or section templates as defined in this IG.
Compartment Security Observation

[Observation: templateId 2.16.840.1.113883.3.5019.1.4]

Compartment Security Observation is the HL7 Healthcare Privacy and Security Classification System [HCS] [http://www.hl7.org/v3ballotarchive_temp_B4C4D2D9-1C23-BA17-0CD7117D3EEA452B/v3ballot/html/infrastructure/security/healthcare_class_sys.html] Security Label Tag valued with codes used in the DPROV Security Labels on the CDA Privacy Marking Section and in Entry Security Labels to convey special "need to know" information categories at applicable levels of a DPROV conformant CDA.

Access is permitted under Attribute Based Access Control schemes to requesters who have Compartment tag values that meet or exceed those on requested CDA content. These may be part of a Relationship Based Access Control scheme as well.

For example, a patient's consent directive may restrict access to the patient's records to "compartments" such as family members, healthcare professional care team members, or to members of a specific Precision Medicine research project.

This is the healthcare analog to the US Intelligence Community's concept of a Special Access Program. Compartment codes may be used in as a field value Map: Aligns with ISO 2382-8 definition of Compartment - "A division of data into isolated blocks with separate security controls for the purpose of reducing risk."

Aligns with ISO 2382-8 definition of Compartment - "A division of data into isolated blocks with separate security controls for the purpose of reducing risk."

### Contained By Contains

1. SHALL contain exactly one [1..1] `templateId` (CONF-DPROV-4) such that it
   a. SHALL contain exactly one [1..1] `@root`="2.16.840.1.113883.3.5019.1.4"
2. SHALL conform to `Security Observation` template (templateId: 2.16.840.1.113883.3.5019.1.35)
3. SHALL contain exactly one [1..1] `code` (CONF:17243), which SHALL be selected from ValueSet `SecurityCategoryObservationType 2.16.840.1.113883.1.11.20459 STATIC` (CONF:17244)
4. SHALL contain exactly one [1..1] `value` (CONF:17245), which SHALL be selected from ValueSet `Compartment 2.16.840.1.113883.1.11.20478 STATIC` (CONF:17246)

  The Compartment Security Observation value attribute shall be selected from the Compartment valueset contained by the Security Category Observation Value valueset.

5. SHOULD contain zero or one [0..1] `text` (CONF:17247)

Compartment Security Observation example

Error: Missing Runtime Class

Confidentiality Security Observation

[Observation: templateId 2.16.840.1.113883.3.5019.1.7]

Confidentiality Security Observation is the HL7 Healthcare Privacy and Security Classification System [HCS] [http://www.hl7.org/v3ballotarchive_temp_B4C4D2D9-1C23-BA17-0CD7117D3EEA452B/v3ballot/html/infrastructure/security/healthcare_class_sys.html] Security Label Tag valued with codes used in the Clinical Document confidentialityCode attribute, the DPROV Security Labels on the CDA Privacy Marking Section, the
Section level confidentialityCode attribute, and in Entry Security Labels to convey the Classification of information categories at applicable levels of a DPROV conformant CDA.

Access is permitted under Attribute Based Access Control schemes to requesters who have Confidentiality Classification tag values that meet or exceed those on requested content.

For example, privacy law may restrict access to tagged information to requesters whose Confidentiality Classification equals or exceeds the Confidentiality code on the requested CDA content. This is the healthcare analog to the US Intelligence Community's concept of Classification such as Secret and Top Secret.

Aligns with ISO 7498-2:1989 - Confidentiality is the property that information is not made available or disclosed to unauthorized individuals, entities, or processes. Confidentiality codes are used as metadata indicating the receiver responsibilities to ensure that the information is not made available or redisclosed to unauthorized individuals, entities, or processes (security principals) per applicable policies. These responsibilities may be further specified by the handling caveat Security Labels: Purpose of Use, Obligation, and Refrain Policies.

The CDA limits the values in the Confidentiality code system to codes included in the x_BasicConfidentialityKind value set 2.16.840.1.113883.1.11.16926:
1. N - normal
2. R - restricted
3. V - very restricted

x_BasicConfidentialityKind is a subset of Confidentiality codes that are used as metadata indicating the receiver responsibility to comply with normally applicable jurisdictional privacy law or disclosure authorization; that the receiver may not disclose this information except as directed by the information custodian, who may be the information subject; or that the receiver may not disclose this information except as directed by the information custodian, who may be the information subject.

<table>
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<tr>
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<th>Contains</th>
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<tr>
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<td>a. SHALL contain exactly one [1..1] @root=&quot;2.16.840.1.113883.3.5019.1.7&quot;</td>
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<tr>
<td>2. SHALL conform to Security Observation template (templateId: 2.16.840.1.113883.3.5019.1.35)</td>
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<td>3. SHALL contain exactly one [1..1] code (CONF:17233), which SHALL be selected from ValueSet SecurityClassificationObservationType 2.16.840.1.113883.1.11.20458 STATIC (CONF:17234)</td>
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</tbody>
</table>

Privacy metadata indicating the sender's sensitivity classification, which is based on an analysis of applicable privacy policies and the risk of harm that could result from unauthorized disclosure.

Map: Definition aligns with ISO 7498-2:1989 - Confidentiality is the property that information is not made available or disclosed to unauthorized individuals, entities, or processes. Confidentiality codes are used as metadata indicating the receiver responsibilities to ensure that the information is not made available or redisclosed to unauthorized individuals, entities, or processes (security principals) per applicable policies.

4. SHALL contain exactly one [1..1] value (CONF:17235), which SHALL be selected from ValueSet Confidentiality 2.16.840.1.113883.1.11.10228 DYNAMIC (CONF:17236)

The Confidentiality Security Observation value attribute shall be selected from the Confidentiality value set contained by the Security Classification Observation Value valueset.

5. SHOULD contain zero or one [0..1] text (CONF:17237)

Confidentiality Security Observation example

Error: Missing Runtime Class
### Data Alteration Label

[Observation: templateId null]

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<tr>
<td><strong>2.</strong> SHALL contain exactly one [1..1] code (CONF:16934), which SHALL be selected from ValueSet SecurityAlterationIntegrityObservationType 2.16.840.1.113883.1.11.20465 STATIC (CONF:17098)</td>
<td></td>
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<tr>
<td><strong>3.</strong> SHALL contain exactly one [1..1] statusCode (CONF:16936)</td>
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</tr>
<tr>
<td><strong>4.</strong> SHALL contain exactly one [1..1] effectiveTime (CONF:16935)</td>
<td></td>
</tr>
<tr>
<td><strong>5.</strong> SHALL contain exactly one [1..1] value with @xsi:type=&quot;ANY&quot; (CONF:16938), which SHALL be selected from ValueSet SecurityAlterationIntegrityObservationValue 2.16.840.1.113883.1.11.20482 STATIC (CONF:17099)</td>
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<tr>
<td><strong>6.</strong> SHALL contain exactly one [1..1] text (CONF:16937)</td>
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Data Alteration Label example

Error: Missing Runtime Class

### Data Integrity Label

[Observation: templateId null]

<table>
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<th>Contained By</th>
<th>Contains</th>
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</thead>
<tbody>
<tr>
<td><strong>1.</strong> SHALL contain exactly one [1..1] id (CONF:16940)</td>
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<tr>
<td><strong>2.</strong> SHALL contain exactly one [1..1] code (CONF:16941), which SHALL be selected from ValueSet SecurityDataIntegrityObservationType 2.16.840.1.113883.1.11.20464 STATIC (CONF:17100)</td>
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<td><strong>3.</strong> SHALL contain exactly one [1..1] statusCode (CONF:16943)</td>
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<tr>
<td><strong>4.</strong> SHALL contain exactly one [1..1] effectiveTime (CONF:16942)</td>
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</tr>
<tr>
<td><strong>5.</strong> SHALL contain exactly one [1..1] value with @xsi:type=&quot;ANY&quot; (CONF:16945), which SHALL be selected from ValueSet SecurityDataIntegrityObservationValue 2.16.840.1.113883.1.11.20483 STATIC (CONF:17101)</td>
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</tr>
<tr>
<td><strong>6.</strong> SHALL contain exactly one [1..1] text (CONF:16944)</td>
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</table>

Data Integrity Label example

Error: Missing Runtime Class

### Obligation Security Observation

[Observation: templateId 2.16.840.1.113883.3.5019.1.12]

Obligation Security Observation is the HL7 Healthcare Privacy and Security Classification System [HCS] [http://www.hl7.org/v3ballotarchive_temp_B4C4D2D9-1C23-BA17-0CD7117D3EEA432B/v3ballot/html/infrastructure/]
security/healthcare_class_sys.html] Security Label Tag valued with codes used in the DPROV Security Labels on the CDA Privacy Marking Section and in Entry Security Labels to convey the mandated workflow action that an information custodian, receiver, or user must perform.

Obligation Security Observation values are drawn from the ObligationPolicy value set (2.16.840.1.113883.1.120445). Examples include: "encrypt", "comply with consent directive", "deidentify", "disclose minimum necessary" and "mask".

Alignment with other standards: Per ISO 22600-2, ObligationPolicy instances are event-triggered and define actions to be performed by manager agent. Per HL7 Composite Security and Privacy Domain Analysis Model: This value set refers to the action required to receive the permission specified in the privacy rule. Per OASIS XACML, an obligation is an operation specified in a policy or policy that is performed in conjunction with the enforcement of an access control decision. See the HL7 Privacy, Access and Security Services (PASS) - Access Control Services (ACS) Conceptual Model, Release 1. http://www.hl7.org/v3ballotarchive_temp_B4970CD4-1C23-BA17-0CEFBC26757E09D3/v3ballot/html/infrastructure/security/pass_acs.html

<table>
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</table>

1. SHALL contain exactly one [1..1] `templateId` (CONF-DPROV-12) such that it
   a. SHALL contain exactly one [1..1] `@root`="2.16.840.1.113883.3.5019.1.12"
2. SHALL conform to Security Observation template (templateId: 2.16.840.1.113883.3.5019.1.35)
3. SHALL contain exactly one [1..1] `code` (CONF:17258), which SHALL be selected from ValueSet SecurityControlObservationType 2.16.840.1.113883.1.11.20460 STATIC (CONF:17259)
4. SHALL contain exactly one [1..1] `value` (CONF:17260), which SHALL be selected from ValueSet ObligationPolicy 2.16.840.1.113883.1.11.20445 STATIC (CONF:17261)
5. SHOULD contain zero or one [0..1] `text` (CONF:17262)

Obligation Security Observation example

Error: Missing Runtime Class

Observation Generated By Assembler

[Observation: templateId 2.16.840.1.113883.3.5019.1.13]

The Observation Generated By Assembler template constrains the CDA to create an exemplar Entry authored entirely of preexisting content. An Observation generated by Assembler is created under the auspices of the Organization scoping the role of the Assembler Assigned Author, which is required to be a Provenance CDA Person, and should be identified if known. The scoping Organization is required to be specified.

The Assembler Assigned Author, oversees and is responsible for the automatic generation of the Entry with the assistance of a participating Assembler. The participating Assembler is device software, which independently of a person author, collates and repackages selected preexisting content and its associated provenance in accordance with algorithms selected by the Assigned Author as authorized by the scoping Organization. Assembly software is required to be compatible with the formats in which the selected preexisting content is maintained by the custodian.

For example, the Medical Officer of a Health Information Exchange Organization could be identified as the person playing the role of the Assembler Assigned Author. The Medical Officer oversees and is responsible for the Assembly software used in a device to generate documents comprised of preexisting content with associated provenance intact. Alternatively, the System Administrator for an HIE could be named the Assembler Assigned Author because this
position is responsible for selecting and maintaining oversight of the Assembler Software algorithms, which reflect the business requirements of the HIE Document Generation facilities that this person oversees.

As an alternative to a direct association between an assembler generated entry with another entry or externally reference act, observation, procedure or document, this IG supports specification of the lifecycle relationship about the assembler generated entry with a predecessor entry using the Provenance Metadata template. A Provenance Metadata entry may be used to specify the state change between an assembler generated entry and a predecessor entry or referenced external act. It may also be used to convey additional provenance metadata using the Provenance Label entry to list, for example, transforms applied to a Clinical Statement, or the Provenance Policy Information File, which is describes the semantics of any applied Provenance Labels as well as the sender's expectations about how the receiver will handle provenance, e.g., that the receiver will persist the provenance metadata in a manner that binds it to the target content.

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<thead>
<tr>
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<tbody>
<tr>
<td></td>
<td>Assembler Entry Participant</td>
</tr>
<tr>
<td></td>
<td>External Consent Directive Reference Choice</td>
</tr>
<tr>
<td></td>
<td>Provenance Metadata Relationship</td>
</tr>
<tr>
<td></td>
<td>Provider Author Participant</td>
</tr>
</tbody>
</table>

1. SHALL contain exactly one [1..1] `templateId` (CONF-DPROV-13) such that it
   a. SHALL contain exactly one [1..1] `@root="2.16.840.1.113883.3.5019.1.13"`

2. SHALL NOT contain [0..0] `informant` with `@xsi:type="Informant12"

   An Observation Generated by Assembler by definition consists entirely pre-existing content. Therefore input a content by an informant participant is precluded in the generation of this entry.

3. SHOULD contain [0..*] `author` (CONF:17064)

   An ObservationGeneratedByAssembler may not have an identified accountable author assigned by the Provenance Scoping Organization, which typically is the same or is accountable for the participating Assembler's Scoping Organization.
   a. Contains exactly one [1..1] `Provider Author Participant` (templateId: 2.16.840.1.113883.3.5019.1.40)

4. SHALL contain [1..*] `participant` (CONF:108)
   a. Contains exactly one [1..1] `Assembler Entry Participant` (templateId: 2.16.840.1.113883.3.5019.1.2)

5. SHALL contain [1..*] `reference` (CONF:17165)
   a. Contains exactly one [1..1] `External Consent Directive Reference Choice` (templateId: 2.16.840.1.113883.3.5019.1.10)

6. SHALL contain exactly one [1..1] `entry` (CONF:17164)
   a. This entry SHOULD contain zero or one [0..1] `@nullFlavor` (CONF:17150)
   b. This entry SHALL contain at least one [1..*] `@typeCode` (CONF:17151), which SHALL be selected from ValueSet `x_ActRelationshipEntry` 2.16.840.1.113883.1.11.19446 STATIC (CONF:17152)
   c. This entry SHALL contain exactly one [1..1] `act`, where its type is CDA Clinical Statement (CONF:17383)

7. SHALL contain at least one [1..*] `reference`, where its type is `Reference Choice` (CONF:16862)

8. SHALL contain at least one [1..*] `entryRelationship`, where its type is `Provenance Metadata Relationship` (CONF:17166)

9. SHALL contain exactly one [1..1] `entryRelationship`, where its type is `Security Label Entry Relationship` (CONF:17167)
Observation Generated By Assembler example

Error: Missing Runtime Class

Observation Generated By Device

[Observation: templateId 2.16.840.1.113883.3.5019.1.14]

The Observation Generated by Device template constrains the CDA to create an exemplar Entry authored by a device, which is comprised of device generated information, and may include device selected preexisting associated entries authored by other persons or devices with provenance information intact. Both the new content authored by the device and any preexisting content included in associated entries may have been facilitated with the assistance of Assembly software, which should be conveyed if known. A Device Generated By Device with Provenance is generated under the auspices of the Organization scoping the role of the Device Assigned Author. This Organization is required to be specified.

The Device Assigned Author, which is required to be specified, generates the Observation entry, which may be associated with an entry generated by a participating Assembler. A participating Assembler is device software, which independently of a device author, collates and repackages selected preexisting content and its associated provenance in accordance with algorithms programmatically selected by the Device Assigned Author as authorized by the scoping Organization. Assembly software is required to be compatible with the formats in which the selected preexisting content is maintained by the custodian.

Note: The participating Assembler is represented by the Assembler Entry Participant Template rather than Assembler Document Participant Template because different participant role types at the CDA Header and Entry. A Device Assigned Author does not make use of a Composer software to generate content as it is programmatically configured to do so without actively engaging with other software such as an EHR Record Entry system. In addition, a Device Assigned Author is not configured to input information reported by informants, who typically report to Provider or Patient Assigned Authors.

A Device Assigned Author may use preexisting content with associated provenance aggregated by participating Assembler software to augment device generated content via associated entries. For example, the device author may select a preexisting condition observation that the device is monitoring accompanied by the authors, informants and devices used to generate a Problem list as input to the device generated Organizer entry to group associated diagnoses, findings, and conditions comprising that list.

As an alternative to a direct association between a device generated entry with another entry or externally reference act, observation, procedure or document, this IG supports specification of the lifecycle relationship about the device generated entry with a predecessor entry using the Provenance Metadata template. A Provenance Metadata entry may be used to specify the state change between a device generated entry and a predecessor entry or referenced external act. It may also be used to convey additional provenance metadata using the Provenance Label entry to list, for example, transforms applied to a Clinical Statement, or the Provenance Policy Information File, which is describes the semantics of any applied Provenance Labels as well as the sender's expectations about how the receiver will handle provenance, e.g., that the receiver will persist the provenance metadata in a manner that binds it to the target content.

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<tbody>
<tr>
<td>Assembler Entry Participant</td>
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<tr>
<td>Device Author Participant</td>
<td></td>
</tr>
<tr>
<td>External Consent Directive Reference Choice</td>
<td></td>
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</tbody>
</table>
1. **SHALL** contain exactly one [1..1] `templateId` (CONF-DPROV-14) such that it
   a. **SHALL** contain exactly one [1..1] `@root`="2.16.840.1.113883.3.5019.1.14"

2. **SHALL NOT** contain [0..0] `informant` with `@xsi:type=Informant12` 

   An Observation Generated by Device by definition consists entirely pre-existing content. Therefore input a content by an informant participant is precluded in the generation of this entry

3. **SHALL** contain [1..*] `author` (CONF:97)

   Specifies provenance-related details about the Device Author participant, which is mandatory for a DPROV conformant Entry.
   a. Contains exactly one [1..1] Device Author Participant (templateId: 2.16.840.1.113883.3.5019.1.8)

4. **SHOULD** contain [0..*] `participant` (CONF:104)

   If needed, an assembler may be specified. e.g., an optional device manager may be involved in recording the results authored by a device.
   a. Contains exactly one [1..1] Assembler Entry Participant (templateId:
      2.16.840.1.113883.3.5019.1.2)

5. **SHOULD** contain [0..*] `participant` (composerParticipant) (CONF:17173)

   a. Contains exactly one [1..1] Composer Entry Participant (templateId:
      2.16.840.1.113883.3.5019.1.6)

6. **SHALL** contain [1..*] `reference` (CONF:17175)

   a. Contains exactly one [1..1] External Consent Directive Reference Choice (templateId:
      2.16.840.1.113883.3.5019.1.10)

7. If section/@nullFlavor is not present, **SHALL** contain [1..1] `entry` (CONF:17174)

   a. Contains exactly one [1..1] CDA Entry

8. **SHALL** contain at least one [1..*] `reference`, where its type is Reference Choice (CONF:16862)

9. **SHALL** contain exactly one [1..1] `entryRelationship`, where its type is Provenance Metadata Relationship (CONF:17050)

10. **SHOULD** contain [0..*] `performer` (CONF:98)

    This performer identifies the operator of the device.
    a. Contains exactly one [1..1] CDA Performer2

11. **SHALL** contain exactly one [1..1] `entryRelationship`, where its type is Security Label Entry Relationship (CONF:17176)

**Observation Generated By Device example**

```
Error: Missing Runtime Class
```

**Observation Generated By Patient**

[Observation: templateId 2.16.840.1.113883.3.5019.1.15]

*The Observation Generated by Patient template constrains the CDA to create an exemplar Entry authored by a patient or their personal representative (hereafter included in the concept of patient), which is comprised of patient generated information, and may include patient selected pre-existing associated entries authored by other persons or*
devices with provenance information intact. Both the new content authored by the patient and any preexisting content included in the associated entries may have been facilitated with the assistance of informants and software devices.

A Observation Generated by Patient does not require that the role of Patient Assigned Author be scoped by an Organization, but that is not precluded. (According to RIM Role definition usage notes: "the Role of "patient" may be played by a person and scoped by the provider organization from which the patient will receive services."). The Patient Assigned Author, which must be specified, generates the entry with the assistance of a composer and may incorporate information reported by informant. The patient generated entry may be associated with an entry generated by an assembler. These facilitating participants may be authorized by a scoping organization, e.g., a Provider's Patient Portal, or may be patient selected, in which case there is no scoping organization:

1. A participating Composer, which is the device software with which a Patient Assigned Author interacts to create new content, such as a Family History Section, and to select and structure preexisting content with provenance, such as a Section containing the Chief Complaint and Reason for Visit with provenance, including the authors, informants, and participating devices used to generate that content. Examples include software used for PHR record entry and for selecting pre-existing content persisted in the PHR or other databases. Any Composer software used is required to be conveyed in order to specify the software that the Patient Assigned Author necessarily used in order to generate the authored document.

2. A participating Assembler, which is device software that collates and repackages selected content in accordance with algorithms selected by the Patient Assigned Author as authorized by e.g., the patient, the patient selected mHealth App or PHR or a Provider's Patient Portal acting as the scoper.

Note: The participating Assembler is represented by the Assembler Entry Level Participant Template rather than Assembler Document Header Participant Template because different participant role types at the CDA Header and Entry. A Patient Assigned Author may use Assembler software to aggregate preexisting content with provenance. For example, the author may select a preexisting medication list accompanied by the authors, informants and devices used to generate that list, and then select that list with the Composer software as part of the input to the composed document after reconciling that medication list with medications listed in the Patient's PHR. Any Assembler software should be conveyed if known.

3. A participating Informant, who is either an assigned provider or professional, such as a teacher or office staff, authorized by a scoping organization to provide information about the patient, or a related person, such as a patient's family member or an acquaintance, who is not scoped by an organization. Any Informant participant is required to be conveyed if known.

As an alternative to a direct association between a patient generated entry with another entry or externally reference act, observation, procedure or document, this IG supports specification of the lifecycle relationship about the patient generated entry with a predecessor entry using the Provenance Metadata template. A Provenance Metadata entry may be used to specify the state change between a patient generated entry and a predecessor entry or referenced external act. It may also be used to convey additional provenance metadata using the Provenance Label entry to list, for example, transforms applied to a Clinical Statement, or the Provenance Policy Information File, which is describes the semantics of any applied Provenance Labels as well as the sender's expectations about how the receiver will handle provenance, e.g., that the receiver will persist the provenance metadata in a manner that binds it to the target content.

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<tr>
<td></td>
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<tr>
<td></td>
<td>Patient Author Participant</td>
</tr>
<tr>
<td></td>
<td>Provenance Informant Participant Choice</td>
</tr>
</tbody>
</table>
1. **SHALL** contain exactly one [1..1] `templateId` (CONF-DPROV-15) such that it
   a. **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.3.5019.1.15"

2. **SHALL** contain [1..*] `author` (Patient Author Participant) (CONF:95)
   a. Contains exactly one [1..1] *Patient Author Participant* (templateId: 
   2.16.840.1.113883.3.5019.1.17)

3. **SHOULD** contain [0..*] `participant` (Assembler Entry participant) (CONF:96)
   
   If needed, an assembler may be specified.
   a. Contains exactly one [1..1] *Assembler Entry Participant* (templateId: 
   2.16.840.1.113883.3.5019.1.2)

4. **SHALL** contain [1..*] `participant` (Composer Entry Participant) (CONF:193)
   
   *For this type of document, the Composer Document Header Participant must be used to identify any software used to compose existing content as determined by the Organization scoping the Assembler/Device/provider/patient Assigned Author.*
   a. Contains exactly one [1..1] *Composer Entry Participant* (templateId: 
   2.16.840.1.113883.3.5019.1.6)

5. **SHALL** contain [1..*] `provenanceInformantParticipant` (Provenance Informant Participant) (CONF:194)
   a. Contains exactly one [1..1] *Provenance Informant Participant Choice* (templateId: 
   2.16.840.1.113883.3.5019.1.21)

6. **SHALL** contain [1..*] `reference` (CONF:17142)
   a. Contains exactly one [1..1] *External Consent Directive Reference Choice* (templateId: 
   2.16.840.1.113883.3.5019.1.10)

7. If section/@nullFlavor is not present, **SHALL** contain [1..1] `entry` (CONF:17141)
   a. Contains exactly one [1..1] CDA Entry

8. **SHALL** contain at least one [1..*] `reference`, where its type is Reference Choice (CONF:16862)

9. **SHALL** contain exactly one [1..1] `entryRelationship`, where its type is Provenance Metadata Relationship (CONF:17035)

10. **SHALL** contain exactly one [1..1] `entryRelationship`, where its type is Security Label Entry Relationship (CONF:17143)

### Observation Generated By Patient example

```xml
<!-- ObservationGeneratedByPatient -->
<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.3.5019.1.26" assigningAuthorityName="HL7"/>
  <code code="420144006" displayName="Propensity to adverse reactions" codeSystemName="SNOMED CT" codeSystem="2.16.840.1.113883.6.96"/>
  <statusCode code="completed"/>
  <!-- @value= AllergyOnsetDate(date?) -->
  <effectiveTime value="2014"/>
  <!-- Patient Author -->
  <author>
    <!-- Mandatory Author Participation -->
```
<templateId root="2.16.840.1.113883.3.5019.1.10"
assigningAuthorityName="HL7"/>

<!--  Mandatory date time-->
<time value="20141021120500-0500"/>
<assignedAuthor>
 <!--  Mandatory Assigned Author -->
<templateId root="2.16.840.1.113883.3.5019.1.9"
assigningAuthorityName="HL7"/>
 <!--  Mandatory Author Identifier - at least one is required -->
?id root="7bb42322-9de2-4d40-94c9-2fc23979d5fc"
assigningAuthorityName="Example Organization"/>
<!-- Dynamic value set binding to "2.16.840.1.113883.11.20.12.1" -->
<code code="ONESELF" displayName="self"
codeSystem="2.16.840.1.113883.5.111"/>
<addr>
<streetAddressLine>Example Address Line</streetAddressLine>
<city>ExampleCity</city>
<state>NH</state>
<postalCode>99999</postalCode>
</addr>
<telecom value="tel:+1-555-555-1212" use="WP"/>
<telecom value="mailto:Hippocrates@Clinic.org" use="EC"/>
<assignedPerson>
 <!--  Mandatory Assigned Authoring Person -->
<templateId root="2.16.840.1.113883.3.5019.1.5"
assigningAuthorityName="HL7"/>
 <!--  Mandatory Name -->
<name>
<given>Mary</given>
<given>A</given>
<family>Everyperson</family>
</name>
</assignedPerson>
</author>
<!-- Mandatory Composer, e.g., PHR, optionally specified -->
<participant typeCode="DEV">
<functionCode ParticipationFunction= "Composer">
 <!-- Composer Entry Level Participant -->
<templateId root="2.16.840.1.113883.3.5019.1.22"
assigningAuthorityName="HL7"/>
 <!--  Mandatory date time-->
<time value="20141021120500-0500"/>
<participantRole classCode="MANU">
<playingDevice>
 <!-- ParticipatingDeviceEntity -->
<templateId root="2.16.840.1.113883.3.5019.1.28"/>
<manufacturerModelName>PHR4US</manufacturerModelName>
<softwareName>PHR composer software</softwareName>
</playingDevice>
</participantRole>
</functionCode>
</participant>
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<participantRole classCode="MANU">
<addr>
The Observation Generated by Provider template constrains the CDA to create an exemplar Entry authored by a provider. A provider generated entry is comprised of provider generated information, and may be associated with entries comprised of preexisting content that the provider selected with assistance of composing software or was automatically associated by assembly software. The composer or assembly software facilitated content is comprised of preexisting entries authored by other persons, who may have used assembly or composer software or have incorporated informant reported information, or by devices with associated provenance information intact. An Observation Generated by Provider is generated under the auspices of the Organization scoping the role of the Provider Assigned Author. This Organization is required to be specified.

The Provider Assigned Author, which is required to be specified, generates the entry and any associated entries with the assistance of one or more of the following participants, as applicable and authorized by the scoping Organization:

1. A participating Composer, which is any device software with which a Provider Assigned Author interacts to create new content and to select and structure preexisting content and its associated provenance including the authors, informants, and participating devices used to generate that content. The Composer software is required to be compatible with the formats in which the selected preexisting content is maintained by the custodian. Examples include software used for EHR record entry and for selecting preexisting content persisted in the EHR or other databases. Any Composer software used is required to be conveyed in order to specify the software that the Provider Assigned Author necessarily used in order to generate the authored entry.

2. A participating Assembler is device software, which independently of a person author, collates and repackages selected preexisting content and its associated provenance in accordance with algorithms selected by the Provider Assigned Author as authorized by the scoping Organization. Assembly software is required to be compatible with the formats in which the selected preexisting content is maintained by the custodian. A Provider Assigned Author may use preexisting content with associated provenance aggregated by participating Assembler software to augment provider generated content with associated preexisting entries. For example, the author may select a preexisting medication list accompanied by the authors, informants and devices used to generate that list, and then select that list with the Composer software as part of the input to the composed associated entries after reconciling that medication list with medications listed in the Provider's EHR.

Any Assembler software should be conveyed if known.

3. A participating Informant, who is either an assigned provider or professional, such as a teacher or office staff, authorized by a scoping organization to provide information about the patient, or a related person, such as a patient's family member or an acquaintance, who is not scoped by an organization. Any Informant participant is required to be conveyed if known.

As an alternative to a direct association between a provider generated entry with another entry or externally reference act, observation, procedure or document, this IG supports specification of the lifecycle relationship about the provider generated entry with a predecessor entry using the Provenance Metadata template. A Provenance
Metadata entry may be used to specify the state change between a provider generated entry and a predecessor entry or referenced external act.

It may also be used to convey additional provenance metadata using the Provenance Label entry to list, for example, transforms applied to a Clinical Statement, or the Provenance Policy Information File, which is describes the semantics of any applied Provenance Labels as well as the sender's expectations about how the receiver will handle provenance, e.g., that the receiver will persist the provenance metadata in a manner that binds it to the target content.

Both the new content authored by the provider and any preexisting content in associated entries may have been facilitated with the assistance of informants and software devices, which are required to be conveyed.

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<td>Provenance Metadata Relationship</td>
</tr>
<tr>
<td></td>
<td>Provider Author Participant</td>
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</tbody>
</table>

1. **SHALL** contain exactly one [1..1] `templateId` (CONF-DPROV-16) such that it
   a. **SHALL** contain exactly one [1..1] `@root"=2.16.840.1.113883.3.5019.1.16"
2. **SHALL** contain [1..*] `author` (CONF:89)
   a. Contains exactly one [1..1] `Provider Author Participant` (templateId:
      2.16.840.1.113883.3.5019.1.40)
3. **SHOULD** contain [0..*] `participant` (CONF:90)
   For this type of entry, Assembler Entry Level Participant should be used to identify any software used to assemble the content generated by the Provider Generated Author.
   a. Contains exactly one [1..1] `Assembler Entry Participant` (templateId:
      2.16.840.1.113883.3.5019.1.2)
4. **SHALL** contain [1..*] `participant` (CONF:191)
   For this type of document, the Composer Document Header Participant must be used to identify any software used to compose existing content as determined by the Organization scoping the Assembler/Device/provider/patient Assigned Author.
   a. Contains exactly one [1..1] `Composer Entry Participant` (templateId:
      2.16.840.1.113883.3.5019.1.6)
5. **SHALL** contain [1..*] `provenanceInformantParticipant` (CONF:192)
   a. Contains exactly one [1..1] `Provenance Informant Participant Choice` (templateId:
      2.16.840.1.113883.3.5019.1.21)
6. **SHALL** contain [1..*] `reference` (CONF:17129)
   a. Contains exactly one [1..1] `External Consent Directive Reference Choice` (templateId:
      2.16.840.1.113883.3.5019.1.10)
7. If section/@nullFlavor is not present, **SHALL** contain [1..1] `entry` (CONF:17128)
   a. Contains exactly one [1..1] CDA Entry
8. **SHALL** contain at least one [1..*] `reference`, where its type is `Reference Choice` (CONF:16862)
9. **SHALL** contain exactly one [1..1] `entryRelationship`, where its type is `Provenance Metadata Relationship` (CONF:17032)
10. SHALL contain exactly one [1..1] entryRelationship, where its type is Security Label Entry Relationship (CONF:17130)

Observation Generated By Provider example

Error: Missing Runtime Class

Privacy Consent Directive Type Security Observation

[Observation: templateId 2.16.840.1.113883.3.5019.1.19]

<table>
<thead>
<tr>
<th>Contained By</th>
<th>Contains</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

1. SHALL contain exactly one [1..1] templateId (CONF-DPROV-19) such that it
   a. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.3.5019.1.19"

2. SHALL conform to Security Observation template (templateId: 2.16.840.1.113883.3.5019.1.35)

3. SHALL contain exactly one [1..1] code with @xsi:type="CD" (CONF:17328), which SHALL be selected from ValueSet SecurityCategoryObservationType 2.16.840.1.113883.1.11.20459 STATIC (CONF:17329)

4. SHALL contain exactly one [1..1] value with @xsi:type="CE" (CONF:17330), which SHALL be selected from ValueSet ActConsentDirectiveType 2.16.840.1.113883.1.11.20551 DYNAMIC (CONF:17331)

5. SHOULD contain zero or one [0..1] text (CONF:17332)

Privacy Consent Directive Type Security Observation example

Error: Missing Runtime Class

Provenance Confidence Label

[Observation: templateId null]

<table>
<thead>
<tr>
<th>Contained By</th>
<th>Contains</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. SHALL contain exactly one [1..1] id (CONF:16947)

2. SHALL contain exactly one [1..1] code (CONF:16948), which SHALL be selected from ValueSet SecurityIntegrityConfidenceObservationType 2.16.840.1.113883.1.11.20460 STATIC (CONF:17102)

3. SHALL contain exactly one [1..1] statusCode (CONF:16950)

4. SHALL contain exactly one [1..1] effectiveTime (CONF:16949)

5. SHALL contain exactly one [1..1] value with @xsi:type="ANY" (CONF:16952), which SHALL be selected from ValueSet SecurityIntegrityConfidenceObservationValue 2.16.840.1.113883.1.11.20484 STATIC (CONF:17103)

6. SHALL contain exactly one [1..1] text (CONF:16951)

Provenance Confidence Label example

Error: Missing Runtime Class
Provenance Metadata

[Act: templateId 2.16.840.1.113883.3.5019.1.22]

Provenance Metadata records the actions by a performer on predecessor entries or external references that result in the current state of the successor to which this metadata applies. The changed state or "state transition" is conveyed with the ProvenanceEvent ActCodes. Note that the current value set is limited to a subset of codes in the ActStatus and DocumentCompletion code systems, which is acknowledged as being insufficient. However, there is ongoing development of a more extensive value set that will likely be substituted when this DSTU goes to Normative ballot.

The Provenance Metadata template may be used to connect predecessor artifacts with a target successor, which is the subject of this metadata, via an inverted SUBJ ActRelationship. It may also be used to add additional provenance metadata to a Clinical Statement such as Provenance Labels that indicate the information source, e.g., reported by a patient or asserted by another provider; the level of confidence the Provenance Metadata author has in the reliability of the target entry; any manipulation of the content such as translations or transforms, redaction or masking (if policy permits disclosing these flags); and evidence that the content or its aggregated predecessor content was digitally signed by its author or authenticator prior to breaking the signature.

1. SHALL contain exactly one [1..1] templateId (CONF-DPROV-22) such that it
   a. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.3.5019.1.22"
2. SHALL contain exactly one [1..1] @classCode="STC" (CONF:82), where the @code SHALL be selected from (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)(CONF:16861)
3. SHALL contain exactly one [1..1] @moodCode="EVN" (CONF:27), where the @code SHALL be selected from (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)(CONF:124)
4. SHALL contain at least one [1..*] id (CONF:17091)
5. SHALL contain exactly one [1..1] code (CONF:25), where the @code SHALL be selected from ValueSet ProvenanceEventCurrentState 2.16.840.1.113883.1.11.20547 DYNAMIC (CONF:24)
6. SHALL contain exactly one [1..1] effectiveTime (CONF:26)
7. SHALL contain [1..*] entryAct (CONF:130)
   a. Contains exactly one [1..1] CDA Clinical Statement
8. SHALL contain at least one [1..*] reference, where its type is Reference Choice (CONF:16862)
9. SHALL contain [1..*] author (Provenance Author) (CONF:129)
   a. Contains exactly one [1..1] Provenance Author Participant Choice (templateId: 2.16.840.1.113883.3.5019.1.20)
10. SHALL contain [1..*] participant (CONF:132)
    This is the Assembler that authored the Provenance Metadata. If an Assembler was used to generate the subject of Provenance Metadata, that relationship is conveyed by the entry's Assembler participation.
    a. Contains exactly one [1..1] Assembler Entry Participant (templateId: 2.16.840.1.113883.3.5019.1.2)
11. SHALL contain [1..*] participant (CONF:154)
    This is the Composer that an author used to author the Provenance Metadata. If a Composer was used to generate the subject of Provenance Metadata, that relationship is conveyed by the entry's Composer participation.
    a. Contains exactly one [1..1] Composer Entry Participant (templateId: 2.16.840.1.113883.3.5019.1.6)
12. SHALL contain at least one [1..*] performer, where its type is Provenance Performer Participant Choice (CONF:16863)
13. **SHOULD** contain zero or more [0..*] `provenanceLabelComponent`, where its type is `Provenance Label Component Choice` (CONF:16865)

14. **SHOULD** contain zero or more [0..*] `entryRelationship` (Signature Observation Component), where its type is `Provenance Signature Observation` (CONF:16864)

15. **SHOULD** contain zero or more [0..*] `entryRelationship`, where its type is `Provenance Policy Information File Relationship` (CONF:17092)

16. **SHOULD** satisfy: zero or one [0..1] @nullFlavor="NI". Analysis rule on entry relationships generally: null flavors are allowed per base CDA schema to use the Provenance Metadata template for purposes of adding provenance metadata without relating the successor target entry to a predecessor. (CONF:17423)

**Provenance Metadata example**

```xml
<!-- Provenance Metadata - Entry Relationship -->
<entryRelationship typeCode="SUBJ">
    <templateId root="2.16.840.1.113883.3.5019.1.32"/>
    <!-- Provenance Template specifies certain actions-->
    <act classCode="STC" moodCode="EVN">
        <!-- Provenance Metadata -->
        <templateId root="2.16.840.1.113883.3.5019.1.12"/>
        <!-- Provenance Metadata "code" event, binding to value set 2.16.840.1.113883.11.20527 in code system ActCode-->
        <code code="DO" displayName="documented" codeSystem="2.16.840.1.113883.5.4" codeSystemName="ActCode"/>
        <!-- Person responsible for the event in "code" -->
        <performer typeCode="PRF">
            <time value="20141021120500-0500"/>
            <assignedEntity>
                <id root="4d0c8e77-ea1d-4f41-9858-88806852e774" assigningAuthorityName="Example Organization"/>
            </assignedEntity>
        </performer>
        <!-- Root means NPI and the @extension specifies the value of the NPI -->
        <id root="2.16.840.1.113883.4.6" extension="99999999"/>
        <!-- Dynamic value set binding to "2.16.840.1.114222.4.11.1066" -->
        <code code="1223G0001X" displayName="General Practice" codeSystem="2.16.840.1.113883.6.101"/>
        <addr>
            <streetAddressLine>Example Address Line</streetAddressLine>
            <city>ExampleCity</city>
            <state>NH</state>
            <postalCode>99999</postalCode>
        </addr>
        <telecom value="tel:+1-555-555-1212" use="WP"/>
        <telecom value="mailto:Hippocrates@Clinic.org" use="EC"/>
    </act>
</entryRelationship>
```

<templateId root="2.16.840.1.113883.3.5019.1.5" assigningAuthorityName="HL7"/>
<!-- Mandatory Name -->
<name>
  <prefix>Dr.</prefix>
  <family>Hippocrates</family>
  <given>Harold</given>
</name>
</assignedPerson>
<!-- Scoping Organization -->
<representedOrganization>
  <templateId root="2.16.840.1.113883.3.5019.1.19" assigningAuthorityName="HL7"/>
  <id root="96449e6d-24c8-4be7-a02c-4536f83f4423" assigningAuthorityName="Issuing Organization"/>
  <name>Example Organization</name>
  <telecom value="tel:+1-555-555-1212" use="WP"/>
  <addr>
    <streetAddressLine>Example Organization Address Line</streetAddressLine>
    <city>Example City</city>
    <state>NH</state>
    <postalCode>99999</postalCode>
  </addr>
</representedOrganization>
</assignedEntity>
</performer>
<!--Provenance Metadata Author - this is the author of the Provenance Metadata recording the performer's action that transitioned the Provenance Metadata subject to its current state. E.g., Dr. Patricia Psych documents that Dr. Hippocrates completed an observation about the patient's cannabis dependence using predecessor entries or external references which were input into the observation that Dr. Hippocrates entered into the patient's record.-->
<assignedAuthor>
  <!-- Mandatory Author Identifier - if Provider Author is specified, and if a HIPAA covered provider, then at least one identifier must be a National Provider Identifier where the id/@root ="2.16.840.1.113883.4.6" is the NPI number for the provider.-->
  <id extension="1234567890" root="2.16.840.1.113883.4.6" assigningAuthorityName="National Plan and Provider Enumeration System"/>
  <!-- Dynamic value set binding to Healthcare Provider Taxonomy (NUCC-HIPAA) "2.16.840.1.114222.4.11.1066" -->
  <code code="207LA0401X" displayName="Addiction Medicine" codeSystem="2.16.840.1.113883.6.101" codeSystemName="NUCC"/>
  <addr>
    <streetAddressLine>1004 Healthcare Drive</streetAddressLine>
    <city>Portland</city>
    <state>OR</state>
    <postalCode>99123</postalCode>
  </addr>
  <telecom use="WP" value="tel:+1(555)555-1004"/>
  <assignedPerson>
    <name>
      <given>Patricia</given>
      <given qualifier="CL">Patty</given>
    </name>
  </assignedPerson>
</assignedAuthor>
<family>Psych</family>
<suffix qualifier="AC">M.D.</suffix>
</name>
</assignedPerson>
</assignedAuthor>
<!-- Author's Mandatory Provenance Scoping Organization -->
<representedOrganization>
<templateId root="2.16.840.1.113883.3.5019.1.26"
assigningAuthorityName="HL7 Security CBCC"/>
<!-- NPI for the organization -->
<id root="1881638559" assigningAuthorityName="National Plan and Provider Enumeration System"/>
</representedOrganization>
</assignedAuthor>
</author>
<!-- Mandatory Assembler specified -->
<participant typeCode="DEV" nullFlavor="NA"/>
<!-- Mandatory Composer specified -->
<participant typeCode="DEV"/>
<!-- Composer Entry Level Participant used by Dr. Patricia Psych to author the Provenance Metadata--> 
<templateId root="2.16.840.1.113883.3.5019.1.6"
assigningAuthorityName="HL7"/>
<!-- Mandatory date time -->
<time value="20141021120500-0500"/>
<participantRole classCode="MANU"/>
</playingDevice>
<!-- ParticipatingDeviceEntity -->
<manufacturerModelName>software manufacturer</manufacturerModelName>
<softwareName>assembler software</softwareName>
<!-- Composer - Device AssociatedEntity with UDI & SNOMED Device code. Could be GMDN. templateId null.-->
<id root="2.16.840.1.113883.3.3719"
extension="(01)51022222233336(11)141231(17)150707(10)A213B1(21)1234"
assigningAuthorityName="GS1 2.51.1.1"/>
<code code="46462944003" codeSystem="2.16.840.1.113883.6.96"
displayName=" Hospital-administration information system application software"/>
</scopingOrganization>
<templateId root="2.16.840.1.113883.3.5019.1.26"
assigningAuthorityName="HL7 CBCC"/>
<id nullFlavor="NA"/>
</name>
<vendorOrganization name="Example Organization"
<telecom value="tel:+1-555-555-1212" use="WP"/>
<addr>
<streetAddressLine>Example Organization Address Line</streetAddressLine>
<city>ExampleCity</city>
<state>NH</state>
<postalCode>99999</postalCode>
</addr>
</vendorOrganization>
<!DOCTYPE html>
<html>
<head>
</head>
<body>

Provenance Policy Information File

[Act: templateId 2.16.840.1.113883.3.5019.1.24]

<table>
<thead>
<tr>
<th>Contained By</th>
<th>Contains</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Provenance Author Participant Choice</td>
</tr>
</tbody>
</table>

1. SHALL contain exactly one [1..1] templateId (CONF-DPROV-24) such that it
   a. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.3.5019.1.24"

2. SHALL contain exactly one [1..1] @classCode (CONF:17287), which SHALL be selected from ValueSet ActClassPolicy 2.16.840.1.113883.1.11.19818 STATIC (CONF:17288)

3. SHALL contain at least one [1..*] id (CONF:17289)

</body>
</html>
4. SHALL contain exactly one [1..1] code (CONF:17290), which SHALL be selected from ValueSet ActPolicyType 2.16.840.1.113883.1.11.19886 STATIC (CONF:17291)

5. SHALL contain exactly one [1..1] effectiveTime (CONF:17292)

6. SHALL contain exactly one [1..1] text (CONF:17293)

7. SHOULD contain [0..*] author (CONF:56)

Specifies provenance-related details about the Author participant.

a. Contains exactly one [1..1] Provenance Author Participant Choice (templateId: 2.16.840.1.113883.3.5019.1.20)

Provenance Policy Information File example

Error: Missing Runtime Class

Provenance Source Label

[Observation: templateId null]

<table>
<thead>
<tr>
<th>Contains By</th>
<th>Contains</th>
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<tr>
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</tr>
</tbody>
</table>

1. SHALL contain exactly one [1..1] id (CONF:16954)

2. SHALL contain exactly one [1..1] code (CONF:16955), which SHALL be selected from ValueSet SecurityIntegrityProvenanceObservationType 2.16.840.1.113883.1.11.20466 STATIC (CONF:17104)

3. SHALL contain exactly one [1..1] statusCode (CONF:16957)

4. SHALL contain exactly one [1..1] effectiveTime (CONF:16956)

5. SHALL contain exactly one [1..1] value with @xsi:type="ANY" (CONF:16959), which SHALL be selected from ValueSet SecurityIntegrityProvenanceObservationValue 2.16.840.1.113883.1.11.20485 STATIC (CONF:17105)

6. SHALL contain exactly one [1..1] text (CONF:16958)

Provenance Source Label example

Error: Missing Runtime Class

Purpose Of Use Security Observation

[Observation: templateId 2.16.840.1.113883.3.5019.1.28]

<table>
<thead>
<tr>
<th>Contains By</th>
<th>Contains</th>
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<tbody>
<tr>
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</tr>
</tbody>
</table>

1. SHALL contain exactly one [1..1] templateId (CONF-DPROV-28) such that it

a. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.3.5019.1.28"

2. SHALL conform to Security Observation template (templateId: 2.16.840.1.113883.3.5019.1.35)

3. SHALL contain exactly one [1..1] code (CONF:17253), which SHALL be selected from ValueSet SecurityControlObservationType 2.16.840.1.113883.1.11.20460 STATIC (CONF:17254)

4. SHALL contain exactly one [1..1] value (CONF:17255), which SHALL be selected from ValueSet PurposeOfUse 2.16.840.1.113883.1.11.20448 STATIC (CONF:17256)
The Purpose Of Use Security Observation value attribute shall be selected from the Purpose Of Use Policy valueset contained by the Security Control Observation Value valueset.

5. **SHOULD** contain zero or one \([0..1]\) **text** (CONF:17257)

Purpose Of Use Security Observation example

Error: Missing Runtime Class

---

Refrain Policy Security Observation

[Observation: templateId 2.16.840.1.113883.3.5019.1.29]

The Obligation Security Observation value attribute shall be selected from the Obligation Policy valueset contained by the Security Control Observation Value valueset.

<table>
<thead>
<tr>
<th>Contained By</th>
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</tr>
</tbody>
</table>

1. **SHALL** contain exactly one \([1..1]\) **templateId** (CONF-DPROV-29) such that it
   a. **SHALL** contain exactly one \([1..1]\) \[@root\]="2.16.840.1.113883.3.5019.1.29"

2. **SHALL** conform to Security Observation template (templateId: 2.16.840.1.113883.3.5019.1.35)

3. **SHALL** contain exactly one \([1..1]\) **code** (CONF:17263), which **SHALL** be selected from ValueSet SecurityControlObservationType 2.16.840.1.113883.1.11.20460 STATIC (CONF:17264)

4. **SHALL** contain exactly one \([1..1]\) **value** (CONF:17265), which **SHALL** be selected from ValueSet RefrainPolicy 2.16.840.1.113883.1.11.20446 STATIC (CONF:17266)

   The Refrain Policy Security Observation value attribute shall be selected from the Refrain Policy valueset contained by the Security Control Observation Value valueset.

5. **SHOULD** contain zero or one \([0..1]\) **text** (CONF:17267)

Refrain Policy Security Observation example

Error: Missing Runtime Class

---

Security Label

[Organizer: templateId 2.16.840.1.113883.3.5019.1.34]

The CDA security label is a set of security observations that allow for specific privacy metadata to be identified and assigned to any entry in a document if that entry overrides or constrains in any way the overall confidentiality of the document or section or specifies additional security label observations. For instance if a document is identified as "Restricted" but a specific entry is of "Normal" confidentiality, a specific SecurityObservation will be used to set the confidentiality of that entry to "Normal". Similarly if an entry has additional security handling or obligations, they may be added using this template to the appropriate entry.

The cda security label is required to contain, at a minimum, security observations to represent confidentiality, sensitivity, and governing privacy policy(s), which dictates the level of confidentiality. The cda security label is also required to include any handling instructions dictated by applicable policy, which typically stipulate permissible purpose of use, and may specify obligations and refrain policies listing prohibited actions. Security labels are applied by the senders and processed by the receiver(s) of the information.
As a precondition of generating security labels, the sender’s system must be capable of determining the sensitivity of information entered into the system based on social perceptions of the vulnerability or risk of stigma that may result from unauthorized access, use, or disclosure of clinical facts contained in the information. Information sensitivity may be stipulated by organizational or jurisdictional privacy policy. This may be done manually by the author at the time of entry; algorithmically discerned by the presence of codes within structured data; or by analyzing contextual information related to the entry of unstructured data, e.g., kind of document or entry [Consult Note], type of service [assessment], the setting [inpatient], and subject matter of the entry [addiction psychiatry], and the author’s role [psychiatrist] to generate a LOINC Clinical Document code to be applied to the information.

The sender’s access control system must be capable of generating security labels using a security labeling service. This service assigns security label codes based on the information sensitivity in accordance with the overarching privacy policy set, which combines and reconciles applicable organizational, jurisdictional, and patient privacy policies [consent directives]. The handling instructions are determined by matching the permissible purpose of use against those for which the receiver is authorized, and by deriving the obligations and prohibitions from the privacy policy set. Once all information components are labeled, the security label service labels the document header with the most restrictive confidentiality code assigned within the document.

Prior to any disclosure, the sending system must be capable of executing stored procedures based upon request type, destination authorizations, environmental factors and security labels assigned to the information being disclosed to perform privacy protective functions including application of privacy marks with warnings and confidentiality notices, which the receiving system must display to end users; and masking, redaction, anonymization, and minimizing the data disclosed as required by the security label obligations and refrain policies.

<table>
<thead>
<tr>
<th>Contained By</th>
<th>Contains</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Provenance Author Participant Choice</td>
</tr>
</tbody>
</table>

1. SHALL contain exactly one [1..1] `templateId` (CONF-DPROV-34) such that it
   a. SHALL contain exactly one [1..1] `@root"2.16.840.1.113883.3.5019.1.34"
2. SHALL contain exactly one [1..1] `@moodCode"EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF:16830)
3. SHALL contain at least one [1..*] `id` (CONF:17193)
4. SHOULD contain zero or one [0..1] `effectiveTime` (CONF:17194)
5. SHALL contain exactly one [1..1] `statusCode` (CONF:9054)/@code="active" `Active (CodeSystem: 2.16.840.1.113883.5.14 ActStatus) (CONF:16831)

   Default "active" status.
6. SHALL contain at least one [1..*] `component`, where its type is Confidentiality Security Observation Component (CONF:17195)
7. SHALL contain at least one [1..*] `component`, where its type is Sensitivity Security Observation Component (CONF:17196)
8. SHALL contain at least one [1..*] `component`, where its type is Compartment Security Observation Component (CONF:17197)
9. SHALL contain at least one [1..*] `component`, where its type is Privacy Consent Directive Type Security Observation Component (CONF:17198)
10. SHALL contain at least one [1..*] `component`, where its type is US Privacy Law Security Observation Component (CONF:17199)
11. SHALL contain at least one [1..*] `component`, where its type is Purpose Of Use Security Observation Component (CONF:17200)
12. SHALL contain at least one [1..*] `component`, where its type is Obligation Security Observation Component (CONF:17201)
13. SHALL contain at least one [1..*] `component`, where its type is Refrain Policy Security Observation Component (CONF:17202)
14. SHALL contain at least one [1..*] `securityPolicyInformationFileReference`, where its type is Security Policy Information File Reference (CONF:17203)
15. SHOULD contain [0..*] author (CONF:56)

Specifies provenance-related details about the Author participant, which is mandatory for this type of section. Author participation constrained for a section generated by a Provider, a Patient, or a Device.

a. Contains exactly one [1..1] Provenance Author Participant Choice (templateId: 2.16.840.1.113883.3.5019.1.20)

Security Label example

```xml
<entry typeCode="COMP">
<!-- Security Label Entry to indicate the precise/computable Security Labels for the Document -->
<templateId root="2.16.840.1.113883.3.3251.1.9" assigningAuthorityName="HL7 Security CBCC "/>
<organizer classCode="CLUSTER" moodCode="EVN">
<!-- Privacy Annotations are organized using template "2.16.840.1.113883.3.3251.1.4" -->
<templateId root="2.16.840.1.113883.3.3251.1.4" assigningAuthorityName="HL7 Security CBCC"/>
<statusCode code="active"/>
<component typeCode="COMP">
<observation classCode="OBS" moodCode="EVN">
<!-- Security Label Observation -->
<templateId root="2.16.840.1.113883.3.445.21" assigningAuthorityName="HL7 CBCC"/>
<!-- Confidentiality Security Observation template -->
<templateId root="2.16.840.1.113883.3.5019.1.5" assigningAuthorityName="HL7 CBCC"/>
<code code="SECCLASSOBS" codeSystem="2.16.840.1.113883.1.11.20458" displayName="Security Classification Observation Type" codeSystemName="SecurityClassificationObservationType Value Set"/>
<!-- Value set constraint: Confidentiality value set "2.16.840.1.113883.1.11.10228", which is contained in Security Classification Observation Value "2.16.840.1.113883.1.11.20479" -->
<value xsi:type="CE" code="R" codeSystem="2.16.840.1.113883.1.11.10228" codeSystemName="Confidentiality Value Set" displayName="restricted">
<originalText>Privacy metadata indicating highly sensitive, potentially stigmatizing information, which presents a high risk to the information subject if disclosed without authorization.</originalText>
</value>
</observation>
</component>
</component>
<component typeCode="COMP">
<observation classCode="OBS" moodCode="EVN">
<!-- Security Label Observation -->
<templateId root="2.16.840.1.113883.3.445.12" assigningAuthorityName="HL7 CBCC"/>
<!-- Sensitivity Security Observation template -->
<templateId root="2.16.840.1.113883.3.5019.1.14" assigningAuthorityName="HL7 CBCC"/>
<code code="SECCATOBS" codeSystem="2.16.840.1.113883.1.11.20459" displayName="SecurityCategoryObservationType Value Set"/>
</component>
</observation>
</component>
```

<!-- Value set constraint: Security InformationSensitivityPolicy Observation Value "2.16.840.1.113883.1.11.20428" contained in the SecurityCategoryObservationValue "2.16.840.1.113883.1.11.20470" -->
<value xsi:type="CE" code="ETH" codeSystem="2.16.840.1.113883.1.11.20428" codeSystemName="InformationSensitivityPolicy" displayName="substance abuse information sensitivity">
<originalText>Policy for handling alcohol or drug-abuse information, which will be afforded heightened confidentiality. Information handling protocols based on organizational policies related to alcohol or drug-abuse information that is deemed sensitive.</originalText>
</value>
</observation>
</component>

<component typeCode="COMP">
<observation classCode="OBS" moodCode="EVN">
<templateId root="2.16.840.1.113883.3.445.21" assigningAuthorityName="HL7 CBCC"/>
<templateId root="2.16.840.1.113883.3.5019.1.8" assigningAuthorityName="HL7 CBCC"/>
<code code="SECCATOBS" codeSystem="2.16.840.1.113883.1.11.20459" displayName="Privacy Consent Directive Type Security Observation" codeSystemName="SecurityCategoryObservationType Value Set"/>
<value xsi:type="CE" code="IDSCL" codeSystem="2.16.840.1.113883.5.1063" codeSystemName="HL7 Security Observation Value Code System" displayName="information disclosure">
<originalText>Consent to have collected healthcare information disclosed.</originalText>
</value>
</observation>
</component>

<component typeCode="COMP">
<observation classCode="OBS" moodCode="EVN">
<templateId root="2.16.840.1.113883.3.445.21" assigningAuthorityName="HL7 CBCC"/>
<templateId root="2.16.840.1.113883.3.5019.1.15" assigningAuthorityName="HL7 CBCC"/>
<code code="SECCATOBS" codeSystem="2.16.840.1.113883.1.11.20459" displayName="US Privacy Law Security Observation" codeSystemName="SecurityCategoryObservationType Value Set"/>
<value xsi:type="CE" code="Title38Section7332" codeSystem="2.16.840.1.113883.1.11.20427" codeSystemName="ActUSPrivacyLaw" displayName="information disclosure">
<originalText>Consent to have collected healthcare information disclosed.</originalText>
</value>
</observation>
</component>
<component typeCode="COMP">
<observation classCode="OBS" moodCode="EVN">
<!-- Security Label Observation --></component>
<templateId root="2.16.840.1.113883.3.445.21" assigningAuthorityName="HL7 CBCC"/>
<!-- Compartment Type Security Observation template --></templateId>
<templateId root="2.16.840.1.113883.3.5019.1.4" assigningAuthorityName="HL7 CBCC"/>
<code code="SECCATOBS" codeSystem="2.16.840.1.113883.1.11.20459" displaySystemName="Compartment Security Observation" codeSystemName="SecurityCategoryObservationType Value Set"/>
<!-- Value set constraint: Compartment "2.16.840.1.113883.1.11.20478" value set contained in the SecurityCategoryObservationValue "2.16.840.1.113883.1.11.20470" -->
<value xsi:type="CE" code="IDSCL" codeSystem="2.16.840.1.113883.5.1063" codeSystemName="HL7 Security Observation Value Code System" displaySystemName="research project compartment">
<originalText> A security category label field value, which indicates that access and use of an IT resource is restricted to members of a research project. </originalText>
</value>
</component>

<component typeCode="COMP">
<observation classCode="OBS" moodCode="EVN">
<!-- Security Observation --></component>
<templateId root="2.16.840.1.113883.3.445.21" assigningAuthorityName="HL7 CBCC"/>
<!-- Purpose Of Use Security Observation template --></templateId>
<templateId root="2.16.840.1.113883.3.445.22" assigningAuthorityName="HL7 CBCC"/>
<code code="SECCONOBS" codeSystem="2.16.840.1.113883.1.11.20457" displaySystemName="Purpose Of Use Security Observation" codeSystemName="SecurityControlObservationType Value Set"/>
<!-- Value set constraint: Security Control Observation Value "2.16.840.1.113883.1.11.20471", which contains the Purpose of Use value set "2.16.840.1.113883.1.11.20448" -->
<value xsi:type="CE" code="TREAT" codeSystem="2.16.840.1.113883.1.11.20448" codeSystemName="PurposeOfUse Value Set" displaySystemName="Treatment">
<originalText> To perform one or more operations on information for provision of health care. </originalText>
</value>
</component>

<component typeCode="COMP">
<observation classCode="OBS" moodCode="EVN">
<!-- Security Label Observation --></component>
<templateId root="2.16.840.1.113883.3.445.21" assigningAuthorityName="HL7 CBCC"/>
<!-- Obligation Security Observation template --></templateId>
<templateId root="2.16.840.1.113883.3.445.14" assigningAuthorityName="HL7 CBCC"/>
<code code="SECCONOBS" codeSystem="2.16.840.1.113883.1.11.20457" displaySystemName="Obligation Security Control Observation Type" codeSystemName="SecurityControlObservationType Value Set"/>
<!-- Value set constraint: Security Control Observation Value "2.16.840.1.113883.1.11.20471", which contains the ObligationPolicy value set "2.16.840.1.113883.1.11.20445" -->
<value xsi:type="CE" code="ENCRYPT" codeSystem="2.16.840.1.113883.1.11.20445" codeSystemName="ObligationPolicy" displaySystemName="Encrypt information"/>
<originalText>Custodian system must render information unreadable by algorithmically transforming plain text into cipher text. </originalText>
</value>
</observation>
</component>

<component typeCode="COMP">
<observation classCode="OBS" moodCode="EVN">
<!-- Security Label Observation -->
<templateId root="2.16.840.1.113883.3.445.21" assigningAuthorityName="HL7 CBCC"/>
<!-- Refrain Security Observation template -->
<templateId root="2.16.840.1.113883.3.5019.1.10" assigningAuthorityName="HL7 CBCC"/>
<code code="SECCONOBS" codeSystem="2.16.840.1.113883.1.11.20457" displayName="Refrain Policy Security Control Observation Type" codeSystemName="SecurityControlObservationType Value Set"/>
<!-- Value set constraint: Security Control Observation Value "2.16.840.1.113883.1.11.20471", which contains the RefrainPolicy value set "2.16.840.1.113883.1.11.20446" -->
:value xsi:type="CE" code="NORDSLCDS" codeSystem="2.16.840.1.113883.1.11.20446" codeSystemName="RefrainPolicy Value Set" displayName="Prohibition on redisclosure without patient consent directive">
<originalText>Prohibition on disclosure without a consent directive from the information subject.</originalText>
</value>
</observation>
</component>
</organizer>
</entry>

Security Observation

Abstract [Observation: templateId 2.16.840.1.113883.3.5019.1.35]


This template is used to specify an security observation associated with an information type specified in the privacy consent document or information instance that appears in a CDA document. A security observation is an abstract template intended to specialized for use to indicate a security classification, control, category, or integrity criterion.

1. SHALL contain exactly one [1..1] templateId (CONF-DPROV-35 ) such that it
   a. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.3.5019.1.35"
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF:16841)

A security observation specifies a field in a security label rather than a typical clinical observation. It provides a way of expressing privacy metadata associated with specific clinical statements included in a document section.

3. SHALL contain exactly one [1..1] code (CONF:16837), where the @code SHALL be selected from ValueSet SecurityObservationType 2.16.840.1.113883.1.11.20457 STATIC (CONF:17231)

The code identifies the observation as a security observation using a static
terminology binding.

4. **SHALL** contain exactly one [1..1] `value` with `@xsi:type="ANY"` (CONF:16839), where the `@code` **SHALL** be selected from ValueSet `SecurityObservationValue` 2.16.840.1.113883.1.11.20469 STATIC (CONF:17232)

The value specifies the security observation value that may be further constrained for various subclasses/specializations.

Security Observation example

Error: Missing Runtime Class

---

**Security Policy Information File**

[Act: templateId 2.16.840.1.113883.3.5019.1.36]

<table>
<thead>
<tr>
<th>Contained By</th>
<th>Contains</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Provenance Author Participant Choice</td>
</tr>
</tbody>
</table>

1. **SHALL** contain exactly one [1..1] `templateId` (CONF-DPROV-36) such that it

   a. **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.3.5019.1.36"`

2. **SHALL** contain exactly one [1..1] `@classCode` (CONF:17276), which **SHALL** be selected from ValueSet `ActClassPolicy` 2.16.840.1.113883.1.11.19818 STATIC (CONF:17275)

   A mandate, regulation, obligation, requirement, rule, or expectation unilaterally imposed by one party on:
   The activity of another party, the behavior of another party
   The manner in which an act is executed

3. **SHALL** contain exactly one [1..1] `id` (CONF:17277)

4. **SHALL** contain exactly one [1..1] `code` (CONF:17278), which **SHALL** be selected from ValueSet `ActPolicyType` 2.16.840.1.113883.1.11.19886 STATIC (CONF:17279)

5. **SHOULD** contain zero or one [0..1] `statusCode` (CONF:17282)

6. **SHALL** contain exactly one [1..1] `effectiveTime` (CONF:17280)

7. **SHOULD** contain zero or one [0..1] `languageCode` (CONF:17281)

8. **SHOULD** contain zero or one [0..1] `text` (CONF:17283)

9. **SHOULD** contain [0..*] `author` (CONF:56)

   Specifies provenance-related details about the Author participant.

   a. Contains exactly one [1..1] `Provenance Author Participant Choice` (templateId: 2.16.840.1.113883.3.5019.1.20)

10. **SHOULD** contain [0..*] `reference` (CONF:17268)

    a. Contains exactly one [1..1] CDA Reference

Security Policy Information File example

Error: Missing Runtime Class

---

**Sensitivity Security Observation**

[Observation: templateId 2.16.840.1.113883.3.5019.1.37]
1. SHALL contain exactly one [1..1] `templateId` (CONF-DPROV-37) such that it
   a. SHALL contain exactly one [1..1] `@root"="2.16.840.1.113883.3.5019.1.37"
2. SHALL conform to `Security Observation` template (templateId: 2.16.840.1.113883.3.5019.1.35)
3. SHALL contain exactly one [1..1] `code` (CONF:17238), which SHALL be selected from ValueSet `SecurityCategoryObservationType` 2.16.840.1.113883.1.11.20459 STATIC (CONF:17239)
4. SHALL contain exactly one [1..1] `value` (CONF:17240), which SHALL be selected from ValueSet `InformationSensitivityPolicy` 2.16.840.1.113883.1.11.20428 STATIC (CONF:17241)
   The Sensitivity Security Observation value attribute shall be selected from the Information Sensitivity valueset contained by the Security Category Observation Value valueset.
5. SHOULD contain zero or one [0..1] `text` (CONF:17242)

Sensitivity Security Observation example

Error: Missing Runtime Class

US Privacy Law Security Observation

[Observation: templateId 2.16.840.1.113883.3.5019.1.39]

The US Privacy Law Security Observation value attribute shall be used instead of the universal realm ActPrivacyLaw value set contained in the Security Category Observation Value valueset. This value set includes codes for US Privacy Laws that may be needed by implementers of the US realm DPROV IG.
Note that this value set is extensible to accommodate the inclusion of other US Privacy Laws.

Error: Missing Runtime Class

US Privacy Law Security Observation example
Chapter 5

OTHER CLASSES

Topics:

- Assembler Author Participant
- Assembler Document Participant
- Assembler Entry Participant
- Assigned Author
- Authenticator
- Clinical Statement Entry
- Compartment Security Observation Component
- Composer Document Participant
- Composer Entry Participant
- Confidentiality Security Observation Component
- Consent Category Directive
- Consent Security Directive
- Device Associated Entity
- Device Author Participant
- Device Entity
- Device Entry Associated Entity
- External Act
- External Consent Directive Act
- External Consent Directive Document
- External Consent Directive Observation
- External Consent Directive Reference Choice
- External Document
- External Observation
- External Procedure
- External Reference Choice
- Informant Assigned Entity
- Obligation Security Observation Component
- Patient Author Participant
- Privacy Consent Directive

This section of the Implementation Guide describes other classes that are not CDA Clinical Documents, Sections, or Clinical Statements.
• Privacy Consent Directive
  Type Security Observation Component
• Privacy Marking Entry
• Provenance Author Participant Choice
• Provenance Device Role
• Provenance Informant Participant Choice
• Provenance Label Component Choice
• Provenance Metadata Relationship
• Provenance Parent Document
• Provenance Patient Person Role
• Provenance Performer Participant Choice
• Provenance Policy Information File Relationship
• Provenance Provider Role
• Provenance Related Document
• Provenance Scoping Organization
• Provenance Signature Observation
• Provenance String With Code
• Provider Author Participant
• Purpose Of Use Security Observation Component
• Reference Choice
• Refrain Policy Security Observation Component
• Security Label Entry Relationship
• Security Policy Information File Reference
• Sensitivity Security Observation Component
• Sensitivity Security Observation Component
• US Privacy Law Security Observation Component
• US Realm Address
Assembler Author Participant

Assembler Author Participant example

```xml
<!-- Assembler Author Participant-->
<author>
  <templateId root="null templateID" assigningAuthorityName="HL7 CBCC"/>
  <!-- Mandatory date time-->  
  <time value="20141021120500-0500"/>
  <assignedAuthor>
    <!-- Mandatory Assembler AssignedAuthor Identifier may be null
    when there is no identifiable Assigned Author overseeing the Assembler
    participant, and the Organization scoping the Assembler AssignedAuthor,
    e.g., an HIE, is accountable for the Assembler operation and algorithms,
    but must have Provenance Scoping Organization-->  
    <templateId root="null templateID" assigningAuthorityName="HL7 CBCC"/>
    <id nullFlavor="NA"/>
    <code nullFlavor="NA"/>
    <addr nullFlavor="NA"/>
    <telecom nullFlavor="NA"/>
    <!-- Mandatory Author's Provenance Scoping Organization -->
    <representedOrganization>
      <templateId root="2.16.840.1.113883.3.5019.1.26"
      assigningAuthorityName="HL7 CBCC"/>
      <!-- Mandatory Scoping Organization Identifier - if Scoping
      Organization is specified, and if a HIPAA covered provider organization,
      then at least one identifier must be a National Provider Identifier where
      the id/@root ="2.16.840.1.113883.4.6" is the NPI number for the provider.-->
      <id root="1881638559" assigningAuthorityName="National Plan and
      Provider Enumeration System"/>
      <name>Example Organization</name>
      <telecom value="tel:+1-555-555-1212" use="WP"/>
      <addr>
        <streetAddressLine>Example Organization Address Line</streetAddressLine>
        <city>ExampleCity</city>
        <state>NH</state>
        <postalCode>99999</postalCode>
      </addr>
      <standardIndustryClassCode code="541513" displayName="Computer
      Facilities Management Services" codeSystem="2.16.840.1.113883.11.19298"/>
    </representedOrganization>
  </assignedAuthor>
</author>
```

Assembler Document Participant

[Participant1: templateId 2.16.840.1.113883.3.5019.1.1]

The Assembler Document Header Participant "DEV" represents the software that programmatically assembles pre-existing content into a Clinical Document.
The Assembler Assigned Author's scoping Organization is responsible for the selected participating Assembler Device, which must be appropriate for generating a conformant CDA from the custodian's preexisting document components to ensure integrity of the content.

<table>
<thead>
<tr>
<th>Contained By</th>
<th>Contains</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assembler Generated Document With Provenance</td>
<td></td>
</tr>
<tr>
<td>Device Generated Document With Provenance</td>
<td></td>
</tr>
<tr>
<td>Patient Generated Document With Provenance</td>
<td></td>
</tr>
<tr>
<td>Provider Generated Document With Provenance</td>
<td></td>
</tr>
<tr>
<td>Unstructured Document With Provenance</td>
<td></td>
</tr>
</tbody>
</table>

1. **SHALL** contain exactly one [1..1] `templateId` (CONF-DPROV-1) such that it
   
a. **SHALL** contain exactly one [1..1] `@root`="2.16.840.1.113883.3.5019.1.1"

2. **SHOULD** contain zero or one [0..1] `@nullFlavor` (CONF:17087)
   
   Implementers should use nullFlavor on the AssemblerDocumentParticipant if no Assembler device facilitated in the generation of the Document.

3. **SHALL** contain exactly one [1..1] `@typeCode`="DEV" (CONF:80)
   
   This attribute is fixed to "DEV" to specify assembler software.

4. **SHALL** contain exactly one [1..1] `functionCode`="ASSEMBLER" with @xsi:type="CE" (CONF:8), where the @code **SHALL** be selected from ValueSet ParticipationFunction 2.16.840.1.113883.1.11.10267 DYNAMIC (CONF:128)
   
   This attribute is fixed to "ASSEMBLER" to specify assembler software.

   The Assembler ParticipationFunction code represents the manner in which device software participated in the generation of a Document by facilitating the aggregation of preexisting content into prescribed formats.

   The Assembler software applies an algorithm that enables an identified or not specified Assigned Author to select pre-existing content with provenance.

   The algorithm used by the Assembler must be compatible with the possibly different formats in which the Custodian persists the pre-existing content.

5. **SHALL** contain exactly one [1..1] `time` (CONF:9)
   
   The time stamp is mandatory, and may not be null. Note that the matching of the Assembler Participant effective.Time with that of the Assigned Author Participation is the means for maintaining the association of any Assigned Author with a facilitating DEV participant.

6. **SHALL NOT** contain [0..0] `functionCode`="COMPOSER" with @xsi:type="CE"
   
   The Assembler Document Participant is prohibited from conveying a Composer participation function. An Assembler Generated Document by definition is generated solely by Assembler software i.e., SHALL NOT contain any [0..0] composer.

7. **SHALL** contain exactly one [1..1] `associatedEntity`, where its type is Device Associated Entity (CONF:63)

Assembler Document Participant example

```xml
<!-- Assembler participation type code @typeCode="DEV"-->
<participant typeCode="DEV" codeSystem="2.16.840.1.113883.1.11.10901">
  <!-- AssemblerDocumentParticipant -->
  <templateId root="2.16.840.1.113883.3.5019.1.1"
assigningAuthorityName="HL7 CBCC"/>
```
<functionCode code="ASSEMBLER" codeSystem="2.16.840.1.113883.1.11.10267"/>
<time value="20141021120500-0500"/>
<associatedEntity classCode="MANU">
<!-- AssemblerDocumentParticipant - Device AssociatedEntity with UDI & SNOMED Device code. Could be GMDN. templateId null.-->
  <id root="2.16.840.1.113883.3.3719" extension="(01)51022222233336(11)141231(17)150707(10)A213B1(21)1234" assigningAuthorityName="GS1 2.51.1.1"/>
  <code code="46462944003" codeSystem="2.16.840.1.113883.6.96" displayName="Hospital-administration information system application software"/>
  <scopingOrganization>
    <templateId root="2.16.840.1.113883.3.5019.1.2" assigningAuthorityName="HL7 CBCC"/>
    <id nullFlavor="NA"/>
    <name>Vendor Organization</name>
    <telecom value="tel:+1-555-555-1212" use="WP"/>
    <addr>
      <!-- Address fields -->
      <streetAddressLine>Example Address Line</streetAddressLine>
      <city>ExampleCity</city>
      <state>NH</state>
      <postalCode>99999</postalCode>
    </addr>
  </scopingOrganization>
</associatedEntity>
</participant>

**Assembler Entry Participant**

[Participant2: templateId 2.16.840.1.113883.3.5019.1.2]

*The Assembler Entry Participant "DEV" must be used to identify any software that programmatically assembles pre-existing content into a Clinical Statement. Note that the entry level Assembler participation does not include a functionCode unlike the document level Assembler participation because the functionCode is not support at the CDA entry. If it were, then it would be fixed to "ASSEMBLER" to specify assembler software.*

<table>
<thead>
<tr>
<th>Contained By</th>
<th>Contains</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observation Generated By Assembler</td>
<td></td>
</tr>
<tr>
<td>Observation Generated By Device</td>
<td></td>
</tr>
<tr>
<td>Observation Generated By Patient</td>
<td></td>
</tr>
<tr>
<td>Observation Generated By Provider</td>
<td></td>
</tr>
<tr>
<td>Provenance Metadata</td>
<td></td>
</tr>
</tbody>
</table>

1. SHALL contain exactly one [1..1] templateId (CONF-DPROV-2) such that it
2. SHOULD contain exactly one [1..1] @root="2.16.840.1.113883.3.5019.1.2"
3. SHOULD contain zero or one [0..1] @nullFlavor (CONF:17136)

*Implementers should use nullFlavor on the AssemblerDocumentParticipant if no Assembler device facilitated in the generation of the Entry.*

4. SHALL contain exactly one [1..1] @typeCode="DEV" (CONF:119)
This attribute is fixed to “DEV” to specify assembler software.

4. SHALL contain exactly one [1..1] time (CONF:91)

The time stamp is mandatory, and may not be null.

5. SHALL NOT contain [0..0] functionCode="COMPOSER" with xsi:type="ParticipationFunction"

The Assembler Entry Participant is prohibited from conveying a Composer participation function. An Observation Generation by Assembler is by definition, generated solely by Assembler software i.e., SHALL NOT contain any [0..0] composer.

6. SHALL contain exactly one [1..1] participantRole, where its type is Device Entry Associated Entity (CONF:112)

Assembler Entry Participant example

Error: Missing Runtime Class

Assigned Author

[AssignedAuthor: templateId null]

<table>
<thead>
<tr>
<th>Contained By</th>
<th>Contains</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Provenance Scoping Organization</td>
</tr>
</tbody>
</table>

1. SHALL contain at least one [1..*] id with @xsi:type="II" (CONF:17392)

   This is the Provider Assigned Author's identifier, which is required if known. If the Provider Assigned Author is a HIPAA covered provider, then at least one identifier must be a National Provider Identifier where the id/@root ="2.16.840.1.113883.4.6" is the NPI number for the provider. Since not all clinicians have a National Provider Identifier [NPI] or in cases where the Assembler Assigned Author is not a clinician, use of another identifier is acceptable if known. Otherwise, use null flavor NI. The ids MAY reference the id of a person specified elsewhere in the document.

2. SHALL contain exactly one [1..1] code (CONF:17411), which SHALL be selected from ValueSet Healthcare Provider Taxonomy (NUCC-HIPAA) 2.16.840.1.114222.4.11.1066 DYNAMIC (CONF:17413)

   If the Assembler Author Participant is a provider, then use the Provider Taxonomy code used for electronic HIPAA Transactions. Non-HIPAA providers should select the most applicable Provider Taxonomy code for their credentials, licensure, or practiced. If the Assembler Author's profession can be conveyed with an occupational code from, e.g., the U.S. Census Bureau at http://www2.census.gov/programs-surveys/acs/tech_docs/code_lists/2014_ACS_Code_Lists.pdf, then this professional code should be used if known.

   a. SHOULD satisfy: zero or one [0..1] @nullFlavor="NI" (CONF:17412)

3. SHALL contain at least one [1..*] addr with xsi:type="AD" (CONF:17393)

   a. SHOULD satisfy: zero or one [0..1] @nullFlavor="NI" (CONF:17390)

4. SHALL contain at least one [1..*] telecom with @xsi:type="TEL" (CONF:17394)

   a. SHOULD satisfy: zero or one [0..1] @nullFlavor="NI" (CONF:17391)

5. SHALL contain exactly one [1..1] assignedPerson (CONF:17346)

   a. This assignedPerson SHALL contain at least one [1..*] name (CONF:17368)
   b. This assignedPerson SHOULD contain zero or one [0..1] @nullFlavor="NI" (CONF:17395)

6. SHALL contain exactly one [1..1] representedOrganization, where its type is Provenance Scoping Organization (CONF:17347)
Assigned Author example

Error: Missing Runtime Class

Authenticator

[Authenticator: templateId null]

The authenticator identifies a participant or participants who attest to the accuracy of the information in the document. The DPROV Authenticator can be used with any of the C-CDA use cases, e.g., the authenticator may represent a patient agreement or sign-off of the Care Plan.

DPROV requires that all authors of a DPROV CDA IG authenticate the document if that information is available. The DPROV Authenticator function may be delegated to a device or system that generates the clinical document. In these cases, the legal authenticator is a person accepting responsibility for the document, not the generating device or system.

NullFlavor on sDTCSignatureText is permitted only on patient/person authenticators. Device and Provider authenticators are expected to sign DPROV CDA instances with digital signatures.

<table>
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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Assembler Generated Document With Provenance</td>
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</tr>
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<td></td>
</tr>
<tr>
<td>Provider Generated Document With Provenance</td>
<td></td>
</tr>
<tr>
<td>Unstructured Document With Provenance</td>
<td></td>
</tr>
</tbody>
</table>

1. **SHALL** conform to Consol Authenticator
2. **SHALL** contain exactly one [1..1] **signatureCode** (CONF:16987), which **SHALL** be selected from (CodeSystem: 2.16.840.1.113883.5.89 Participationsignature) (CONF:17338)
   
   The signatureCode "S" is defined as: "Signature Code has been affixed, either written on file, or electronic (incl. digital) signature in Participation.signatureText."

3. **SHALL** contain exactly one [1..1] **sDTCSignatureText** (CONF:16986)
   
   The sdtc:signatureText extension provides a location in CDA for a textual or multimedia depiction of the signature by which the participant endorses and accepts responsibility for his or her participation in the Act as specified in the Participation.typeCode. Details of what goes in the field are described in the HL7 CDA Digital Signature Standard balloted in Fall of 2013.

   Note: The signature can be represented either inline or by reference according to the ED data type. Typical cases for CDA are:
   
   1) Electronic signature: this attribute can represent virtually any electronic signature scheme.
   2) Digital signature: this attribute can represent digital signatures by reference to a signature data block that is constructed in accordance to a digital signature standard, such as XML-DSIG, PKCS-7, PGP, etc.

   The DPROV Authenticator, if present, **SHALL** contain exactly one [1..1] sdtc:signatureText

   NullFlavor on sdtc:signatureText is permitted only on patient/person authenticators. Device and Provider authenticators are expected to sign DPROV CDA instances with digital signatures.

   a. **SHOULD** satisfy: zero or one [0..1] @nullFlavor="NI" (CONF:17425)
4. **SHALL** contain exactly one [1..1] **time** (CONF:5608)

5. **SHALL** contain one and only one of the following

   - **SHALL** contain exactly one [1..1] **assignedEntity**, where its type is *Provenance Device Role* (CONF:5612)
   - **SHALL** contain exactly one [1..1] **assignedEntity2**, where its type is *Provenance Patient Person Role* (CONF:17426)
   - **SHALL** contain exactly one [1..1] **assignedEntity3**, where its type is *Provenance Provider Role* (CONF:17427)

Authenticator example

```xml
<authenticator>
  <time value="20141021120500-0500"/>
  <signatureCode code="S"/>
  <sdtc:signatureText mediaType="text/xml" representation="B64">
    omSJUEdmde9j44zmMirpMDSsWdIjdksIJR3373jeu83
    6edjzMMIjMDSsWdIjdksIJR3373jeu83MNYD83jmMdomSJUEdmde9j44zmMr...  
    MNYD83jmMdomSJUEdmde9j44zmMieryMMIjMDSsWdIjdksIJR3373jeu83
    4zmMir6edjzMMIjdMDSsWdIjdksIJR3373jeu83="/sdtc:signatureText">
    <assignedEntity>
      <id extension="1234567890" root="2.16.840.1.113883.19.5"/>
      <code code="207LA0401X" displayName="Self" codeSystem="2.16.840.1.113883.5.111" codeSystemName="HL7 Role Code"/>
    </assignedEntity>
  </sdtc:signatureText>
</authenticator>
```

Clinical Statement Entry

1. **SHOULD** contain zero or one [0..1] **nullFlavor** with @xsi:type="NullFlavor", which **SHOULD** be selected from ValueSet *STATIC* (CONF:17189)

2. **SHALL** contain exactly one [1..1] **typeCode="COMP"** with @xsi:type="x_ActRelationshipEntry", which **SHALL** be selected from ValueSet *STATIC* (CONF:17190)

3. contain exactly one [1..1] **act**, where its type is CDA Clinical Statement
   a. Contains exactly one [1..1] CDA Clinical Statement

Compartment Security Observation Component

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<thead>
<tr>
<th>Contained By</th>
<th>Contains</th>
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</thead>
<tbody>
<tr>
<td>Security Label</td>
<td>Compartment Security Observation</td>
</tr>
</tbody>
</table>

| 1. **SHOULD** contain zero or one [0..1] @nullFlavor="NI" (CONF:17210) |
| 2. **SHALL** contain exactly one [1..1] @typeCode="COMP" (CONF:17211) |
3. **SHALL** contain exactly one \([1..1]\) **observation**, where its type is *Compartment Security Observation* (CONF:17212)

**Compartment Security Observation Component example**

Error: Missing Runtime Class

---

**Composer Document Participant**

[Participant1: templateId 2.16.840.1.113883.3.5019.1.5]

For this type of document, the Composer Document Header Participant "DEV" represents the software used by an author to record new information, and which may also be used by the author to select existing information for aggregation with newly recorded information for the purpose of generating a new document. The Assigned Author's scoping Organization is responsible for participating the Composer Device selected by the author, which must be appropriate for generating a conformant CDA from the custodian's preexisting document components as well as recording new information generated by the Assigned Author to ensure integrity of the content.

<table>
<thead>
<tr>
<th>Contained By</th>
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</thead>
<tbody>
<tr>
<td>Device Generated Document With Provenance</td>
<td></td>
</tr>
<tr>
<td>Patient Generated Document With Provenance</td>
<td></td>
</tr>
<tr>
<td>Provider Generated Document With Provenance</td>
<td></td>
</tr>
<tr>
<td>Unstructured Document With Provenance</td>
<td></td>
</tr>
</tbody>
</table>

1. **SHALL** contain exactly one \([1..1]\) **templateId** (CONF-DPROV-5) such that it

   a. **SHALL** contain exactly one \([1..1]\) **@root**="2.16.840.1.113883.3.5019.1.5"

2. **SHOULD** contain zero or one \([0..1]\) **@nullFlavor** (CONF:17182)

3. **SHALL** contain exactly one \([1..1]\) **@typeCode**="DEV" (CONF:160)

   *This attribute is fixed to "DEV" to specify Composer software.*

4. **SHALL** contain exactly one \([1..1]\) **functionCode** (CONF:157), where the **@code** **SHALL** be selected from ValueSet **ParticipationFunction** 2.16.840.1.113883.1.11.10267 **DYNAMIC** (CONF:158)

   *This attribute is fixed to "COMPOSER" to specify Composer software.*

   The Composer ParticipationFunction code represents the manner in which device software participated in the generation of a Document or Entry, by facilitating the aggregation of originally authored and preexisting content into prescribed formats.

   *The Composer software enables the Assigned Author to select and modify pre-existing content as well as facilitate the input of new information.*

   *The Composer software selected must be compatible with the possibly different formats in which the Custodian persists the pre-existing content.*

5. **SHALL** contain exactly one \([1..1]\) **time** (CONF:159)

   *The time stamp is mandatory, and may not be null. Note that the matching of the Composer Participant effectiveTime with that of the Assigned Author Participation is the means for maintaining the association of any Assigned Author with a facilitating DEV participant, or generally, any other participant level.*

6. **SHALL** contain exactly one \([1..1]\) **associatedEntity**, where its type is *Device Associated Entity* (CONF:161)
Composer Document Participant example

<!-- A PHR Composer software used by the Patient Author to facilitate
generation of this document with type code @typeCode="DEV"-->
<participant typeCode="DEV" codeSystem="2.16.840.1.113883.1.11.10901">
  <!--Composer Document Header Participant -->
  <templateId root="2.16.840.1.113883.3.5019.1.1"
    assigningAuthorityName="HL7 CBCC"/>
  <!--Composer functionCode from ValueSet-->  
  <functionCode code="COMPOSER" codeSystem="2.16.840.1.113883.1.11.10267"/>

  <!-- Date time (time zone added -0500)-->
  <time value="20141021120500-0500"/>
  <associatedEntity classCode="MANU">
    <!-- Composer Document Header Participant - Device AssociatedEntity
     with UDI & SNOMED Device code. Could be GMDN. templateId null.-->
    <id root="2.16.840.1.113883.3.3719"
      extension="(01)51022222233336(11)141231(17)150707(10)A213B1(21)1234"
      assigningAuthorityName="GS1 2.51.1.1"/>
    <code code="706689003 " codeSystem="2.16.840.1.113883.6.96"
      displayName=" Application program software"/>
    <scopingOrganization>
      <templateId root="2.16.840.1.113883.3.5019.1.33"
        assigningAuthorityName="HL7 CBCC"/>
      <id nullFlavor="NA"/>
      <name>Vendor Organization</name>
      <telecom value="tel:+1-555-555-1212" use="WP"/>
      <addr>
        <!-- Address fields -->
        <streetAddressLine>Example Address Line</streetAddressLine>
        <city>ExampleCity</city>
        <state>NH</state>
        <postalCode>99999</postalCode>
      </addr>
    </scopingOrganization>
    </associatedEntity>
  </participant>

Composer Entry Participant

[Participant2: templateId 2.16.840.1.113883.3.5019.1.6]

The Composer Entry Level Participant is required to identify any software used to compose the content generated
by the Entry Assigned Author and selected from existing content for which the Entry Assigned Author's scoping
Organization is responsible.

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<tr>
<th>Contained By</th>
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<tbody>
<tr>
<td>Observation Generated By Device</td>
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<tr>
<td>Observation Generated By Patient</td>
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<tr>
<td>Observation Generated By Provider</td>
<td></td>
</tr>
<tr>
<td>Provenance Metadata</td>
<td></td>
</tr>
</tbody>
</table>

1. SHALL contain exactly one [1..1] templateId (CONF-DPROV-6) such that it
a. SHALL contain exactly one [1..1] root="2.16.840.1.113883.3.5019.1.6"

2. SHOULD contain zero or one [0..1] nullFlavor (CONF:17183)

3. SHALL contain exactly one [1..1] typeCode="DEV" (CONF:201)

4. SHALL contain exactly one [1..1] time (CONF:164)

    The time stamp is mandatory, and may not be null.

5. SHALL contain exactly one [1..1] participantRole, where its type is Device Entry Associated Entity (CONF:202)

Composer Entry Participant example

Error: Missing Runtime Class

Confidentiality Security Observation Component

[Component4: templateId null]

<table>
<thead>
<tr>
<th>Contains By</th>
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</thead>
<tbody>
<tr>
<td>Security Label</td>
<td>Confidentiality Security Observation</td>
</tr>
</tbody>
</table>

1. SHOULD contain zero or one [0..1] nullFlavor="NI" (CONF:17204)

2. SHALL contain exactly one [1..1] typeCode="COMP" (CONF:17205)

3. SHALL contain exactly one [1..1] observation, where its type is Confidentiality Security Observation (CONF:17206)

Confidentiality Security Observation Component example

Error: Missing Runtime Class

Consent Category Directive

[Authorization: templateId null]

The Consent Category Directive conveys nonhierarchical categories of sensitivity metadata that apply to an Unstructured Document with Provenance, and is used to control access to data more finely than with hierarchical security classification alone. The sensitivity is due to the value or importance of a resource and may include its vulnerability. (Based on ISO7498-2:1989. Note: The vulnerability of personally identifiable sensitive information may be based on concerns that the unauthorized disclosure may result in social stigmatization or discrimination.) The sensitivity ascribed may be based on jurisdictional or organizational policy, or based on the patient’s Privacy Consent Directive. For example, an organization could use this Directive to indicate that an Unstructured Document contains an employee’s patient records. That information would be used to limit access to authorized users. An Unstructured Document with a Privacy Consent Directive may include the Consent Category Directive to indicate the types of information to which the patient’s consent restrictions or authorizations applies or the privacy law that govern it.

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<th>Contains By</th>
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<tbody>
<tr>
<td>Unstructured Document With Provenance</td>
<td></td>
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</table>

1. SHALL contain exactly one [1..1] consent (CONF:17407)

    a. This consent SHALL contain exactly one [1..1] classCode="CONS" (CONF:17371)
b. This consent SHALL contain at least one [1..*] id (CONF:17374)

c. This consent SHALL contain exactly one [1..1] code (CONF:17372), which SHALL be selected from ValueSet SecurityCategoryObservationValue 2.16.840.1.113883.1.11.20470 STATIC (CONF:17373)

d. This consent SHALL contain exactly one [1..1] statusCode (CONF:17375)/@code="completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus)(CONF:17376)

Consent Category Directive example

Error: Missing Runtime Class

Consent Security Directive

[Authorization: templateId null]

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<tbody>
<tr>
<td>Unstructured Document With Provenance</td>
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</tbody>
</table>

1. SHALL contain exactly one [1..1] consent (CONF:17408)

   a. This consent SHALL contain exactly one [1..1] @classCode="CONS" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)(CONF:17377)

   b. This consent SHALL contain at least one [1..*] id (CONF:17380)

   c. This consent SHALL contain exactly one [1..1] code (CONF:17379), which SHALL be selected from ValueSet SecurityControlObservationValue 2.16.840.1.113883.1.11.20471 STATIC (CONF:17378)

   d. This consent SHALL contain exactly one [1..1] statusCode (CONF:17381)/@code="complete" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus)(CONF:17382)

Consent Security Directive example

Error: Missing Runtime Class

Device Associated Entity

[AssociatedEntity: templateId null]

This is the facilitating device participant role at the document level, which is used to convey information about a Composer or Assembler that facilitated the generation of the document in the Document Generated by a Deviced template.

Unlike a Device Assigned Author or a participating entry level Device, the CDA does not support a playing entity on the header participant.

The Device AssignedAuthor role identifier and code are required and should be conformant with U.S. Food and Drug Administration required Unique Device Identifier (UDI) in labeling and coded with a Global Medical Device Nomenclature [GMDN] code.

GMDN is a system of internationally agreed descriptors used to represent common device types for the purposes of grouping or categorization of individual medical devices. GMDN is implemented by GUDID as a required data element on each device record. If GMDN does not have an applicable code, then implementers should select applicable device codes from SNOMED or other device code system that can be mapped to GMDN.
The Device Associated Entity identifier is permitted to be null, because the healthcare industry has not yet fully implemented the U.S. Food and Drug Administration required Unique Device Identifier (UDI) in labeling, and the identifier of facilitating devices are less likely to be captured than those of authoring devices.

For more information on adoption rate, see "Unique Device Identifier Study: Adoption and Use Trends for Medical Devices" http://www.boozallen.com/media/file/UDI_Study.pdf

For more information on UDI see Universal Medical Device Nomenclature System https://www.ecri.org/Products/Pages/UMDNS.aspx.

For GMDN consult https://gmdnagency.org/ and https://gmdnagency.org/FAQ.aspx

For information on UDI adoption rate and implementation approaches, see "Unique Device Identifier Study: Adoption and Use Trends for Medical Devices" http://www.boozallen.com/media/file/UDI_Study.pdf

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<thead>
<tr>
<th>Contained By</th>
<th>Contains</th>
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<tbody>
<tr>
<td>Assembler Document Participant</td>
<td>Provenance Scoping Organization</td>
</tr>
<tr>
<td>Composer Document Participant</td>
<td></td>
</tr>
</tbody>
</table>

1. SHALL contain exactly one [1..1] @classCode="MANU" (CONF:10026)

   Manufactured product that is scoped by the manufacturer.

2. SHALL contain at least one [1..*] id with @xsi:type="II" (CONF:10027)

   The Device associatedEntity.identifier is required, but may be null. At least one must be a conformant US FDA Unique Device Identifier with identifier root OID for FDA UDI: 2.16.840.1.113883.3.3719 and the extension shall be the Human Readable Form appropriate for the style of content. See the HL7 Harmonization Pattern for Unique Device Identifiers http://wiki.hl7.org/images/2/24/Harmonization_Pattern_for_Unique_Device_Identifiers_20141113.pdf

3. SHALL contain exactly one [1..1] code with @xsi:type="CE" (CONF:17414), which SHALL be selected from (CodeSystem: ) (CONF:17415)

   The Device associatedEntity.code is used to further qualify the device playing the Device Associated Entity, e.g., software used for health information exchange document generation, or document generation modules use in EHR or PHR system.

   The Device associatedEntity.code is required to use a code from a value set of device types that meets the definition of ProvenancePassiveDeviceRoleType concept domain: "A role type that indicates the type of device that authors or in some manner contributes to generation, management, and/or transmission of health information, the use of which may be tracked for purposes of determining the provenance of health information".

   The preferred device type code system is the Global Medical Device Nomenclature [GMDN] if it contains an applicable code. If GMDN does not have an applicable code, then implementers should select applicable device codes from SNOMED or other device code system that can be mapped to GMDN.

4. SHALL contain at least one [1..*] addr with @xsi:type="AD" (CONF:17088)

5. SHALL contain at least one [1..*] telecom with @xsi:type="TEL" (CONF:17089)

6. SHALL contain exactly one [1..1] scopingOrganization, where its type is Provenance Scoping Organization (CONF:10029)

Device Associated Entity example

Error: Missing Runtime Class
Device Author Participant

[Author: templateId 2.16.840.1.113883.3.5019.1.8]

Device Author Participant is constrained for content generated by a device.

<table>
<thead>
<tr>
<th>contained By</th>
<th>Contains</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Generated Document With Provenance</td>
<td></td>
</tr>
<tr>
<td>Observation Generated By Device</td>
<td></td>
</tr>
<tr>
<td>Section Generated By Device</td>
<td></td>
</tr>
</tbody>
</table>

1. SHALL contain exactly one [1..1] **templateId** (CONF-DPROV-8) such that it
   a. SHALL contain exactly one [1..1] **@root**="2.16.840.1.113883.3.5019.1.8"
2. SHALL contain exactly one [1..1] **time** (CONF:48)
   The time stamp is mandatory, and may not be null.
3. SHALL contain exactly one [1..1] **assignedAuthor**, where its type is **Provenance Device Role** (CONF:49)

Device Author Participant example

Error: Missing Runtime Class

Device Entity

[AuthoringDevice: templateId null]

**DPROV Device Entity** specifies constraints on the RIM Data Types Release 2 to require that both a code and text version of the code be included, as well as a code system. Inclusion of the code system name, version, and display name are recommended.

For more information on SC datatype, see Normative Edition Data Types: Abstract Release 2 Section 4.4.

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</table>

1. SHOULD contain zero or one [0..1] **code** (CONF:10067)
2. SHALL contain at least one [1..*] **manufacturerModelName** with @xsi:type="SC" (CONF:10069)
3. SHALL contain at least one [1..*] **softwareName** with @xsi:type="SC" (CONF:10070)

Device Entity example

Error: Missing Runtime Class

Device Entry Associated Entity

[ParticipantRole: templateId null]

This is the facilitating device participant role at the entry level, which is used to convey information about a Composer or Assembler that facilitated the generation of the entry in the Observation Generated by a Device template.
The Device Associated Entity role identifier and code are required and should be conformant with U.S. Food and Drug Administration required Unique Device Identifier (UDI) in labeling and coded with a Global Medical Device Nomenclature [GMDN] code. The Device Associated Entity identifier is permitted to be null, because the healthcare industry has not yet fully implemented the U.S. Food and Drug Administration required Unique Device Identifier (UDI) in labeling, and the identifier of facilitating devices are less likely to be captured than those of authoring devices.

GMDN is a system of internationally agreed descriptors used to represent common device types for the purposes of grouping or categorization of individual medical devices. GMDN is implemented by GUDID as a required data element on each device record. If GMDN does not have an applicable code, then implementers should select applicable device codes from SNOMED or other device code system that can be mapped to GMDN.

For more information on adoption rate, see "Unique Device Identifier Study: Adoption and Use Trends for Medical Devices" http://www.boozallen.com/media/file/UDI_Study.pdf

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<tr>
<th>Contained By</th>
<th>Contains</th>
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</thead>
<tbody>
<tr>
<td>Assembler Entry Participant</td>
<td>Provenance Scoping Organization</td>
</tr>
<tr>
<td>Composer Entry Participant</td>
<td></td>
</tr>
</tbody>
</table>

1. SHALL contain exactly one [1..1] @classCode="MANU" (CONF:10078)
2. SHALL contain at least one [1..*] id with @xsi:type="II" (CONF:10079)

The Assembler Entry Participant associatedEntity.identifier is mandatory, and may not be null. At least one must be a conformant US FDA Unique Device Identifier with identifier root OID for FDA UDI: 2.16.840.1.113883.3.3719 and the extension shall be the Human Readable Form appropriate for the style of content. See the HL7 Harmonization Pattern for Unique Device Identifiers http://wiki.hl7.org/images/2/24/Harmonization_Pattern_for_Unique_Device_Identifiers_20141113.pdf

3. SHALL contain exactly one [1..1] code with @xsi:type="CE" (CONF:10080), which SHALL be selected from (CodeSystem: ) (CONF:17417)

The Assembler Entry Participant associatedEntity.code is used to further qualify the device playing the Assembler Entry Participant Associated Entity, e.g., software used for health information exchange document generation, or document generation modules use in EHR or PHR system.

The Assembler Entry Participant associatedEntity.code is required to use a code from a value set of device types that meets the definition of the definition of ProvenancePassiveDeviceRoleType concept domain: "A role type that indicates the type of device that authors or in some manner contributes to generation, management, and/or transmission of health information, the use of which may be tracked for purposes of determining the provenance of health information."

The preferred device type code system is the Global Medical Device Nomenclature [GMDN] if it contains an applicable code. If GMDN does not have an applicable code, then implementers should select applicable device codes from SNOMED or other device code system that can be mapped to GMDN.

4. SHOULD contain zero or more [0..*] addr with @xsi:type="AD" (CONF:17137)
5. SHOULD contain zero or more [0..*] telecom with @xsi:type="TEL" (CONF:17138)
6. SHALL contain exactly one [1..1] playingDevice, where its type is Device Entity (CONF:17139)
7. **SHALL** contain exactly one [1..1] `scopingOrganization`, where its type is `Provenance Scoping Organization` (CONF:10081)

**Device Entry Associated Entity example**

Error: Missing Runtime Class

---

**External Act**

[ExternalAct: templateId null]

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<thead>
<tr>
<th>Contained By</th>
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<tbody>
<tr>
<td>External Reference Choice</td>
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</tbody>
</table>

1. **SHALL** contain exactly one [1..1] `@classCode`="ACT" `Act` (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:16870)
2. **SHALL** contain at least one [1..*] `id` (CONF:16871)
3. **SHALL** contain exactly one [1..1] `code` (CONF:16872)
4. **SHOULD** contain zero or one [0..1] `text` (CONF:16873)

**External Act example**

Error: Missing Runtime Class

---

**External Consent Directive Act**

[ExternalAct: templateId null]

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<thead>
<tr>
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<tr>
<td>External Consent Directive Reference Choice</td>
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</tbody>
</table>

1. **SHALL** contain exactly one [1..1] `@classCode`="CONS" `Act` (CONF:17303), which **SHALL** be selected from ValueSet ActClassConsent 2.16.840.1.113883.1.11.20206 STATIC (CONF:17304)
2. **SHALL** contain exactly one [1..1] `@moodCode`="EVN" `Event` (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF:17305)
3. **SHALL** contain at least one [1..*] `id` (CONF:17306)
4. **SHALL** contain exactly one [1..1] `code` (CONF:17307), which **SHALL** be selected from ValueSet ActConsentDirectiveType 2.16.840.1.113883.1.11.20551 DYNAMIC (CONF:17308)
5. **SHALL** contain exactly one [1..1] `text` with `@xsi:type="ED"` (CONF:17309)

**External Consent Directive Act example**

Error: Missing Runtime Class

---

**External Consent Directive Document**

[ExternalDocument: templateId null]
### External Consent Directive Reference Choice

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<th>Contains</th>
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1. **SHALL** contain exactly one [1..1] `@classCode="DOC"` *(CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)* (CONF:17311)
2. **SHALL** contain at least one [1..*] `id` (CONF:17312)
3. **SHALL** contain exactly one [1..1] `code`, which **SHALL** be selected from ValueSet `ActConsentDirectiveType 2.16.840.1.113883.1.11.20551 DYNAMIC` (CONF:17313)
4. **SHALL** contain exactly one [1..1] `text` (CONF:17314)
5. **SHOULD** contain zero or one [0..1] `setId` (CONF:17315)
6. **SHOULD** contain zero or one [0..1] `versionNumber` (CONF:17316)

**External Consent Directive Document example**

Error: Missing Runtime Class

### External Consent Directive Observation

[ExternalObservation: templateId null]

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</table>

1. **SHALL** contain exactly one [1..1] `@classCode="OBS"` *Observation* *(CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)* (CONF:17317)
2. **SHALL** contain exactly one [1..1] `@moodCode="EVN"` *Event* *(CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)* (CONF:17318)
3. **SHALL** contain at least one [1..*] `id` (CONF:17319)
4. **SHALL** contain exactly one [1..1] `code` (CONF:17320), which **SHALL** be selected from ValueSet `ActConsentDirectiveType 2.16.840.1.113883.1.11.20551 DYNAMIC` (CONF:17321)
5. **SHALL** contain exactly one [1..1] `text` with `@xsi:type="ED"` (CONF:17322)

**External Consent Directive Observation example**

Error: Missing Runtime Class

### External Consent Directive Reference Choice

[Reference: templateId 2.16.840.1.113883.3.5019.1.10]

<table>
<thead>
<tr>
<th>Contained By</th>
<th>Contains</th>
</tr>
</thead>
</table>

1. **SHALL** contain exactly one [1..1] `templateId` *(CONF-DPROV-10)* such that it
a. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.3.5019.1.10"

2. SHOULD contain zero or one [0..1] @nullFlavor="NI" (CONF:17296)

3. SHALL contain exactly one [1..1] @typeCode="REFR" (CONF:17301), which SHALL be selected from ValueSet x_ActRelationshipExternalReference 2.16.840.1.113883.1.11.19000 STATIC 1312-20140807 (CONF:17302)

4. SHOULD contain zero or one [0..1] seperatableInd (CONF:17297)

5. SHALL contain one and only one of the following
   • SHALL contain exactly one [1..1] externalAct, where its type is External Consent Directive Act (CONF:17298)
   • SHALL contain exactly one [1..1] externalDocument, where its type is External Consent Directive Document (CONF:17299)
   • SHALL contain exactly one [1..1] externalObservation, where its type is External Consent Directive Observation (CONF:17300)

External Consent Directive Reference Choice example

Error: Missing Runtime Class

External Document

[ExternalDocument: templateId null]

<table>
<thead>
<tr>
<th>Contained By</th>
<th>Contains</th>
</tr>
</thead>
<tbody>
<tr>
<td>External Reference Choice</td>
<td></td>
</tr>
</tbody>
</table>

1. SHALL contain exactly one [1..1] @classCode="DOC" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:16874)

2. SHALL contain at least one [1..*] id (CONF:16875)

3. SHALL contain exactly one [1..1] code (CONF:16876)

4. SHOULD contain zero or one [0..1] text (CONF:16877)

5. SHOULD contain zero or one [0..1]setId (CONF:17285)

6. SHOULD contain zero or one [0..1]versionNumber (CONF:17286)

External Document example

Error: Missing Runtime Class

External Observation

[ExternalObservation: templateId null]

<table>
<thead>
<tr>
<th>Contained By</th>
<th>Contains</th>
</tr>
</thead>
<tbody>
<tr>
<td>External Reference Choice</td>
<td></td>
</tr>
</tbody>
</table>

1. SHALL contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:16878)
2. SHALL contain at least one [1..*] id (CONF:16879)
3. SHALL contain exactly one [1..1] code (CONF:16880)
4. SHOULD contain zero or one [0..1] text (CONF:16881)

External Observation example

Error: Missing Runtime Class

External Procedure

[ExternalProcedure: templateId null]

<table>
<thead>
<tr>
<th>Contained By</th>
<th>Contains</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>External Reference Choice</strong></td>
<td></td>
</tr>
</tbody>
</table>

1. SHALL contain exactly one [1..1] @classCode="PROC" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:16882)
2. SHALL contain at least one [1..*] id (CONF:16883)
3. SHALL contain exactly one [1..1] code (CONF:16884)
4. SHOULD contain zero or one [0..1] text (CONF:16885)

External Procedure example

Error: Missing Runtime Class

External Reference Choice

[Reference: templateId 2.16.840.1.113883.3.5019.1.11]

<table>
<thead>
<tr>
<th>Contained By</th>
<th>Contains</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>External Reference Choice</strong></td>
<td></td>
</tr>
</tbody>
</table>

1. SHALL contain exactly one [1..1] templateId (CONF-DPROV-11) such that it
   a. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.3.5019.1.11"
2. SHALL contain one and only one of the following
   • SHALL contain exactly one [1..1] externalAct, where its type is External Act (CONF:16866)
   • SHALL contain exactly one [1..1] externalDocument, where its type is External Document (CONF:16867)
   • SHALL contain exactly one [1..1] externalObservation, where its type is External Observation (CONF:16868)
   • SHALL contain exactly one [1..1] externalProcedure, where its type is External Procedure (CONF:16869)

   (CONF:17284)

External Reference Choice example

Error: Missing Runtime Class
Informant Assigned Entity

[AssignedEntity: templateId null]

An informant assigned entity role may be played by a healthcare provider such as physician or nurse who is not caring for the patient, or by a non-provider professional such as a police officer, a teacher or a social worker, who provides information about the patient.

<table>
<thead>
<tr>
<th>Contains</th>
<th>Contains</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provenance Informant Participant Choice</td>
<td>Provenance Scoping Organization</td>
</tr>
</tbody>
</table>

1. SHALL contain at least one [1..*] id with @xsi:type="II" (CONF:216)

   This is the Informant Assigned Entity Role identifier, which is mandatory if known.

2. SHALL contain exactly one [1..1] code (CONF:215), which SHALL be selected from ValueSet Healthcare Provider Taxonomy (NUCC-HIPAA) 2.16.840.1.114222.4.11.1066 DYNAMIC (CONF:17421)

   An Informant Assigned Entity may not have a provider taxonomy code. If this Informant's profession has a code system then this professional code is required if known (e.g., type of teaching certificate, social worker, law enforcement officer). For example, many professions can be conveyed with an occupational code from, e.g., the U.S. Census Bureau at http://www2.census.gov/programs-surveys/acs/tech_docs/code_lists/2014_ACS_Code_Lists.pdf. If this entity is a HIPAA covered provider, then use the Provider Taxonomy code used for electronic HIPAA Transactions. Non-HIPAA providers should select the most applicable Provider Taxonomy code for their credentials, licensure, or practiced.

   a. SHOULD satisfy: zero or one [0..1] @nullFlavor="NI" (CONF:17420)

3. SHALL contain at least one [1..*] addr with @xsi:type="AD" (CONF:214)

   Informant Assigned Entity address is required if known to assist with locating this informant for verification purposes if needed.

   a. SHOULD satisfy: zero or one [0..1] @nullFlavor="NI" (CONF:17418)

4. SHALL contain at least one [1..*] telecom with @xsi:type="TEL" (CONF:217)

   Informant Assigned Entity SHALL contain telecom if known.

   a. SHOULD satisfy: zero or one [0..1] @nullFlavor="NI" (CONF:17419)

5. SHALL contain exactly one [1..1] assignedPerson (CONF:218)

   a. This assignedPerson SHALL contain at least one [1..*] name (CONF:17053)

6. SHALL contain exactly one [1..1] representedOrganization, where its type is Provenance Scoping Organization (CONF:219)

Informant Assigned Entity example

<!--Provenance Informant Assigned Entity-->
<informant>
  <templateId root="2.16.840.1.113883.3.5019.1.21"
      assigningAuthorityName="HL7 CBCC"/>
  <!-- Mandatory date time-->  
  <time value="20151021120500-0500"/>
  <assignedEntity>
    <!--Provenance Informant Assigned Entity Occupation ID-->
  </assignedEntity>
</informant>
<id extension="1234567890" root="2.16.840.1.113883.3.4784" assigningAuthorityName="State of Maine Health and Human Services Department"/>

<!--Provenance Informant Assigned Entity Occupation code-->
<code code="21-109X" displayName="Miscellaneous community and social service specialists, including health educators and community health workers" codeSystem="2.16.840.1.113883.6.240" codeSystemName="US Census Occupation Code"/>
</addr>

<streetAddressLine>1004 Healthcare Drive</streetAddressLine>
<city>Portland</city>
<state>ME</state>
<postalCode>04102</postalCode>
<country>US</country>
</addr>
<telecom use="WP" value="tel:+1(555)555-1004"/>

<assignedPerson>
<name>
<given>Sarah</given>
<given qualifier="CL">Sally</given>
?family>Social</family>
<suffix qualifier="AC">CSWE</suffix>
</name>
</assignedPerson>
</assignedEntity>

<!-- Informant Assigned Entity's Mandatory Provenance Scoping Organization -->
<representedOrganization>
<templateId root="2.16.840.1.113883.3.5019.1.26" assigningAuthorityName="HL7 Security CBCC"/>
<!-- NPI for the organization -->
<id root="1881638559" assigningAuthorityName="National Plan and Provider Enumeration System"/>

<!-- Provenance Informant Assigned Entity's Mandatory Provenance Scoping Organization -->
<representedOrganization>
<templateId root="2.16.840.1.113883.3.5019.1.26" assigningAuthorityName="HL7 Security CBCC"/>
<!-- NPI for the organization -->
<id root="1881638559" assigningAuthorityName="National Plan and Provider Enumeration System"/>

<streetAddressLine>Example Organization Address Line</streetAddressLine>
<city>ExampleCity</city>
<state>ME</state>
<postalCode>04102</postalCode>
</addr>

<NorthAmericanIndustryClassificationSystemNAICS code="8093" displayName="Specialty Outpatient Facilities, Not Elsewhere Classified" codeSystem="2.16.840.1.113883.6.85"/>
</representedOrganization>
</informant>

---

**Obligation Security Observation Component**

[Component4: templateId null]

<table>
<thead>
<tr>
<th>Contained By</th>
<th>Contains</th>
</tr>
</thead>
<tbody>
<tr>
<td>Security Label</td>
<td>Obligation Security Observation</td>
</tr>
</tbody>
</table>

1. **SHOULD** contain zero or one [0..1] @nullFlavor="NI" (CONF:17222)
2. **SHALL** contain exactly one [1..1] @typeCode="COMP" (CONF:17223)
3. **SHALL** contain exactly one [1..1] `observation`, where its type is *Obligation Security Observation* (CONF:17224)

**Obligation Security Observation Component example**

Error: Missing Runtime Class

---

**Patient Author Participant**

[Author: templateId 2.16.840.1.113883.3.5019.1.17]

*Patient Author Participant is constrained for content generated by a patient.*

<table>
<thead>
<tr>
<th>Contained By</th>
<th>Contains</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observation Generated By Patient</td>
<td></td>
</tr>
<tr>
<td>Patient Generated Document With Provenance</td>
<td></td>
</tr>
<tr>
<td>Section Generated By Patient</td>
<td></td>
</tr>
</tbody>
</table>

1. **SHALL** contain exactly one [1..1] `templateId` (CONF-DPROV-17) such that it
   a. **SHALL** contain exactly one [1..1] `@root"2.16.840.1.113883.3.5019.1.17"`

2. **SHALL** contain exactly one [1..1] `time` (CONF:70)

   *The time stamp is mandatory, and may not be null.*

3. **SHALL** contain exactly one [1..1] `assignedAuthor`, where its type is *Provenance Patient Person Role* (CONF:69)

**Patient Author Participant example**

Error: Missing Runtime Class

---

**Privacy Consent Directive**

[Authorization: templateId null]

*The Privacy Consent Directive conveys a patient's authorizations or restrictions on access, used, and disclosure of health information. The patient's privacy preferences may be limited by jurisdictional law or organizational policy.*

<table>
<thead>
<tr>
<th>Contained By</th>
<th>Contains</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assembler Generated Document With Provenance</td>
<td></td>
</tr>
<tr>
<td>Device Generated Document With Provenance</td>
<td></td>
</tr>
<tr>
<td>Patient Generated Document With Provenance</td>
<td></td>
</tr>
<tr>
<td>Provider Generated Document With Provenance</td>
<td></td>
</tr>
<tr>
<td>Unstructured Document With Provenance</td>
<td></td>
</tr>
</tbody>
</table>

1. **SHALL** conform to *Consol Authorization*

2. **SHALL** contain exactly one [1..1] `consent` (CONF:16793)
   a. This consent **SHALL** contain at least one [1..*] `id` (CONF:16794)
b. This consent SHALL contain exactly one [1..1] code (CONF:16795), which SHALL be selected from ValueSet ActConsentDirectiveType 2.16.840.1.113883.1.11.20551 DYNAMIC (CONF:16989)

c. This consent SHALL contain exactly one [1..1] statusCode (CONF:16797)/@code="completed" Completed (CodeSystem: 2.16.840.1.113883.5.14 ActStatus) (CONF:16798)

Privacy Consent Directive example

```xml
<authorization typeCode="AUTH">
  <consent classCode="CONS" moodCode="EVN">
    <id root="629deb70-5306-11df-9879-0800200c9a67"/>
    <code codeSystem="2.16.840.1.113883.1.11.20425" codeSystemName="ActConsentDirectiveType" code="OPTIN" displayName="Opt-in to disclosure of health information"/>
    <statusCode code="completed"/>
  </consent>
</authorization>

<authorization typeCode="AUTH">
  <consent classCode="CONS" moodCode="EVN">
    <id root="629deb70-5306-11df-9879-0800200c9a66"/>
    <code codeSystem="2.16.840.1.113883.1.11.20425" codeSystemName="ActConsentDirectiveType" code="IDSCL" displayName="Consent to disclose information."/>
    <statusCode code="completed"/>
  </consent>
</authorization>

<authorization typeCode="AUTH">
  <consent classCode="CONS" moodCode="EVN">
    <id root="629deb70-5306-11df-9879-0800200c9a65"/>
    <code codeSystem="2.16.840.1.113883.1.11.20470" codeSystemName="USPrivacyLaw" code= "Title38Section7332" displayName="Title 38 Section 7332 governed health information"/>
    <statusCode code="completed"/>
  </consent>
</authorization>

<authorization typeCode="AUTH">
  <consent classCode="CONS" moodCode="EVN">
    <id root="629deb70-5306-11df-9879-0800200c9a64"/>
    <code codeSystem="2.16.840.1.113883.1.11.20470" codeSystemName="ActInformationSensitivityPolicy" code="ETH" displayName=" substance abuse information sensitivity"/>
    <statusCode code="completed"/>
  </consent>
</authorization>
```
<!--The Security Control Observation Value conveys the purpose of use, obligations [mandates], and Refrains [prohibitions] that follow from the patient's Consent Directive, jurisdictional law, or organizational policy.--> 

```xml
<authorization typeCode="AUTH">
  <consent classCode="CONS" moodCode="EVN">
    <id root="629deb70-5306-11df-9879-0800200c9a63"/>
    <code codeSystem="2.16.840.1.113883.1.11.20471" codeSystemName="SecurityControlObservationValue" code="TREAT" displayName="Treatment purpose of use"/>
    <statusCode code="completed"/>
  </consent>
</authorization>

<authorization typeCode="AUTH">
  <consent classCode="CONS" moodCode="EVN">
    <id root="629deb70-5306-11df-9879-0800200c9a62"/>
    <code codeSystem="2.16.840.1.113883.1.11.20471" codeSystemName="SecurityControlObservationValue" code="ENCRYPT" displayName="Encrypt"/>
    <statusCode code="completed"/>
  </consent>
</authorization>

<authorization typeCode="AUTH">
  <consent classCode="CONS" moodCode="EVN">
    <id root="629deb70-5306-11df-9879-0800200c9a61"/>
    <code codeSystem="2.16.840.1.113883.1.11.20471" codeSystemName="SecurityControlObservationValue" code="NORDSCLCDS" displayName="No redisclosure without information subject's consent directive")"/>
    <statusCode code="completed"/>
  </consent>
</authorization>
```

### Privacy Consent Directive Type Security Observation Component

[Component4: templateId null]

<table>
<thead>
<tr>
<th>Contained By</th>
<th>Contains</th>
</tr>
</thead>
<tbody>
<tr>
<td>Security Label</td>
<td>Privacy Consent Directive Type Security Observation</td>
</tr>
</tbody>
</table>

1. **SHOULD** contain zero or one [0..1] [@nullFlavor="NI"] (CONF:17213)
2. **SHALL** contain exactly one [1..1] @typeCode="COMP" (CONF:17214)
3. **SHALL** contain exactly one [1..1] observation, where its type is Privacy Consent Directive Type Security Observation (CONF:17215)

#### Privacy Consent Directive Type Security Observation Component example

Error: Missing Runtime Class

### Privacy Marking Entry

[Entry: templateId null]
The Privacy Marking Entry links the Privacy Marking Section to the Security Label Organizer.

<table>
<thead>
<tr>
<th>Contained By</th>
<th>Contains</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provenance Privacy Marking Section</td>
<td>Security Label</td>
</tr>
</tbody>
</table>

1. SHALL contain exactly one [1..1] organizer, where its type is Security Label (CONF:17274)

The PrivacyMarkingEntry is intended to specify a SecurityLabel, which is a set of security observations.

Privacy Marking Entry example

Error: Missing Runtime Class

Provenance Author Participant Choice

[Author: templateId 2.16.840.1.113883.3.5019.1.20]

Provenance author constrained for a section with provenance. The Provenance Author Participant must be used to identify any software used to compose the content generated by the Entry Assigned Author and selected from existing content for which the Entry Assigned Author's scoping Organization is responsible.

<table>
<thead>
<tr>
<th>Contained By</th>
<th>Contains</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provenance Metadata</td>
<td></td>
</tr>
<tr>
<td>Provenance Policy Information File</td>
<td></td>
</tr>
<tr>
<td>Provenance Privacy Marking Section</td>
<td></td>
</tr>
<tr>
<td>Section Generated By Mandatory Author</td>
<td></td>
</tr>
<tr>
<td>Security Label</td>
<td></td>
</tr>
<tr>
<td>Security Policy Information File</td>
<td></td>
</tr>
<tr>
<td>Unstructured Document With Provenance</td>
<td></td>
</tr>
</tbody>
</table>

1. SHALL contain exactly one [1..1] templateId (CONF-DPROV-20) such that it
   a. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.3.5019.1.20"
2. SHALL contain exactly one [1..1] @typeCode="AUT" (CONF:16961)
3. SHALL contain exactly one [1..1] time (CONF:87)

   The time stamp is mandatory, and may not be null.

4. SHALL contain one and only one of the following
   • SHALL contain exactly one [1..1] assignedAuthor, where its type is Provenance Device Role (CONF:35)
   • SHALL contain exactly one [1..1] assignedAuthor, where its type is Provenance Patient Person Role (CONF:10036)
   • SHALL contain exactly one [1..1] assignedAuthor, where its type is Provenance Provider Role (CONF:10095)
      (CONF:10094)

Provenance Author Participant Choice example

Error: Missing Runtime Class
Provenance Device Role

[AssignedAuthor: templateId null]

Provenance Device Role is the assigned author used in the Device Generated Document With Provenance and Section Generated by Device. The Device AssignedAuthor role identifier and code are required and must be conformant with U.S. Food and Drug Administration required Unique Device Identifier (UDI) in labeling and coded with a Global Medical Device Nomenclature [GMDN] code.

GMDN is a system of internationally agreed descriptors used to represent common device types for the purposes of grouping or categorization of individual medical devices. GMDN is implemented by GUDID as a required data element on each device record. If GMDN does not have an applicable code, then implementers should select applicable device codes from SNOMED or other device code system that can be mapped to GMDN.

The Device Associated Entity identifier is mandatory, but identifiers other than UDI may be used if no UDI exists because the healthcare industry has not yet fully implemented the U.S. Food and Drug Administration required Unique Device Identifier (UDI) in labeling.

For more information on UDI see Universal Medical Device Nomenclature System https://www.ecri.org/Products/Pages/UMDNS.aspx.

For GMDN consult https://gmdnagency.org/ and https://gmdnagency.org/FAQ.aspx

For information on UDI adoption rate and implementation approaches, see "Unique Device Identifier Study: Adoption and Use Trends for Medical Devices" http://www.boozallen.com/media/file/UDI_Study.pdf

<table>
<thead>
<tr>
<th>Contained By</th>
<th>Contains</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Author Participant</td>
<td>Provenance Scoping Organization</td>
</tr>
<tr>
<td>Provenance Author Participant Choice</td>
<td></td>
</tr>
</tbody>
</table>

1. SHALL contain at least one [1..*] id (CONF:10064)

   The Device Author assignedAuthor.identifier is mandatory, and may not be null. At least one must be a conformant US FDA Unique Device Identifier with identifier root OID for FDA UDI:2.16.840.1.113883.3.3719 and the extension shall be the Human Readable Form appropriate for the style of content. See the HL7 Harmonization Pattern for Unique Device Identifiers http://wiki.hl7.org/images/2/24/Harmonization_Pattern_for_Unique_Device_Identifiers_20141113.pdf

2. SHALL contain exactly one [1..1] code with @xsi:type="CE" (CONF:10063), which SHALL be selected from (CodeSystem: 2.16.840.1.113883.6.276 GlobalMedicalDeviceNomenclature) (CONF:17416)

   The Device Author assignedEntity.code is used to further qualify the device playing the document device author role e.g., software used to record observations about a patient and to generate a report about those observations independently of a person author.

   The Device Author assignedEntity.code is required to use a code from a value set of device types that meets the definition of ProvenanceAssignedDeviceRoleType concept domain: "A role type that indicates the type of device that authors or in some manner contributes to generation, management, and/or transmission of health information, the use of which may be tracked for purposes of determining the provenance of health information. The playing device acts or is authorized to act on behalf of a scoping entity".

   The preferred device type code system is the Global Medical Device Nomenclature [GMDN] if it contains an applicable code. If GMDN does not have an applicable code, then implementers should select applicable device codes from SNOMED or other device code system that can be mapped to GMDN.
3. SHALL contain at least one [1..*] **addr** with @xsi:type="AD" (CONF:17333)
4. SHALL contain at least one [1..*] **telecom** with @xsi:type="TEL" (CONF:17334)
5. SHALL contain exactly one [1..1] **assignedAuthoringDevice**, where its type is *Device Entity* (CONF:10065)
6. SHALL contain exactly one [1..1] **representedOrganization**, where its type is *Provenance Scoping Organization* (CONF:10066)

**Provenance Device Role example**

Error: Missing Runtime Class

---

**Provenance Informant Participant Choice**

[Participant1: templateId 2.16.840.1.113883.3.5019.1.21]

An Informant Participant is required be used if known to record when an authorized healthcare provider or a non-healthcare professional person, or a patient or a person knowledgeable about the patient shares information verbally or by electronic means, which is then documented by the author as part of the record.

An assigned entity role may be played by a healthcare provider such as physician or nurse or by a non-provider professional such as a police officer, a teacher or a social worker, who provides information about the patient.

The Provider Informant Assigned Entity is required to have a National Provider Identifier [NPI], and a provider taxonomy code from the NUCC Provider Taxonomy Code System. The Non-Provider Informant Assigned Entity, such as a profession who is authorized by a scoping organization to provide information about the patient, does not have a National Provider Identifier [NPI], and a provider taxonomy code, but may have a code relating to their professional non-clinical role.

When the informant is a patient or a person with information about the patient, that informant is represented in the Informant Related Entity element, even if the personal relation is a medical professional. The code element of the Informant Related Entity describes the relationship between the informant and the patient. The relationship between the informant and the patient is required to be described to help the receiver of the clinical document understand the context and reliability of the information source.

The informant.contextControlCode is mandatory and default to = "OP" (overriding and propagating).

Implementers should note that the informant template can be asserted in the document header, but from there, the informant assertion propagates to contained sections and contained entries, unless explicitly overridden. Caution should be used to avoid unintended semantics implied by the cascading property of this participation where it does not apply.

<table>
<thead>
<tr>
<th>Contained By</th>
<th>Contains</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observation Generated By Patient</td>
<td></td>
</tr>
<tr>
<td>Observation Generated By Provider</td>
<td></td>
</tr>
<tr>
<td>Patient Generated Document With Provenance</td>
<td></td>
</tr>
<tr>
<td>Provider Generated Document With Provenance</td>
<td></td>
</tr>
<tr>
<td>Section Generated By Mandatory Author</td>
<td></td>
</tr>
<tr>
<td>Section Generated By Patient</td>
<td></td>
</tr>
<tr>
<td>Section Generated By Provider</td>
<td></td>
</tr>
</tbody>
</table>
1. SHALL contain exactly one [1..1] `templateId` (CONF-DPROV-21) such that it
   a. SHALL contain exactly one [1..1] `@root="2.16.840.1.113883.3.5019.1.21"`
2. SHALL contain exactly one [1..1] `@typeCode="INF"` (CONF:175)

A source of reported information (e.g., a next of kin who answers questions about the patient's history). For history questions, unless otherwise stated, the patient is implicitly the informant. This attribute is fixed to "INF" to specify informant participant

3. SHALL contain one and only one of the following
   • SHALL contain exactly one [1..1] `informantAssignedEntity`, where its type is Informant Assigned Entity (CONF:204)
   • SHALL contain exactly one [1..1] `informantRelatedEntity`, where its type is Provenance Patient Person Role (CONF:177)
   • SHALL contain exactly one [1..1] `providerInformantAssignedEntity`, where its type is Provenance Provider Role (CONF:227)

(CONF:17051)

Provenance Informant Participant Choice example

```xml
<!--Provenance Informant Assigned Entity-->
<informant>
    <templateId root="2.16.840.1.113883.3.5019.1.21"
assigningAuthorityName="HL7 CBCC"/>
    <!-- Mandatory date time-->
    <time value="20151021120500-0500"/>
    <assignedEntity>
        <!--Provenance Informant Assigned Entity Occupation ID-->
        <id extension="1234567890"
root="2.16.840.1.113883.3.4784"assigningAuthorityName="State of Maine Health and Human Services Department"/>
         <!--Provenance Informant Assigned Entity Occupation code-->
        <code code="21-109X" displayName="Miscellaneous community and social service specialists, including health educators and community health workers" codeSystem="2.16.840.1.113883.6.240" codeSystemName="US Census Occupation Code "/>
        <addr>
            <streetAddressLine>1004 Healthcare Drive</streetAddressLine>
            <city>Portland</city>
            <state>ME</state>
            <postalCode>04102</postalCode>
            <country>US</country>
        </addr>
        <telecom use="WP" value="tel:+1(555)555-1004"/>
        <assignedPerson>
            <name>
                <given>Sarah</given>
                <given qualifier="CL">Sally</given>
                <family>Social</family>
                <suffix qualifier="AC">CSWE</suffix>
            </name>
        </assignedPerson>
    </assignedEntity>
</informant>
<!-- Informant Assigned Entity's Mandatory Provenance Scoping Organization -->
```
Provenance Label Component Choice

The Provenance Labels are a subset of the HL7 Security Labels, which provide a "short-hand" code for aspects of provenance for access control and data integration decisions.

<table>
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<tr>
<th>Contains By</th>
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<tbody>
<tr>
<td>Provenance Metadata</td>
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</tbody>
</table>

1. SHALL contain one and only one of the following
   - SHALL contain at least one \([1..*] \) observation (Data Alteration Label), where its type is Data Alteration Label (CONF:16929)
   - SHALL contain at least one \([1..*] \) observation (Data Integrity Label), where its type is Data Integrity Label (CONF:16930)
   - SHALL contain at least one \([1..*] \) observation (Provenance Source Label), where its type is Provenance Source Label (CONF:16932)
   - SHALL contain at least one \([1..*] \) observation (Provenance Confidence Label), where its type is Provenance Confidence Label (CONF:16931) (CONF:17096)

Provenance Metadata Relationship

This entryRelationship may be used to (1) connect predecessor artifacts with a target successor, which is the subject of this metadata, and/or (2) apply additional provenance metadata to a Clinical Statement via an inverted SUBJ ActRelationship.

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Observation Generated By Assembler</td>
<td>Provenance Metadata</td>
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</tbody>
</table>
Provenance Parent Document

[ParentDocument: templateId null]

Per CDA R2 Section 4.2.3.1, “The ParentDocument represents the source of a document revision, addenda, or transformation.” The DPROV IG requires use of the ParentDocument if known as the means for conveying document lifecycle events. It is possible for a DPROV conformant document to have more than one lifecycle "lineage" involving identical ParentDocument content, i.e., a DPROV document instance might be a replacement of a ParentDocument generated from an EHR v2 feeds, and then transformed into a CDA. It could also be an algorithmically generated document from a PHR, which previously received and disaggregated a replacement document from an EHR, and then regenerated as the CDA Document instance. In this case, there would be three ParentDocuments with different identifiers.

If there are document management systems involved in this scenario, then this IG strongly recommends inclusion of the setId and versionNumbers used by the PHR and the EHR to differentiate the distinct contexts in which the DPROV document instance was generated. If the SubmissionSet metadata can be retrieved, it will include important provenance and lifecycle attributes as stipulated by IHE IT Infrastructure Technical Framework Volume 3 Cross-Transaction Specifications and Content Specifications http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol3.pdf:

1. Provenance - Attributes that describe where the document comes from. These items are highly influenced by medical records regulations. This includes human author, identification of system that authored, the organization that authored, predecessor documents, successor documents, and the pathway that the document took.

2. Object Lifecycle - Attributes that describe the current lifecycle state of the document including relationships to other documents. This would include classic lifecycle states of created, published, replaced, transformed, and deprecated.
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<td>Sensitivity Security Observation</td>
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<td>US Privacy Law Security Observation</td>
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</table>

1. **SHALL** contain at least one [1..*] `id` (CONF:17077)
2. **SHALL** contain exactly one [1..1] `code` (CONF:17078)
3. **SHOULD** contain zero or one [0..1] `text` (CONF:17079)
4. **SHOULD** contain zero or one [0..1] `setId` (CONF:17080)
5. **SHOULD** contain zero or one [0..1] `versionNumber` (CONF:17081)
Provenance Parent Document example

<!-- <!-- NullId Template - Provenance Parent Document 1 - current document is replacement "RPLC" [df. = A replacement source act replaces an existing target act. The state of the target act being replaced becomes obsolete, but the act is typically still retained in the system for historical reference. The source and target must be of the same type.] -->
Provenance Parent Document 1 - current document is replacement "RPLC" [df. = A replacement source act replaces an existing target act. The state of the target act being replaced becomes obsolete, but the act is typically still retained in the system for historical reference. The source and target must be of the same type.] -->
<relatedDocument typeCode="RPLC">
  <parentDocument>
    <id root="relatedDocument1" extension="v1" assigningAuthorityName="External Organization"/>
    <code code="34133-9" displayName="Summarization of episode note" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
    <setId root="004bb033-b948-4f4c-b5bf-a8dbd7d8dd40"/>
    <versionNumber value="1"/>
  </parentDocument>
  </relatedDocument>
<relatedDocument typeCode="RPLC">
  <parentDocument>
    <id root="b99f94e4-34a9-4c14-8135-e394fc24ae12" extension="v1" assigningAuthorityName="External Organization"/>
    <code code="34133-9" displayName="Summarization of episode note" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
    <setId root="003bb033-b948-4d4c-b5cf-a8dbd7d8ee34"/>
    <versionNumber value="2"/>
  </parentDocument>
  </relatedDocument>
</relatedDocument>

<!--Provenance Parent Document 2 - current document is replacement of type"XFRM" [df. = Used when the target Act is a transformation of the source Act.] -->
<relatedDocument typeCode="XFRM">
  <parentDocument>
    <id root="relatedDocument1" extension="v1" assigningAuthorityName="External Organization"/>
    <code code="34133-9" displayName="Summarization of episode note" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
    <versionNumber value="3"/>
  </parentDocument>
  </relatedDocument>
<relatedDocument typeCode="XFRM">
  <parentDocument>
    <id root="b99f94e4-34a9-4c14-8135-e394fc24ae21" extension="v1" assigningAuthorityName="External Organization"/>
    <code code="34133-9" displayName="Summarization of episode note" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
    <versionNumber value="3"/>
  </parentDocument>
  </relatedDocument>
</relatedDocument>

Provenance Patient Person Role

[AssignedAuthor: templateId null]
Author constrained to a Patient, a person recording health information, or a personal or legal representative of the subject of this health information.

<table>
<thead>
<tr>
<th>Contained By</th>
<th>Contains</th>
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</thead>
<tbody>
<tr>
<td>Patient Author Participant</td>
<td>Provenance Scoping Organization</td>
</tr>
<tr>
<td>Provenance Author Participant Choice</td>
<td></td>
</tr>
<tr>
<td>Provenance Informant Participant Choice</td>
<td></td>
</tr>
</tbody>
</table>

1. **SHALL** contain at least one [1..*] id (CONF:10045)
2. **SHALL** contain exactly one [1..1] code (CONF:10046), which **SHALL** be selected from ValueSet PersonalAndLegalRelationshipRoleType 2.16.840.1.113883.11.20.12.1 DYNAMIC (CONF:10047)
   
   If an Authoring Person is not a legal or personal relationship with a patient, and this person’s profession is relevant and has a code system, then it is required if known.
3. **SHALL** contain at least one [1..*] addr with @xsi:type="AD" (CONF:10048)
4. **SHALL** contain at least one [1..*] telecom with @xsi:type="TEL" (CONF:10049)
5. **SHALL** contain exactly one [1..1] assignedPerson (CONF:10050)
   
   a. This assignedPerson **SHALL** contain at least one [1..*] name (CONF:10052)
6. **SHOULD** contain zero or one [0..1] representedOrganization, where its type is Provenance Scoping Organization (CONF:10051)
   
   Use only if there is an organization scoping the patient person role, e.g., the provider organization hosting the patient portal used by a patient author or informant.

**Provenance Patient Person Role example**

Error: Missing Runtime Class

---

**Provenance Performer Participant Choice**

[Performer2: templateId null]

This is the actor(s) who performed this provenance relevant state transition.

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<thead>
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<th>Contained By</th>
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<tbody>
<tr>
<td>Provenance Metadata</td>
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</tbody>
</table>

1. **SHALL** contain exactly one [1..1] @typeCode="PRF" (CONF:16888)
2. **SHALL** contain exactly one [1..1] time (CONF:16887)
3. **SHALL** contain one and only one of the following
   
   a. **SHALL** contain exactly one [1..1] deviceAssignedPerformer (Device Assigned Performer), where its type is Provenance Device Role (CONF:16889)
   b. **SHALL** contain exactly one [1..1] patientPersonAssignedPerformer, where its type is Provenance Patient Person Role (CONF:16890)
   c. **SHALL** contain exactly one [1..1] providerPerformer, where its type is Provenance Provider Role (CONF:16891)
Provenance Performer Participant Choice example

Error: Missing Runtime Class

Provenance Policy Information File Relationship

[EntryRelationship: templateId null]

This policy act is the computable and discoverable provenance policy by which trading partners convey their business requirements, semantics, and syntax used in recording, binding, persisting, and conveying Provenance Metadata.

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<th>Contained By</th>
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<tr>
<td>Provenance Metadata</td>
<td>Provenance Policy Information File</td>
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</table>

1. SHOULD contain zero or one [0..1] @nullFlavor="NI"  (CONF:17106)
2. SHALL contain exactly one [1..1] @typeCode="REFR"  (CONF:17107)
3. SHALL contain exactly one [1..1] act, where its type is Provenance Policy Information File (CONF:17108)

Error: Missing Runtime Class

Provenance Policy Information File Relationship example

Provenance Provider Role

[AssignedAuthor: templateId null]

In the scenario where an Organization that scopes the facilitating participating Assembler, if there is no identified Provenance Provider Role participating as the Clinical Statement/entry's author, then use of nullFlavor is permitted.

In order to convey the Assembler Assigned Author Scoping Organization without specifying a particular author [to accommodate the HIE use case], all Assembler document and entry Author Participant Attributes and the Assigned Person must be made nullFlavor together.

As stated previously, nullFlavors are permitted to maximize conformance while leaving flexibility for specific use cases; e.g., where conformant systems are unable to supply values in an instance, but are nevertheless equipped to do so if that information is collected by the scoping organization or available from other sources.

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<td>Provenance Informant Participant Choice</td>
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<td>Provider Author Participant</td>
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1. SHALL contain at least one [1..*] id with @xsi:type="II" (CONF:10053)

This is the Provider Role identifier, which is required if known. If the Provider plays the role of a HIPAA covered provider, then at least one identifier must be a National Provider Identifier where the id/@root ="2.16.840.1.113883.4.6" is the NPI number for the provider. Since not all clinicians have a National Provider Identifier [NPI], use of another identifier is acceptable if known. Otherwise, use null flavor NI. The ids MAY reference the id of a person specified elsewhere in the document.
2. SHALL contain exactly one [1..1] code (CONF:10054), which SHALL be selected from ValueSet

Healthcare Provider Taxonomy (NUCC-HIPAA) 2.16.840.1.114222.4.11.1066

DYNAMIC (CONF:17399)

HIPAA covered providers are required to use the Provider Taxonomy code used for electronic HIPAA
Transactions. Non-HIPAA providers should select the most applicable Provider Taxonomy code for their
credentials, licensure, or practiced.

a. SHOULD satisfy: zero or one [0..1] @nullFlavor="NI". NullFlavor is only permitted on an entry generated by
Assembler. (CONF:17409)

3. SHALL contain at least one [1..*] addr with @xsi:type="AD" (CONF:10056)

Provider Role address is required if known to assist with locating this provider for the verification purposes if
needed.

a. SHOULD satisfy: zero or one [0..1] @nullFlavor="NI". NullFlavor is only permitted on an entry generated by
Assembler. (CONF:17397)

4. SHALL contain at least one [1..*] telecom with @xsi:type="TEL" (CONF:10057)

a. SHOULD satisfy: zero or one [0..1] @nullFlavor="NI". NullFlavor is only permitted on an entry generated by
Assembler. (CONF:17398)

5. SHALL contain exactly one [1..1] assignedPerson (CONF:10058)

a. This assignedPerson SHALL contain at least one [1..*] name (CONF:10060)
b. This assignedPerson SHOULD contain zero or one [0..1] @nullFlavor="NI" (CONF:17400)

6. SHALL contain exactly one [1..1] representedOrganization, where its type is Provenance Scoping
Organization (CONF:10059)

Provenance Related Document

```
[RelatedDocument: templateId null]
```

Whenever a Document Generated by an Assembler, a Device, a Provider, or a Person/Patient appends, replaces
or transforms the directly proceeding version or a document, then a conformant DPROV Document shall indicate
whether the current documents is an addendum to the ParentDocument (APND (append)); the current document
is a replacement of the ParentDocument (RPLC (replace)); or the current document is a transformation of the
ParentDocument (XFRM (transform)).

A conformant CDA document can have a single relatedDocument with typeCode "APND"; a single relatedDocument
with typeCode "RPLC"; a single relatedDocument with typeCode "XFRM"; a combination of two relatedDocuments
with typeCodes "XFRM" and "RPLC"; or a combination of two relatedDocuments with typeCodes "XFRM" and
"APND". No other combinations are allowed.

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<tbody>
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<td>Device Generated Document With Provenance</td>
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<td>Provider Generated Document With Provenance</td>
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<td>Unstructured Document With Provenance</td>
<td>External Reference Choice</td>
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<tr>
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<td>Contains</td>
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<td>Obligation Security Observation</td>
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<td>Privacy Consent Directive Type Security Observation</td>
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<td>Provenance Metadata</td>
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<td>Security Policy Information File</td>
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<tr>
<td></td>
<td>Sensitivity Security Observation</td>
</tr>
<tr>
<td></td>
<td>US Privacy Law Security Observation</td>
</tr>
</tbody>
</table>

1. **SHOULD** contain zero or one [0..1] @nullFlavor="NI" (CONF:17074)
2. **SHALL** contain exactly one [1..1] @typeCode (CONF:17075)
3. **SHALL** contain exactly one [1..1] parentDocument, where its type is *Provenance Parent Document* (CONF:17076)

**Provenance Related Document example**

```xml
<relatedDocument typeCode="XFRM">
  <parentDocument>
    <id/>
    <code/>
  </parentDocument>
</relatedDocument>
```
Provenance Scoping Organization

[Organization: templateId 2.16.840.1.113883.3.5019.1.26]

The purpose of the Scoping Organization template is to specify the required minimum set of information that supports identifying the scoping organization of the assigned author or entity. This template is not required to be applied to patient roles when there is no scoping organization, e.g. when a patient generates content using a patient controlled PHR, but should be used when a patient generates content or provides information to a provider via a provider controlled patient portal.

<table>
<thead>
<tr>
<th>Contained By</th>
<th>Contains</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. SHALL contain exactly one [1..1] templateId (CONF-DPROV-26) such that it</td>
<td></td>
</tr>
<tr>
<td>a. SHALL contain exactly one [1..1] @root=&quot;2.16.840.1.113883.3.5019.1.26&quot;</td>
<td></td>
</tr>
<tr>
<td>2. SHALL contain at least one [1..*] id (CONF:74)</td>
<td></td>
</tr>
<tr>
<td>The Scoping Organization's identifier is mandatory, and may not be null. If the Provenance Scoping Organization is a HIPAA covered provider, then at least one identifier must be a National Provider Identifier where the id/@root =&quot;2.16.840.1.113883.4.6&quot; is the NPI number for the provider organization. For non-HIPAA provider organizations, use of another identifier is acceptable if known. Otherwise, use null flavor NI. The ids MAY reference the id of an organization entity specified elsewhere in the document.</td>
<td></td>
</tr>
<tr>
<td>3. SHALL contain at least one [1..*] addr with @xsi:type=&quot;AD&quot; (CONF:73)</td>
<td></td>
</tr>
<tr>
<td>Scoping organization address is required if known to assist with locating this organization for verification purposes if needed.</td>
<td></td>
</tr>
<tr>
<td>a. SHOULD satisfy: zero or one [0..1] @nullFlavor=&quot;NI&quot; (CONF:17403)</td>
<td></td>
</tr>
<tr>
<td>4. SHALL contain at least one [1..*] telecom=&quot;HV&quot; with @xsi:type=&quot;TEL&quot; (CONF:76)</td>
<td></td>
</tr>
<tr>
<td>The Scoping Organization's telecom is mandatory, and may not be null.</td>
<td></td>
</tr>
<tr>
<td>a. SHOULD satisfy: zero or one [0..1] @nullFlavor=&quot;NI&quot; (CONF:17404)</td>
<td></td>
</tr>
<tr>
<td>5. SHOULD contain zero or one [0..1] standardIndustryClassCode (CONF:17030), which SHALL be selected from ValueSet OrganizationIndustryClassNAICS 2.16.840.1.113883.1.11.19298 DYNAMIC (CONF:17365)</td>
<td></td>
</tr>
<tr>
<td>The Scoping Organization's North American Industry Classification System (NAICS) code can be found at <a href="http://www.census.gov/cgi-bin/sssd/naics/naicsrch">http://www.census.gov/cgi-bin/sssd/naics/naicsrch</a> if an appropriate code exists.</td>
<td></td>
</tr>
<tr>
<td>6. SHALL contain at least one [1..*] name with @xsi:type=&quot;ON&quot; (CONF:75)</td>
<td></td>
</tr>
</tbody>
</table>

provenance Scoping Organization example

Error: Missing Runtime Class

Provenance Signature Observation

[EntryRelationship: templateId null]
This relationship links the observation about whether and how the predecessor entries or external references were digitally signed prior to their incorporation into their successor as such incorporation necessarily breaks signatures on any input.

<table>
<thead>
<tr>
<th>Contained By</th>
<th>Contains</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provenance Metadata</td>
<td></td>
</tr>
</tbody>
</table>

1. SHALL contain exactly one [1..1] observation (CONF:16920)
   a. This observation SHALL contain exactly one [1..1] id (CONF:16921)
   b. This observation SHALL contain exactly one [1..1] code (CONF:16922)
   c. This observation SHALL contain exactly one [1..1] statusCode (CONF:16924)
   d. This observation SHALL contain exactly one [1..1] effectiveTime (CONF:16923)
   e. This observation SHALL contain exactly one [1..1] value (CONF:16926)
   f. This observation SHALL contain exactly one [1..1] text (CONF:16925)
   g. This observation SHALL contain at least one [1..*] author, where its type is CDA Author (CONF:16927)

Provenance Signature Observation example

Error: Missing Runtime Class

Provenance String With Code

*Provenance String With Code* datatype flavor records a string or text description with a code, which is used to specify both the manufacturerModelName and the softwareName attributes of the Authoring Device Entity at the Document and Section Levels, and the Device Participating Entity at the Entry Level. If there are codes for the text names, they should be included to provide additional identifying information about the device and the software used to generate content.

1. Extends SC
2. SHOULD contain zero or one [0..1] code with @xsi:type="csType" (CONF:165)
3. SHOULD contain zero or one [0..1] codeSystem (CONF:166)
4. SHOULD contain zero or one [0..1] codeSystemName (CONF:167)
5. SHOULD contain zero or one [0..1] codeSystemVersion (CONF:168)
6. SHOULD contain zero or one [0..1] displayName (CONF:169)

Provider Author Participant

[Author: templateId 2.16.840.1.113883.3.5019.1.40]

*Provider Author Participant* is constrained for content generated by a provider.

<table>
<thead>
<tr>
<th>Contained By</th>
<th>Contains</th>
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</thead>
<tbody>
<tr>
<td>Observation Generated By Assembler</td>
<td></td>
</tr>
<tr>
<td>Observation Generated By Provider</td>
<td></td>
</tr>
<tr>
<td>Provider Generated Document With Provenance</td>
<td></td>
</tr>
<tr>
<td>Section Generated By Provider</td>
<td></td>
</tr>
</tbody>
</table>

1. SHALL contain exactly one [1..1] templateId (CONF-DPROV-40 ) such that it
a. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.3.5019.1.40"
2. SHALL contain exactly one [1..1] time (CONF:70)

The time stamp is mandatory, and may not be null.
3. SHALL contain exactly one [1..1] assignedAuthor, where its type is Provenance Provider Role (CONF:17387)

Provider Author Participant example

Error: Missing Runtime Class

Purpose Of Use Security Observation Component

[Component4: templateId null]

<table>
<thead>
<tr>
<th>Contained By</th>
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</thead>
<tbody>
<tr>
<td>Security Label</td>
<td>Purpose Of Use Security Observation</td>
</tr>
</tbody>
</table>

1. SHOULD contain zero or one [0..1] @nullFlavor="NI" (CONF:17219)
2. SHALL contain exactly one [1..1] @typeCode="COMP" (CONF:17220)
3. SHALL contain exactly one [1..1] observation, where its type is Purpose Of Use Security Observation (CONF:17221)

Purpose Of Use Security Observation Component example

Error: Missing Runtime Class

Reference Choice

[Reference: templateId null]

<table>
<thead>
<tr>
<th>Contained By</th>
<th>Contains</th>
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</thead>
<tbody>
<tr>
<td>Observation Generated By Assembler</td>
<td>External Reference Choice</td>
</tr>
<tr>
<td>Observation Generated By Device</td>
<td></td>
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<tr>
<td>Observation Generated By Patient</td>
<td></td>
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<tr>
<td>Observation Generated By Provider</td>
<td></td>
</tr>
<tr>
<td>Provenance Metadata</td>
<td></td>
</tr>
</tbody>
</table>

1. SHOULD contain zero or one [0..1] @nullFlavor="NI" (CONF:17093)
2. SHALL contain exactly one [1..1] @typeCode="REFR", which SHALL be selected from ValueSet x_ActRelationshipExternalReference 2.16.840.1.113883.1.11.19000 STATIC 1312-20140807 (CONF:17094)
3. SHALL contain exactly one [1..1] act, where its type is External Reference Choice (CONF:17095)

Reference Choice example

Error: Missing Runtime Class
Refrain Policy Security Observation Component

[Component4: templateId null]

<table>
<thead>
<tr>
<th>Contained By</th>
<th>Contains</th>
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</thead>
<tbody>
<tr>
<td>Security Label</td>
<td>Refrain Policy Security Observation</td>
</tr>
</tbody>
</table>

1. **SHOULD** contain zero or one [0..1] @nullFlavor="NI" (CONF:17225)
2. **SHALL** contain exactly one [1..1] @typeCode="COMP" (CONF:17226)
3. **SHALL** contain exactly one [1..1] observation, where its type is *Refrain Policy Security Observation* (CONF:17227)

Refrain Policy Security Observation Component example

Error: Missing Runtime Class

Security Label Entry Relationship

[EntryRelationship: templateId null]

The Security Label Entry Relationship template is used to specify an association from a Clinical Statement Entry to a Security Label organizer that holds the applicable Security Label Observations or "tags".

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<tr>
<th>Contained By</th>
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<tbody>
<tr>
<td>Observation Generated By Assembler</td>
<td>Security Label</td>
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<tr>
<td>Observation Generated By Device</td>
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<tr>
<td>Observation Generated By Patient</td>
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<tr>
<td>Observation Generated By Provider</td>
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</tr>
</tbody>
</table>

1. **SHALL** contain exactly one [1..1] organizer, where its type is *Security Label* (CONF:17172)

Security Label Entry Relationship example

Error: Missing Runtime Class

Security Policy Information File Reference

[EntryRelationship: templateId null]

<table>
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<tr>
<th>Contained By</th>
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<tbody>
<tr>
<td>Security Label</td>
<td>Security Policy Information File</td>
</tr>
</tbody>
</table>

1. **SHOULD** contain zero or one [0..1] @nullFlavor="NI" (CONF:17228)
2. **SHALL** contain exactly one [1..1] @typeCode="REFR" (CONF:17229)
3. **SHALL** contain at least one [1..*] act, where its type is *Security Policy Information File* (CONF:17230)
Security Policy Information File Reference example

Error: Missing Runtime Class

Sensitivity Security Observation Component

[Component4: templateId null]

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</table>

1. SHOULD contain zero or one [0..1] @nullFlavor="NI" (CONF:17207)
2. SHALL contain exactly one [1..1] @typeCode="COMP" (CONF:17208)
3. contain exactly one [1..1] observation with @xsi:type="Observation"

Sensitivity Security Observation Component example

Error: Missing Runtime Class

Sensitivity Security Observation Component

[Component4: templateId null]

<table>
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<tr>
<th>Contained By</th>
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</table>

1. SHOULD contain zero or one [0..1] @nullFlavor="NI" (CONF:17207)
2. SHALL contain exactly one [1..1] @typeCode="COMP" (CONF:17208)
3. contain exactly one [1..1] observation with @xsi:type="Observation"

Sensitivity Security Observation Component example

Error: Missing Runtime Class

US Privacy Law Security Observation Component

[Component4: templateId null]

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<tr>
<th>Contained By</th>
<th>Contains</th>
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<tbody>
<tr>
<td>Security Label</td>
<td>US Privacy Law Security Observation</td>
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</tbody>
</table>

1. SHOULD contain zero or one [0..1] @nullFlavor="NI" (CONF:17216)
2. SHALL contain exactly one [1..1] @typeCode="COMP" (CONF:17217)
3. SHALL contain exactly one [1..1] observation, where its type is US Privacy Law Security Observation (CONF:17218)

US Privacy Law Security Observation Component example

Error: Missing Runtime Class
**US Realm Address**

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

1. Extends \( AD \)
2. **SHOULD** contain zero or one \([0..1]\) @use (CONF:7290), which **SHALL** be selected from ValueSet PostalAddressUse 2.16.840.1.113883.1.11.10637 **STATIC** (CONF:10093)
3. **SHALL** contain at least one \([1..*]\) streetAddressLine (CONF:7291)
4. **SHALL** contain exactly one \([1..1]\) city (CONF:7292)
5. **SHOULD** contain zero or one \([0..1]\) country (CONF:7295)
6. **SHOULD** contain zero or one \([0..1]\) postalCode (CONF:7294)

*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.*

7. **SHOULD** contain zero or one \([0..1]\) state (CONF:7293)

*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.*

8. 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)
9. 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)
10. **SHALL NOT** have mixed content except for white space (CONF:7296)
11. **SHALL** contain at least one and not more than 4 streetAddressLine (CONF:7291)
The following tables summarize the value sets used in this Implementation Guide. These value sets are provided to constrain coded concepts for the requirements of the project.

### Topics:
- *Act Class Policy*
- *Act Consent Directive*
- *Act Consent Directive Type*
- *Act Consent Type*
- *Act Information Sensitivity Policy*
- *Act Policy Type*
- *Act Privacy Law*
- *Act Privacy Policy*
- *ActUSPrivacyLaw*
- *Compartment*
- *Entity Information Sensitivity Policy*
- *Global Medical Device Nomenclature*
- *HL7 Act Class*
- *HL7 Act Code*
- *HL7 Act Mood*
- *HL7 Act Relationship Type*
- *HL7 Entity Code*
- *HL7 Observation Value*
- *HL7 Participation Function*
- *HL7 Role Code*
- *Healthcare Provider Taxonomy (NUCC-HIPAA)*
- *InformationSensitivityPolicy*
- *Loinc Document Ontology International Document Type*
- *NUCC Health Care Provider Taxonomy Coding System*
- *Obligation Policy*
- *Observation Value*
- *Participation Function*
- *Personal And Legal Relationship Role Type*
- *Provenance Event Current State*
- Purpose Of Use
- Refrain Policy
- Role Information Sensitivity Policy
- Security Alteration Integrity Observation Type
- Security Alteration Integrity Observation Value
- Security Category Observation Type
- Security Category Observation Value
- Security Classification Observation Type
- Security Classification Observation Value
- Security Control Observation Type
- Security Control Observation Value
- Security Data Integrity Observation Type
- Security Data Integrity Observation Value
- Security Integrity Confidence Observation Type
- Security Integrity Confidence Observation Value
- Security Integrity Provenance Observation Type
- Security Integrity Provenance Observation Value
- Security Observation Type
- Security Observation Value
- x Act Relationship Entry
- x Act Relationship Entry Relationship
- x Act Relationship External Reference
## Act Class Policy

<table>
<thead>
<tr>
<th>Value Set</th>
<th>ActClassPolicy - 2.16.840.1.113883.1.11.19818</th>
</tr>
</thead>
<tbody>
<tr>
<td>Source</td>
<td>HL7</td>
</tr>
</tbody>
</table>

## Act Consent Directive

<table>
<thead>
<tr>
<th>Value Set</th>
<th>ActConsentDirective - 2.16.840.1.113883.1.11.20425</th>
</tr>
</thead>
<tbody>
<tr>
<td>Source</td>
<td>HL7</td>
</tr>
<tr>
<td>Description</td>
<td>Specifies the type of consent directive indicated by an ActClassPolicy e.g., a 3rd party authorization to disclose or consent for a substitute decision maker (SDM) or a notice of privacy policy. Usage Note: ActConsentDirective codes are used to specify the type of Consent Directive to which a Consent Directive Act conforms.</td>
</tr>
</tbody>
</table>

## Act Consent Directive Type

<table>
<thead>
<tr>
<th>Value Set</th>
<th>ActConsentDirectiveType - 2.16.840.1.113883.1.11.20551</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition</td>
<td>ActConsentDirective and ActConsentType codes, which are included in the ActConsentDirectiveType value set, are used to specify the type of consent directive to which, for example, a Consent Act conforms, to which a Security Observation (Security Label) refers to, or to which a Privacy or Security Act refers.</td>
</tr>
<tr>
<td>Description</td>
<td>Specifies the type of consent directive indicated by an ActClassPolicy e.g., a 3rd party authorization to disclose or consent for a substitute decision maker (SDM) or a notice of privacy policy. Usage Note: ActConsentDirectiveType codes are used to specify the type of Consent Directive to which a Consent Directive Act conforms.</td>
</tr>
</tbody>
</table>

## Act Consent Type

<table>
<thead>
<tr>
<th>Value Set</th>
<th>ActConsentType - 2.16.840.1.113883.1.11.19897</th>
</tr>
</thead>
<tbody>
<tr>
<td>Source</td>
<td>HL7</td>
</tr>
<tr>
<td>Description</td>
<td>The type of consent directive, e.g., to consent or dissent to collect, access, or use in specific ways within an EHRS or for health information exchange; or to disclose health information for purposes such as research.</td>
</tr>
</tbody>
</table>

## Act Information Sensitivity Policy

<table>
<thead>
<tr>
<th>Value Set</th>
<th>ActInformationSensitivityPolicy - 2.16.840.1.113883.1.11.20429</th>
</tr>
</thead>
<tbody>
<tr>
<td>Source</td>
<td>HL7</td>
</tr>
<tr>
<td>Description</td>
<td>Types of sensitivity policies that apply to Acts. Description: Act.confidentialityCode is defined in the RIM as &quot;constraints around appropriate disclosure of information about this Act, regardless of mood.&quot; Usage Notes: ActSensitivity codes are used to bind information to an Act.confidentialityCode according to local sensitivity policy so that those confidentiality codes can then govern its handling across enterprises. Internally to a policy domain,</td>
</tr>
</tbody>
</table>
however, local policies guide the access control system on how end users in that policy domain are able to use information tagged with these sensitivity values. Note: Specializes InformationSensitivityPolicy

### Act Policy Type

<table>
<thead>
<tr>
<th>Value Set</th>
<th>ActPolicyType - 2.16.840.1.113883.1.11.19886</th>
</tr>
</thead>
<tbody>
<tr>
<td>Source</td>
<td>HL7</td>
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</table>

### Act Privacy Law

<table>
<thead>
<tr>
<th>Value Set</th>
<th>ActPrivacyLaw - 2.16.840.1.113883.1.11.20427</th>
</tr>
</thead>
<tbody>
<tr>
<td>Source</td>
<td>HL7</td>
</tr>
<tr>
<td>Description</td>
<td>A mandate, obligation, requirement, rule, or expectation characterizing the value or importance of a resource and may include its vulnerability. (Based on ISO7498-2:1989. Note: The vulnerability of personally identifiable sensitive information may be based on concerns that the unauthorized disclosure may result in social stigmatization or discrimination.) Description: Types of Sensitivity policy that apply to Acts or Roles. A sensitivity policy is adopted by an enterprise or group of enterprises (a policy domain) through a formal data use agreement that stipulates the value, importance, and vulnerability of information. A sensitivity code representing a sensitivity policy may be associated with criteria such as categories of information or sets of information identifiers (e.g., a value set of clinical codes or branch in a code system hierarchy). These criteria may in turn be used for the Policy Decision Point in a Security Engine. A sensitivity code may be used to set the confidentiality code used on information about Acts and Roles to trigger the security mechanisms required to control how security principals (i.e., a person, a machine, a software application) may act on the information (e.g., collection, access, use, or disclosure). Sensitivity codes are never assigned to the transport or business envelope containing patient specific information being exchanged outside of a policy domain as this would disclose the information intended to be protected by the policy. When sensitive information is exchanged with others outside of a policy domain, the confidentiality code on the transport or business envelope conveys the receiver's responsibilities and indicates the how the information is to be safeguarded without unauthorized disclosure of the sensitive information. This ensures that sensitive information is treated by receivers as the sender intends, accomplishing interoperability without point to point negotiations. Usage Note: Sensitivity codes are not useful for interoperability outside of a policy domain without an out-of-band agreement on semantics because sensitivity policies are typically localized and vary drastically across policy domains even for the same information category because of differing organizational business rules, security policies, and jurisdictional requirements. For example, an employee sensitivity code (EMPL) would make little sense for use outside of a policy domain. The code &quot;taboo&quot; (TBOO) would rarely be useful outside of a policy domain unless there are jurisdictional requirements requiring that a provider disclose sensitive information to a patient directly. Sensitivity codes may be more appropriate in a legacy system's Master Files in order to notify those who access a patient's orders and observations about the sensitivity policies that apply. Newer systems may have a security engine that uses a sensitivity policy criteria directly. The specializable InformationSensitivityPolicy Act.code may be useful in some scenarios if used in combination with a sensitivity identifier and/or Act.title.</td>
</tr>
</tbody>
</table>
### Act Privacy Policy

<table>
<thead>
<tr>
<th>Value Set</th>
<th>ActPrivacyPolicy - 2.16.840.1.113883.1.11.20424</th>
</tr>
</thead>
<tbody>
<tr>
<td>Source</td>
<td>HL7</td>
</tr>
<tr>
<td>Description</td>
<td>A policy deeming certain information to be private to an individual or organization. A mandate, obligation, requirement, rule, or expectation relating to privacy. Discussion: ActPrivacyPolicyType codes support the designation of the 1..* policies that are applicable to an Act such as a Consent Directive, a Role such as a VIP Patient, or an Entity such as a patient who is a minor. 1..* ActPrivacyPolicyType values may be associated with an Act or Role to indicate the policies that govern the assignment of an Act or Role confidentialityCode. Use of multiple ActPrivacyPolicyType values enables fine grain specification of applicable policies, but must be carefully assigned to ensure cogency and avoid creation of conflicting policy mandates. Usage Note: Statutory title may be named in the ActClassPolicy Act Act.title to specify which privacy policy is being referenced.</td>
</tr>
</tbody>
</table>

### ActUSPrivacyLaw

<table>
<thead>
<tr>
<th>Value Set</th>
<th>ActUSPrivacyLaw - 2.16.840.1.113883.1.11.20427</th>
</tr>
</thead>
<tbody>
<tr>
<td>Source</td>
<td>HL7</td>
</tr>
<tr>
<td>Definition</td>
<td>May be associated with an Act or a Role to indicate the legal provision to which the assignment of an Act.confidentialityCode or Role.confidentialityCode complies.</td>
</tr>
<tr>
<td>Description</td>
<td>A jurisdictional mandate in the U.S. relating to privacy. Usage Note: ActPrivacyLaw codes may be associated with an Act or a Role to indicate the legal provision to which the assignment of an Act.confidentialityCode or Role.confidentialityCode complies. May be used to further specify rationale for assignment of other ActPrivacyPolicy codes in the US realm, e.g., ETH and 42CFRPart2 can be differentiated from ETH and Title38Part1.</td>
</tr>
</tbody>
</table>

### Compartment

<table>
<thead>
<tr>
<th>Value Set</th>
<th>Compartment - 2.16.840.1.113883.1.11.20478</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition</td>
<td>This is the healthcare analog to the US Intelligence Community's concept of a Special Access Program. Compartment codes may be used in as a field value in an initiator's clearance to indicate permission to access and use an IT Resource with a security label having the same compartment value in security category label field.</td>
</tr>
<tr>
<td>Description</td>
<td>A named tag set for metadata used to populate a security category label field that &quot;segments&quot; an IT resource per policy by indicating that access and use is restricted to members of a defined community or project. (HL7 Healthcare Privacy and Security Classification System)</td>
</tr>
</tbody>
</table>

### Entity Information Sensitivity Policy

<table>
<thead>
<tr>
<th>Value Set</th>
<th>EntityInformationSensitivityPolicy - 2.16.840.1.113883.1.11.20431</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>Types of sensitivity policies that may apply to a sensitive attribute on an Entity. Usage Notes: EntitySensitivity codes are used to convey a policy that is applicable to sensitive information conveyed by an entity attribute. May be used to bind a Role.confidentialityCode</td>
</tr>
</tbody>
</table>
associated with an Entity per organizational policy. Role.confidentialityCode is defined in
the RIM as "an indication of the appropriate disclosure of information about this Role with
respect to the playing Entity." Note: Specializes InformationSensitivityPolicy

<table>
<thead>
<tr>
<th>Value Set</th>
<th>GlobalMedicalDeviceNomenclature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>A system of internationally agreed generic descriptors used to identify all medical device products. Such products include those used in the diagnosis, prevention, monitoring, treatment or alleviation of disease or injury in humans. The main purpose of the GMDN is to provide health authorities and regulators, health care providers, medical device manufacturers and suppliers, conformity assessment bodies and others with a single generic naming system that will support patient safety. The GMDN is used for: 1. Data exchange between manufacturers, regulators and healthcare authorities 2. Exchange of post-market vigilance information 3. Supporting inventory control in hospitals 4. Purchasing and supply chain management medical device experts from around the world (manufacturers, healthcare authorities and regulators) compiled the GMDN, based on the international standard ISO 15225. <a href="http://www.gmdnagency.com/">http://www.gmdnagency.com/</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Value Set</th>
<th>HL7ActClass</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>A record of something that is being done, has been done, can be done, or is intended or requested to be done. Examples: The kinds of acts that are common in health care are (1) a clinical observation, (2) an assessment of health condition (such as problems and diagnoses), (3) healthcare goals, (4) treatment services (such as medication, surgery, physical and psychological therapy), (5) assisting, monitoring or attending, (6) training and education services to patients and their next of kin, (7) and notary services (such as advanced directives or living will), (8) editing and maintaining documents, and many others.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Value Set</th>
<th>HL7ActCode</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>A code specifying the particular kind of Act that the Act-instance represents within its class. Constraints: The kind of Act (e.g. physical examination, serum potassium, inpatient encounter, charge financial transaction, etc.) is specified with a code from one of several, typically external, coding systems. The coding system will depend on the class of Act, such as LOINC for observations, etc. Conceptually, the Act.code must be a specialization of the Act.classCode. This is why the structure of ActClass domain should be reflected in the superstructure of the ActCode domain and then individual codes or externally referenced vocabularies subordinated under these domains that reflect the ActClass structure. Act.classCode and Act.code are not modifiers of each other but the Act.code concept should really imply the Act.classCode concept. For a negative example, it is not appropriate to use an Act.code &quot;potassium&quot; together with and Act.classCode for &quot;laboratory observation&quot; to somehow mean &quot;potassium laboratory observation&quot; and then use the same Act.code for &quot;potassium&quot; together with Act.classCode for &quot;medication&quot; to mean &quot;substitution of potassium&quot;. This mutually modifying use of Act.code and Act.classCode is not permitted.</td>
</tr>
</tbody>
</table>
### HL7 Act Mood

<table>
<thead>
<tr>
<th>Value Set</th>
<th>HL7ActMood</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>A code distinguishing whether an Act is conceived of as a factual statement or in some other manner as a command, possibility, goal, etc. Constraints: An Act-instance must have one and only one moodCode value. The moodCode of a single Act-instance never changes. Mood is not state. To describe the progression of a business activity from defined to planned to executed, etc. one must instantiate different Act-instances in the different moods and link them using ActRelationship of general type &quot;sequel&quot;. (See ActRelationship.type.)</td>
</tr>
</tbody>
</table>

### HL7 Act Relationship Type

<table>
<thead>
<tr>
<th>Value Set</th>
<th>HL7ActRelationshipType</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>A code specifying the meaning and purpose of every ActRelationship instance. Each of its values implies specific constraints to what kinds of Act objects can be related and in which way.</td>
</tr>
</tbody>
</table>

### HL7 Entity Code

<table>
<thead>
<tr>
<th>Value Set</th>
<th>HL7EntityCode</th>
</tr>
</thead>
</table>

### HL7 Observation Value

<table>
<thead>
<tr>
<th>Value Set</th>
<th>HL7ObservationValue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>This domain is the root domain to which all HL7-recognized value sets for the Observation.value attribute will be linked when Observation.value has a coded data type.</td>
</tr>
</tbody>
</table>

### HL7 Participation Function

<table>
<thead>
<tr>
<th>Value Set</th>
<th>HL7ParticipationFunction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>This code is used to specify the exact function an actor had in a service in all necessary detail. This domain may include local extensions (CWE).</td>
</tr>
</tbody>
</table>

### HL7 Role Code

<table>
<thead>
<tr>
<th>Value Set</th>
<th>HL7RoleCode</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>A set of codes further specifying the kind of Role; specific classification codes for further qualifying RoleClass codes.</td>
</tr>
</tbody>
</table>

### Healthcare Provider Taxonomy (NUCC-HIPAA)

<table>
<thead>
<tr>
<th>Value Set</th>
<th>Healthcare Provider Taxonomy (NUCC-HIPAA) - 2.16.840.1.114222.4.11.1066</th>
</tr>
</thead>
</table>
Code System | Code System sources is NUCC.
--- | ---
Source URL | http://www.hl7.org/v3ballotarchive_temp_051FAD8C-1C23-BA17-0C1B7A67AD11C859/v3ballot2014JAN/html/infrastructure/vocabulary/nuccProviderCodes.html

**Definition**
The Health Care Provider Taxonomy value set is a collection of unique alphanumeric codes, ten characters in length. The code set is structured into three distinct Levels including Provider Type, Classification, and Area of Specialization. The Health Care Provider Taxonomy code set allows a single provider (individual, group, or institution) to identify their specialty category. Providers may have one or more than one value associated to them. When determining what value or values to associate with a provider, the user needs to review the requirements of the trading partner with which the value(s) are being used.

**Description**
In the absence of an all-encompassing Provider Classification System, both X12N and the National Provider System Workgroup from the Centers for Medicare and Medicaid Services (CMS) commenced work on identifying and coding an external provider table that would be able to codify provider type and provider area of specialization for all medical related providers. CMS' intent was to provide a single coding structure to support work on the National Provider System, while X12N needed a single common table for trading partner use. The two projects worked independently to some extent until April 1996 when the lists were coordinated and a single taxonomy was proposed. A sub-group of the X12N TG2 WG 15 was charged with resolving differences in the two proposed taxonomies. Their work resulted in a single taxonomy that both CMS and members of X12N found meaningful, easy to use, and functional for electronic transactions. The sub-group initially started with the CMS draft taxonomy. This list incorporated all types of providers associated with medical care in various ways. Many of the providers listed, such as technologists or technicians, support or repair equipment/machinery. A number of the providers offer medical services, in concert with others, and do not or cannot bill independently for their portion. The amount of research to validate and classify all providers using the proposed hierarchical structure was enormous. The X12N sub-group focused on medical providers who are licensed practitioners, those who bill for health-related services rendered, and those who appeared on the Medicare CMS Provider Specialty listing. This included providers who were licensed to practice medicine via state licensure agencies. In addition, a very broad definition of "areas of specialization" was used, which included nationally recognized specialties, provider self-designated specialties, areas of practice focus, and any request by any agency or trading partner submitted before the first taxonomy release. This level of detail captured specialty information in categories detailed enough to support those trading credentialing information, yet broad enough to support those wishing to trade directory level specialization information. In 2001, ANSI ASC X12N asked the NUCC to become the official maintainer of the Health Care Provider Taxonomy List. The NUCC has a formal operating protocol and its membership includes representation from key provider and payer organizations, as well as state and federal agencies, standard development organizations and the National Uniform Billing Committee (NUBC). Criteria for membership includes a national scope and representation of a unique constituency affected by health care electronic commerce, with an emphasis on maintaining a provider/payer balance.

<table>
<thead>
<tr>
<th>Code</th>
<th>Code System</th>
<th>Print Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1223G0001X</td>
<td>NUCC Health Care Provider Taxonomy Coding System</td>
<td></td>
</tr>
</tbody>
</table>
InformationSensitivityPolicy

<table>
<thead>
<tr>
<th>Value Set</th>
<th>InformationSensitivityPolicy - 2.16.840.1.113883.1.11.20428</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>Sensitivity codes are not useful for interoperability outside of a policy domain because sensitivity policies are typically localized and vary drastically across policy domains even for the same information category because of differing organizational business rules, security policies, and jurisdictional requirements. For example, an &quot;employee&quot; sensitivity code would make little sense for use outside of a policy domain. &quot;Taboo&quot; would rarely be useful outside of a policy domain unless there are jurisdictional requirements requiring that a provider disclose sensitive information to a patient directly. Sensitivity codes may be more appropriate in a legacy system's Master Files in order to notify those who access a patient's orders and observations about the sensitivity policies that apply. Newer systems may have a security engine that uses a sensitivity policy's criteria directly. The specializable Sensitivity Act.code may be useful in some scenarios if used in combination with a sensitivity identifier and/or Act.title. Note: Generalizes ActInformationSensitivityPolicy, EntityInformationSensitivityPolicy, and RoleInformationSensitivityPolicy.</td>
</tr>
</tbody>
</table>

Loinc Document Ontology International Document Type

<table>
<thead>
<tr>
<th>Value Set</th>
<th>LoincDocumentOntologyInternational - 2.16.840.1.113883.1.11.20507</th>
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</thead>
<tbody>
<tr>
<td>Source</td>
<td>HL7</td>
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</tbody>
</table>

NUCC Health Care Provider Taxonomy Coding System

<table>
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<tr>
<th>Value Set</th>
<th>NUCC Health Care Provider Taxonomy Coding System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>The Provider Taxonomy Code List is published (released) twice a year on July 1st and January 1st. The July publication is effective for use on October 1st and the January publication is effective for use on April 1st. The time between the publication release and the effective date is considered an implementation period to allow providers, payers and vendors an opportunity to incorporate any changes into their systems.</td>
</tr>
</tbody>
</table>

Obligation Policy

<table>
<thead>
<tr>
<th>Value Set</th>
<th>ObligationPolicy - 2.16.840.1.113883.1.11.20445</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition</td>
<td>Conveys prohibited actions which an information custodian, receiver, or user is not permitted to perform unless otherwise authorized or permitted under specified circumstances.</td>
</tr>
<tr>
<td>Description</td>
<td>ISO 22600-2 species that a Refrain Policy &quot;defines actions the subjects must refrain from performing&quot;. Per HL7 Composite Security and Privacy Domain Analysis Model: May be used to indicate that a specific action is prohibited based on specific access control attributes e.g., purpose of use, information type, user role, etc. Specializes: ActSecurityPolicyType Generalizes (derived): NOAUTH NOCOLLECT NOINTEGRATE NOLIST NOMOU NOORGPOL NOPERSIST NORDSCLW NORELINK NODSCLCD NORDSCLCD NOREUSE</td>
</tr>
</tbody>
</table>
### Observation Value

<table>
<thead>
<tr>
<th>Value Set</th>
<th>ObservationValue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>This value set is the parent value set for purpose of use, obligation, refrain. etc.</td>
</tr>
</tbody>
</table>

### Participation Function

<table>
<thead>
<tr>
<th>Value Set</th>
<th>ParticipationFunction - 2.16.840.1.113883.11.10267</th>
</tr>
</thead>
<tbody>
<tr>
<td>Code System</td>
<td>HL7ParticipationFunction - 2.16.840.1.113883.5.88</td>
</tr>
<tr>
<td>Version</td>
<td>1312-20140807</td>
</tr>
<tr>
<td>Source</td>
<td>HL7</td>
</tr>
<tr>
<td>Definition</td>
<td>This code is used to specify the exact function an actor had in a service in all necessary detail. This domain may include local extensions (CWE).</td>
</tr>
<tr>
<td>Description</td>
<td>This implementation guide specifies two provenance related participation functions for the participation type &quot;DEV&quot;.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Code</th>
<th>Code System</th>
<th>Print Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASSEMBLER</td>
<td>HL7ParticipationFunction</td>
<td>Assembly Software</td>
</tr>
<tr>
<td>COMPOSER</td>
<td>HL7ParticipationFunction</td>
<td>Composer Software</td>
</tr>
</tbody>
</table>

### Personal And Legal Relationship Role Type

<table>
<thead>
<tr>
<th>Value Set</th>
<th>PersonalAndLegalRelationshipRoleType - 2.16.840.1.113883.11.20.12.1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Code System</td>
<td>HL7RoleCode - 2.16.840.1.113883.5.111</td>
</tr>
<tr>
<td>Version</td>
<td>1312-20140807</td>
</tr>
<tr>
<td>Source</td>
<td>HL7 Role Code</td>
</tr>
<tr>
<td>Source URL</td>
<td><a href="http://www.hl7.org/v3ballotarchive_temp_051FAD8C-1C23-BA17-0C1B7A67AD11C859/v3ballot2014JAN/html/infrastructure/vocabulary/vs_RoleCode.html#PersonalAndLegalRelationshipRoleType">http://www.hl7.org/v3ballotarchive_temp_051FAD8C-1C23-BA17-0C1B7A67AD11C859/v3ballot2014JAN/html/infrastructure/vocabulary/vs_RoleCode.html#PersonalAndLegalRelationshipRoleType</a></td>
</tr>
<tr>
<td>Definition</td>
<td>PersonalAndLegalRelationshipRoleType is defined as: The role of a person in relation to another person, or a person to himself or herself. This value set is to be used when recording relationships based on personal or family ties or through legal assignment of responsibility.</td>
</tr>
<tr>
<td>Description</td>
<td>This value set records the role of a person in relation to another person, or a person to himself or herself. This value set is to be used when recording relationships based on personal or family ties or through legal assignment of responsibility.</td>
</tr>
</tbody>
</table>
### Provenance Event Current State

<table>
<thead>
<tr>
<th>Value Set</th>
<th>ProvenanceEventCurrentState - 2.16.840.1.113883.1.11.20547</th>
</tr>
</thead>
<tbody>
<tr>
<td>Code System</td>
<td>HL7ActCode - 2.16.840.1.113883.5.4</td>
</tr>
<tr>
<td>Version</td>
<td>1312-20140807</td>
</tr>
<tr>
<td>Source</td>
<td>HL7</td>
</tr>
<tr>
<td>Definition</td>
<td>ProvenanceEventCurrentState is defined as: Specifies the state change of a target Act, such as a document or an entry, from its previous state as a predecessor Act. For example, if the target Act is the result of a predecessor Act being &quot;obsoleted&quot; and replaced with the target Act, the source ProvenanceEventCurrentState Act code would be &quot;obsoleted&quot;.</td>
</tr>
<tr>
<td>Description</td>
<td>ProvenanceEventCurrentState valueset is based on ActStatus and DocumentCompletion CodeSystem.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Code</th>
<th>Code System</th>
<th>Print Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>DI</td>
<td>HL7ActCode</td>
<td>Dictated</td>
</tr>
</tbody>
</table>

### Purpose Of Use

<table>
<thead>
<tr>
<th>Value Set</th>
<th>PurposeOfUse - 2.16.840.1.113883.1.11.20448</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition</td>
<td>Reason for performing one or more operations on information, which may be permitted by source system's security policy in accordance with one or more privacy policies and consent directives. Description: The rationale or purpose for an act relating to the management of personal health information, such as collecting personal health information for research or public health purposes.</td>
</tr>
<tr>
<td>Description</td>
<td>Specializes: _ActHealthInformationManagementReason Generalizes (derived): TREAT HPAYMT HOPERAT HMARKT HRESCH PATRQT</td>
</tr>
</tbody>
</table>

### Refrain Policy

<table>
<thead>
<tr>
<th>Value Set</th>
<th>RefrainPolicy - 2.16.840.1.113883.1.11.20446</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition</td>
<td>Definition: Conveys prohibited actions which an information custodian, receiver, or user is not permitted to perform unless otherwise authorized or permitted under specified circumstances.</td>
</tr>
<tr>
<td>Description</td>
<td>Description: ISO 22600-2 species that a Refrain Policy &quot;defines actions the subjects must refrain from performing&quot;. Per HL7 Composite Security and Privacy Domain Analysis Model: May be used to indicate that a specific action is prohibited based on specific access control attributes e.g., purpose of use, information type, user role, etc. Specializes: ActSecurityPolicyType Generalizes (derived): NOAUTH NOCOLLECT NOINTEGRATE</td>
</tr>
</tbody>
</table>
## Role Information Sensitivity Policy

<table>
<thead>
<tr>
<th>Value Set</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>RoleInformationSensitivityPolicy - 2.16.840.1.113883.1.11.20430</td>
<td>Types of sensitivity policies that apply to Roles. Usage Notes: RoleSensitivity codes are used to bind information to a Role.confidentialityCode per organizational policy. Role.confidentialityCode is defined in the RIM as &quot;an indication of the appropriate disclosure of information about this Role with respect to the playing Entity.&quot; Note: Specializes InformationSensitivityPolicy</td>
</tr>
</tbody>
</table>

## Security Alteration Integrity Observation Type

<table>
<thead>
<tr>
<th>Value Set</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>SecurityAlterationIntegrityObservationType - 2.16.840.1.113883.1.11.20465</td>
<td>Type of security metadata observation made about the alteration integrity of an IT resource (data, information object, service, or system capability), which indicates the mechanism used for authorized transformations of the resource. Examples: Types of security alteration integrity observation metadata, which may value the observation with a code used to indicate the mechanism used for authorized transformation of an IT resource, including: translation syntactic transformation semantic mapping redaction masking pseudonymization anonymization subsetted</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Code</th>
<th>Code System</th>
<th>Print Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>SECALTINTOBS</td>
<td></td>
<td></td>
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</tbody>
</table>

## Security Alteration Integrity Observation Value

<table>
<thead>
<tr>
<th>Value Set</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>SecurityAlterationIntegrityObservationValue - 2.16.840.1.113883.1.11.20482</td>
<td>Type of security metadata observation made about the category of an IT resource (data, information object, service, or system capability), which may be used to make access control decisions. Security category metadata is defined by ISO/IEC 2382-8:1998(E/F)/T-REC-X.812-1995 as: &quot;A nonhierarchical grouping of sensitive information used to control access to data more finely than with hierarchical security classification alone.&quot; Rationale: A security category observation supports requirement to specify the type of IT resource to facilitate application of appropriate levels of information security according to a range of levels of impact or consequences that might result from the unauthorized disclosure, modification, or use of the information or information system. A resource is assigned to a specific category of information (e.g., privacy, medical, proprietary, financial, investigative,</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Code</th>
<th>Code System</th>
<th>Print Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>SECALTINTOBV</td>
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</table>

## Security Category Observation Type

<table>
<thead>
<tr>
<th>Value Set</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>SecurityCategoryObservationType - 2.16.840.1.113883.1.11.20459</td>
<td>Type of security metadata observation made about the category of an IT resource (data, information object, service, or system capability), which may be used to make access control decisions. Security category metadata is defined by ISO/IEC 2382-8:1998(E/F)/T-REC-X.812-1995 as: &quot;A nonhierarchical grouping of sensitive information used to control access to data more finely than with hierarchical security classification alone.&quot; Rationale: A security category observation supports requirement to specify the type of IT resource to facilitate application of appropriate levels of information security according to a range of levels of impact or consequences that might result from the unauthorized disclosure, modification, or use of the information or information system. A resource is assigned to a specific category of information (e.g., privacy, medical, proprietary, financial, investigative,</td>
</tr>
</tbody>
</table>
contractor sensitive, security management) defined by an organization or in some instances, by a specific law, Executive Order, directive, policy, or regulation. [FIPS 199]

<table>
<thead>
<tr>
<th>Code</th>
<th>Code System</th>
<th>Print Name</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Security Category Observation Type</td>
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Security Category Observation Value

<table>
<thead>
<tr>
<th>Value Set</th>
<th>SecurityCategoryObservationValue - 2.16.840.1.113883.1.11.20470</th>
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</table>

<table>
<thead>
<tr>
<th>Code</th>
<th>Code System</th>
<th>Print Name</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Security Category Observation Value</td>
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Security Classification Observation Type

<table>
<thead>
<tr>
<th>Value Set</th>
<th>SecurityClassificationObservationType - 2.16.840.1.113883.1.11.20458</th>
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</thead>
<tbody>
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<tr>
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<td>SecurityClassificationObservationType</td>
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Security Classification Observation Value

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<tr>
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<th>SecurityClassificationObservationValue - 2.16.840.1.113883.1.11.20470</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition</td>
<td>Abstract security observation values used to indicate security classification metadata.</td>
</tr>
<tr>
<td>Code</td>
<td>Code System</td>
</tr>
<tr>
<td>-----------------------------------------------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>SECCCLASSOBV</td>
<td>ObservationValue</td>
</tr>
<tr>
<td>V</td>
<td>ObservationValue</td>
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<tr>
<td>R</td>
<td>ObservationValue</td>
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</table>
### Security Control Observation Type

<table>
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<tr>
<td>N</td>
<td>ObservationValue</td>
<td>Normal</td>
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<tr>
<td>M</td>
<td>ObservationValue</td>
<td>Moderate</td>
</tr>
<tr>
<td>L</td>
<td>ObservationValue</td>
<td>Low</td>
</tr>
<tr>
<td>U</td>
<td>ObservationValue</td>
<td>Unrestricted</td>
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</table>

**Value Set**

SecurityControlObservationType - 2.16.840.1.113883.1.11.20460

**Definition**

Type of security metadata observation made about the control of an IT resource (data, information object, service, or system capability), which may be used to make access control decisions. Security control metadata convey instructions to users and receivers for secure distribution, transmission, and storage; dictate obligations or mandated actions; specify any action prohibited by refrain policy such as dissemination controls; and stipulate the permissible purpose of use of an IT resource.

**Description**

Rationale: A security control observation supports requirement to specify applicable management, operational, and technical controls (i.e., safeguards or countermeasures) prescribed for an information system to protect the confidentiality, integrity, and availability of the system and its information. [FIPS 199] Examples: Types of security control metadata include: handling caveats dissemination controls obligations refrain policies purpose of use constraints

### Security Control Observation Value

<table>
<thead>
<tr>
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<th>Code System</th>
<th>Print Name</th>
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</thead>
<tbody>
<tr>
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**Value Set**

SecurityControlObservationValue - 2.16.840.1.113883.1.11.20471

**Source**

HL7

**Definition**

Security observation values used to indicate security control metadata.

**Description**

V:SecurityControl is the union of V:SecurityPolicy, V:ObligationPolicy, V:RefrainPolicy, V:PurposeOfUse, and V:GeneralPurpose of Use used to populate the SecurityControlObservationValue attribute in order to convey one or more nonhierarchical security control metadata dictating handling caveats, purpose of use, dissemination controls and other refrain policies, and obligations to which a custodian or receiver is required to comply.

### Security Data Integrity Observation Type

<table>
<thead>
<tr>
<th>Code</th>
<th>Code System</th>
<th>Print Name</th>
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**Value Set**

SecurityDataIntegrityObservationType - 2.16.840.1.113883.1.11.20464
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**Security Data Integrity Observation Value**

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<tr>
<th>Value Set</th>
<th>SecurityDataIntegrityObservationValue - 2.16.840.1.113883.1.11.20483</th>
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<tbody>
<tr>
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**Security Integrity Confidence Observation Type**

<table>
<thead>
<tr>
<th>Value Set</th>
<th>SecurityIntegrityConfidenceObservationType - 2.16.840.1.113883.1.11.20460</th>
</tr>
</thead>
</table>

**Description**

Type of security metadata observation made about the integrity confidence of an IT resource (data, information object, service, or system capability), which may be used to make access control decisions. Examples: Types of security integrity confidence observation metadata, which may value the observation, include highly reliable, uncertain reliability, and not reliable. Usage Note: A security integrity confidence observation on an Act may indicate that a valued Act.uncertaintycode attribute has been overridden by the entity responsible for ascribing the SecurityIntegrityConfidenceObservationValue. This supports the business requirements for increasing or decreasing the assessment of the reliability or trustworthiness of an IT resource based on parameters beyond the original assignment of an Act statement level of uncertainty.

<table>
<thead>
<tr>
<th>Code</th>
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<th>Print Name</th>
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**Security Integrity Confidence Observation Value**

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<tbody>
<tr>
<td>SECINTCONOBV</td>
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**Security Integrity Provenance Observation Type**

<table>
<thead>
<tr>
<th>Value Set</th>
<th>SecurityIntegrityProvenanceObservationType - 2.16.840.1.113883.1.11.20466</th>
</tr>
</thead>
</table>

**Description**

Type of security metadata observation made about the provenance integrity of an IT resource (data, information object, service, or system capability), which indicates the lifecycle completeness of an IT resource in terms of workflow status such as its creation, modification, suspension, and deletion; locations in which the resource has been collected or archived, from which it may be retrieved, and the history of its distribution and disclosure. Integrity provenance metadata about an IT resource may be used to assess its veracity, reliability, and trustworthiness. Examples: Types of security integrity provenance observation metadata, which may value the observation about an IT resource, include:
completeness or workflow status, such as authentication the entity responsible for original authoring or informing about an IT resource the entity responsible for a report or assertion about an IT resource relayed second-hand the entity responsible for excerpting, transforming, or compiling an IT resource

<table>
<thead>
<tr>
<th>Code</th>
<th>Code System</th>
<th>Print Name</th>
</tr>
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## Security Integrity Provenance Observation Value

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## Security Observation Type

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</tr>
</thead>
<tbody>
<tr>
<td>Source</td>
<td>HL7</td>
</tr>
<tr>
<td>Description</td>
<td>Type of security metadata observation made about an IT resource (data, information object, service, or system capability), which may be used to make access control decisions. Security metadata are used in security labels. According to ISO/TS 22600-3:2009(E) A.9.1.7 SECURITY LABEL MATCHING, Security label matching compares the initiator's clearance to the target's security label. All of the following must be true for authorization to be granted:</td>
</tr>
</tbody>
</table>

## Security Observation Value

<table>
<thead>
<tr>
<th>Value Set</th>
<th>SecurityObservationValue - 2.16.840.1.113883.1.11.20469</th>
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</thead>
<tbody>
<tr>
<td>Source</td>
<td>HL7</td>
</tr>
<tr>
<td>Description</td>
<td>This value set is the parent value set for purpose of use, obligation, refrain. etc.</td>
</tr>
</tbody>
</table>

## x Act Relationship Entry

<table>
<thead>
<tr>
<th>Value Set</th>
<th>x_ActRelationshipEntry - 2.16.840.1.113883.1.11.19446</th>
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<tbody>
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## x Act Relationship Entry Relationship

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<tbody>
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### x Act Relationship External Reference

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</tr>
</thead>
<tbody>
<tr>
<td>Definition</td>
<td>Used to enumerate the relationships between two CDA entries.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Value Set</th>
<th>x_ActRelationshipExternalReference - 2.16.840.1.113883.1.11.19000</th>
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<tbody>
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<tr>
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<td>Source URL</td>
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</tr>
<tr>
<td>Definition</td>
<td>Used to enumerate the relationships between a CDA entry and an externally referenced act.</td>
</tr>
</tbody>
</table>
This implementation guides uses concepts and contents documented in related standard specifications and external project artifacts:

- Data Provenance documents referenced in this IG are available on the Data Provenance Initiative (DPROV) S&I Framework Initiative
- For a detailed description of the project, refer to the Data Provenance S&I Framework Initiative Executive Summary

The DPROV Initiative builds on existing standards and projects and seeks to align and harmonize concepts to support the use cases and regulatory requirements within the US Realm. The following standards and activities have informed this IG:

- W3C PROV Family of Documents

HL7 v.2 and v.3 standards that support interoperable provenance capabilities, including:

- HL7 v2 Chapter 2 Control
- HL7 v3 Trigger Event Act (MCAL_RM700200UV)
- HL7 v3 Result Event (POLB_RM004000UV01)
- HL7 Data Segmentation for Privacy (DS4)CDA R2 IG (Chapter 5: Other Templates) HL7_IG_DS4P_R1_CH1_CONTENT_N2_2014JAN

HL7 EHR Functional Model profiles, including:

- HL7 EHR-System Functional Model, R2
- HL7 EHR Records Management and Evidentiary Support Functional Model, Release 1
- HL7 FHIR DSTU Release 1.1 HL7 FHIR DSTU Release 1.1 Provenance Resources

Implementation guidance:
