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HL7 Implementation Guide for CDA Release 2: Unstructured Documents, Release 1

Level 1 (Universal Realm)

Draft Standard for Trial Use

September 2010

Publication of this draft standard for trial use and comment has been approved by Health Level Seven International (HL7). This draft standard is not an accredited American National Standard. The comment period for use of this draft standard shall end 24 months from the date of publication. Suggestions for revision should be submitted at http://www.hl7.org/dstucomments/index.cfm.

Following this 24 month evaluation period, this draft standard, revised as necessary, will be submitted to a normative ballot in preparation for approval by ANSI as an American National Standard. Implementations of this draft standard shall be viable throughout the normative ballot process and for up to six months after publication of the relevant normative standard.

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Revision History

Rev	Date	By Whom	Changes	Notes
1.0	December 11, 2009	Sean McIlvenna	Initial ballot package	
1.1	May 13, 2010	Kate Hamilton	Incorporating ballot reconciliation	
1.2	July 19, 2010	Rick Giemer, Brett Marquard	Additional information on relationship to IHE's XDS-SD profile	

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1 INTRODUCTION

1.1 Purpose

The purpose of this document is to describe constraints on the Clinical Document Architecture (CDA) header and body elements for an Unstructured Document.

In many environments much of the patient record is still captured in an unstructured format that is encapsulated within an image file or as unstructured text in an electronic file such as a word processing or Portable Document Format (PDF) documents.

There is a need to raise the level of interoperability for these documents to provide full access to the longitudinal patient record across a continuum of care. Until this gap is addressed, image and multi-media files will continue to be a portion of the patient record that remains difficult to access and share with all participants in a patient's care. (See Relationship to IHE's XDS-SD on the relationship of this guide to IHE's XDS-SD.)

This project addresses this gap by providing consistent guidance on the use of CDA for Unstructured Documents.

1.2 Audience

The audience for this document includes software developers and consultants responsible for implementation of universal realm Electronic Health Record (EHR) systems, Personal Health Record (PHR) systems, dictation/transcription systems, and document management applications; and local, regional, and national health information exchange networks that wish to create and/or process CDA documents developed according to this specification.

1.3 Approach

The approach taken in the development of this specification was to review existing draft and final specifications or implementation guides for similar artifacts in the U.S.:

- Clinical LOINC® document and section codes
- Health Information Technology Standards Panel (HITSP) Constructs, including the Encounter Document Using IHE Medical Summary (XDS-MS) Component (C48)
- HL7 Clinical Document Architecture, Release 2 Normative Web Edition, 2005
- Integrating the Healthcare Enterprise (IHE) Profiles, including the content profiles within Patient Care Coordination (PCC) and specifically the IHE IT Infrastructure Technical Framework Volume 3 (ITI TF-3) Cross-Transaction Specifications and Content Specifications Revision 6.0. (See Relationship to IHE's XDS-SD on the relationship of this guide to XDS-SD.)
- Non-CDA sample documents supplied by participating providers and vendors

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1.4 Organization of This Guide

The requirements of this Draft Standard for Trial Use (DSTU) are on track to become normative after a trial period and will be subject to change under the policies for DSTU per the HL7 Governance and Operations Manual. This guide is organized into the following major sections:

- General Header Constraints
- Header Constraints Specific to Unstructured Documents
- Body

Each major section or subsection of the document is organized to provide:

- A narrative overview and scope for that section
- CDA Release 2 (R2) constraints

1.5 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 template in question.

1.5.1 Originator Responsibilities: General Case

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 that an object in an instance document conforms to. This implementation guide asserts when `templateIds` are required for conformance.

1.5.2 Recipient Responsibilities: General Case

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

A recipient may process objects in an instance document 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`).

If an object does not have a `templateId`, a recipient shall not report a conformance error about a failure to conform to a particular template on classes that do not claim conformance to that template and that are not required to be conformant by other templates.

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1.6 Conventions Used in This Guide

1.6.1 Conformance Requirements

The conformance statements are numbered sequentially and listed within the body of the guide as follows:

CONF-ex1: Conformance requirements original to this guide are numbered CONF UD 1, CONF UD 2, etc.

1.6.2 Vocabulary Conformance

Formalisms for value-set constraints are based on the latest recommendations from the HL7 Vocabulary Committee. Value-set constraints can be "**STATIC**," meaning that they are bound to a specified version of a value set, or "**DYNAMIC**," meaning that they are bound to the most current version of a value set. A simplified constraint is used when binding is to a single code.

Syntax for vocabulary binding to **DYNAMIC** or **STATIC** value sets:

A (`pathname of coded element`) element (**SHALL** | **SHOULD** | **MAY**) be present where the value of (`pathname of coded element`) is selected from Value Set `valueSetOID localValueSetName` [**DYNAMIC** | **STATIC** (`valueSetEffectiveDate`)].

CONF-ex2: A `code` element **SHALL** be present where the value of `@code` is selected from Value Set `2.16.840.1.113883.19.3 LoincDocumentTypeCode` **DYNAMIC**.

CONF-ex3: A `code` element **SHALL** be present where the value of `@code` is selected from Value Set `2.16.840.1.113883.19.3 LoincDocumentTypeCode` **STATIC** `20061017`.

Syntax for vocabulary binding to a single code:

A (`pathname of coded element`) element (**SHALL** | **SHOULD** | **MAY**) be present where the value of (`pathname of coded element`) is `code [displayName] codeSystemOID [codeSystemName]` **STATIC**.

CONF-ex4: A `code` element **SHALL** be present where the value of `@code` is `34133-9 Summarization of episode note 2.16.840.1.113883.6.1 LOINC` **STATIC**.

1.6.3 Keywords

The keywords **SHALL**, **SHALL NOT**, **SHOULD**, **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 that the element or attribute be present; it may take a nullFlavor unless otherwise prohibited
- **SHALL NOT**: an absolute prohibition against inclusion of the element or attribute
- **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

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1.6.4 XPath Notation

Instead of the traditional dotted notation used by HL7 to represent Reference Information Model (RIM) classes, this document uses XPath notation in conformance statements and elsewhere to identify the Extensible Markup Language (XML) elements and attributes within the CDA document instance to which various constraints are applied. The implicit context of these expressions is the root of the document. The purpose of using this notation is to provide a mechanism for identifying parts of an XML document that will be familiar to developers.

1.6.5 XML Examples

XML examples appear in various figures in this document in `this monospace font`. Portions of the XML content may be omitted from the content for brevity, marked by an ellipsis (…) as shown in the example below.

Figure 1: ClinicalDocument example

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

1.7 Scope

This implementation guide is a conformance profile, as described in the Refinement and Localization section of the HL7 Version 3 standards. The base standard for this implementation guide is the HL7 Clinical Document Architecture, Release 2.0. As defined in that document, this implementation guide is both an annotation profile and a localization profile. CDA R2 is not fully described in this guide, so implementers must be familiar with the requirements of the base specification.

As an annotation profile, portions of this guide summarize or explain the base standard; therefore, some requirements stated here originate not in this guide but in the base specification. Requirements that do not add further constraints to the base standard and that can be validated through CDA.xsd do not have corresponding conformance statements in this guide. However, the header constraints in this guide necessarily differ in some points from the CDA General Header Constraints, and are provided at the same level of detail as the CDA General Header Constraints to make explicit these differences.

This guide is the seventh in a series being developed in part through the efforts of Health Story (formerly CDA4CDT). In the other guides in this series, the CDA architecture is defined down to CDA Level 2 granularity with reuse of previously created entry-level templates where appropriate. The Health Story guides will be compiled into a single implementation guide for normative balloting at the conclusion of the DSTU trial period.

The present specification defines only Level 1 constraints on CDA header and body elements used in Unstructured Documents in the universal realm.

Where no constraints are stated in this guide, instances are subject to and are to be created in accordance with the base CDA R2 specification. Where, for instance, the CDA

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R2 specification declares an attribute to be optional and this specification contains no additional constraints, that attribute remains optional.

1.7.1 Relationship to IHE's XDS-SD

This guide is not intended to be a replacement for IHE's XDS-SD (Cross-Transaction Specifications and Content Specifications, Scanned Documents Module) profile. Rather, it serves a more generic use case. XDS-SD is specifically for scanned documents, and limits content to PDF-A or text. This Unstructured Documents implementation guide is applicable not only for scanned documents in non-PDF formats, but also for clinical documents produced through word processing applications, etc.

It is possible for documents to conform to both XDS-SD and the Unstructured Documents specification; however, Unstructured Documents is not a pure superset of XDS-SD, and is in some cases more restrictive. For example, <title> is optional in XDS-SD, but is required in the Unstructured Documents specification. For conformance with both specifications, please review Appendix D – XDS-SD and CDA General Header Constraints Comparison and ensure that your documents at a minimum conform to all the SHALL constraints from either specification.

1.7.2 Levels of Constraint

CDA specifies three levels of conformance requirements:

- Level 1 requirements specify constraints upon the CDA header and the content of the document.
- Level 2 requirements specify constraints at the section level of the `structuredBody` of the `ClinicalDocument` element of the CDA document.
- Level 3 requirements specify constraints at the entry level within a section.

Note that these levels are rough indications of what a recipient can expect in terms of machine-processable coding and content reuse. They do not reflect the level or type of clinical content; many additional distinctions in reusability could be defined.

This guide addresses only Level 1 constraints because of the nature and purpose of this guide: additional levels of coding are not applicable since they require the use of a `structuredBody`, which this implementation guide prohibits.

1.7.3 Future Work

Future work in the Health Story project includes the definition of increasingly refined (granular) machine-verifiable processing structures. This work will be performed in conjunction with other HL7 work groups and in cooperation with professional societies and other Standards Development Organizations (SDOs). There are many parallel efforts to create CDA implementation guides and standards based on CDA. Future work will address libraries of templates, including those defined and reused here, and refinement of the document type hierarchy.

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2 CDA HEADER – GENERAL CONSTRAINTS

2.1 General Header Constraints

The History and Physical (H&P) Note guide defined a set of general constraints against the CDA header, referenced in this document as the CDA General Header Constraints template. This guide cannot require the template because the template requires the U.S. realm code. Further, the constraints asserted here are in some places looser than those of the CDA General Header Constraints template because information such as the author may not be available for Unstructured Documents.

Therefore, where other guides in the Health Story series simply reference the CDA General Header Constraints, this guide repeats the constraints, modified as necessary for the realm and use case. A note with each set of constraints states whether they modify or provide the same constraints as the CDA General Header Constraints.

Within the U.S., implementers may assert conformance with the CDA General Header Constraints template for consistency across implementations.

The Comparison of XDS-SD and CDA General Header Constraints table in Appendix D can help the implementer decide whether or not to assert conformance to the CDA General Header Constraints. [See References for a link to XDS-SD (Cross-Transaction Specifications and Content Specifications, Scanned Documents Module).]

The following constraint relaxes the requirement to include the CDA General Header Constraints `templateId`.

CONF-UD-1: A U.S.-realm document conforming to the CDA General Header Constraints template **SHOULD** include the `ClinicalDocument/templateId 2.16.840.1.113883.10.20.3.`

Figure 2: Clinical Document/templateId example: general header constraints

```
<templateId root="2.16.840.1.113883.10.20.3"/>
```

The CDA General Header Constraints apply to:

- Clinical document and associated metadata
- ID, type ID
- Level of constraint
- Code, title
- Set ID and version number
- Effective time, confidentiality code
- Language code, realm code
- Participants
- Record target (patient)
- Author

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- Authenticator and legal authenticator
- Custodian
- Data enterer (transcriptionist)
- Informant
- Health care providers
- Personal relations and unrelated persons
- Information recipient (entered in "cc" field)
- Participant telephone number

2.2 OIDs and UUIDs

Object Identifiers (OIDs) are limited by this specification to no more than 64 characters in length for compatibility with other standards and implementation guides.

The following constraints conform to the CDA General Header Constraints.

CONF-UD-2: UUIDs **SHALL** be represented in the form XXXXXXXX-XXXX-XXXX-XXXX-XXXXXXXXXXXX, where each X is a character from the set [A-Fa-f0-9].

CONF-UD-3: OIDs **SHALL** be represented in dotted decimal notation, where each decimal number is either 0, or starts with a nonzero digit. More formally, an OID **SHALL** be in the form ([0-2])(.([1-9][0-9]*|0))+.

CONF-UD-4: OIDs **SHALL** be no more than 64 characters in length.

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3 CDA HEADER – CONSTRAINTS SPECIFIC TO UNSTRUCTURED DOCUMENTS

3.1 ClinicalDocument Constraints

This section describes the `ClinicalDocument` header constraints specific to Unstructured Documents.

This DSTU recommends but does not require conformance to the CDA General Header Constraints. Some constraints in this section therefore must duplicate constraints in the General Header Constraints; these are identified to assist the implementer.

3.1.1 ClinicalDocument namespace

The namespace for CDA Release 2.0 is *urn:hl7-org:v3*. Appropriate namespace declarations shall be used in the XML instance of the `ClinicalDocument`. In the examples in this specification, all elements are shown un-prefixed, assuming that the default namespace is declared to be *urn:hl7-org:v3*.

This constraint conforms to the CDA General Header Constraints.

CONF-UD-5: The root of an Unstructured Document **SHALL** be a `ClinicalDocument` element from the *urn:hl7-org:v3* namespace.

3.1.2 ClinicalDocument/typeId

The clinical document `typeId` identifies the constraints imposed by CDA R2 on the content, essentially acting as a version identifier. The `@root` and `@extension` values of this element are specified as shown below.

This constraint conforms to the CDA General Header Constraints.

CONF-UD-6: The value of `typeId/@root` **SHALL** be `2.16.840.1.113883.1.3` and the value of `typeId/@extension` **SHALL** be `POCD_HD000040`.

Figure 3: ClinicalDocument/typeId example

```
<typeId extension="POCD_HD000040" root="2.16.840.1.113883.1.3"/>
```

3.1.3 ClinicalDocument/templateId

Conformant Unstructured Documents must carry the document-level `templateId` asserting conformance with this DSTU.

The following constraints conform to the CDA General Header Constraints.

CONF-UD-7: A `ClinicalDocument/templateId` element **SHALL** be present with the value `2.16.840.1.113883.10.20.19.1` indicating conformance to this guide.

Unstructured Documents can also conform to the IHE XDS-SD profile, in which case the following `templateId` could be asserted. See the Comparison of XDS-SD and CDA General Header Constraints table for the requirements for conformance to XDS-SD.

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Note: the CDA Header Constraints used by this guide are not a superset of the header constraints described in the IHE XDS-SD profile (i.e. there are areas where this guide uses tighter constraints than XDS-SD). The HL7 Structured Documents Working Group will coordinate with IHE to harmonize these differences.

CONF-UD-8: A `ClinicalDocument/templateId` element **MAY** be present with the value `XDS-SD-OID`.

Figure 4: ClinicalDocument/templateId example

```
<templateId root="2.16.840.1.113883.10.20.19.1"/>
```

3.1.4 ClinicalDocument/id

The `ClinicalDocument/id` element is an instance identifier data type (see HL7 Version 3 Abstract Data in References). The `root` attribute is a UUID or OID. The `root` uniquely identifies the scope of the `extension`. The `root` and `extension` attributes uniquely identify the document.

This constraint conforms to the CDA General Header Constraints.

CONF-UD-9: The `ClinicalDocument/id` element **SHALL** be present. The `ClinicalDocument/id/@root` attribute **SHALL** be a syntactically correct UUID or OID.

Figure 5: ClinicalDocument/id example

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

3.1.5 ClinicalDocument/code

To support use in the international realm, this guide places no constraints on the vocabulary for document type codes.

This differs from the CDA General Header Constraints.

Figure 6: ClinicalDocument/code example

```
<code codeSystem="2.16.840.1.113883.6.1"
  codeSystemName="LOINC"
  code="11490-0"
  displayName="Discharge Summarization Note (physician)" />
```

3.1.6 ClinicalDocument/title

The document title need not be the same as the display name provided with the document type code. The title can be localized, as appropriate.

This constraint conforms to the CDA General Header Constraints.

CONF-UD-10: The `title` element **SHALL** be present and specify the local name used for the document.

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Figure 7: ClinicalDocument/title example

```
<title>Discharge Summary</title>
```

3.1.7 ClinicalDocument/effectiveTime

The `effectiveTime` records the time of creation of the original document.

If the referenced document is a scan, the date of scan can be recorded in `dataEnterer`.

If the date of creation of the original document is not known, CDA allows the document `effectiveTime` to have a `nullFlavor`. See section 1.6.3, Keywords.

This constraint on time relaxes the constraints in the CDA General Header Constraints to address the use case specific to Unstructured Documents.

CONF-UD-11: The `ClinicalDocument/effectiveTime` element **SHALL** be present. It **SHALL** be precise at least to the year and **SHOULD** be precise to the day. If more precise than to the day it **SHALL** include a time-zone.

Figure 8: ClinicalDocument/effectiveTime example

```
<effectiveTime value="20050303171504+0500"/>
```

3.1.8 ClinicalDocument/confidentialityCode

CDA R2 requires that the `ClinicalDocument/confidentialityCode` be present. It specifies the confidentiality assigned to the document. This DSTU provides no further guidance on documents with respect to the vocabulary used for `confidentialityCode`, nor treatment or implementation of confidentiality.

If the `confidentialityCode` cannot be determined for an Unstructured Documents instance, the HL7 code `"N"` (normal confidentiality) is recommended.

Figure 9: CinicalDocument/confidentialityCode example

```
<confidentialityCode codeSystem="2.16.840.1.113883.5.25"
                     codeSystemName="HL7 Confidentiality Code"
                     code="N"
                     displayName="Normal"/>
```

3.1.9 ClinicalDocument/languageCode

The General Header Constraints require `ClinicalDocument/languageCode` and specify that it records the primary language of the header. If the language of the body is different from the language in the header, the `languageCode` can be overridden within the body.

The following constraints conform to the CDA General Header Constraints.

CONF-UD-12: `ClinicalDocument/languageCode` **SHALL** be present.

CONF-UD-13: `ClinicalDocument/languageCode` **SHALL** be in the form `nn`, or `nn-CC`.

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CONF-UD-14: The `nn` portion of `ClinicalDocument/languageCode` **SHALL** be a legal ISO-639-1 language code in lowercase.

CONF-UD-15: The `CC` portion `ClinicalDocument/languageCode`, if present, **SHALL** be an ISO-3166 country code in uppercase.

Figure 10: ClinicalDocument/languageCode example with language only

```
<languageCode code="en"/>
```

Figure 11: ClinicalDocument/languageCode example with language and country

```
<languageCode code="en-US"/>
```

3.2 Participants

This section describes constraints on header participants specified by this guide.

3.2.1 recordTarget

The `recordTarget` element records the patient or patients whose health information is recorded in the Unstructured Documents instance.

Constraint 17 is an addition to the CDA General Header Constraints.

CONF-UD-16: At least one `recordTarget/patientRole` element **SHALL** be present.

CONF-UD-17: A `patientRole` element **SHALL** contain an `id` element.

CONF-UD-18: A `patientRole` element **SHALL** contain a `patient/birthTime` element. The value of `patient/birthTime/@value` **SHALL** be precise at least to the year, and **SHOULD** be precise at least to the day, and **MAY** omit time zone. If unknown, it **SHALL** be represented using a flavor of null.

CONF-UD-19: A `patientRole element` **SHALL** contain a `patient/administrativeGenderCode` element. If the administrative gender is unknown, it **SHALL** be represented using a flavor of null. Values for `administrativeGenderCode` **SHOULD** be drawn from the HL7 AdministrativeGender vocabulary.

CONF-UD-20: When the patient is a minor child, a `patientRole` element **SHOULD** contain a `patient/guardian` element.

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Figure 12: recordTarget example

```
<recordTarget>
  <patientRole>
    <id extension="12345" root="2.16.840.1.113883.3.933"/>
    <addr>
      <streetAddressLine>17 Daws Rd.</streetAddressLine>
      <city>Blue Bell</city>
      <state>MA</state>
      <postalCode>02368</postalCode>
      <country>USA</country>
    </addr>
    <telecom value="tel:(781)555-1212"/>
    <patient>
      <name>
        <given>Henry</given>
        <family>Levin</family>
      </name>
      <administrativeGenderCode code="M"
                                codeSystem="2.16.840.1.113883.5.1"/>
      <birthTime value="19490125"/>
      <guardian>
        <id extension="23456" root="2.16.840.1.113883.19.5"/>
        <addr>
          <streetAddressLine>17 Daws Rd.</streetAddressLine>
          <city>Blue Bell</city>
          <state>MA</state>
          <postalCode>02368</postalCode>
          <country>USA</country>
        </addr>
        <telecom value="tel:(781)555-1212" use="HP"/>
        <guardianPerson>
          <name>
            <given>Father</given>
            <family>Last</family>
          </name>
        </guardianPerson>
      </guardian>
    </patient>
  </patientRole>
</recordTarget>
```

3.2.2 author

The `author` represents the person who created the original document.

If the referenced document is a scan, the person who did the scan must be recorded in `dataEnterer`.

If address and telecom are not known, they can be represented with `nullFlavors`. See section 1.6.3, Keywords.

Constraints 25 and 26 are in addition to the CDA General Header Constraints.

CONF-UD-21: The `author` element **SHALL** be present.

CONF-UD-22: An `assignedAuthor` **SHALL** be present.

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CONF-UD-23: An `assignedAuthor` **SHALL** contain an `id` element. If the `id` is unknown, it **SHALL** be represented using the appropriate flavor of null.

CONF-UD-24: An `assignedAuthor` **SHALL** contain an assignedPerson/`name` element. If the `name` is unknown, it **SHALL** be represented using the appropriate flavor of null.

CONF-UD-25: An `assignedAuthor` element **SHALL** contain an `addr` element. If `addr` is unknown it **SHALL** be represented using the appropriate flavor of null.

CONF-UD-26: An `assignedAuthor` element **SHALL** contain a `telecom` element. If `telecom` is unknown it **SHALL** be represented using the appropriate flavor of null.

Figure 13: author example

```
<author>
  <assignedAuthor>
    <id extension="1" root="2.16.840.1.113883.19"/>
    <addr>
      <streetAddressLine>21 North Ave</streetAddressLine>
      <city>Burlington</city>
      <state>MA</state>
      <postalCode>01803</postalCode>
      <country>USA</country>
    </addr>
    <telecom nullFlavor='UNK'/>
    <assignedPerson>
      <name>
        <prefix>Dr.</prefix>
        <given>Bernard</given>
        <family>Wiseman</family>
        <suffix>Sr.</suffix>
      </name>
    </assignedPerson>
  </assignedAuthor>
</author>
```

3.2.3 custodian

CDA R2 requires a `custodian` element be present (Section 4.2.2.3 of the CDA Normative Web Edition; see References), representing the custodian of the clinical document.

If address and telecom are not known, they can be represented with `nullFlavors`. See section 1.6.3, Keywords.

The following constraints are in addition to the CDA General Header Constraints.

CONF-UD-27: The `custodian` element **SHALL** be present.

CONF-UD-28: The `custodian` element **SHALL** contain an `assignedCustodian/representedCustodianOrganization` element.

CONF-UD-29: A `representedCustodianOrganization` element **SHALL** contain an `id` element.

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CONF-UD-30: A `representedCustodianOrganization` element **SHALL** contain a `name` element.

CONF-UD-31: A `representedCustodianOrganization` element **SHALL** contain a `telecom` element.

CONF-UD-32: A `representedCustodianOrganization` element **SHALL** contain an `addr` element.

Figure 14: custodian example

```
<custodian>
  <assignedCustodian>
    <representedCustodianOrganization>
      <id extension="1" root="1.3.6.4.1.4.1.2835.3"/>
      <name>Community Health Hospital</name>
      <telecom value="tel:(999)555-1212" use="WP"/>
      <addr>
        <streetAddressLine>21 North Ave</streetAddressLine>
        <city>Burlington</city>
        <state>MA</state>
        <postalCode>01803</postalCode>
        <country>USA</country>
      </addr>
    </representedCustodianOrganization>
  </assignedCustodian>
</custodian>
```

3.2.4 legalAuthenticator

The `legalAuthenticator` element identifies the legal authenticator of the Unstructured Document and must be present if the document has been legally authenticated. Based on local practice, clinical documents may be released before legal authentication. This implies that a clinical document that does not contain this element has not been legally authenticated.

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

Local policy may delegate the function of asserting legal authentication to a device or system that generates the clinical document.[1] In these cases, the legal authenticator is a person accepting responsibility for the document, not the generating device or system.

These constraints conform to the CDA General Header Constraints. [2]

CONF-UD-33: If the referenced Unstructured Document is signed, a `legalAuthenticator/assignedEntity/assignedPerson` element **SHALL** be present.

[1] An example of a document that is automatically signed is a check with a machine-generated signature.
[2] The constraint (CONF-UD-34) is being considered for addition to CDA R3.

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Figure 15: legalAuthenticator example

```
<legalAuthenticator>
  <time value="20050329224512+0500"/>
  <signatureCode code="S"/>
  <assignedEntity>
    <id extension="1" root="2.16.840.1.113883.19"/>
    <addr>
      <streetAddressLine>21 North Ave</streetAddressLine>
      <city>Burlington</city>
      <state>MA</state>
      <postalCode>01803</postalCode>
      <country>USA</country>
    </addr>
    <telecom value="tel:(999)555-1212" use="WP"/>
    <assignedPerson>
      <name>
        <prefix>Dr.</prefix>
        <given>Bernard</given>
        <family>Wiseman</family>
        <suffix>Sr.</suffix>
      </name>
    </assignedPerson>
  </assignedEntity>
</legalAuthenticator>
```

3.3 Rendering Header Information for Human Presentation

Metadata carried in the header may already be available for rendering from electronic medical records (EMRs) or other sources external to the document; therefore, there is no strict requirement to render directly from the document. An example of this would be a doctor using an EMR that already contains the patient's name, date of birth, current address, and phone number. When a CDA document is rendered within that EMR, those pieces of information may not need to be displayed since they are already known and displayed within the EMR's user interface.

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

- Document title and document dates
- Service and encounter types, and date ranges as appropriate
- Names of all persons along with their roles, participations, participation date ranges, identifiers, address, and telecommunications information
- Names of selected organizations along with their roles, participations, participation date ranges, identifiers, address, and telecommunications information
- Date of birth for recordTarget(s)

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4 BODY

A CDA Unstructured Document can include unstructured content directly in a text element with a `mediaType` attribute, or it can reference a single document file using a `text/reference` element.

4.1 Multiple Files and File Packaging

If multiple files, such as several scanned files, constitute a single document, options include: use a CDA document type that has a `structuredBody`, use a multi-page/graphic file type such as PDF, or stitch the separate images into a single image.

For guidance on how to package a CDA Unstructured Document together with an unstructured document it references, see the MIME Multipart/Related Messages appendix.

4.2 Media Types Supported

The media types supported by this guide may be encountered within a healthcare setting as part of the patient record. This guide does not support all possible file formats and it excludes structured formats such as generic XML, which are considered under the Structured Document ballot process.

The CDA data types specification provides an extensible value set of MIME (Multipurpose Internet Mail Extensions) media types that are supported by base CDA. The list of media types supported by this guide excludes some of these and includes commonly used types that are not in the CDA data types list of media types. Exclusions from and extensions to the CDA list of media types are discussed below.

4.2.1 Media Type Exclusions

This guide restricts usage of media types listed in the CDA DataTypes specification. In the absence of a use case for a video format as part of the patient record, video formats are not included. However, an Unstructured Document might link to a video or other file format; for example, a Microsoft Word file might contain a link to a video.

4.2.2 Media Type Extensions

Although the CDA DataTypes specification indicates that 'application/msword' should not be used, this guide allows it because it is very common in use cases that apply to Unstructured Documents. The usage applies only to documents in binary format; it is not appropriate for rich text format (RTF) which has a separate MIME type, or the .docx format, which is not currently recommended for use in an Unstructured Document.

4.2.3 Local Policy

Some content formats—in particular, tagged-image file format (TIFF)—entail further complexity. In that case the business partners need to put in place policy further defining what format variants will be exchanged. This guide can't specify business arrangements.

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While this guide allows TIFF because it is in common use, there are profound interoperability issues because of its variants, and local implementations would place constraints that ensure appropriate interoperability.

Microsoft Word binary formats entail similar issues.

4.3 Identification of Referenced Files

For ease of comprehension, the example code below and in the sample file use simple filenames with relative paths. However, relative paths and simple filenames can be problematic for files that will be moved among systems.

The hazard to be avoided can be illustrated as follows: Suppose an Unstructured Document that references a file "ekg.pdf" is transmitted to a receiver who places that Unstructured Document in a directory that already contains an Unstructured Document for another patient, which also references a file "ekg.pdf". Now the patient header information for the transmitted document is associated with the ekg.pdf of the existing document. Thus, the use of relative paths and simple filenames can pose a danger to patient safety.

The alternative of providing an absolute URL (Uniform Resource Locator) will fail if the URL is inaccessible; even within a single organization, machine identifiers may be mapped differently at different locations.

This guide, while it cannot specify business practices recommends the use of unique names for referenced files.

One approach to generating a unique name is to construct it from the document `id` (`root` and `extension`), which are globally unique, concatenated to a locally unique reference for the external file. The following figure shows such a reference that uses the `id` of the sample document that accompanies this guide.

Figure 16: Unique file reference example

```
<reference value="ref-2.16.840.1.113883.19-999021-ekg-1.pdf"/>
```

CONF-UD-34: The `ClinicalDocument` element **SHALL** contain `component/nonXMLBody/text` element.

CONF-UD-35: The `text` element **SHALL** either contain a reference element with a value attribute, or have a `representation` attribute with the value of `B64`, a mediaType attribute, and contain the media content.

CONF-UD-36: The value of `@mediaType` **SHALL** be drawn from the value set `2.16.840.1.113883.11.20.7.1 SupportedFileFormats` **STATIC** `20100512` (see the Supported File Formats Value Set table).

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Table 1: Supported File Formats Value Set

Value Set: SupportedFileFormats 2.16.840.1.113883.11.20.7.1	
Word Processing/Narrative Formats	**Code**
MSWORD	application/msword
PDF	application/pdf
Plain Text	text/plain
RTF Text	text/rtf
HTML	text/html
Graphic Formats	**Code**
GIF Image	image/gif
TIF Image	image/tiff
JPEG Image	image/jpeg
PNG Image	image/png

Figure 17: nonXMLBody example with embedded content

```
<component>
  <nonXMLBody>
    <text mediaType="text/rtf" representation="B64">e1xydGY...</text>
  </nonXMLBody>
</component>
```

Figure 18: nonXMLBody example with referenced content

```
<component>
  <nonXMLBody>
    <text>
      <reference value="UD_sample.pdf"/>
    </text>
  </nonXMLBody>
</component>
```


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5 REFERENCES

- ASTM's Standard Specifications for Healthcare Document Formats (E2184.02) (Headings and subheadings used in the health care industry and associated with specific report types). http://www.astm.org/cgi-bin/SoftCart.exe/DATABASE.CART/REDLINE_PAGES/E2184.htm?L+memberstore+psnw2999
- LOINC®: Logical Observation Identifiers Names and Codes, Regenstrief Institute. http://www.loinc.org
- CCD: Continuity of Care Document (CCD) ASTM/HL7. http://www.hl7.org/documentcenter/ballots/2007JAN/downloads/CDAR2_IMPL_CCD_I2_2007JAN.zip
- CDA: Clinical Document Architecture Release 2: Clinical Document Architecture (CDA) Release 2, May 2005. http://www.hl7.org/v3ballot/html/infrastructure/cda/cda.htm
- Health Information Technology Standards Panel (HITSP) Constructs, including the Encounter Document Using IHE Medical Summary (XDS-MS) Component (C48). http://www.hitsp.org/
- HL7 Version 3 Standard, Data Types: Abstract, section 2.17 "Instance Identifier (II)". http://www.hl7.org/v3ballot2009SEP/html/welcome/environment/index.htm
- IHE IT Infrastructure Technical Framework Volume 3 (ITI TF-3) Cross-Transaction Specifications and Content Specifications Revision 6.0. http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_6-0_Vol3_FT_2009-08-10-2.pdf

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APPENDIX A — ACRONYMS AND ABBREVIATIONS

AHDI	Association for Healthcare Documentation Integrity
AHIMA	American Health Information Management Association
ASTM	American Society for Testing and Materials
B64	Base 64
CCD	Continuity of Care Document
CDA	Clinical Document Architecture
CDA4CDT	Clinical Documentation Architecture for Common Document Types
CDC	Centers for Disease Control and Prevention
cid	Content ID
CRS	Care Record Summary
DSTU	Draft Standard for Trial Use
EHR	Electronic health record
EMR	Electronic medical record
ftp	File Transfer Protocol
GIF	Graphics Exchange Format
H&P	History and Physical
HITSP	Health Information Technology Standards Panel
HL7	Health Level Seven
HTML	HyperText Markup Language
http	Hypertext Transfer Protocol
IHE	Integrating the Healthcare Enterprise
IHTSDO	International Health Terminology Standard Development Organisation
ITI-TF	IT Infrastructure Technical Framework
JPEG	Joint Photographic Experts Group
LOINC	Logical Observation Identifiers Names and Codes
MD-IT	Medical Documentation Intuitive Technology
MHTML	MIME HTML
MIME	Multipurpose Internet Mail Exchange
MTIA	Medical Transcription Industry Association
OID	Object Identifier
PCC	Patient Care Coordination
PDF	Portable Document Format

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PHR	Personal Health Record
PNG	Portable Network Graphics
POCD_HD000040	Unique Identifier for CDA
R2	Release 2
RFC	Request for Comments
RIM	Reference Information Model
RTF	Rich Text Format
SDO	Standards Development Organization
SDWG	Structured Documents Work Group
SE	X12 Transaction Set Trailer
SNOMED-CT	Systemized Nomenclature for Medicine – Clinical Terms
ST	X12 Transaction Set Header
TIFF	Tagged Image Format File
UD	Unstructured Document
URL	Uniform Resource Location
UUID	Universally Unique Identifier
XDS-MS	Cross-Transaction Specifications and Content Specifications, Medical Summary Module (Encounter Document Using IHE Medical Summary)
XDS-SD	Cross-Transaction Specifications and Content Specifications, Scanned Documents Module
XML	Extensible Markup Language
xsd	XML Schema Definition

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APPENDIX B — TEMPLATE IDS DEFINED IN THIS GUIDE

Table 2: TemplateIds in This Guide

Template ID	Description
2.16.840.1.113883.10.20.19.1	Indicates conformance to this Unstructured Documents Guide
XDS-SD-OID	Indicates conformance to the IHE XDS-SD content profile

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APPENDIX C — VALUE SETS DEFINED IN THIS GUIDE

Table 3: Value Sets Defined in This Guide

Value Set OID	Value Set Name
2.16.840.1.113883.11.20.7.1	SupportedFileFormats

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APPENDIX D — XDS-SD AND CDA GENERAL HEADER CONSTRAINTS COMPARISON

The following table can help the implementer familiar with XDS-SD decide whether to assert conformance to this specification and the CDA General Header Constraints. [See References for a link to XDS-SD (Cross-Transaction Specifications and Content Specifications, Scanned Documents Module).]

Areas where this specification and the CDA General Header constraints are more restrictive than XDS-SD have been highlighted in yellow.

Table 4: Comparison of XDS-SD and CDA General Header Constraints

CDA	XDS-SD	GHCT
ClinicalDocument	SHALL	SHALL
ClinicalDocument/ realmcode	SHALL	SHALL
ClinicalDocument/ typeId	SHALL	SHALL
ClinicalDocument/ templateID	SHALL	SHALL
ClinicalDocument/ id	SHALL	SHALL
ClinicalDocument/ code	SHALL	SHALL
ClinicalDocument/ title	SHOULD	SHALL
ClinicalDocument/ effectiveTime	SHALL	SHALL
ClinicalDocument/ confidentialityCode	SHALL	SHALL
ClinicalDocument/ languageCode	SHALL	SHALL
ClinicalDocument/ documentationOf/ serviceEvent/ effectiveTime	SHALL	Not required
ClinicalDocument/ recordTarget	SHALL	SHALL
ClinicalDocument/ recordTarget/ patientRole	SHALL	SHALL
ClinicalDocument/ recordTarget/ patientRole/ addr	SHALL	SHALL
ClinicalDocument/ recordTarget/ patientRole/ telecom	Not required	SHALL
ClinicalDocument/ recordTarget/ patientRole/ patient/ name	SHALL	SHALL
ClinicalDocument/ recordTarget/ patientRole/ patient/ administrativeGenderCode	SHALL	SHALL
ClinicalDocument/ recordTarget/ patientRole/ patient/ birthTime	SHALL	SHALL
ClinicalDocument/ author/ time	Not required	SHALL
ClinicalDocument/ author/ assignedAuthor	SHALL	SHALL
ClinicalDocument/ author/ assignedAuthor/ id	assignedPerson: SHOULD assignedAuthoringDevice:	SHALL

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CDA	XDS-SD	GHCT
	SHALL	
ClinicalDocument/ author/ assignedAuthor/ addr	Not required	SHALL
ClinicalDocument/ author/ assignedAuthor/ telecom	Not required	SHALL
ClinicalDocument/ custodian	SHALL	SHALL
ClinicalDocument/ custodian/ assignedCustodian/ representedCustodianOrganization/ name	SHALL	SHALL
ClinicalDocument/ custodian/ assignedCustodian/ representedCustodianOrganization/ addr	SHALL	SHALL
ClinicalDocument/ custodian/ assignedCustodian/ representedCustodianOrganization/ telecom	Not required	SHALL
ClinicalDocument/ author (scanner)	SHALL	
ClinicalDocument/ author/ assignedAuthor/ authoringDevice (scanner)	SHALL	
ClinicalDocument/ dataEnterer	SHALL	
ClinicalDocument/ legalAuthenticator	SHOULD	
ClinicalDocument/ component/ nonXMLBody	SHALL	

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APPENDIX E — MIME MULTIPART/RELATED MESSAGES

The following text is taken from the Claims Attachments Implementation Guide (AIS00000) in Section 2.4. For up-to-date guidance, refer to the latest edition of that specification.

MIME Multipart/Related Messages

An attachment is comprised of the CDA document, including any supporting files necessary to render the attested content of the document. Two Internet request for comments (RFCs) are needed to properly construct the mime multipart message. When supporting files are needed, the collection of information shall be organized using a MIME multipart/related package constructed according to RFC 2557. Within the MIME package, supporting files must be encoded using Base-64. RFC-4648 should be used when encoding the contents of the MIME package using Base-64. Finally, RFC-2392 may be used to reference other content that appears in the same X12 transaction to use the same content to answer multiple questions for a single claim. Internet RFCs can be downloaded from the RFC editor page at http://www.rfc-editor.org.

RFC-2557 MIME Encapsulation of Aggregate Documents, Such as HTML (MHTML)

This RFC describes how to construct a MIME multipart/related package, and how URLs are resolved within content items of that package. RFC-2557 can be obtained at: www.rfc-editor.org/rfc/rfc2557.txt

A MIME multipart/related package is made up of individual content items. Each content item has a MIME header identifying the item. Each content item is delimited from other content items using a string of application specified text. In addition, there must be an ending boundary. The actual content is recorded between these delimiter strings using a BASE-64 encoding of the content item. There is also a MIME header for the entire package.

The first content item of a multipart/related message supporting attachments is the CDA document, containing the header and structured or non-structured body. Subsequent content items included in this package will contain additional content that appears within the body of the document. The CDA document will reference these additional content items by their URLs.

Referencing Supporting Files in Multipart/Related Messages

Because the CDA document and its supporting files may have already existed in a clinical information system, references may already exist within the CDA document to URLs that are not accessible outside of the clinical information system that created the document. When the CDA document is sent via attachments, these URLs may no longer be accessible by the receiving information system. Therefore, each content item that is referenced by a URL within the CDA document must be included as a content item in the MIME package. Each content item may specify the URL by which it is known using the Content-Location header. The receiver of this MIME package shall translate URL references according the RFC-2557. This will ensure resolution of the

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original URL to the correct content item within the MIME package. Thus, URL references contained within an original document need not be rewritten when the CDA package is transmitted. Instead, these URLs are simply supplied as the value of the Content-Location header in the MIME package.

This capability allows for the same content item to be referred to more than once in a MIME multipart/related package without requiring the content item to be supplied twice. However, it does not allow a separate MIME multipart/related package to contain references to information sent in a previously recorded package.

Referencing Documents from Other Multiparts within the Same X12 Transactions

RFC-2392 is used when referencing content across MIME package boundaries, but still contained within the same X12 transaction (ST to SE). This can occur when the same document answers multiple questions for a single claim. Each component of a MIME package may be assigned a content identifier using the Content-ID header for the content item. For example, this header would appear as:

Content-ID: <07EE4DAC-76C4-4a98-967E-F6EF9667DED1>

This content identifier is a unique identifier for the content item, which means it must never be used to refer to any other content item. RFC-2392 defines the cid: URL scheme (http: and ftp: are two other URL schemes). This URL scheme allows for references by the Content-ID header to be resolved. The URL for the content item identified above would be:

cid:07EE4DAC-76C4-4a98-967E-F6EF9667DED1

Receivers of the MIME multipart message must be able to resolve a cid: URL to the content item that it identifies. Senders must ensure that they only refer to items that have already been transmitted to the receiver by their cid: URL. Thus, this implementation guide prohibits forward URL references using the cid: URL scheme.

Content items shall not be referenced across X12 transactions using the cid: URL scheme. For example, if the payer previously requested information using a 277, and the provider returned that information in a MIME multipart/related package in a 275, and then the payer requested additional information in another 277, the provider may not refer to the content item previously returned in the prior 275 transaction.

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