HL7 Implementation Guide for CDA Release 2.0
CDA Header

(DK CDA Header)

Draft for Trial Use

Release 0.9

19. March 2015
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<th>Date</th>
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1 INTRODUCTION

1.1 Purpose

The purpose of this document is to describe the generic elements in the CDA Header which are used in the Danish CDA profiles.

1.2 Scope

This DK CDA Header document is a conformance profile, as described in the “Refinement and Localization” section of the *HL7 Version 3 Interoperability Standards*. The base standard for this document is the *HL7 Clinical Document Architecture, Release 2.0*.

This document does not describe every aspect of the CDA. Rather, it defines constraints on selected generic elements in the CDA Header for the use in the Danish Healthcare sector. The aim is that the CDA Header constraints are specified and maintained in this document and are only referenced in the specific HL7 CDA profile used in Denmark.

1.3 Approach

Overall, the approach taken here is consistent with balloted implementation guides (IGs) for CDA. These publications view the ultimate implementation specification as a series of layered constraints. CDA itself is a set of constraints on the Health Level Seven (HL7) Reference Information Model (RIM). Implementation guides such as this document add constraints to CDA through conformance statements that further define and restrict the sequence and cardinality of CDA objects and the vocabulary sets for coded elements.

1.3.1 Keywords

The keywords **SHALL**, **SHALL NOT**, **SHOULD**, **SHOULD NOT**, **MAY**, and **NEED NOT** in this document is 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**: best practice or recommendation. There may be valid reasons to ignore an item, but the full implications must be understood and carefully weighed before choosing a different course

---

2 *HL7 Clinical Document Architecture (CDA Release 2).*
http://www.hl7.org/implement/standards/cda.cfm
• MAY/NEED NOT: truly optional; can be included or omitted as the author decides with no implications

The keyword SHALL allow the use of nullFlavor unless the requirement is on an attribute or the use of nullFlavor is explicitly precluded. Legal values according to this specification come from the HL7 NullFlavor vocabulary.

In this profile the HL7 NullFlavor vocabulary is constrained to the value set in Table 1 below.

<table>
<thead>
<tr>
<th>NullFlavor</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>NI</td>
<td>No information. This is the most general default null flavor</td>
</tr>
<tr>
<td>NA</td>
<td>Not applicable. Known to have no proper value (e.g. last menstrual period for a male)</td>
</tr>
</tbody>
</table>

Table 1: DK NullFlavor Value Set

![Figure 1: Example for the use of nullFlavor](image)

1.3.2 Conformance Requirements

The constraints in this DK CDA document are carried on by using the conformance identification identifier CONF-DK:XX.

All conformance requirements are numbered sequentially.

1.4 Organization of this document

The main chapters of this document are:

• Chapter 2: This chapter gives a brief overview of the HL7 CDA
• Chapter 3: This chapter is an introduction to object identifiers and the use in CDA
• Chapter 4: This chapter describes the constraints to the HL7 CDA Header elements and attributes to be used in Denmark
• Chapter 5: This chapter describes the key participants to be used in a DK CDA document

1.5 Content of the Package

The following files comprise the package:
### Table 2: Content of the Package

<table>
<thead>
<tr>
<th>Filename</th>
<th>Description</th>
<th>Standards Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>TBD</td>
<td>This implementation guide</td>
<td>Normative</td>
</tr>
<tr>
<td>TBD</td>
<td>The sample CDA XML file that includes examples of templates discussed in this guide:</td>
<td>Informative</td>
</tr>
<tr>
<td>TBD</td>
<td>The style sheet for rendering ?? in a browser.</td>
<td>Informative</td>
</tr>
<tr>
<td>Cda.xsl</td>
<td>Stylesheet for display of CDA instances</td>
<td>Informative</td>
</tr>
</tbody>
</table>
2 CDA

The HL7 Clinical Document Architecture (CDA) is an XML-based markup standard intended to specify the encoding, structure and semantics of clinical documents for exchange. The CDA standard doesn’t specify how the documents should be transported.

CDA is a part of the HL7 version 3 standard and was developed using the HL7 Development Framework (HDF) and it is based on the HL7 Reference Information Model (RIM) and the HL7 Version 3 Data Types. CDA documents are persistent in nature.

2.1 Structure of a CDA Document

A CDA document is comprised of two parts.

The document header sets the context for the clinical document. It contains information such as when it was written, who wrote it, for what organisation, which patient it applies to, and the encounter for which it describes the healthcare services.

The document body contains the human readable narrative text. The body may also include machine-readable information called entries. The CDA standard has one restriction on the unstructured text. The format cannot be XML.

2.2 Levels of CDA

CDA includes the use of three levels. Each level introduced a higher degree of semantic interoperability into the exchange of the clinical documents.

At Level 1, the CDA provides a collection of metadata used to describe the clinical document, along with the human readable content in application specific or proprietary formats.

Level 2 introduces structures to convey the human readable content in a form similar to HTML, and to identify sections of that content using coded terms.

Finally, level 3 provides not only human readable semantics, but also machine readable semantic content.
2.3 Persistence

According to the CDA standard, persistence is a characteristic of a clinical document. A CDA document continues to exist in an unaltered state, for a time period defined by regulatory requirements. Health care providers and provider organizations are required to retain documentation of care that has been provided for specific time periods.

2.4 Stewardship

Clinical documents are “maintained” by an organization entrusted with its care. This means that an organization must be able to produce the original of a clinical document, sometimes years after it was created.

The CDA format requires that the name of the organization be recorded as of the time the document was created. Over time, organizations may merge with other organizations, may be split off to other organizations. CDA does not require that the history of organizational changes be recorded and maintained. Instead, it assumes that knowledge of the original steward should be sufficient to locate any subsequent organization that would retain the original copy of the document.

The steward of a CDA document is known as its custodian. The CDA standard does not allow for individual persons to be stewards of documents, only organizations.

2.5 Human readability
Clinical documents are intended to communicate information between healthcare providers. Healthcare providers are humans so clinical documents must be human readable.

The CDA specifies that the content of the document consist of a mandatory textual part (which ensures human interpretation of the document and content) and optional structured parts (for software processing). The structured part relies on coding systems to represent concepts.

The human readability means that there must be a way to display the contents of the clinical document in a way that will allow a human to read it. This display can be through a separate application using proprietary formats such as a word processor, or it can be through the narrative format defined in the CDA standard.
3 UNIQUE IDENTIFIERS AND CODES

The CDA allows more than one type of unique identifier scheme, but most implementations will use ISO object identifiers (OIDs) to uniquely specify the domain of a coded data value or an identifier for a person, organization, or other entity.

The identifier consists of two parts:

- **root**: a globally unique identifier composed of an OID or UUID whose root is assigned by an ISO-assigning authority or obtained from HL7.
- **extension**: The value of this attribute is the responsibility of the organization, system, and/or application where the document is created and stored.

In HL7 specifications an OID is represented as a sequence of non-negative integers separated by periods. They look like an IP address on steroids. For example, the OID for HL7 appears as 2.16.840.1.113883. HL7 provides a publically available OID registry from which anyone can obtain their own use or look up OIDs used or assigned to others. This is available at [http://www.hl7.org/oid/index.cfm](http://www.hl7.org/oid/index.cfm).

In the Danish CDA profiles as many as possible existing OID’s have been reused. However, not all OID’s can be found in the HL7 OID registry. In some cases there is need for specific constrants in a Danish CDA profile. MedCom (as author for the profiles) have done a registration of a ”MedCom OID node = 1.2.208.184” by Danish Standard

The MedCom OID node is a reference or link [http://svn.medcom.dk](http://svn.medcom.dk) where additional information on OID’s and codes to be used in Danish CDA profiles can be found.
4 DK HEADER GENERIC ELEMENTS

4.1 Patient Identification

The Danish Personal Identification number (Danish: CPR-nummer or personnummer) is a national identification number, which is part of the personal information stored in the Civil Registration System (Danish: Det Centrale Personregister).

It is a ten-digit number with the format DDMMYYSSSS, where DDMMYY is the date of birth and SSSS is a sequence number. The last digit of the sequence number is odd for males and even for females.

CONF-DK: 1
If the Danish Personal Identification number is unknown a validated replacement Danish Personal Identification number SHALL be used.

CONF-DK: 2
The id element SHALL be present.

CONF-DK: 3
The value of the @extension SHALL be a valid Danish Personal Identification number (cpr-nummer)

CONF-DK: 4
The value of the @root SHALL be set to the associated OID for "Det Centrale Personregister"

CONF-DK: 5
The value of the @assignedAuthorityName SHALL be set to "CPR".

Figure 3: Danish Personal Identification example

4.2 Name, Address and Telecommunications

To support communication between the receiver of the document and the patient or any other person or organization mentioned within it, the elements representing them will be named.

III https://cpr.dk/cpr-systemet/erstatningspersonnummer-i-eksterne-systemer/
4.2.1 Name

The name element is a set of reusable constraints that can be used for the patient or any other person. It requires a first (given) and last (family) name. One or more middle names can be inserted between the first and last name. If a patient or person has only one name part (e.g., patient with first name only) then place the name part in the best matching field. Use the appropriate nullFlavor, "Not Applicable" (NA), in the other field.

CONF-DK: 6

**SHALL** contain exactly one [1..1] family element. In this profile the @qualifier is not used.

CONF-DK: 7

**SHALL** contain at least one [1..*] given element. In this profile the @qualifier is not used. The second occurrence of given (given[2]) if provided, **SHALL** include middle name or middle initial.

```xml
<name>
  <given>Nancy</given>
  <given>Ann</given>
  <family>Berggren</family>
</name>
```

**Figure 4: Name example**

CONF-DK: 8

**MAY** contain one [0..1] prefix element, e.g. to include the title for a health professional. In this profile the @qualifier is not used.

```xml
<name>
  <prefix>Lege</prefix>
  <given>Anders</given>
  <family>Andersen</family>
</name>
```

**Figure 5: Prefix example**

4.2.2 Address

This section describes constrains for a reusable "address" template, designed for use in the DK CDA Header.
CONF-DK: 9

SHOULD contain exactly one [1..1] @use, which SHALL be selected from ValueSet PostalAddressUse in Table 3

CONF-DK: 10

SHALL contain at least one and not more than 4 streetAddressLine.

CONF-DK: 11

SHALL contain exactly one [1..1] postalcode.

CONF-DK: 12

SHALL contain exactly one [1..1] city.

CONF-DK: 13

SHOULD contain zero or one [0..1] country.

```xml
<addr use="H">
  <streetAddressLine>Skovvejen 12</streetAddressLine>
  <streetAddressLine>Landet</streetAddressLine>
  <postalCode>5700</postalCode>
  <city>Svendborg</city>
  <country>Danmark</country>
</addr>
```

Figure 6: Address example

<table>
<thead>
<tr>
<th>Code</th>
<th>Code system</th>
<th>Print name</th>
</tr>
</thead>
<tbody>
<tr>
<td>H</td>
<td>AddressUse</td>
<td>home address</td>
</tr>
<tr>
<td>WP</td>
<td>AddressUse</td>
<td>work place</td>
</tr>
</tbody>
</table>

Table 3: PostalAddressUse Value Set

4.2.3 Telecommunications Address

The telecommunications address or endpoint specifies how to contact someone or something using telecommunications equipment. That includes the telephone, a fax machine, e-mail, the web, instant messaging etc. All telecommunications addresses can be represented by a URI.

The `telecom` element is used to provide contact information for the various participants that require it. The `@value` attribute of this element is a URL that specifies the telephone number, by using the `tel:` data type.
E-mail addresses are represented using the \texttt{mailto:} URI scheme defined in RFC 2368. Technically, more than one e-mail address is permitted in the \texttt{mailto:} URI scheme.

Web site addresses are formatted using the \texttt{http:} and \texttt{https:} URI formats, which are described in RFC 2396.

Text messages are formatted using the \texttt{sms:} URI format, which are described in the RFC 5724.

The \texttt{use} attribute provides codes from PostalAddressUse as shown in Table 3, describing the type of communications endpoint.

\textbf{CONF-DK: 14}

Telephone numbers \textbf{SHALL} match the regular expression pattern:

\begin{verbatim}
tel:\+?[0-9().]+</telecom value="tel:86121824" use="H"/>
<telecom value="mailto:info@medcom.dk" use="WF"/>
\end{verbatim}

\textbf{Figure 7: Telecommunication example}

\section*{4.2.4 Support of communication}

To support communication between the receiver of the document and the patient or any other person or organization mentioned within it, the elements representing them will be named.

\textbf{CONF-DK: 15}

All patient elements \textbf{SHALL} have a name.

\textbf{CONF-DK: 16}

All patientRole and assignedAuthor elements \textbf{SHOULD} have addr and telecom elements.

\textbf{CONF-DK: 17}

All participantRole elements \textbf{SHOULD} have addr and telecom elements.

\textbf{CONF-DK: 18}

All providerOrganization elements \textbf{SHALL} have name, addr, and telecom elements.

When name, address, or telecom information is unknown and where these elements are required to be present, as with CDA conformance if
the information is unknown, these elements will be represented using an appropriate value for the nullFlavor attribute on the element.

4.3 Health Care Actors Identification

Identifying the health care actors in the CDA shall be done by using unique identifiers as described below.

4.3.1 Hospital Identification

The hospital sector is the responsibility of the five regions. It is normally necessary to be referred by a general practitioner to a hospital for medical examination and treatment, unless it is a question of an accident or an acute illness. It will also normally be necessary to be referred by a general practitioner for treatment by a specialist.

The hospitals are responsible for specialized examinations, treatment and care of somatic and mental illnesses which it would not be more expedient to treat in the primary or social sector because of the need for specialist knowledge, equipment or intensive care and monitoring.

The Health Service Organisation Registry (Danish: Sundhedsvæsenets Organisationsregister - SOR) includes organisation and address information for the public and private Hospitals in Denmark.

CONF-DK: 19

The id SHALL be present

CONF-DK: 20

The value of the @extension SHALL be valid SOR code for a Hospital or a Hospital ward.

CONF-DK: 21

The value of the @root SHALL be set to the associated OID for Sundhedsvæsenets Organisationsregister.

CONF-DK: 22

The value of the @assignedAuthorityName SHALL be set to “SOR”.

```
<id extension="310541000016007" root="1.2.208.176.1" assigningAuthorityName="SOR"/>
```
4.3.2 Municipality Identification

The 98 municipalities are local administrative bodies. The municipalities have a number of tasks, of which health represents one part. In the health field, the municipalities are responsible for home nursing, public health care, school health service, child dental treatment, prevention and rehabilitation. The municipalities are also responsible for a majority of the social services, some of which (subsidized housing for older people in the form of non-profit housing, including homes for elderly people with care facilities and associated care staff) have to do with the health care service and they are of great importance to the functioning of this service.

The Health Service Organisation Registry (Danish: Sundhedsvæsenets Organisationsregister - SOR) includes organisation and address information for the municipalities in Denmark.

CONF-DK: 23
The id SHALL be present

CONF-DK: 24
The value of the @extension SHALL be valid SOR code for a Hospital or a Hospital ward.

CONF-DK: 25
The value of the @root SHALL be set to the associated OID for Sundhedsvæsenets Organisationsregister.

CONF-DK: 26
The value of the @assignedAuthorityName SHALL be set to “SOR”.

4.3.3 General Practitioners and Specialists

In the health care service, the general practitioners act as “gate-keepers” with regard to hospital treatment and treatment by specialists. This means that patients usually start by consulting their general practitioners, whose job it is to ensure that they are offered the treatment they need
and that they will not be treated on a more specialized level than necessary.

Information for General Practitioners, specialists, dentists, physiotherapists, psychologists etc. in Denmark can be found in Yderregisteret (Danish).

CONF-DK: 27
The id SHALL be present

CONF-DK: 28
The value of the @extension SHALL be valid code from Yderregisteret

CONF-DK: 29
The value of the @root SHALL be set to the associated OID Yderregisteret

CONF-DK: 30
The value of the @assignedAuthorityName SHALL be set to "Yderregisteret".

<id extension="524799" root="2.16.840.1.113883.3.1208.100.3" assigningAuthorityName="Yderregisteret"/>

Figure 10: General Practitioner Identification example

4.3.4 Individual health professionals

CONF-DK: 31
The id SHALL NOT be present for identifying individual health professionals

CONF-DK: 32
The name element MAY be present for identifying individual health professionals

4.4 Time stamp

Events occurring at a single point in time that are represented in the Clinical Document Header will in general be precise to the time. These point-in-time events are the time of creation of the document; the
starting time of participation by an author, data enterer or the starting and ending time of an encounter.

**CONF-DK: 33**

Times or time intervals found in all elements in the CDA Header e.g. `ClinicalDocument/effectiveTime`, `author/time` **SHALL** be precise to the year, month and day, **SHALL** be precise to the hours, minutes, second **SHALL** include a time zone.

**CONF-DK: 34**

The representation of time **SHALL** use the format `YYYYMMDDhhmmss±ZZzz`

<table>
<thead>
<tr>
<th>YYYYMMDDhhmmss±ZZzz</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>YYYY</td>
<td>The year of the event</td>
</tr>
<tr>
<td>MM</td>
<td>The month in the full year</td>
</tr>
<tr>
<td>DD</td>
<td>The day in the month and year</td>
</tr>
<tr>
<td>hh</td>
<td>The hour in the day</td>
</tr>
<tr>
<td>mm</td>
<td>The minutes in the day</td>
</tr>
<tr>
<td>ss</td>
<td>The second in the minutes</td>
</tr>
<tr>
<td>±</td>
<td>Direction of offset from UTC</td>
</tr>
<tr>
<td>ZZ</td>
<td>Hours offset from UTC</td>
</tr>
<tr>
<td>zz</td>
<td>Minutes offset from UTC</td>
</tr>
</tbody>
</table>

![Figure 11: Time stamp example](image)

**CONF-DK: 35**

If the time is unknown the `hhmmss` **SHALL** be set to `hhmmss = 000000+0000`

![Figure 12: Time stamp for birthTime example](image)

### 4.5 Confidentiality

**CONF-DK: 36**

The `ClinicalDocument/confidentialityCode` **SHALL** be present. It specifies the confidentiality assigned to the document.
The `@code` value **SHALL** be selected from the DK CDA Confidentiality Kind Value Set.

The `@codeSystem` value **SHALL** be set to the associated OID for the DK CDA Confidentiality Kind Value Set.

<table>
<thead>
<tr>
<th>Code</th>
<th>Code system</th>
<th>Print name</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>Confidentiality Code</td>
<td>Normal</td>
</tr>
</tbody>
</table>

Table 4. DK CDA Confidentiality Kind Value Set

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

Figure 13: ClinicalDocument/confidentialityCode example

4.6 Language

The `languageCode` specifies the language of the clinical document or a part of the clinical document.

**CONF-DK: 37**

The `ClinicalDocument/languageCode` **SHALL** be present in the DK CDA Header.

**CONF-DK: 38**

The `ClinicalDocument/languageCode` **SHALL** be in the form `nn-CC`.

**CONF-DK: 39**


**CONF-DK: 40**

The `CC` portion `ClinicalDocument/languageCode`, if present, **SHALL** be an ISO-3166 country code in upper case.

```xml
<languageCode code="da-DK"/>
```

Figure 14: Example with language code and country code

4.7 Gender
CONF-DK: 41

In the DK CDA Header an `administrativeGenderCode` element **SHALL** be present. Values for `administrativeGenderCode` **SHALL** be drawn from the HL7 AdministrativeGender vocabulary.

<table>
<thead>
<tr>
<th>Code</th>
<th>Code system</th>
<th>Print name</th>
</tr>
</thead>
<tbody>
<tr>
<td>F</td>
<td>AdministrativeGender</td>
<td>Female</td>
</tr>
<tr>
<td>M</td>
<td>AdministrativeGender</td>
<td>Male</td>
</tr>
<tr>
<td>UN</td>
<td>AdministrativeGender</td>
<td>Undifferentiated</td>
</tr>
</tbody>
</table>

*Table 5: Administrative Gender (HL7) Value Set*

5 PARTICIPANTS AND ROLES

The participants and their roles by creating a CDA document, includes organizations, people, medical devices and applications. In this DK CDA Header profile only organizations and people are allowed. Each of these participants associates to the document to a role.

This section describes the following participants:

- Patient
- Author
- Stewart
- Data enterer
- Recipients
- Signers of the document

This description below of the participants describes and shows example of the elements to be included. Further details on the use of the participants may be included in the specific profiles where they are used.

5.1 Patient

The patient is the most important person associated with the clinical document. A CDA document requires at least one patient.

The name of the participation association class is `recordTarget`.

The `patientRole` class represents the person playing the role of patient.
5.2 Author

There must be at least one author in a CDA instance. Authors create information in the clinical document based on their knowledge.

The author participation associates someone in the assigned role as document author.

5.3 Steward

Every valid CDA document must have a steward. The steward is the organisation that is responsible for the maintaining a true and accurate copy of the document for as long as is required by local policy. The steward is associated with the clinical document through the custodian participation class.
The custodian association links the assignedCustodian to the clinical document. The assignedCustodian is the organization that has been assigned the role to be the steward of the clinical document.

```xml
<custodian>
  <assignedCustodian>
    <representedCustodianOrganization>
      <id extension="..." root="...">
        <assigningAuthorityName="..."></assigningAuthorityName>
      </id>
      <name>...</name>
      <telecom value="..."/>
      <addr>...</addr>
    </representedCustodianOrganization>
  </assignedCustodian>
</custodian>
```

**Figure 17: Custodian Example**

### 5.4 Data enterer

The dataEnterer role is a person who enters the information into the clinical document by transferring it into an information system from other sources, paper forms, transcription of audio etc. The dataEnterer does not create new information; they simply transfer information from one medium to another.

The dataEnterer association class creates a link between the clinical document and the person assigned to enter the data.

```xml
<dataEnterer>
  <time value="..."/>
  <assignedEntity>
    <id extension="..." root="..."
        <assigningAuthorityName="..."></assigningAuthorityName>
    </id>
    <addr>...</addr>
    <telecom value="..."/>
    <assignedPerson>
      <name>...</name>
    </assignedPerson>
    <representedOrganisation>...</representedOrganisation>
  </assignedEntity>
</dataEnterer>
```

**Figure 18: Data enterer Example**
5.5 Recipients

Recipients of the information are associated with the clinical document through the informationRecipient association class.

The receivedOrganization scopes the role and usually represents the organization that binformationRecipient.

```
<informationRecipient>
  <intendedRecipient classCode="ASSIGNED">
    <id extension="..." root="...
      assigningAuthorityName="...
    </id>
    <addr>...</addr>
    <telecom value="..."/>
    <informationRecipient>
      <name>..."/name>
    </informationRecipient>
  </intendedRecipient>
</informationRecipient>
```

Figure 19: Information Recipient Example

5.6 Signers of the document

A CDA document includes the potential for authentication.

The authenticator and legalAuthenticator is not used in the DK CDA Header profile.