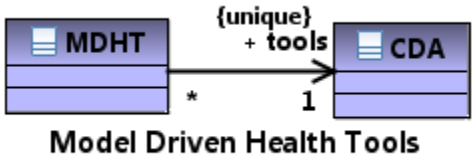
Implementation Guide for CDA Release 2
MDHT Example Project
Optional Subtitle



PROTOTYPE: FOR DISCUSSION AND DEMONSTRATION USE ONLY

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Acknowledgments

This document contains an example of healthcare standards and specifications publication generated from UML models, using the OHT Model Driven Health Tools (MDHT). Some portions of this document may not be publicly available but are included for demonstration purposes only, therefore this version of the document is to be treated as CONFIDENTIAL by the project participants.

This demonstration document contains informtion from the following sources:

Revision History

Rev	Date	By Whom	Changes
New	July 2010	Dave Carlson	
First draft for posting	December 2010	Dave Carlson	Updated model content and publication format

Chapter 1

INTRODUCTION

Topics:

- *Overview*
- *Approach*
- *Scope*
- *Audience*
- *Organization of This Guide*
- *Use of Templates*
- *Conventions Used in This Guide*

Overview

This implementation guide is generated from UML models developed in the Open Health Tools (OHT) Model-Driven Health Tools (MDHT) project. The data specifications have been formalized into computational models expressed in UML. These models are used by automated tooling to generate this publication, plus validation tools and Java libraries for implementers.

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.

This project supports reusability and ease of data collection through a standard data representation harmonized with work developed through Health Information Technology Expert Panel (HITEP), balloted through Health Level Seven (HL7) and/or recognized by the Health Information Technology Standards Panel (HITSP).

This implementation guide (IG) specifies a standard for electronic submission of NCRs in a Clinical Document Architecture (CDA), Release 2 format.

Scope

TODO: scope of this implementation guide.

Audience

The audience for this document includes software developers and implementers who wish to develop...

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. When SNOMED codes are used, rules defined in Using SNOMED CT in HL7 Version 3 are adhered to. 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 that will be maintained by CHCA.

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 that an object in an instance document conforms to. This implementation guide asserts when `templateId`s 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 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 `templateId`s).

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).
2. A problem observation SHALL include exactly one Observation / statusCode. (CONF: 815).
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, 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.

```
<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:

- *General Header Constraints*
- *Personal Healthcare Monitoring Report*

This section contains the document level constraints for CDA documents that are compliant with this implementation guide.

General Header Constraints

[ClinicalDocument: templateId `null`]

This section describes constraints that apply to the H and P Note and to other types of CDA documents defined for general exchange. The template defined here should be reused wherever these general header constraints are applied.

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.

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.

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

Within the specification, all telephone numbers are to be encoded using a grammar which is a restriction on the TEL data type and RFC 2806. It simplifies interchange between applications as it removes optional URL components found in RFC 2806 that applications typically do not know how to process, such as ISDN sub-address, phone context, or other dialing parameters.

Organizations that wish to use OIDs should properly register their OID root and ensure uniqueness of the OID roots used in identifiers. A large number of mechanisms exist for obtaining OID roots for free or for a reasonable fee. HL7 maintains an OID registry page from which organizations may request an OID root under the HL7 OID root. This page can be accessed at: http://www.hl7.org/oid.

Another useful resource lists the many ways to obtain a registered OID Root for free or a small fee anywhere in the world and is located at:

http://www.dclunie.com/medical-image-faq/html/part8.html#UIDRegistration.

The manner in which the OID root is obtained is not constrained by this DSTU.

1. **SHALL** contain exactly one [1..1] **`code/@code`**`="53576-5"` *Personal Health Monitoring Report* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)
   - Specifies the type of the clinical document.
2. **SHALL** contain exactly one [1..1] **`confidentialityCode`**
   - Specifies the confidentiality assigned to the document. This specification provides no further guidance beyond CDA R2 on documents with respect to the vocabulary used for confidentialityCode, nor treatment or implementation of confidentiality.
3. **SHALL** contain exactly one [1..1] **`effectiveTime`**
   - Specifies the creation time of the document. All documents authored by direct input to a computer system should record an effectiveTime that is precise to the second. When authored in other ways, for example, by filling out a paper form that is then transferred into an EHR system, the precision of effectiveTime may be less than to the second.
4. **SHALL** contain exactly one [1..1] **`id`**
   - The ClinicalDocument/id element is an instance identifier data type (see HL7 Version 3 Abstract Data in Section 5 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.
5. **SHALL** contain exactly one [1..1] **`languageCode`**
6. **SHALL** contain exactly one [1..1] **`title`**
   - Specifies the local name used for the document. Note that the title does not need to be the same as the display name provided with the document type code. For example, the display name provided by LOINC® as an aid in debugging may be "HISTORY AND PHYSICAL." The title can be localized, as appropriate.

7. **SHALL** contain exactly one [1..1] **`typeId`**
    - The clinical document type ID identifies the constraints imposed by CDA R2 on the content, essentially acting as a version identifier.
8. Contains at least one [1..*] **`author`**, where its type is CDA Author
9. Contains zero or one [0..1] **`dataEnterer`**, where its type is CDA Data Enterer
10. Contains exactly one [1..1] **`custodian`**, where its type is CDA Custodian
11. Contains zero or more [0..*] **`informationRecipient`**, where its type is CDA Information Recipient
12. Contains zero or one [0..1] **`legalAuthenticator`**, where its type is CDA Legal Authenticator
13. Contains zero or more [0..*] **`authenticator`**, where its type is CDA Authenticator
14. **SHALL** satisfy: All patient, guardianPerson, assignedPerson, maintainingPerson, relatedPerson, intendedRecipient/informationRecipient, associatedPerson, and relatedSubject/subject elements have a name.
15. **SHALL** satisfy: All patientRole, assignedAuthor, assignedEntity[not(parent::dataEnterer)] and associatedEntity elements have an addr and telecom element.
16. **SHOULD** satisfy: All guardian, dataEnterer/assignedEntity, relatedEntity, intendedRecipient, relatedSubject and participantRole elements have an addr and telecom element.
17. **SHALL** satisfy: All guardianOrganization, providerOrganization, wholeOrganization, representedOrganization, representedCustodianOrganization, receivedOrganization, scopingOrganization and serviceProviderOrganization elements 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. Legal values according to this specification come from the HL7 NullFlavor vocabulary.
18. Times or time intervals found in the ClinicalDocument/effectiveTime, author/time, dataEnterer/time, legalAuthenticator/time, authenticator/time and encompassingEncounter/effectiveTime elements **SHALL** be precise to the day, **SHALL** include a time zone if more precise than to the day, and **SHOULD** be precise to the second.
19. Times or time intervals found in the asOrganizationPartOf/effectiveTime, asMaintainedEntity/effectiveTime, relatedEntity/effectiveTime, serviceEvent/effectiveTime, ClinicalDocument/participant/time, serviceEvent/performer/time and encounterParticipant/time **SHALL** be precise at least to the year, **SHOULD** be precise to the day, and **MAY** omit time zone.
20. **SHALL** satisfy: Telephone numbers match the regular expression pattern tel:\+?[-0-9().]+
    - The telecom element is used to provide a contact telephone number for the various participants that require it. The value attribute ofthis elements is a URL that specifies the telephone number, as indicated by the TEL data type.
    - All telephone numbers are to be encoded using a restricted form of the tel: URL scheme. A telephone number used for voice calls begins with the URL scheme tel:. If the number is a global phone number, it starts with a plus (+) sign. The remaining number is made up of the dialing digits and an optional extension and may also contain visual separators.
21. **SHALL** satisfy: At least one dialing digit is present in the phone number after visual separators are removed.
22. **SHALL** satisfy: If the telephone number is unknown it is represented using the appropriate flavor of null.
    - There is no way to distinguish between an unknown phone number and an unknown e-mail or other telecommunications address. Therefore, the following convention will be used: Any telecom element that uses a flavor of null (has a nullFlavor attribute) is assumed to be a telephone number, which is the only required telecommunications address element within this DSTU.
23. **SHALL** satisfy: The extension attribute of the typeId element is POCD_HD000040.
    - `[OCL]: self.typeId.extension = 'POCD_HD000040'`
24. **SHALL** satisfy: The id/@root attribute is a syntactically correct UUID or OID.
25. **SHALL** satisfy: UUIDs are represented in the form XXXXXXXX-XXXX-XXXX-XXXXXXXXXXXXXXXX, where each X is a character from the set [A-Fa-f0-9].
26. OIDs are 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))+.

- Organizations that wish to use OIDs should properly register their OID root and ensure uniqueness of the OID roots used in identifiers. A large number of mechanisms exist for obtaining OID roots for free or for a reasonable fee. HL7 maintains an OID registry page from which organizations may request an OID root under the HL7 OID root. This page can be accessed at: http://www.hl7.org/oid.

  Another useful resource lists the many ways to obtain a registered OID Root for free or a small fee anywhere in the world and is located at: http://www.dclunie.com/medical-image-faq/html/part8.html#UIDRegistration.

  The manner in which the OID root is obtained is not constrained by this DSTU.

27. **SHALL** satisfy: OIDs are no more than 64 characters in length.
    - OIDs are limited by this specification to no more than 64 characters in length for compatibility with other standards and Implementation Guides.
28. **SHALL** satisfy: languageCode has the form nn, or nn-CC.
29. **SHALL** satisfy: The nn portion of languageCode is a legal ISO-639-1 language code in lowercase.
30. The CC portion languageCode, if present, **SHALL** be an ISO-3166 country code in uppercase.
31. Both setId and versionNumber **SHALL** be present or both **SHALL** be absent.
    - The ClinicalDocument/setId element uses the instance identifier (II) data type. The root attribute is a UUID or OID that uniquely identifies the scope of the identifier, and the extension attribute is a value that is unique within the scope of the root for the set of versions of the document. See Document Identification, Revisions, and Addenda in Section 4.2.3.1 of the CDA Specification for some examples showing the use of the setId element.
    - ```
      [OCL]: (self.setId.oclIsUndefined() and
       self.versionNumber.oclIsUndefined())
         xor (not self.setId.oclIsUndefined() and not
       self.versionNumber.oclIsUndefined())
      ```
32. The @extension and/or @root of setId and id **SHALL** be different when both are present.
    - ```
      [OCL]: (not self.setId.oclIsUndefined() and not self.id.oclIsUndefined())
         implies (self.setId.root <> self.id.root or self.setId.extension <>
       self.id.extension)
      ```
33. A copyTime element **SHALL NOT** be present.
    - The ClinicalDocument/copyTime element has been deprecated in CDA R2.
    - ```
      [OCL]: self.copyTime.oclIsUndefined()
      ```
34. **SHALL** satisfy: At least one recordTarget/patientRole element is present.
    - ```
      [OCL]: self.recordTarget->size() > 0 and self.recordTarget-
      >exists(target : cda::RecordTarget | not
       target.patientRole.oclIsUndefined())
      ```
35. A patient/birthTime element **SHALL** be present. The patient/birthTime element **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.
    - ```
      [OCL]: self.recordTarget->forAll(target : cda::RecordTarget | not
       target.patientRole.oclIsUndefined()
         implies (not
       target.patientRole.patient.birthTime.value.oclIsUndefined()
            or not
       target.patientRole.patient.birthTime.nullFlavor.oclIsUndefined()))
      ```
36. A patient/administrativeGenderCode element **SHALL** be present. If unknown, it **SHALL** be represented using a flavor of null. Values for administrativeGenderCode **SHOULD** be drawn from the HL7 AdministrativeGender vocabulary.
    - ```
      [OCL]: self.recordTarget->forAll(target : cda::RecordTarget | not
       target.patientRole.oclIsUndefined()
         implies (not
       target.patientRole.patient.administrativeGenderCode.code.oclIsUndefined()
            or not
       target.patientRole.patient.administrativeGenderCode.nullFlavor.oclIsUndefined()))
      ```

37. The maritalStatusCode, religiousAffiliationCode, raceCode and ethnicGroupCode **MAY** be present. If maritalStatusCode, religiousAffiliationCode, raceCode and ethnicGroupCode elements are present, they **SHOULD** be encoded using the appropriate HL7 vocabularies.
38. **SHOULD** satisfy: The guardian element is present when the patient is a minor child.
39. **MAY** satisfy: The providerOrganization element is present.
    - `[OCL]: self.recordTarget->exists(target : cda::RecordTarget | not target.patientRole.providerOrganization.oclIsUndefined())`
40. **SHALL** satisfy: The author/time element is present.
    - The author/time element represents the start time of the author's participation in the creation of the clinical document.
    - `[OCL]: self.author->forAll(author : cda::Author | not author.time.oclIsUndefined())`
41. **SHALL** satisfy: The assignedAuthor/id element is present.
    - `[OCL]: self.author->forAll(author : cda::Author | author.assignedAuthor.id->size() > 0)`
42. **SHALL** satisfy: An assignedAuthor element contains at least one assignedPerson or assignedAuthoringDevice elements.
    - `[OCL]: self.author->forAll(author : cda::Author | not author.assignedAuthor.assignedPerson.oclIsUndefined() or not author.assignedAuthor.assignedAuthoringDevice.oclIsUndefined())`
43. **SHALL** satisfy: When dataEnterer is present, an assignedEntity/assignedPerson element is present.
    - `[OCL]: not self.dataEnterer.oclIsUndefined() implies not self.dataEnterer.assignedEntity.assignedPerson.oclIsUndefined()`
44. The dataEnterer/time element **MAY** be present. If present, it represents the starting time of entry of the data.
    - `[OCL]: not self.dataEnterer.oclIsUndefined() implies not self.dataEnterer.time.oclIsUndefined()`
45. **MAY** satisfy: The informant element is present.
    - `[OCL]: self.informant->size() > 0`
46. When informant is present, an assignedEntity/assignedPerson or relatedEntity/relatedPerson element **SHALL** be present.
    - `[OCL]: self.informant->forAll(i : cda::Informant12 | not i.assignedEntity.assignedPerson.oclIsUndefined() or not i.relatedEntity.relatedPerson.oclIsUndefined())`
47. When the informant is a healthcare provider with an assigned role, the informant **SHALL** be represented using the assignedEntity element
    - Assigned health care providers may be a source of information when a document is created. (e.g., a nurse's aide who provides information about a recent significant health care event that occurred within an acute care facility.) In these cases, the assignedEntity element is used.
48. Allowable values for informant/relatedEntity/@classCode **SHALL** be CON, PRS, CAREGIVER, AGNT or PROV from the RoleClass vocabulary.
    - When the informant is a personal relation, that informant is represented in the relatedEntity element. The code element of the relatedEntity describes the relationship between the informant and the patient.

      The relationship between the informant and the patient needs to be described to help the receiver of the clinical document understand the information in the document.
49. When relatedEntity/@classCode is PRS, values in relatedEntity/code **SHALL** come from the HL7 PersonalRelationshipRoleType vocabulary or from SNOMED, any subtype of "Person in the family" (303071001).
50. When an informant is an unrelated person not otherwise specified, the value relatedEntity/@classCode **SHALL** be set to CON to indicate that this person is a contact.

- Individuals with no prior personal relationship to the patient (e.g., a witness to a significant health care event) may provide information about the patient.

51. When the informant is a healthcare provider without an assigned role, the informant **SHALL** be represented using the relatedEntity element and the value of relatedEntity/@classCode **SHALL** be set to PROV.

- A health care provider who does not have an assigned role at the institution may provide information. To record an informant that does not have an assigned role that can be represented within the context of the document, the information will be represented using the relatedEntity element and the value of relatedEntity/@classCode will be set to PROV.

52. When the informant is a healthcare provider, the value of relatedEntity/code **SHOULD** be present and indicate the type of healthcare provider.

53. The ClinicalDocument/informationRecipient element **MAY** be present. When informationRecipient is used, at least one informationRecipient/intendedRecipient/informationRecipient or informationRecipient/intendedRecipient/receivedOrganization **SHALL** be present.

54. The assignedEntity/assignedPerson element **SHALL** be present in legalAuthenticator.

- ```
  [OCL]: not self.legalAuthenticator.oclIsUndefined() implies not
   self.legalAuthenticator.assignedEntity.assignedPerson.oclIsUndefined()
  ```

55. The assignedEntity/assignedPerson element **SHALL** be present in an authenticator element.

- ```
  [OCL]: self.authenticator->forAll(auth : cda::Authenticator |
   auth.assignedEntity->forAll(entity : cda::AssignedEntity |
     not entity.assignedPerson.oclIsUndefined()))
  ```

56. Times or time intervals found in the ClinicalDocument/effectiveTime, author/time, dataEnterer/time, legalAuthenticator/time, authenticator/time and encompassingEncounter/effectiveTime elements **SHALL** be precise to the day, **SHALL** include a time zone if more precise than to the day, and **SHOULD** be precise to the second.

57. Times or time intervals found in the asOrganizationPartOf/effectiveTime, asMaintainedEntity/effectiveTime, relatedEntity/effectiveTime, serviceEvent/effectiveTime, ClinicalDocument/participant/time, serviceEvent/performer/time and encounterParticipant/time **SHALL** be precise at least to the year, **SHOULD** be precise to the day, and **MAY** omit time zone.

58. if a template has no templateId (OID) then the templateId **SHALL NOT** be present

General Header Constraints example

Personal Healthcare Monitoring Report

Personal Healthcare Monitoring Report example

Chapter 3

SECTION TEMPLATES

Topics:

- *Functional Status*
- *Medical Equipment*
- *Medication*
- *Purpose*
- *Results*
- *Vital Signs*

Functional Status

[Section: templateId `null`]

1. **SHALL** conform to *CCD Functional Status Section* template (templateId: `2.16.840.1.113883.10.20.1.5`)

Functional Status example

Medical Equipment

[Section: templateId `2.16.840.1.113883.10.20.9.1`]

A Medical Equipment section SHALL contain two templateIds. CCD templateId 2.16.840.1.113883.10.20.1.7 SHALL be present and the section SHALL conform to all the constraints specified in CCD for that template. An additional templateId SHALL be present where the value of @root is 2.16.840.1.113883.10.20.9.1, indicating conformance to the constraints specified in this DSTU.

1. **SHALL** conform to *CCD Medical Equipment Section* template (templateId: `2.16.840.1.113883.10.20.1.7`)
2. **SHOULD** contain zero or more [0..*] **`entry`**, such that
   a. Contains **`@typeCode="DRIV"`** *DRIV (is derived from)*
   b. Contains exactly one [1..1] *Device Definition Organizer* (templateId: `2.16.840.1.113883.10.20.9.4`)
3. **SHALL** contain exactly one [1..1] **`text`**

Medical Equipment example

Medication

[Section: templateId `null`]

1. **SHALL** conform to *CCD Medications Section* template (templateId: `2.16.840.1.113883.10.20.1.8`)

Medication example

Purpose

[Section: templateId `null`]

1. **SHALL** conform to *CCD Purpose Section* template (templateId: `2.16.840.1.113883.10.20.1.13`)

Purpose example

Results

[Section: templateId `2.16.840.1.113883.10.20.9.14`]

The results section is only required if there is no Vital Signs section.

1. **SHALL** conform to *CCD Results Section* template (templateId: `2.16.840.1.113883.10.20.1.14`)
2. **SHOULD** contain zero or one [0..1] **`entry`**, such that
   a. Contains **`@typeCode="DRIV"`** *DRIV (is derived from)*

Results example

Vital Signs

[Section: templateId `2.16.840.1.113883.10.20.9.2`]

The Vital Signs section is only required if there is no Results section. If the following values are present in the PHMR, they SHOULD be recorded in the Vital Signs section: blood pressure, temperature, O2 saturation, respiratory rate, pulse. All other values SHOULD be recorded in the Results section.

1. **SHALL** conform to *CCD Vital Signs Section* template (templateId: `2.16.840.1.113883.10.20.1.16`)
2. **SHOULD** contain zero or one [0..1] **`entry`**, such that
   a. Contains **`@typeCode="COMP"`** *COMP (component)*

Vital Signs example

Chapter 4

CLINICAL STATEMENT TEMPLATES

Topics:

- *Device Accuracy Observation*
- *Device Definition Organizer*
- *Device Measurement Range Observation*
- *Device Resolution Observation*
- *Event Observation*
- *Numeric Observation*
- *Observation Media JPG*
- *Observation Null Flavor*
- *Result Organizer*
- *Sampling Frequency Observation*
- *Vital Signs Organizer*
- *Waveform Observation*
- *Waveform Sample Period Observation*
- *Waveform Series Observation*

This section of the Implementation Guide details the clinical statement entries referenced in the document section templates. The clinical statement entry templates are arranged alphabetically.

Device Accuracy Observation

[Observation: templateId `2.16.840.1.113883.10.20.9.3`]

The accuracy of the device may be reported in the PHM report (for example, the values reported by a device may be within +/- 3% of the actual value). However, it will not currently be automatically derived from device data, i.e., it may be manually entered or derived through other means.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="DEF"` (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="MDC_ATTR_NU_ACCUR_MSMT"` (CodeSystem: `2.16.840.1.113883.6.24 IEEE 11073`)
4. **SHALL** contain exactly one [1..1] **`value`**
5. A value element **SHALL** be present where @xsi:type is PQ (for a physical quantity) or ST (for a simple text description) describing the processing accuracy of the device.

Device Accuracy Observation example

Device Definition Organizer

[Organizer: templateId `2.16.840.1.113883.10.20.9.4`]

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="CLUSTER"` (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHOULD** contain zero or one [0..1] **`effectiveTime`**
4. **MAY** contain zero or one [0..1] **`component`**, such that
   a. Contains exactly one [1..1] *Sampling Frequency Observation* (templateId: `2.16.840.1.113883.10.20.9.10`)
5. **MAY** contain zero or one [0..1] **`component`**, such that
   a. Contains exactly one [1..1] *Device Measurement Range Observation* (templateId: `2.16.840.1.113883.10.20.9.5`)
6. **MAY** contain zero or one [0..1] **`component`**, such that
   a. Contains exactly one [1..1] *Device Resolution Observation* (templateId: `2.16.840.1.113883.10.20.9.6`)
7. **MAY** contain zero or one [0..1] **`component`**, such that
   a. Contains exactly one [1..1] *Device Accuracy Observation* (templateId: `2.16.840.1.113883.10.20.9.3`)
8. **SHALL** contain exactly one [1..1] **`participant`**, such that

Device Definition Organizer example

Device Measurement Range Observation

[Observation: templateId `2.16.840.1.113883.10.20.9.5`]

The measurement range of the device may be communicated in the PHMR (for example, a thermometer may report values between 0 and 100 degrees Celsius). However, it will not currently be automatically derived from device data, i.e., it may be manually entered or derived through other means.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="DEF"` (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="MDC_ATTR_NU_RANGE_MSMT"` (CodeSystem: `2.16.840.1.113883.6.24 IEEE 11073`)
4. Contains exactly one [1..1] **`value`**
5. A value element **SHALL** be present where @xsi:type is IVL_PQ (for a range of physical quantities) or ST (for a simple text description) describing the resolution of the device.

Device Measurement Range Observation example

Device Resolution Observation

[Observation: templateId `2.16.840.1.113883.10.20.9.6`]

The reporting resolution of the device may be communicated in the PHMR (for example, a thermometer may have a resolution of 0.1 degrees Celsius). However, it will not currently be automatically derived from device data, i.e., it may be manually entered or derived through other means.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="DEF"` (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="17441009"` (CodeSystem: `2.16.840.1.113883.6.96 SNOMED CT`)
4. **SHALL** contain exactly one [1..1] **`value`**
5. A value element **SHALL** be present where @xsi:type is PQ (for a physical quantity) or ST (for a simple text description) describing the resolution of the device, in whatever units are appropriate for the device in question (though units must still be a valid UCUM expression).

Device Resolution Observation example

Event Observation

[Observation: templateId `2.16.840.1.113883.10.20.9.7`]

Sometimes devices report events that are not related to the health of the patient, but are necessary to properly perform remote monitoring. Events can be present directly inside a section/entry, organizer/component, or related to any other clinical statement via an entryRelationship element.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)

3. **SHALL** contain exactly one [1..1] **`code`** (CodeSystem: `2.16.840.1.113883.6.24 MDC`)
4. **SHALL** contain exactly one [1..1] **`value`**
   - Note that the codes reported by the devices are typically arbitrary values defined in device specific specifications, and are currently not part of any code system; thus it is often most useful to translate such a code into a human readable string (thus the ST datatype).
5. **SHOULD** contain zero or one [0..1] **`pHMRProductInstanceReference`**, such that
6. A value element **SHALL** be present where @xsi:type is CS or ST describing the event. Note that the codes reported by the devices are typically arbitrary values defined in device specific specifications, and are currently not part of any code system; thus it is often most useful to translate such a code into a human readable string (thus the ST datatype).

Event Observation example

Numeric Observation

[Observation: templateId `2.16.840.1.113883.10.20.9.8`]

Most devices will report data consisting of a code identifying the type of data being reported, a numeric value, and a unit.

1. **SHALL** conform to *CCD Result Observation* template (templateId: `2.16.840.1.113883.10.20.1.31`)
2. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
3. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-408)
4. **SHALL** contain exactly one [1..1] **`code`** (CONF-412)
5. **SHALL** contain exactly one [1..1] **`value`**, where its data type is PQ (CONF-416)
6. **SHOULD** contain zero or one [0..1] **`pHMRProductInstanceReference`**, such that
7. A code element **SHALL** be present where @codeSystem is 2.16.840.1.113883.6.96 SNOMED CT (DYNAMIC) or 2.16.840.1.113883.6.24 MDC (DYNAMIC).

Numeric Observation example

Observation Media JPG

[ObservationMedia: templateId `null`]

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`value`**
4. The observableMedia element **SHALL** include a reference to a displayable graphic containing a graphic representation of the data in the waveform.

Observation Media JPG example

Observation Null Flavor

[Observation: templateId `null`]

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBSCOR"` (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain at least one [1..*] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain zero or one [0..1] **`entryRelationship`**, where its type is *Waveform Observation*
   a. Contains exactly one [1..1] *Waveform Observation* (templateId: `2.16.840.1.113883.10.20.9.11`)
4. **SHALL** contain exactly one [1..1] **`entryRelationship`**, where its type is *Waveform Sample Period Observation*
   a. Contains exactly one [1..1] *Waveform Sample Period Observation* (templateId: `2.16.840.1.113883.10.20.9.13`)

Observation Null Flavor example

Result Organizer

[Organizer: templateId `null`]

1. **SHALL** conform to *CCD Result Organizer* template (templateId: `2.16.840.1.113883.10.20.1.32`)
2. **SHOULD** contain zero or more [0..*] **`component`**, where its type is *Numeric Observation*
   a. Contains exactly one [1..1] *Numeric Observation* (templateId: `2.16.840.1.113883.10.20.9.8`)
3. **MAY** contain zero or more [0..*] **`component`**, where its type is *Waveform Series Observation*
   a. Contains exactly one [1..1] *Waveform Series Observation* (templateId: `2.16.840.1.113883.10.20.9.12`)

Result Organizer example

Sampling Frequency Observation

[Observation: templateId `2.16.840.1.113883.10.20.9.10`]

The sampling period (frequency) of the device may be communicated in the PHMR. However, it will not be automatically derived from device data, i.e., it may be manually entered.

1. Contains exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="DEF"` (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="MDC_ATTR_TIME_PD_SAMP"` (CodeSystem: `2.16.840.1.113883.6.24 IEEE 11073`)
4. **SHALL** contain exactly one [1..1] **`value`**, where its data type is PQ
5. A value element **SHALL** be present where @xsi:type is PQ containing the sampling period in milliseconds (@unit= "ms").

Sampling Frequency Observation example

Vital Signs Organizer

[Organizer: templateId `null`]

1. **SHALL** conform to *Result Organizer*

Vital Signs Organizer example

Waveform Observation

Waveform Observation example

Waveform Sample Period Observation

[Observation: templateId `2.16.840.1.113883.10.20.9.13`]

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="TIME_ABSOLUTE"` (CodeSystem: `2.16.840.1.113883.5.4 ActCode`)
4. **SHALL** contain exactly one [1..1] **`value`**
5. A value element **SHALL** be present where @xsi:type is GLIST_TS containing a head element which stores the time of the first data point waveform, and an increment element showing the sample period (the time between data points).

Waveform Sample Period Observation example

Waveform Series Observation

Waveform Series Observation example

Chapter 5

OTHER CLASSES

Topics:

- *PHMR Product Instance*
- *PHMR Product Instance Reference*
- *Participant*
- *Participant Role*
- *Playing Device*
- *Scoping Entity*

This section of the Implementation Guide describes other classes that are not CDA Clinical Documents, Sections, or Clinical Statements.

PHMR Product Instance

[ParticipantRole: templateId `2.16.840.1.113883.10.20.9.9`]

1. **SHALL** conform to *CCD Product Instance* template (templateId: `2.16.840.1.113883.10.20.1.52`)
2. **MAY** contain zero or one [0..1] **`code`**
3. **SHALL** contain exactly one [1..1] **`id`**
4. **SHOULD** contain zero or one [0..1] **`scopingEntity`**, such that
5. **SHALL** contain exactly one [1..1] **`playingDevice`**, such that
6. **SHALL** satisfy: A code elemen containing an originalText element describing the regulatory status of the device in plain text (e.g., " Regulated Device " or " Unregulated Device").
7. A code element **MAY** be present where @nullFlavor is OTH (other).
8. An id element **SHALL** be present where @root is OID of device numbering space and @extension is a valid device ID within that space. (e.g. @root is 1.2.840.10004.1.1.1.0.0.1.0.0.1.2680 and @extension is a valid EUI-64 device ID).

PHMR Product Instance example

PHMR Product Instance Reference

[Participant2: templateId `null`]

A PHMR Product Instance Reference is used to refer to a PHMR Product Instance defined in the Device Definition Organizer for the device. Note: Per SDWG recommendations, there is no templateId for a device reference act. The guidance for any act reference is to include only the ID of the source act, and the minimal number of elements and attributes required as defined by the CDA schema. Note: Some information regarding the device (device accuracy, et cetera) is found in the Device Definition Organizer, not the PHMR Product Instance. Therefore, someone following a PHMR Product Instance Reference may need to traverse to the Device Definition Organizer parent element to retrieve all related device information.

1. **SHALL** contain exactly one [1..1] **`@typeCode`**`="SBJ"`
2. **SHALL** contain exactly one [1..1] **`participantRole`**, where its type is *Participant Role*

PHMR Product Instance Reference example

Participant

[Participant2: templateId `null`]

1. **SHALL** contain zero or one [0..1] **`pHMRProductInstance`**, where its type is *PHMR Product Instance*
   a. Contains exactly one [1..1] *PHMR Product Instance* (templateId: `2.16.840.1.113883.10.20.9.9`)

Participant example

Participant Role

[ParticipantRole: templateId `null`]

1. **SHALL** contain exactly one [1..1] **`id`**

Participant Role example

Playing Device

[Device: templateId `null`]

1. **SHALL** contain exactly one [1..1] **`code`** (CodeSystem: `2.16.840.1.113883.6.24 IEEE 11073`)
2. **SHALL** contain exactly one [1..1] **`manufacturerModelName`**

Playing Device example

Scoping Entity

[Entity: templateId `null`]

1. **SHALL** contain exactly one [1..1] **`desc`**

Scoping Entity example

Chapter 6

VALUE SETS

Topics:

- *My Problem Values*
- *New Value Set Version1*
- *phmrWaveformSeriesObservation*

The following tables summarize the value sets used in this Implementation Guide.

My Problem Values

Value Set	My Problem Values - 1.2.3.4.100.2
Code System	SNOMEDCT - 2.16.840.1.113883.6.96
Source	Veterans Administration/Kaiser Permanente (VA/KP)
Source URL	http://evs.nci.nih.gov/ftp1/FDA/ProblemList/
Definition	This describes the problem. Diagnosis/Problem List is broadly defined as a series of brief statements that catalog a patient s medical, nursing, dental, social, preventative and psychiatric events and issues that are relevant to that patient s healthcare (e.g., signs, symptoms, and defined conditions).

New Value Set Version1

Value Set	NewValueSetVersion1 - (OID not specified)

phmrWaveformSeriesObservation

Value Set	phmrWaveformSeriesObservation - 1.2.3.4.100.1
Code System	SNOMEDCT - 2.16.840.1.113883.6.96
Definition	The SNOMED CT has been limited to a value set that indicates the level of medical judgment used to determine the existence of a problem.

Concept Code	Concept Name	Code System	Description
404684003	Finding	SNOMEDCT	
409586006	Complaint	SNOMEDCT	
282291009	Diagnosis	SNOMEDCT	
64572001	Condition	SNOMEDCT	
248536006	Functional limitation	SNOMEDCT	
418799008	Symptom	SNOMEDCT	
55607006	Problem	SNOMEDCT	

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- HL7 Implementation Guide for CDA Release 2 Quality Reporting Document Architecture (QRDA) Draft Standard for Trial Use March 2009. Available at: *Quality Reporting Document Architecture (QRDA)*
- HL7 Implementation Guide for CDA Release 2 CDA for Public Health Case Reports (PHCR) Informative Standard October 2009. Available through *HL7* .
- HL7 Implementation Guide for CDA Release 2: NHSN Healthcare Associated Infection (HAI) Reports, Release 2 Draft Standard for Trial Use January 2009 Available at: *NHSN Healthcare Associated Infection (HAI) Reports*
- Dolin RH, Alschuler L, Boyer S, Beebe C, Behlen FM, Biron PV, Shabo A, (Editors). HL7 Clinical Document Architecture, Release 2.0. ANSI-approved HL7 Standard; May 2005. Ann Arbor, Mich.: Health Level Seven, Inc. Available through *HL7* or if an HL7 member with the following link: *CDA Release 2 Normative Web Edition.*
- *LOINC®* : Logical Observation Identifiers Names and Codes, Regenstrief Institute.
- *SNOMED CT®* : SNOMED Clinical Terms SNOMED International Organization.
- Extensible Markup Language, *www.w3.org/XML* .
- Dolin RH, Alschuler L, Boyer S, Beebe C, Behlen FM, Biron PV, Shabo A., HL7 Clinical Document Architecture, Release 2. J Am Med Inform Assoc. 2006;13:30-39. Available at: *http://www.jamia.org/cgi/reprint/13/1/30* .
- Using SNOMED CT in HL7 Version 3; Implementation Guide, Release 1.5. Available through *HL7* or if an HL7 member with the following link: *Using SNOMED CT in HL7 Version 3*