Implementation Guide for CDA Release 2

Immunization Exchange

Federal Health Architecture

Contents

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LEAD PARTNERS:

Department of Health & Human Services *(Managing Partner)*, Department of Defense, Department of Veterans Affairs

PARTICIPATING AGENCIES:


Administration for Children and Families


Administration on Aging


Agency for Healthcare Research and Quality


Agency for Toxic Substances and Disease Registry


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National Disaster Medical Systems


Office of Personnel Management


Railroad Retirement Board


Small Business Administration


Social Security Administration


United States Agency for International Development

Revision History

Rev	Date	By Whom	Changes
Initial Draft	September 2012	Federal Health Architecture	

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Chapter 1

INTRODUCTION

Topics:

The FHIMS program is intended to coordinate the efforts of the partner agencies with the development of Electronic Medical Records, information and terminology standards, including the coordination of agency efforts at relevant Standards Development Organizations (SDOs). The FHIMS is an information model rather than a data model. Data models are meant to be implemented, whereas information models are higher level specifications.

This guide defines the information exchange requirements for the proper exchange of Immunizations in the context of public health.

Overview

The Federal Health Architecture (FHA) is an e-government initiative managed by the Office of the National Coordinator for Health IT (ONC) within the Department of Health and Human Services (HHS). FHA was formed to coordinate health IT activities among the more than 20 federal agencies that provide health and healthcare services to citizens.

FHA and its federal partners are helping build a federal health information technology environment that is interoperable with private sector systems and supports the President's plan to enable better point-of-service care, increased efficiency and improved overall health in the U.S. population.

FHA is responsible for:

- Supporting federal efforts to deploy standardized health IT systems and measure health IT standard adoption
- Ensuring that federal agencies can seamlessly exchange health data among themselves, with state, local and tribal governments, and with private-sector partners
- Providing guidance to federal agencies on how to best manage and maintain health IT investments

FHA contributes to the national health IT agenda through:

- Input: FHA provides a coordinated federal voice and collaboration on national health IT solutions
- Implementation: FHA gives guidance to federal agencies on standards-compliant health IT investments that support interoperability
- Accountability: FHA ensures accountability for health IT programs in the federal government in an effort to advance interoperability

At their core, all FHA activities focus on improving citizen access to care, improving quality of care and reducing costs.

FHA is working with federal agencies to build the Federal Health Information Model (FHIM), a modeling initiative focused on producing a logical, health information model that supports semantic interoperability among federal agencies and their health information exchange partners. The model is built by harmonizing information from federal partners and standards development organizations (SDOs) and presenting it in logical and conceptual views based on specialized health domains.

This logical model uses the HL7 Reference Information Model (RIM) as its reference model and is designed to support multiple Office of Interoperability and Standards initiatives, including CONNECT and the S&I Framework. FHA and its stakeholders also use the FHIM to view and analyze information exchanges that have been identified by federal partners and SDOs, and the FHIM model is also used to support the development of National Information Exchange Model (NIEM) compliant information exchanges by the S&I Framework.

Approach

This implementation guide was produced from the FHIM leveraing the 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.

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

Scope

This CDA Implementation Guide defines the data exchange for Immunizations between Federal Agencies and their partners as define in the Federal Health Information Model.

Audience

The audience for this document includes analysts, software developers and implementers who need to exchange Immunziation information with Federal partners using a HL7 Clinical Document.

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:

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

Immunization Submission

[ClinicalDocument: templateId `2.16.840.1.113883.10.20.22.2.2.9999`]

1. **SHALL** conform to *Consol General Header Constraints* template (templateId: `2.16.840.1.113883.10.20.22.1.1`)
2. **SHALL** contain exactly one [1..1] **`component`**
   a. Contains exactly one [1..1] *Immunization Registry Submission* (templateId: `2.16.840.1.113883.10.20.22.2.2.1`)

Immunization Submission example

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <typeId root="2.16.840.1.113883.1.3"/>
  <id root="MDHT" extension="1257971377"/>
  <code code="465657774"/>
  <title>TEXT FOR TITLE</title>
  <effectiveTime/>
  <confidentialityCode code="827764267"/>
  <setId root="MDHT" extension="062014bd-2c53-4e34-bc89-403388c3d40c"/>
  <versionNumber value="1"/>
  <recordTarget>
    <typeId root="2.16.840.1.113883.1.3"/>
    <patientRole/>
  </recordTarget>
  <author>
    <typeId root="2.16.840.1.113883.1.3"/>
    <time/>
    <assignedAuthor/>
  </author>
  <custodian/>
  <component>
    <structuredBody>
      <component>
        <section>
          <typeId root="2.16.840.1.113883.1.3"/>
          <id root="MDHT" extension="1420022338"/>
          <code code="445530500"/>
          <title>TEXT FOR TITLE</title>
          <entry>
            <substanceAdministration classCode="SBADM">
              <typeId root="2.16.840.1.113883.1.3"/>
              <id root="MDHT" extension="1382841211"/>
              <code code="1101109948"/>
              <effectiveTime value="20121003"/>
              <consumable/>
              <participant/>
              <entryRelationship>
                <observation/>
              </entryRelationship>
              <entryRelationship>
                <observation/>
              </entryRelationship>
              <entryRelationship>
                <act/>
              </entryRelationship>
              <entryRelationship>
                <act/>
```

```
              </entryRelationship>
              <entryRelationship>
                <observation/>
              </entryRelationship>
              <entryRelationship>
                <act/>
              </entryRelationship>
            </substanceAdministration>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Chapter 3

SECTION TEMPLATES

Topics:

Immunization Registry Submission

[Section: templateId `2.16.840.1.113883.10.20.22.2.2.1`]

1. **SHALL** conform to *Consol Immunizations Section* template (templateId: `2.16.840.1.113883.10.20.22.2.2.1`)
2. Contains exactly one [1..1] **`entry`**
   a. Contains exactly one [1..1] *Vaccination Event* (templateId: `2.16.840.1.113883.10.20.22.4.52`)

Immunization Registry Submission example

```
<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <id root="MDHT" extension="1872469316"/>
  <code code="823239775"/>
  <title>TEXT FOR TITLE</title>
  <text/>
  <entry>
    <substanceAdministration>
      <id root="MDHT" extension="1977826204"/>
      <code code="1938103332"/>
      <text>Text Value</text>
      <effectiveTime value="20121003"/>
      <consumable/>
      <participant>
        <participantRole/>
      </participant>
      <entryRelationship>
        <observation>
          <id root="MDHT" extension="353983537"/>
          <code code="1575942797"/>
          <text>Text Value</text>
          <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
          </effectiveTime>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <observation>
          <id root="MDHT" extension="1150185146"/>
          <code code="1495385726"/>
          <text>Text Value</text>
          <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
          </effectiveTime>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <act/>
      </entryRelationship>
      <entryRelationship>
        <act/>
      </entryRelationship>
      <entryRelationship>
        <observation>
          <id root="MDHT" extension="1052879460"/>
          <code code="916555149"/>
```

```
          <text>Text Value</text>
          <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
          </effectiveTime>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <act>
          <id root="MDHT" extension="431871327"/>
          <code code="946045809"/>
          <text>Text Value</text>
          <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
          </effectiveTime>
        </act>
      </entryRelationship>
    </substanceAdministration>
  </entry>
</section>
```

Chapter 4

CLINICAL STATEMENT TEMPLATES

Topics:

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.

Contra Indication

[Observation: templateId `2.16.840.1.113883.10.20.22.4.19`]

An Immunization Activity describes immunization substance administrations that have actually occurred or are intended to occur. Immunization Activities in "INT" mood are reflections of immunizations a clinician intends a patient to receive. Immunization Activities in "EVN" mood reflect immunizations actually received.

An Immunization Activity is very similar to a Medication Activity with some key differentiators. The drug code system is constrained to CVX codes. Administration timing is less complex. Patient refusal reasons should be captured. All vaccines administered should be fully documented in the patient's permanent medical record. Healthcare providers who administer vaccines covered by the National Childhood Vaccine Injury Act are required to ensure that the permanent medical record of the recipient indicates:

1. Date of administration
2. Vaccine manufacturer
3. Vaccine lot number
4. Name and title of the person who administered the vaccine and the address of the clinic or facility where the permanent record will reside
5. Vaccine information statement (VIS)
   a. date printed on the VIS
   b. date VIS given to patient or parent/guardian.

1. **SHALL** conform to *Consol Indication* template (templateId: `2.16.840.1.113883.10.20.22.4.19`)
2. **SHALL** contain exactly one [1..1] **code** with data type CD

- *"A factor that renders the administration of a drug or the carrying out of a medical procedure inadvisable." - Stedman's Medical Dictionary.*

  Note that because almost all Contra-Indications are Health Concerns, for example, "Allergy to Eggs", "Allergy to Aluminum", "Current fever with moderate-to-severe illness", the Contra-Indication is modeled as relationship to Health Concern, and the Contra-Indication code may be derived from the Health Concern code. This having been said, there are some members of the Contra-Indication Value Set that are too general to point to a single Health Concern, even though they might still be derivable from the Health Concern list. Examples include "Chronic disease (disorder)", and "Immunodeficiency due to any cause, including HIV (hematologic and solid tumors, congenital immunodeficiency, long-term immunosuppressive therapy, including steroids)".

Contra Indication example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <id root="MDHT" extension="62403037"/>
  <code code="950318047"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
</observation>
```

Exemption

[Observation: templateId `2.16.840.1.113883.10.20.22.4.53`]

1. **SHALL** conform to *Consol Immunization Refusal Reason* template (templateId: `2.16.840.1.113883.10.20.22.4.53`)
2. **SHALL** contain exactly one [1..1] **`effectiveDate`** with data type CD
3. **SHALL** contain exactly one [1..1] **`values`** with data type CD

Exemption example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <id root="MDHT" extension="713387839"/>
  <code code="1566475621"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
</observation>
```

Indication

[Act: templateId `null`]

1. **SHALL** contain exactly one [1..1] **`indicationCode`** with data type CD

Indication example

```
<?xml version="1.0" encoding="UTF-8"?>
<act xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <id root="MDHT" extension="988884413"/>
  <code code="1398356061"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
</act>
```

Medication Administration Promise

[Act: templateId `null`]

1. **SHALL** contain exactly one [1..1] **`administrationStatus`** with data type CD

Medication Administration Promise example

```
<?xml version="1.0" encoding="UTF-8"?>
<act xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <id root="MDHT" extension="713723930"/>
  <code code="1019479553"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
</act>
```

Observed Reaction

[Observation: templateId `2.16.840.1.113883.10.20.22.4.9`]

1. **SHALL** conform to *Consol Reaction Observation* template (templateId: `2.16.840.1.113883.10.20.22.4.9`)
2. **SHOULD** contain zero or one [0..1] **`value`** with data type CD
   - *Indicates the symptom observed that is suspected to have been caused by adverse reaction.*

     "Identifies the specific allergic reaction that was documented." - HL7 Version 2.8, AL1-5 and IAM-5

Observed Reaction example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <id root="MDHT" extension="213322465"/>
  <code code="1463826552"/>
  <text>Text Value</text>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="CD" code="551108236"/>
</observation>
```

Patient Document Presentation

[Act: templateId `2.16.840.1.113883.10.20.22.4.20`]

1. **SHALL** conform to *Consol Instructions* template (templateId: `2.16.840.1.113883.10.20.22.4.20`)
2. **SHALL** contain exactly one [1..1] **`effectiveTime`** with data type CD

Patient Document Presentation example

```
<?xml version="1.0" encoding="UTF-8"?>
<act xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <id root="MDHT" extension="2048031323"/>
  <code code="922103141"/>
  <text>Text Value</text>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
</act>
```

Vaccination Event

[SubstanceAdministration: templateId `2.16.840.1.113883.10.20.22.4.52`]

The Immunizations section defines a patient's current immunization status and pertinent immunization history. The primary use case for the Immunization section is to enable communication of a patient's immunization status. The

section should include current immunization status, and may contain the entire immunization history that is relevant to the period of time being summarized.

1. **SHALL** conform to *Consol Immunization Activity* template (templateId: `2.16.840.1.113883.10.20.22.4.52`)
2. Contains exactly one [1..1] **`entryRelationship`**
   a. Contains exactly one [1..1] *Contra Indication* (templateId: `2.16.840.1.113883.10.20.22.4.19`)
3. Contains exactly one [1..1] **`participant`**
   a. Contains exactly one [1..1] *Primary Performer*
4. Contains exactly one [1..1] **`entryRelationship`**
   a. Contains exactly one [1..1] *Exemption* (templateId: `2.16.840.1.113883.10.20.22.4.53`)
5. Contains exactly one [1..1] **`entryRelationship`**
   a. Contains exactly one [1..1] *Indication*
6. Contains exactly one [1..1] **`entryRelationship`**
   a. Contains exactly one [1..1] *Medication Administration Promise*
7. Contains exactly one [1..1] **`entryRelationship`**
   a. Contains exactly one [1..1] *Observed Reaction* (templateId: `2.16.840.1.113883.10.20.22.4.9`)
8. Contains exactly one [1..1] **`entryRelationship`**
   a. Contains exactly one [1..1] *Patient Document Presentation* (templateId: `2.16.840.1.113883.10.20.22.4.20`)
9. **SHALL** contain exactly one [1..1] **`statusCode`** with data type CD
   - *"Status of treatment administration event. Refer to HL7 Table 0322 - Completion Status in Chapter 2C for valid values." - HL7 Version 2.8, RXA-20*

     The current state of the Substance Administration. Possible values include: Infusing, Given, Held, Completed, etc.
10. **SHOULD** contain zero or one [0..1] **`treatmentRefusalReason`** with data type CD
    - *"Contains the reason the patient refused the medical substance/treatment. Any entry in the field indicates that the patient did not take the substance." - HL7 Version 2.8, RXA-18*

Vaccination Event example

```
<?xml version="1.0" encoding="UTF-8"?>
<substanceadministration xmlns:xsi="http://www.w3.org/2001/XMLSchema-
instance" xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3
 CDA.xsd">
  <id root="MDHT" extension="1051651988"/>
  <code code="119622262"/>
  <text>Text Value</text>
  <statusCode code="completed"/>
  <effectiveTime value="20121003"/>
  <repeatNumber value="1"/>
  <routeCode code="844950161"/>
  <approachSiteCode code="1469551482"/>
  <doseQuantity/>
  <administrationUnitCode code="118567244"/>
  <consumable/>
  <participant>
    <participantRole/>
  </participant>
  <entryRelationship>
    <observation>
      <id root="MDHT" extension="1933489624"/>
```

```
      <code code="786562582"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <repeatNumber value="1"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="MDHT" extension="1040530509"/>
      <code code="454423110"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <repeatNumber value="1"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act/>
  </entryRelationship>
  <entryRelationship>
    <act/>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="MDHT" extension="1528130977"/>
      <code code="1155257828"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <repeatNumber value="1"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act>
      <id root="MDHT" extension="810595555"/>
      <code code="1230440180"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </act>
  </entryRelationship>
</substanceadministration>
```

Chapter 5

OTHER CLASSES

Topics:

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

Individual Provider

[ParticipantRole: templateId `null`]

1.

Individual Provider example

```
<?xml version="1.0" encoding="UTF-8"?>
<participantrole xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <id root="MDHT" extension="1507307159"/>
</participantrole>
```

Primary Performer

[Participant2: templateId `null`]

1. Contains exactly one [1..1] **`participantRole`**, where its type is *Individual Provider*
   a. Contains exactly one [1..1] *Individual Provider*

Primary Performer example

```
<?xml version="1.0" encoding="UTF-8"?>
<participant2 xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <time>
    <low value="2012"/>
    <high value="2012"/>
  </time>
  <participantRole/>
</participant2>
```

Chapter 6

VALUE SETS

Topics:

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

FHIM Immunization Funding Source

Value Set	FHIM_ImmunizationFundingSource - 2.16.840.1.113883.3.2074.1.1.1
Version	1
Source	PHVS_ImmunizationFundingSource_IIS 2.16.840.1.114222.4.11.3287
Source URL	TBD
Definition	Immunization Funding Source (Used in OBX- 5) - Indicates funding source for an immunization.Includes all the codes from the orignal value sets except for"other" and "unknown".
Description	It is the same the PHVS value set except it does not include null flavors "other" (OTH) and "unknown" (UNK) to specify other funding or uknown funding sources.

Code	Code System	Print Name
VXC1		
PHC68		
PHC70		
VXC2		
VXC3		

FHIM Substance Refusal Reason

Value Set	FHIM_SubstanceRefusalReason - 2.16.840.1.113883.3.2074.1.1.4
Version	1
Source	PHVS_SubstanceRefusalReason_IIS 2.16.840.1.114222.4.11.3380
Source URL	tbd
Definition	Includes all the codes from the orignal value sets (PHVS_SubstanceRefusalReason_IIS 2.16.840.1.114222.4.11.3380) except "Other". If the reason is not included, the sender should use the textual description rather than a coded concept.

Code	Code System	Print Name
00		
01		
03		

PHVS Act No Immunization Reason HL7 V3

Value Set	PHVS_ActNoImmunizationReason_HL7_V3 - 2.16.840.1.113883.1.11.19717
Code System	ActReason - 2.16.840.1.113883.5.8
Version	1
Source	HL7

Source URL	http://phinvads.cdc.gov/vads/ViewValueSet.action?id=7BFDBFB5-A277-DE11-9B52-0015173D1785
Definition	This identifies the reason why the immunization did not occur

Code	Code System	Print Name
IMMUNE	ActReason	
MEDPREC	ActReason	
OSTOCK	ActReason	
PATOBJ	ActReason	
PHILISOP	ActReason	
RELIG	ActReason	
VACEFF	ActReason	
VACSAF	ActReason	

PHVS Administrative Site IIS

Value Set	PHVS_AdministrativeSite_IIS - 2.16.840.1.114222.4.11.3370
Version	1
Source	HL7
Source URL	https://phinvads.cdc.gov/vads/ViewValueSet.action?id=98257779-17B8-DF11-9BDD-0015173D1785
Definition	HL7-defined Table 0163 - Administrative site [only selected values listed] (use in RXR-2)
Description	This value set is used as-is.

PHVS Vaccination Contraindication IIS

Value Set	PHVS_VaccinationContraindication_IIS - 2.16.840.1.114222.4.11.3288
Version	1
Source	PHIN VS and SNOMED-CT
Source URL	http://phinvads.cdc.gov/vads/ViewValueSet.action?id=DAEDFBD4-9BB9-DF11-9BDD-0015173D1785#
Description	This value set is a mix of two coding systems.

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