CDAR2\_IG\_QRDA\_CATIII\_RI\_AUG



Quality Reporting Document Architecture Category III

Release 1

Implementation Guide for CDA Release 2

(US Realm)

Based on HL7 CDA Release 2.0

August 2012

Produced in collaboration with:



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# Introduction

"If you cannot measure it, you cannot improve it."

Lord Kelvin (1824-1907)

## Purpose

This document describes constraints on the Clinical Document Architecture Release 2 (CDA R2) header and body elements for Quality Reporting Document Architecture (QRDA) Category III documents. The Institute of Medicine (IOM) definition of quality is: “The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.”[[1]](#footnote-1) For care quality to be evaluated, it must be standardized and communicated to the appropriate organizations.

QRDA Category III is a document format that provides a standard structure with which to report aggregated quality measure data to organizations that will analyze and interpret the data. Quality measurement in health care is complex. Accurate, interpretable data efficiently gathered and communicated is key in correctly assessing that quality care is delivered

## Audience

The audience for this document includes software developers and implementers with reporting capabilities within their electronic health record (EHR) systems; developers and analysts in receiving institutions; and local, regional, and national health information exchange networks who wish to create and/or process CDA reporting documents created according to this specification.

## 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 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.

This implementation guide is release 2 (R2) of the QRDA Draft Standard for Trial Use (DSTU), Category III. The [Background](#_Background_1) and [Current Project](#_Current_Project_1) sections describe the development of the DSTU.

## CDA R2

CDA R2 is “… a document markup standard that specifies the structure and semantics of ‘clinical documents’ for the purpose of exchange” [CDA R2, Section 1.1; see [References](#_References_2)]. Clinical documents, according to CDA, have six characteristics:

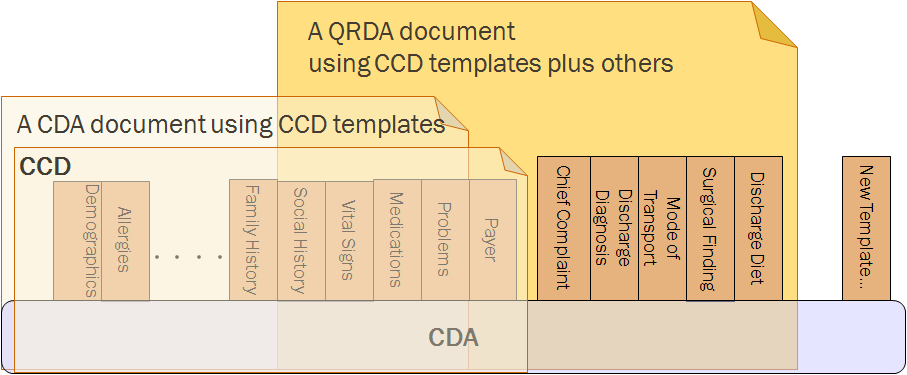
* Persistence
* Stewardship
* Potential for authentication
* Context
* Wholeness
* Human readability

CDA defines a header for classification and management and a document body that carries the clinical record. While the header metadata are prescriptive and designed for consistency across all instances, the body is highly generic, leaving the designation of semantic requirements to implementation guides such as this one.

## Templated CDA

CDA R2 can be constrained by mechanisms defined in the “Refinement and Localization”[[2]](#footnote-2) section of the *HL7 Version 3 Interoperability Standards*. The mechanism most commonly used to constrain CDA is referred to as “templated CDA”. In this approach, a library of modular CDA templates are constructed such that they can be reused across any number of CDA document types, as shown in the following figure.

Figure : Templated CDA



There are many different kinds of templates that might be created. Among them, the most common are:

* **Document-level templates**: These templates constrain fields in the CDA header, and define containment relationships to CDA sections. For example, a History-and-Physical document-level template might require that the patient’s name be present, and that the document contain a Physical Exam section.
* **Section-level templates**: These templates constrain fields in the CDA section, and define containment relationships to CDA entries. For example, a Physical-exam section-level template might require that the section/code be fixed to a particular LOINC code, and that the section contain a Systolic Blood Pressure observation.
* **Entry-level templates**: These templates constrain the CDA clinical statement model in accordance with real world observations and acts. For example, a Systolic-blood-pressure entry-level template defines how the CDA Observation class is constrained (how to populate observation/code, how to populate observation/value, etc) to represent the notion of a systolic blood pressure.

A CDA implementation guide (such as this one) includes reference to those templates that are applicable. On the implementation side, a CDA instance populates the templateId field where it wants to assert conformance to a given template. On the receiving side, the recipient can then not only test the instance for conformance against the CDA XML schema, but can also test the instance for conformance against asserted templates.

## Background

In early pilots of the QRDA initiative, participating organizations confirmed the feasibility of using the HL7 Clinical Document Architecture (CDA) as the foundation for the QRDA specification. The participants concluded that CDA provided the technical underpinnings for communicating pediatric and adult quality measures for both inpatient and ambulatory care settings.

In later pilots, the HL7 Child Health Work Group and the Structured Documents Work Group developed a QRDA DSTU, Release 1 (R1), first published in September 2008.

The QRDA DSTU R1 defined three categories of quality reporting: A [QRDA Category I – Single Patient Report](#_QRDA_Category_I), a [QRDA Category II – Patient List Report](#_QRDA_Category_II), and a [QRDA Category III – Calculated Report](#_QRDA_Category_III). Only the QRDA Category I report was balloted, while the sections of the DSTU that define QRDA Category II and Category III reports were for comment only. The concept of the Release 1 report types are described below.

Add a section about Query Health here. Include the fact that where the term “quality measure” or “eMeasure” is used, queries that use the HMQF syntax are implied, i.e., for the purposes of QRDA Cat III, anything encoded in HQMF that conforms to the specification is considered to be an eMeasure.

### QRDA Category I – Single Patient Report

A QRDA Category I report is an individual-patient-level quality report. Each report contains quality data for one patient for one or more quality measures, where the data elements in the report are defined by the particular measure(s) being reported on. A QRDA Category I report contains raw applicable patient data. When pooled and analyzed, each report contributes the quality data necessary to calculate population measure metrics.

QRDA R1 defined the CDA framework for quality reports and a method for referencing a quality measure. The DSTU recommended the re-use of Continuity of Care Document (CCD)[[3]](#footnote-3) clinical statements to send measure data elements. Two measure-specific implementation guides were created as part of the guide.

### QRDA Category II – Patient List Report

A QRDA Category II report is a multi-patient-level quality report. Each report contains quality data for a set of patients for one or more quality measures, where the data elements in the report are defined by the particular measure(s) being reported on.

Whereas a QRDA Category I report contains only raw applicable patient data, a QRDA Category II report includes flags for each patient indicating whether the patient qualifies for a measure’s numerator, denominator, exclusion, or other aggregate data element. These qualifications can be pooled and counted to create the QRDA Category III report.

### QRDA Category III – Calculated Report

A QRDA Category III report is an aggregate quality report. Each report contains calculated summary data for one or more measures for a specified population of patients within a particular health system over a specific period of time.

Data needed to generate QRDA Category II and QRDA Category III reports must be included in the collected QRDA Category I reports, as the processing entity will not have access to additional data sources.

This implementation guide contains the definition of Category III reports. The reader is referred to the related implementation guides for definitions of Category I and Category II reports.

## Relationship to Health Quality Measures Format: eMeasures

The HL7 Health Quality Measures Format (HQMF) is a standard for representing a health quality measure as an electronic document. A quality measure is a quantitative tool that provides an indication of the performance of an individual or organization in relation to a specified process or outcome via the measurement of an action, process or outcome of clinical care. Quality measures are often derived from clinical guidelines and are designed to determine whether the appropriate care has been provided given a set of clinical criteria and an evidence base. Quality measures are also often referred to as performance measures or quality indicators. A quality measure expressed in HQMF format is referred to as an "eMeasure".

Add a paragraph about the relationship to HQMF used for queries, taken from the existing QH documents.

## Current Project

This implementation guide is a conformance profile, as described in the “Refinement and Localization”[[4]](#footnote-4) section of the *HL7 Version 3 Interoperability Standards*. The base standard for this implementation guide is the *HL7 Clinical Document Architecture, Release 2.0.*[[5]](#footnote-5) This implementation guide does not describe every aspect of CDA. Rather, it defines constraints on the base CDA used in a QRDA Category III document in the US realm. Additional optional CDA elements, not included here, can be included and the result will be compliant with the specifications in this guide.

## Organization of This Guide

This guide includes a set of CDA Templates and prescribes their use within a QRDA document. The main chapters are:

TBD when closer to completion

## Conformance Conventions Used in This Guide

### Erratas or Enhancements

Comments regarding errata or enhancements may be noted on the HL7 DSTU QRDA Comments page: <http://www.hl7.org/dstucomments/>. This implementation guide references several templates that have been balloted and published elsewhere. The [Previously Published Templates](#A_Previously_Published_Templates) appendix lists these templates.

### Templates and Conformance Statements

Conformance statements within this implementation guide are presented as constraints from a Template Database (Tdb). An algorithm converts constraints recorded in a Templates Database to a printable presentation. Each constraint is uniquely identified by an identifier at or near the end of the constraint (e.g., CONF:7345). These identifiers are persistent but not sequential.

Bracketed information following each template title indicates the template type (section, observation, act, procedure, etc.), the templateId, and whether the template is [open or closed](#_Open_and_Closed).

Each section and entry template in the guide includes a context table. The "Used By" column indicates which documents or sections use this template, and the "Contains Entries" column indicates templates contained within this template. Each entry template also includes a constraint overview table to summarize the constraints following the table. For templates that are children ("Conforms to") of parent constraints, the constraint overview tables are labeled “differential” to indicate that rows that duplicate the parent constraints have been removed. Value set tables, where applicable, and brief XML example figures are included with most explanations.

A typical template, as presented in this guide, is shown in the [Constraints format example figure](#F_Constraints_format_example). The next sections describe specific aspects of conformance statements—open vs. closed statements, conformance verbs, cardinality, vocabulary conformance, containment relationships, and null flavors.

Figure : Constraints format example

**Severity Observation**

[observation: templateId 2.16.840.1.113883.10.20.22.4.8(open)]

Table xxx: Severity Observation Contexts

| Used By: | Contains Entries: |
| --- | --- |
| Reaction Observation  Allergy Observation |  |

This clinical statement represents the severity of the reaction to an agent. A person may manifest many symptoms …

Table yyy: Severity Observation Constraints Overview

| Name | XPath | Card. | Verb | Data Type | CONF# | Fixed Value |
| --- | --- | --- | --- | --- | --- | --- |
|  | observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.8'] | | | | | |
|  | @classCode | 1..1 | SHALL |  | 7345 | 2.16.840.1.113883.5.6 (HL7ActClass) = OBS |
| … |  |  |  |  |  |  |

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:7345).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 ActMood) **STATIC** (CONF:7346).
3. SHALL contain exactly one [1..1] templateId (CONF:7347) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.8" (CONF:10525).
4. **SHALL** contain exactly one [1..1] **code**="SEV" Severity Observation (CodeSystem: 2.16.840.1.113883.5.4 ActCode) **STATIC** (CONF:7349).
5. **SHOULD** contain zero or one [0..1] **text** (CONF:7350).
   1. This text, if present, **SHOULD** contain zero or one [0..1] **reference/@value** (CONF:7351).
      1. This reference/@value SHALL begin with a '#' and SHALL point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:7378).
6. **SHALL** contain …

### Open and Closed Templates

In open templates, all of the features of the CDA R2 base specification are allowed except as constrained by the templates. By contrast, a closed template specifies everything that is allowed and nothing further may be included. Templates in a QRDA document are open.

### Keywords

The keywords shall, should, may, need not, should not, and shall not in this document are to be interpreted as described in the *HL7 Version 3 Publishing Facilitator's Guide*[[6]](#footnote-6):

* shall: an absolute requirement for the particular element. Where a SHALL constraint is applied to an XML element, that element must be present in an instance, but may have an exceptional value (i.e., may have a nullFlavor), unless explicitly precluded. Where a SHALL constraint is applied to an XML attribute, that attribute must be present, and must contain a conformant value.
* 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
* may/need not: truly optional; can be included or omitted as the author decides with no implications

### Cardinality

The cardinality indicator (0..1, 1..1, 1..\*, etc.) specifies the allowable occurrences within a document instance. The cardinality indicators are interpreted with the following format “m…n” where m represents the least and n the most:

* 0..1 zero or one
* 1..1 exactly one
* 1..\* at least one
* 0..\* zero or more
* 1..n at least one and not more than n

When a constraint has subordinate clauses, the scope of the cardinality of the parent constraint must be clear. In the next figure, the constraint says exactly one participant is to be present. The subordinate constraint specifies some additional characteristics of that participant.

Figure : Constraints format – only one allowed

1. SHALL contain exactly one [1..1] **participant** (CONF:2777).

a. This participantSHALL contain exactly one [1..1] **@typeCode**="LOC"   
 (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType)   
 (CONF:2230).

In the next figure, the constraint says only one participant “like this” is to be present. Other participant elements are not precluded by this constraint.

Figure : Constraints format – only one like this allowed

1. SHALL contain exactly one [1..1] **participant** (CONF:2777) such that it

a. SHALL contain exactly one [1..1] **@typeCode**="LOC" (CodeSystem:

2.16.840.1.113883.5.90 HL7ParticipationType) (CONF:2230).

### Vocabulary Conformance

The templates in this document use terms from several code systems. These vocabularies are defined in various supporting specifications and may be maintained by other bodies, as is the case for the LOINC® and SNOMED CT® vocabularies.

Note that value-set identifiers (e.g., ValueSet 2.16.840.1.113883.1.11.78 Observation Interpretation (HL7) **DYNAMIC)** do not appear in CDA instances; they tie the conformance requirements of an implementation guide to the allowable codes for validation.

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. Value-set constraints can be static, meaning that they are bound to a specified version of a value set, or dynamic, meaning that they are bound to the most current version of the value set. A simplified constraint, used when the binding is to a single code, includes the meaning of the code.

Figure : Constraint binding to a single code

1. … code/@code="11450-4" Problem List (CodeSystem: 2.16.840.1.113883.6.1 LOINC).

In this example, the notation conveys the actual code (11450-4), the code’s displayName (Problem List), the object identifier (OID) of the codeSystem from which the code is drawn (2.16.840.1.113883.6.1), and the codeSystemName (LOINC).

HL7 Data Types Release 1 requires the codeSystem attribute unless the underlying data type is “Coded Simple” or “CS”, in which case it is prohibited. The displayName and the codeSystemName are optional, but often useful to include in an instance.

The above example would be properly expressed as follows.

Figure : XML expression of a single-code binding

<code code="11450-4" codeSystem="2.16.840.1.113883.6.1"/>

<!-- or -->

<code code="11450-4" codeSystem="2.16.840.1.113883.6.1"

displayName="Problem List"

codeSystemName="LOINC"/>

A full discussion of the representation of vocabulary is outside the scope of this document; for more information, see the *HL7 Version 3 Interoperability Standards,* Normative Edition 2010[[7]](#footnote-7) sections on Abstract Data Types and XML Data Types R1.

There is a discrepancy in the implementation of translation code versus the original code between HL7 Data Types R1 and the convention agreed upon for this implementation guide. The R1 data type requires the original code in the root. This implementation guide specifies the standard code in the root, whether it is original or a translation. This discrepancy is resolved in HL7 Data Types R2[[8]](#footnote-8).

Figure : Translation code example

<code code='206525008’

displayName='neonatal necrotizing enterocolitis' 🡨 **standard code**  
 codeSystem='2.16.840.1.113883.6.96'

codeSystemName='SNOMED CT'>

<translation code='NEC-1' 🡨 **source’s original code**

displayName='necrotizing enterocolitis'

codeSystem='2.16.840.1.113883.19'/>

</code>

### Null Flavor

Information technology solutions store and manage data, but sometimes data are not available; an item may be unknown, not relevant, or not computable or measureable. In HL7, a *flavor* of null, or nullFlavor, describes the reason for missing data.

Figure : nullFlavor example

<birthTime nullFlavor="NI"/> <!--coding a birthdate when there is no birthdate available-->

Use null flavors for unknown, required, or optional attributes:

* NI No information. This is the most general and default null flavor.
* NA Not applicable. Known to have no proper value (e.g., last menstrual period for a male).
* UNK Unknown. A proper value is applicable, but is not known.
* ASKU Asked, but not known. Information was sought, but not found (e.g., the patient was asked but did not know).
* NAV Temporarily unavailable. The information is not available, but is expected to be available later.
* NASK Not asked. The patient was not asked.
* MSK There is information on this item available but it has not been provided by the sender due to security, privacy, or other reasons. There may be an alternate mechanism for gaining access to this information.
* OTH The actual value is not and will not be assigned a standard coded value. An example is the name or identifier of a clinical trial.

This above list contains those null flavors that are commonly used in clinical documents. For the full list and descriptions, see the nullFlavor vocabulary domain in the CDA normative edition.[[9]](#footnote-9)

Any SHALLconformance statement may use nullFlavor, unless the attribute is required or the nullFlavor is explicitly disallowed. SHOULD and MAY conformance statement may also use nullFlavor.

Figure : Attribute required

1. SHALL contain exactly one [1..1] **code/@code**="11450-4" Problem List (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:7878)

or

2**.** SHALL contain exactly one [1..1] **effectiveTime/@value** (CONF:5256).

Figure : Allowed nullFlavors when element is required (with xml examples)

1. SHALL contain at least one [1..\*] id

2. SHALL contain exactly one [1..1] code

3. SHALL contain exactly one [1..1] effectiveTime

<entry>

<observation classCode="OBS" moodCode="EVN">

<id nullFlavor="**NI**"/>

<code nullFlavor="**OTH**">

<originalText>New Grading system</originalText>

</code>

<statusCode code="completed"/>

<effectiveTime nullFlavor="**UNK**"/>

<value xsi:type="CD" nullFlavor="OTH">

<originalText>Spiculated mass grade 5</originalText>

</value>

</observation>

</entry>

Figure : nullFlavor explicitly disallowed

1.SHALL contain exactly one [1..1] **effectiveTime** (CONF:5256).

a. SHALL NOT contain [0..0] @nullFlavor (CONF:52580).

### Asserting an Act Did Not Occur with a Reason

The negationInd attribute, if true, specifies that the act indicated was observed to not have occurred (which is subtly but importantly different from having not been observed). NegationInd='true' is an acceptable way to make a clinical assertion that something did not occur, for example, "no gestational diabetes".

A nested reason for the act not being done can be represented through the use of an entryRelationship clinical statement with an actRelationship type of “RSON”.

Figure : Asserting an act did not occur with reason

<entry>

<substanceAdministration classCode="SBADM" moodCode="EVN" negationInd="true">

<templateId root="2.16.840.1.113883.10.20.22.4.52"/>

<statusCode code="completed"/>

<effectiveTime nullFlavor="NI"/>

<doseQuantity nullFlavor="NI"/>

<consumable>

<manufacturedProduct>

<templateId root="2.16.840.1.113883.10.20.22.4.54"/>

<!-- \*\*\*\*\*\*\*\* Immunization Medication Information \*\*\*\*\*\*\*\* -->

<manufacturedMaterial>

<code code="88" codeSystem="2.16.840.1.113883.6.59"

displayName="Influenza virus vaccine" codeSystemName="CVX">

</code>

</manufacturedMaterial>

</manufacturedProduct>

</consumable>

<entryRelationship typeCode="RSON">

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.24.3.88"/>

<code code="410666004"

codeSystem="2.16.840.1.113883.6.96"

displayName="reason"

codeSystemName="SNOMED CT"/>

<value xsi:type="CD"

code="275984001"

codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED CT"

displayName="Immunization refused"/>

</observation>

</entryRelationship>

</substanceAdministration>

</entry>

### Data Types

All data types used in a CDA document are described in the CDA R2 normative edition.[[10]](#footnote-10) All attributes of a data type are allowed unless explicitly prohibited by this specification.

## XML Conventions Used in This Guide

### XPath Notation

Instead of the traditional dotted notation used by HL7 to represent Reference Information Model (RIM) classes, this document uses XML Path Language (XPath) notation[[11]](#footnote-11) in conformance statements and elsewhere to identify the Extended Markup Language (XML) elements and attributes within the CDA document instance to which various constraints are applied. The implicit context of these expressions is the root of the document. This notation provides a mechanism that will be familiar to developers for identifying parts of an XML document.

XPath statements appear in this document in a monospace font.

XPath syntax selects nodes from an XML document using a path containing the context of the node(s). The path is constructed from node names and attribute names (prefixed by an ‘@’) and concatenated with a ‘/’ symbol.

Figure : XML document example

<author>

<assignedAuthor>

...

<code codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'

code='17561000' displayName='Cardiologist' />

</assignedAuthor>

</author>

In the above example, the code attribute of the code could be selected with the XPath expression in the next figure.

Figure : XPath expression example

author/assignedAuthor/code/@code

### XML Examples and Sample Documents

Extended Mark-up Language (XML) examples appear in figures in this document in this monospace font. Portions of the XML content may be omitted from the content for brevity, marked by an ellipsis (...) as shown in the example below.

Figure : ClinicalDocument example

<ClinicalDocument xmls="urn:h17-org:v3">

...

</ClinicalDocument>

Within the narrative, XML element (code, assignedAuthor, etc.) and attribute (SNOMED CT, 17561000, etc.) names also appear in this monospace font.

This package includes 2 complete sample documents as listed in the [Content of the Package](#T_Contents_of_the_Package) table below.

## Rendering Header Information for Human Presentation

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

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

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

## Content of the Package

The following files comprise this package.

Table : Content of the Package

|  |  |  |
| --- | --- | --- |
| Filename | Description | Ballot Applicability |
|  | This guide | Normative |
|  | Sample QRDA category III | Informative |
|  | Sample QRDA category III | Informative |
| cda.xsl | Stylesheet for display of CDA instances | Informative |

# QRDA Category III

A QRDA Category III report is a summary report containing aggregated data. Each report contains quality data for a number of patients for one or more quality measures, where the data elements and grouping or stratification levels in the report are defined by the particular measure(s) being reported on.

## Measure Section

The [Measure Section](#S_Measure_Section) template contains explicit reference to the measure or measures being reported. The standard allows a QRDA Category III instance to contain data for any number of measures.

## Reporting Parameters Section

The [Reporting Parameters Section](#S_Reporting_Parameters_Section) provides information about the reporting time interval, and may contain other information that provides context for the calculated aggregate data being reported. The receiving organization may tell the reporting organizations what information they want in this section.

# Document Templates

This chapter defines the document-level templates in a QRDA Category III document. All of the templates in the QRDA IG are CDA templates.

## QRDA Category III Report

[ClinicalDocument: templateId QRDACATIII-TEMP-OID (open)]

Table 2: QRDA Category III Report Contexts

| Used By: | Contains Entries: |
| --- | --- |
|  | [QRDA Category III Measure Section](#S_QRDA_Category_III_Measure_Section)  [Reporting Parameters Section](#S_Reporting_Parameters_Section) |

This template describes constraints that apply to the Quality Reporting Document Architecture (QRDA) Document Category III report framework. Document-level templates describe the purpose and rules for constructing a conforming CDA document. Document templates include constraints on the CDA header and identify contained section-level templates.

The document-level template contains the following information:

• Description and explanatory narrative.

• Template metadata (e.g., templateId, etc.)

• Header constraints

• Required section-level templates

1. SHALL contain exactly one [1..1] realmCode (CONF:17226).
   1. This realmCode SHALL contain exactly one [1..1] @code="US" (CONF:17227).
2. SHALL contain exactly one [1..1] typeId (CONF:17228).
   1. This typeId SHALL contain exactly one [1..1] @root="TBD" (CONF:17229).
   2. This typeId SHALL contain exactly one [1..1] @extension="TBD" (CONF:17230).
3. SHALL contain exactly one [1..1] templateId (CONF:17208) such that it
   1. SHALL contain exactly one [1..1] @root="QRDACATIII-TEMP-OID" (CONF:17209).
4. SHALL contain exactly one [1..1] id (CONF:17236).
   1. This id SHALL be a globally unique identifier for the document (CONF:17242).
5. SHALL contain exactly one [1..1] code="55182-0" Quality Measure Report (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:17210).
6. SHALL contain exactly one [1..1] title (CONF:17211).
7. SHALL contain exactly one [1..1] effectiveTime (CONF:17237).
8. SHALL contain exactly one [1..1] confidentialityCode (CONF:17238).
9. MAY contain zero or one [0..1] languageCode (CONF:17239).
10. MAY contain zero or one [0..1] setId (CONF:17240).
    1. If setId is present versionNumber SHALL be present (CONF:17243).
11. MAY contain zero or one [0..1] versionNumber (CONF:17241).
    1. If versionNumber is present setId SHALL be present (CONF:17244).

The QRDA Category III document contains calculated measure data for a set of patients. Only one recordTarget is allowed, and it must have the nullFlavor "NA".

1. SHALL contain exactly one [1..1] recordTarget (CONF:17212).
   1. This recordTarget SHALL contain exactly one [1..1] patientRole (CONF:17232) such that it
      1. SHALL contain exactly one [1..1] id (CONF:17233).
         1. This id SHALL contain exactly one [1..1] @nullFlavor="NA" (CONF:17234).

The custodian is the organization that owns and reports the data (e.g., hospital). This element is required in QRDA Category III documents.

1. SHALL contain exactly one [1..1] custodian (CONF:17213).
   1. This custodian SHALL contain exactly one [1..1] assignedCustodian (CONF:17214).
      1. This assignedCustodian SHALL contain exactly one [1..1] representedCustodianOrganization (CONF:17215).
         1. This assignedCustodian SHALL represent the organization that owns and reports the data (<CONF:17216>).
   2. Todo: specify the elements that must be contained, if any other than these
2. SHALL contain exactly one [1..1] legalAuthenticator (<CONF:17225>).
   1. Todo: specify the elements the legalAuthenticator must contain (name, organization, date stamp, organization ID?)

#### Participant Scenarios in a QRDA Category III Document

Several CDA Header participations can be played by the same person. In such cases, the person should be identified as the player for each appropriate participation. For instance, if a person is both the author and the legal authenticator of a document, the CDA Header should identify that person as both the author participant and the authenticator participant.

On other occasions, CDA Header participants are played by different people. The following table shows a number of scenarios and the appropriate values for various participants. The informant element is not used in QRDA Category III documents. These scenarios are the same as defined in QRDA Category I.

Table : Participant Scenarios

|  |  |  |  |
| --- | --- | --- | --- |
| Scenario | Author | Custodian | Legal Authenticator |
| QRDA is wholly constructed automatically by device | Device | Organization that owns and Reports the data (e.g., hospital) | A designated person in the organization (may be assigned to the report automatically) |
| QRDA is partially constructed automatically by device, partially constructed by quality manager | Device;  Quality Manager | Organization that owns and Reports the data (e.g., hospital) | A designated person in the organization (such as the Quality Manager) |
| QRDA is constructed manually (e.g., by an organization that doesn’t have an EHR) | Quality Manager | Organization that owns and Reports the data (e.g., hospital) | A designated person in the organization (such as the Quality Manager) |

In HAI pop-sum reports, the following are also defined in the header. Does it make sense to add this to the QRDA Cat III header?

1. **SHALL** contain [1..1] **participant** (CONF:4352) such that it
   1. **SHALL** contain [1..1] **@typeCode**="SBJ" Subject (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) (CONF:4353).
   2. **SHALL** contain [1..1] **@contextControlCode**="OP" (CodeSystem: 2.16.840.1.113883.5.1057 HL7 Context Control Code) (CONF:4354).
   3. **SHALL** contain [1..1] **associatedEntity** (CONF:4355).
      1. This associatedEntity **SHALL** contain [1..1] **@classCode**="PRS" Person (CodeSystem: 2.16.840.1.113883.5.41 HL7EntityClass) (CONF:4356).
      2. This associatedEntity **SHALL** contain [1..1] **code** (CONF:16157)
         1. This code **SHALL** contain [1..1] **@code**="389109008" Group (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) (CONF:4357).

### QRDA Category III Body Constraints

A QRDA Category III document contains a Reporting Parameters Section and a Measure section.

1. SHALL contain exactly one [1..1] component (CONF:17217).
   1. This component SHALL contain exactly one [1..1] structuredBody (CONF:17235).
      1. This structuredBody SHALL contain exactly one [1..1] component (CONF:17281) such that it
         1. SHALL contain exactly one [1..1] [Reporting Parameters Section](#S_Reporting_Parameters_Section) (templateId:2.16.840.1.113883.10.20.17.2.1) (CONF:17282).
      2. This structuredBody SHALL contain exactly one [1..1] component (CONF:17283) such that it
         1. SHALL contain exactly one [1..1] [QRDA Category III Measure Section](#S_QRDA_Category_III_Measure_Section) (templateId:QRDACATIII-TEMP-OID-MEASURE-SECTION) (CONF:17301).

# Section-Level Templates

This section contains the section-level templates. Section-level templates are always included in a document with a structured body. All of the templates in the QRDA IG are CDA templates. See Chapter 1.5 on [Templated CDA](#_Development_of_This).

Each section-level template contains the following:

* Template metadata (e.g., templateId)
* Description and explanatory narrative
* LOINC section code
* Section title
* Entry-level template names and Ids for referenced templates.

The text element within the section stores the narrative to be rendered, as described in the CDA R2 specification[[12]](#footnote-12), and is referred to as the CDA narrative block.

The content model of the CDA narrative block schema is hand crafted to meet requirements of human readability and rendering. The schema is registered as a MIME type (text/x-hl7-text+xml), which is the fixed media type for the text element.

As noted in the CDA R2 specification, the document originator is responsible for ensuring that the narrative block contains the complete, human readable, attested content of the section. Structured entries support computer processing and computation and are not a replacement for the attestable, human-readable content of the CDA narrative block. The special case of structured entries with an entry relationship of "DRIV" (is derived from) indicates to the receiving application that the source of the narrative block is the structured entries, and that the narrative is wholly derived from the structured entries.

As for all CDA documents—even when a report consisting entirely of structured entries is transformed into CDA—the encoding application must ensure that the authenticated content (narrative plus multimedia) is a faithful and complete rendering of the clinical content of the structured source data. As a general guideline, a generated narrative block should include the same human readable content that would be available to users viewing that content in the originating system. Although content formatting in the narrative block need not be identical to that in the originating system, the narrative block should use elements from the CDA narrative block schema to provide sufficient formatting to support human readability when rendered according to the rules defined in Section Narrative Block (§ 4.3.5 ) of the CDA R2 specification.

By definition, a receiving application cannot assume that all clinical content in a section (i.e., in the narrative block and multimedia) is contained in the structured entries unless the entries in the section have an entry relationship of "DRIV".

Additional specification information for the CDA narrative block can be found in the CDA R2 specification in sections 1.2.1, 1.2.3, 1.3, 1.3.1, 1.3.2, 4.3.4.2, and 6.

* 1. QRDA Category III Measure Section

[section: templateId QRDACATIII-TEMP-OID-MEASURE-SECTION (open)]

Table 2: QRDA Category III Measure Section Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [QRDA Category III Report](#D_QRDA_Category_III_Report) (required) | [Numerator](#E_Numerator) |

Notes: Copied from QRDA Cat I measure section and then changed. May change to conform to that, or just to align closely with it.

1. SHALL contain exactly one [1..1] templateId (CONF:17284).
   1. This templateId SHALL contain exactly one [1..1] @root="QRDACATIII-TEMP-OID-MEASURE-SECTION" (CONF:17285).
2. SHALL contain exactly one [1..1] id (CONF:17286).
   1. This id SHALL contain exactly one [1..1] @root (CONF:17287).
3. SHALL contain exactly one [1..1] code="55186-1" Measure Document (CodeSystem: LOINC 2.16.840.1.113883.6.1 STATIC) (CONF:17288).
4. SHALL contain exactly one [1..1] title="Measure Section" (CONF:17289).
5. SHALL contain at least one [1..\*] entry (CONF:17290).
   1. Such entries SHALL contain exactly one [1..1] @typeCode="DRIV" is derived from (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:17291).
   2. Such entries SHALL contain exactly one [1..1] organizer (CONF:17624).
      1. This organizer SHALL contain exactly one [1..1] @classCode="CLUSTER" (CONF:17625).
      2. This organizer SHALL contain exactly one [1..1] @moodCode="EVN" (CONF:17626).
      3. This organizer SHALL contain exactly one [1..1] statusCode="completed" (CONF:17627).
      4. This organizer SHALL contain exactly one [1..1] reference (CONF:17628).
         1. This reference SHALL contain exactly one [1..1] @typeCode="REFR" (CONF:17629).
         2. This reference SHALL contain exactly one [1..1] externalDocument="DOC" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:17630).
            1. This externalDocument SHALL contain exactly one [1..1] id (CONF:17631).

This id SHALL contain exactly one [1..1] @root (CONF:17632).

This ID references the ID of the Quality Measure (CONF:17633).

* + - * 1. This externalDocument SHOULD contain zero or one [0..1] text (CONF:17634).

This text is the title of the eMeasure (Quality Measure) (CONF:17635).

* + 1. This organizer SHALL contain at least one [1..\*] component (CONF:17636) such that it
       1. SHALL contain exactly one [1..1] [Numerator](#E_Numerator) (templateId:QRDACATIII-TEMP-OID-NUMERATOR) (CONF:17637).
  1. Reporting Parameters Section

[section: templateId 2.16.840.1.113883.10.20.17.2.1 (open)]

Table 3: Reporting Parameters Section Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [QRDA Category III Report](#D_QRDA_Category_III_Report) (required) | [Reporting Parameters Act](#E_Reporting_Parameters_Act) |

The Reporting Parameters Section provides information about the reporting time interval, and may contain other information that provides context for the patient data being reported. The receiving organization may tell the reporting institution what information they want in this section.

1. SHALL contain exactly one [1..1] templateId (CONF:14611) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.17.2.1" (CONF:14612).
2. SHALL contain exactly one [1..1] code="55187-9" Reporting Parameters with @xsi:type="CD" (CodeSystem: LOINC 2.16.840.1.113883.6.1 STATIC) (CONF:4141).
3. SHALL contain exactly one [1..1] title="Reporting Parameters" (CONF:4142).
4. SHALL contain exactly one [1..1] text (CONF:4143).
5. SHALL contain exactly one [1..1] entry (CONF:3277) such that it
   1. SHALL contain exactly one [1..1] @typeCode="DRIV" Is derived from (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:3278).
   2. SHALL contain exactly one [1..1] [Reporting Parameters Act](#E_Reporting_Parameters_Act) (templateId:2.16.840.1.113883.10.20.17.3.8) (CONF:17496).

# Other Templates

* 1. Count

[observation: templateId QRDACATIII-TEMP-OID-COUNT (open)]

Table 4: Count Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Ethnicity Stratifier](#E_Ethnicity_Stratifier) (required)  [Numerator](#E_Numerator) (required) |  |

This template is used for the count in measures involving integer counts of patients, such as numerator, denominator, and denominator exclusions.

1. SHALL contain exactly one [1..1] @classCode="OBS" (CONF:17563).
2. SHALL contain exactly one [1..1] @moodCode="EVN" (CONF:17564).
3. SHALL contain exactly one [1..1] templateId="QRDACATIII-TEMP-OID-COUNT" (CONF:17565).
4. SHALL contain exactly one [1..1] code (CONF:17566).
5. SHALL contain exactly one [1..1] value with @xsi:type="INT" (CONF:17567).
   1. This value SHALL contain exactly one [1..1] @value (CONF:17568).
   2. Ethnicity Stratifier

[observation: templateId QRDACATIII-TEMP-OID-ETH-STRAT (open)]

Table 5: Ethnicity Stratifier Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Numerator](#E_Numerator) (optional) | [Count](#E_Count) |

1. SHALL contain exactly one [1..1] @classCode="OBS" (CONF:17575).
2. SHALL contain exactly one [1..1] @moodCode="EVN" (CONF:17576).
3. SHALL contain exactly one [1..1] code (CONF:17577).
   1. This code SHALL contain exactly one [1..1] @code="ASSERTION" (CodeSystem: ActCode 2.16.840.1.113883.5.4) (CONF:17578).
4. SHALL contain exactly one [1..1] statusCode="completed" (CONF:17579).
5. SHALL contain exactly one [1..1] value with @xsi:type="CD", where the @code SHALL be selected from ValueSet Ethnicity group 2.16.840.1.114222.4.11.837 (CONF:17580).
6. SHALL contain exactly one [1..1] entryRelationship (CONF:17581).
   1. This entryRelationship SHALL contain exactly one [1..1] @typeCode="SUBJ" (CONF:17582).
   2. This entryRelationship SHALL contain exactly one [1..1] @inversionInd="true" (CONF:17583).
   3. This entryRelationship SHALL contain exactly one [1..1] [Count](#E_Count) (templateId:QRDACATIII-TEMP-OID-COUNT) (CONF:17584).
   4. Numerator

[observation: templateId QRDACATIII-TEMP-OID-NUMERATOR (open)]

Table 6: Numerator Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [QRDA Category III Measure Section](#S_QRDA_Category_III_Measure_Section) (required) | [Count](#E_Count)  [Ethnicity Stratifier](#E_Ethnicity_Stratifier) |

Notes: can use the same pattern for denominator, or is there a better way to do this?

1. SHALL contain exactly one [1..1] @classCode="OBS" (CONF:17615).
2. SHALL contain exactly one [1..1] @moodCode="EVN" (CONF:17616).
3. SHALL contain exactly one [1..1] code="ASSERTION" (CodeSystem: ActCode 2.16.840.1.113883.5.4) (CONF:17617).
4. SHALL contain exactly one [1..1] value="NUMER" included in numerator population with @xsi:type="CD" (CodeSystem: ObservationValue 2.16.840.1.113883.5.1063) (CONF:17618).
5. SHALL contain at least one [1..\*] entryRelationship (CONF:17619) such that it
   1. SHALL contain exactly one [1..1] [Count](#E_Count) (templateId:QRDACATIII-TEMP-OID-COUNT) (CONF:17620).
6. MAY contain zero or one [0..1] entryRelationship (CONF:17621) such that it
   1. SHALL contain exactly one [1..1] [Ethnicity Stratifier](#E_Ethnicity_Stratifier) (templateId:QRDACATIII-TEMP-OID-ETH-STRAT) (CONF:17622).
   2. Reporting Parameters Act

[act: templateId 2.16.840.1.113883.10.20.17.3.8 (open)]

Table 7: Reporting Parameters Act Contexts

| Used By: | Contains Entries: |
| --- | --- |
| [Reporting Parameters Section](#S_Reporting_Parameters_Section) (required) |  |

The reporting parameters act provides information about the reporting time interval, and helps provide context for the patient data being reported to the receiving organization. The receiving organization may tell the reporting hospitals what information to include, such as dates representing the quarters of the year for which patient data is desired.

1. SHALL contain exactly one [1..1] @classCode="ACT" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC) (CONF:3269).
2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC) (CONF:3270).
3. SHALL contain exactly one [1..1] code="252116004" Observation Parameters with @xsi:type="CD" (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96 STATIC) (CONF:3272).
4. SHALL contain exactly one [1..1] effectiveTime (CONF:3273).
   1. This effectiveTime SHALL contain exactly one [1..1] low (CONF:3274).
   2. This effectiveTime SHALL contain exactly one [1..1] high (CONF:3275).

# References

* CDC, *Epidemiology and Prevention of Vaccine-Preventable Diseases (The Pink Book), Appendix D: Vaccine Administration Guidelines.* <http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/D/vacc_admin.pdf>
* *eMeasure Health Quality Measure Format, Release 1*. HL7 Version 3 September 2009 Ballot Site. <http://archive.hl7.org/v3ballotarchive/v3ballot2009sep/html/welcome/environment/index.htm>
* *Extensible Markup Language (XML) 1.0* (Fifth Edition), W3C Recommendation, 26 November 2008. <http://www.w3.org/TR/2008/REC-xml-20081126/#sec-mixed-content>
* *HL7 Clinical Document Architecture (CDA Release 2)*. <http://www.hl7.org/implement/standards/cda.cfm>
* *HL7 Clinical Document Architecture, Release 2* (April 21, 2005). <http://www.hl7.org/v3ballot/html/infrastructure/cda/cda.htm>
* *HL7 Implementation Guide for CDA Release 2.0, Consolidated CDA Templates*. December 2011. <http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258>
* *HL7 Implementation Guide for CDA Release 2.0, Quality Reporting Document Architecture (QRDA)*. March 2009. <http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35>
* *HL7 Implementation Guide: CDA Release 2 - Continuity of Care Document CCD* April 1, 2007. <http://www.hl7.org/implement/standards/product_brief.cfm?product_id=6>
* *Refinement, Constraint and Localization, Release 2* <http://www.hl7.org/v3ballotarchive_temp_B4AB52A9-1C23-BA17-0CEFB898BD964052/v3ballot2012may/html/infrastructure/conformance/conformance.html> (must be an HL7 member)
* *HL7 Version 3 Interoperability Standards,* Normative Edition 2010. [http://www.hl7.org/memonly/downloads/v3edition.cfm](http://www.hl7.org/memonly/downloads/v3edition.cfm#V32010) (must be an HL7 member)
* *HL7 Version 3 Publishing Facilitator's Guide* <http://www.hl7.org/v3ballot/html/help/pfg/pfg.htm>
* HL7 Version 3 Standard: Refinement, Constraint and Localization, Release 2. <http://www.hl7.org/v3ballot/html/infrastructure/conformance/conformance.htm>
* Institute of Medicine of the National Academies, “Crossing the quality chasm: the IOM health care quality initiative,” announcement, July 5, 2011. [http://www.iom.edu/Global/News Announcements/Crossing-the-Quality-Chasm-The-IOM-Health-Care-Quality-Initiative.aspx](http://www.iom.edu/Global/News%20Announcements/Crossing-the-Quality-Chasm-The-IOM-Health-Care-Quality-Initiative.aspx) (accessed April 2012).
* *National Quality Forum,* Quality Data Model. <http://www.qualityforum.org/QualityDataModel.aspx>
* *XML Path Language (XPath) Version 1.0.* <http://www.w3.org/TR/xpath/>

1. Acronyms and Abbreviations

AHIMA American Health Information Management Association

AMA American Medical Association

CCD Continuity of Care Document

CDA Clinical Document Architecture

CDA R2 CDA Release 2

CDC Centers for Disease Control and Prevention

CHCA The Child Health Corporation of America

CMS Centers for Medicare and Medicaid Services

DSTU Draft Standard for Trial Use

EHR Electronic Health Record

HL7 Health Level Seven

IG Implementation Guide

IHE Integrating the Healthcare Enterprise

IHTSDO International Health Terminology Standard Development Organisation

IOM Institute of Medicine

IPP Initial Patient Population

LOINC Logical Observation Identifiers Names and Codes

NCQA National Committee for Quality Assurance

NHIN Nationwide Health Information Network

NHSN National Healthcare Safety Network

NQF National Quality Forum

OID Object identifier

PHIN VADS Public Health Information Network Vocabulary Access and Distribution System

QDM Quality Data Model

QRDA Quality Reporting Document Architecture

R2 Release 2

RIM Reference Information Model

SDWG Structured Documents Working Group

SNOMED CT Systematized Nomenclature of Medicine, Clinical Terms

Tdb Template Database

XML Extensible Mark-up Language

1. Template IDs Used in This Guide

This appendix lists all templateIds used in this guide in [alphabetical order](#T_Alpha_List_Of_TemplateIds) and in [containment order](#T_Template_Containment).

Table 9: List of Template IDs in This Guide

Table 9: Template Containment in This Guide

1. code systems in this guide

The following table lists all the code systems used in this guide.

Table : Code Systems in This Guide

| Code System Name | Code System OID |
| --- | --- |
| ActClass | 2.16.840.1.113883.5.6 |
| ActCode | 2.16.840.1.113883.5.4 |
| ActMood | 2.16.840.1.113883.5.1001 |
| ActPriority | 2.16.840.1.113883.5.7 |
| ActReason | 2.16.840.1.113883.5.8 |
| ActStatus | 2.16.840.1.113883.5.14 |
| AddressUse | 2.16.840.1.113883.5.1119 |
| Adminstrative Gender | 2.16.840.1.113883.5.1 |
| ASC X12 | 2.16.840.1.113883.6.255.1336 |
| Confidentiality Code | 2.16.840.1.113883.5.25 |
| CPT | 2.16.840.1.113883.6.12 |
| CVX | 2.16.840.1.113883.12.292 |
| DCM | 1.2.840.10008.2.16.4 |
| EntityNamePartQualifier | 2.16.840.1.113883.5.43 |
| EntityNameUse | 2.16.840.1.113883.5.45 |
| FIPS 5-2 (State) | 2.16.840.1.113883.6.92 |
| HealthcareServiceLocation | 2.16.840.1.113883.6.259 |
| ICD9 CM | 2.16.840.1.113883.6.2 |
| ICD9 CM Procedures | 2.16.840.1.113883.6.104 |
| ICD10 CM | 2.16.840.1.113883.6.90 |
| ICD10 PCS | 2.16.840.1.113883.6.4 |
| Internet Society Language | 2.16.840.1.113883.1.11.11526 |
| ISO 3166-1 Country Codes | 1.0.3166.1 |
| LanguageAbilityMode | 2.16.840.1.113883.5.60 |
| LanguageAbilityProficiency | 2.16.840.1.113883.5.61 |
| LOINC | 2.16.840.1.113883.6.1 |
| MaritalStatus | 2.16.840.1.113883.5.2 |
| National Cancer Institute (NCI) Thesaurus | 2.16.840.1.113883.3.26.1.1 |
| NDF-RT | 2.16.840.1.113883.3.26.1.5 |
| NUCC Health Care Provider Taxonomy | 2.16.840.1.113883.6.101 |
| ObservationInterpretation | 2.16.840.1.113883.5.83 |
| ParticipationFunction | 2.16.840.1.113883.5.88 |
| Participationsignature | 2.16.840.1.113883.5.89 |
| Public Health Data Standards Consortium Source of Payment Typology | 2.16.840.1.113883.3.221.5 |
| Race and Ethnicity - CDC | 2.16.840.1.113883.6.238 |
| Religious Affiliation | 2.16.840.1.113883.5.1076 |
| RoleClass | 2.16.840.1.113883.5.110 |
| RoleCode | 2.16.840.1.113883.5.111 |
| RXNorm | 2.16.840.1.113883.6.88 |
| SNOMED CT | 2.16.840.1.113883.6.96 |
| Unified Code for Units of Measure (UCUM) | 2.16.840.1.113883.6.8 |
| Unique Ingredient Identifier (UNII) | 2.16.840.1.113883.4.9 |
| US Postal Codes | 2.16.840.1.113883.6.231 |
| Vaccines administered (CVX) | 2.16.840.1.113883.12.292 |

1. QRDA Category III Report Draft

This appendix includes the Category III Calculated Report from the QRDA DSTU, release 1, published in March 2009.

Header Constraints

This section describes constraints that apply to the QRDA Category III report Header.

Header Attributes

ClinicalDocument/realmCode

1. The realmCode element shall be present where the value of @code is US.

Figure : realmCode Category III example

<realmCode code="US"/>

ClinicalDocument/typeID

1. The value of typeID/@root shall be 2.16.840.1.113883.1.3 and value of typeID/@extension shall be POCD\_HD000040.

ClinicalDocument/templateId

This ClinicalDocument/templateId element identifies the template that defines constraints on the content of a QRDA Category III document.

1. A QRDA Category III report shall contain at least one ClinicalDocument/templateId element.
2. The value of one ClinicalDocument/templateId/@root shall be 2.16.840.1.113883.10.20.14 representing conformance to the generic QRDA Category III framework constraints.

Figure : ClinicalDocument/templateId Category III example

<templateId root= "2.16.840.1.113883.10.20.14"/> <!-- conforms to the DSTU -->

ClinicalDocument/code

1. A QRDA Category III report shall contain exactly one ClinicalDocument/code with a value of 55184-6 2.16.840.1.113883.6.1 LOINC static.

ClinicalDocument/title

1. A QRDA Category III report shall contain exactly one ClinicalDocument/title element valued with a case-insensitive, text string containing “QRDA Calculated Summary Report.”

Participants

This section describes the participants in the QRDA Category III report.

Author

The author may be a device (e.g., data aggregation software), a person (e.g., a quality manager), or an organization (e.g., a processing entity).

1. A QRDA Category III shall contain one or more ClinicalDocument/author/assignedAuthor/assignedPerson and/or ClinicalDocument/author/assignedAuthor/representedOrganization and/or ClinicalDocument/author/assignedAuthor/authoringDevice.

The example shows how a processing entity can be represented as the author.

Figure : AssignedAuthor as a processing entity Category III example

<author>

<time value="20080513"/>

<assignedAuthor>

<id nullFlavor="NA"/>

<representedOrganization>

<id root="2.16.840.1.113883.19.598"/>

<name>Good Health Processing Entity</name>

</representedOrganization>

</assignedAuthor>

</author>

Custodian

The custodian is the organization that is responsible for maintaining the QRDA Category II report. The custodian is not necessarily the reporting entity, as there may be workflows where the processing entity itself assumes custodianship.

1. A QRDA Category III report shall contain exactly one custodian/assignedCustodian/representedCustodianOrganization/  
   id element.
2. The value of custodian/assignedCustodian/  
   representedCustodianOrganization/id element @root shall be the id root of the custodian.

Figure : Custodian Category III example

<custodian>

<assignedCustodian>

<representedCustodianOrganization>

<id root="2.16.840.1.113883.19.5"/>

<name>Good Health Clinic</name>

</representedCustodianOrganization>

</assignedCustodian>

</custodian>

legalAuthenticator

A legal authenticator is a verifier who officially authenticates the accuracy of the document. An example would be the health care organization that compiles the quality report. A legalAuthenticator is required, but the value will vary depending on the workflow or rules of the organization.

1. A QRDA Category III report shall contain exactly one legalAuthenticator element.
2. A QRDA Category III report legalAuthenticator shall contain exactly one ClinicalDocument/legalAuthenticator/time element.
3. A QRDA Category III report shall contain exactly one signatureCode element.
4. The value of a QRDA ClinicalDocument/signatureCode/@code shall be S.
5. A QRDA Category III report shall contain exactly one assignedEntity element the represents the legalAuthenticator of the document.
6. The ClinicalDocument/assigned entity shall contain an id element.

Figure : legalAuthenticator Category III example

<legalAuthenticator>

<time value="20080513"/>

<signatureCode code="S"/>

<assignedEntity>

<id nullFlavor="NA"/>

<representedOrganization>

<id root="2.16.840.1.113883.19.5"/>

<name>Good Health Clinic</name>

</representedOrganization>

</assignedEntity>

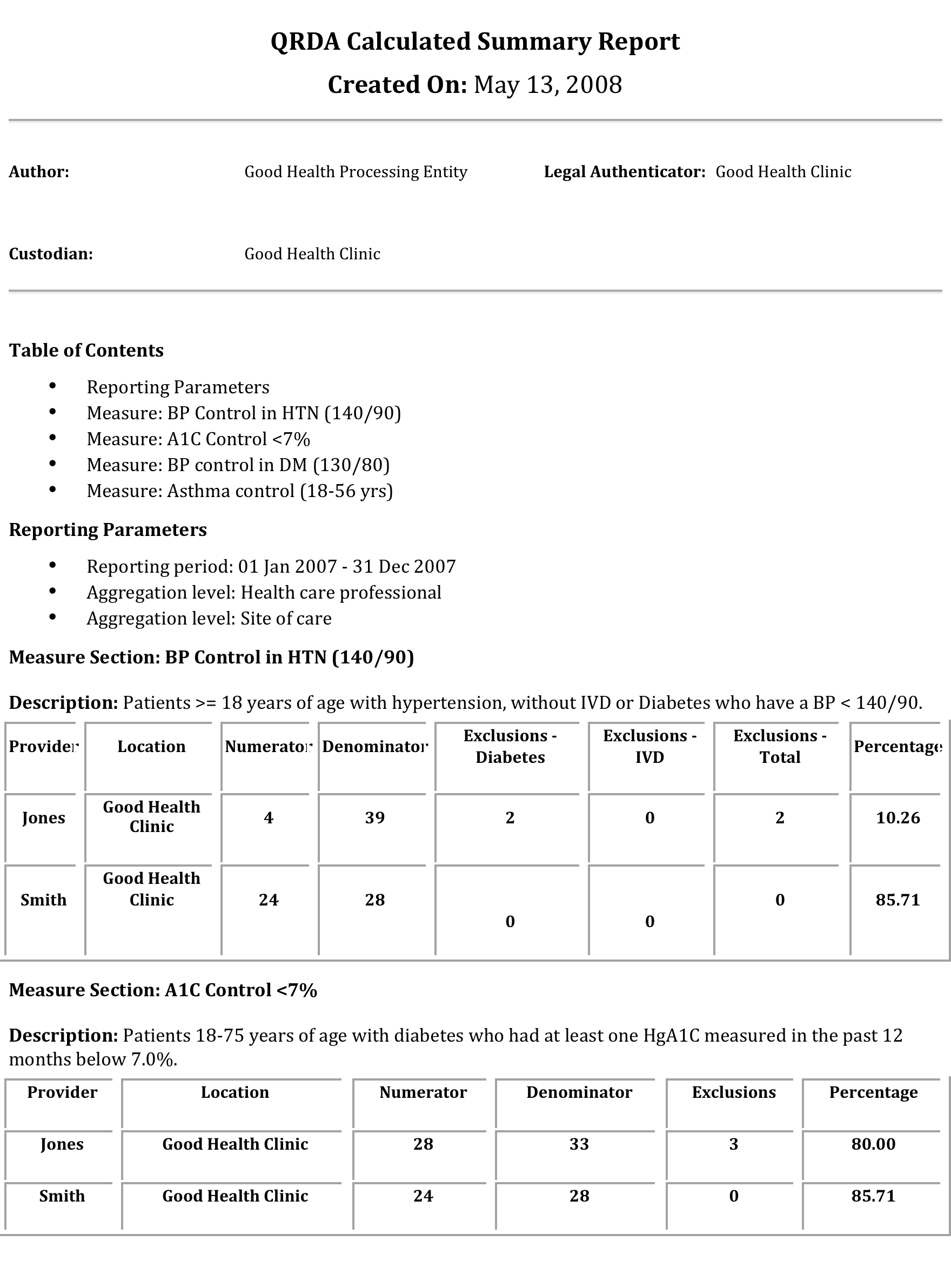
</legalAuthenticator>

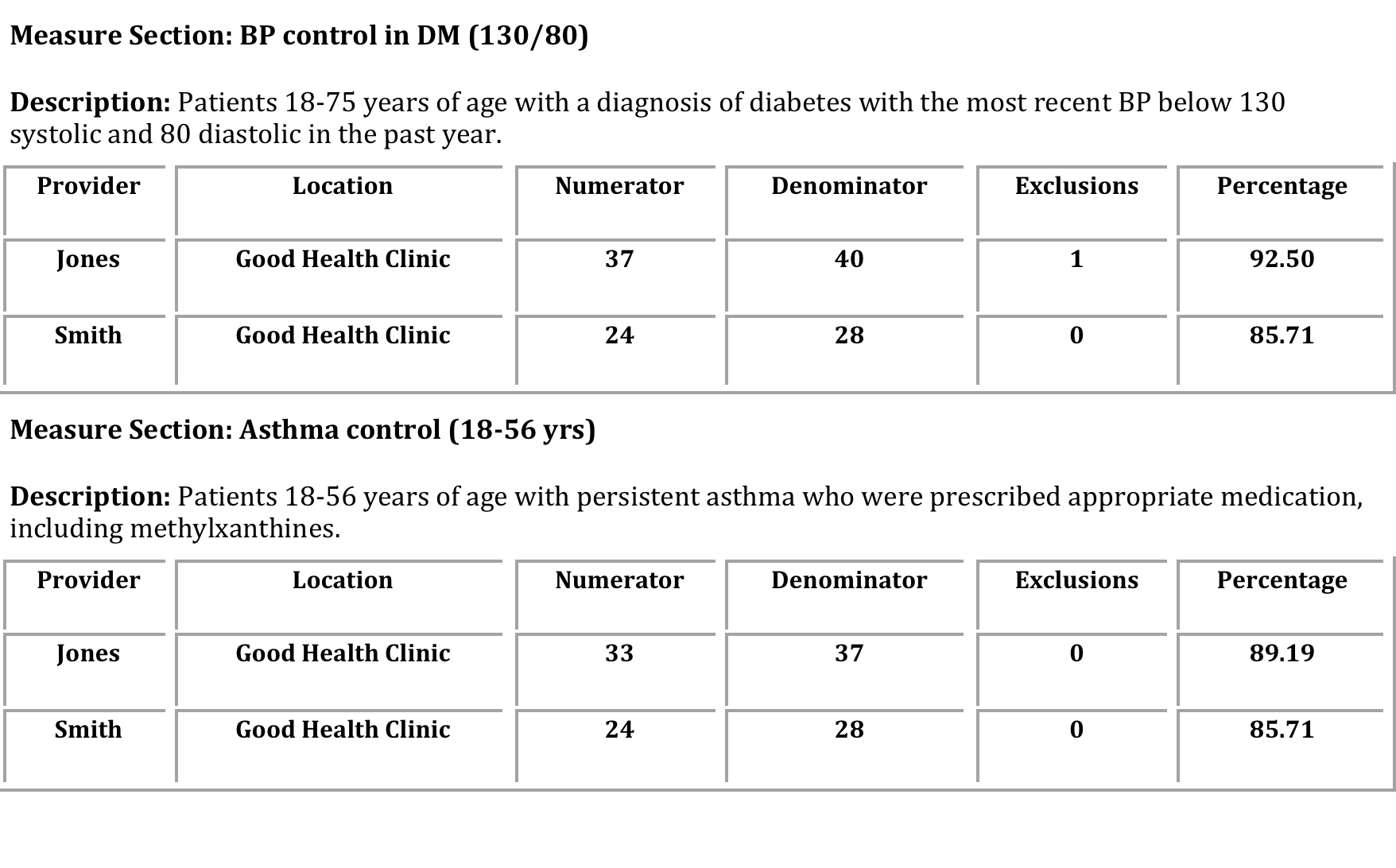
Body Constraints

A QRDA Category III report requires a structuredBody. The report will typically contain several sections and subsections. The top-level sections may be either Measure sections, where each section is reporting quality data defined by a single measure; or they may be Measure Set sections, where each section contains one or more Measure sections; or they may be both. There will also be a single top-level Reporting Parameters section. This is illustrated above in the figure [Category II/III use of Measure Set and Measure sections](#F_CategoryII_III_use_of_Measure_Set_and).The [Sample Category III QRDA Calculated Summary Report](#F_Sample_CategoryIII_QRDA_Calculated_Sum) figure shows an example of a QRDA Category III report.

1. A QRDA Category III report shall contain exactly one ClinicalDocument/component/structuredBody.
2. A QRDA Category III report shall contain at least one and may contain more than one Measure Set section containing information about the measure set.
3. A QRDA Category III report shall contain at least one and may contain more than one Measure section, each containing information about a single measure.
4. A QRDA Category III report shall contain exactly one Reporting Parameters section.

Figure : Sample Category III QRDA Calculated Summary Report





Section Constraints

This section describes constraints that apply to the QRDA Category III report sections. A section is required for each measure being reported.

Reporting Parameters Section

The Reporting Parameters section provides information about the reporting time interval and may contain other information that helps provide context for the patient data being reported.

1. The Reporting Parameters section shall contain a section/code element.
2. The value for section/code shall be 55187-9 Reporting Parameters 2.16.840.1.113883.6.1 LOINC static.
3. The Reporting Parameters section shall be valued with section/title with a case-insensitive, text string containing "Reporting Parameters".
4. The Reporting Parameters section shall contain exactly one Observation Parameters Act.
5. The value for act/@classCode in an Observation Parameters Act shall be ACT 2.16.840.1.113883.5.6 ActClass static.
6. The value for act/@moodCode in an Observation Parameters Act shall be EVN 2.16.840.1.113883.5.1001 ActMood static.
7. The reporting time period in a Reporting Period Act shall be represented with an effectiveTime/low element combined with a high element representing respectively the first and last days of the period reported.

Figure : Reporting parameters section Category III example

<section>

<code code="55187-9"

codeSystem="2.16.840.1.113883.6.1"

codeSystemName="LOINC"/>

<title>Reporting Parameters</title>

<text>

<list>

<item>Reporting period: 01 Jan 2007 - 31 Dec 2007</item>

<item>Aggregation level: Healthcare professional</item>

<item>Aggregation level: Site of care</item>

</list>

</text>

<entry>

<act classCode="ACT" moodCode="EVN">

<id root="55a43e20-6463-46eb-81c3-9a3a1ad41225"/>

<code code="252116004"

codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED CT"

displayName="Observation Parameters"/>

<effectiveTime>

<low value="20070101"/>

<high value="20071231"/>

</effectiveTime>

<entryRelationship typeCode="COMP">

<observation classCode="OBS" moodCode="EVN">

<code nullFlavor="OTH"><originalText>Aggregation

level</originalText></code>

<value xsi:type="CD" code="223366009"

codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED CT"

displayName="Healthcare professional"/>

</observation>

</entryRelationship>

<entryRelationship typeCode="COMP">

<observation classCode="OBS" moodCode="EVN">

<code nullFlavor="OTH"><originalText>Aggregation

level</originalText></code>

<value xsi:type="CD"

code="43741000"

codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED CT"

displayName="Site of care"/>

</observation>

</entryRelationship>

</act>

</entry>

</section>

Measure Section

Each QRDA Category III Measure section corresponds to one measure and contains a measure identifier, along with aggregate data elements and measure-specific grouping data elements.

An aggregate data element is a measure-specified calculated summary derived from patient data elements. Examples include: the number of patients meeting a measure’s numerator criteria, the number of patients meeting a measure’s denominator criteria, and the number of patients excluded due to weight criteria.

A measure-specific grouping data element defines a subgroup population criterion. These data elements define how patient data elements are to be cumulated into aggregate data elements. Examples include:

* a measure-specific grouping data element of “primary surgeon” indicates that the primary surgeon of an individual’s operative procedure be captured in the QRDA Category I report, and that aggregate data elements in a QRDA Category III report are to be calculated per each primary surgeon;
* a measure-specific grouping data element of “outborn” indicates that the infant in a neonatal population was not born at the reporting hospital and will be cohorted into an “outborn” group in the QRDA Category III report.

In the [Sample Category II QRDA Calculated Summary Report](#F_Sample_CategoryIII_QRDA_Calculated_Sum) figure, aggregate data elements are “Numerator”, “Denominator”, “Exclusions”, and “Percentage”; and measure-specific grouping data elements are “Provider” and “Location”.

1. Each Measure section shall contain a templateId uniquely identifying the Measure name and version
2. Each Measure section shall contain a section/code element.
3. The value for section/code shall be 55186-1 Measure 2.16.840.1.113883.6.1 LOINC static.
4. Each Measure section shall be valued with section/title with a case-insensitive, text string containing "measure section: <measure name>".
5. The Measure Section may contain a section/text element for the description of the measure.

Representation of the Measure Data Elements

Representation of a measure act within a Measure section will identify the constraints for each measure act. The measure act will contain participant elements if the specific measures require aggregation or grouping in specific ways such as by provider or location.

A key point is that a measure defines its aggregate data elements, and the purpose of the qualification in a QRDA Category II report is to assert whether or not a patient is to be counted in the corresponding aggregate. For instance, the HEDIS “Treat Adults w/Acute Bronchitis” defines the following aggregate data elements:

* Eligible population by ER/urgent care visits
* Eligible population by non-ER/urgent care visits
* Exclusions for comorbid conditions
* Exclusions for completing diagnosis
* Exclusions for Medication History
* Numerator by ER/urgent care visits
* Numerator by non-ER/urgent care visits
* etc.

For each of these elements, the QRDA Category II report will say whether or not the patient qualified, whereas the QRDA Category III report will show the total number of patients that qualified.

Each QRDA Category III Measure section contains an outer act in event mood for each unique combination of measure-specific grouping data elements. This outer act has act/id to uniquely identify the act, act/code corresponding to the measure, and act/text where optionally one can give a description of the measure.

1. Measure data, whether aggregate data elements or measure-specific grouping data elements, shall be represented with clinical statements.
2. Measure data using SNOMED shall be represented per the “Using SNOMED CT® in HL7 Version 3” DSTU.
3. Measure data should use CCD and other CDA IG templates where possible.
4. A QRDA Category III report Measure section shall contain a Measure Event Act in event mood for each unique combination of measure-specific grouping data elements.
5. A Measure Event Act shall contain exactly one act/code to encode the particular measure.
6. A Measure Event Act shall represent a measure-specific grouping data element of a performing provider with act/performer [@typeCode="PRF"] representing the provider associated with the patients whose measure data is being reported.

Figure : Act/performer Category III example representing a provider with which to group data

<performer>

<assignedEntity>

<id extension="00017" root="2.16.840.1.113883.19.5"/>

<assignedPerson>

<name>

<given>Robert</given>

<family>Jones</family>

<suffix>MD</suffix>

</name>

</assignedPerson>

</assignedEntity>

</performer>

1. A Measure Event Act shall represent a measure-specific grouping data element of encounter location with the CCD Location Participation (2.16.840.1.113883.10.20.1.45).

Figure : Location Category III example representing a clinic with which to group data

<participant typeCode="LOC">

<templateId root="2.16.840.1.113883.5.90"/>

<participantRole classCode="SDLOC">

<playingEntity classCode="PLC">

<name>Good Health Clinic</name>

</playingEntity>

</participantRole>

</participant>

1. Aggregation data elements and measure-specific grouping data elements shall be components within a Measure Event Act.
2. entryRelationships shall be used to link aggregation data elements and measure-specific grouping data elements with the corresponding Reporting Parameter section.

Figure : entryRelationship Category III example referring to the reporting parameters

<entryRelationship typeCode="REFR">

<act classCode="ACT" moodCode="EVN">

<id root="55a43e20-6463-46eb-81c3-9a3a1ad41225"/>

<code code="252116004"

codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED CT"

displayName="Observation Parameters"/>

</act>

</entryRelationship>

In the QRDA Category III Measure section, aggregate data elements such as numerator, denominator, or exclusion are modeled as observations. The example shows the use of a local code. Standard codes, such as SNOMED, for these commonly used terms in quality reporting, would be preferred, but will have to be requested.

1. An aggregate data element shall be represented with Observation.
2. The value for observation/@moodCode in an aggregate data element shall be EVN 2.16.840.1.113883.5.1001 ActMood static.
3. An aggregate data element should contain at least one observation/id.
4. An aggregate data element shall contain exactly one observation/statusCode.
5. The value of observation/statusCode shall be Completed.

Figure : entryRelationship Category III observation of an integer value as a numerator example

<entryRelationship typeCode="COMP">

<observation classCode="OBS" moodCode="EVN">

<id root="b61afff0-1654-4122-aa1d-7113d3b26c3a"/>

<code code="NUM"

codeSystem="TCNYcodeSystemOID"

displayName="Numerator"/>

<statusCode code="completed"/>

<value xsi:type="INT" value="4"/>

</observation>

</entryRelationship>

1. [http://www.iom.edu/Global/News Announcements/Crossing-the-Quality-Chasm-The-IOM-Health-Care-Quality-Initiative.aspx](http://www.iom.edu/Global/News%20Announcements/Crossing-the-Quality-Chasm-The-IOM-Health-Care-Quality-Initiative.aspx) [↑](#footnote-ref-1)
2. <http://www.hl7.org/v3ballot/html/infrastructure/conformance/conformance.htm> [↑](#footnote-ref-2)
3. *HL7 Implementation Guide: CDA Release 2 - Continuity of Care Document CCD* April 1, 2007. <http://www.hl7.org/implement/standards/product_brief.cfm?product_id=6> [↑](#footnote-ref-3)
4. <http://www.hl7.org/v3ballot/html/infrastructure/conformance/conformance.htm> [↑](#footnote-ref-4)
5. *HL7 Clinical Document Architecture (CDA Release 2).* <http://www.hl7.org/implement/standards/cda.cfm> [↑](#footnote-ref-5)
6. Publishing Facilitator's Guide. <http://www.hl7.org/v3ballot/html/help/pfg/pfg.htm> [↑](#footnote-ref-6)
7. <http://www.hl7.org/memonly/downloads/v3edition.cfm#V32010> (must be a member to view) [↑](#footnote-ref-7)
8. <http://www.hl7.org/v3ballotarchive_temp_B1459CB3-1C23-BA17-0CDABC2572844D45/v3ballot2012may/html/welcome/environment/index.html> > Foundation > Data Types: abstract R2 9must be a member to view) [↑](#footnote-ref-8)
9. *HL7 Clinical Document Architecture (CDA Release 2).* <http://www.hl7.org/implement/standards/cda.cfm> [↑](#footnote-ref-9)
10. *HL7 Clinical Document Architecture (CDA Release 2)*. http://www.hl7.org/implement/standards/cda.cfm [↑](#footnote-ref-10)
11. *XML Path Language (XPath) Version 1.0.* <http://www.w3.org/TR/xpath/> [↑](#footnote-ref-11)
12. HL7 Clinical Document Architecture, Release 2 (April 21, 2005). <http://www.hl7.org/v3ballot/html/infrastructure/cda/cda.htm> [↑](#footnote-ref-12)