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Data Submission Specifications Utilizing HL7 QRDA Implementation Guide Based on HL7 CDA Release 2.0

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09/23/09	Kathy Kain	Further updates to name elements. See Release Notes for complete details.	1.3

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Introduction

1.1 Purpose

This document describes the EHR data submission required for reporting information for the CMS physician-focused EHR quality initiatives. The data consists primarily of patient observational data related to a physician's practice. From this information, EHR quality measures are computed.

The purpose of this Specification is to communicate the data requirements necessary for Electronic Health Record (EHR) vendors to incorporate into their applications. It is intended to serve as the roadmap for software vendors to use on behalf of physician offices submitting data into the CMS EHR Warehouse.

By leveraging the HL7 Quality Reporting Document Architecture (QRDA) standard, the CMS EHR Warehouse becomes another ancillary system to which health care systems can submit information in a standard format. In order to transmit data into the CMS EHR Warehouse, the EHR system must transmit data pursuant to the Health Level Seven (HL7) QRDA standard.

The Consolidated Health Informatics (CHI) is fostering the adoption of federal health information interoperability standards for health data segments. For example, vocabulary that includes specific health data models and communication standards; alignment with HIPAA administration transaction records and code sets; and data registry functionality are objectives that CHI hopes to achieve. This Specification requires the use of a standard coding system(s) to identify diagnoses, medical exclusions, vital signs, drug history, observations, and lab test results. Standard coding systems such as ICD-9, CPT4, NDC, LOINC and SNOMED will be used for recording patient activities.

1.2 Conceptual Approach

1.2.1 Background

The CMS EHR Warehouse will accept clinical documents originating from EHR systems. Upon transmission of data to the warehouse, the messages will be validated per the edit requirements and inserted into the CMS EHR Warehouse. Subsequently, the CMS EHR Warehouse will evaluate the clinical documents to determine if the measurement criteria have been satisfied for a given patient. If this occurs, the CMS EHR Warehouse will process the clinical documents and calculate measurements in accordance with the analytical specifications approved by CMS.

The EHR system must generate clinical documents for each patient according to the specifications. The physician office transfers the clinical documents to the CMS EHR Warehouse.

1.3 CMS EHR Warehouse Quality Measures

This list represents the CMS EHR measures. Additional measures may be adopted as deemed appropriate. The patient clinical documents will be used to determine if the patient has met the measurement criteria and the accompanying results. For applicable measures, refer Appendix_S-Measure_Codes tab of the Downloadable Resources table.

1.4 Standards

The use of standards, both clinical and systems integration is a prerequisite for data submission to the CMS EHR Warehouse. This Specification will adopt future standards as they evolve and are approved by CMS.

1.4.1   Logical Observation Identifier Names and Codes (LOINC®)

HL7 encoding makes extensive use of the code set, *Logical Observation Identifier Names and Codes (LOINC).* LOINC codes are available for commercial use without charge, subject to the terms of a license that assures the integrity and ownership of the codes. The LOINC database provides sets of universal names and ID codes for identifying laboratory and clinical observations and other units of information meaningful in cancer registry records.

Each LOINC record corresponds to a single observation. The LOINC codes are not intended to transmit all possible information about a test or observation. They are only intended to *identify* the observations. The LOINC code for a name is unique and permanent. LOINC codes must always be transmitted with a hyphen before the check digit (e.g., "10154-3"). The numeric code is transmitted as a variable length number, without leading zeros.

LOINC codes are copyrighted by Regenstrief Institute and the Logical Observation Identifier Names and Codes Consortium.

The LOINC database can be obtained from
Regenstrief Institute
1001 West 10th Street RG-5
Indianapolis, IN 46202
Telephone: (317) 630-7433

1.4.2   SNOMED Clinical Terms (SNOMED-CT®)

Systematized Nomenclature of Medicine Clinical Terms, or SNOMED CT. is a registered trademark of SNOMED International. SNOMED CT contains over 357,000 health care concepts with unique meanings and formal logic-based definitions organized into hierarchies. The fully populated table with unique descriptions for each concept contains more than 957,000 descriptions. Approximately 1.37 million semantic relationships exist to enable reliability and consistency of data retrieval.

SNOMED International maintains the SNOMED CT technical design, the core content architecture, and the SNOMED CT Core content. SNOMED CT Core content includes the technical Specification of SNOMED CT and fully integrated multi-specialty clinical content. The Core content includes the concepts table, description table, relationships table, history table, and ICD-9-CM mapping, and the Technical Reference Guide.
Each SNOMED record corresponds to a single observation. The SNOMED codes are not intended to transmit all possible information about an observation, or procedure. They are only intended to *identify* the observation or procedure. The SNOMED code for a name is unique and permanent.

SNOMED CT combines the content and structure of the SNOMED Reference Terminology (SNOMED RT) with the United Kingdom's Clinical Terms Version 3 (formerly known as the Read Codes). For information on obtaining the standard, contact:

SNOMED International
College of American Pathologists
325 Waukegan Rd
Northfield, IL 60093-2750
Telephone: (800) 323-4040, Ext 7700
http://www.snomed.org

1.4.3   Current Procedural Terminology, Fourth Edition (CPT4®)

CPT is a registered trademark of the American Medical Association for the Current Procedural Terminology, Fourth Edition (CPT4). The CPT4 is a listing of descriptive terms and identifying codes for reporting medical services and procedures performed by physicians. The purpose of the terminology is to provide a uniform language that will accurately describe medical, surgical, and diagnostic services, and will thereby provide an effective means for reliable nationwide communication among physicians, patients, and third parties.

Each CPT4 record corresponds to a single observation or diagnosis. The CPT4 codes are not intended to transmit all possible information about an observation, or diagnosis. They are only intended to *identify* the observation or diagnosis. The CPT4 code for a name is unique and permanent.

Current Procedural Terminology, Fourth Edition (CPT®) is copyrighted by the American Medical Association, Washington DC: Public Health Service, US Department of Health and Human Services. All Rights Reserved. CPT is a registered trademark of the American Medical Association. For questions regarding the use of CPT codes, contact the American Medical Association CPT Information and Education Services at (800) 634-6922 or via the web at http://www.ama-assn.org.

1.4.4   International Classification of Diseases, Ninth Revision, Clinical Modifications (CM)

The International Classification of Diseases, Ninth Revision, Clinical Modification ICD9 (CM) is based on the U.S. modification of the World Health Organization's Ninth Revision, International Classification of Diseases ICD9 (CM). ICD9 (CM) classifies morbidity data for indexing medical records, medical care review, ambulatory and other medical care programs, as well as for basic health statistics.

Each ICD9 (CM) record corresponds to a single diagnosis. The ICD9 (CM) codes are not intended to transmit all possible information about a diagnosis. They are only intended to *identify* the diagnosis. The ICD9 (CM) code for a name is unique and permanent.

For questions regarding ICD9 (CM) codes, contact the American Medical Association, International Classification of Diseases, Ninth Revision, Clinical Modification ICD9 (CM). Washington DC: Public Health Service, US Department of Health and Human Services. Copyright © Ingenix, Inc.

1.4.5   National Drug Code (NDC)

The NDC System was originally established as an essential part of an out-of-hospital drug reimbursement program under Medicare. The NDC serves as a universal product identifier for human drugs. The current edition of the National Drug Code Directory is limited to prescription drugs and a few selected OTC products.

The NDC codes are not intended to transmit all possible information about a pharmacy order. They are only intended to *identify* the drug or vaccination. The NDC code for a name is unique and permanent.

Each drug product listed under Section 510 of the Federal Food, Drug, and Cosmetic Act is assigned a unique 10-digit, 3-segment number. This number, known as the National Drug Code (NDC), identifies the labeler/vendor, product, and trade package size. The first segment, the labeler code, is assigned by the FDA. A labeler is any firm that manufactures, repacks or distributes a drug product. The second segment, the product code, identifies a specific strength, dosage form, and formulation for a particular firm. The third segment, the package code, identifies package sizes. Both the product and package codes are assigned by the firm.

Requests for more specific information should be submitted in writing or directed to FDA's Freedom of Information Staff at:
Food and Drug Administration
Freedom of Information Office, HFI-35
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 827-6500
FAX: (301) 443-1726

1.5 Definition of a Quality Measure and QRDA's Role

> "A quality measure is a mechanism that enables the user to quantify the quality of a selected aspect of care by comparing it to a criterion. A subtype of a quality measure is a clinical performance measure. Specifically, a clinical performance measure is a mechanism for assessing the degree to which a provider competently and safely delivers clinical services that are appropriate for the patient in the optimal time period."[1, 2]

Quality measures are used for three general purposes: quality improvement, accountability, and research.[3] Without the ability to accurately communicate the data in these measures to external agencies, the benefit of collecting the information is limited. QRDA's role is to standardize the representation of measure-defined data elements to enable interoperability between all of the stakeholder organizations.

1.5.1 Types of Quality Measure Reports

Three types of QRDA quality measure reports have been defined as described in the following sections.

1.5.1.1 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 or more quality measures, where the data elements in the report are defined by the particular

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[1] Center for Health Policy Studies, Harvard School of Public Health, Center for Quality of Care Research and Education. Understanding and choosing clinical performance measures for quality improvement: development of typology: final report. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 1995 Jan 31. Various pages.
[2] Lawthers AW, Palmer H. In search of a few good performance measures. In: Seltzer J, Nash DB, editors. Models for measuring quality in managed care: analysis and impact. New York (NY): Faulkner & Gray's Healthcare Information Center; 1997. p. 121-150. (Medical outcomes & practice guidelines library II).
[3] Obtained from AHRQ National Quality Measures Clearinghouse webpage:
http://www.qualitymeasures.ahrq.gov/resources/measure_use.aspx#reflist 1 August 2008

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.

Note: **CMS EHR Warehouse accepts only QRDA Category I reports.**

1.5.1.2 QRDA Category II – Multi-patient-level 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 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.

1.5.1.3 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.

Whereas a QRDA Category I and a QRDA Category II report contain data for individual patients, a QRDA Category III report only contains calculated data (e.g., number of meeting numerator criteria, number of meeting denominator criteria) on the population.

HITSP's Quality Implementation Specification (HITSP IS06) describes a "processing entity," which is an application role that collects QRDA Category I reports and generates QRDA Category II and QRDA Category III reports. From the perspective of a processing entity, all 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.

1.6 Approach

This Technical Specification uses Continuity Care Document (CCD) templates for collecting patient data as the CCD documents are well-known to the EHR vendors and there is an existing certification process by Certification Commission for Healthcare Information Technology (CCHIT) for generation and consumption of CCD documents by EHR systems. The usage of standard CCD templates would make the adoption of this Technical Specification by the EHR vendors relatively an easy task.

NOTE: Any additional CCD templates submitted beyond what is specified in this specification will not be validated or cause the file to reject.

1.6.1 Use of Templates

When valued in an instance, the template identifier signals the imposition of a set of template-defined constraints. The value of this attribute provides a unique identifier for the templates in question.

1.6.1.1 Originator Responsibilities

An originator can apply a templateId if there is a desire to assert conformance with a particular template.

In the most general forms of QRDA exchange, an originator need not apply a templateId for every template that an object in an instance document conforms to. When templateIds are required for conformance, it shall be asserted within the Technical Specification.

1.6.1.2 Recipient Responsibilities

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

A recipient may process clinical data in incoming QRDA files that do not contain a templateId (e.g., a recipient can process entries that contain Observation acts within a Problems section, even if the entries do not have templateIds).

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

1.6.2 Conventions Used in This Specification

This Specification is a conformance profile, as described in the Refinement and Localization section of the HL7 Version 3 standards. The base standards for this Specification are the QRDA and HL7 Clinical Document Architecture, Release 2.0. Though effort is made to describe all the aspects of applicable QRDA and CDA R2, every aspect of the QRDA and CDA R2 may not be described in this Specification.

1.6.2.1 Explanatory Statements

As an annotation profile, portions of this Specification summarize or explain the base standard. Some originate in the base Specification. Those requirements that do not add further constraints to the base standard and which can be validated through CDA.xsd do not have corresponding conformance statements.

Where no constraints are stated in this Specification, the report instances are subject to and are to be created in accordance with the QRDA and base CDA R2 Specification. Where, for instance, the CDA R2 Specification declares an attribute to be optional and this Specification contains no additional constraints that attribute remains optional for use.

1.6.2.2 Conformance Requirements

Conformance requirements for the EHR HL7 QRDA Technical Specification are numbered sequentially and are displayed as shown in the following example:

CONF-QRDA1-1: Conformance statement for the QRDA Category I framework.

1.6.2.3 Vocabulary Conformance

Measure-specific modeling and constraints should use and define the formalisms for value set constraints when applicable. In addition, when SNOMED codes are used in this text, the rules defined in "Using SNOMED CT in HL7 Version 3" should be adhered to.

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

Syntax for vocabulary binding to **DYNAMIC** or **STATIC** value sets is as follows:
The value for ("pathname of coded element") (**SHALL** | **SHOULD** | **MAY**) be selected from ValueSet valueSetOID localValueSetName **DYNAMIC** | **STATIC** (valueSetEffectiveDate).

CONF-ex1: The value for `"ClinicalDocument/code"` **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.10870 DocumentType **DYNAMIC**.

CONF-ex2: The value for `"ClinicalDocument/code"` **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.10870 DocumentType **STATIC** 20061017.

Syntax for vocabulary binding to a single code is as follows:
The value for (`"pathname of coded element"`) (**SHALL** | **SHOULD** | **MAY**) be `"code"`
[`"displayName"`] codeSystemOID [codeSystemName] **STATIC**.

CONF-ex3: The value for `"ClinicalDocument/code"` **SHALL** be `"34133-9"`
`"Summarization of episode note"` 2.16.840.1.113883.6.1 LOINC **STATIC**.

1.6.2.4 XPath Notation

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

1.6.2.5 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. The keyword "**SHALL**" implies a lower cardinality of 1 but does not disallow **NULL** values. If **NULL** values are to be excluded, it will be via additional explicit conformance statement.

Table 1 Keywords

To convey the sense of:	Use the following:	
Required/Mandatory	**SHALL**	**SHALL NOT**
Best Practice/Recommendation	**SHOULD**	**SHOULD NOT**
Acceptable/Permitted	**MAY**	**NEED NOT**

1.6.2.6 XML Examples

XML examples appear in various figures in this document in this 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.

Figure 1: ClinicalDocument Example

```
<ClinicalDocument mins='urn:h17-org:v3'>
    …
</ClinicalDocument>
```

Users requiring additional assistance in viewing examples, may contact the QualityNet Help Desk at 866-288-8912 or email at qnetsupport@sdps.org. Hours of operation are 7 am to 7 pm Central Time.

XPath expressions are used in the narrative and conformance requirements to identify elements because they are familiar to many XML implementers.

1.6.2.7 File Size Limitations

A CDA document is a defined and complete information object that can include text, images, sounds, and other multimedia content. This Specification does not expect the inclusion of multimedia content. To prevent inclusion of multimedia content, the CMS EHR QRDA report size **SHALL NOT** be more than 10 MB.

1.6.2.8 Use of Object Identifiers (OIDs)

The CMS EHR QRDA Report will use ISO object identifiers (OIDs) to uniquely specify the domain of a coded data value or an identifier for a person, organization, or other entity. OIDs are used in HL7 Clinical Documents to add global uniqueness to the various identifiers used within the document.

The identifier consists of two parts:

root: a globally unique identifier composed of an OID whose root is registered at HL7 or constructed based on US National Provider Identifier (NPI).

extension: The value of this attribute is the responsibility of the organization, system, and/or application where the document is created and stored.

Together, the root and extension, when concatenated, result in a universally unique string for identification of the document, person, or organization.

Restrictions on OIDs: An OID is an identifier in the form of a tree of nodes and arcs. Each arc is represented by an unbounded decimal number. OIDs are limited to no more than 64 characters. Although the digit sequences between the decimal points are unbounded, some implementations that deal with an OID data type use integers to represent each arc. The practical limit for an internal arc is $2^{31}-1$. HL7 treats OIDs as opaque identifiers. The only meaningful comparison between two OIDs is that of equivalence. If two OIDs match character for character, they are equivalent.

OID Usage Scenarios
The various kinds of identifiers appearing in QRDA documents are described in more detail below.

Documents
The first identifier encountered in a QRDA document is the one that explicitly identifies the document. There is only one of these identifiers in the document, and it uniquely identifies the specific document that contains it.

Patients
Several types of patient identifiers will likely need to be managed. First, organizationally assigned patient ids should have their own unique root OID that scopes them. Each type of id should have a separate OID.

In addition to organizationally assigned ids, it is likely that external ids for a person will also appear in QRDA documents (i.e. Social Security Number, driver's license numbers, etc.). For ids that already have OIDs, the existing ones should be utilized for interoperability. Otherwise an organizational OID should be created for each namespace to scope each type of id.

Personnel
In cases where the organization instead of some other authority assigns an identifier to non-patient personnel, the issues surrounding OID management for those persons (authors,

authenticators, informants, healthcare providers, and other document participants) are largely the same as for patients.

Locations
If facilities or locations will be listed in QRDA documents, then each facility should have a unique id. Each facility can be assigned its own unique OID, or an organization can create an OID for facility ids in general, and then assign unique extensions for each facility.

Devices and Systems
It will likely be very useful to assign OIDs to systems that span multiple locations. These OIDs will be usable directly when they are listed as authors of a QRDA document (/ClinicalDocument/author/id).

Encounters
OIDs should be created to scope any service event or encounter ids.

Orders
OIDs should be created to scope the different kinds of identifiers generated by an application for orders. Some applications generate a placer order number, others generate a filler order number, and yet others generate both, though usually not for the same order.

Sections
Sections within a QRDA document may be identified. An OID should be generated to identify the namespace of QRDA sections.

Entries
Entries within a QRDA document may also be identified.

Templates
Templates can also be identified. Each template has its own unique OID.

Obtaining an OID
Organizations that do not already have an OID may obtain a root OID from a number of different sources. These are described in further detail below. There is no requirement that an organization obtain the OIDs used in their QRDA documents from any particular source. However obtained, an OID owned by an organization should be registered with the HL7 registry to enable others to identify the organization as the owner. See Registering an OID with HL7 below.

From HL7
An OID can be obtained from HL7 by using the HL7 OID Registry found on the web at http://www.hl7.org/oid/index.cfm. When the organization obtains a new OID from HL7, it is automatically registered rather than requiring an additional step.

From a US National Provider Identifier (NPI)
For providers in the US that do not already have an OID from another source, an OID can be constructed from the National Provider Identifier assigned to an organization or individual provider by concatenating the assigned NPI to the string "HL7-NPI-AUTOMATIC-OID-ROOT" (Note: this value is currently a placeholder for a true OID that will be assigned by HL7) Thus, if a provider organization is assigned the NPI of 999999999, then their root OID could be "HL7-NPI-AUTOMATIC-OID-ROOT.999999999". The other OIDs needed in a QRDA document would then be created by adding additional arcs to this OID to create new root OIDs for the different kind of identifiers being used in the QRDA document.

Important: It should be noted that OIDs, once created, are simply strings, and are not bound in any way to an NPI that may have been used to create it. The sole purpose of this method is to make it easy to receive an OID. Once received, one should not treat it like an NPI in any way, or assume that an OID must change with an NPI. This is of particular importance when organizations split or merge. If the lack of a persistent binding between an NPI and an OID seems confusing, it may be more appropriate for an organization to obtain an OID from another source such as the HL7 OID registry, so that it is very clear that there is no link whatsoever.

Suggestions for Partitioning an OID for Use in an Organization
The following guidelines are for use by organizations that are new to OIDs and are looking for some guidance on OID implementation and management.

Important: This Specification does not suggest that organizations that already have OIDs and have been managing them for some time should change to using the approaches outlined below.

Small to Medium Sized Organizations (such as Practices)
There are several assumptions made in this section with regard to the way that OIDs are managed. If these assumptions do not apply, then one should look to the OID partitioning scheme defined for Large Organizations.

- The organization uses the same identifier to uniquely identify a patient across different encounters and locations. This can either be the medical record number or master patient identifier used by the organization to identify a patient.

- The organization makes use of a single electronic medical record system (EMR) across its various locations of care.

- The organization uses the same identifier to uniquely identify personnel regardless of location.

- There is a manageable number of locations, and a way to uniquely identify each of these within the scope of the organization.

- There is a manageable number of entities that the organization places orders with, and a way to uniquely identify each of these within the scope of the organization.

- Once an organization receives a root OID of their own, it is recommended that they create arcs below that OID using the values in the table below.

Table 2:OIDArc Values

Arc	Description
.1	Documents
.2	Patients
.3	Non-licensed Personnel
.4	Locations
.5	Non-licensed Organizations
.6	Devices
.7	Encounters
.8	Orders
.9	Sections
.10	Entries
.11	Templates

For example: if an organization had a root OID of 2.16.840.1.113883.19.4, then their arc for documents would be 2.16.840.1.113883.19.4.1, patients would be 2.16.840.1.113883.19.4.2, etc.

Large Organizations (such as Hospitals)

The recommended solution for managing OIDs for large organizations or organizations with the potential to expand is to start with the organization's OID and having a three leaf hierarchy for each particular OID.

The organizational OID would be the root to start. The first leaf is the assigned system IDs. The second leaf is the site specific ID, and the third leaf is the OID category (1 for document ids, 2 for patient ids, 3 for provider ids, etc.). The OID categories should be predefined as much as possible, but if the local site needed an OID category that was not predefined, they would have the flexibility to define their own OID category. If possible, that new OID category should be added to this document so other sites can use the same OID category if needed.

Scenario: In order to completely explain how the recommended solution should work, here are a few pieces of information that will be used to create the organizational OIDs.

• Good Health Clinic has an organizational NPI of 999999999 and has multiple facilities in several locations.

• Each facility uses the same computer systems which they have identified as system 120 (outpatient care), 150 (inpatient care) and 170 (emergency care). Each of those systems operates independently.

• There is one central master patient index (MPI) that helps tie all of the records together. The MPI has been identified as system 2000 and is located at the main clinic which is clinic 1.

• Each of the clinics has been incrementally assigned an ID in order that the clinic was opened. The first clinic has an ID of 001. The second clinic is 002, etc. When using these in an OID, the leading zeros need to be removed.

Based on the information above, here are a few examples of how the OIDs would be created: (each example is followed by the explanation)

• HL7-NPI-AUTOMATIC-OID-ROOT.999999999

Good Health organizational OID

• HL7-NPI-AUTOMATIC-OID-ROOT.999999999.120

(120) is the outpatient system. (This is the first leaf and the OID is not yet complete.)

• HL7-NPI-AUTOMATIC-OID-ROOT.999999999.120.1

The outpatient system (120) hosted at clinic 001 (1). (This is the second leaf and the OID is not yet complete.)

• HL7-NPI-AUTOMATIC-OID-ROOT.999999999.120.1.1

A document ID (1) on that system. (This is the third leaf - the complete OID)

More examples of complete OIDs:

• HL7-NPI-AUTOMATIC-OID-ROOT.999999999.120.1.2

Description: outpatient system (120), hosted at clinic 001 (1), with a patient ID (2)

• HL7-NPI-AUTOMATIC-OID-ROOT.999999999.120.5.2

Description: outpatient system (120), hosted at clinic 005 (5), with a patient ID (2)

• HL7-NPI-AUTOMATIC-OID-ROOT.999999999.150.5.2

Description: inpatient system (150), hosted at clinic 005 (5), with a patient ID (2)

• HL7-NPI-AUTOMATIC-OID-ROOT.999999999.2000.1.2

Description: MPI system (2000), hosted at clinic 001 (1), with a patient ID (2)

2 CMS EHR QRDA (CATEGORY I) REPORT CONSTRAINTS

2.1 CMS EHR QRDA Report Header Constraints

This section describes constraints that apply to the CMS EHR Quality Reporting Document Architecture document (QRDA) report header.

2.1.1 Header Attributes

2.1.1.1 ClinicalDocument/realmCode

CONF-QRDA1-1: The `realmCode` element **SHALL** be present where the value of `@code` is US.

Figure 2: RealmCode Example

```
<realmCode code='US' />
```

Users requiring additional assistance in viewing examples, may contact the QualityNet Help Desk at 866-288-8912 or email at qnetsupport@sdps.org. Hours of operation are 7 am to 7 pm Central Time.

2.1.1.2 ClinicalDocument/typeId

CONF-QRDA1-2: The value of `typeId/@root` **SHALL** be 2.16.840.1.113883.1.3 and value of `typeId@etxension` **SHALL** be POCD_HD000040.

2.1.1.3 ClinicalDocument/templateId

This `ClinicalDocument/templateId` element identifies the template that defines constraints on the content of an EHR QRDA document.

CONF-QRDA1-3: A CMS EHR QRDA Report **SHALL** contain at least one `Clinical Document/templateId` element.

CONF-QRDA1-4: The value of one `ClinicalDocument/templateId/ @root` **SHALL** be "2.16.840.1.113883.10.20.12" representing conformance to the generic QRDA framework constraints.

Figure 3: ClinicalDocument/TemplateId Example

```
<templateId root= "2.16.840.1.113883.10.20.12"/>
```

Users requiring additional assistance in viewing examples, may contact the QualityNet Help Desk at 866-288-8912 or email at qnetsupport@sdps.org. Hours of operation are 7 am to 7 pm Central Time.

2.1.1.4 ClinicalDocument/id

The id represents the unique instance identifier (UID) of a clinical document. The id element uniquely and universally distinguishes a document from all other documents. This allows documents to move among systems without ID collision within those systems. The id element contains a root and an extension attribute.

CONF-QRDA1-5: A `clinicalDocument/id` **SHALL** be present.

CONF-QRDA1-6:

Figure 4: id Example

```
<id root="2.16.840.1.113883.19.4" extension="c266"/>
```

Users requiring additional assistance in viewing examples, may contact the QualityNet Help Desk at 866-288-8912 or email at qnetsupport@sdps.org. Hours of operation are 7 am to 7 pm Central Time.

2.1.1.5 ClinicalDocument/code

CONF-QRDA1-7: A CMS EHR QRDA Report **SHALL** contain exactly one `ClinicalDocument/code` with a value of "55182-0" 2.16.840.1.113883.6.1 LOINC **STATIC**.

2.1.1.6 ClinicalDocument/title

CONF-QRDA1-8: A CMS EHR QRDA Report **SHALL** contain exactly one `clinicalDocument/title` element valued with a case-insensitive, text string containing "QRDA Incidence Report" or "Quality measure Report."

2.1.1.7 ClinicalDocument/effectiveTime

Signifies the document creation time, when the document first came into being. Where the CDA document is a transform from an original document in some other format, the effectiveTime is the time the original document was created.

CONF-QRDA1-9: A `clinicalDocument/effectiveTime` **SHALL** be present.

CONF-QRDA1-10: The value of `effectiveTime/@value` **SHALL** be at least precise to the day (YYYYMMDD).

```
<effectiveTime value="20080407"/>
```

Users requiring additional assistance in viewing examples, may contact the QualityNet Help Desk at 866-288-8912 or email at qnetsupport@sdps.org. Hours of operation are 7 am to 7 pm Central Time.

2.1.1.8 ClinicalDocument/confidentialityCode

Confidentiality is a required contextual component of this Specification, where the value expressed in the header holds true for the entire document.

CONF-QRDA1-11: A `clinicalDocument/confidentialityCode` **SHALL** be present.

CONF-QRDA1-12: The value of `confidentialityCode/@code` **SHALL** be "N" (Normal confidentiality, only authorized individuals with medical or business need may access this clinical document) and the value of `confidentialityCode/@codeSystem` **SHALL** be "2.16.840.1.113883.5.25".

Figure 6: confidentialityCode Example

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

Users requiring additional assistance in viewing examples, may contact the QualityNet Help Desk at 866-288-8912 or email at qnetsupport@sdps.org. Hours of operation are 7 am to 7 pm Central Time.

2.1.1.9 ClinicalDocument/setId

The elements – setId and versionNumber establish a specific version of a document in a series or set. Each document is a member of a set as determined by the value of the setId with the versionNumber indicating where in a series of documents a particular instance is located. This Specification allows replacements to the parent documents. Hence the setId element is a required element of this Specification.

CONF-QRDA1-13: A `clinicalDocument/setId` **SHALL** be present.

CONF-QRDA1-14: Providers that already have OIDs and have been managing them for some time **MAY** continue using their existing OID policy to populate the value of `setId/@root`

CONF-QRDA1-15: The value of `setId` **SHALL** remain the same as the Parent document for "replacements".

Figure 7: setId Example

```
<setId root="2.16.840.1.113883.19.4" extension="c266"/>
```

Users requiring additional assistance in viewing examples, may contact the QualityNet Help Desk at 866-288-8912 or email at qnetsupport@sdps.org. Hours of operation are 7 am to 7 pm Central Time.

2.1.1.10 ClinicalDocument/versionNumber

The elements – setId and versionNumber establish a specific version of a document in a series or set. Each document is a member of a set as determined by the value of the setId with the versionNumber

indicating where in a series of documents a particular instance is located. This Specification allows replacements to the parent documents. Hence the versionNumber element is a required element of this Specification.

> **CONF-QRDA1-16:** A `clinicalDocument/versionNumber` **SHALL** be present.

> **CONF-QRDA1-17:** The value of `versionNumber/@value` **SHALL** be integer.

Figure 8: versionNumber Example

```
<versionNumber value="2"/>
```

Users requiring additional assistance in viewing examples, may contact the QualityNet Help Desk at 866-288-8912 or email at qnetsupport@sdps.org. Hours of operation are 7 am to 7 pm Central Time.

2.1.2 Header Participants

This section describes the participants in a CMS EHR QRDA Report header.

2.1.2.1 recordTarget

CMS EHR QRDA Report contains quality measure information about a single patient.

> **CONF-QRDA1-18:** CMS EHR QRDA Report SHALL contain exactly one `clinicalDocument/recordTarget/PatientRole`.

> **CONF-QRDA1-19:** A `recordTarget/patientRole/id` element SHALL be present where the value of `@root` contains OID for the coding system used to identify the patient. Provider may obtain a unique OID for their practice from HL7 OID Registry and use the same for `@root`. In addition a provider could use NPI number to create unique OID (Refer section:1.6.2.7) for the provider organization. The value of `@extension` contains unique patient identifier, the EHR system uses to record activity on a patient. Commonly used OIDs for entities to identify patient such as SSN, TIN, DLN etc. are available at Appendix_I-OIDs tab of the Downloadable Resources table.

> **CONF-QRDA1-20:** The value of `recordTarget/patientRole/id` element **SHALL** remain the same throughout the reporting period.

> **CONF-QRDA1-21:** The report **MAY** contain one `recordTarget/PatientRole/addr`.

> **CONF-QRDA1-22:** The report **SHALL** contain exactly one `recordTarget/PatientRole/patient`.

> **CONF-QRDA1-23:** The report **SHALL** at least contain patient's legal name at `recordTarget/PatientRole/patient/name`.

> **CONF-QRDA1-24:** The report **SHALL** contain at least one `recordTarget/patientRole/patient/name/given` element for patient's legal name.

> **CONF-QRDA1-25:** The report **SHALL** contain at least one `recordTarget/patientRole/patient/name/family` element for patient's legal name.

> **CONF-QRDA1-26:** A `recordTarget/patientRole/patient/ethnicGroupCode` element **SHALL** be present where the value of `@codeSystem` **SHALL** be

2.16.840.1.113883.5.50 and the value of `@code` **SHALL** be from Appendix_J-Ethnicity tab of the Downloadable Resources table.

CONF-QRDA1-27: `recordTarget/patientRole/patient/administrativeGender Code` element **SHALL** be present where the value of `@codeSystem` **SHALL** be 2.16.840.1.113883.5.1 and the value of `@code` **SHALL** be from Appendix_K-Gender tab of the Downloadable Resources table.

CONF-QRDA1-28: A `recordTarget/patientRole/patient/raceCode` element **SHALL** be present where the value of `@codeSystem` **SHALL** be 2.16.840.1.113883.5.104 and the value of `@code` **SHALL** be from Appendix_L-Race tab of the Downloadable Resources table.

CONF-QRDA1-29: A `recordTarget/patientRole/patient/birthTime` element **SHALL** be present.

CONF-QRDA1-30: `recordTarget/patientRole/patient/birthTime` **SHALL** be at least precise to the day (YYYYMMDD).

CONF-QRDA1-31: The report **SHALL** contain exactly one `recordTarget/PatientRole/providerOrganization`

CONF-QRDA1-32: A `recordTarget/patientRole/providerOrganization/id` element **SHALL** be present where the value of `@root` **SHALL** be 2.16.840.1.113883.4.6 and the value of `@extension` contains the National Provider Identifier (NPI) of the provider.

CONF-QRDA1-33: `recordTarget/patientRole/providerOrganization/name` element **SHOULD** be present.

CONF-QRDA1-34: The report **SHALL** contain at least one `recordTarget/patientRole/providerOrganization/addr`.

CONF-QRDA1-35: `recordTarget/patientRole/providerOrganization/addr/st reetAddressLine` element **MAY** be present.

CONF-QRDA1-36: `recordTarget/patientRole/providerOrganization/addr/ci ty` element **MAY** be present.

CONF-QRDA1-37: `recordTarget/patientRole/providerOrganization/addr/st ate` element **SHALL** be present. All the applicable states that could be used in this element are available in Appendix_T-States.

CONF-QRDA1-38: `recordTarget/patientRole/providerOrganization/addr/po stalCode` element **MAY** be present.

CONF-QRDA1-39: The report **SHALL** contain exactly one `recordTarget/patientRole/providerOrganization/asOrganizationPartOf.`

CONF-QRDA1-40: The report **SHALL** contain exactly one `recordTarget/patientRole/providerOrganization/asOrganizationPartOf/ wholeOrganization.`

CONF-QRDA1-41: A `recordTarget/patientRole/providerOrganization/asOrganizationPartOf/ wholeOrganization/id` element **SHALL** be present where the value of `@root` **SHALL**

be 2.16.840.1.113883.4.2 and the value of `@extension` contains the Taxpayer
Identification Number (TIN) of the provider.

Figure 9: recordTarget Example

```
<recordTarget>
    <patientRole>
        <!-- patient SSN -->
        <id root="2.16.840.1.113883.4.1" extension="654329876"/>
        <addr>
            <streetAddressLine>1200 Eads Street</streetAddressLine>
            <city>Arlington</city>
            <state>VA</state>
            <postalCode>22202</postalCode>
        </addr>
        <telecom value="tel:(888)555-1212"/>
        <patient>
            <name use="L">
                <given>John</given>
                <given>Walker</given>
                <family>Doe</family>
            </name>
            <name use="P">
                <given qualifier="CL">John</given>
            </name>
            <administrativeGenderCode code="M" codeSystem="2.16.840.1.113883.5.1"/>
            <birthTime value="19361209"/>
            <raceCode code="2106-3" codeSystem="2.16.840.1.113883.5.104"/>
            <ethnicGroupCode code="2186-5" codeSystem="2.16.840.1.113883.5.50"/>
        </patient>
        <providerOrganization>
            <!--provider NPI-->
            <id root="2.16.840.1.113883.4.6" extension="9234567896"/>
            <name>Good Health Clinic</name>
            <addr>
                <streetAddressLine>1200 Joyce Street</streetAddressLine>
                <city>Arlington</city>
                <state>VA</state>
                <postalCode>22202</postalCode>
            </addr>
            <asOrganizationPartOf>
                <wholeOrganization>
                    <!--provider TIN-->
                    <id root="2.16.840.1.113883.4.2" extension="122454245"/>
                </wholeOrganization>
            </asOrganizationPartOf>
        </providerOrganization>
    </patientRole>
</recordTarget>
```

2.1.2.2 author

CONF-QRDA1-42: CMS EHR QRDA Report **SHALL** contain exactly one
`clinicalDocument/author`.

CONF-QRDA1-43: An `author/time` element **SHALL** be present.

CONF-QRDA1-44: An `author/time` **SHALL** be at least precise to the day (YYYYMMDD).

CONF-QRDA1-45: An `author/assignedAuthor` element **SHALL** be present.

CONF-QRDA1-46: An `author/assignedAuthor/id` element **SHALL** be present.

CONF-QRDA1-47: An `author/assignedAuthor/assignedPerson` element **SHALL** be present.

CONF-QRDA1-48: The report **SHALL** contain exactly one `author/assignedAuthor/assignedPerson`.

CONF-QRDA1-49: The report **MAY** contain at least one legal name `author/assignedAuthor/assignedPerson/name`.

CONF-QRDA1-50: At least one `author/assignedAuthor/assignedPerson/name/given` element **MAY** be present.

CONF-QRDA1-51: At least one `author/assignedAuthor/assignedPerson/name/family` element **MAY** be present.

CONF-QRDA1-52: The report **SHOULD** contain one `author/assignedAuthor/representedOrganization`

CONF-QRDA1-53: If present, an `author/assignedAuthor/representedOrganization/id` element **SHOULD** be present where the value `of` `@root` contains OID for the authoring organization.

CONF-QRDA1-54: If present, an `author/assignedAuthor/representedOrganization/name` element **SHOULD** be present.

Figure 10: Author Example

```
<author>
    <time value="20080401"/>
    <assignedAuthor>
        <id root="2.16.840.1.113883.19.5.3" extension="100001"/>
        <assignedPerson>
            <name>
                <given>Mary</given>
                <family>Smith</family>
            </name>
        </assignedPerson>
        <representedOrganization>
            <id root="2.16.840.1.113883.19.5"/>
            <name>Good Health Clinic</name>
        </representedOrganization>
    </assignedAuthor>
</author>
```

2.1.2.3 informant

CMS EHR QRDA Report must have a stated source so that any data within the report can be validated. An informant (or source of information) is an entity that provides relevant information, such as the parent of a comatose patient who describes the patient's behavior prior to the onset of coma.

CONF-QRDA1-55: CMS EHR QRDA Report **SHALL** contain exactly one `clinicalDocument/informant`, which may represent a reporting facility.

CONF-QRDA1-56: The report **SHALL** contain exactly one informant/assignedEntity.

CONF-QRDA1-57: An informant/assignedEntity/id element **SHALL** be present.

CONF-QRDA1-58: If informant has no valid value for id of `assignedEntity`, then the value for `informant/assignedEntity/id` @NullFlavor **SHALL** be "NA" (Not applicable).

CONF-QRDA1-59: An `informant/assignedEntity/representedOrganization` element **SHALL** be present.

CONF-QRDA1-60: An `informant/assignedEntity/representedOrganization/id` element **SHALL** be present.

CONF-QRDA1-61: An `informant/assignedEntity/representedOrganization/name` element **SHOULD** be present.

Figure 11: Informant Example

```
<informant>
      <assignedEntity>
            <id nullFlavor="NA"/>
            <representedOrganization>
                  <id root="2.16.840.1.113883.19.5"/>
                  <name>Good Health Clinic</name>
            </representedOrganization>
      </assignedEntity>
</informant>
```

2.1.2.4 custodian

Custodian represents the organization from which the document originates and that is in charge of maintaining the document. The custodian is the steward that is entrusted with the care of the document.

> **CONF-QRDA1-62:**   An CMS EHR QRDA Report **SHALL** contain exactly one
>
> `custodian/assignedCustodian/representedCustodianOrganization/id`
> element.

> **CONF-QRDA1-63:**   The value of
>
> `custodian/assignedCustodian/representedCustodianOrganization/id`
> element **SHALL** be the id of the custodian organization.

> **CONF-QRDA1-64:**   A
>
> `custodian/assignedCustodian/representedCustodianOrganization/name`
> element **SHOULD** be present.

Figure 12: Custodian Example

```
<custodian>
      <assignedCustodian>
            <representedCustodianOrganization>
                  <id root="2.16.840.1.113883.19.5"/>
                  <name>Good Health Clinic</name>
            </representedCustodianOrganization>
      </assignedCustodian>
</custodian>
```

2.1.2.5 legalAuthenticator

A legal authenticator is a verifier who officially authenticates the accuracy of the document. An example would be a Quality Nurse Manager who compiles a quality report and is responsible for verifying and sending the quality reports. A `legalAuthenticator` is recommended in CMS EHR QRDA Report, but workflow may be such that in some institutions' legal authenticator may not be identified. In the case where a local document is transformed into a QRDA document for exchange, authentication occurs on the local document, and that fact is reflected in the exchanged QRDA document.

> **CONF-QRDA1-65:**   CMS EHR QRDA Report **SHOULD** contain exactly one
>
> `legalAuthenticator` element.

> **CONF-QRDA1-66:**   If legalAuthenticator is present, CMS EHR QRDA Report
>
> `legalAuthenticator` **SHALL** contain exactly one
> `clinicalDocument/legalAuthenticator/time` element.

CONF-QRDA1-67: If legalAuthenticator is present, `clinicalDocument/legalAuthenticator/time` **SHALL** be at least precise to the day (YYYYMMDD).

CONF-QRDA1-68: If legalAuthenticator is present, CMS EHR QRDA Report `legalAuthenticator` **SHALL** contain exactly one `signatureCode` element.

CONF-QRDA1-69: If legalAuthenticator is present, the value of a QRDA `clinicalDocument/signatureCode` **SHALL** be @code "S" (signed).

CONF-QRDA1-70: If legalAuthenticator is present, CMS EHR QRDA Report `legalAuthenticator` **SHALL** contain exactly one `assignedEntity` element that represents the legalauthenticator of the document.

CONF-QRDA1-71: If legalAuthenticator is present, the `clinicalDocument/legalAuthenticator/assignedEntity` **SHALL** contain an `id` element.

CONF-QRDA1-72: If legalAuthenticator is present, a `clinicalDocument/legalAuthenticator/assignedEntity/assignedPerson` **SHOULD** be present.

CONF-QRDA1-73: If legalAuthenticator is present, `clinicalDocument/legalAuthenticator/assignedEntity/assignedPerson/name/given` **MAY** be present.

CONF-QRDA1-74: If legalAuthenticator is present, `clinicalDocument/legalAuthenticator/assignedEntity/assignedPerson/name/family` **MAY** be present.

CONF-QRDA1-75: If legalAuthenticator is present, a `clinicalDocument/legalAuthenticator/assignedEntity/representedOrganization` **SHOULD** be present.

CONF-QRDA1-76: If legalAuthenticator is present, `clinicalDocument/legalAuthenticator/assignedEntity/representedOrganization/id` **SHALL** be present.

CONF-QRDA1-77: If legalAuthenticator is present, `clinicalDocument/legalAuthenticator/assignedEntity/representedOrganization/name` **SHOULD** be present.

```
<legalAuthenticator>
        <time value="20080401"/>
        <signatureCode code="S"/>
        <assignedEntity>
                <id root="2.16.840.1.113883.19.5.3" extension="100050"/>
                <assignedPerson>
                        <name>
                                <prefix>Dr.</prefix>
                                <given>Nancy</given>
                                <family>Nightingale</family>
                                <suffix>MD</suffix>
                        </name>
                </assignedPerson>
                <representedOrganization>
                        <id root="2.16.840.1.113883.19.5"/>
                        <name>Good Health Clinic</name>
                </representedOrganization>
        </assignedEntity>
</legalAuthenticator>
```

2.1.2.6 participant (Primary Care Provider)

The participant header element is used to capture the details of the Primary care provider.

CONF-QRDA1-78:   The value of `participant@typeCode` **SHALL** be "PRF" (performer).

CONF-QRDA1-79:   A `participant/functionCode` element **SHALL** be present.

CONF-QRDA1-80:   The value of `participant/functionCode@code` **SHALL** be "PCP" (primary care physician).

CONF-QRDA1-81:   The value of `participant/functionCode@codeSystem` **SHALL** be 2.16.840.1.113883.5.88.

CONF-QRDA1-82:   A `participant/associatedEntity` element **SHALL** be present.

CONF-QRDA1-83:   The value of `participant/associatedEntity@classCode` **SHALL** be "PROV" (healthcare provider).

CONF-QRDA1-84:   A `participant/associatedEntity/id` element **SHALL** be present.

CONF-QRDA1-85:   A `participant/associatedEntity/associatedPerson` element **SHOULD** be present.

CONF-QRDA1-86:   If `participant/associatedEntity/associatedPerson` element is present, `participant/associatedEntity/associatedPerson/name/given` at least one legal given name **MAY** be present.

CONF-QRDA1-87:   If `participant/associatedEntity/associatedPerson` element is present, `participant/associatedEntity/associatedPerson/name/family` at least one legal family name **MAY** be present.

Figure 14: Participant Example

```
<participant typeCode="PRF">
    <functionCode code="PCP" codeSystem="2.16.840.1.113883.5.88"/>
    <associatedEntity classCode="PROV">
        <id extension="1" root="1.3.6.4.1.4.1.2835.1"/>
        <associatedPerson>
            <name>
                <prefix>Dr.</prefix>
                <given>John</given>
                <family>Doe</family>
            </name>
        </associatedPerson>
    </associatedEntity>
</participant>
```

2.1.2.7 documentationOf

The `documentationOf` element describes the encounter during which the subject was seen and may include a code to describe the encounter as well as identifying the provider, location, time. There could be one or more `documentationOf` elements depending upon number of encounters that are being documented during the reporting period. Each `documentationOf` element shall elaborate one single service event. The encounter codes associated with patient visits are captured using this element.

CONF-QRDA1-88: A CMS EHR QRDA Report SHALL contain one or more `clinicalDocument/documentationOf` elements.

CONF-QRDA1-89: A `documentationOf/serviceEvent` element **SHALL** be present.

CONF-QRDA1-90: A `documentationOf/serviceEvent/code` element **SHALL** be present. All the applicable encounter codes that could be used in this element are available in Appendix_B_Encounters.

CONF-QRDA1-91: A `documentationOf/serviceEvent/effectiveTime` element **SHALL** be present.

CONF-QRDA1-92: A `documentationOf/serviceEvent/effectiveTime` element **SHALL** contain one low element and one high element indicating the starting and ending times of the encounter.

CONF-QRDA1-93: A `documentationOf/serviceEvent/effectiveTime` low and high element **SHALL** be at least precise to the day (YYYYMMDD).

CONF-QRDA1-94: A `documentationOf/serviceEvent/performer@typeCode` **SHALL** be either PRF (performer – a person who actually and principally carries out an action) or PPRF (primary performer - principal performer of the Service event) or SPRF (secondary performer – a person assisting in the Service event through their substantial presence and involvement. This may include assistants, technicians, associates, or other performers).

CONF-QRDA1-95: A `documentationOf/serviceEvent/performer/assignedEntity` element **SHALL** be present.

CONF-QRDA1-96: A `documentationOf/serviceEvent/performer/assigndedEntity/id` element

SHALL be present, where the value of @root **SHALL** be 2.16.840.1.113883.4.6 and the value of @extension **SHALL** contain the National Provider Identifier (NPI) of the provider, whom the patient had encountered during the service event.

CONF-QRDA1-97:   A `documentationOf/serviceEvent/performer/assigndedEntity/code` element **SHOULD** be present.

CONF-QRDA1-98:   A `documentationOf/serviceEvent/performer/assigndedEntity/addr` element **SHOULD** be present.

CONF-QRDA1-99:   If `documentationOf/serviceEvent/performer/assigndedEntity/addr` is present, `documentationOf/serviceEvent/performer/assigndedEntity/addr/streetAddressLine` element **SHOULD** be present.

CONF-QRDA1-100:   If `documentationOf/serviceEvent/performer/assigndedEntity/addr` is present, `documentationOf/serviceEvent/performer/assigndedEntity/addr/city` element **SHOULD** be present

CONF-QRDA1-101:   If `documentationOf/serviceEvent/performer/assigndedEntity/addr` is present, `documentationOf/serviceEvent/performer/assigndedEntity/addr/state` element **SHOULD** be present. All the applicable states that could be used in this element are available in Appendix_T-States.

CONF-QRDA1-102:   If `documentationOf/serviceEvent/performer/assigndedEntity/addr` is present, `documentationOf/serviceEvent/performer/assigndedEntity/addr/postalcode` element **SHOULD** be present.

CONF-QRDA1-103:   A `documentationOf/serviceEvent/performer/assigndedEntity/assignedPerson` element **SHOULD** be present.

CONF-QRDA1-104:   If `documentationOf/serviceEvent/performer/assignedEntity/assignedPerson` is present, `documentationOf/serviceEvent/performer/assignedEntity/assignedPerson/name` at least one legal name element **MAY** be present.

CONF-QRDA1-105:   If `documentationOf/serviceEvent/performer/assignedEntity/assignedPerson` is present, `documentationOf/serviceEvent/performer/assignedEntity/assignedPerson/name/given` at least one legal given name element **MAY** be present.

CONF-QRDA1-106:   If `documentationOf/serviceEvent/performer/assignedEntity/assignedPerson` is present,

documentationOf/serviceEvent/performer/assigndedEntity/assignedPers
on/name/family at least one legal family name element **MAY** be present.

Figure 15: documentationOf Example

```
<documentationOf>
    <serviceEvent>
            <code code="97804" codeSystem="2.16.840.1.113883.6.12"
codeSystemName="C4"/>
        <effectiveTime>
            <low value="20080127"/>
            <high value="20080127"/>
        </effectiveTime>
        <performer typeCode="PRF">
            <assignedEntity>
                <!—provider NPI →
                <id root="2.16.840.1.113883.4.6" extension="9234567896"/>
                <code code="59058001" codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMED CT"
                    displayName="General Physician"/>
                <addr>
                    <streetAddressLine>21 North Ave</streetAddressLine>
                    <city>Burlington</city>
                    <state>MA</state>
                    <postalCode>01803</postalCode>
                </addr>
                <assignedPerson>
                    <name>
                        <prefix>Dr.</prefix>
                        <given>Bernard</given>
                        <family>Wiseman</family>
                        <suffix>Sr.</suffix>
                    </name>
                </assignedPerson>
            </assignedEntity>
        </performer>
    </serviceEvent>
</documentationOf>
```

2.2 CMS EHR QRDA Report Body Constraints

A CMS EHR QRDA Report requires a structuredBody. The report will typically contain several sections and subsections. The top-level sections shall be Measure Set sections which contain a group of measures being reported. This is illustrated in Figure 17: CMS EHR QRDA Report Use of Measure Set Sections.

Figure 17: CMS EHR QRDA Report Use of Measure Set Sections

```
Measure Set Section
  - Description and Version of Measure Set
      Measure Section
       - Measure One entries
       - Measure Two entries
       - Measure Three entries
         Reporting Parameters Section
             - Reporting Period Entry
         Patient Data Section
             - Problems Section
             - Procedures Section
             - Payers Section
             - Alerts Section
             - Medications Section
             - Immunizations Section
             - Vital signs Section
             - Results Section
             - Structural Data Section
```

Users requiring additional assistance in viewing examples may contact the QualityNet Help Desk at 866-288-8912 or email at qnetsupport@sdps.org. Hours of operation are 7 am to 7 pm Central Time.

CONF-QRDA1-113: An CMS EHR QRDA Report **SHALL** contain exactly one `clinicalDocument/component/structuredBody`.

CONF-QRDA1-114: An `CMS EHR QRDA Report` **SHALL** contain exactly one Measure Set section.

CONF-QRDA1-115: The Measure Set section **SHALL** contain one nested Measure section and **SHALL NOT** contain more than one nested Measure section.

2.3 CMS EHR QRDA Report Section Constraints

This section describes constraints that apply to the CMS EHR QRDA Report sections within the Body of the document.

2.3.1 Measure Set Section

A measure set is a group of individual quality measures applicable to patients with an identified health-related status such as a demographic profile (i.e., age and sex parameters germane to preventive health measure sets) or an abnormal health condition (e.g., pneumonia, diabetes mellitus).

Quality measures within a measure set may or may not have the same denominator. For example, measures within the Pneumonia (PN) measure set from the National Hospital Quality Measures manual utilize a consistent definition of pneumonia (from a specified ICD-9 value set) contributing to denominator inclusion, but other denominator inclusion criteria, such as age, vary according to the intent of the specific quality measure.

The Measure Set section will contain measures from the measure set that are applicable to the patient. It does not have to contain all of the measures within a given professionally defined measure set.

Note: Make sure that you supply appropriate "section-code" for this section, to ensure that correct validation rules could be performed on the section.

>
> **CONF-QRDA1-116:** The Measure Set section **SHALL** contain a templateId uniquely identifying the Measure Set name and version. Use the value from Appendix_S-Measure_Codes tab of the Downloadable Resources table.
>
> **CONF-QRDA1-117:** The Measure Set section **SHALL** contain a `section/code` element.
>
> **CONF-QRDA1-118:** The value for `section/code` **SHALL** be `55185-3 MEASURE SET` 2.16.840.1.113883.6.1 LOINC **STATIC**.
>
> **CONF-QRDA1-119:** The Measure Set section **SHALL** be valued with `section/title` with a case-insensitive, text string containing `Measure set: CMS EHR Measure Set`.
>
> **CONF-QRDA1-120:** The Measure Set section **MAY** contain a section/text element for the description of the measure set or **MAY** contain a formal representation of a description of the measure set.

Figure 18: Measure Set section Example

```
<component>
   <section>
     <templateId root="2.16.840.1.113883.3.249.11.12"/> <!-- templateId uniquely
      identifies the measure -->
     <code code="55185-3" codeSystem="2.16.840.1.113883.6.1" />
     <title>Measure Set: CMS EHR Measure Set</title>
     <text>... (optional) description of measure set ...</text>       ...
   <section>
</component>
```

Users requiring additional assistance in viewing examples, may contact the QualityNet Help Desk at 866-288-8912 or email at qnetsupport@sdps.org. Hours of operation are 7 am to 7 pm Central Time.

>
> **CONF-QRDA1-121:** The nested Measure section **SHALL** contain at least one measure that belongs to the measure set.
>
> **CONF-QRDA1-122:**

2.3.2 Measure Section

The Measure section contains information about the measure or measures and patient data about the measure being reported. The Measure section contains two nested sections: the Reporting Parameters section and the Patient Data section, which are required.

Note: Make sure that you supply appropriate "section-code" for this section, to ensure that correct validation rules could be performed on the section.

CONF-QRDA1-123: A nested Measure section **SHALL** be valued with `section/title` with a case-insensitive, text string containing `Measure section`. The nested measure section **SHALL** contain `section/code` element. In the nested measure section, the value for `section/code` **SHALL** be 55186-1 MEASURE 2.16.840.1.113883.6.1 LOINC **STATIC**

CONF-QRDA1-124: A nested Measure section **SHALL** contain at least one `templateId` corresponding to the measures. Refer Appendix_S-Measure_Codes tab of the Downloadable Resources table.

CONF-QRDA1-125: A Measure section **SHALL** contain exactly one nested Reporting Parameters section (as described in Section 2.3.3 Reporting Parameters Section).

CONF-QRDA1-126: A Measure section **SHALL** contain exactly one nested Patient Data section (as described in Section 2.3.4 Patient Data Section).

CONF-QRDA1-127: The Measure section **MAY** contain a section/text element for the description of the measure(s).

Figure 19: Nested Measure Section in Measure Set Example

```
<section>
        <!-- EHR QRDA measure-specific template ID for each measure in this
        Section -->
        <templateId root="2.16.840.1.113883.3.249.11.2"/>
        <templateId root="2.16.840.1.113883.3.249.11.3"/>
        <templateId root="2.16.840.1.113883.3.249.11.4"/>
       <code code="55186-1" codeSystem="2.16.840.1.113883.6.1" />
        <title>Measure Section</title>
        <text>
           <list>
               <item> Measure #1: Diabetes Mellitus: Hemoglobin A1c Poor Control in
Diabetes Mellitus </item>
                <item> Measure #2: Diabetes Mellitus: Low Density Lipoprotein (LDL-C)
Control in Diabetes Mellitus </item>
                <item> Measure #3: Diabetes Mellitus: High Blood Pressure Control in
Diabetes Mellitus </item>
           </list>
        </text>
      ...
           <section>
              <code code="55187-9" codeSystem="2.16.840.1.113883.6.1" />
              <title>Reporting Parameters</title>
            ...
           </section>
           <section>
              <code code="55188-7" codeSystem="2.16.840.1.113883.6.1" />
              <title>Patient Data </title>
              ...
           </section>
        ...
</section>
```

Users requiring additional assistance in viewing examples, may contact the QualityNet Help Desk at 866-288-8912 or email at qnetsupport@sdps.org. Hours of operation are 7 am to 7 pm Central Time.

2.3.2.1 Representation of the Measure(s)

The measure is represented as an <act> in definition mood. The version number or code of the professional society's definition of the measure is captured in the act's code.

CONF-QRDA1-128: Each measure **SHALL** be represented with act.

CONF-QRDA1-129: For each Act in the Measure section, the value for `act @classCode` in a measure act **SHALL** be ACT 2.16.840.1.113883.5.6 ActClass **STATIC**.

CONF-QRDA1-130: For each act in the Measure section the `act/@moodCode` in a measure act **SHALL** be DEF 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-QRDA1-131: For each act in the Measure section there **SHALL** be an `act/code` reflecting the measure name and version. Refer Appendix_S-Measure_Codes tab of the Downloadable Resources table.

CONF-QRDA1-132: Each measure act **MAY** contain an act/text element containing a description of the measure.

Figure 20: MeasureAct Example

```
<entry typeCode="DRIV">
   <act classCode="ACT" moodCode="DEF">
      <!--  code for illustration* -->
      <code code="PQRI-3" codeSystem="2.16.840.1.113883.3.249.12" displayName="
Measure #3: Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus "/>
      <text>... (optional) description of measure ...</text>
      <statusCode code="completed" />
   </act>
</entry>
```

Users requiring additional assistance in viewing examples, may contact the QualityNet Help Desk at 866-288-8912 or email at qnetsupport@sdps.org. Hours of operation are 7 am to 7 pm Central Time.

2.3.3   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.

Note: Make sure that you supply appropriate "section-code" for this section, to ensure that correct validation rules could be performed on the section.

CONF-QRDA1-133:   The Reporting Parameters section **SHALL** contain a `section/code` element.

CONF-QRDA1-134:   The value for Section/code **SHALL** be `55187-9 Reporting Parameters` 2.16.840.1.113883.6.1 LOINC **STATIC**.

CONF-QRDA1-135:   The Reporting Parameters section **SHALL** be valued with Section/title with a case-insensitive, text string containing `Reporting Parameters`.

CONF-QRDA1-136:   The Reporting Parameters section **SHALL** contain exactly one Observation Parameters Act, represented as an Act.

CONF-QRDA1-137:   The value for `act/@classCode` in an Observation Parameters Act **SHALL** be `ACT` 2.16.840.1.113883.5.6 ActClass **STATIC**.

CONF-QRDA1-138:   The value for `act/@moodCode` in an Observation Parameters Act **SHALL** be EVN 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-QRDA1-139:   The reporting time period **SHALL** be represented with `effectiveTime/low` element combined with a high element representing respectively the first and last days of the period reported. The effectiveTime (start date and end date) **SHALL** be at least precise to the day (YYYYMMDD).

Figure 21: Reporting parameters TimeElement Example

```
<entry>
   <act classCode="ACT" moodCode="EVN">
       <code code="252116004" codeSystem="2.16.840.1.113883.6.96"
       displayName="Observation Parameters" />
       <effectiveTime>
          <low value="20080101" /> <!-- The first day of the period reported. -->
          <high value="20080331" /> <!-- The last day of the period reported. -->
       </effectiveTime>
   </act>
```

2.3.4 Patient Data Section

The Patient Data section contains patient data elements and measure-specific grouping data elements as defined by the particular measure(s).

A patient data element is information about a particular person (as opposed to a population). Examples include: individual's test results, individual's encounter location, individual's date of birth etc.

This section reuses CCD section templates and clinical statement templates when appropriate, such as the problem observation and result observation template to model the observations.

Note: Make sure that you supply appropriate "section-code" for this section, to ensure that correct validation rules could be performed on the section.

CONF-QRDA1-140:   The Patient Date section **SHALL** contain a `section/code` element.

CONF-QRDA1-141:   The value for Section/code **SHALL** be `55188-7 Patient Data` 2.16.840.1.113883.6.1 LOINC **STATIC**.

CONF-QRDA1-142:   The Patient Data section **SHALL** be valued with `section/title` with a case-insensitive, text string containing `Patient Data`.

CONF-QRDA1-143:   The Patient Data section **SHOULD** contain patient data pertaining to measures stated in the Measure section. Any patient data that is not applicable to the measures will be ignored.

CONF-QRDA1-144:   The measure data **SHALL** be represented as clinical statements.

CONF-QRDA1-145:   Measure data using SNOMED **SHALL** be represented per the `Using SNOMED CT`® `in HL7 Version 3` DSTU.

CONF-QRDA1-146:   Measure data **SHOULD** use CCD and other CDA IG templates where possible. All the templates that are used by this Specification are described in Chapter-3

3 TEMPLATES USED IN EHR QRDA TECHNICAL SPECIFICATION

3.1 Templates

This Specification uses several HL7 Continuity Care Document (CCD) templates. For more information on these templates, refer to the Continuity of Care Document Quick Start Guide (QSG), which is provided free of charge by HIMSS Electronic Health Record Association (EHRVA), as a service to vendors and others who will be implementing healthcare documents based on the CCD Implementation Guide. EHRVA's goal is to accelerate implementation of this standard which is endorsed by HIMSS, integral to several key HITSP interoperability specifications and IHE content profiles, and is expected to be required for CCHIT certification. The link to the Quick Start Guide is: http://www.himssehra.org/docs/ccd_qsg.zip.

The pattern for section templates specifies required elements and attributes that establish an unambiguous context for each section.

NOTE: CCD body section templates share a common pattern that applies across all sections. This pattern is described here and is not repeated in the content areas devoted to individual sections.

NOTE: Make sure that you supply appropriate "template ID" for all the CCD templates in the Data Submission files, to ensure that correct validation rules could be performed on the Data Submission files. Any additional CCD templates submitted beyond what is specified in this specification will not be validated or cause the file to reject.

3.1.1 Overview of Templates

3.1.1.1 Section-level Templates

All CCD section-level templates share these requirements:

- CCD contains one, but not more than one, instance of a type of **section**

- **section SHALL** contain a **templateId** with the value assigned to that type of section

- **section SHALL** contain a narrative block

- **section SHOULD** contain clinical statements

- **section SHALL** contain a **code** specific to that section type; all sections in the CCD body are assigned LOINC codes.

- **section SHALL** contain a **title**, and the text string within the **title SHALL** include a string specific to that section. (Case and language are not significant.)

In XML Examples
XML examples are set in a monospaced font with a specific color to differentiate required, optional, variable, and fixed content:

```
Black = required markup and all delimiters, e.g., =, ""
Red = fixed content, enter exactly as shown.
Blue = optional elements, attributes or content.
Green = variable – new content is required.
     Thus:

  <requiredElement requiredAtt = "fixedValue"  optionalAtt = "variableValue">
  <optionalElement requiredAtt = "variableValue" optionalAtt = "variableValue">
```

For users requiring additional assistance regarding the color-coded data, may contact the QualityNet Help Desk at 866-288-8912 or email at qnetsupport@sdps.org. Hours of operation are 7 am to 7 pm Central Time.

The following example illustrates the pattern for section-level templates:

Section-level Template

```xml
<component>
  <section>
    <templateId root="2.16.840.1.113883.10.20.1.13" />
       <!--  Purpose section template -->
    <code code="LOINCSectionCodeGoesHere" codeSystem="2.16.840.1.113883.6.1"/>
    <title>section title text goes here</title>
    <text>
       <!-- Tables, lists or paragraphs go here. -->
    </text>
    <entry typeCode="DRIV"> <!-- can also be "COMP" -->
       <!-- Clinical statements (entries, acts, etc.) go here -->
    </entry>
  </section>
</component>
```

NOTE: For brevity, all subsequent examples include only the entry elements, excluding the wrapping component, section, section-level templateId, and required code, title, and text elements.

For users requiring additional assistance regarding the color-coded data, may contact the QualityNet Help Desk at 866-288-8912 or email at qnetsupport@sdps.org. Hours of operation are 7 am to 7 pm Central Time.

3.1.1.2 Clinical Statement Templates

Collectively, the nine **act** classes within the CDA RMIM and their associated relationships and **participants** constitute the Clinical Statement pattern and constraints on the pattern are called "clinical statements." Combining the semantic classes within the CDA body in a defined pattern is an example of use of the Clinical Statement pattern developed by HL7 and used in CDA and other RIM-based Specifications. Therefore, such constructs are called clinical statements.

A key component of the Clinical Statement is the **entryRelationship** and **entryRelationship@typeCode**, which create relationships between the **entries.** While CDA allows arbitrary **entry** to **entryRelationship** structures, only certain combinations of source, target, and typeCode make sense.

Clinical statement templates describe patterns that can be used within one or more sections. Thus, a problem template may also be used in a family history section, possibly with addition constraints required for that section.

Clinical Statement Template Example

```
<entry typeCode="DRIV">
    <observation classCode="OBS" moodCode="RQO">
        <templateId root="2.16.840.1.113883.10.20.1.25"/>
            <!-- Plan of Care Activity template -->
        <id root="someIdString"/>
        <code code="23426006" codeSystem="2.16.840.1.113883.6.96"
displayName="Pulmonary function test"/>
        <statusCode code="new"/>
        <effectiveTime><center value="20000421"/></effectiveTime>
    </observation>
</entry>
```

For users requiring additional assistance regarding the color-coded data, may contact the QualityNet Help Desk at 866-288-8912 or email at qnetsupport@sdps.org. Hours of operation are 7 am to 7 pm Central Time.

3.1.1.3 Supporting (Entry) Templates

Supporting templates are used for recurring concepts such as status, age, product, and reaction observation. In the example that follows, the reaction observation template is the target of an alert observation. Taken together, they assert that hives is a manifestation of an allergic reaction to penicillin. Supporting templates may be used within clinical statement templates.

Supporting Template Example

```
<observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.1.18" />
        <!--  Alert observation template -->
    <id root="IDGoesHere" />
    <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4" />
    <statusCode code="completed" />
```

```xml
        <value xsi:type="CD" code="282100009" codeSystem="2.16.840.1.113883.6.96"
displayName="Adverse reaction to substance" />
    <participant typeCode="CSM">
        <participantRole classCode="MANU">
            <playingEntity classCode="MMAT">
                <code code="70618" codeSystem="2.16.840.1.113883.6.88"
displayName="Penicillin" />
            </playingEntity>
        </participantRole>
    </participant>
    <entryRelationship typeCode="MFST" inversionInd="true">
        <observation classCode="OBS" moodCode="EVN">
            <templateId root="2.16.840.1.113883.10.20.1.54" />
                <!-- Reaction observation template  -->
            <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4" />
            <statusCode code="completed" />
            <value xsi:type="CD" code="247472004" codeSystem="2.16.840.1.113883.6.96"
displayName="Hives" />
        </observation>
    </entryRelationship>
    <!-- Alert status observation template goes here -->
</observation>
```

For users requiring additional assistance regarding the color-coded data, may contact the QualityNet Help Desk at 866-288-8912 or email at qnetsupport@sdps.org. Hours of operation are 7 am to 7 pm Central Time.

3.1.2 Problems Section

The template identifier for the problem section is 2.16.840.1.113883.10.20.1.11.
This section lists and describes all relevant clinical problems for the reporting period. At a minimum, all pertinent current and historical problems should be listed. CDA R2 represents problems as Observations.

> **CONF-QRDA1-147:** The CMS EHR QRDA Report **SHOULD** contain exactly one and **SHALL NOT** contain more than one `Problem section` (templateId 2.16.840.1.113883.10.20.1.11). The `Problem section` **SHALL** contain a narrative block, and **SHALL** contain clinical statements. Clinical statements **SHALL** include one or more `problem acts` (templateId 2.16.840.1.113883.10.20.1.27). A problem act **SHALL** include one or more `problem observations` (templateId 2.16.840.1.113883.10.20.1.28).

3.1.2.1 Section Conformance

> **CONF-QRDA1-148:** The problem section **SHALL** contain `Section / code`.

> **CONF-QRDA1-149:** The value for `Section / code` SHALL be 11450-4 Problem list 2.16.840.1.113883.6.1 LOINC **STATIC**.

> **CONF-QRDA1-150:** The problem section **SHALL** contain `Section / title`.

> **CONF-QRDA1-151:** Section / title **SHOULD** be valued with a case-insensitive language-insensitive text string containing problems.

3.1.2.2 Clinical Statement Conformance

3.1.2.2.1 Representation of Problems

The template identifier for a problem act is 2.16.840.1.113883.10.20.1.27.
The template identifier for a problem observation is 2.16.840.1.113883.10.20.1.28.
A problem is a clinical statement that a clinician is particularly concerned about and wants to track. It has important patient management use cases (e.g. health records often present the problem list as a way of summarizing a patient's medical history).

3.1.2.2.1.1   Problem Act

CONF-QRDA1-152:   A `problem act` (templateId 2.16.840.1.113883.10.20.1.27) **SHALL** be represented with Act.

CONF-QRDA1-153:   The value for `Act / @classCode` in a problem act **SHALL** be `ACT` 2.16.840.1.113883.5.6 `ActClass` **STATIC**.

CONF-QRDA1-154:   The value for `Act / @moodCode` in a problem act **SHALL** be `EVN` 2.16.840.1.113883.5.1001 `ActMood` **STATIC**.

CONF-QRDA1-155:   A problem act **SHALL** contain at least one `Act / id`.

CONF-QRDA1-156:   The value for `Act / code / @NullFlavor` in a problem act **SHALL** be `NA Not applicable` 2.16.840.1.113883.5.1008 `NullFlavor` **STATIC**.

CONF-QRDA1-157:   A problem act **MAY** contain exactly one `Act / effectiveTime`, to indicate the timing of the concern (e.g. the interval of time for which the problem is a concern).

CONF-QRDA1-158:   A problem act **SHALL** contain one or more `Act / entryRelationship`.

CONF-QRDA1-159:   A problem act **MAY** reference a problem observation, alert observation or other clinical statement that is the subject of concern, by setting the value for `Act / entryRelationship / @typeCode` to be `SUBJ` 2.16.840.1.113883.5.1002 `ActRelationshipType` **STATIC**.

CONF-QRDA1-160:   The target of a problem act with `Act / entryRelationship / @typeCode=SUBJ` **SHOULD** be a problem observation (in the Problem section) or alert observation, but **MAY** be some other clinical statement.

3.1.2.2.1.2   Problem Observation

CONF-QRDA1-161:   A `problem observation` (templateId 2.16.840.1.113883.10.20.1.28) **SHALL** be represented with Observation.

CONF-QRDA1-162:   The value for `Observation / @moodCode` in a problem observation **SHALL** be EVN 2.16.840.1.113883.5.1001 `ActMood` **STATIC**.

CONF-QRDA1-163:   A problem observation **SHALL** include exactly one `Observation / statusCode`.

CONF-QRDA1-164:   The value for `Observation / statusCode` in a problem observation **SHALL** be completed 2.16.840.1.113883.5.14 `ActStatus` **STATIC**.

CONF-QRDA1-165: A problem observation **SHALL** 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). Observation/effectiveTime **SHALL** be at least precise to the day. (YYYYMMDD).

CONF-QRDA1-166: The value for `Observation / code` in a problem observation **MAY** be selected from `ValueSet` 2.16.840.1.113883.1.11.20.14 `ProblemTypeCode` **STATIC** 20061017.

CONF-QRDA1-167: The value for `Observation / entryRelationship / @typeCode` in a problem observation **MAY** be SUBJ Subject 2.16.840.1.113883.5.1002 `ActRelationshipType` **STATIC** to reference an `age observation` (templateId 2.16.840.1.113883.10.20.1.38).

CONF-QRDA1-168: The value for `Observation / value/@code` in a problem observation **SHALL** be from the Appendix_C-Problems tab of the Downloadable Resources table.

3.1.2.2.2   Representation of "Status" Values

The template identifier for a problem status observation is 2.16.840.1.113883.10.20.1.50.
The template identifier for a problem `healthstatus` observation is 2.16.840.1.113883.10.20.1.51.

CONF-QRDA1-169: A problem observation **SHALL** contain exactly one problem status observation.

CONF-QRDA1-170: The value for observation/code/@code in `problem status observation` (templateId 2.16.840.1.113883.10.20.1.50) **SHALL** be 33999-4 status 2.16.840.1.113883.6.1 LOINC **STATIC**

CONF-QRDA1-171: The value for `Observation / value` in a problem status observation **SHALL** be selected from `ValueSet` 2.16.840.1.113883.1.11.20.13 `ProblemStatusCode` STATIC 20061017. Refer Appendix_N-Vocabs_and_ValueSets tab of the Downloadable Resources table

CONF-QRDA1-172: A problem observation **MAY** contain exactly one `problem healthstatus observation.`

CONF-QRDA1-173: Value for `Observation / code` in a `problem healthstatus observation` **SHALL** be 11323-3 `Health status` 2.16.840.1.113883.6.1 LOINC **STATIC**.

CONF-QRDA1-174: The value for `Observation / value` in a problem `healthstatus observation` **SHALL** be selected from `ValueSet` 2.16.840.1.113883.1.11.20.12 `ProblemHealthStatusCode` **STATIC** 20061017. Refer Appendix_N-Vocabs_and_ValueSets tab of the Downloadable Resources table

Problem Entry Example

```
<entry typeCode="DRIV">
    <act classCode="ACT" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.1.27"/>
        <!-- Problem act template -->
```

```
            <id root="2.16.840.1.113883.19.5.9" extension="123001"/>
            <code nullFlavor="NA"/>
            <entryRelationship typeCode="SUBJ">
                <observation classCode="OBS" moodCode="EVN">
                    <templateId root="2.16.840.1.113883.10.20.1.28"/>
                    <!-- Problem observation template -->
                    <id root="2.16.840.1.113883.19.5.9" extension="123501"/>
                    <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
                    <statusCode code="completed"/>
                    <effectiveTime>
                        <low value="20080812"/>
                    </effectiveTime>
                    <value xsi:type="CD" code="366.41"
codeSystem="2.16.840.1.113883.6.103"
                        displayName="DIABETIC CATARACT"/>
                    <entryRelationship typeCode="REFR">
                        <observation classCode="OBS" moodCode="EVN">
                            <templateId root="2.16.840.1.113883.10.20.1.50"/>
                            <!-- Problem status observation template -->
                            <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
displayName="Status"/>
                            <statusCode code="completed"/>
                            <value xsi:type="CE" code="55561003"
codeSystem="2.16.840.1.113883.6.96"
                                displayName="Active"/>
                        </observation>
                    </entryRelationship>
                </observation>
            </entryRelationship>
        </act>
    </entry>
</entry>
```

3.1.3 Procedures Section

The template identifier for the procedures section is 2.16.840.1.113883.10.20.1.12.

This section defines all interventional, surgical, diagnostic, or therapeutic procedures or treatments pertinent to the patient historically at the time the document is generated. The section may contain all procedures for the period of time being summarized, but should include notable procedures.

> **CONF-QRDA1-175:** The EHR QRDA Document SHOULD contain exactly one and **SHALL NOT** contain more than one Procedures section (templateId 2.16.840.1.113883.10.20.1.12). The Procedures section **SHALL** contain a narrative block, and **SHALL** contain clinical statements. Clinical statements **SHALL** include one or more procedure activities (templateId 2.16.840.1.113883.10.20.1.29).

3.1.3.1 Section conformance

CONF-QRDA1-176:   The procedure section **SHALL** contain `Section / code`.

CONF-QRDA1-177:   The value for `Section / code` **SHALL** be `47519-4 History of procedures` 2.16.840.1.113883.6.1 LOINC **STATIC**.

CONF-QRDA1-178:   The procedure section **SHALL** contain `Section / title`.

CONF-QRDA1-179:   `Section / title` **SHOULD** be valued with a case-insensitive language-insensitive text string containing procedures.

3.1.3.2 Clinical statement conformance

3.1.3.2.1   Procedure activity

The template identifier for a procedure activity is 2.16.840.1.113883.10.20.1.29.

CONF-QRDA1-180:   A procedure activity (templateId 2.16.840.1.113883.10.20.1.29) **SHALL** be represented with Act, Observation, or Procedure.

CONF-QRDA1-181:   The value for `[Act | Observation | Procedure] / @moodCode` in a procedure activity **SHALL** be `EVN` 2.16.840.1.113883.5.1001 `ActMood` **STATIC.**

CONF-QRDA1-182:   A procedure activity **SHALL** contain at least one `[Act | Observation | Procedure] / id`.

CONF-QRDA1-183:   A procedure activity **SHALL** contain exactly one `[Act | Observation | Procedure] / statusCode`.

CONF-QRDA1-184:   The value for `[Act | Observation | Procedure] / statusCode` in a procedure activity **SHALL** be selected from `ValueSet` 2.16.840.1.113883.1.11.20.15 `ProcedureStatusCode` **STATIC** 20061017.

CONF-QRDA1-185:   A procedure activity **SHALL** contain exactly one `[Act | Observation | Procedure] / effectiveTime`. The effectiveTime **SHALL** be at least precise to the day (YYYYMMDD).

CONF-QRDA1-186:   A procedure activity **SHALL** contain exactly one `[Act | Observation | Procedure] / code`.

CONF-QRDA1-187:   The value for `[Act | Observation | Procedure] / code/ @code and @codeSystem` in a procedure activity **SHALL** be selected from the Appendix_G-Procedures tab of the Downloadable Resources table.

3.1.3.2.2   Procedure related products

Procedure Example

```
<entry typeCode="DRIV">
    <procedure classCode="PROC" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.1.29"/>
        <!-- Procedure activity template -->
```

```
        <id root="2.16.840.1.113883.19.5.9" extension="123601"/>
        <code code="45.23" codeSystem="2.16.840.1.113883.6.104"
displayName="COLONOSCOPY"/>
        <statusCode code="completed"/>
        <effectiveTime value="20080510"/>
        <participant typeCode="DEV">
            <participantRole classCode="MANU">
                <templateId root="2.16.840.1.113883.10.20.1.52"/>
                <!-- Product instance template -->
                <id root="2.16.840.1.113883.19.5.9" extension="123609"/>
            </participantRole>
        </participant>
    </procedure>
</entry>
```

3.1.4 Payers Section

The template identifier for the Payers section is 2.16.840.1.113883.10.20.1.9.

Payers contains data on the patient's payers, whether "third party" insurance, self-pay, other payer or guarantor, or some combination of payers, and is used to define which entity is the responsible fiduciary for the financial aspects of a patient's care.

Each unique instance of a payer and all the pertinent data needed to contact, bill to, and collect from that payer should be included. Authorization information that can be used to define pertinent referral, authorization tracking number, procedure, therapy, intervention, device, or similar authorizations for the patient or provider, or both should be included. At a minimum, the patient's pertinent current payment sources should be listed.

The CMS EHR QRDA Report represents the sources of payment as a coverage act, which identifies all of the insurance policies or government or other programs that cover some or all of the patient's healthcare expenses. The policies or programs are sequenced by order of preference. Each policy or program identifies the covered party with respect to the payer, so that the identifiers can be recorded.

> **CONF-QRDA1-188:** CMS EHR QRDA Report **SHALL** contain exactly one and **SHALL NOT** contain more than one `Payers` section (templateId 2.16.840.1.113883.10.20.1.9). The Payers section **SHALL** contain a narrative block, and **SHALL** contain clinical statements. Clinical statements **SHALL** include one or more coverage activities (templateId 2.16.840.1.113883.10.20.1.20).

3.1.4.1 Section conformance

> **CONF-QRDA1-189:** The payer section **SHALL** contain `Section / code`.

> **CONF-QRDA1-190:** The value for Section / code **SHALL** be `48768-6 Payment sources` 2.16.840.1.113883.6.1 LOINC **STATIC**.

> **CONF-QRDA1-191:** The payer section **SHALL** contain `Section / title`.

> **CONF-QRDA1-192:** Section / title **SHOULD** be valued with a case-insensitive language-insensitive text string containing insurance or payers.

3.1.4.2 Clinical statement conformance

3.1.4.2.1   Payer representation

The template identifier for a coverage activity is 2.16.840.1.113883.10.20.1.20.

The template identifier for a policy activity is 2.16.840.1.113883.10.20.1.26.

The template identifier for an authorization activity is 2.16.840.1.113883.10.20.1.19.

Insurance and authorization acts are represented as Acts within the section. These acts are grouped together under a single coverage activity, which serves to order the payment sources. A coverage activity contains one or more policy activities, each of which contains zero or more authorization activities.

3.1.4.2.1.1   Coverage activity

> **CONF-QRDA1-193:**   A `coverage activity` (templateId 2.16.840.1.113883.10.20.1.20) **SHALL** be represented with `Act`.
>
> **CONF-QRDA1-194:**   The value for `Act / @classCode` in a coverage activity **SHALL** be ACT 2.16.840.1.113883.5.6 `ActClass` **STATIC**.
>
> **CONF-QRDA1-195:**   The value for `Act / @moodCode` in a coverage activity **SHALL** be DEF 2.16.840.1.113883.5.1001 `ActMood` **STATIC**.
>
> **CONF-QRDA1-196:**   A coverage activity **SHALL** contain at least one `Act / id`.
>
> **CONF-QRDA1-197:**   A coverage activity **SHALL** contain exactly one `Act / statusCode`.
>
> **CONF-QRDA1-198:**   The value for `Act / statusCode` in a coverage activity **SHALL** be completed 2.16.840.1.113883.5.14 `ActStatus` **STATIC**.
>
> **CONF-QRDA1-199:**   A coverage activity **SHALL** contain exactly one `Act / code`.
>
> **CONF-QRDA1-200:**   The value for `Act / code` in a coverage activity SHALL be 48768-6 `Payment sources` 2.16.840.1.113883.6.1 LOINC **STATIC**.
>
> **CONF-QRDA1-201:**   A coverage activity **SHALL** contain one or more `Act / entryRelationship`.
>
> **CONF-QRDA1-202:**   An `entryRelationship` in a coverage activity **MAY** contain exactly one `entryRelationship / sequenceNumber`, which serves to prioritize the payment sources.
>
> **CONF-QRDA1-203:**   The value for `Act / entryRelationship / @typeCode` in a coverage activity **SHALL** be COMP 2.16.840.1.113883.5.1002 `ActRelationshipType` STATIC.
>
> **CONF-QRDA1-204:**   The target of a coverage activity **SHALL** be a `policy activity` (templateId 2.16.840.1.113883.10.20.1.26).

3.1.4.2.1.2 Policy Activity

A policy activity represents the policy or program providing the coverage. The person for whom payment is being provided (i.e. the patient) is the covered party. The subscriber of the policy or program is represented as a participant that is the holder the coverage. The payer is represented as the performer of the policy activity.

> **CONF-QRDA1-205:** A `policy activity` (templateId 2.16.840.1.113883.10.20.1.26) **SHALL** be represented with Act.
>
> **CONF-QRDA1-206:** The value for `Act / @classCode` in a policy activity **SHALL** be `ACT` 2.16.840.1.113883.5.6 `ActClass` **STATIC**.
>
> **CONF-QRDA1-207:** The value for `Act / @moodCode` in a policy activity **SHALL** be `EVN` 2.16.840.1.113883.5.1001 `ActMood` **STATIC**.
>
> **CONF-QRDA1-208:** A policy activity **SHALL** contain at least one `Act / id`, which represents the group or contract number related to the insurance policy or program.
>
> **CONF-QRDA1-209:** A policy activity **SHALL** contain exactly one `Act / statusCode`.
>
> **CONF-QRDA1-210:** The value for `Act / statusCode` in a policy activity **SHALL** be completed 2.16.840.1.113883.5.14 `ActStatus` **STATIC**.
>
> **CONF-QRDA1-211:** A policy activity **SHOULD** contain zero to one `Act / code`., which represents the type of coverage.
>
> **CONF-QRDA1-212:** The value for `Act / code / @code` in a policy activity **SHALL** be selected from `ValueSet` 2.16.840.1.113883.1.11.19832 `ActCoverageType` DYNAMIC. The applicable values of ActCoverageType are available at Appendix_P-Payers of Downloadable Resource table. The value of Act/code/@codeSystem **SHALL** be 2.16.840.1.113883.5.4
>
> **CONF-QRDA1-213:** A policy activity **SHALL** contain exactly one `Act / performer [@typeCode=PRF]`, representing the payer.
>
> **CONF-QRDA1-214:** A payer in a policy activity **SHALL** contain one or more `performer / assignedEntity / id`, to represent the payer identification number. In addition to the payer identification number, an additional `id` **SHALL** be submitted, which represents the insurance plan type. The insurance plan type id/ @root **SHALL** be represented as 2.16.840.1.113883.12.86 where as the id/ @extension **SHALL** be selected from the values at Appendix_Q-Insurance_Plan_Type. **NOTE:** The EHR Warehouse allows patients with any type of insurance to be submitted. CMS EHR program participants must submit all Medicare beneficiary data related to the measures to ensure comparable data is available for potential incentive calculations.
>
> **CONF-QRDA1-215:** A policy activity **SHALL** contain exactly one `Act / participant [@typeCode=COV]`, representing the covered party.
>
> **CONF-QRDA1-216:** A covered party in a policy activity SHOULD contain one or more `participant / participantRole / id`, to represent the patient's member or subscriber identifier with respect to the payer. For `participant/participantRole/id`, either Social Security Number or HIC Number **SHALL** be submitted for Medicare patients.

For SSN, id/@root SHALL be 2.16.840.1.113883.4.1, where as for HIC number, id/@root **SHALL** be 2.16.840.1.113883.3.249.13

CONF-QRDA1-217:   A covered party in a policy activity **SHOULD** contain exactly one `participant / participantRole / code`, to represent the reason for coverage (e.g. Self, Family dependent, student).

CONF-QRDA1-218:   The value for `participant / participantRole / code` in a policy activity's covered party **MAY** be selected from `ValueSet` 2.16.840.1.113883.1.11.19809 `PolicyOrProgramCoverageRoleType` **DYNAMIC**.

CONF-QRDA1-219:   A covered party in a policy activity **MAY** contain exactly one `participant / time`, to represent the time period over which the patient is covered.

CONF-QRDA1-220:   A policy activity **MAY** contain exactly one `Act / participant [@typeCode=HLD]`, representing the subscriber.

CONF-QRDA1-221:   A subscriber in a policy activity **SHOULD** contain one or more `participant / participantRole / id`, to represent the subscriber's identifier with respect to the payer.

CONF-QRDA1-222:   A subscriber in a policy activity **MAY** contain exactly one `participant / time`, to represent the time period for which the subscriber is enrolled.

CONF-QRDA1-223:   The value for `Act / entryRelationship / @typeCode` in a policy activity **SHALL** be REFR 2.16.840.1.113883.5.1002 ActRelationshipType **STATIC**.

CONF-QRDA1-224:   The target of a policy activity with `Act / entryRelationship / @typeCode=REFR` **SHALL** be an `authorization activity` (templateId 2.16.840.1.113883.10.20.1.19) or an Act, with `Act [@classCode = ACT]` and `Act [@moodCode = DEF]`, representing a description of the coverage plan.

CONF-QRDA1-225:   A description of the coverage plan **SHALL** contain one or more `Act / Id`, to represent the plan identifier.

3.1.4.2.1.3   Authorization Activity

An authorization activity represents authorizations or pre-authorizations currently active for the patient for the particular payer.

Authorizations are represented using an act subordinate to the policy or program that provided it. The policy or program is referred to by the authorization. Authorized treatments can be grouped into an Organizer class, where common properties, such as the reason for the authorization, can be expressed. Subordinate acts represent what was authorized.

CONF-QRDA1-226:   An `authorization activity` (templateId 2.16.840.1.113883.10.20.1.19) **SHALL** be represented with Act.

CONF-QRDA1-227:   The value for `Act / @classCode` in an authorization activity **SHALL** be ACT 2.16.840.1.113883.5.6 ActClass **STATIC**.

CONF-QRDA1-228:   An authorization activity **SHALL** contain at least one `Act / id`.

CONF-QRDA1-229:   The value for `Act / @moodCode` in an authorization activity **SHALL** be EVN 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-QRDA1-230: An authorization activity **SHALL** contain one or more `Act /`
`entryRelationship`.

CONF-QRDA1-231: The value for `Act / entryRelationship / @typeCode` in an
authorization activity **SHALL** be SUBJ 2.16.840.1.113883.5.1002 ActRelationshipType **STATIC**.

CONF-QRDA1-232: The target of an authorization activity with `Act /`
`entryRelationship / @typeCode=SUBJ` **SHALL** be a clinical statement with
moodCode = PRMS (Promise).

CONF-QRDA1-233: The target of an authorization activity **MAY** contain one or more performer,
to indicate the providers that have been authorized to provide treatment.

Payers Example

```
<entry typeCode="DRIV">
    <act classCode="ACT" moodCode="DEF">
        <templateId root="2.16.840.1.113883.10.20.1.20"/>
        <!-- Coverage activity template -->
        <id root="2.16.840.1.113883.19.5.10" extension="100007"/>
        <code code="48768-6" codeSystem="2.16.840.1.113883.6.1" displayName="Payment
sources"/>
        <statusCode code="completed"/>
        <entryRelationship typeCode="COMP">
            <act classCode="ACT" moodCode="EVN">
                <templateId root="2.16.840.1.113883.10.20.1.26"/>
                <!-- Policy activity template -->
                <id root="2.16.840.1.113883.19.5.10" extension="100008"/>
                <code code="PUBLICPOL" codeSystem="2.16.840.1.113883.5.4"
                    displayName="Public healthcare"/>
                <statusCode code="completed"/>
                <performer typeCode="PRF">
                    <assignedEntity>
                        <!-- Medicare -->
                        <id root="2.16.840.1.113883.12.86" extension="MC"/>
                        <representedOrganization>
                            <name>CMS</name>
                        </representedOrganization>
                    </assignedEntity>
                </performer>
                <participant typeCode="COV">
                    <participantRole>
                        <!-- Medicare patients needs provide either SSN or HIC number
-->
                        <!-- SSN for the patient is given below -->
                        <id root="2.16.840.1.113883.4.1" extension="654329876"/>
                        <code code="SELF" codeSystem="2.16.840.1.113883.5.111"
displayName="Self"/>
                    </participantRole>
                </participant>
                <entryRelationship typeCode="REFR">
                    <act classCode="ACT" moodCode="EVN">
                        <templateId root="2.16.840.1.113883.10.20.1.19"/>
                        <!-- Authorization activity template -->
                        <id root="2.16.840.1.113883.19.5.10" extension="100010"/>
                        <code nullFlavor="NA"/>
                        <entryRelationship typeCode="SUBJ">
                            <procedure classCode="PROC" moodCode="PRMS">
                                <code code="73761001"
codeSystem="2.16.840.1.113883.6.96"
```

```
                              displayName="Colonoscopy"/>
                    </procedure>
                </entryRelationship>
            </act>
        </entryRelationship>
    </act>
</entryRelationship>
    </act>
</entry>
```

3.1.5 Alerts (Allergies, Adverse Reactions) Section

The template identifier for the alerts section is 2.16.840.1.113883.10.20.1.2.

This section is used to list and describe any allergies, adverse reactions, and alerts that are pertinent to the patient's current or past medical history. At a minimum, currently active and any relevant historical allergies and adverse reactions should be listed.

CONF-QRDA1-234:   The CMS EHR QRDA Report SHOULD contain exactly one and **SHALL NOT** contain more than one `Alerts section` (templateId 2.16.840.1.113883.10.20.1.2). The Alerts section **SHALL** contain a narrative block, and **SHALL** contain clinical statements. Clinical statements **SHALL** include one or more problem acts (templateId 2.16.840.1.113883.10.20.1.27). A problem act **SHALL** include one or more `alert observations` (templateId 2.16.840.1.113883.10.20.1.18).

CONF-QRDA1-235:   The absence of known allergies, adverse reactions, or alerts **SHALL** be explicitly asserted.

3.1.5.1 Section conformance

CONF-QRDA1-236:   The `alert section` **SHALL** contain `Section / code`.

CONF-QRDA1-237:   The value for `Section / code` **SHALL** be 48765-2 `Allergies, adverse reactions, alerts` 2.16.840.1.113883.6.1 LOINC **STATIC**.

CONF-QRDA1-238:   The alert section **SHALL** contain `Section / title`.

CONF-QRDA1-239:   `Section / title` **SHOULD** be valued with a case-insensitive language-insensitive text string containing `alert` and/or `allergies and adverse reactions`.

3.1.5.2 Clinical statement conformance

3.1.5.2.1 Representation of alerts

The template identifier for a problem act is 2.16.840.1.113883.10.20.1.27.
The template identifier for an alert observation is 2.16.840.1.113883.10.20.1.18.

A problem is a clinical statement that a clinician is particularly concerned about and wants to track.

3.1.5.2.1.1 Problem act

The problem act (templateId 2.16.840.1.113883.10.20.1.27) is defined above in the Problem section.

3.1.5.2.1.2 Alert Observation

CONF-QRDA1-240:   An `alert observation` (templateId 2.16.840.1.113883.10.20.1.18) **SHALL** be represented with Observation.

CONF-QRDA1-241:   The value for `Observation / @moodCode` in an alert observation **SHALL** be `EVN` 2.16.840.1.113883.5.1001 `ActMood` **STATIC**.

CONF-QRDA1-242:   An alert observation **SHALL** include exactly one `Observation / statusCode.`

CONF-QRDA1-243:   The value for `Observation / statusCode` in an alert observation **SHALL** be completed 2.16.840.1.113883.5.14 `ActStatus` **STATIC**.

CONF-QRDA1-244:   An alert observation **SHALL** 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). Observation/effectiveTime **SHALL** be at least precise to the day (YYYYMMDD).

CONF-QRDA1-245:   The value for `Observation / value` in an alert observation **MAY** be slected from Valueset 2.16.840.1.113883.1.11.20.4 AlertTypeCode **STATIC** 20061017

CONF-QRDA1-246:   The absence of known allergies **SHOULD** be represented in an alert observation by valuing `Observation / value` with 160244002 No known allergies 2.16.840.1.113883.6.96 SNOMED CT **STATIC**.

3.1.5.2.2 Representation of "Status" Values

The template identifier for an alert status observation is 2.16.840.1.113883.10.20.1.39.

CONF-QRDA1-247:   An alert observation **SHALL** contain exactly one alert status observation.

CONF-QRDA1-248:   The value of observation/code in `alert status observation` (templateId 2.16.840.1.113883.10.20.1.39) **SHALL** be 33999-4 status 2.16.840.1.113883.6.1 LOINC **STATIC**

CONF-QRDA1-249:   The value for `Observation / value` in an alert status observation **SHALL** be selected from `ValueSet` 2.16.840.1.113883.1.11.20.3 `AlertStatusCode` **STATIC** 20061017.

3.1.5.2.3 Representation of Agent

The agent indicates the entity that is the cause of the allergy or adverse reaction. While the agent is often implicit in the alert observation (e.g. "allergy to penicillin"), it should also be asserted explicitly as an entity.

CONF-QRDA1-250: An alert observation **SHALL** contain at least one `Observation / participant`, representing the agent that is the cause of the allergy or adverse reaction.

CONF-QRDA1-251: An agent participation in an alert observation **SHALL** contain exactly one `participant / participantRole / playingEntity`.

CONF-QRDA1-252: The value for `Observation / participant / @typeCode` in an agent participation **SHALL** be CSM Consumable 2.16.840.1.113883.5.90 ParticipationType STATIC.

CONF-QRDA1-253: The value for `Observation / participant / participantRole / @classCode` in an agent participation **SHALL** be `MANU Manufactured` 2.16.840.1.113883.5.110 RoleClass **STATIC**.

CONF-QRDA1-254: The value for `Observation / participant / participantRole / playingEntity / @classCode` in an agent participation **SHALL** be `MMAT Manufactured` material 2.16.840.1.113883.5.41 `EntityClass` **STATIC**.

CONF-QRDA1-255: An agent participation in an alert observation **SHALL** contain exactly one `participant / participantRole / playingEntity / code`.

CONF-QRDA1-256: The value for `participant / participantRole / playingEntity / code` **SHALL** be selected from the Appendix_H-Alerts tab of the Downloadable Resources table.

3.1.5.2.4 Reaction Observations and Interventions

The template identifier for a reaction observation is 2.16.840.1.113883.10.20.1.54.
The template identifier for a severity observation is 2.16.840.1.113883.10.20.1.55.
A reaction represents an adverse event due to an administered or exposed substance. A reaction can be defined with respect to its severity, and can have been treated by one or more interventions.

CONF-QRDA1-257: An alert observation MAY contain one or more `reaction observations` (templateId 2.16.840.1.113883.10.20.1.54), each of which **MAY** contain exactly one severity observation (templateId 2.16.840.1.113883.10.20.1.55) AND/OR one or more reaction interventions.

CONF-QRDA1-258: The value for `entryRelationship / @typeCode` in a relationship between an alert observation and reaction observation **SHALL** be `MFST Is manifestation of` 2.16.840.1.113883.5.1002 `ActRelationshipType` **STATIC**.

3.1.5.2.4.1 Reaction Observation

CONF-QRDA1-259: A `reaction observation` (templateId 2.16.840.1.113883.10.20.1.54) **SHALL** be represented with Observation.

CONF-QRDA1-260: The value for `Observation / @classCode` in a reaction observation **SHALL** be OBS 2.16.840.1.113883.5.6 `ActClass` **STATIC**.

CONF-QRDA1-261: The value for `Observation / @moodCode` in a reaction observation **SHALL** be EVN 2.16.840.1.113883.5.1001 `ActMood` **STATIC**.

CONF-QRDA1-262: A reaction observation **SHALL** include exactly one `Observation / statusCode`.

CONF-QRDA1-263: The value for `Observation / statusCode` in a reaction observation **SHALL** be completed 2.16.840.1.113883.5.14 `ActStatus` **STATIC**.

3.1.5.2.4.2   Severity Observation

CONF-QRDA1-401: A severity observation (templateId 2.16.840.1.113883.10.20.1.55) **SHALL** be represented with `Observation`.

CONF- QRDA1-402: The value for `entryRelationship / @typeCode` in a relationship between a reaction observation and severity observation **SHALL** be SUBJ Has subject 2.16.840.1.113883.5.1002 `ActRelationshipType` **STATIC**.

CONF- QRDA1-403: The value for `Observation / @classCode` in a severity observation **SHALL** be OBS 2.16.840.1.113883.5.6 `ActClass` **STATIC**.

CONF- QRDA1-404: The value for `Observation / @moodCode` in a severity observation **SHALL** be EVN 2.16.840.1.113883.5.1001 `ActMood` **STATIC**.

CONF- QRDA1-405: A severity observation **SHALL** include exactly one `Observation / statusCode`.

CONF- QRDA1-406: The value for `Observation / statusCode` in a severity observation **SHALL** be `completed` 2.16.840.1.113883.5.14 `ActStatus` **STATIC**.

CONF- QRDA1-407: A severity observation **SHALL** contain exactly one Observation / code.

CONF- QRDA1-408: The value for `Observation / code` in a severity observation **SHALL** be SEV Severity observation 2.16.840.1.113883.5.4 ActCode **STATIC**.

CONF- QRDA1-409: A severity observation **SHALL** contain exactly one `Observation / value`. The <value> element contains the level of severity. It is always represented using the CD datatype (xsi:type='CD'), even though the value may be a coded or uncoded string. If coded, it should use the HL7 SeverityObservation vocabulary (codeSystem='2.16.840.1.113883.5.1063') containing three values (H, M, and L), representing high, moderate and low severity depending upon whether the severity is life threatening, presents noticeable adverse consequences, or is unlikely substantially effect the situation of the subject.

3.1.5.2.5   Reaction Intervention

CONF-QRDA1-264: The value for `entryRelationship / @typeCode` in a relationship between a reaction observation and reaction intervention **SHALL** be `RSON Has reason` 2.16.840.1.113883.5.1002 `ActRelationshipType` **STATIC**.

CONF-QRDA1-265: A `reaction intervention` **SHALL** be represented as a `procedure activity` (templateId 2.16.840.1.113883.10.20.1.29), a `medication activity` (templateId 2.16.840.1.113883.10.20.1.24), or some other clinical statement.

Alerts Example

```
<entry typeCode="DRIV">
    <act classCode="ACT" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.1.27"/>
        <!-- Problem act template -->
        <id root="2.16.840.1.113883.19.5.10" extension="100015"/>
        <code nullFlavor="NA"/>
        <entryRelationship typeCode="SUBJ">
            <observation classCode="OBS" moodCode="EVN">
                <templateId root="2.16.840.1.113883.10.20.1.18"/>
                <!-- Alert observation template -->
                <id root="2.16.840.1.113883.19.5.10" extension="100016"/>
                <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
                <statusCode code="completed"/>
                <effectiveTime>
                    <low value="20080812"/>
                </effectiveTime>
                <value xsi:type="CD" code="282100009"
codeSystem="2.16.840.1.113883.6.96"
                    displayName="Adverse reaction to substance"/>
                <participant typeCode="CSM">
                    <participantRole classCode="MANU">
                        <playingEntity classCode="MMAT">
                            <code code="294647003" codeSystem="2.16.840.1.113883.6.96"
                                displayName="INFLUENZA VACCINE"/>
                        </playingEntity>
                    </participantRole>
                </participant>
                <entryRelationship typeCode="MFST" inversionInd="true">
                    <observation classCode="OBS" moodCode="EVN">
                        <templateId root="2.16.840.1.113883.10.20.1.54"/>
                        <!-- Reaction observation template -->
                        <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
                        <statusCode code="completed"/>
                        <value xsi:type="CD" code="247472004"
codeSystem="2.16.840.1.113883.6.96"
                            displayName="Hives"/>
                    </observation>
                </entryRelationship>
                <entryRelationship typeCode="REFR">
                    <observation classCode="OBS" moodCode="EVN">
                        <templateId root="2.16.840.1.113883.10.20.1.39"/>
                        <!-- Alert status observation template -->
                        <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
displayName="Status"/>
                        <statusCode code="completed"/>
                        <value xsi:type="CE" code="55561003"
codeSystem="2.16.840.1.113883.6.96"
                            displayName="Active"/>
```

```
            </observation>
          </entryRelationship>
        </observation>
      </entryRelationship>
    </act>
  </entry>
</entry>
```

3.1.6 Medications Section

The template identifier for the medications section is 2.16.840.1.113883.10.20.1.8.

The Medications section defines a patient's current medications and pertinent medication history. At a minimum, the currently active medications should be listed. The section may also include a patient's prescription history, and enables the determination of the source of a medication list (e.g. from a pharmacy system vs. from the patient).

> **CONF-QRDA1-266:** The CMS EHR QRDA Report **SHOULD** contain exactly one and **SHALL NOT** contain more than one Medications section (templateId 2.16.840.1.113883.10.20.1.8). The Medications section **SHALL** contain a narrative block, and **SHALL** contain clinical statements. Clinical statements **SHALL** include one or more medication activities (templateId 2.16.840.1.113883.10.20.1.24) and/or supply activities (templateId 2.16.840.1.113883.10.20.1.34).

> **CONF-QRDA1-267:** The absence of known medications **SHALL** be explicitly asserted.

3.1.6.1 Section conformance

> **CONF-QRDA1-268:** The medications section **SHALL** contain Section / code.

> **CONF-QRDA1-269:** The value for Section / code **SHALL** be 10160-0 History of medication use 2.16.840.1.113883.6.1 LOINC **STATIC**.

> **CONF-QRDA1-270:** The medications section **SHALL** contain Section / title.

> **CONF-QRDA1-271:** Section / title **SHOULD** be valued with a case-insensitive language-insensitive text string containing medication.

3.1.6.2 Clinical statement conformance

3.1.6.2.1 Medication and supply activities

The template identifier for a medication activity is 2.16.840.1.113883.10.20.1.24.
The template identifier for a supply activity is 2.16.840.1.113883.10.20.1.34.

A medication activity (templateId 2.16.840.1.113883.10.20.1.24) is used to describe what is administered whereas a supply activity (templateId 2.16.840.1.113883.10.20.1.34) is used to describe what has been dispensed.

3.1.6.2.1.1 Medication activity

CONF-QRDA1-272: A `medication activity` (templateId 2.16.840.1.113883.10.20.1.24) **SHALL** be represented with `SubstanceAdministration`.

CONF-QRDA1-273: The value for `SubstanceAdministration / @moodCode` in a medication activity **SHALL** be `EVN` or `INT` 2.16.840.1.113883.5.1001 `ActMood` **STATIC**.

CONF-QRDA1-274: A medication activity **SHALL** contain at least one `SubstanceAdministration / id`.

CONF-QRDA1-275: A medication activity **SHOULD** contain exactly one `SubstanceAdministration / status`Code.

CONF-QRDA1-276: A medication activity **SHALL** contain one or more `SubstanceAdministration / effectiveTime` elements, used to indicate the actual or intended start and stop date of a medication, and the frequency of administration. SubstanceAdministration/effectiveTime **SHALL** be at least precise to the day (YYYYMMDD).

CONF-QRDA1-277: A medication activity **SHOULD** contain exactly one `SubstanceAdministration / route`Code.

CONF-QRDA1-278: The value for `SubstanceAdministration / route`Code in a medication activity **SHOULD** be selected from the HL7 `RouteOfAdministration` (2.16.840.1.113883.5.112) code system.

CONF-QRDA1-279: A medication activity **SHOULD** contain exactly one `SubstanceAdministration / doseQuantity` or `SubstanceAdministration / rateQuantity`.

CONF-QRDA1-280: A medication activity **MAY** contain exactly one `SubstanceAdministration / maxDoseQuantity`, which represents a maximum dose limit.

CONF-QRDA1-281: A medication activity **MAY** contain one or more `SubstanceAdministration / performer`, to indicate the person administering a substance.

3.1.6.2.1.2   Supply activity

CONF-QRDA1-282: A `supply activity` (templateId 2.16.840.1.113883.10.20.1.34) **SHALL** be represented with `Supply`.

CONF-QRDA1-283: The value for `Supply / @mood`Code in a supply activity **SHALL** be `EVN` or `INT` 2.16.840.1.113883.5.1001 `ActMood` **STATIC**.

CONF-QRDA1-284: A supply activity **SHALL** contain at least one `Supply / id`.

CONF-QRDA1-285: A supply activity **SHOULD** contain exactly one `Supply / statusCode`.

CONF-QRDA1-286: A supply activity **SHOULD** contain exactly one `Supply / effectiveTime`, to indicate the actual or intended time of dispensing.

CONF-QRDA1-287: A supply activity **MAY** contain exactly one `Supply / repeatNumber`, to indicate the number of fills. (Note that Supply / repeatNumber corresponds to the number of fills, as opposed to the number of refills).

CONF-QRDA1-288: A supply activity **MAY** contain exactly one `Supply / quantity`, to indicate the actual or intended supply quantity.

CONF-QRDA1-289: A supply activity **MAY** contain one or more `Supply / author`, to indicate the prescriber.

CONF-QRDA1-290: A supply activity **MAY** contain one or more `Supply / performer`, to indicate the person dispensing the product.

CONF-QRDA1-291: A supply activity **MAY** contain exactly one `Supply / participant / @typeCode = LOC`, to indicate the supply location.

3.1.6.2.2 Medication related information

The template identifier for a patient instruction is 2.16.840.1.113883.10.20.1.49.

The template identifier for a fulfillment instruction is 2.16.840.1.113883.10.20.1.43.

The template identifier for a medication series number observation is 2.16.840.1.113883.10.20.1.46. The template identifier for a reaction observation is 2.16.840.1.113883.10.20.1.54.

The template identifier for a severity observation is 2.16.840.1.113883.10.20.1.55.

3.1.6.2.2.1 Indications

An indication describes the rationale for an activity. The indication can be an existing problem or can be a criterion that if met would warrant the activity. Criteria are typically associated with PRN (from the Latin "pro re nata", meaning "as needed") medications (e.g. "give Medication X as needed for nausea").

CONF-QRDA1-292: A medication activity **MAY** contain one or more `SubstanceAdministration / precondition / Criterion`, to indicate that the medication is administered only when the associated (coded or free text) criteria are met.

CONF-QRDA1-293: A medication activity **MAY** contain one or more `SubstanceAdministration / entryRelationship`, whose value for `entryRelationship / @type`Code **SHALL** be `RSON Has reason` 2.16.840.1.113883.5.1002 `ActRelationshipType` **STATIC**, where the target of the relationship represents the indication for the activity.

CONF-QRDA1-294: `SubstanceAdministration / entryRelationship / @typeCode=RSON` in a medication activity **SHALL** have a target of `problem act` (templateId 2.16.840.1.113883.10.20.1.27), `problem observation` (templateId 2.16.840.1.113883.10.20.1.28), or some other clinical statement.

3.1.6.2.2.2 Patient Instructions

Patient instructions are additional information provided to a patient related to one of their medications (e.g. "take on an empty stomach").

CONF-QRDA1-295: A medication activity **MAY** contain one or more `patient instructions`.

CONF-QRDA1-296: A patient instruction (templateId 2.16.840.1.113883.10.20.1.49) **SHALL** be represented with `Act`.

CONF-QRDA1-297: The value for `Act / @mood`Code in a patient instruction **SHALL** be `INT Intent` 2.16.840.1.113883.5.1001 `ActMood` **STATIC**.

CONF-QRDA1-298: The value for `entryRelationship / @type`Code in a relationship to a patient instruction **SHALL** be `SUBJ Subject` 2.16.840.1.113883.5.1002 `ActRelationshipType` **STATIC**.

3.1.6.2.2.3 Fulfillment Instructions

Fulfillment instructions are additional information provided to the dispensing party (e.g. "label in Spanish").

CONF-QRDA1-299: A supply activity **MAY** contain one or more `fulfillment instructions`.

CONF-QRDA1-300: A fulfillment instruction (templateId 2.16.840.1.113883.10.20.1.43) **SHALL** be represented with `Act`.

CONF-QRDA1-301: The value for `Act / @mood`Code in a fulfillment instruction **SHALL** be `INT Intent` 2.16.840.1.113883.5.1001 `ActMood` **STATIC**.

CONF-QRDA1-302: The value for `entryRelationship / @type`Code in a relationship between a supply activity and fulfillment instruction **SHALL** be `SUBJ Subject` 2.16.840.1.113883.5.1002 `ActRelationshipType` **STATIC**.

3.1.6.2.2.4 Medication Series Number Observation

The medication series number observation can be used to indicate which in a series of administrations a particular administration represents (e.g. "hepatitis B vaccine number 2 was administered on Feb 07, 2004).

CONF-QRDA1-303: A medication activity **MAY** contain exactly one `medication series number observations`.

CONF-QRDA1-304: The value for `entryRelationship / @type`Code in a relationship between a medication activity and medication series number observation **SHALL** be `SUBJ Subject` 2.16.840.1.113883.5.1002 `ActRelationshipType` **STATIC**.

CONF-QRDA1-305: A `medication series number observation` (templateId 2.16.840.1.113883.10.20.1.46) **SHALL** be represented with Observation.

CONF-QRDA1-306: The value for `Observation / @class`Code in a medication series number observation **SHALL** be `OBS` 2.16.840.1.113883.5.6 `ActClass` **STATIC**.

CONF-QRDA1-307: The value for `Observation / @mood`Code in a medication series number observation **SHALL** be `EVN` 2.16.840.1.113883.5.1001 `ActMood` **STATIC**.

CONF-QRDA1-308: A medication series number observation **SHALL** include exactly one `Observation / statusCode`.

CONF-QRDA1-309: A medication series number observation **SHALL** contain exactly one `Observation / code`.

CONF-QRDA1-310: The value for `Observation / code` in a medication series number observation **SHALL** be 30973-2 `Dose number` 2.16.840.1.113883.6.1 LOINC **STATIC**.

CONF-QRDA1-311: A medication series number observation **SHALL** contain exactly one `Observation / value`.

CONF-QRDA1-312: The data type for `Observation / value` in a medication series number observation **SHALL** be `INT (integer)`.

3.1.6.2.2.5   Reaction Observations and Interventions

A reaction represents an adverse event due to an administered substance. Significant reactions are to be listed in the Alerts section. Reactions in the Medications section can be used to track reactions associated with individual substance administrations or to track routine follow up to an administration (e.g. "no adverse reaction 30 minutes post administration").

The reaction observation (templateId 2.16.840.1.113883.10.20.1.54) and severity observation (templateId 2.16.840.1.113883.10.20.1.55) templates are defined above, in the Alerts section.

CONF-QRDA1-313: A medication activity **MAY** contain one or more `reaction observations` (templateId 2.16.840.1.113883.10.20.1.54), each of which **MAY** contain exactly one `severity observation` (templateId 2.16.840.1.113883.10.20.1.55) AND/OR one or more reaction interventions.

CONF-QRDA1-314: The value for `entryRelationship / @type`Code in a relationship between a medication activity and reaction observation **SHALL** be `CAUS Is etiology for` 2.16.840.1.113883.5.1002 `ActRelationshipType` **STATIC**.

3.1.6.2.3   Representation of "Status" Values

The template identifier for a medication status observation is 2.16.840.1.113883.10.20.1.47.

CONF-QRDA1-315: A medication activity **MAY** contain exactly one medication status observation.

CONF-QRDA1-316: A supply activity **MAY** contain exactly one medication status observation.

CONF-QRDA1-317: A medication `status observation` (templateId 2.16.840.1.113883.10.20.1.47) **SHALL** be a conformant `status observation` (templateId 2.16.840.1.113883.10.20.1.57).

CONF-QRDA1-318: The value for `Observation / value` in a medication status observation **SHALL** be selected from `ValueSet` 2.16.840.1.113883.1.11.20.7 `MedicationStatusCode` **STATIC** 20061017.

3.1.6.2.4   Representation of a Product

The template identifier for a product is 2.16.840.1.113883.10.20.1.53.

The template identifier for a product instance is 2.16.840.1.113883.10.20.1.52.

CONF-QRDA1-319: A medication activity **SHALL** contain exactly one SubstanceAdministration / consumable, the target of which is a product template.

CONF-QRDA1-320: A supply activity **MAY** contain exactly one Supply / product, the target of which is a product template.

CONF-QRDA1-321: A product (templateId 2.16.840.1.113883.10.20.1.53) **SHALL** be represented with the manufacturedProduct class.

CONF-QRDA1-322: A manufacturedProduct in a product template **SHALL** contain exactly one manufacturedProduct / manufacturedMaterial.

CONF-QRDA1-323: A manufacturedMaterial in a product template **SHALL** contain exactly one manufacturedMaterial / code.

CONF-QRDA1-324: The value for manufacturedMaterial / code in a product template **SHALL** be selected from the Appendix_A-Medications tab of the Downloadable Resources table.

CONF-QRDA1-325: The value for `manufacturedMaterial / code` in a product template **SHALL** contain `a precoordinated product strength, product form, or product concentration` (e.g. "metoprolol 25mg tablet", "amoxicillin 400mg/5mL suspension").

CONF-QRDA1-326: If `manufacturedMaterial / code` contains a precoordinated unit dose (e.g. "metoprolol 25mg tablet"), then `SubstanceAdministration / doseQuantity` **SHALL** be a unitless number that indicates the number of products given per administration.

CONF-QRDA1-327: If `manufacturedMaterial / code` does not contain a precoordinated unit dose (e.g. "metoprolol product"), then `SubstanceAdministration / doseQuantity` **SHALL** be a physical quantity that indicates the amount of product given per administration.

CONF-QRDA1-328: A `manufacturedMaterial` in a product template **SHALL** contain exactly one `Material / code / originalText`, which represents the generic name of the product.

CONF-QRDA1-329: A `manufacturedMaterial` in a product template **MAY** contain exactly one `Material / name`, which represents the brand name of the product.

CONF-QRDA1-330: A `manufacturedProduct` in a product template **MAY** contain exactly one `manufacturedProduct / manufacturerOrganization`, which represents the manufacturer of the Material.

CONF-QRDA1-331: A `manufacturedProduct` in a product template **MAY** contain one or more `manufacturedProduct / id`, which uniquely represent a particular kind of product.

CONF-QRDA1-332: `manufacturedProduct` in a product template contains `manufacturedProduct / id`, then `ManufacturedProduct` **SHOULD** also contain `manufacturedProduct / manufacturerOrganization`.

CONF-QRDA1-333: A medication activity **MAY** contain one or more `product instance` templates (templateId 2.16.840.1.113883.10.20.1.52) to identify a particular product instance.

CONF-QRDA1-334: A supply activity **MAY** contain one or more product instance templates (templateId 2.16.840.1.113883.10.20.1.52) to identify a particular product instance.

CONF-QRDA1-335: Supply / participant / participantRole / id **SHOULD** be set to equal a [Act | Observation | Procedure] / participant / participantRole / id to indicate that the Supply and the Procedure are referring to the same product instance.

Medication Example

```
<entry typeCode="DRIV">
    <substanceAdministration classCode="SBADM" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.1.24"/>
        <!-- Medication activity template -->
        <id root="2.16.840.1.113883.19.5.10" extension="100016"/>
        <statusCode code="active"/>
        <effectiveTime xsi:type="IVL_TS">
            <low value="19900328"/>
        </effectiveTime>
        <effectiveTime xsi:type="PIVL_TS" operator="A">
            <period value="24" unit="h"/>
        </effectiveTime>
        <routeCode code="PO" codeSystem="2.16.840.1.113883.5.112"
            codeSystemName="RouteOfAdministration"/>
        <doseQuantity value="1"/>
        <consumable>
            <manufacturedProduct>
                <templateId root="2.16.840.1.113883.10.20.1.53"/>
                <!-- Product template -->
                <manufacturedMaterial>
                    <code code="00006057782" codeSystem="2.16.840.1.113883.6.69"
                        displayName="Metformin-Sitagliptin 1000 mg-50 mg oral tablet">
                        <originalText>Metformin</originalText>
                    </code>
                </manufacturedMaterial>
            </manufacturedProduct>
        </consumable>
    </substanceAdministration>
</entry>
```

3.1.7 Immunizations Section

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.

CONF-QRDA1-336: The CMS EHR QRDA Report **SHOULD** contain exactly one and **SHALL NOT** contain more than one Immunizations section (templateId 2.16.840.1.113883.10.20.1.6). The Immunizations section **SHALL** contain a narrative block, and **SHALL** contain clinical statements. Clinical statements **SHALL** include one or more medication activities (templateId 2.16.840.1.113883.10.20.1.24) and/or supply activities (templateId 2.16.840.1.113883.10.20.1.34).

3.1.7.1 Section conformance

CONF-QRDA1-337: The immunizations section **SHALL** contain `Section / code`.

CONF-QRDA1-338: The value for Section / code **SHALL** be `11369-6 History of immunizations` 2.16.840.1.113883.6.1 LOINC **STATIC**.

CONF-QRDA1-339: The immunizations section **SHALL** contain `Section / title`.

CONF-QRDA1-340: Section / title **SHOULD** be valued with a case-insensitive language-insensitive text string containing immunization.

3.1.7.2 Clinical statement conformance

The CMS EHR QRDA Report defines Immunizations using the same data objects and constraints as for Medications except use Appendix_D-Immunizations tab of the Downloadable Resources table for value for manufacturedMaterial / code in a product template.

Immunization Example

```
<entry typeCode="DRIV">
    <substanceAdministration classCode="SBADM" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.1.24"/>
        <!-- Medication activity template -->
        <id root="2.16.840.1.113883.19.5.10" extension="100020"/>
        <statusCode code="completed"/>
        <effectiveTime xsi:type="IVL_TS">
            <center value="20051128"/>
        </effectiveTime>
        <routeCode code="IM" codeSystem="2.16.840.1.113883.5.112"
            codeSystemName="RouteOfAdministration" displayName="Intramuscular
injection"/>
        <consumable>
            <manufacturedProduct>
                <templateId root="2.16.840.1.113883.10.20.1.53"/>
                <!-- Product template -->
                <manufacturedMaterial>
                    <code code="15" codeSystem="2.16.840.1.113883.6.59"
                        displayName="INFLUENZA VIRUS VACCINE, SPLIT">
                        <originalText>INFLUENZA VIRUS VACCINE, SPLIT</originalText>
                    </code>
                </manufacturedMaterial>
            </manufacturedProduct>
        </consumable>
    </substanceAdministration>
</entry>
```

3.1.8 Results

The template identifier for the results section is 2.16.840.1.113883.10.20.1.14.

This section contains the results of observations generated by laboratories, imaging procedures, and other procedures. The scope includes hematology, chemistry, serology, virology, toxicology, microbiology,

plain x-ray, ultrasound, CT, MRI, angiography, cardiac echo, nuclear medicine, pathology, and procedure observations. The section may contain all results for the period of time being summarized, but should include notable results such as abnormal values or relevant trends.

Lab results are typically generated by laboratories providing analytic services in areas such as chemistry, hematology, serology, histology, cytology, anatomic pathology, microbiology, and/or virology. These observations are based on analysis of specimens obtained from the patient, submitted to the lab. Imaging results are typically generated by a clinician reviewing the output of an imaging procedure, such as where a cardiologist reports the left ventricular ejection fraction based on the review of a cardiac echo. Procedure results are typically generated by a clinician wanting to provide more granular information about component observations made during the performance of a procedure, such as where a gastroenterologist reports the size of a polyp observed during a colonoscopy.

> **CONF-QRDA1-341:**   The CMS EHR QRDA Report SHOULD contain exactly one and **SHALL NOT** contain more than one `Results section` (templateId 2.16.840.1.113883.10.20.1.14). The Results section **SHALL** contain a narrative block, and **SHALL** contain clinical statements. Clinical statements **SHALL** include one or more `result organizers` (templateId 2.16.840.1.113883.10.20.1.32), each of which **SHALL** contain one or more `result observations` (templateId 2.16.840.1.113883.10.20.1.31).

3.1.8.1 Section conformance

> **CONF-QRDA1-342:**   The result section **SHALL** contain `Section / code`.

> **CONF-QRDA1-343:**   The value for Section / code **SHALL** be 30954-2 `Relevant diagnostic tests and/or laboratory data` 2.16.840.1.113883.6.1 LOINC **STATIC**.

> **CONF-QRDA1-344:**   The results section **SHALL** contain `Section / title`.

> **CONF-QRDA1-345:**   Section / title **SHOULD** be valued with a case-insensitive language-insensitive text string containing results.

3.1.8.2 Clinical statement conformance

3.1.8.3 Results representation

The template identifier for a result organizer is 2.16.840.1.113883.10.20.1.32.

The template identifier for a result observation is 2.16.840.1.113883.10.20.1.31.

3.1.8.3.1.1   Result organizer

The result organizer identifies an observation set, contained with the result organizer as a set of result observations. It contains information applicable to all of the contained result observations.

> **CONF-QRDA1-346:**   A `result organizer` (templateId 2.16.840.1.113883.10.20.1.32) **SHALL** be represented with Organizer.

CONF-QRDA1-347: The value for `Organizer / @moodCode` in a result organizer **SHALL** be EVN 2.16.840.1.113883.5.1001 `ActMood` **STATIC**.

CONF-QRDA1-348: A result organizer **SHALL** contain at least one `Organizer / id`.

CONF-QRDA1-349: A result organizer **SHALL** contain exactly one `Organizer / statusCode`.

CONF-QRDA1-350: A result organizer **SHALL** contain exactly one `Organizer / code`.

CONF-QRDA1-351: The value for `Organizer / code` in a result organizer **MAY** be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96), and **MAY** be selected from `CPT-4` (codeSystem 2.16.840.1.113883.6.12) or `ValueSet` 2.16.840.1.113883.1.11.20.16 `ResultTypeCode` **STATIC**.

CONF-QRDA1-352: A result organizer **SHOULD** include one or more `Organizer / specimen` if the specimen isn't inherent in `Organizer / code`.

CONF-QRDA1-353: `Organizer / specimen` **SHALL NOT** conflict with the specimen inherent in `Organizer / code`.

CONF-QRDA1-354: `Organizer / specimen / specimenRole / id` **SHOULD** be set to equal a `Procedure / specimen / specimenRole / id` to indicate that the Results and the Procedure are referring to the same specimen.

CONF-QRDA1-355: A result organizer **SHALL** contain one or more `Organizer / component`.

CONF-QRDA1-356: The target of one or more result organizer `Organizer / component` relationships **MAY** be a procedure, to indicate the means or technique by which a result is obtained, particularly if the means or technique isn't inherent in `Organizer / code` or if there is a need to further specialize the `Organizer / code` value.

CONF-QRDA1-357: A result organizer `Organizer / component / procedure` **MAY** be a reference to a procedure described in the Procedure section.

CONF-QRDA1-358: The target of one or more result organizer `Organizer / component` relationships **SHALL** be a result observation.

3.1.8.3.1.2 Result observation

CONF-QRDA1-359: A result observation (templateId 2.16.840.1.113883.10.20.1.31) **SHALL** be represented with Observation.

CONF-QRDA1-360: The value for Observation / @moodCode in a result observation **SHALL** be EVN 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-QRDA1-361: A result observation **SHALL** contain at least one Observation / id.

CONF-QRDA1-362: A result observation **SHALL** contain exactly one Observation / statusCode.

CONF-QRDA1-363: A result observation **SHALL** contain exactly one Observation / effectiveTime, which represents the biologically relevant time (e.g. time the specimen was obtained from the patient). The result observation time **SHALL** be at least precise to the day.

CONF-QRDA1-364: A result observation **SHALL** contain exactly one Observation / code.

CONF-QRDA1-365: The value for Observation / code in a result observation **SHALL** be selected from Appendix_F-Results tab of the Downloadable Resources table.

CONF-QRDA1-366: A result observation **MAY** contain exactly one Observation / methodCode if the method isn't inherent in Observation / code or if there is a need to further specialize the method in Observation / code.

CONF-QRDA1-367: Observation / methodCode **SHALL NOT** conflict with the method inherent in Observation / code.

CONF-QRDA1-368: A result observation **SHALL** contain exactly one Observation / value.

CONF-QRDA1-369: The Results observation 'value' **SHALL** be great than or equal to the MINIMUM VALUE and less than or equal to the MAXIUMUM VALUE as referenced in Appendix F of the Downloadable Resource table for the observation 'code' submitted. The Results observation 'unit' value **SHALL** be submitted using a valid UNIT OF MEASURE as referenced in Appendix F of the Downloadable Resource table for the observation 'code' submitted.

CONF-QRDA1-370: A result observation **SHOULD** contain exactly one Observation / interpretationCode, which can be used to provide a rough qualitative interpretation of the observation, such as "N" (normal), "L" (low), "S" (susceptible), etc. Interpretation is generally provided for numeric results where an interpretation range has been defined, or for antimicrobial susceptibility test interpretation.

CONF-QRDA1-371: A result observation **SHOULD** contain one or more Observation / referenceRange to show the normal range of values for the observation result.

CONF-QRDA1-372: A result observation **SHALL NOT** contain Observation / referenceRange / observationRange / code, as this attribute is not used by the HL7 Clinical Statement or Lab Committee models.

CONF-QRDA1-373: A result observation **SHALL** contain one or more sources of information.

Results Example

```
<entry contextConductionInd="true" typeCode="DRIV">
    <organizer classCode="BATTERY" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.1.32"/>
        <id root="2.16.840.1.113883.19.5.10" extension="112708"/>
        <code code="275711006" codeSystem="2.16.840.1.113883.6.96"
displayName="Chemistry"/>
        <statusCode code="completed"/>
        <effectiveTime value="20000323"/>
        <component contextConductionInd="true">
            <observation classCode="OBS" moodCode="EVN">
                <templateId root="2.16.840.1.113883.10.20.1.31"/>
                <id root="2.16.840.1.113883.19.5.10" extension="112709"/>
                <code xsi:type="CE" code="12773-8" codeSystem="2.16.840.1.113883.6.1"
displayName="LDLC SERPL ELPH-ACNC"/>
```

```xml
                    <statusCode code="completed"/>
                    <effectiveTime value="200003231430"/>
                    <value xsi:type="PQ" unit="mg/dl" value="200"/>
                    <interpretationCode code="N" codeSystem="2.16.840.1.113883.5.83"/>
                    <referenceRange>
                        <observationRange>
                            <text>20-600 mg/dl</text>
                        </observationRange>
                    </referenceRange>
                </observation>
            </component>
        </organizer>
    </entry>
```

3.1.9   Vital Signs Section

The template identifier for the vital signs section is 2.16.840.1.113883.10.20.1.16.
This section contains current and historically relevant vital signs, such as blood pressure, heart rate, respiratory rate, height, weight, body mass index, head circumference, crown-to-rump length, and pulse oximetry. The section may contain all vital signs for the reporting period of time.
Vital signs are represented like other results, but are aggregated into their own section in order to follow clinical conventions.

> **CONF-QRDA1-374:**   The CMS EHR QRDA Report **SHOULD** contain exactly one and **SHALL NOT** contain more than one `Vital signs` section (templateId 2.16.840.1.113883.10.20.1.16). The Vital signs section **SHALL** contain a narrative block, and **SHALL** contain clinical statements. Clinical statements **SHALL** include one or more `vital signs organizers` (templateId 2.16.840.1.113883.10.20.1.35), each of which **SHALL** contain one or more `result observations` (templateId 2.16.840.1.113883.10.20.1.31).

3.1.9.1   Section conformance

> **CONF-QRDA1-375:**   The vital signs section **SHALL** contain `Section / code`.

> **CONF-QRDA1-376:**   The value for Section / code **SHALL** be `8716-3 Vital signs` 2.16.840.1.113883.6.1 LOINC **STATIC**.

> **CONF-QRDA1-377:**   The vital signs section **SHALL** contain `Section / title`.

> **CONF-QRDA1-378:**   `Section / title` **SHOULD** be valued with a case-insensitive language-insensitive text string containing vital signs.

3.1.9.2 Clinical statement conformance

The template identifier for a vital signs organizer is 2.16.840.1.113883.10.20.1.35.

Vital signs are represented like other results with additional vocabulary constraints. Except the value for Observation / code in a result observation template of Vital Signs Entry **SHALL** be selected from Appendix_E-Vital_Signs tab of the Downloadable Resources table.

> **CONF-QRDA1-379:**   A vital signs organizer (templateId 2.16.840.1.113883.10.20.1.35) **SHALL** be a `conformant results organizer` (templateId 2.16.840.1.113883.10.20.1.32).

Vital Signs Example

```
<entry contextConductionInd="true" typeCode="DRIV">
    <organizer classCode="CLUSTER" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.1.35"/>
        <id root="2.16.840.1.113883.19.5.10" extension="112880"/>
        <code code="46680005" codeSystem="2.16.840.1.113883.6.96" displayName="Vital
signs"/>
        <statusCode code="completed"/>
        <component contextConductionInd="true">
            <observation classCode="OBS" moodCode="EVN">
                <templateId root="2.16.840.1.113883.10.20.1.31"/>
                <id root="2.16.840.1.113883.19.5.10" extension="112881"/>
                <code xsi:type="CE" code="50373000"
codeSystem="2.16.840.1.113883.6.96"
                    displayName="Body height"/>
                <statusCode code="completed"/>
                <effectiveTime value="20081114"/>
                <value xsi:type="PQ" unit="cm" value="177.0"/>
            </observation>
        </component>
        <component contextConductionInd="true">
            <observation classCode="OBS" moodCode="EVN">
                <templateId root="2.16.840.1.113883.10.20.1.31"/>
                <id root="2.16.840.1.113883.19.5.10" extension="112882"/>
                <code xsi:type="CE" code="27113001"
codeSystem="2.16.840.1.113883.6.96"
                    displayName="Body weight"/>
                <statusCode code="completed"/>
                <effectiveTime value="20081114"/>
                <value xsi:type="PQ" unit="kg" value="86.0"/>
            </observation>
        </component>
        <component contextConductionInd="true">
            <observation classCode="OBS" moodCode="EVN">
                <templateId root="2.16.840.1.113883.10.20.1.31"/>
                <id root="2.16.840.1.113883.19.5.10" extension="112883"/>
                <code xsi:type="CE" code="271649006"
codeSystem="2.16.840.1.113883.6.96"
                    displayName="Systolic BP"/>
                <statusCode code="completed"/>
                <effectiveTime value="20081114"/>
                <value xsi:type="PQ" unit="mm[Hg]" value="132.0"/>
            </observation>
        </component>
        <component contextConductionInd="true">
            <observation classCode="OBS" moodCode="EVN">
```

```
            <templateId root="2.16.840.1.113883.10.20.1.31"/>
            <id root="2.16.840.1.113883.19.5.10" extension="112884"/>
            <code xsi:type="CE" code="271650006"
codeSystem="2.16.840.1.113883.6.96"
                displayName="Diastolic BP"/>
            <statusCode code="completed"/>
            <effectiveTime value="20081114"/>
            <value xsi:type="PQ" unit="mm[Hg]" value="86.0"/>
        </observation>
      </component>
    </organizer>
</entry>
```

3.1.10 Structural Data Section

This is an optional section, needed to supply information applicable to structural measures to indicate the use of specific types of health information technology systems. Refer to Appendix_R-Structural_Codes_Downloadable_Resources_Table.

CONF-QRDA1-380: Structural Data **SHOULD** be represented with Act.

CONF-QRDA1-381: The value for `Act / @classCode` in a Structural Data **SHALL** be ACT 2.16.840.1.113883.5.6 ActClass **STATIC**.

CONF-QRDA1-382: The value for `Act / @moodCode` in a Structural Data **SHALL** be EVN 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-QRDA1-383: A Structural Data entry **SHOULD** contain at least one Act / id.

CONF-QRDA1-384: A Structural Data entry **SHALL** contain exactly one Act / code.

CONF-QRDA1-385: The value for `Act / code` in a Structural Data entry **SHALL** be selected from Appendix_R-Structural_Codes tab of the Downloadable Resources table.

CONF-QRDA1-386: In a Structured Data entry, an act/effectiveTime element **SHALL** be present. An act/effectiveTime element **SHALL** at least be precise to the day (YYYYMMDD).

CONF-QRDA1-387: One Structured Data entry **MAY** need to be supplied for each of the patient encounters during the reporting period. The encounter dates that are mentioned in the documentationOf Header element **MAY** match with the date elements of the Structured Data entry elements.

CONF-QRDA1-388: Structured Data Section **SHALL** contain section/code element, the value of section/code/@code **SHALL** be STRUCT and the value of section/code/@codeSystem **SHALL** be 2.16.840.1.113883.3.249.12

CONF-QRDA1-389: The CMS EHR QRDA Report **SHOULD** contain exactly one and **SHALL NOT** contain more than one Structural Data section (templateId 2.16.840.1.113883.3.249.11.16).

CONF-QRDA1-390: The template identifier for EHR measure act is 2.16.840.1.113883.3.249.11.13 The template identifier for eRx measure act is 2.16.840.1.113883.3.249.11.14

Figure 22: Structural Data Section Example

```
<section>
    <templateId root="2.16.840.1.113883.3.249.11.16"/>
    <code code="STRUCT" codeSystem="2.16.840.1.113883.3.249.12"/>
    <title> Structured data section </title>
    <text> ..some text on Structured data section></text>
    <entry>
        <act classCode="ACT" moodCode="EVN">
            <templateId root="2.16.840.1.113883.3.249.11.13"/>
            <id root="2.16.840.1.113883.19.5" extension="96756495"/>
            <code code="G8447" codeSystem="2.16.840.1.113883.6.14"
                displayName="Patient encounter was documented using a CCHIT certified
EHR"/>
            <effectiveTime value="20090106"/>
        </act>
    </entry>
    <entry>
        <act classCode="ACT" moodCode="EVN">
            <templateId root="2.16.840.1.113883.3.249.11.13"/>
            <id root="2.16.840.1.113883.19.5" extension="96756555"/>
            <code code="G8447" codeSystem="2.16.840.1.113883.6.14"
                displayName="Patient encounter was documented using a CCHIT certified
EHR"/>
            <effectiveTime value="20090210"/>
        </act>
    </entry>
    <entry>
        <act classCode="ACT" moodCode="EVN">
            <templateId root="2.16.840.1.113883.3.249.11.14"/>
            <id root="2.16.840.1.113883.19.5" extension="96756615"/>
            <code code="GXXXX" codeSystem="2.16.840.1.113883.6.14"
                displayName="Electronic prescription has been generated using a
qualified eRx system"/>
            <effectiveTime value="20090106"/>
        </act>
    </entry>
</section>
```

4 REFERENCES

- Implementation Guide for CDA Release 2 – Quality Reporting Document Architecture (QRDA) Release 1 – Draft Standard for Trial use - available through Health Level Seven®, Inc. All Rights Reserved.

- AMA Collaborative for Performance Measure Integration with EHR Systems

- CDA: Clinical Document Architecture Release 2: Last Published: 09/25/2005 9:14 PM - available through Health Level Seven®, Inc. All Rights Reserved.

- CCD: Continuity of Care Document - available through Health Level Seven®, Inc. All Rights Reserved.

- CMS Quality Net

- Collaborative for Performance Measure Integration within EHR Systems

- Collaborative for Performance Measure Integration with EHR Systems Work Group A Recommendations to full Collaborative

- HIMSS Electronic Health Record Association - Continuity of Care Document (CCD) Quick Start Guide

- HITSP Quality Interoperability Specification Version 1.0

- LOINC®

- National Quality Forum

- NCQA > HEDIS & Quality Measurement

- SNOMED CT®

- Using SNOMED CT in HL7 Version 3 - available through Health Level Seven®, Inc. All Rights Reserved.