Centers for Medicare & Medicaid Services
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Data Submission Specifications Utilizing HL7 QRDA Implementation Guide Based on HL7 CDA Release 2.0

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4/25/2012	Llewelyn Brown	Updated record target to specify inclusion of email address. Updated Payor Section to require HIC number. Updated reference to figure 16.	4.1

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1 Introduction

1.1 Purpose

This document describes the Electronic Health Record (EHR) data submission required for reporting information for the Center for Medicare & Medicaid Services (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 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 Health Level Seven (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 Health Insurance Portability and Accountability Act (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 International Classification of Diseases, Ninth Revision, Clinical Modifications (ICD-9 CM), International Classification of Diseases, Tenth Edition, Clinical Modifications (ICD-10-CM), Current Procedural Terminology, Fourth Edition (CPT4), RxNorm, Logical Observation Identifier Names and Codes (LOINC) and Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) 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_AJ-Custom_Template_IDs 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:

The Regenstrief Institute, Inc
410 West 10th Street, Suite 2000
Indianapolis, IN 46202
Telephone: (317) 423-5558

1.4.2 SNOMED Clinical Terms (SNOMED-CT®)

Systematized Nomenclature of Medicine Clinical Terms or SNOMED CT. is a registered trademark of the International Health Terminology Standards Development Organisation (IHTSDO). SNOMED CT contains over 300,000 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.

IHTSDO 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 and ICD-10-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:

IHTSDO
Rued Langgaards Vej 7, 5te, 5A56
2300 Copenhagen S
Denmark
Telephone: +45 36 44 87 36
www.ihtsdo.org/snomed-ct

1.4.3 Current Procedural Terminology, Fourth Edition (CPT4®)

CPT is a registered trademark of the American Medical Association (AMA) 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.

1.4.4 The International Classification of Diseases.

The International Classification of Diseases, Ninth Revision, Clinical Modification ICD9 (CM) and Tenth Revision, Clinical Modification (CM) are based on the U.S. modification of the World Health Organization's International Classification of Diseases. ICD9 (CM) and ICD10 (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) and ICD10 (CM) record corresponds to a single diagnosis. The ICD9 (CM) and ICD10 (CM) codes are not intended to transmit all possible information about a diagnosis. They are only intended to *identify* the diagnosis. The ICD9 (CM) and ICD10 (CM) code for a name is unique and permanent.

For questions regarding ICD9 (CM) and ICD10 (CM) codes, refer to the National Center for Health Statistics at: www.cdc.gov/nchs/

1.4.5 RxNorm

RxNorm is the recommended national standard for medication vocabulary for clinical drugs and drug delivery devices produced by the National Library of Medicine (NML). RxNorm is intended to cover all prescription medications approved for human use in the United States.

Because every drug information system that is commercially available today follows somewhat different naming conventions, a standardized nomenclature is needed for the smooth exchange of information. The goal of RxNorm is to allow various systems using different drug nomenclatures to share data efficiently at the appropriate level of abstraction.

Each (RxNorm) clinical drug name reflects the active ingredients, strengths, and dose form comprising that drug. When any of these elements vary, a new RxNorm drug named is created as a separate concept.

More information may be found at the U.S. National Library of Medicine Unified Medical Language System: http://www.nlm.nih.gov/research/umls/rxnorm/docs/index.html

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."

Quality measures are used for three general purposes: quality improvement, accountability, and research. 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 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.

Healthcare Information Technology Standards Panel (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.

1.5.2 Approach

This Technical Specification uses Continuity of 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.

1.5.3 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.

1.5.3.1 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.

1.5.3.2 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.

1.5.4 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 Clinical Document Architecture Release 2 (CDA R2), every aspect of the QRDA and CDA R2 may not be described in this Specification.

1.5.4.1 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 contain no additional constraints that attribute remains optional for use.

1.5.4.2 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.

1.5.4.3 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**.

1.5.4.4 XPath Notation

Instead of the traditional dotted notation used by HL7 to represent Reference Information Model (RIM) classes, this document uses XPath notation in conformance statements and elsewhere to identify the Extensible Markup Language (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.

1.5.4.5 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**

1.5.4.6 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>
```

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

1.5.4.7 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.

1.5.4.8 Use of Object Identifiers (OIDs)

The CMS EHR QRDA Report will use International Organization for Standardization (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 (NPI) 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)

1.6 Road map

1.6.1 OID

The vendors and providers need to approach HL7 to obtain an object identifier (OID).

1.6.2 Qualified EHR Software Version – Security Code

The Submission Engine Validation Tool (SEVT) within the PQRS Portal shall assign a unique security Code for each CMS qualified EHR vendor application. Prior to submitting any vetting data the vendor shall request a security code from SEVT within the PRQS portal. Each Provider needs to include the Security Code within the generated QRDA files. (NOTE: Author Header Element is used for that purpose). In the long term, this Qualification ID will likely move to the metadata layer or to the XDR wrapper information in the Nationwide Health Information Network (NHIN) environment.

1.7 Key Assumptions

1.7.1 Updates to Specification

Recognize that this "final" version of the specification is the best information available till date. If continued qualification or testing reveals new essential changes and CMS and all vendors concur, there may be further specification updates published.

1.7.2 Transmission Media Impacts

There may be impacts to the specifications based on the transmission media technology (e.g., Portal submissions VS. NHIN submissions).

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' />
```

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: The CMS EHR QRDA Report **SHALL** contain at least one `Clinical Document/templateId` element.

CONF-QRDA1-4: `QRDA Category I templateId 'root' value` **SHALL** be '2.16.840.1.113883.10.20.12' and PQRI QRDA category I templateId `'root' value` **SHALL** be.'2.16.840.1.113883.3.249.11.100.1'

Figure 3: ClinicalDocument/TemplateId Example

```
<templateId root= "2.16.840.1.113883.10.20.12"/>
<templateId root= "2.16.840.1.113883.3.249.11.100.1"/>
```

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.

Figure 4: id Example

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

2.1.1.5 ClinicalDocument/code

CONF-QRDA1-6: The 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-QRDA1-7: The 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-QRDA1-8: A `clinicalDocument/effectiveTime` **SHALL** be present.

CONF-QRDA1-9: The value of `effectiveTime/@value` **SHALL** be at least precise to the day (YYYYMMDD).

Figure 5: effectiveTime Example

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

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-QRDA1-10: A `clinicalDocument/confidentialityCode` **SHALL** be present.

CONF-QRDA1-11: 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"/>
```

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-QRDA1-12: A `clinicalDocument/setId` **SHALL** be present.

CONF-QRDA1-13: 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-QRDA1-14: 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"/>
```

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-QRDA1-15: A `clinicalDocument/versionNumber` **SHALL** be present.

CONF-QRDA1-16: The value of `versionNumber/@value` **SHALL** be integer.

Figure 8: versionNumber Example

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

2.1.2 Header Participants

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

2.1.2.1 recordTarget

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

CONF-QRDA1-17: The CMS EHR QRDA Report **SHALL** contain exactly one `clinicalDocument/recordTarget/PatientRole`.

CONF-QRDA1-18: A `recordTarget/patientRole/id` element **SHALL** be present where the value of `@root` contains OID for the coding system used to identify the patient. 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 TIN, DLN etc. are available at Appendix_AA-OIDs tab of the Downloadable Resources table.

CONF-QRDA1-19: The value of `recordTarget/patientRole/id` element **SHALL** remain the same throughout the reporting period.

CONF-QRDA1-20: The report **MAY** contain one `recordTarget/PatientRole/addr`.

CONF-QRDA1-21: The report **SHALL** contain exactly one `recordTarget/PatientRole/patient`.

CONF-QRDA1-22: The report **SHALL** at least contain patient's legal name at `recordTarget/PatientRole/patient/name`.

CONF-QRDA1-23: The report **SHALL** contain at least one `recordTarget/patientRole/patient/name/given` element for patient's legal name.

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

CONF-QRDA1-25: A `recordTarget/patientRole/patient/ethnicGroupCode` element **SHOULD** 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_AB-Ethnicity tab of the Downloadable Resources table.

CONF-QRDA1-26: `recordTarget/patientRole/patient/administrativeGenderCode` 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_AC-Gender tab of the Downloadable Resources table.

CONF-QRDA1-27: A `recordTarget/patientRole/patient/raceCode` element **SHOULD** 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_AD-Race tab of the Downloadable Resources table.

CONF-QRDA1-28: A `recordTarget/patientRole/patient/birthTime` element **SHALL** be present.

CONF-QRDA1-29: `recordTarget/patientRole/patient/birthTime` **SHALL** be at least precise to the day (YYYYMMDD).

CONF-QRDA1-30: The report **SHALL** contain exactly one `recordTarget/PatientRole/providerOrganization`

CONF-QRDA1-31: 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-QRDA1-32: `recordTarget/patientRole/providerOrganization/name` element **SHOULD** be present.

CONF-QRDA1-33: The report **SHALL** contain at least one `recordTarget/patientRole/providerOrganization/addr`.

CONF-QRDA1-34: `recordTarget/patientRole/providerOrganization/addr/streetAddressLine` element **MAY** be present.

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

CONF-QRDA1-36: `recordTarget/patientRole/providerOrganization/addr/state` element **SHALL** be present. All the applicable states that could be used in this element are available in Appendix_AK-States.

CONF-QRDA1-37: `recordTarget/patientRole/providerOrganization/addr/postalCode` element **MAY** be present.

CONF-QRDA1-38: The report **SHALL** contain exactly one `recordTarget/patientRole/providerOrganization/asOrganizationPartOf`.

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

CONF-QRDA1-40: 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.

CONF-QRDA1-41.1: The report **SHOULD** contain exactly one email address for the provider at `recordTarget/patientRole/providerOrganization/telecom`.

CONF-QRDA1-41.2: The report **SHOULD** contain exactly one email address for the organization at `recordTarget/patientRole/providerOrganization/asOrganizationPartOf/wholeOrganization/telecom`.

Figure 9: recordTarget Example

```
<recordTarget>
    <patientRole>
        <!—patient identifier with extension are required -->
        <id root=" 2.16.840.1.113883.4.3.40" 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>
                    <telecom value="mailto:npiUser@aClinic.com"/>
            <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"/>
                           <telecom value="mailto:tinUser@aClinic.com"/>
                </wholeOrganization>
            </asOrganizationPartOf>
        </providerOrganization>
    </patientRole>
</recordTarget>
```

2.1.2.2 author

CONF-QRDA1-41: The CMS EHR QRDA Report **SHALL** contain exactly one `clinicalDocument/author`.

CONF-QRDA1-42: An `author/time` element **SHALL** be present.

CONF-QRDA1-43: An `author/time` **SHALL** be at least precise to the day (YYYYMMDD).

CONF-QRDA1-44: An `author/assignedAuthor` element **SHALL** be present.

CONF-QRDA1-45: An `author/assignedAuthor/id` element **SHALL** be present. The value of `ClinicalDocument/author/assignedAuthor/id @root` **SHALL** be

"2.16.840.1.113883.3.249.6". The @extension value represents Security Code assigned by the SEVT.

CONF-QRDA1-46: An author/assignedAuthor/id element **MAY** be present. The value of ClinicalDocument/author/assignedAuthor/id @root **SHALL** be "2.16.840.1.113883.3.249.14". The @extension value represents the ONC Approved EHR certification number. It **MAY** be populated when the submissions are for a provider participating in the PQRS/HITECH combination.

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

CONF-QRDA1-48: The report **MAY** 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 **MAY** contain one author/assignedAuthor/representedOrganization

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

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

Figure 10: Author Example

```
<author>
    <time value="20080401"/>
    <assignedAuthor>
         <!--Here 1ABC00001 is the security code assigned by SEVT -->
        <id root="2.16.840.1.113883.3.249.6" extension="1ABC00001"/>
           <!--Here 123456 is ONC Certified System number -->
        <id root="2.16.840.1.113883.3.249.14" extension="123456"/>
    </assignedAuthor>
</author>
```

2.1.2.3 informant

The CMS EHR QRDA Report must have a stated source so that any data within the report can be validated. The Source of report is the reporting facility collected via the informant participant.

CONF-QRDA1-55: The 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: The 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 the 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: The 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.

Figure 13: legalAuthenticator Example

```
<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/@root` 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 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: The 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.
`documentationOf/serviceEvent/performer/assigndedEntity/code` element **SHALL** be submitted at least once.

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_AK-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/assignedEntity/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/assignedEntity/assignedPerson/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

The 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 16: CMS EHR QRDA Report Use of Measure Set Sections.

Figure 16: 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
            - Advance Directives Section
            - Plan of Care Section
            - Social History Section
            - Encounters Section
             - Family History
            - Medical equipment
```

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

CONF-QRDA1-114: The `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 Inpatient Quality Measures manual utilize a consistent definition of pneumonia (from a specified ICD-9 or ICD-10 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_AJ - Custom_Template_IDs 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 17: Measure Set section Example

```
<component>
   <section>
      <templateId root="2.16.840.1.113883.3.249.11.350"/> <!-- templateId uniquely
       identifies the measureSet for the Program year -->
      <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>
```

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_AJ-Custom_Template_IDs 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 18: Nested Measure Section in Measure Set Example

```
<section>
         <!—CMS 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>
```

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_AJ-Custom_Template_IDs 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 19: Measure Act Example

```
<entry typeCode="DRIV">
   <act classCode="ACT" moodCode="DEF">
      <code code=" PhysicianQualityReporting-3"
codeSystem="2.16.840.1.113883.3.249.200" displayName=" Measure #3: Diabetes
Mellitus: High Blood Pressure Control in Diabetes Mellitus "/>
      <text>... (optional) description of measure ...</text>
      <statusCode code="completed" />
   </act>
</entry>
```

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).

CONF-QRDA1-139.1: The value for `act / code` **SHALL** be 252116004 Observation Parameters 2.16.840.1.113883.6.96 SNOMED-CT STATIC.

Figure 20: Reporting parameters Time 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 Data 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 CCD templates. For more information on these templates, refer to the CCD 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 Healthcare Information and Management Systems Society (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.)

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

Figure 21: Generic Section level Template Example

```
<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.

3.1.1.2 Clinical Statement Templates

Collectively, the nine **act** classes within the CDA Refined Message Information Model (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.

Figure 22: Generic Clinical Statement Template Example

```
<entry typeCode="DRIV">
   <observation classCode="OBS" moodCode="RQO">
      <templateId root="2.16.840.1.113883.10.20.1.25"/>
<templateId root="2.16.840.1.113883.3.249.11.100.2"/>
         <!-- 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>
```

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.

Figure 23: Generic Supporting Template Example

```
<observation classCode="OBS" moodCode="EVN">
   <templateId root="2.16.840.1.113883.10.20.1.18" />
<templateId root="2.16.840.1.113883.3.249.11.100.6" />
      <!--  Alert observation template -->
   <id root="IDGoesHere" />
   <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4" />
   <statusCode code="completed" />
   <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" />
<templateId root="2.16.840.1.113883.3.249.11.100.14" />
            <!-- 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>
```

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). A problem observation **MAY** include one or more negation reasons (templateId 2.16.840.1.113883.3.249.13.100.25)

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: The CMS EHR QRDA Report Problem observation (2.16.840.1.113883.3.249.11.100.8) SHALL confirm to the rules of Problem observation (2.16.840.1.113883.10.20.1.28) and **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 the time Stamp of the format YYYYMMDDHHMMSS.

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.

CONF-QRDA-168.1: The value for `observation / @negationInd` in Problem Observation **SHALL** be either “true” or “false”.

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 CMS EHR QRDA Problem status observation and A CMS EHR QRDA Problem status observation (2.16.840.1.113883.3.249.11.100.12) SHALL confirm to the rules of Problem status observation (2.16.840.1.113883.10.20.1.50).

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_AE-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_AE-Vocabs_and_ValueSets tab of the Downloadable Resources table

CONF-QRDA-174.1: A problem status observation **SHALL** contain exactly one `observation / effectiveTime`. The value for ovservation / effectiveTime Shall be at least precise to the day (YYYYMMDD).

3.1.2.2.3 Problem Negation reason template

CONF-QRDA-174.2: CMS EHR QRDA Problem negation reason (2.16.840.1.113883.3.249.11.100.25) **SHALL** confirm to the rules of CMS EHR QRDA Negation reason (2.16.840.1.113883.3.249.11.100.24).

CONF-QRDA-174.3: The value for `observation / @classCode` in a Negation reason **SHALL** be OBS.

CONF-QRDA-174.4: The Value for `observation / @moodCode` in a Negation reason **SHALL** be EVN.

CONF-QRDA-174.5: The value for `observation / code@code` **SHALL** be ASSERTION and the value for `observation / code@codeSystem` **SHALL** be 2.16.840.1.113883.5.4.

CONF-QRDA-174.6: The value for Problem Negation Reason `observation / value/ @code` and `observation / value / @codeSystem` **SHALL** be from the Appendix_C1-Problems (negation) tab of the Downloadable Resource table.

CONF-QRDA-174.7: The value for `observation / statusCode` in a Negation Reason **SHALL** be “completed” 2.16.840.1.113883.5.14 Act Status STATIC.

CONF-QRDA-174.8: Negation Reason **SHALL** contain exactly one `observation / effectiveTime`, which **SHALL** be at least precise to the day (YYYYMMDD).

Figure 24: Problem Entry Example

```
<entry typeCode="DRI">
    <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" negationInd="false">
                <templateId root="2.16.840.1.113883.10.20.1.28"/>
<templateId root="2.16.840.1.113883.3.249.11.100.8"/>
                <!-- 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="20080812093000"/>
                </effectiveTime>
                <value xsi:type="CD" code="4006F" codeSystem="2.16.840.1.113883.6.12">
                 <qualifier>
              <name code="2P"/>
                 </qualifier>
                </value>
                <entryRelationship typeCode="REFR">
                    <observation classCode="OBS" moodCode="EVN">
                        <templateId root="2.16.840.1.113883.10.20.1.50"/>
<templateId root="2.16.840.1.113883.3.249.11.100.12"/>
                        <!-- Problem status observation template -->
                        <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
displayName="Status"/>
                        <statusCode code="completed"/>
                                        <effectiveTime>
                                               <low value="20080812"/>
                                        </effectiveTime>

             <value xsi:type="CE" code="55561003" codeSystem="2.16.840.1.113883.6.96"
                               displayName="Active"/>
                    </observation>
                </entryRelationship>
            </observation>
        </entryRelationship>
    </act>
</entry>
```

Figure 25: Problem Entry Negation 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="12302334"/>
        <code nullFlavor="NA"/>
        <entryRelationship typeCode="SUBJ">
            <observation classCode="OBS" moodCode="EVN" negationInd="true">
                <templateId root="2.16.840.1.113883.10.20.1.28"/>
                        <templateId root="2.16.840.1.113883.3.249.11.100.8"/>
                <!-- Problem observation template -->
                <id root="2.16.840.1.113883.19.5.9" extension="1235345"/>
                <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
                <statusCode code="completed"/>
                <effectiveTime>
                    <low value="20080812093000"/>
                </effectiveTime>
                <value xsi:type="CD" code="418304008" codeSystem="2.16.840.1.113883.6.96"
                            displayName="Diastolic heart failure"/>
                        <entryRelationship typeCode="RSON">
                              <observation classCode="OBS" moodCode="EVN">
                                <templateId root="2.16.840.1.113883.3.249.11.100.24"/>
                                <templateId root="2.16.840.1.113883.3.249.11.100.25"/>
                                <!-- Negation Reason template -->

                                <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
                                <statusCode code="completed"/>
                                <effectiveTime>
                                          <low value="20080812"/>
                                </effectiveTime>
                                <value xsi:type="CD" code="14880"
codeSystem="2.16.840.1.113883.5.8"
                                     displayName="Patient request"/>
                              </observation>
                        </entryRelationship>
                <entryRelationship typeCode="REFR">
                    <observation classCode="OBS" moodCode="EVN">
                        <templateId root="2.16.840.1.113883.10.20.1.50"/>
                                  <templateId root="2.16.840.1.113883.3.249.11.100.12"/>
                        <!-- Problem status observation template -->
                        <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
displayName="Status"/>
                        <statusCode code="completed"/>
                                  <effectiveTime>
                                        <low value="20080812"/>
                                  </effectiveTime>
                        <value xsi:type="CE" code="55561003" codeSystem="2.16.840.1.113883.6.96"
                            displayName="Active"/>
                    </observation>
                </entryRelationship>
            </observation>
        </entryRelationship>
    </act>
</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 CMS EHR QRDA Report 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). A procedure activity **MAY** include one or more negation reasons (templateId 2.16.840.1.113883.3.249.11.100.26).

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: The CMS EHR QRDA Report Procedure activity (2.16.840.1.113883.3.249.11.100.9) **SHALL** confirm to the rules of Procedure activity (2.16.840.1.113883.10.20.1.29) and **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 the time stamp of the format YYYYMMDDHHMMSS.

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.

CONF-QRDA1-187.1: The value for `procedure / @negationInd` in procedure activity **SHALL** be either “true” or “false”.

CONF-QRDA1-187.2: CMS EHR QRDA Procedure negation reason (2.16.840.1.113883.3.249.11.100.26) **SHALL** confirm to the rules of CMS EHR QRDA negation reason (2.16.840.1.113883.3.249.11.100.24).

CONF-QRDA1-187.3: The value for `observation / @classCode` in a negation reason **SHALL** be OBS.

CONF-QRDA1-187.4: The value for `observation / @moodCode` in a negation reason **SHALL** be EVN.

CONF-QRDA1-187.5: The value for `observation / code@code` in a negation reason **SHALL** be ASSERTION and the value for `observation / code@codeSystem` **SHALL** be 2.16.840.1.113883.5.4.

CONF-QRDA1-187.6: The value for procedure negation reason `observation / value / @code` and `observation / value / @codeSystem` **SHALL** be from the Appendix_G1- Procedures (negation) tab of the Downloadable Resource Table.

CONF-QRDA1-187.7: The value for `observation / statuscode` in a negation reason SHALL be “completed” 2.16.840.1.113883.5.14 Act Status STATIC.

CONF-QRDA1-187.8: Negation reason **SHALL** contain exactly one `observation / effectiveTime`, which **SHALL** be at least precise to the day (YYYYMMDD)

3.1.3.2.2 Procedure related products

Figure 26: Procedure Example

```
<entry typeCode="DRIV">
       <procedure classCode="PROC" moodCode="EVN" negationInd="false">
              <templateId root="2.16.840.1.113883.10.20.1.29"/>
              <templateId root="2.16.840.1.113883.3.249.11.100.9"/>
              <!-- Procedure activity template -->
              <id root="2.16.840.1.113883.19.5.10" extension="103207"/>
              <code code="14564-9" codeSystem="2.16.840.1.113883.6.1"
displayName="HEMOCCULT, QUAL, 2ND SPECIMEN"></code>
              <statusCode code="completed"/>
              <effectiveTime value="20090714093000"/>
       </procedure>
</entry>
```

Figure 27: Procedure Negation Example

```
<entry typeCode="DRIV">
       <procedure classCode="PROC" moodCode="EVN" negationInd="true">
              <templateId root="2.16.840.1.113883.10.20.1.29"/>
              <templateId root="2.16.840.1.113883.3.249.11.100.9"/>
              <!-- Procedure activity template -->
              <id root="2.16.840.1.113883.19.5.10" extension="1032072"/>
              <code code="412808005" codeSystem="2.16.840.1.113883.6.96"
                     displayName="serum total cholesterol measurement"></code>
              <statusCode code="completed"/>
              <effectiveTime value="20090714093000"/>
              <entryRelationship typeCode="RSON">
                     <observation classCode="OBS" moodCode="EVN">
                       <templateId root="2.16.840.1.113883.3.249.11.100.24"/>
                       <templateId root="2.16.840.1.113883.3.249.11.100.26"/>
                       <!-- Negation Reason template -->

                       <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
                       <statusCode code="completed"/>
                       <effectiveTime>
                                  <low value="20090714"/>
                       </effectiveTime>
                       <value xsi:type="CD" code="21741"
codeSystem="2.16.840.1.113883.5.8"
                              displayName="religious objection"/>
                     </observation>
              </entryRelationship>
       </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: The 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 with Act / entryRelationship / @typeCode='COMP' **SHALL** be the CMS EHR QRDA Policy activity (2.16.840.1.113883.3.249.11.100.7) which **SHALL** confirm to the rules of Policy activity (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 of 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_AH-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_AI-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 **SHALL** 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`, HIC Number **SHALL** be submitted for Medicare patients. 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.

Figure 28: 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="103209"/>
              <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"/>
                           <templateId root="2.16.840.1.113883.3.249.11.100.7"/>
                           <!-- Policy activity template -->
                           <id root="2.16.840.1.113883.19.5.10"
                                  extension="103210"/>
                           <code code="EHCPOL" codeSystem="2.16.840.1.113883.5.4"
                                  displayName="Extended Healthcare"/>
                           <statusCode code="completed"/>
                           <performer typeCode="PRF">
                                  <assignedEntity>
                                         <id root="2.16.840.1.113883.12.86"
                                                xtension="PI"/>
                                         <!-- private pay insurance-->
                                         <representedOrganization>
                                                <name>
                                                       TN Blue Insurance Organization
                                                </name>
                                         </representedOrganization>
                                  </assignedEntity>
                           </performer>
                           <participant typeCode="COV">
                                  <participantRole>
                                         <id root="2.16.840.1.113883.3.249.13"
                                                extension="A199999"/>
                                         <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="103212"/>
                                         <code nullFlavor="NA"/>
                                         <entryRelationship typeCode="SUBJ">
                                                <procedure classCode="PROC"
                                                       moodCode="PRMS">
                                                       <!-- Nothing written in
                                                              spec regarding
                                                              this entry but shown
                                                              in the example,
                                                              followed example -->
                                                       <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: The CMS EHR QRDA Report Alert observation (2.16.840.1.113883.3.249.11.100.6) SHALL confirm to the rules of Alert observation (2.16.840.1.113883.10.20.1.18) and **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 CMS EHR QRDA Alert status observation (2.16.840.1.113883.3.249.11.100.11) which SHALL confirm to the rules of Alert status observation (2.16.840.1.113883.10.20.1.39)

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: The CMS EHR QRDA Report Reaction observation (2.16.840.1.113883.3.249.11.100.14) SHALL confirm to the rules of Reaction observation (2.16.840.1.113883.10.20.1.54) and **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.

Figure 29: 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="103213"/>
              <code nullFlavor="NA"/>
              <statusCode code="active"/>
              <effectiveTime>
                     <low value="20020214"/>
              </effectiveTime>
              <entryRelationship typeCode="SUBJ">
                     <observation classCode="OBS" moodCode="EVN">
                           <templateId root="2.16.840.1.113883.10.20.1.18"/>
                           <templateId root="2.16.840.1.113883.3.249.11.100.6"/>
                           <!-- Alert observation template -->
                           <id root="2.16.840.1.113883.19.5.10"
                                  extension="103214"/>
                           <code code="200009" codeSystem=
                                  "2.16.840.1.113883.6.96"/>
                           <statusCode code="completed"/>
                           <effectiveTime>
                                  <low value="20020214"/>
                           </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="995.27" codeSystem=
                                                "2.16.840.1.113883.6.103"
                                                displayName=
                                                "DRUG ALLERGY NEC"/>
                                         </playingEntity>
                                  </participantRole>
                           </participant>
                           <entryRelationship typeCode="MFST" inversionInd="true">
                                  <observation classCode="OBS" moodCode="EVN">
                                         <!-- Reaction observation template -->
                                         <code code="SEV" codeSystem="2.16.840.1.113883.5.4"
                                         codeSystemName="ActCode" displayName="Severity"/>
                                         <statusCode code="completed"/>
                                         <value code="403607004" codeSystem=
                                         "2.16.840.1.113883.6.96"
                                         codeSystemName="SNOMED CT"
                                         displayName="moderate"
                                         xsi:type="CD" xmlns:xsi=
                                         "http://www.w3.org/2001/XMLSchema-instance"/>
                                         <!--<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"/>
                                        <templateId
root="2.16.840.1.113883.3.249.11.100.11"/>
                                        <!-- Alert status observation template -->
                                        <code code="11323-3" 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>
```

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 **SHOULD** 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.

CONF-QRDA1-267.1: A medication activity **MAY** include one or more negation reasons (templateId 2.16.840.1.113883.3.249.11.100.27).

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`. CMS EHR QRDA Medication Activity (2.16.840.1.113883.3.249.11.100.28) SHALL confirm to the rules of Medication Activity (templateId 2.16.840.1.113883.10.20.1.24).

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 the timestamp of the format YYYYMMDDHHMMSS.

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.

CONF-QRDA1-281.1: The value for the `substanceadministration / @negationInd` in a medication acitivity **SHALL** be either “true” or “false”.

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 / @typeCode` 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 / @classCode` 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 / @moodCode` 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 / @typeCode` 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: The CMS EHR QRDA Report Product (2.16.840.1.113883.3.249.11.100.13) SHALL confirm to the rules of Product (2.16.840.1.113883.10.20.1.53) and **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.

3.1.6.2.5 Medication Negation Reason template

CONF-QRDA1-335.1: CMS EHR QRDA Medication negation reason (2.16.840.1.113883.3.249.11.100.27) **SHALL** confirm to the rules of CMS EHR QRDA negation reason (2.16.840.1.113883.3.249.11.100.24).

CONF-QRDA1-335.2: The value for `observation / @classCode` in a negation reason **SHALL** be OBS.

CONF-QRDA1-335.3: The value for `observation / @moodCode` in a negation reason **SHALL** be EVN.

CONF-QRDA1-335.4: The value for `observation / code@code` in a negation reason **SHALL** be ASSERTION and the value for `observation / code@codeSystem` **SHALL** be 2.16.840.1.113883.5.4.

CONF-QRDA1-335.5: The value for Medication Negation reason `observation / value / @code` and `observation / value / @codeSystem` **SHALL** be from the Appendix_ A1 – Medications (negation) tab of the Downloadable Resource table.

CONF-QRDA1-335.6: The value for `observation / statuscode` in a negation reason **SHALL** be "completed" 2.16.840.1.133833.5.14 ActStatus STATIC.

CONF-QRDA1-335.7: Negation reason **SHALL** contain exactly one observation / effectiveTime, which **SHALL** be at least precise to the day (YYYYMMDD).

Figure 30: Medication Example

```
<entry typeCode="DRIV">
<entry typeCode="DRIV">
    <substanceAdministration classCode="SBADM" moodCode="EVN" negationInd="false">
        <templateId root="2.16.840.1.113883.10.20.1.24"/>
             <templateId root="2.16.840.1.113883.3.249.11.100.28"/>
        <!-- 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="19900328093000"/>
        </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"/>
                          <templateId root="2.16.840.1.113883.3.249.11.100.13"/>
                <!-- Product template -->
                <manufacturedMaterial>
                    <code code=" 860978 " codeSystem=" 2.16.840.1.113883.6.88"
                        displayName=" Metformin hydrochloride 500 MG Extended Release
Tablet">
                        <originalText>
                                                24 HR Metformin hydrochloride 750 MG Extended
Release Tablet
                                          </originalText>
                    </code>
                </manufacturedMaterial>
            </manufacturedProduct>
        </consumable>
    </substanceAdministration>
</entry>
             <entryRelationship typeCode="RSON">
                    <observation classCode="OBS" moodCode="EVN">
                      <templateId root="2.16.840.1.113883.3.249.11.100.24"/>
                      <templateId root="2.16.840.1.113883.3.249.11.100.27"/>
                      <!-- Negation Reason template -->
                      <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
                      <statusCode code="completed"/>
                      <effectiveTime>
                                 <low value="19900328"/>
                      </effectiveTime>
                      <value xsi:type="CD" code="21990" codeSystem="2.16.840.1.113883.5.8"
                           displayName="intolerance"/>
                    </observation>
             </entryRelationship>
    </substanceAdministration>
</entry>
```

Figure 31: Medication Negation Example

```
<entry typeCode="DRIV">
    <substanceAdministration classCode="SBADM" moodCode="EVN" negationInd="true">
        <templateId root="2.16.840.1.113883.10.20.1.24"/>
             <templateId root="2.16.840.1.113883.3.249.11.100.28"/>
        <!-- Medication activity template -->
        <id root="2.16.840.1.113883.19.5.10" extension="10001623"/>
        <statusCode code="active"/>
        <effectiveTime xsi:type="IVL_TS">
            <low value="19900328093000"/>
        </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"/>
                          <templateId root="2.16.840.1.113883.3.249.11.100.13"/>
                <!-- Product template -->
                <manufacturedMaterial>
                    <code code=" 860978 " codeSystem=" 2.16.840.1.113883.6.88"
                        displayName=" Metformin hydrochloride 500 MG Extended
Release Tablet">
                        <originalText>
                                                24 HR Metformin hydrochloride 750 MG
Extended Release Tablet
                                            </originalText>
                    </code>
                </manufacturedMaterial>
            </manufacturedProduct>
        </consumable>
```

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 **SHOULD** 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. Also use Appendix_D1-Immunizations (negation) tab of the Downloadable Resource table for the values of `observation / value / @code` and `@codeSystem`. Further the immunization negation reason template (2.16.840.1.113883.3.249.11.100.29) **SHALL** confirm to the rules of CMS EHR QRDA negation reason template (2.16.840.1.113883.3.249.11.10.24).

Figure 32: Immunization Example

```
<entry typeCode="DRIV">
       <substanceAdministration classCode="SBADM" moodCode="EVN" negationInd="false">
              <templateId root="2.16.840.1.113883.10.20.1.24"/>
              <templateId root="2.16.840.1.113883.3.249.11.100.28"/>
              <!-- Medication activity template -->
              <id root="2.16.840.1.113883.19.5.10" extension="1723677"/>
              <statusCode code="completed"/>
              <effectiveTime xsi:type="IVL_TS">
                     <low value="20090714093000"/>
                     <high value="20090714100000"/>
              </effectiveTime>
              <routeCode code="IM" codeSystem=
              "2.16.840.1.113883.5.112"
              codeSystemName="RouteOfAdministration"
              displayName="Intramuscular injection"/>
              <consumable>
                     <manufacturedProduct classCode="MANU">
                            <templateId root=
                            "2.16.840.1.113883.10.20.1.53"/>
                            <templateId root=
                            "2.16.840.1.113883.3.249.11.100.13"/>
                            <!-- Product template -->
                            <manufacturedMaterial>
                                   <code code="86198006" codeSystem=
                                   "2.16.840.1.113883.6.96"
                                   displayName=
                                   "INFLUENZA VACCINATION PROCEDURE">
                                          <originalText>
                                                 INFLUENZA VACCINATION PROCEDURE
                                          </originalText>
                                   </code>
                            </manufacturedMaterial>
                     </manufacturedProduct>
              </consumable>
       </substanceAdministration>
</entry>
                            </manufacturedMaterial>
                     </manufacturedProduct>
              </consumable>
              <entryRelationship typeCode="RSON">
                     <observation classCode="OBS" moodCode="EVN">
                       <templateId root="2.16.840.1.113883.3.249.11.100.24"/>
                       <templateId root="2.16.840.1.113883.3.249.11.100.29"/>
                       <!-- Negation Reason template -->

                       <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
                       <statusCode code="completed"/>
                       <effectiveTime>
                                  <low value="20090714"/>
                       </effectiveTime>
                       <value xsi:type="CD" code="21990"
codeSystem="2.16.840.1.113883.5.8"
                              displayName="intolerance"/>
                     </observation>
              </entryRelationship>
       </substanceAdministration>
</entry>
```

Figure 33: Immunization Negation Example

```
<entry typeCode="DRIV">
      <substanceAdministration classCode="SBADM" moodCode="EVN" negationInd="true">
            <templateId root="2.16.840.1.113883.10.20.1.24"/>
            <templateId root="2.16.840.1.113883.3.249.11.100.28"/>
            <!-- Medication activity template -->
            <id root="2.16.840.1.113883.19.5.10" extension="1723677"/>
            <statusCode code="completed"/>
            <effectiveTime xsi:type="IVL_TS">
                  <low value="20090714093000"/>
                  <high value="20090714100000"/>
            </effectiveTime>
            <routeCode code="IM" codeSystem=
            "2.16.840.1.113883.5.112"
            codeSystemName="RouteOfAdministration"
            displayName="Intramuscular injection"/>
            <consumable>
                  <manufacturedProduct classCode="MANU">
                        <templateId root=
                        "2.16.840.1.113883.10.20.1.53"/>
                        <templateId root=
                        "2.16.840.1.113883.3.249.11.100.13"/>
                        <!-- Product template -->
                        <manufacturedMaterial>
                              <code code="86198006" codeSystem=
                              "2.16.840.1.113883.6.96"
                              displayName=
                              "INFLUENZA VACCINATION PROCEDURE">
                                    <originalText>
                                          INFLUENZA VACCINATION PROCEDURE
                                    </originalText>
                              </code>
```

3.1.8 Results Section

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: The CMS EHR QRDA Report Result observation (2.16.840.1.113883.3.249.11.100.10) SHALL confirm to the rules of Result observation (2.16.840.1.113883.10.20.1.31) and **SHALL** be represented with the 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 the time stamp of the format YYYYMMDDHHMMSS.

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 greater than or equal to the MINIMUM VALUE and less than or equal to the MAXIMUM 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.

CONF-QRDA-373.1: The value for `observation / @negationInd` in a result observation **SHALL** be either “true” or “false”.

CONF-QRDA-373.2: A `result observation` **MAY** include one or more negation reasons (templateId 2.16.840.1.113883.3.249.11.100.30).

3.1.8.3.1.3 Result negation reason template

CONF-QRDA-373.3: CMS EHR QRDA results negation reason (2.16.840.1.113883.3.249.11.100.30) **SHALL** confirm to the rules of CMS EHR QRDA negation reason (2.16.840.1.113883.3.249.11.100.24).

CONF-QRDA-373.4: The value for `observation / @classCode` in a negation reason **SHALL** be OBS.

CONF-QRDA-373.5: The value for `observation / @moodCode` in a negation reason **SHALL** be EVN.

CONF-QRDA-373.6: The value for `observation / code@code` **SHALL** be ASSERTION and the value for `observation / code@codeSystem` **SHALL** be 2.16.840.1.113883.5.4.

CONF-QRDA-373.7: The value for result negation reason `observation / value / @code` and `observation / value / @codeSystem` **SHALL** be from the Appendix_F1-Results (negation) tab of the Downloadable Resources table.

CONF-QRDA-373.8: The value for `observation / statuscode` in a negation reason **SHALL** be “completed” 2.16.840.1.113883.5.14 ActStatus STATIC.

CONF-QRDA-373.9: Negation reason **SHALL** contain exactly one `observation / effectivetime`, which **SHALL** be at least precise to the day (YYYYMMDD).

Figure 34: Results Example

```
<entry 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="103218"/>
		<code code="252275004" codeSystem="2.16.840.1.113883.6.96"
		displayName="Hematology"/>
		<statusCode code="completed"/>
		<effectiveTime value="20090714"/>
		<component>
			<observation classCode="OBS" moodCode="EVN" negationInd="false">
				<templateId root="2.16.840.1.113883.10.20.1.31"/>
				<templateId root="2.16.840.1.113883.3.249.11.100.10"/>
				<!-- Result observation template -->
				<id root="2.16.840.1.113883.19.5.10" extension="103219"/>
				<code code="83037" codeSystem="2.16.840.1.113883.6.12"/>
				<statusCode code="completed"/>
				<effectiveTime value="20090714093000"/>
				<value xsi:type="PQ" value="4.3" unit="%"/>
				<interpretationCode code="N" codeSystem=
				"2.16.840.1.113883.5.83"/>
				<referenceRange>
					<observationRange>
						<text>4 - 6%</text>
					</observationRange>
				</referenceRange>
			</observation>
		</component>
	</organizer>
</entry>
```

Figure 35: Results Negation Example

```
<entry 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="103218"/>
              <code code="252275004" codeSystem="2.16.840.1.113883.6.96"
              displayName="Hematology"/>
              <statusCode code="completed"/>
              <effectiveTime value="20090714"/>
              <component>
                     <observation classCode="OBS" moodCode="EVN" negationInd="true">
                           <templateId root="2.16.840.1.113883.10.20.1.31"/>
                           <templateId root="2.16.840.1.113883.3.249.11.100.10"/>
                           <!-- Result observation template -->
                           <id root="2.16.840.1.113883.19.5.10" extension="103219"/>
                           <code code="83037" codeSystem="2.16.840.1.113883.6.12"/>
                           <statusCode code="completed"/>
                           <effectiveTime value="20090714093000"/>
                           <value xsi:type="PQ" value="4.3" unit="%"/>
                           <interpretationCode code="N" codeSystem=
                           "2.16.840.1.113883.5.83"/>
                           <entryRelationship typeCode="RSON">
                                  <observation classCode="OBS" moodCode="EVN">
                                    <templateId
root="2.16.840.1.113883.3.249.11.100.24"/>
                                    <templateId
root="2.16.840.1.113883.3.249.11.100.30"/>
                                    <!-- Negation Reason template -->

                                    <code code="ASSERTION"
codeSystem="2.16.840.1.113883.5.4"/>
                                    <statusCode code="completed"/>
                                    <effectiveTime>
                                                <low value="200907140"/>
                                    </effectiveTime>
                                    <value xsi:type="CD" code="19729"
codeSystem="2.16.840.1.113883.5.8"
                                       displayName="deceased"/>
                                  </observation>
                           </entryRelationship>
                           <referenceRange>
                                  <observationRange>
                                        <text>4 - 6%</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). A result observation **MAY** include one or more negation reasons (templateId 2.16.840.1.113883.3.249.11.100.31). A vital signs result observation (2.16.840.1.113883.3.249.11.100.33) **SHALL** confirm to the rules of Result observation (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. Also use Appendix_E1- Vital_Signs(negation) tab of Downloadable Resource table for the values of `observation / value / @code` and `@codeSystem`. Further the vital signs negation reason template (2.16.840.1.113883.3.249.11.100.31) **SHALL** confirm to the rules of CMS EHR QRDA negation reason template (2.16.840.1.113883.3.249.11.100.24).

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).

Figure 36: 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="116622"/>
        <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"
negationInd="false">
                    <templateId root="2.16.840.1.113883.10.20.1.31"/>
                    <templateId root="2.16.840.1.113883.3.249.11.100.33"/>
                    <!-- Result observation template -->
                           <code code="60621009"
codeSystem="2.16.840.1.113883.6.96"
       displayName="Body mass index"/>
                           <statusCode code="completed"/>
                           <effectiveTime value="20080202093000"/>
                           <value xsi:type="PQ" value="70" unit="%"/>
                    </observation>
             </component>
    </organizer>
</entry>
```

Figure 37: Vital Signs Negation 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="116622"/>
        <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" negationInd="true">
                    <templateId root="2.16.840.1.113883.10.20.1.31"/>
                    <templateId root="2.16.840.1.113883.3.249.11.100.33"/>
                    <!-- Result observation template -->
                           <code code="60621009" codeSystem="2.16.840.1.113883.6.96"
                                        displayName="Body mass index"/>
                           <statusCode code="completed"/>
                           <effectiveTime value="20080202093000"/>
                           <value xsi:type="PQ" value="70" unit="%"/>
                           <entryRelationship typeCode="RSON">
                                  <observation classCode="OBS" moodCode="EVN">
                                    <templateId
root="2.16.840.1.113883.3.249.11.100.24"/>
                                    <templateId
root="2.16.840.1.113883.3.249.11.100.31"/>
                                    <!-- Negation Reason template -->
                                    <code code="ASSERTION"
codeSystem="2.16.840.1.113883.5.4"/>
                                    <statusCode code="completed"/>
                                    <effectiveTime>
                                                <low value="20080202"/>
                                    </effectiveTime>
                                    <value xsi:type="CD" code="19729"
codeSystem="2.16.840.1.113883.5.8"
                                       displayName="deceased"/>
                                  </observation>
                           </entryRelationship>
                    </observation>
             </component>
    </organizer>
</entry>
```

3.1.10 Structural Design 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_K-Structural_Codes of the 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_K-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 38: Structural Data 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="2.16.840.1.113883.3.249.11.14"/>
            <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>
```

3.1.11 Advance Directives Section

The template identifier for the Advance Directives section is 2.16.840.1.113883.10.20.1.1.

This section contains data defining the patient's advance directives and any reference to supporting documentation. The most recent and up-to-date directives are required, if known, and should be listed in as much detail as possible. This section contains data such as the existence of living wills, healthcare proxies, and CPR and resuscitation status.

> NOTE: The descriptions in this section differentiate between "advance directives" and "advance directive documents". The former are the directions whereas the latter are legal documents containing those directions. Thus, an advance directive might be "no cardiopulmonary resuscitation", and this directive might be stated in a legal advance directive document.

CONF-QRDA1-470: The CMS EHR QRDA Report **SHOULD** contain exactly one and **SHALL NOT** contain more than one Advance directives section (templateId 2.16.840.1.113883.10.20.1.1). The Advance directives section **SHALL** contain a narrative block, and **SHOULD** contain clinical statements. Clinical statements **SHOULD** include one or more advance directive observations (templateId 2.16.840.1.113883.10.20.1.17). An advance directive observation **MAY** contain exactly one advance directive reference (templateId 2.16.840.1.113883.10.20.1.36) to an external advance directive document. The Advance directives section SHOULD include one or more CMS EHR QRDA Advance directive observations (templateId 2.16.840.1.113883.3.249.11.100.15) and it SHALL confirm to the rules of Advance directive observation (2.16.840.1.113883.10.20.1.17).

3.1.11.1 Section conformance

CONF-QRDA1-471: The advance directive section SHALL contain Section / code.

CONF-QRDA1-472: The value for "**Section / code**" **SHALL** be "42348-3" "Advance directives" 2.16.840.1.113883.6.1 LOINC **STATIC**.

CONF-QRDA1-473: The advance directive section **SHALL** contain **Section / title.**

CONF-QRDA1-474: Section / title SHOULD be valued with a case-insensitive language-insensitive text string containing "advance directives".

3.1.11.2 Advance directive observations

The template identifier for an advance directive observation is 2.16.840.1.113883.10.20.1.17.

The template identifier for verification of an advance directive observation is templateId 2.16.840.1.113883.10.20.1.58.

CONF-QRDA1-475: Advance directive observation SHALL be represented with Observation

CONF-QRDA1-476: The value for "**Observation / @classCode**" in an advance directive observation **SHALL** be "OBS" 2.16.840.1.113883.5.6 ActClass **STATIC**.

CONF-QRDA1-477: The value for "**Observation / @moodCode**" in an advance directive observation **SHALL** be "EVN" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-QRDA1-478: An advance directive observation **SHALL** contain at least one **Observation / id**.

CONF-QRDA1-479: An advance directive observation **SHALL** contain exactly one **Observation / statusCode**.

CONF-QRDA1-480: The value for "**Observation / statusCode**" in an advance directive observation **SHALL** be "completed" 2.16.840.1.113883.5.14 ActStatus **STATIC**.

CONF-QRDA1-481: An advance directive observation **SHOULD** contain exactly one **Observation / effectiveTime**, to indicate the effective time of the directive.

CONF-QRDA1-482: An advance directive observation **SHALL** contain exactly one **Observation / code**.

CONF-QRDA1-483: The value for "**Observation / code"** in an advance directive observation **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.20.2 AdvanceDirectiveTypeCode **STATIC** 20061017.

CONF-QRDA1-484: There **SHOULD** be an advance directive observation whose value for "**Observation / code"** is "304251008" "Resuscitation status" 2.16.840.1.113883.6.96 SNOMED CT **STATIC**.

CONF-QRDA1-485: A verification of an advance directive observation (templateId 2.16.840.1.113883.10.20.1.58) **SHALL** be represented with **Observation / participant**.

CONF-QRDA1-486: An advance directive observation **SHALL** include one or more verifications.

CONF-QRDA1-487: The value for "**Observation / participant /** @**typeCode**" in a verification **SHALL** be "VRF" "Verifier" 2.16.840.1.113883.5.90 ParticipationType **STATIC**.

CONF-QRDA1-488: A verification of an advance directive observation **SHOULD** contain **Observation / participant / time**.

CONF-QRDA1-489: The data type of **Observation / participant / time** in a verification **SHALL** be at least precise to the day (YYYYMMDD).

3.1.11.3 Representation of "status" values

The template identifier for an advance directive status observation is 2.16.840.1.113883.10.20.1.37.

CONF-QRDA1-491: An advance directive observation **SHALL** contain exactly one advance directive status observation.

CONF-QRDA1-492: An advance directive status observation (templateId 2.16.840.1.113883.10.20.1.37) **SHALL** be a conformant status observation (templateId 2.16.840.1.113883.10.20.1.57).

CONF-QRDA1-493: The value for "**Observation / value**" in an advance directive status observation **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.20.1 AdvanceDirectiveStatusCode **STATIC** 20061017.

3.1.11.4 Advance directive references

The template identifier for an advance directive reference is 2.16.840.1.113883.10.20.1.36.

Referenced advance directive documents are represented with the **ExternalDocument** class.

CONF-QRDA1-494: An advance directive reference (templateId 2.16.840.1.113883.10.20.1.36) **SHALL** be represented with **Observation / reference / ExternalDocument**.

CONF-QRDA1-495: An advance directive observation **MAY** contain exactly one advance directive reference.

CONF-QRDA1-496: The value for "**Observation / reference /** @**typeCode**" in an advance directive reference **SHALL** be "REFR" 2.16.840.1.113883.5.1002 ActRelationshipType **STATIC**.

CONF-QRDA1-497: ExternalDocument **SHALL** contain at least one ExternalDocument / id.

CONF-QRDA1-498: The URL of a referenced advance directive document **MAY** be present, and **SHALL** be represented in **Observation / reference / ExternalDocument / text / reference**. A **<linkHTML>** element containing the same URL **SHOULD** be present in the associated CDA Narrative Block.

CONF-QRDA1-499: The MIME type of a referenced advance directive document **MAY** be present, and **SHALL** be represented in **Observation / reference / ExternalDocument / text / @mediaType**.

Figure 39: Advance Directives Example

This description of a “Do not resuscitate” order is verified, current and links to a PDF document.

```
<entry typeCode="DRIV">
       <observation classCode="OBS" moodCode="EVN">
              <templateId root='2.16.840.1.113883.10.20.1.17'/>
              <templateId root="2.16.840.1.113883.3.249.11.100.15"/>
              <!-- Advance directive observation template -->
              <id root="2.16.840.1.113883.19.5.10" extension="1123223"/>
              <code code="304251008" codeSystem="2.16.840.1.113883.6.96"
              displayName="Resuscitation"/>
              <statusCode code="completed"/>
              <value xsi:type="CD" code="304253006" codeSystem=
              "2.16.840.1.113883.6.96" displayName="Do not resuscitate">
                     <originalText>
                            <reference value="#AD1"/>
                     </originalText>
              </value>
              <participant typeCode="VRF">
                     <templateId root='2.16.840.1.113883.10.20.1.58'/>
                     <!-- Verification of an advance directive
                     observation template -->
                     <time value="19991107"/>
                     <participantRole>
                            <id root="2.16.840.1.113883.19.5.10"
                            extension="1123424"/>
                     </participantRole>
              </participant>
              <entryRelationship typeCode="REFR">
                     <observation classCode="OBS" moodCode="EVN">
                            <templateId root=
                            "2.16.840.1.113883.10.20.1.37"/>
                            <!-- Advance directive status
                            observation template -->
                            <id root="2.16.840.1.113883.19.5.10"
                            extension="11343533"/>
                            <code code="33999-4" codeSystem=
                            "2.16.840.1.113883.6.1"
                            displayName="Status"/>
                            <statusCode code="completed"/>
                            <effectiveTime xsi:type="IVL_TS"/>
                            <value xsi:type="CE" code="425392003"
                            codeSystem="2.16.840.1.113883.6.96"
                            displayName="Current and verified"/>
                     </observation>
              </entryRelationship>
              <reference typeCode="REFR">
                     <externalDocument>
                            <templateId root="2.16.840.1.113883.10.20.1.36"/>
                            <!-- Advance directive reference template -->
                            <id root="2.16.840.1.113883.19.5.10"
                            extension="11534546"/>
                            <code code="371538006" codeSystem=
                            "2.16.840.1.113883.6.96"
                            displayName="Advance directive"/>
                            <text mediaType="application/pdf">
                                   <reference value=
                                   "AdvanceDirective_331.pdf"/>
                            </text>
                     </externalDocument>
              </reference>
       </observation>
</entry>
```

3.1.12 Plan of Care Section

The template identifier for the plan of care section is 2.16.840.1.113883.10.20.1.10.

The plan of care section contains data defining pending orders, interventions, encounters, services, and procedures for the patient. It is limited to prospective, unfulfilled, or incomplete orders and requests only. All active, incomplete, or pending orders, appointments, referrals, procedures, services, or any other pending event of clinical significance to the current and ongoing care of the patient should be listed, unless constrained due to issues of privacy.

The plan of care section also contains information regarding goals and clinical reminders. Clinical reminders are placed here for purposes of providing prompts that may be used for disease prevention, disease management, patient safety, and healthcare quality improvements, including widely accepted performance measures.

CONF-QRDA1-550: The CMS EHR QRDA Report **SHOULD** contain exactly one and **SHALL NOT** contain more than one Plan of Care section (templateId 2.16.840.1.113883.10.20.1.10). The Plan of Care section **SHALL** contain a narrative block, and **SHOULD** contain clinical statements. Clinical statements **SHALL** include one or more plan of care activities (templateId 2.16.840.1.113883.10.20.1.25). Plan of Care section **SHALL** include one or more CMS EHR QRDA Plan of care activity (2.16.840.1.113883.3.249.11.100.2) which **SHALL** confirm to the rules of Plan of care activity (2.16.840.1.113883.10.20.1.25).

3.1.12.1 Section conformance

CONF-QRDA1-551: The plan of care section **SHALL** contain **Section / code**.

CONF-QRDA1-552: The value for "**Section / code**" **SHALL** be "18776-5" "Treatment plan" 2.16.840.1.113883.6.1 LOINC **STATIC**.

CONF-QRDA1-553: The plan of care section **SHALL** contain **Section / title.**

CONF-QRDA1-554: Section / title SHOULD be valued with a case-insensitive language-insensitive text string containing "plan".

3.1.12.2 Clinical statement conformance

3.1.12.3 Plan of care activities

The template identifier for a plan of care activity is 2.16.840.1.113883.10.20.1.25.

CONF-QRDA1-555: Plan of care activity **SHALL** be represented with Observation.

CONF-QRDA1-556: A plan of care activity **SHALL** contain at least one **Observation / id**.

CONF-QRDA1-557: A plan of care activity **SHALL** contain exactly one **Observation / @moodCode**.

CONF-QRDA1-560: The value for "**Observation / @moodCode**" in a plan of care activity **SHALL** be ["INT" (intent) | "PRMS" (promise) | "PRP" (proposal) | "RQO" (request) | "GOL" (goal)] 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-QRDA1-561: The Plan of care section SHALL contain exactly one observation combination of 'code' and 'codeSystem' attribute values from Appendix_I of the Downloadable Resource table (for the current program year) identifying clinical data according to the specifications.

CONF-QRDA1-562: The value for "Observation / statusCode" in a Plan of care observation SHOULD be selected from ValueSet 2.16.840.1.113883.1.11.20.10 PlanOfCareStatusCode STATIC 20061017.

CONF-QRDA1-563: Plan of care observation 'effectiveTime' in the Plan of care activity entry SHALL be the time stamp of the format (YYYYYMMDDHHMMSS).

Figure 40: Plan of Care Example

```
<entry typeCode="DRIV">
       <observation classCode="OBS" moodCode="RQO">
              <templateId root="2.16.840.1.113883.10.20.1.25"/>
              <templateId root="2.16.840.1.113883.3.249.11.100.2"/>
              <!-- Plan of Activity activity template -->
              <id root="2.16.840.1.113883.19.5.10" extension="10322552"/>
              <code code="97802" codeSystem="2.16.840.1.113883.6.12"/>
              <statusCode code="Aborted"/>
              <effectiveTime>
                     <center value="20000421093000"/>
              </effectiveTime>
       </observation>
</entry>
```

3.1.13 Social History Section

The template identifier for the social history section is 2.16.840.1.113883.10.20.1.15.

This section contains data defining the patient's occupational, personal (e.g. lifestyle), social, and environmental history and health risk factors, as well as administrative data such as marital status, race, ethnicity and religious affiliation. Social history can have significant influence on a patient's physical, psychological and emotional health and wellbeing so should be considered in the development of a complete record.

CONF-QRDA1-590: The CMS EHR QRDA Report **SHOULD** contain exactly one and **SHALL NOT** contain more than one Social history section (templateId 2.16.840.1.113883.10.20.1.15). The Social history section **SHALL** contain a narrative block, and **SHOULD** contain clinical statements. Clinical statements **SHOULD** include one or more social history observations (templateId 2.16.840.1.113883.10.20.1.33). Social history section SHOULD include one or more CMS EHR QRDA Social history observations (templateId 2.16.840.1.113883.3.249.11.100.5) and it SHALL confirm to the Social History Observation (2.16.840.1.113883.10.20.1.33).

3.1.13.1 Section conformance

CONF-QRDA1-591: The social history section **SHALL** contain **Section / code**.

CONF-QRDA1-592: The value for "**Section / code**" **SHALL** be "29762-2" "Social history" 2.16.840.1.113883.6.1 LOINC **STATIC**.

CONF-QRDA1-593: The social history section **SHALL** contain **Section / title.**

CONF-QRDA1-594: Section / title SHOULD be valued with a case-insensitive language-insensitive text string containing "social history".

3.1.13.2 Social history observation

The template identifier for a social history observation is 2.16.840.1.113883.10.20.1.33.

CONF-QRDA1-595: A Social history observation **SHALL** be represented with **Observation.**

CONF-QRDA1-596: The value for "**Observation / @classCode**" in a social history observation **SHALL** be "OBS" 2.16.840.1.113883.5.6 ActClass **STATIC**.

CONF-QRDA1-597: The value for "**Observation / @moodCode**" in a social history observation **SHALL** be "EVN" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-QRDA1-598: A social history observation **SHALL** contain at least one **Observation / id**.

CONF-QRDA1-599: A social history observation **SHALL** include exactly one **Observation / statusCode**.

CONF-QRDA1-600: The value for "**Observation / statusCode**" in a social history observation **SHALL** be "completed" 2.16.840.1.113883.5.14 ActStatus **STATIC**.

CONF-QRDA1-601: The value for "**Observation / code**" in a social history observation **SHALL** be selected from Appendix_J_Social_History.

CONF-QRDA1-602: Observation / value can be any datatype. Where **Observation / value** is a physical quantity, the unit of measure **SHALL** be expressed using a valid Unified Code for Units of Measure (UCUM) expression.

3.1.13.3 Representation of "status" values

The template identifier for a social history status observation is 2.16.840.1.113883.10.20.1.56.

CONF-QRDA1-604: A social history observation SHALL contain exactly one CMS EHR QRDA Social history status observation (2.16.840.1.113883.3.249.11.100.4) which SHALL confirm to the rules of Social history status observation (2.16.840.1.113883.10.20.1.56).

CONF-QRDA1-605: Social history status observation **SHALL** be a conformant status observation (templateId 2.16.840.1.113883.10.20.1.57).

CONF-QRDA1-606: The value for "**Observation / value**" in a social history status observation **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.20.17 SocialHistoryStatusCode **STATIC** 20061017.

3.1.13.4 Episode observations

The template identifier for an episode observation is 2.16.840.1.113883.10.20.1.41.

CONF-QRDA1-607: A social history observation **MAY** contain exactly one episode observation (templateId 2.16.840.1.113883.10.20.1.41).

Figure 41: Social History Example

```
<entry typeCode="DRIV">
       <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.33"/>
              <templateId root="2.16.840.1.113883.3.249.11.100.5"/>
              <!-- social history observations template -->
              <id root="2.16.840.1.113883.19.5.10" extension="1032134248"/>
              <code code="56578002" codeSystem="2.16.840.1.113883.6.96"
                     displayName="Moderate smoker, 20 or less per day"/>
              <statusCode code="completed"/>
              <effectiveTime>
                     <center value="20000421"/>
              </effectiveTime>
              <entryRelationship typeCode="REFR">
                     <observation classCode="OBS" moodCode="EVN">
                            <!-- social history status observation template -->
                            <templateId root="2.16.840.1.113883.10.20.1.56"/>
                            <templateId root="2.16.840.1.113883.3.249.11.100.4"/>
                            <code code="33999-4"
codeSystem="2.16.840.1.113883.6.1"/>
                            <statusCode code="completed"/>
                            <value xsi:type="CD" code="55561003"
                            codeSystem="2.16.840.1.113883.6.96"
                            displayName="active"/>
                     </observation>
              </entryRelationship>
       </observation>
</entry>
```

3.1.14 Encounters Section

The template identifier for the encounters section is 2.16.840.1.113883.10.20.1.3.

This section is used to list and describe any healthcare encounters pertinent to the patient's current health status or historical health history. An Encounter is an interaction, regardless of the setting, between a patient and a practitioner who is vested with primary responsibility for diagnosing, evaluating, or treating the patient's condition. It may include visits, appointments, as well as non face-to-face interactions. It is also a contact between a patient and a practitioner who has primary responsibility for assessing and treating the patient at a given contact, exercising independent judgment. This section may contain all encounters for the time period being summarized, but should include notable encounters.

CONF-QRDA1-630: The CMS EHR QRDA Report **SHOULD** contain exactly one and **SHALL NOT** contain more than one Encounters section (templateId 2.16.840.1.113883.10.20.1.3). The Encounters section **SHALL** contain a narrative block, and **SHOULD** contain clinical statements. Clinical statements **SHOULD** include one or more encounter activities (templateId 2.16.840.1.113883.10.20.1.21). Encounters section SHOULD include one or more CMS EHR QRDA Encounter activity (2.16.840.1.113883.3.249.11.100.3) which SHALL confirm to the rules of Encounter activity (2.16.840.1.113883.10.20.1.21)

3.1.14.1 Section conformance

CONF-QRDA1-631: The encounters section **SHALL** contain **Section / code**.

CONF-QRDA1-632: The value for "**Section / code**" **SHALL** be "46240-8" "History of encounters" 2.16.840.1.113883.6.1 LOINC **STATIC**.

CONF-QRDA1-633: The encounters section **SHALL** contain **Section / title.**

CONF-QRDA1-634: Section / title SHOULD be valued with a case-insensitive language-insensitive text string containing "encounters".

3.1.14.2 Encounter activities

The template identifier for an encounter activity is 2.16.840.1.113883.10.20.1.21.

CONF-QRDA1-635: Encounter activity **SHALL** be represented with **Encounter**.

CONF-QRDA1-636: The value for "**Encounter / @classCode**" in an encounter activity **SHALL** be "ENC" 2.16.840.1.113883.5.6 ActClass **STATIC**.

CONF-QRDA1-637: The value for "**Encounter / @moodCode**" in an encounter activity **SHALL** be "EVN" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-QRDA1-638: An encounter activity **SHALL** contain at least one **Encounter / id**.

CONF-QRDA1-639: An encounter activity **SHALL** contain exactly one **Encounter / code**.

CONF-QRDA1-640: The value for "**Encounter / code**" in an encounter activity **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.13955 EncounterCode 2.16.840.1.113883.5.4 ActCode **DYNAMIC**.

CONF-QRDA1-641: An encounter activity **SHALL** contain exactly one **Encounter / effectiveTime**, and it **SHALL** be at least precise to the day (YYYYMMDD).

CONF-QRDA1-642: An encounter activity **MAY** contain one or more **Encounter / entryRelationship**, whose value for "**entryRelationship / @typeCode**" **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-QRDA1-643: An encounter activity **MAY** contain one or more **Encounter / performer**, used to define the practioners involved in an encounter.

CONF-QRDA1-644: Encounter / performer MAY contain exactly one **Encounter / performer / assignedEntity / code**, to define the role of the practioner.

CONF-QRDA1-645: An encounter activity **MAY** contain one or more patient instructions (templateId 2.16.840.1.113883.10.20.1.49).

CONF-QRDA1-646: The value for "**Encounter / entryRelationship / @typeCode**" in an encounter activity **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-QRDA1-647: One Encounter Activity **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 Encounter Activity.

3.1.14.3 Encounter location

The template identifier for a location participation is 2.16.840.1.113883.10.20.1.45.

CONF-QRDA1-648: An encounter activity **MAY** contain one or more location participations.

CONF-QRDA1-649: A location participation (templateId 2.16.840.1.113883.10.20.1.45) **SHALL** be represented with the **participant** participation.

CONF-QRDA1-650: The value for "**participant / @typeCode**" in a location participation **SHALL** be "LOC" 2.16.840.1.113883.5.90 ParticipationType **STATIC**.

CONF-QRDA1-651: A location participation **SHALL** contain exactly one **participant / participantRole**.

CONF-QRDA1-652: The value for "**participant / participantRole / @classCode**" in a location participation **SHALL** be "SDLOC" "Service delivery location" 2.16.840.1.113883.5.110 RoleClass **STATIC**.

CONF-QRDA1-653: Participant / participantRole in a location participation **MAY** contain exactly one **participant / participantRole / code**.

CONF-QRDA1-654: The value for "**participant / participantRole / code**" in a location participation **SHOULD** be selected from ValueSet 2.16.840.1.113883.1.11.17660 ServiceDeliveryLocationRoleType 2.16.840.1.113883.5.111 RoleCode **DYNAMIC**.

CONF-QRDA1-655: Participant / participantRole in a location participation **MAY** contain exactly one **participant / participantRole / playingEntity**.

CONF-QRDA1-656: The value for "**participant / participantRole / playingEntity / @classCode**" in a location participation **SHALL** be "PLC" "Place" 2.16.840.1.113883.5.41 EntityClass **STATIC**.

Figure 42: Encounter Example

```
<<entry typeCode="DRIV">
       <encounter classCode="ENC" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.21"/>
              <templateId root="2.16.840.1.113883.3.249.11.100.3"/>
              <!-- Encounter activity template -->
              <id root="2.16.840.1.113883.19.5.10"
              extension="1032432405"/>
              <code code="IMP" codeSystem="2.16.840.1.113883.5.4"
              displayName="Inpatient"/>
              <effectiveTime value="20000407"/>
              <participant typeCode="LOC">
                     <templateId root="2.16.840.1.113883.10.20.1.45"/>
                     <!-- Location participation template -->
                     <participantRole classCode="SDLOC">
                            <id root="2.16.840.1.113883.19.5.10"
                                   extension="103545405"/>
                            <code code="CATH" codeSystem=
                                   "2.16.840.1.113883.5.111"/>
                            <playingEntity classCode="PLC">
                                   <name>Good Health Clinic</name>
                            </playingEntity>
                     </participantRole>
              </participant>
       </encounter>
</entry>
```

3.1.15 Medical Equipment

The template identifier for the medical equipment section is 2.16.840.1.113883.10.20.1.7.

The Medical Equipment section defines a patient's implanted and external medical devices and equipment that their health status depends on, as well as any pertinent equipment or device history. This section is also used to itemize any pertinent current or historical durable medical equipment (DME) used to help maintain the patient's health status. All pertinent equipment relevant to the diagnosis, care, and treatment of a patient should be included.

The CMS EHR QRDA report defines medical equipment using the same data objects and constraints as for Medications.

CONF-QRDA1-657: The CMS EHR QRDA report **SHOULD** contain exactly one and **SHALL NOT** contain more than one Medical Equipment section (templateId 2.16.840.1.113883.10.20.1.7). The Medical Equipment section **SHALL** contain a narrative block, and **SHOULD** contain clinical statements. Clinical statements **SHOULD** include one or more supply activities (templateId 2.16.840.1.113883.10.20.1.34) and **MAY** include one or more medication activities (templateId 2.16.840.1.113883.10.20.1.24).

3.1.15.1 Section conformance

CONF-QRDA1-658: **The medical equipment section** SHALL **contain** Section / code**.**

CONF-QRDA1-659: The value for "**Section / code / @code**" **SHALL** be "46264-8" "History of medical device use". The value for "**Section / code / @codeSystem**" **SHALL** be 2.16.840.1.113883.6.1 LOINC **STATIC**.

CONF-QRDA1-660: The medical equipment section **SHALL** contain **Section / title**.

CONF-QRDA1-661: Section / title SHOULD be valued with a case-insensitive language-insensitive text string containing “equipment”.

3.1.15.2 Clinical Statement conformance

The CMS EHR QRDA report defines medical equipment using the same data objects and constraints as for Medications.

3.1.15.2.1.1 Supply activity

CONF-QRDA1-662: A `supply activity` (templateId 2.16.840.1.113883.10.20.1.34) **SHALL** be represented with `Supply`. The CMS EHR QRDA Report supply activity (2.16.840.1.113883.3.249.11.100.22) **SHALL** confirm to the rules of Supply Activity (2.16.840.1.113883.10.20.1.34).

CONF-QRDA1-663: 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-QRDA1-664: A supply activity **SHALL** contain at least one `Supply / id`.

CONF-QRDA1-665: A supply activity **SHOULD** contain exactly one `Supply / statusCode`.

CONF-QRDA1-666: A supply activity **SHALL** contain exactly one `Supply / effectiveTime`, to indicate the actual or intended time of dispensing. Supply / effectiveTime **SHALL** be the time stamp of the format YYYYMMDDHHMMSS.

3.1.15.2.2 Representation of “Status” Values

The template identifier for a medication status observation is 2.16.840.1.113883.10.20.1.47.

CONF-QRDA1-667: A supply activity **SHALL** contain exactly one medication status observation.

CONF-QRDA1-668: 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-QRDA1-669: 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.

3.1.15.3 Representation of a Product instance

The template identifier for a product instance is 2.16.840.1.113883.10.20.1.52.

CONF-QRDA1-670: The CMS EHR QRDA Report Product instance (2.16.840.1.113883.3.249.11.100.23) **SHALL** confirm to the rules of Product instance (2.16.840.1.113883.10.20.1.52).

CONF-QRDA1-671: The value for playingDevice / code in a product instance template **SHALL** be selected from the Appendix_L-Medical Equipment table of the Downloadable Resoure table.

CONF-QRDA1-672: A supply activity **SHALL** contain one or more product instance templates (templateId 2.16.840.1.113883.10.20.1.52) to identify a particular product instance.

Figure 43: Medical Equipment Example

```
       <entry typeCode="DRIV">
              <supply classCode="SPLY" moodCode="EVN">
                     <templateId root="2.16.840.1.113883.10.20.1.34"/>
                     <templateId root="2.16.840.1.113883.3.249.11.100.22"/>
                     <!-- Supply activity template -->
                     <id root="2.16.840.1.113883.19.5.10" extension="32328395"/>
                     <statusCode code="completed"/>
                     <effectiveTime xsi:type="IVL_TS">
                            <center value="20051101"/>
                     </effectiveTime>
                     <participant typeCode="DEV">
                            <participantRole classCode="MANU">
                                   <templateId root="2.16.840.1.113883.10.20.1.52"/>
                                   <templateId
root="2.16.840.1.113883.3.249.11.100.23"/>
                                   <!-- Product instance template -->
                                   <playingDevice>
                                          <code code="14106009"
codeSystem="2.16.840.1.113883.6.96"
                                          displayName="Cardiac pacemaker"/>
                                   </playingDevice>
                            </participantRole>
                     </participant>
                     <entryRelationship typeCode="REFR">
                       <observation classCode="OBS" moodCode="EVN">
                            <templateId root="2.16.840.1.113883.10.20.1.47"/>
                            <!-- Medication status observation template -->
                            <code codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC"
                              code="33999-4"  displayName="Status"/>
                            <statusCode code="completed"/>
                            <value xsi:type="CE" codeSystem="2.16.840.1.113883.6.96"
                              codeSystemName="SNOMED-CD" code="55561003"
displayName="Active"/>
                       </observation>
                     </entryRelationship>
              </supply>
       </entry>
```

3.1.16 Family History

The template identifier for the family history section is 2.16.840.1.113883.10.20.1.4.

This section contains data defining the patient's genetic relatives in terms of possible or relevant health risk factors that have potential impact on the patient's heathcare risk profile.

CONF-QRDA1-673: The CMS EHR QRDA Report SHOULD contain exactly one and **SHALL NOT** contain more than one Family history section (templateId 2.16.840.1.113883.10.20.1.4). The Family history section **SHALL** contain a narrative block, and **SHOULD** contain clinical statements. Clinical statements **SHOULD** include one or more family history observations (templateId 2.16.840.1.113883.10.20.1.22), which **SHALL** be contained within family history organizers (templateId 2.16.840.1.113883.10.20.1.23). Family history section **SHOULD** include one or more CMS EHR Family History Organizers (2.16.840.1.113883.3.249.11.100.20) which **SHALL** confirm to the rules of Family History Organizers (2.16.840.1.113883.10.20.11.23).

3.1.16.1 Section conformance

CONF-QRDA1-674: The family history section **SHALL** contain **Section / code.**

CONF-QRDA1-675: The value for "**Section / code / @code**" **SHALL** be "10157-6" "History of family member diseases". The value for "**Section / code / @codeSystem**" **SHALL** be 2.16.840.1.113883.6.1 LOINC **STATIC**.

CONF-QRDA1-676: The family history section **SHALL** contain **Section / title**.

CONF-QRDA1-677: **Section / title SHOULD** be valued with a case-insensitive language-insensitive text string containing "family history".

CONF-QRDA1-678: The family history section **SHALL NOT** contain **Section / subject**.

3.1.16.2 Clinical conformance

3.1.16.2.1 Family history representation

The template identifier for a family history observation is 2.16.840.1.113883.10.20.1.22.

The template identifier for a family history organizer is 2.16.840.1.113883.10.20.1.23.

Family history observations shall be contained within a family history organizer in order to group those observations related to a particular family member.

3.1.16.2.1.1 Family history observation

CONF-QRDA1-679: A family history observation (templateId 2.16.840.1.113883.10.20.1.22) **SHALL** be represented with **Observation.**

CONF-QRDA1-680: The value for "**Observation / @moodCode**" in a family history observation **SHALL** be "EVN" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-QRDA1-681: A family history observation **SHALL** contain at least one **Observation / id**.

CONF-QRDA1-682: A family history observation **SHALL** include exactly one **Observation / statusCode**.

CONF-QRDA1-683: The value for "**Observation / statusCode**" in a family history observation **SHALL** be "completed" 2.16.840.1.113883.5.14 ActStatus **STATIC.**

CONF-QRDA1-684: A family history observation **SHOULD** include **Observation / effectiveTime**.

CONF-QRDA1-685: The value for "**Observation / value / @code**" and "**@CodeSystem**" in a Family history observation **SHALL** be selected from Appendix_M- Family_History.

3.1.16.2.1.2 Family history organizer

CONF-QRDA1-686: A family history organizer (templateId 2.16.840.1.113883.10.20.1.23) **SHALL** be represented with **Organizer.**

CONF-QRDA1-687: The value for "**Organizer / @classCode**" in a family history organizer **SHALL** be "CLUSTER" 2.16.840.1.113883.5.6 ActClass **STATIC.**

CONF-QRDA1-688: The value for "**Organizer /** @**moodCode**" in a family history organizer **SHALL** be "EVN" 2.16.840.1.113883.5.1001 ActMood **STATIC.**

CONF-QRDA1-689: A family history organizer **SHALL** contain exactly one **Organizer / statusCode.**

CONF-QRDA1-690: The value for "**Organizer / statusCode**" in a family history organizer **SHALL** be "completed" 2.16.840.1.113883.5.14 ActStatus **STATIC**.

CONF-QRDA1-691: A family history organizer **SHALL** contain one or more **Organizer / component**.

CONF-QRDA1-692: The target of a family history organizer **Organizer / component** relationship **SHALL** be a family history observation. Family history organizer SHALL include one or more CMS EHR QRDA Family history observations (2.16.840.1.13883.3.249.1.100.21) which SHALL conform to the rules of Family history observations (2.16.840.1.113883.10.20.1.22).

3.1.16.2.2 Family history participants

CONF-QRDA1-693: A family history organizer **SHALL** contain exactly one **subject** participant, representing the family member who is the subject of the family history observations.

CONF-QRDA1-694: A **subject** participant **SHALL** contain exactly one **RelatedSubject**, representing the relationship of the subject to the patient.

CONF-QRDA1-695: The value for "**RelatedSubject /** @**classCode**" **SHALL** be "PRS" "Personal relationship" 2.16.840.1.113883.5.110 RoleClass **STATIC**

CONF-QRDA1-696: RelatedSubject **SHALL** contain exactly one RelatedSubject / code.

CONF-QRDA1-697: The value for "**RelatedSubject / code**" **SHOULD** be selected from ValueSet 2.16.840.1.113883.1.11.19579 FamilyHistoryRelatedSubjectCode **DYNAMIC** or 2.16.840.1.113883.1.11.20.21 FamilyHistoryPersonCode **DYNAMIC**.

CONF-QRDA1-698: RelatedSubject **SHOULD** contain exactly one **RelatedSubject / subject.**

CONF-QRDA1-699: RelatedSubject / subject **SHOULD** contain exactly one **RelatedSubject / subject / administrativeGenderCode.**

CONF-QRDA1-700: RelatedSubject / subject **SHALL** contain exactly one **RelatedSubject / subject / birthtime.**

Figure 44: Family History Example

```
<entry typeCode="DRIV">
       <organizer moodCode="EVN" classCode="CLUSTER">
              <templateId root="2.16.840.1.113883.10.20.1.23"/>
              <templateId root="2.16.840.1.113883.3.249.11.100.20"/>
              <!-- Family history organizer template -->
              <statusCode code="completed"/>
              <subject>
                     <relatedSubject classCode="PRS">
                            <code code="NMTH" codeSystem="2.16.840.1.113883.5.111"
                                          displayName="Natural mother"/>
                            <subject>
                                   <administrativeGenderCode code="F"
codeSystem="2.16.840.1.113883.5.1"
                                                displayName="Female"/>
                                   <birthTime value="1922"/>
                            </subject>
                     </relatedSubject>
              </subject>
              <component>
                     <observation classCode="OBS" moodCode="EVN">
                            <templateId root="2.16.840.1.113883.10.20.1.22"/>
                            <templateId root="2.16.840.1.113883.3.249.11.100.21"/>
                            <!-- Family history observation template -->
                            <id root="2.16.840.1.113883.19.5.10"
extension=”32328383”/>
                            <code code="ASSERTION"
codeSystem="2.16.840.1.113883.5.4"/>

                            <statusCode code="completed"/>
                            <effectiveTime>
                                   <low value="1962"/>
                            </effectiveTime>
                            <value xsi:type="CD" code="81266008"
codeSystem="2.16.840.1.113883.6.96"
                                          displayName="heart revascularization"/>
                     </observation>
              </component>
       </organizer>
</entry>
```

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: http://www.ama-assn.org/go/collaborative
- 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.
- Collaborative for Performance Measure Integration with EHR Systems Work Group A Recommendations to full Collaborative: http://www.ama-assn.org/ama1/pub/upload/mm/472/wkgrparecommendation.pdf
- HIMSS Electronic Health Record Association - Continuity of Care Document (CCD) Quick Start Guide: http://www.himssehra.org/docs/ccd_qsg.zip
- HITSP Quality Interoperability Specification: http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=1&PrefixNumeric=06
- ICD-10 Implementation Guide: https://www.cms.gov/ICD10/
- Logical Observation Identifiers Names and Codes (LOINC®) http://loinc.org/
- National Quality Forum: http://www.qualityforum.org/
- NCQA > HEDIS & Quality Measurement: http://www.ncqa.org/tabid/59/Default.aspx
- SNOMED CT®: http://www.ihtsdo.org/snomed-ct