



Centers for Medicare & Medicaid Services

CMS Implementation Guide for Quality Reporting Document Architecture Category I

Hospital Quality Reporting Implementation Guide for 2018

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QRDA Guide Overview

1 Introduction

1.1 Overview

The Health Level Seven International (HL7) Quality Reporting Document Architecture (QRDA) defines constraints on the HL7 Clinical Document Architecture Release 2 (CDA R2). QRDA is a standard document format for the exchange of electronic clinical quality measure (eCQM) data. QRDA reports contain data extracted from electronic health records (EHRs) and other information technology systems. The reports are used for the exchange of eCQM data between systems for quality measurement and reporting programs.

This QRDA guide contains the Centers for Medicare & Medicaid Services (CMS) implementation guide to the *HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture Category I, Release 1, Standard for Trial Use (STU) Release 4, US Realm*, Jan 2017¹ for the 2018 reporting year.

1.2 Organization of the Guide

Chapter 1 and Chapter 2 contain introductory material that pertains to this guide.

- Chapter 1: Introduction
- Chapter 2: Conformance Conventions Used in This Guide — describes the formal representation of templates and additional information necessary to understand and correctly implement the content found in this guide

Chapter 3 to Chapter 5 contain technical specifications of QRDA I STU R4 CMS Implementation Guide for Hospital Quality Reporting

- Chapter 3: Overview
- Chapter 4: QRDA Category I Requirements — information on succession management, value sets, and time zones
- Chapter 5: QRDA Category I Validation — contains the formal definitions for the QRDA Category I Report:
 - Document-level template that defines the document type and header constraints specific to CMS reporting
 - Section-level templates that define measure reporting, reporting parameters, and patient data
 - Additional validations rules performed by the HQR system

APPENDIX

- Chapters 6-13 provide references and resources, including a change log of changes made to the QRDA Category I base standard to produce the CMS Implementation Guide, a change log for the 2018 CMS QRDA IG for HQR programs from the 2017 CMS QRDA IG, and validation rules for data types, National Provider Identifier (NPI), and Tax Identification Number (TIN).

¹ HL7 QRDA I R1 STU R4. http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35

2 Conformance Conventions Used in This Guide

2.1 Conformance Verbs (Keywords)

The keywords **SHALL**, **SHOULD**, **MAY**, **NEED NOT**, **SHOULD NOT**, and **SHALL NOT** in this guide are to be interpreted as follows:

- **SHALL**: an absolute requirement for the particular element. Where a **SHALL** constraint is applied to an Extensible Markup Language (XML) element, that element must be present in an instance, but may have an exceptional value (i.e., may have a `nullFlavor`), unless explicitly precluded. Where a **SHALL** constraint is applied to an XML attribute, that attribute must be present, and must contain a conformant value.
- **SHALL NOT**: an absolute prohibition against inclusion.
- **SHOULD/SHOULD NOT**: best practice or recommendation. There may be valid reasons to ignore an item, but the full implications must be understood and carefully weighed before choosing a different course.
- **MAY/NEED NOT**: truly optional; can be included or omitted as the author decides with no implications.

2.2 Cardinality

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

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

When a constraint has subordinate clauses, the scope of the cardinality of the parent constraint must be clear. In Figure 1, the constraint says exactly one participant is to be present. The subordinate constraint specifies some additional characteristics of that participant.

Figure 1: Constraints Format – only one allowed

- | |
|---|
| <ol style="list-style-type: none"> 1. SHALL contain exactly one [1..1] participant (CONF:2777). <ol style="list-style-type: none"> a. This participant SHALL contain exactly one [1..1] <code>@typeCode="LOC" (CodeSystem: 2.16.840.1.113883.5.90</code> <code>HL7ParticipationType) (CONF:2230).</code> |
|---|

In Figure 2, the constraint says only one participant “like this” is to be present. Other participant elements are not precluded by this constraint.

Figure 2: Constraints Format – only one like this allowed

- | |
|--|
| <ol style="list-style-type: none"> 1. SHALL contain exactly one [1..1] participant (CONF:2777) such that it <ol style="list-style-type: none"> a. SHALL contain exactly one [1..1] <code>@typeCode="LOC" (CodeSystem: 2.16.840.1.113883.5.90</code> <code>HL7ParticipationType) (CONF:2230).</code> |
|--|

2.3 Null Flavor

Information technology solutions store and manage data, but sometimes data are not available; an item may be unknown, not relevant, or not computable or measureable. In HL7, a flavor of null, or `nullFlavor`, describes the reason for missing data. Please note that although `nullFlavor` may be allowed to be entered in a field, the absence of the actual data for data elements necessary for eCQM calculations may compromise calculation results.

Figure 3: nullFlavor Example

```
<raceCode nullFlavor="ASKU"/>
<!--coding a raceCode when the patient declined to specify his/her
race-->

<raceCode nullFlavor="UNK"/>
<!--coding a raceCode when the patient's race is unknown-->
```

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

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

This list contains those null flavors that are commonly used in clinical documents. For the full list and descriptions, see the `nullFlavor` vocabulary domain in the in the HL7 standard, *Clinical Document Architecture, Release 2.0*.

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

QRDA I STU R4 CMS Implementation Guide for Hospital Quality Reporting

3 Overview

3.1 Background

This guide is a CMS Quality Reporting Document Architecture Category I (QRDA I) implementation guide to the *HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture Category I, Release 1, STU Release 4 (published Jan 2017)*, referred to as the HL7 QRDA I STU R4 in this guide. This guide describes additional conformance statements and constraints for EHR data submissions that are required for reporting information to the CMS for the Hospital Inpatient Quality Reporting Program 2018 Reporting Period.

The purpose of this guide is to serve as a companion to the base HL7 QRDA I STU R4 for entities such as Eligible Hospitals (EH), Critical Access Hospitals (CAH), and vendors to submit QRDA I data for consumption by CMS systems including for Hospital Quality Reporting (HQR).

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

3.2 How to Read This QRDA I Guide

CMS will process Clinical Quality Measure (CQM) QRDA I documents originating from EHR systems. Submitted QRDA I documents for HQR in the 2018 reporting period must meet the conformance statements specified in this guide in addition to the conformance statements specified in the HL7 QRDA I STU R4. Only documents that are valid against the CDA Release 2 schema enhanced to support the *urn:hl7-org:sdtc* namespace (CDA_SDTC.xsd)² will be accepted for processing. Documents that are invalid against this rule will be rejected.

This guide is based on following rules:

1. The HL7 QRDA I STU R4 provides information about QRDA data elements with conformance numbers and constraints. Some of these existing conformance restrictions have been modified in accordance with CMS system requirements. The "CMS_" prefix (e.g., CMS_0001) indicates the new conformance statements. The "_C01" postfix indicates that the conformance statement from the base HL7 QRDA I STU R4 standard is further constrained in this guide.
2. The original **SHALL/SHOULD/MAY** keywords along with conformance numbers from the HL7 QRDA I STU R4 for relevant data elements and attributes have been included in this guide for ease of reference. For brevity, the hierarchy of enclosing elements has not been shown.

² http://www.hl7.org/documentcenter/public/standards/dstu/CDAR2_IG_QRDA_I_R1_S4_2017JAN.zip. CDA_SDTC.xsd is available as part of the HL7 QRDA I STU R4 standard package.

4 QRDA Category I Requirements

4.1 QRDA Category I Reporting

The HL7 QRDA I STU R4 base standard allows either one or multiple measures to be reported in a QRDA I document. For HQR, there should be one QRDA I report per patient for the facility CMS Certification Number (CCN).

4.2 eCQM and Value Set Specifications

The [eCQM Specifications for Eligible Hospitals May 2017](#), and any applicable addenda, must be used for the HQR programs for the 2018 Reporting Period.

The [eCQM Value Sets for Eligible Hospitals Update May 05, 2017](#), and any applicable addenda, published at the Value Set Authority Center (VSAC)³ must be used for the HQR programs for the 2018 Reporting Period.

4.3 Succession Management

This section describes the management of successive replacement documents for QRDA I reports. For example, a submitter notices an error in an earlier submission and wants to replace it with a corrected version.

4.3.1 QRDA I Report Document Succession Management for HQR

For HQR, the QRDA I document/id convention is not used for Document Succession Management. Rather, HQR allows file resubmission to update a previously submitted file. The most recently submitted and accepted Production QRDA I file will overwrite the original file based on the exact match of four key elements identifying the file: CCN, CMS Program Name, EHR Patient ID, and the reporting period specified in the Reporting Parameters Section. The new file must be cumulative and contain all the patient data for the same reporting period not only the corrected or new data. In the event that any of the four key identifiers are incorrect, the HQR system provides the user with the capability to delete a previously submitted file.

4.3.2 Program Identifiers used in Succession Management

The CMS program name requirement for QRDA I submission is specified in [5.1.4 informationRecipient](#). Each QRDA I report **must** contain only one CMS program name, which shall be selected from the [QRDA I CMS Program Name value set \(2.16.840.1.113883.3.249.14.103\)](#).

4.4 Value Sets

4.4.1 eCQM Specified Value Sets Take Precedence

There are some cases where the value sets specified in eCQMs for clinical quality data criteria do not align with the value sets of the corresponding data elements specified in the QRDA I standard, or they are subsets of the value sets that are specified in the QRDA I standard. In these cases, the value sets that are specified in eCQMs always take precedence. For example,

³ Value Set Authority Center. <https://vsac.nlm.nih.gov>

the routeCode attribute is defined to be selected from Medication Route FDA (2.16.840.1.113883.3.88.12.3221.8.7) in QRDA templates, but an eCQM criterion uses "Intravenous route SNOMEDCT Value Set (2.16.840.1.113883.3.117.1.7.1.222)". In this case, the "Intravenous route SNOMEDCT Value Set (2.16.840.1.113883.3.117.1.7.1.222)" shall take precedence over the "Medication Route FDA (2.16.840.1.113883.3.88.12.3221.8.7)" value set in constructing a QRDA I document.

4.4.2 Value Sets Codes Case Sensitive

Codes from some code systems contain alpha characters (e.g., the ONC Administrative Sex value set contains codes "F" for Female and "M" for Male). Case of these alpha characters will be validated by the HQR systems. How codes are displayed in the Vocabulary file (voc.xml) and VSAC and in the VSAC exports will serve as the source of truth for conducting the case validations for value sets specified in eCQM specifications. For example, for a particular code, if alpha characters in this code were shown as upper case in VSAC or the Vocabulary file (voc.xml), then the validation will require them to be upper case.

4.5 Time Zone

Time comparisons or elapsed time calculations are frequently involved as part of determining measure population outcomes.

Table 1: Time Zone Validation Rule

| CONF. # | Rules |
|----------|--|
| CMS_0121 | A Coordinated Universal Time (UTC time) offset should not be used anywhere in a QRDA Category I file or, if a UTC time offset is needed anywhere, then it *must* be specified *everywhere* a time field is provided. |

This time zone validation rule (Table 1) is performed on the following elements:

- effectiveTime/@value
- effectiveTime/low/@value
- effectiveTime/high/@value
- time/@value
- time/low/@value
- time/high/@value

There are two exceptions to this validation rule:

- The effectiveTime element of the Reporting Parameters Act - CMS template (CONF:CMS_0027 and CONF:CMS_0028) will not be validated using this time zone validation rule:


```
act[@templated="2.16.840.1.113883.10.20.17.3.8.1"][@extension="2016-03-01"]/effectiveTime/low
act[@templated="2.16.840.1.113883.10.20.17.3.8.1"][@extension="2016-03-01"]/effectiveTime/high
```
- The time zone validation rule is not performed on birthTime/@value

Figure 4: Time Zone Example

```

<encounter>
  <text>Encounter Performed: Hospital Measures-Encounter
  Inpatient</text>
  ...
  <effectiveTime>
    <!-- Attribute: admission datetime -->
    <low value="20170325090000-0500"/>
    <!-- Attribute: discharge datetime -->
    <high value="20170329103000-0500"/>
  </effectiveTime>
  ...
</encounter>

```

4.6 Submit eCQM Version Specific Measure Identifier ONLY

For the 2018 Reporting Period, only the eCQM Version Specific Measure Identifier is required to uniquely identify the version of an eCQM. The eCQM Version Specific Measure Identifier must be submitted in QRDA I.

It is recommended that eCQM Version Numbers not be included in the QRDA. This is due to a known data type mismatch issue between the HL7 QRDA and Health Quality Measure Format (HQM) standards for the *versionNumber* attribute. The QRDA I standard is based on HL7 CDA R2, which is derived from the HL7 Reference Information Model (RIM) Version 2.07. In RIM 2.07, the *versionNumber* attribute is specified as INT data type. HQMF R2.1, however, is derived from HL7 RIM, Version 2.44, where *versionNumber* is specified as ST data type. The Version Numbers for eCQM Specifications for Eligible Hospitals May 2017 generated by the Measure Authoring Tool (MAT) are string values such as 6.1.000 and 7.1.000 instead of integers such as 6 or 7. If a version number such as 6.1.000 were submitted, the QRDA files will fail the CDA_SDTC.xsd schema validation and will be rejected by the receiving systems. If the *versionNumber* attribute is supplied as an INT value, the file will not be rejected, but the value will be ignored.

4.7 Templates Versioning and Validations

Both the base HL7 QRDA I STU R4 and the CMS QRDA I implementation guide have versioned the templates by assigning a new date value to the `templateId` extension attribute, if changes were made to the previous version of the template. Details about CDA templates versioning in general are described in 4.1.3 Template Versioning of the HL7 QRDA I STU R4. For example, in QRDA I STU R4, the previous `Diagnosis Concern Act` template is now `Diagnosis Concern Act (V2)`, its template identifier is "2.16.840.1.113883.10.20.24.3.137:2016-08-01". Both the `@root` and `@extension` are required as specified in the IG.

- SHALL** contain exactly one [1..1] `templateId` (CONF:3265-28143) such that it
- SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.24.3.137"` (CONF:3265-28146).
 - SHALL** contain exactly one [1..1] `@extension="2016-08-01"` (CONF:3265-28692).

Correct template versions that are specified by both the base HL7 QRDA I STU R4 and the 2018 CMS IG must be used for 2018 CMS QRDA I submissions. For instance, if a QRDA I file used `Diagnosis Concern Act` instead of `Diagnosis Concern Act (V2)`, this older version of the template will be ignored by the CMS receiving systems. Data submitted using template versions that are not specifically required by the base HL7 QRDA I STU R4 and the 2018 CMS QRDA I IG will not be processed by the CMS receiving system; this could lead to

unexpected results in measure calculations. Submitters should ensure correct template versions be used and aware of the consequences if wrong versions are used.

5 QRDA Category I Validation

5.1 Document-Level Template: QRDA Category I Report - CMS

This section defines the document-level templates in a QRDA I document. All of the templates in the HL7 QRDA I STU R4 are Clinical Document Architecture (CDA) templates.

5.1.1 General Header

This template describes header constraints that apply to the QRDA Category I document.

Table 2: QRDA Category I Report - CMS (V4) Constraints Overview
ClinicalDocument (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.1.3:2017-07-01)

| XPath | Card. | Verb | Data Type | CONF. # | Value |
|----------------|-------|-------|-----------|----------------------------|--|
| templateId | 1..1 | SHALL | | CMS_0001 | |
| @root | 1..1 | SHALL | | CMS_0002 | 2.16.840.1.113883.10.20.24.1.3 |
| @extension | 1..1 | SHALL | | CMS_0003 | 2017-07-01 |
| id | 1..1 | SHALL | | 1198-5363 | |
| effectiveTime | 1..1 | SHALL | | 1198-5256 | US Realm Date and Time (DTM.US.FIELDDED) (identifier: urn:oid:2.16.840.1.113883.10.20.2.2.5.4) |
| languageCode | 1..1 | SHALL | | 1198-5372 | urn:oid:2.16.840.1.113883.1.11.11.526 (Language) |
| @code | 1..1 | SHALL | | CMS_0010 | en |
| versionNumber | 0..1 | MAY | | 1198-5264 | |
| component | 1..1 | SHALL | | 3265-12973 | |
| structuredBody | 1..1 | SHALL | | 3265-17081 | |
| component | 1..1 | SHALL | | 3325-28474 | |
| section | 1..1 | SHALL | | 3325-28475 | Reporting Parameters Section - CMS (identifier: urn:hl7ii:2.16.840.1.113883.10.20.17.2.1.1:2016-03-01) |
| component | 1..1 | SHALL | | 3325-28476 | |

| | | | | | |
|-----------|------|-------|--|----------------------------|---|
| section | 1..1 | SHALL | | 3325-28477 | Patient Data Section QDM (V4) - CMS (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.2.1.1:2017-07-01) |
| component | 1..1 | SHALL | | 3265-17082 | |
| section | 1..1 | SHALL | | 3265-17083 | Measure Section QDM (identifier: urn:oid:2.16.840.1.113883.10.20.24.2.3) |

1. **Conforms to QDM-Based QRDA (V4) template** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.1.2:2016-08-01).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:CMS_0001) such that it
 - a. **SHALL** contain exactly one [1..1] **@root="2.16.840.1.113883.10.20.24.1.3"** (CONF:CMS_0002).
 - b. **SHALL** contain exactly one [1..1] **@extension="2017-07-01"** (CONF:CMS_0003).
3. **SHALL** contain exactly one [1..1] **id** (CONF:1198-5363).
 - a. This id **SHALL** be a globally unique identifier for the document (CONF:1198-9991).
4. **SHALL** contain exactly one [1..1] US Realm Date and Time (DTM.US.FIELDDED) (identifier: urn:oid:2.16.840.1.113883.10.20.22.5.4) (CONF:1198-5256).
5. **SHALL** contain exactly one [1..1] **languageCode**, which **SHALL** be selected from ValueSet Language urn:oid:2.16.840.1.113883.1.11.11526 **DYNAMIC** (CONF:1198-5372).
 - a. This languageCode **SHALL** contain exactly one [1..1] **@code="en"** (CONF:CMS_0010).
6. **MAY** contain zero or one [0..1] **versionNumber** (CONF:1198-5264).
 - a. If versionNumber is present setId **SHALL** be present (CONF:1198-6387).
7. **SHALL** contain exactly one [1..1] **component** (CONF:3265-12973).
 - a. This component **SHALL** contain exactly one [1..1] **structuredBody** (CONF:3265-17081).
 - i. This structuredBody **SHALL** contain exactly one [1..1] **component** (CONF:3325-28474) such that it
 1. **SHALL** contain exactly one [1..1] [Reporting Parameters Section - CMS](#) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.17.2.1.1:2016-03-01) (CONF:3325-28475).
 - ii. This structuredBody **SHALL** contain exactly one [1..1] **component** (CONF:3325-28476) such that it
 1. **SHALL** contain exactly one [1..1] [Patient Data Section QDM \(V4\) - CMS](#) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.2.1.1:2017-07-01) (CONF:3325-28477).
 - iii. This structuredBody **SHALL** contain exactly one [1..1] **component** (CONF:3265-17082) such that it
 1. **SHALL** contain exactly one [1..1] [Measure Section QDM](#) (identifier: urn:oid:2.16.840.1.113883.10.20.24.2.3) (CONF:3265-17083).

Figure 5: General Header Example

```
<ClinicalDocument>
  <realmCode code="US"/>
  <typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
  <!-- US Realm Header (V3) -->
  <templateId root="2.16.840.1.113883.10.20.22.1.1" extension="2015-08-01"/>
  <!-- QRDA Category I Framework (V3) -->
  <templateId root="2.16.840.1.113883.10.20.24.1.1" extension="2016-02-01"/>
  <!-- QDM-based QRDA (V4) -->
  <templateId root="2.16.840.1.113883.10.20.24.1.2" extension="2016-08-01"/>
  <!-- QRDA Category I Report - CMS (V4) -->
  <templateId root="2.16.840.1.113883.10.20.24.1.3" extension="2017-07-01"/>
  <!-- This is the globally unique identifier for this QRDA I document -->
  <id root=" 54f83c2b-ed90-439c-9f8d-92a7ad48c134"/>
  <code code="55182-0" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" displayName="Quality Measure Report"/>
  <title>Good Health QRDA I Report</title>
  <!-- This is the document creation time -->
  <effectiveTime value="201801109171504+0500"/>
  <confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25" codeSystemName="HL7Confidentiality"/>
  <languageCode code="en"/>
  ...
</ClinicalDocument>
```

5.1.2 recordTarget

The `recordTarget` records the patient whose health information is described by the clinical document; it must contain at least one `patientRole` element.

Table 3: recordTarget Constraints Overview
ClinicalDocument (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.1.3:2017-07-01)

| XPath | Card. | Verb | Data Type | CONF. # | Value |
|--------------|-------|--------|-----------|----------------------------|-------------------------|
| recordTarget | 1..1 | SHALL | | 3265-16598 | |
| patientRole | 1..1 | SHALL | | 3265-16856 | |
| id | 0..1 | SHOULD | | 3265-16857 | |
| @root | 1..1 | SHALL | | 3265-16858 | 2.16.840.1.113883.4.572 |
| id | 1..1 | SHALL | | CMS_0009 | |
| @root | 1..1 | SHALL | | CMS_0053 | |
| @extension | 1..1 | SHALL | | CMS_0103 | |
| id | 0..1 | MAY | | CMS_0122 | |
| @root | 1..1 | SHALL | | CMS_0123 | 2.16.840.1.113883.4.927 |

| XPath | Card. | Verb | Data Type | CONF. # | Value |
|--------------------------|-------|-------|-----------|--|--|
| addr | 1..* | SHALL | | 1198-5271 | US Realm Address (AD.US.FIELDED) (identifier: urn:oid:2.16.840.1.113883.10.20.2.5.2) |
| patient | 1..1 | SHALL | | 3265-27570 | |
| name | 1..1 | SHALL | | 1198-5284 C01 | US Realm Person Name (PN.US.FIELDED) (identifier: urn:oid:2.16.840.1.113883.10.20.2.5.1.1) |
| administrativeGenderCode | 1..1 | SHALL | | CMS_0011 CMS_0029 | urn:oid:2.16.840.1.113762.1.4.1 (ONC Administrative Sex) |
| birthTime | 1..1 | SHALL | | 1198-5298 1198-5300 C01 1198-32418 | |
| raceCode | 1..1 | SHALL | | CMS_0013 CMS_0030 CMS_0031 | urn:oid:2.16.840.1.114222.4.11.836 (Race) |
| sdtc:raceCode | 0..* | MAY | | CMS_0014 | urn:oid:2.16.840.1.114222.4.11.836 (Race) |
| ethnicGroupCode | 1..1 | SHALL | | 1198-5323 CMS_0032 CMS_0033 | urn:oid:2.16.840.1.114222.4.11.837 (Ethnicity) |

1. **SHALL** contain exactly one [1..1] **recordTarget** (CONF:3265-16598).
 - a. This recordTarget **SHALL** contain exactly one [1..1] **patientRole** (CONF:3265-16856).

Medicare HIC Number is not required for HQR but should be submitted if the payer is Medicare and the patient has an HIC number assigned.

- i. This patientRole **SHOULD** contain zero or one [0..1] **id** (CONF:3265-16857) such that it
 1. **SHALL** contain exactly one [1..1] **@root="2.16.840.1.113883.4.572"** Medicare HIC number (CONF:3265-16858).

Patient Identification Number is required for HQR.

- ii. This patientRole **SHALL** contain exactly one [1..1] **id** (CONF:CMS_0009) such that it
 1. **SHALL** contain exactly one [1..1] **@root** (CONF:CMS_0053).
 Note: This is the provider's organization OID or other non-null value different from the OID for the Medicare HIC Number (2.16.840.1.113883.4.572) and the OID for the Medicare Beneficiary Identifier (2.16.840.1.113883.4.927).

2. **SHALL** contain exactly one [1..1] **@extension** (CONF:CMS_0103).
Note: The value of **@extension** is the Patient ID.

Medicare Beneficiary Identifier (MBI) is not required for HQR but should be submitted if the payer is Medicare and the patient has an MBI number assigned.

- iii. This patientRole **MAY** contain zero or one [0..1] **id** (CONF:CMS_0122) such that it
 1. **SHALL** contain exactly one [1..1] **@root="2.16.840.1.113883.4.927"** Medicare Beneficiary Identifier (CONF:CMS_0123).
- iv. This patientRole **SHALL** contain at least one [1..*] US Realm Address (AD.US.FIELDDED) (identifier: urn:oid:2.16.840.1.113883.10.20.22.5.2) (CONF:1198-5271).
- v. This patientRole **SHALL** contain exactly one [1..1] **patient** (CONF:3265-27570).
 1. This patient **SHALL** contain exactly one [1..1] US Realm Person Name (PN.US.FIELDDED) (identifier: urn:oid:2.16.840.1.113883.10.20.22.5.1.1) (CONF:1198-5284_C01).
 2. This patient **SHALL** contain exactly one [1..1] **administrativeGenderCode**, which **SHALL** be selected from ValueSet **ONC Administrative Sex** urn:oid:2.16.840.1.113762.1.4.1 **DYNAMIC** (CONF:CMS_0011).
 - a. If the patient's administrative sex is unknown, **nullFlavor="UNK"** **SHALL** be submitted (CONF:CMS_0029).
 3. This patient **SHALL** contain exactly one [1..1] **birthTime** (CONF:1198-5298).
 - a. **SHALL** be precise to day (CONF:1198-5300_C01).

For cases where information about newborn's time of birth needs to be captured.

- b. **MAY** be precise to the minute (CONF:1198-32418).
4. This patient **SHALL** contain exactly one [1..1] **raceCode**, which **SHALL** be selected from ValueSet **Race** urn:oid:2.16.840.1.114222.4.11.836 **DYNAMIC** (CONF:CMS_0013).
 - a. If the patient's race is unknown, **nullFlavor="UNK"** **SHALL** be submitted (CONF:CMS_0030).
 - b. If the patient declined to specify his/her race, **nullFlavor="ASKU"** **SHALL** be submitted (CONF:CMS_0031).
5. This patient **MAY** contain zero or more [0..*] **sdtc:raceCode**, which **SHALL** be selected from ValueSet **Race** urn:oid:2.16.840.1.114222.4.11.836 **DYNAMIC** (CONF:CMS_0014).
Note: If a patient has more than one race category, one race is reported in **raceCode**, and additional races are reported using **sdtc:raceCode**.
6. This patient **SHALL** contain exactly one [1..1] **ethnicGroupCode**, which **SHALL** be selected from ValueSet **Ethnicity** urn:oid:2.16.840.1.114222.4.11.837 **DYNAMIC** (CONF:1198-5323).

- a. If the patient's ethnicity is unknown, **nullFlavor** ="UNK" **SHALL** be submitted (CONF:CMS_0032).
- b. If the patient declined to specify his/her ethnicity, **nullFlavor** ="ASKU" **SHALL** be submitted (CONF:CMS_0033).

Figure 6: recordTarget Example, QRDA Category I Report - CMS (V4)

```

<recordTarget>
  <patientRole>
    <!-- Patient Identifier Number. The root OID could be provider's
      organization OID or other value -->
    <id root="2.16.840.1.113883.123.123.1" extension="022354" />
    <addr use="HP">
      <streetAddressLine>101 North Pole Lane</streetAddressLine>
      <city>Ames</city>
      <state>IA</state>
      <postalCode>50014</postalCode>
      <country>US</country>
    </addr>
    <telecom use="WP" value="tel:+1-781-271-3000"/>
    <patient>
      <name>
        <given>Jane</given>
        <family>Doe</family>
      </name>
      <administrativeGenderCode code="F"
        codeSystem="2.16.840.1.113883.5.1"/>
      <!-- If the patient administrative sex is unknown, use
        nullFlavor="UNK" -->
      <!-- <administrativeGenderCode nullFlavor="UNK"/> -->
      <birthTime value="19460102"/>
      <!-- raceCode "2131-1 (Other Race)" shall not be used for
        either raceCode or sdtc:raceCode -->
      <raceCode code="2106-3" codeSystem="2.16.840.1.113883.6.238"/>
      <!-- if the patient declined to specify his/her race, use
        nullFlavor="ASKU" -->
      <!-- <raceCode nullFlavor="ASKU"/> -->
      <!-- if the patient's race is unknown, use nullFlavor="UNK" -->
      <!-- <raceCode nullFlavor="UNK"/> -->
      <!-- Use sdtc:raceCode only if the patient has more than one
        race category -->
      <!-- <sdtc:raceCode code="2054-5"
        codeSystem="2.16.840.1.113883.6.238"/> -->
      <ethnicGroupCode code="2186-5"
        codeSystem="2.16.840.1.113883.6.238"/>
      <!-- if the patient declined to specify his/her ethnicity, use
        nullFlavor="ASKU" -->
      <!-- <ethnicGroupCode nullFlavor="ASKU"/> -->
      <!-- if the patient's ethnicity is unknown, use
        nullFlavor="UNK" -->
      <!-- <ethnicGroupCode nullFlavor="UNK"/> -->
    </patient>
  </patientRole>
</recordTarget>

```

5.1.3 Custodian

The **custodian** element represents the organization that is in charge of maintaining the document. The custodian is the steward that is entrusted with the care of the document.

Table 4: Custodian Constraints Overview

ClinicalDocument (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.1.3:2017-07-01)

| XPath | Card. | Verb | Data Type | CONF. # | Value |
|----------------------------------|-------|-------|-----------|--|-------------------------|
| custodian | 1..1 | SHALL | | 3265-16600 | |
| assignedCustodian | 1..1 | SHALL | | 3265-28239 | |
| representedCustodianOrganization | 1..1 | SHALL | | 3265-28240 | |
| id | 1..1 | SHALL | | 3265-28241_C01 | |
| @root | 1..1 | SHALL | | 3265-28244 | 2.16.840.1.113883.4.336 |
| @extension | 1..1 | SHALL | | 3265-28245 CMS_0035 | |

1. **SHALL** contain exactly one [1..1] **custodian** (CONF:3265-16600).
 - a. This custodian **SHALL** contain exactly one [1..1] **assignedCustodian** (CONF:3265-28239).
 - i. This assignedCustodian **SHALL** contain exactly one [1..1] **representedCustodianOrganization** (CONF:3265-28240).

This representedCustodianOrganization id/@root='2.16.840.1.113883.4.336' coupled with the id/@extension represents the organization's Facility CCN.

CCN is required for HQR.

1. This representedCustodianOrganization **SHALL** contain exactly one [1..1] **id** (CONF:3265-28241_C01) such that it
 - a. **SHALL** contain exactly one [1..1] **@root="2.16.840.1.113883.4.336"** CMS Certification Number (CONF:3265-28244).
 - b. **SHALL** contain exactly one [1..1] **@extension** (CONF:3265-28245).

Note: A fixed CCN value 800890 shall be used for HQR test submission when no hospital is associated with a submitted QRDA document.

 - i. CCN **SHALL** be six to ten characters in length (CONF:CMS_0035).

Figure 7: CCN as Custodian Example, QRDA Category I Report - CMS (V4)

```

<!-- This is an example for QRDA I test submission to HQR.
CCN is required for HQR.-->
<custodian>
  <assignedCustodian>
    <representedCustodianOrganization>
      <!-- @extension attribute contains the submitter's CCN.
      @nullFlavor is not allowed. -->
      <id root="2.16.840.1.113883.4.336" extension="800890"/>
      <name>Good Health Hospital</name>
      <telecom value="tel:(555)555-1212" use="WP"/>
      <addr use="WP">
        <streetAddressLine>17 Daws Rd.</streetAddressLine>
        <city>Blue Bell</city>
        <state>MA</state>
        <postalCode>02368</postalCode>
        <country>US</country>
      </addr>
    </representedCustodianOrganization>
  </assignedCustodian>
</custodian>

```

5.1.4 informationRecipient

The `informationRecipient` element records the intended recipient of the information at the time the document is created.

Table 5: informationRecipient Constraints Overview
 ClinicalDocument (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.1.3:2017-07-01)

| XPath | Card. | Verb | Data Type | CONF. # | Value |
|----------------------|-------|-------|-----------|--------------------------------|---|
| informationRecipient | 1..1 | SHALL | | 3265-16703_C01 | |
| intendedRecipient | 1..1 | SHALL | | 3265-16704 | |
| id | 1..1 | SHALL | | 3265-16705_C01 | |
| @root | 1..1 | SHALL | | CMS_0025 | 2.16.840.1.113883.3.249.7 |
| @extension | 1..1 | SHALL | | CMS_0026 | urn:oid:2.16.840.1.113883.3.249.14.103 (QRDA I CMS Program Name) |

1. **SHALL** contain exactly one [1..1] `informationRecipient` (CONF:3265-16703_C01).
 - a. This `informationRecipient` **SHALL** contain exactly one [1..1] `intendedRecipient` (CONF:3265-16704).
 - i. This `intendedRecipient` **SHALL** contain exactly one [1..1] `id` (CONF:3265-16705_C01).
 1. This `id` **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.3.249.7"` (CONF:CMS_0025).

2. This id **SHALL** contain exactly one [1..1] @extension, which **SHALL** be selected from ValueSet [QRDA I CMS Program Name](#) urn:oid:2.16.840.1.113883.3.249.14.103 **STATIC** 2017-07-01 (CONF:CMS_0026).
 Note: The value of @extension is CMS Program Name.

Table 6: QRDA I CMS Program Name

| Value Set: QRDA I CMS Program Name urn:oid:2.16.840.1.113883.3.249.14.103 | | | |
|---|-------------|-----------------------------------|--|
| Specifies the CMS Program for QRDA I report submissions. | | | |
| Code | Code System | Code System OID | Print Name |
| HQR_EHR | CMS Program | urn:oid:2.16.840.1.113883.3.249.7 | Hospital Quality Reporting for the EHR Incentive Program |
| HQR_IQR | CMS Program | urn:oid:2.16.840.1.113883.3.249.7 | Hospital Quality Reporting for the Inpatient Quality Reporting Program |
| HQR_EHR_IQR | CMS Program | urn:oid:2.16.840.1.113883.3.249.7 | Hospital Quality Reporting for the EHR Incentive Program and the IQR Program |
| HQR_IQR_VOL | CMS Program | urn:oid:2.16.840.1.113883.3.249.7 | Hospital Quality Reporting for Inpatient Quality Reporting Program voluntary submissions |
| HQR_EPM_VOL | CMS Program | urn:oid:2.16.840.1.113883.3.249.7 | Hospital Quality Reporting for Episode Payment Model voluntary submissions |
| CDAC_HQR_EHR | CMS Program | urn:oid:2.16.840.1.113883.3.249.7 | CDAC_HQR_EHR |

Figure 8: informationRecipient Example, QRDA Category I Report - CMS (V4)

```

<!-- This example shows the @extension attribute with a value of
"HQR_EHR", which indicates that this QRDA I report is submitted to the
Hospital Quality Reporting for the EHR Incentive program -->

<informationRecipient>
  <intendedRecipient>
    <!-- CMS Program Name is required. @nullFlavor is not allowed -->
    <id root="2.16.840.1.113883.3.249.7"
      extension="HQR_EHR"/>
  </intendedRecipient>
</informationRecipient>
    
```

5.1.5 Participant (CMS Certification Identification Number)

The Certified Health Information Technology (IT) Product List (CHPL) is the authoritative and comprehensive listing of health IT certified through the Office of the National Coordinator for Health Information Technology (ONC) Health IT Certification Program. A CMS EHR Certification Identification Number is a number generated by the CHPL and used for reporting to CMS. It represents a single product or combination of products in the CHPL. The EH selects a certified health IT product that meets 100% of the requirements for a complete EHR system, or

combines multiple certified health IT products (Modules) to create a complete EHR product suite, as indicated in the CHPL chart on the CHPL website⁴.

CMS EHR Certification ID is different from the CHPL product number. In the CHPL, this would be the number that is generated when select get EHR Certification ID for a suite of products that make up the hospital’s EHR solution. If a product changes, then a different CMS EHR Certification ID will be generated. If there are no changes to the product(s) selected to create the CMS EHR Certification ID, the ID will remain the same. If the EHR product update has a new CHPL product number and occurs during the period of time between the beginning of data capture and export, then a new CMS EHR Certification ID would need to be generated to select the suite of all products used during the data capture and reporting period. The CMS EHR Certification ID is only unique to the product suite, if two different hospitals happen to use the same products, then they will both have the same CMS EHR Certification ID.

Table 7: Participant Constraints Overview

ClinicalDocument (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.1.3:2017-07-01)

| XPath | Card. | Verb | Data Type | CONF. # | Value |
|------------------|-------|-------|-----------|--------------------------------|----------------------------|
| participant | 1..1 | SHALL | | 1198-10003_C01 | |
| associatedEntity | 1..1 | SHALL | | CMS_0004 | |
| id | 1..1 | SHALL | | CMS_0005 | |
| @root | 1..1 | SHALL | | CMS_0006 | 2.16.840.1.113883.3.2074.1 |
| @extension | 1..1 | SHALL | | CMS_0008 | |

1. **SHALL** contain exactly one [1..1] **participant** (CONF:1198-10003_C01).

CMS EHR Certification Number is required for HQR.

a. This participant **SHALL** contain exactly one [1..1] **associatedEntity** (CONF:CMS_0004).

i. This associatedEntity **SHALL** contain exactly one [1..1] **id** (CONF:CMS_0005).

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

@root="2.16.840.1.113883.3.2074.1" CMS EHR Certification Number (CONF:CMS_0006).

2. This id **SHALL** contain exactly one [1..1] **@extension** (CONF:CMS_0008).

Note: The value of @extension is the Certification Number.

⁴Certified Health IT Product List. <https://chpl.healthit.gov/>

5.1.6 documentationOf/serviceEvent

Table 8: documentationOf/serviceEvent Constraints Overview
ClinicalDocument (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.1.3:2017-07-01)

| XPath | Card. | Verb | Data Type | CONF. # | Value |
|-------------------------|-------|--------|-----------|--------------------------------|-----------------------|
| documentationOf | 1..1 | SHALL | | 3265-16579_C01 | |
| serviceEvent | 1..1 | SHALL | | 3265-16580 | |
| performer | 1..* | SHALL | | 3265-16583 | |
| @typeCode | 1..1 | SHALL | | 3265-16584 | PRF |
| assignedEntity | 1..1 | SHALL | | 3265-16586 | |
| id | 0..1 | SHOULD | | 3265-16587 | |
| @root | 1..1 | SHALL | | 3265-16588 | 2.16.840.1.113883.4.6 |
| assignedPerson | 0..1 | MAY | | CMS_0019 | |
| name | 0..1 | MAY | | CMS_0020 | |
| representedOrganization | 1..1 | SHALL | | 3265-16591 | |
| id | 0..1 | SHOULD | | 3265-16592 | |
| @root | 1..1 | SHALL | | 3265-16593 | 2.16.840.1.113883.4.2 |
| name | 0..1 | MAY | | CMS_0022 | |

1. **SHALL** contain exactly one [1..1] **documentationOf** (CONF:3265-16579_C01) such that it
 - a. **SHALL** contain exactly one [1..1] **serviceEvent** (CONF:3265-16580).
 - i. This serviceEvent **SHALL** contain at least one [1..*] **performer** (CONF:3265-16583).
 1. Such performers **SHALL** contain exactly one [1..1] **@typeCode="PRF"** Performer (CONF:3265-16584).
 2. Such performers **SHALL** contain exactly one [1..1] **assignedEntity** (CONF:3265-16586).

This assignedEntity id/@root='2.16.840.1.113883.4.6' coupled with the id/@extension represents the individual provider's NPI number. A valid NPI is 10 numeric digits where the 10th digit is a check digit computed using the Luhn algorithm.

For HQR, NPI may not be applicable. If NPI is submitted for HQR, then the NPI SHALL conform to the constraints specified for NPI and the NPI must be in the correct format.

- a. This assignedEntity **SHOULD** contain zero or one [0..1] **id** (CONF:3265-16587) such that it

- i. **SHALL** contain exactly one [1..1]
@root="2.16.840.1.113883.4.6" National
Provider ID (CONF:3265-16588).
- b. This assignedEntity **MAY** contain zero or one [0..1]
assignedPerson (CONF:CMS_0019).
 - i. The assignedPerson, if present, **MAY** contain zero or
one [0..1] **name** (CONF:CMS_0020).
Note: This is the provider's name.
- c. This assignedEntity **SHALL** contain exactly one [1..1]
representedOrganization (CONF:3265-16591).

This representedOrganization id/@root='2.16.840.1.113883.4.2' coupled with the id/@extension represents the organization's TIN. The provided TIN must be in valid format (9 decimal digits).

For HQR, TIN may not be applicable. If TIN is submitted for HQR, then it SHALL conform to the constraints specified for TIN, and the TIN must be in valid format (9 decimal digits).

- i. This representedOrganization **SHOULD** contain zero or
one [0..1] **id** (CONF:3265-16592).
- 1. The id, if present, **SHALL** contain exactly one [1..1]
@root="2.16.840.1.113883.4.2" Tax ID Number
(CONF:3265-16593).
- ii. This representedOrganization **MAY** contain zero or one
[0..1] **name** (CONF:CMS_0022).
Note: This is the organization's name, such as
hospital's name.

Figure 9: documentationOf / serviceEvent Example

```

<!-- Example for HQR. CMS Program Name for HQR is either "HQR_EHR",
"HQR_IQR", or "HQR_EHR_IQR" -->
<informationRecipient>
  <!-- CMS Program Name is "HQR_EHR" -->
  <intendedRecipient>
    <id root="2.16.840.1.113883.3.249.7" extension="HQR_EHR"/>
  </intendedRecipient>
</informationRecipient>
...
<documentationOf>
  <serviceEvent classCode="PCPR">
    ...
    <performer typeCode="PRF">
      <assignedEntity>
        <representedOrganization/>
      </assignedEntity>
    </performer>
  </serviceEvent>
</documentationOf>

```

5.2 Section-Level Templates

5.2.1 Measure Section

This section contains information about the eCQM or eCQM being reported. It must contain entries with the identifiers of all the eCQMs so that corresponding QRDA Quality Data Model (QDM) data element entry templates to be instantiated in the Patient Data Section are identified.

Each eCQM for which QRDA QDM data elements are being sent must reference eCQM version specific identifier (`QualityMeasureDocument/id`).

Only the list of conformance statements from the eCQM Reference QDM template (`urn:oid:2.16.840.1.113883.10.20.24.3.97`) that specifies how eCQM version specific measure identifier is referenced in the Measure Section are shown below. Please refer to the base HL7 QRDA I STU R4 standard for the full specification of Measure Section.

Table 9: Measure Section (eCQM Reference QDM) Constraints Overview
organizer (identifier: `urn:oid:2.16.840.1.113883.10.20.24.3.97`)

| XPath | Card. | Verb | Data Type | CONF. # | Value |
|------------------|-------|-------|-----------|--------------------------|--|
| reference | 1..1 | SHALL | | 67-12808 | |
| @typeCode | 1..1 | SHALL | | 67-12809 | urn:oid:2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR |
| externalDocument | 1..1 | SHALL | | 67-12810 | |
| @classCode | 1..1 | SHALL | | 67-27017 | urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = DOC |
| id | 1..1 | SHALL | | 67-12811 | |
| @root | 1..1 | SHALL | | 67-12812 | 2.16.840.1.113883.4.738 |
| @extension | 1..1 | SHALL | | 67-12813 | |

1. **SHALL** contain exactly one [1..1] **reference** (CONF:67-12808) such that it
 - a. **SHALL** contain exactly one [1..1] **@typeCode="REFR"** refers to (CodeSystem: HL7ActRelationshipType urn:oid:2.16.840.1.113883.5.1002 **STATIC**) (CONF:67-12809).
 - b. **SHALL** contain exactly one [1..1] **externalDocument** (CONF:67-12810).
 - i. This externalDocument **SHALL** contain exactly one [1..1] **@classCode="DOC"** Document (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6) (CONF:67-27017).
 - ii. This externalDocument **SHALL** contain exactly one [1..1] **id** (CONF:67-12811) such that it
 1. **SHALL** contain exactly one [1..1] **@root="2.16.840.1.113883.4.738"** (CONF:67-12812).
Note: This OID indicates that the @extension contains the version specific identifier for the eMeasure.
 2. **SHALL** contain exactly one [1..1] **@extension** (CONF:67-12813).
Note: This @extension SHALL equal the version specific identifier for eMeasure (i.e., `QualityMeasureDocument/id`)

Figure 10: Measure Section Example

```

<section>
  <!-- This is the templateId for Measure Section -->
  <templateId root="2.16.840.1.113883.10.20.24.2.2"/>
  <!-- This is the templateId for Measure Section QDM -->
  <templateId root="2.16.840.1.113883.10.20.24.2.3"/>
  <code code="55186-1" codeSystem="2.16.840.1.113883.6.1"/>
  <title>Measure Section</title>
  <text>...</text>
  <!-- 1..* Organizers, each containing a reference to an
  eMeasure -->
  <entry>
    <organizer classCode="CLUSTER" moodCode="EVN">
      <!-- This is the templateId for Measure Reference -->
      <templateId root="2.16.840.1.113883.10.20.24.3.98"/>
      <!-- This is the templateId for eMeasure Reference QDM -->
      <templateId root="2.16.840.1.113883.10.20.24.3.97"/>
      <statusCode code="completed"/>
      <reference typeCode="REFR">
        <externalDocument classCode="DOC" moodCode="EVN">
          <!-- This is the eMeasure version specific identifier -->
          <id root="2.16.840.1.113883.4.738"
            extension="40280382-5abd-fa46-015b-168daf752581"/>
        </externalDocument>
      </reference>
    </organizer>
    <organizer>
      ...
    </organizer>
  </entry>
</section>

```

5.2.2 Reporting Parameters Section – CMS

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

Table 10: Reporting Parameters Section – CMS Constraints Overview
 section (identifier: urn:oid:2.16.840.1.113883.10.20.17.2.1.1:2016-03-01)

| XPath | Card. | Verb | Data Type | CONF. # | Value |
|------------|-------|-------|-----------|--------------------------|--|
| templateId | 1..1 | SHALL | | CMS_0040 | |
| @root | 1..1 | SHALL | | CMS_0041 | 2.16.840.1.113883.10.20.17.2.1.1 |
| @extension | 1..1 | SHALL | | CMS_0042 | 2016-03-01 |
| entry | 1..1 | SHALL | | CMS_0023 | |
| act | 1..1 | SHALL | | CMS_0024 | Reporting Parameters Act - CMS (identifier: urn:hl7ii:2.16.840.1.113883.10.20.17.3.8.1:2016-03-01) |

1. **Conforms to** Reporting Parameters Section **template** (identifier: urn:oid:2.16.840.1.113883.10.20.17.2.1).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:CMS_0040) such that it

- a. **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.17.2.1.1"` (CONF:CMS_0041).
- b. **SHALL** contain exactly one [1..1] `@extension="2016-03-01"` (CONF:CMS_0042).
- 3. **SHALL** contain exactly one [1..1] `entry` (CONF:CMS_0023) such that it
 - a. **SHALL** contain exactly one [1..1] [Reporting Parameters Act - CMS](#) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.17.3.8.1:2016-03-01) (CONF:CMS_0024).

5.2.2.1 Reporting Parameters Act – CMS

Table 11: Reporting Parameters Act - CMS Constraints Overview
act (identifier: urn:oid:2.16.840.1.113883.10.20.17.3.8.1:2016-03-01)

| XPath | Card. | Verb | Data Type | CONF. # | Value |
|---------------|-------|-------|-----------|--|----------------------------------|
| templateId | 1..1 | SHALL | | CMS_0044 | |
| @root | 1..1 | SHALL | | CMS_0045 | 2.16.840.1.113883.10.20.17.3.8.1 |
| @extension | 1..1 | SHALL | | CMS_0046 | 2016-03-01 |
| effectiveTime | 1..1 | SHALL | | 23-3273 | |
| low | 1..1 | SHALL | | 23-3274 | |
| @value | 1..1 | SHALL | | CMS_0048 CMS_0027 | |
| high | 1..1 | SHALL | | 23-3275 | |
| @value | 1..1 | SHALL | | CMS_0050 CMS_0028 | |

1. Conforms to Reporting Parameters Act `template` (identifier: urn:oid:2.16.840.1.113883.10.20.17.3.8).
2. **SHALL** contain exactly one [1..1] `templateId` (CONF:CMS_0044) such that it
 - a. **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.17.3.8.1"` (CONF:CMS_0045).
 - b. **SHALL** contain exactly one [1..1] `@extension="2016-03-01"` (CONF:CMS_0046).
3. **SHALL** contain exactly one [1..1] `effectiveTime` (CONF:23-3273).
 - a. This `effectiveTime` **SHALL** contain exactly one [1..1] `low` (CONF:23-3274).
 - i. This `low` **SHALL** contain exactly one [1..1] `@value` (CONF:CMS_0048).
 - ii. **SHALL** be precise to day (CONF:CMS_0027)
 - b. This `effectiveTime` **SHALL** contain exactly one [1..1] `high` (CONF:23-3275).
 - i. This `high` **SHALL** contain exactly one [1..1] `@value` (CONF:CMS_0050).
 - ii. **SHALL** be precise to day (CONF:CMS_0028)

Figure 11: Reporting Parameters Section - CMS and Reporting Parameters Act – CMS Example

```

<section>
  <templateId root="2.16.840.1.113883.10.20.17.2.1"/>
  <templateId root="2.16.840.1.113883.10.20.17.2.1.1"
extension="2016-03-01"/>
  <code code="55187-9" codeSystem="2.16.840.1.113883.6.1"/>
  <title>Reporting Parameters</title>
  <text>
    ...
    <list>
      <item>Reporting period: 01 Jan 2018 - 31 March 2018
    </list>
    ...
  </text>
  <entry typeCode="DRIV">
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.17.3.8"/>
      <templateId root="2.16.840.1.113883.10.20.17.3.8.1"
extension="2016-03-01"/>
      <code code="252116004" codeSystem="2.16.840.1.113883.6.96"
displayName="Observation Parameters"/>
      <effectiveTime>
        <low value="20180101"/>
        <high value="20180331"/>
      </effectiveTime>
    </act>
  </entry>
</section>

```

5.2.3 Patient Data Section QDM (V4) - CMS

The Patient Data Section QDM (V4) - CMS contains entries that conform to the QDM approach to QRDA. The four supplemental data elements (ONC Administrative Sex, Race, Ethnicity, and Payer) specified in the eCQMs are required to be reported to CMS. While the administrative sex, race, and ethnicity data are sent in the document header, the payer supplemental data element is submitted using the Patient Characteristic Payer template contained in the patient data section. Therefore, the Patient Data Section QDM (V4) - CMS shall contain at least one Patient Characteristic Payer template and at least one entry template that is other than the Patient Characteristic Payer template. As for what entry templates and how many entry templates should be included in the patient data section for the referenced eCQMs, it should adhere to the "smoking gun" philosophy described in the QRDA I standard. This guide follows the specifications of entry templates as defined in the base HL7 QRDA I STU R4 standard.

Table 12: Patient Data Section QDM (V4) – CMS Constraints Overview
section (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.2.1.1:2017-07-01)

| XPath | Card. | Verb | Data Type | CONF. # | Value |
|------------|-------|-------|-----------|--------------------------|----------------------------------|
| templateId | 1..1 | SHALL | | CMS_0036 | |
| @root | 1..1 | SHALL | | CMS_0037 | 2.16.840.1.113883.10.20.24.2.1.1 |
| @extension | 1..1 | SHALL | | CMS_0038 | 2017-07-01 |
| entry | 1..* | SHALL | | CMS_0051 | |

| XPath | Card. | Verb | Data Type | CONF. # | Value |
|-------------|-------|-------|-----------|--------------------------------|--|
| entry | 1..* | SHALL | | 3265-14430_C01 | |
| observation | 1..1 | SHALL | | 3265-14431 | Patient Characteristic Payer (identifier: urn:oid:2.16.840.1.113883.10.20.24.3.55) |

1. **Conforms to** Patient Data Section QDM (V4) **template** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.2.1:2016-08-01).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:CMS_0036) such that it
 - a. **SHALL** contain exactly one [1..1] **@root="2.16.840.1.113883.10.20.24.2.1.1"** (CONF:CMS_0037).
 - b. **SHALL** contain exactly one [1..1] **@extension="2017-07-01"** (CONF:CMS_0038).
3. **SHALL** contain at least one [1..*] **entry** (CONF:CMS_0051) such that it
 - a. **SHALL** contain exactly one [1..1] entry template that is other than the Patient Characteristic Payer (identifier: urn:oid:2.16.840.1.113883.10.20.24.3.55) (CONF:CMS_0039).
4. **SHALL** contain at least one [1..*] **entry** (CONF:3265-14430_C01) such that it
 - a. **SHALL** contain exactly one [1..1] Patient Characteristic Payer (identifier: urn:oid:2.16.840.1.113883.10.20.24.3.55) (CONF:3265-14431).

Figure 12: Patient Data Section QDM (V4) – CMS Example

```

<section>
  <!-- Patient Data Section -->
  <templateId root="2.16.840.1.113883.10.20.17.2.4" />
  <!-- Patient Data Section QDM (V4) -->
  <templateId root="2.16.840.1.113883.10.20.24.2.1"
    extension="2016-08-01" />
  <!-- Patient Data Section QDM (V4) - CMS-->
  <templateId root="2.16.840.1.113883.10.20.24.2.1.1"
    extension="2017-07-01" />
  <code code="55188-7" codeSystem="2.16.840.1.113883.6.1"
    displayName="Patient Data"/>
  <title>Patient Data</title>
  <text>...</text>
  <entry typeCode="DRIV">
    ...
  </entry>
  <entry typeCode="DRIV">
    ...
  </entry>
  <!--supplemental data elements-->
  <!-- payer-->
  <entry typeCode="DRIV">
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.24.3.55"/>
      <id root="4ddf1cc3-e325-472e-ad76-b2c66a5ee164" />
      <code code="48768-6" codeSystem="2.16.840.1.113883.6.1"
        codeSystemName="LOINC" displayName="Payment source" />
      <statusCode code="completed" />
      <effectiveTime>
        <low value="20140303" />
        <high value="20171231" />
      </effectiveTime>
      <value xsi:type="CD" code="1"
        codeSystem="2.16.840.1.113883.3.221.5"
        codeSystemName="Source of Payment Typology"
        displayName="Medicare"
        sdtc:valueSet="2.16.840.1.114222.4.11.3591" />
    </observation>
  </entry>
  ...
</section>

```

5.2.3.1 “Not Done” with a Reason

For a QDM data element that is not done (when **negationInd="true"**) with a reason, such as "Medication, Administered not done: Patient Refusal", an **entryRelationship** to a Reason (templateId: 2.16.840.1.113883.10.20.24.3.88") with an **actRelationship** type of "RSON" is required. This is specified in the section 3.4 Asserting an Act Did Not Occur with a Reason in the base HL7 *QRDA I, R4 Implementation Guide, Volume 1*. To summarize, the following steps shall be followed:

- Set the containing act attribute **negationInd="true"**
- Use code/[@nullFlavor="NA"]
- Set code attribute **code/sdtc:valueSet="[VSAC value set OID]"**
- Use code/originalText for the text description of the concept in the pattern "None of value set: [value set name]"

Figure 13: Not Done Example

```

<!--Medication not done, patient refusal: Drug declined by patient -
reason unknown. No "Low Dose Unfractionated Heparin for VTE
Prophylaxis" were administered -->
<act classCode="ACT" moodCode="EVN" negationInd="true">
  <templateId root="2.16.840.1.113883.10.20.24.3.42" extension="2016-
    02-01" />
  <id root="517d5bbb-03a8-4400-8a78-754321641159" />
  <code code="416118004" displayName="Administration"
    codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED-CT" />
  <statusCode code="completed" />
  ...
  <entryRelationship typeCode="COMP">
    <substanceAdministration classCode="SBADM" moodCode="EVN">
      ...
      <manufacturedProduct classCode="MANU">
        <templateId root="2.16.840.1.113883.10.20.22.4.23"
          extension="2014-06-09" />
        <id root="37bfe02a-3e97-4bd6-9197-bbd0ed0de79e" />
        <manufacturedMaterial>
          <code nullFlavor="NA"
            sdtc:valueSet="2.16.840.1.113762.1.4.1045.39
              <originalText> None of value set: Low Dose Unfractionated
Heparin for VTE Prophylaxis</originalText>
            </code>
          </manufacturedMaterial>
        </manufacturedProduct>
      ...
    </substanceAdministration>
  </entryRelationship>
  <entryRelationship typeCode="RSON">
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.24.3.88"
        extension="2014-12-01" />
      <id root="3ff5ea2c-fc03-48ed-a1ee-44b4ee48defc" />
      <code code="77301-0"
        codeSystem="2.16.840.1.113883.6.1"
        displayName="Reason care action performed or not"
        codeSystemName="LOINC" />
      <statusCode code="completed" />
      <effectiveTime>
        <low value="20150301" />
      </effectiveTime>
      <value xsi:type="CD" code="182897004"
        codeSystem="2.16.840.1.113883.6.96"
        displayName="Drug declined by patient - side effects
(situation)"
        codeSystemName="SNOMED CT"
        sdtc:valueSet="2.16.840.1.113883.3.117.1.7.1.93" />
      </observation>
    </entryRelationship>
    ...
  
```

5.3 HQR Validations

This section details additional validation rules specified by CMS for HQR. Submissions that do not conform to these constraints will result in files being rejected by the Hospital eCQM Reporting System.

5.3.1 Validation Rules for Encounter Performed (V3)

The effectiveTime low value represents the encounter performed admission time, and the effectiveTime high value represents the encounter performed discharge time.

The following are additional Encounter Performed validation rules for HQR QRDA I submissions.

- i. The system **SHALL** reject QRDA I files if the Encounter Performed Discharge Date is null (CONF: CMS_0060).
- ii. The system **SHALL** reject QRDA I files if the Encounter Performed Discharge Date (effectiveTime/high value) is after the upload date (discharge date is in the future) (CONF: CMS_0061).
- iii. The system **SHALL** reject QRDA I files if the Encounter Performed Admission Date (effectiveTime/low value) is after the Encounter Performed Discharge Date (effectiveTime/high value) (CONF: CMS_0062).
- iv. There are no Encounter Performed Discharge Dates within the reporting period found in the QRDA (CONF: CMS_0063).

5.3.2 Other HQR Validations

Table 13: Other Validation Rules for HQR Programs

| CONF. # | Validation Performed | Description of Error Message and File Rejection |
|----------|--|--|
| CMS_0066 | CCN (NULL) cannot be validated. | CCN passes Schematron format check but the value does not appear in HQR lookup of valid CCNs. CCN is Null, resulting in this message. |
| CMS_0067 | Submitter (%s) is not authorized to submit for this provider (%s) | Lookup performed and found that the Submitter (vendor) has not been authorized to submit data on behalf of the hospital (using the CCN in the QRDA I file). |
| CMS_0068 | Provider is not allowed to use dummy CCN number (800890) for submissions | Only vendors can use the dummy CCN. |
| CMS_0069 | Dummy CCN (800890) cannot be used for production submissions | Dummy CCN can only be used for Test Data submissions. |
| CMS_0070 | Submission date is not within the submission period. | The validation process compares the upload date with the Production Date Range values stored in internal table. If the upload date is outside the acceptable range(s), which for the 2018 Reporting Period is yet to be finalized, this message is returned. |
| CMS_0071 | Data submitted is not a well formed QRDA XML. | Document violates syntax rule in the XML specification, e.g., missing start/end tag or prime elements missing or not properly nested or not properly written. <u>Processing stops immediately on file.</u> |
| CMS_0072 | QRDA file does not pass XML schema validation (CDA_SDTC.xsd). | QRDA structure does not pass CDA_SDTC.XSD schema check. <u>Processing continues</u> on file to identify other Errors/Warnings. |

| CONF. # | Validation Performed | Description of Error Message and File Rejection |
|----------|---|--|
| CMS_0073 | The document does not conform to QRDA document formats accepted by CMS | <p>Document is not in QRDA Category I STU Release 4 format -- does not contain all four of the required header templateds including both of the R4 templateds and extensions:</p> <p>HL7 R4: <templated root="2.16.840.1.113883.10.20.24.1.2" extension="2016-08-01"/></p> <p>2018 CMS QRDA IG: <templated root="2.16.840.1.113883.10.20.24.1.3" extension="2017-07-01"/></p> <p>This error is also produced for empty file or other non-XML file type (e.g., PDF). <u>Processing stops immediately on file.</u></p> |
| CMS_0074 | The Version Specific Measure Identifier is not valid for the current program year. | Each measure in the QRDA must reference the Version Specific Measure Identifier and only the eCQM Specifications for Eligible Hospitals May 2017 will be accepted for the 2018 reporting period. |
| CMS_0075 | Admission Date is not properly formatted. | Fails validation check for Encounter Performed Admission Date (effectiveTime/low value) as specified in Table 14: Valid Date/Time Format for HQR |
| CMS_0076 | Discharge Date is not properly formatted. | Fails validation check for Encounter Performed Discharge Date (effectiveTime/high value) as specified in Table 14: Valid Date/Time Format for HQR |
| CMS_0077 | Reporting Period Start Date (low value) is after the End Date (high value). | Fails validation check. Reporting Parameters Act effectiveTime low (Reporting Period Start Date) is after effectiveTime high (Reporting Period End Date). |
| CMS_0079 | Reporting Period Effective Date Range does not match one of the Program's calendar year Discharge Quarters. | The Reporting Parameter Section effective date range must exactly match one of the HQR allowable calendar year discharge quarters. |

5.3.3 Date and Time Validation

Table 14: Valid Date/Time Format for HQR

| Attribute | Date and Time Format Validation Rules | Examples |
|---|--|--|
| <Encounter> <EffectiveTime> <low>(Admission Date) <high>(Discharge Date) | Valid Date/Time Format: YYYYMMDDHHMMSSxUUUU where YYYY - year - range 1900 to 9999 MM - month - range 01 to 12 DD - day - range 01 to 31 (note: true to month and leap years) HH - hour - range 0 to 23 MM - minutes - range 0-59 SS - seconds - range 0-59 x - plus or minus sign UUUU - UTC time shift -1300 thru+1400 | For example, 20170130113045+1200 |
| BirthTime Reporting Period <EffectiveTime> <low>(Start Date) <high>(End Date) | Valid Date/Time Format: YYYYMMDD where YYYY - year - range 1900 to 9999 MM - month - range 01 to 12 DD - day - range 01 to 31 (note: true to month and leap years) | For example, partial date/time such as 2017 or 201703 are not allowed. |
| EffectiveTime (US Realm Header) | Valid Date/Time Format: YYYYMMDDHHMMSSxUUUU YYYYMMDDHHMMxUUUU YYYYMMDDHHxUUUU YYYYMMDDxUUUU YYYYMMDD YYYYMMDDHH YYYYMMDDHHMM YYYYMMDDHHMMSS where YYYY - year - range 1900 to 9999 MM - month - range 01 to 12 DD - day - range 01 to 31 (note: true to month and leap years) | For example, 20170930 is valid. |
| NA | Leap year calculation is validated. | For example, 20170229 is invalid because 2017 is not a leap year. |

| Attribute | Date and Time Format Validation Rules | Examples |
|-----------|---|--|
| NA | The UTC time shift range is -1200 thru +1400. Time shifts outside this range are invalid. The last two digits are 'minutes' so they must be in the range of 00 to 59. | For example, -1262 is invalid because 62 is outside the range of 00 to 59. |

5.3.4 Validation XPath

Table 15: Validation XPath

| Validation Item | CONF. # | CDA Template Name and CDA Element XPath |
|-------------------------------------|--|---|
| Admission Date | CMS_0062 CMS_0075 | Encounter Performed /../encounter/effectiveTime/low |
| Discharge Date | CMS_0060 CMS_0061 CMS_0062 CMS_0063 CMS_0076 | Encounter Performed /../encounter/effectiveTime/high |
| Reporting Period Start Date | CMS_0063 CMS_0077 CMS_0027 | /ClinicalDocument/component/structuredBody/component/section[@templateId="2.16.840.1.113883.10.20.17.2.1"]/entry/act[@templateId="2.16.840.1.113883.10.20.17.3.8.1"]/effectiveTime/low |
| Reporting Period End Date | CMS_0063 CMS_0079 CMS_0028 | /ClinicalDocument/component/structuredBody/component/section[@templateId="2.16.840.1.113883.10.20.17.2.1"]/entry/act[@templateId="2.16.840.1.113883.10.20.17.3.8.1"]/effectiveTime/high |
| Version Specific Measure Identifier | CMS_0074 | /ClinicalDocument/component/structuredBody/component/section[@templateId="2.16.840.1.113883.10.20.24.2.2"]/entry/organizer[@templateId="2.16.840.1.113883.10.20.24.3.97"]/reference/externalDocument/id[@root="2.16.840.1.113883.4.738"]/@extension |
| Birth Time | 1198_5300_C01 1198_32418 | /ClinicalDocument/recordTarget/patientRole/patient/birthTime |
| effectiveTime (US Realm Header) | 1098-5256 | /ClinicalDocument/effectiveTime |
| CMS Program Name | CMS_0064 CMS_0080 | /ClinicalDocument/informationRecipient/intendedRecipient/id/@extension |

APPENDIX

6 Troubleshooting and Support

6.1 Resources

The following provide additional information:

- **eCQI Resource Center** is the one-stop shop for the most current resources to support electronic clinical quality improvement: <https://ecqi.healthit.gov/>
- **eCQM Library** contains resources for eCQMs including Measure Logic Guidance: http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html
- **National Library of Medicine (NLM) Value Set Authority Center (VSAC)** contains the official versions of the value sets used for eCQMs: <https://vsac.nlm.nih.gov/>
- **Electronic Clinical Quality Measure specification feedback system** is a tool offered by CMS and ONC for Health Information Technology for implementers to submit issues and request guidance on eCQM logic, specifications, and certification: <https://oncprojecttracking.healthit.gov/>

6.2 Support

Table 16: Support Contact Information

| Contact | Org. | Phone | Email | Role | Responsibility |
|---------------------|------|--------------|--|-------------------|--|
| CMS IT Service Desk | CMS | 866-288-8912 | qnetssupport@hcqis.org | Help desk support | 1 st level user support & problem reporting |

6.3 Errata or Enhancement Requests

Table 17: Errata or Enhancement Request Location

| Contact | Organization | URL | Purpose |
|--|--------------|---|---|
| HL7 QRDA I R1, STU Release 4 Comments page | HL7 | http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=198 | Document errors or enhancement request to the HL7 standard. |

7 Null Flavor Validation Rules for Data Types

CDA, Release 2 uses the HL7 V3 Data Types, Release 1 abstract and XML-specific specification. Every data element either has a proper value or it is considered NULL. If and only if it is NULL, a "null flavor" provides more detail on why or in what way no proper value is supplied. The table below provides clarifications to proper nullFlavor use for a list of common data types used by this guide.

Table 18: Null Flavor Validation Rules for Data Types

| Data Type | CONF. # | Rules |
|----------------------------------|----------|--|
| Boolean (BL) | CMS_0105 | Data types of BL SHALL have either @value or @nullFlavor but SHALL NOT have both @value and @nullFlavor (CONF:CMS_0105). |
| Coded Simple (CS) | CMS_0106 | Data types of CS SHALL have either @code or @nullFlavor but SHALL NOT have both @code and @nullFlavor (CONF:CMS_0106). |
| Coded Descriptor (CD) | CMS_0107 | Data types of CD or CE SHALL have either @code or @nullFlavor or both (@codeSystem and @nullFlavor) but SHALL NOT have both @code and @nullFlavor and SHALL NOT have @codeSystem and @nullFlavor "(CONF:CMS_0107). |
| Coded With Equivalents (CE) | | |
| Instance Identifier (II) | CMS_0108 | Data types of II SHALL have either @root or @nullFlavor or (@root and @nullFlavor) or (@root and @extension) but SHALL NOT have all three of (@root and @extension and @nullFlavor) (CONF:CMS_0108). |
| Integer Number (INT) | CMS_0109 | Data types of INT SHALL NOT have both @value and @nullFlavor (CONF:CMS_0109). |
| Physical Quantity (PQ) | CMS_0110 | Data types of PQ SHALL have either @value or @nullFlavor but SHALL NOT have both @value and @nullFlavor. If @value is present then @unit SHALL be present but @unit SHALL NOT be present if @value is not present (CONF:CMS_0110). |
| Real Number (REAL) | CMS_0111 | Data types of REAL SHALL NOT have both @value and @nullFlavor (CONF:CMS_0111). |
| String (ST) | CMS_0112 | Data types of ST SHALL either not be empty or have @nullFlavor (CONF:CMS_0112). |
| Point in Time (TS) | CMS_0113 | Data types of TS SHALL have either @value or @nullFlavor but SHALL NOT have @value and @nullFlavor (CONF:CMS_0113). |
| Universal Resource Locator (URL) | CMS_0114 | Data types of URL SHALL have either @value or @nullFlavor but SHALL NOT have both @value and @nullFlavor (CONF:CMS_0114). |

8 NPI and TIN Validation Rules

Table 19: NPI Validation Rules and Table 20: TIN Validation Rules list the validation rules performed on the NPI and TIN.

Table 19: NPI Validation Rules

| CONF. # | Rules |
|----------|---|
| CMS_0115 | The NPI should have 10 digits. |
| CMS_0116 | The NPI should be composed of all digits. |
| CMS_0117 | The NPI should have a correct checksum, using the Luhn algorithm. |
| CMS_0118 | The NPI should have @extension or @nullFlavor, but not both. |

Table 20: TIN Validation Rules

| CONF. # | Rules |
|----------|--|
| CMS_0119 | When a Tax Identification Number is used, the provided TIN must be in valid format (9 decimal digits). |
| CMS_0120 | The TIN SHALL have either @extension or @nullFlavor, but not both. |

9 CMS QRDA I Implementation Guide Changes to QRDA I STU R4 Base Standard

This table lists all changes made to the base HL7 QRDA I STU R4 contained in this 2018 guide. The "Base Standard" is the *HL7 Implementation Guide for CDA Release 2: Quality Report Document Architecture, Category I, STU Release 4*, (published Jan 2017).

Table 21: Changes Made to the QRDA I STU R4 Base Standard

| CONF. # | Section | Base Standard | Changed To |
|----------------------------------|---------|---------------|--|
| CMS_0001 | 5.1.1 | n/a | <p>Conforms to QDM-Based QRDA (V4) template (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.1.2:2016-08-01).</p> <p>SHALL contain exactly one [1..1] templateId (CONF:CMS_0001) such that it</p> |
| CMS_0002 CMS_0003 | 5.1.1 | n/a | <p>SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.24.1.3" (CONF:CMS_0002).</p> <p>SHALL contain exactly one [1..1] @extension="2017-07-01" (CONF:CMS_0003).</p> |
| CMS_0010 | 5.1.1 | n/a | <p>This languageCode SHALL contain exactly one [1..1] @code="en" (CONF:CMS_0010).</p> |
| CMS_0009 CMS_0053 CMS_0103 | 5.1.2 | n/a | <p>This patientRole SHALL contain exactly one [1..1] id (CONF:CMS_0009) such that it</p> <p>SHALL contain exactly one [1..1] @root (CONF:CMS_0053). This is the provider's organization OID or other non-null value different from the OID for the Medicare HIC Number (2.16.840.1.113883.4.572) and the OID for the Medicare Beneficiary Identifier (2.16.840.1.113883.4.927).</p> <p>SHALL contain exactly one [1..1] @extension (CONF:CMS_0103). Note: The value of the @root combined with the @extension is the Patient Identifier Number.</p> |

| CONF. # | Section | Base Standard | Changed To |
|----------------------------------|---------|--|---|
| CMS_0122 CMS_0123 | 5.1.2 | n/a | <p>Medicare Beneficiary Identifier (MBI) is not required for HQR but should be submitted if the payer is Medicare and the patient has an MBI number assigned.</p> <p>This patientRole MAY contain zero or one [0..1] id (CONF:CMS_0122) such that it</p> <p>SHALL contain exactly one [1..1] @root="2.16.840.1.113883.4.927" Medicare Beneficiary Identifier (CONF:CMS_0123).</p> |
| 1198_5284_C01 | 5.1.2 | <p>This patient SHALL contain at least one [1..*] US Realm Person Name (PN.US.FIELDDED) (identifier: urn:oid:2.16.840.1.113883.10.20.22.5.1.1) (CONF:1198-5284).</p> | <p>This patient SHALL contain exactly one [1..1] US Realm Person Name (PN.US.FIELDDED) (identifier: urn:oid:2.16.840.1.113883.10.20.22.5.1.1) (CONF:1198-5284_C01).</p> |
| CMS_0011 CMS_0029 | 5.1.2 | <p>This patient SHALL contain exactly one [1..1] administrativeGenderCode, which SHALL be selected from ValueSet Administrative Gender (HL7 V3) (urn:oid:2.16.840.1.113883.11.1 DYNAMIC (CONF:1198-6394).</p> | <p>This patient SHALL contain exactly one [1..1] administrativeGenderCode, which SHALL be selected from ValueSet ONC Administrative Sex (urn:oid:2.16.840.1.113762.1.4.1 DYNAMIC (CONF:CMS_0011).</p> <p>If the patient's administrative sex is unknown, nullFlavor="UNK" SHALL be submitted (CONF:CMS_0029).</p> |
| 1198_5300_C01 | 5.1.2 | <p>This patient SHALL contain exactly one [1..1] birthTime (CONF:1140-27571).</p> <p>SHOULD be precise to day (CONF:1198-5300).</p> | <p>This patient SHALL contain exactly one [1..1] birthTime (CONF:1140-27571).</p> <p>SHALL be precise to day (CONF:1198-5300_C01).</p> |
| CMS_0013 CMS_0030 CMS_0031 | 5.1.2 | <p>This patient SHALL contain exactly one [1..1] raceCode, which SHALL be selected from ValueSet Race Category Excluding Nulls (urn:oid:2.16.840.1.113883.3.2074.1.1.3 DYNAMIC (CONF:1198-5322).</p> | <p>This patient SHALL contain exactly one [1..1] raceCode, which SHALL be selected from ValueSet Race (urn:oid:2.16.840.1.114222.4.1.1.836 DYNAMIC (CONF:CMS_0013).</p> <p>If the patient's race is unknown, nullFlavor="UNK" SHALL be submitted (CONF:CMS_0030).</p> <p>If the patient declined to specify his/her race, nullFlavor="ASKU" SHALL be submitted (CONF:CMS_0031).</p> |

| CONF. # | Section | Base Standard | Changed To |
|--|---------|--|---|
| CMS_0014 | 5.1.2 | This patient MAY contain zero or more [0..*] <code>sdtc:raceCode</code> , which SHALL be selected from ValueSet Race urn:oid:2.16.840.1.113883.1.11.14914 DYNAMIC (CONF:1198-7263). | This patient MAY contain zero or more [0..*] <code>sdtc:raceCode</code> , which SHALL be selected from ValueSet Race urn:oid:2.16.840.1.114222.4.1.1.836 DYNAMIC (CONF:CMS_0014). Note: If a patient has more than one race category, one race is reported in raceCode, and additional races are reported using sdtc:raceCode. |
| CMS_0032 CMS_0033 | 5.1.2 | This patient SHALL contain exactly one [1..1] <code>ethnicGroupCode</code> , which SHALL be selected from ValueSet Ethnicity urn:oid:2.16.840.1.114222.4.1.11.837 DYNAMIC (CONF:1198-5323). | This patient SHALL contain exactly one [1..1] <code>ethnicGroupCode</code> , which SHALL be selected from ValueSet Ethnicity urn:oid:2.16.840.1.114222.4.1.1.837 DYNAMIC (CONF:1198-5323). If the patient's ethnicity is unknown, <code>nullFlavor="UNK"</code> SHALL be submitted (CONF:CMS_0032). If the patient declined to specify his/her ethnicity, <code>nullFlavor="ASKU"</code> SHALL be submitted (CONF:CMS_0033). |
| 3265-28241_C01 | 5.1.3 | This <code>representedCustodianOrganization</code> SHOULD contain zero or one [0..1] <code>id</code> (CONF:3265-28241) such that it | This <code>representedCustodianOrganization</code> SHALL contain exactly one [1..1] <code>id</code> (CONF:3265-28241_C01) such that it |
| CMS_0035 | 5.1.3 | n/a | CCN SHALL be six to ten characters in length (CONF:CMS_0035). |
| 3265_16703_C01 | 5.1.4 | MAY contain zero or more [0..*] <code>informationRecipient</code> (CONF:3265-16703). | SHALL contain exactly one [1..1] <code>informationRecipient</code> (CONF:3265-16703_C01). |
| 3265_16705_C01 CMS_0025 CMS_0026 | 5.1.4 | This <code>intendedRecipient</code> SHALL contain at least one [1..*] <code>id</code> (CONF:3265-16705). | This <code>intendedRecipient</code> SHALL contain exactly one [1..1] <code>id</code> (CONF:3265-16705_C01). This <code>id</code> SHALL contain exactly one [1..1] <code>@root="2.16.840.1.113883.3.249.7"</code> (CONF:CMS_0025). This <code>id</code> SHALL contain exactly one [1..1] <code>@extension</code> , which SHALL be selected from ValueSet QRDA I CMS Program Name urn:oid:2.16.840.1.113883.3.249.14.103 STATIC 2016-07-01 (CONF:CMS_0026). Note: The value of <code>@extension</code> is CMS Program Name. |

| CONF. # | Section | Base Standard | Changed To |
|--|---------|---|---|
| 1198-10003_C01 | 5.1.5 | MAY contain zero or more [0..*] participant (CONF:1198-10003) such that it | SHALL contain exactly one [1..1] participant (CONF:1198-10003_C01). |
| CMS_0004 CMS_0005 CMS_0006 CMS_0008 | 5.1.5 | | <p>The participant SHALL contain exactly one [1..1] associatedEntity (CONF:CMS_0004).</p> <p>This associatedEntity SHALL contain exactly one [1..1] id (CONF:CMS_0005) such that it</p> <p>SHALL contain exactly one [1..1] @root="2.16.840.1.113883.3.2074.1" CMS EHR Certification Number (formerly known as Office of the National Coordinator Certification Number) (CONF:CMS_0006).</p> <p>SHALL contain exactly one [1..1] @extension (CONF:CMS_0008). Note: The value of @extension is the Certification Number.</p> |
| 3265-16579_C01 | 5.1.6 | MAY contain zero or one [0..1] documentationOf (CONF:3265-16579) such that it | SHALL contain exactly one [1..1] documentationOf (CONF:3265-16579_C01) such that it |
| CMS_0019 CMS_0020 | 5.1.6 | n/a | <p>This assignedEntity MAY contain zero or one [0..1] assignedPerson (CONF:CMS_0019).</p> <p>The assignedPerson, if present, MAY contain zero or one [0..1] name (CONF:CMS_0020). Note: This is the provider's name.</p> |
| CMS_0022 | 5.1.6 | n/a | This representedOrganization MAY contain zero or one [0..1] name (CONF:CMS_0022). |

| CONF. # | Section | Base Standard | Changed To |
|---|----------------|---------------|---|
| <p>CMS_0040 CMS_0041 CMS_0042 CMS_0023 CMS_0024</p> | <p>5.2.2</p> | <p>n/a</p> | <p>Conforms to Reporting Parameters Section template (identifier: urn:oid:2.16.840.1.113883.10.20.17.2.1).</p> <p>SHALL contain exactly one [1..1] templated (CONF:CMS_0040) such that it</p> <p>SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.17.2.1" (CONF:CMS_0041).</p> <p>SHALL contain exactly one [1..1] @extension="2015-07-01" (CONF:CMS_0042).</p> <p>SHALL contain exactly one [1..1] entry (CONF:CMS_0023) such that it</p> <p>SHALL contain exactly one [1..1] Reporting Parameters Act - CMS (identifier: urn:hl7ii:2.16.840.1.113883.10.20.17.3.8:2015-07-01) (CONF:CMS_0024).</p> |
| <p>CMS_0044 CMS_0045 CMS_0046</p> | <p>5.2.2.1</p> | <p>n/a</p> | <p>Conforms to Reporting Parameters Act template (identifier: urn:oid:2.16.840.1.113883.10.20.17.3.8).</p> <p>SHALL contain exactly one [1..1] templated (CONF:CMS_0044) such that it</p> <p>SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.17.3.8" (CONF:CMS_0045).</p> <p>SHALL contain exactly one [1..1] @extension="2015-07-01" (CONF:CMS_0046).</p> |

| CONF. # | Section | Base Standard | Changed To |
|--|---------|--|---|
| CMS_0048 CMS_0027 CMS_0050 CMS_0028 | 5.2.2.1 | <p>SHALL contain exactly one [1..1] effectiveTime (CONF:23-3273).</p> <p>This effectiveTime SHALL contain exactly one [1..1] low (CONF:23-3274).</p> <p>This effectiveTime SHALL contain exactly one [1..1] high (CONF:23-3275).</p> | <p>SHALL contain exactly one [1..1] effectiveTime (CONF:23-3273).</p> <p>This effectiveTime SHALL contain exactly one [1..1] low (CONF:23-3274).</p> <p>This low SHALL contain exactly one [1..1] @value (CONF:CMS_0048).</p> <p>SHALL be precise to day (CONF:CMS_0027)</p> <p>This effectiveTime SHALL contain exactly one [1..1] high (CONF:23-3275).</p> <p>This high SHALL contain exactly one [1..1] @value (CONF:CMS_0050).</p> <p>SHALL be precise to day (CONF:CMS_0028)</p> |
| CMS_0036 CMS_0037 CMS_0038 | 5.2.3 | n/a | <p>Conforms to Patient Data Section QDM (V3) template (identifier: urn:h17ii:2.16.840.1.113883.10.20.24.2.1:2016-02-01) .</p> <p>SHALL contain exactly one [1..1] templateId (CONF:CMS_0036) such that it</p> <p>SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.24.2.1" (CONF:CMS_0037).</p> <p>SHALL contain exactly one [1..1] @extension="2016-03-01" (CONF:CMS_0038).</p> |
| CMS_0051 CMS_0039 | 5.2.3 | n/a | <p>SHALL contain at least one [1..*] entry (CONF:CMS_0051) such that it</p> <p>SHALL contain exactly one [1..1] entry template that is other than the Patient Characteristic Payer (identifier: urn:oid:2.16.840.1.113883.10.20.24.3.55) (CONF:CMS_0039).</p> |
| 3265-14430_C01 | 5.2.3 | <p>MAY contain zero or more [0..*] entry (CONF:3265-14430) such that it</p> | <p>SHALL contain at least one [1..*] entry (CONF:3265-14430_C01) such that it</p> <p>SHALL contain at least one [1..*] Patient Characteristic Payer (identifier: urn:oid:2.16.840.1.113883.10.20.24.3.55) (CONF:3265_14431).</p> |

10 Change Log for 2018 CMS QRDA Implementation Guide from the 2017 CMS QRDA Implementation Guide

This appendix summarizes the changes made in this 2018 CMS QRDA Implementation Guide since the release of 2017 CMS QRDA Implementation Guide.

The table below lists the changes made for the QRDA I STU R4 Implementation Guide for Hospital Quality Reporting of the 2018 CMS QRDA IG from the QRDA I STU R4 CMS Implementation Guide for Hospital Quality Reporting of the 2017 CMS QRDA IG.

Table 22: Changes Made for 2018 CMS QRDA IG from 2017 CMS QRDA IG

| Section Heading | 2018 CMS QRDA IG | 2017 CMS QRDA IG |
|--------------------------------|---|--|
| Base Standard | HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture Category I, Release 1, Standard for Trial Use (STU) Release 4, US Realm, 2017 (This is in the process of being publishing by HL7) | HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture Category I, Release 1, Standard for Trial Use (STU) Release 3.1, US Realm, June 2015 |
| 4 QRDA Category I Requirements | Language is updated to reflect the requirement updates for the 2018 reporting year. | n/a |
| 4.5 Time Zone | Removed <code>birthTime/@value</code> from the list of elements that the time zone validation rule is performed on. Added language to indicate the time zone validation rule is not performed on <code>birthTime/@value</code> . | <code>birthTime/@value</code> was listed as one of elements that the time zone validation rule is performed on. |
| 5.1.1 General Header | QRDA Category I Report - CMS HQR (V4) (Note: this template is based on QRDA I, STU R4) | QRDA Category I Report - CMS EP & HQR (V2) (Note: this template is based on QRDA I, STU R3.1) |
| 5.1.2 recordTarget | Medicare Beneficiary Identifier (MBI) is not required for HQR but should be submitted if the payer is Medicare and the patient has an MBI number assigned. This patientRole MAY contain zero or one [0..1] <code>id</code> (CONF:CMS_0122) such that it SHALL contain exactly one [1..1] <code>@root="2.16.840.1.11388.3.4.927"</code> Medicare Beneficiary Identifier (CONF:CMS_0123). | n/a |

| Section Heading | 2018 CMS QRDA IG | 2017 CMS QRDA IG |
|----------------------------|---|---|
| 5.1.3 Custodian | Removed CMS_0034 (Because CONF:3265-28244 and 3265-28245 require the presence of both @root and @extension, hence @nullFlavor is not allowed.) | [HQR] SHALL NOT contain [0..0] @nullFlavor (CONF:CMS_0034). |
| 5.1.4 informationRecipient | Removed CMS_0043 (Because CONF:CMS_0025 and CMS_0026 require the presence of both @root and @extension, hence @nullFlavor is not allowed.) | This intendedRecipient SHALL contain exactly one [1..1] id (CONF:1140-16705_C01). SHALL NOT contain [0..0] @nullFlavor (CONF:CMS_0043). This id SHALL contain exactly one [1..1] @root="2.16.840.1.113883.3.249.7" (CONF:CMS_0025). This id SHALL contain exactly one [1..1] @extension, which SHALL be selected from ValueSet QRDA I CMS Program Name urn:oid:2.16.840.1.113883.3.249.14.103 STATIC 2015-07-01 (CONF:CMS_0026). Note: The value of @extension is CMS Program Name. |

| Section Heading | 2018 CMS QRDA IG | 2017 CMS QRDA IG |
|--|--|---|
| <p>5.1.5 Participant (CMS Certification Identification Number)</p> | <p>(New section 5.1.5 Participant) SHALL contain exactly one [1..1] participant (CONF:1198-10003_C01).</p> <p>CMS EHR Certification Identification Number is required for HQR.</p> <p>This participant SHALL contain exactly one [1..1] associatedEntity (CONF:CMS_0004).</p> <p>This associatedEntity SHALL contain exactly one [1..1] id (CONF:CMS_0005).</p> <p>This id SHALL contain exactly one [1..1] @root="2.16.840.1.113883.3.2074.1" CMS EHR Certification Identification Number (CONF:CMS_0006).</p> <p>This id SHALL contain exactly one [1..1] @extension (CONF:CMS_0008). Note: The value of @extension is the Certification Number.</p> | <p>(5.1.1 General Header) MAY contain zero or more [0..*] participant (CONF:1098-10003).</p> <p>CMS EHR Certification Number is optional. If it is submitted, it SHALL conform to the constraints specified for the CMS EHR Certification Number.</p> <p>The participant, if present, SHALL contain exactly one [1..1] associatedEntity (CONF:CMS_0004).</p> <p>This associatedEntity SHALL contain exactly one [1..1] id (CONF:CMS_0005) such that it SHALL NOT contain [0..0] @nullFlavor (CONF:CMS_0052). SHALL contain exactly one [1..1] @root="2.16.840.1.113883.3.2074.1" CMS EHR Certification Number (formerly known as Office of the National Coordinator Certification Number) (CONF:CMS_0006). SHALL contain exactly one [1..1] @extension (CONF:CMS_0008). Note: The value of @extension is the Certification Number.</p> |
| <p>5.1.6 documentationOf/serviceEvent</p> | <p>This assignedEntity SHOULD contain zero or one [0..1] id (CONF:3265-16587) such that it SHALL contain exactly one [1..1] @root="2.16.840.1.113883.4.6" National Provider ID (CONF:3265-16588).</p> | <p>This assignedEntity SHALL contain exactly one [1..1] id (CONF:1140-16587_C01) such that it SHALL contain exactly one [1..1] @root="2.16.840.1.113883.4.6" National Provider ID (CONF:1140-16588).</p> |
| <p>5.1.6 documentationOf/serviceEvent</p> | <p>This assignedEntity SHALL contain exactly one [1..1] representedOrganization (CONF:3265-16591).</p> | <p>This assignedEntity SHALL contain exactly one [1..1] representedOrganization (CONF:1140-16591_C01).</p> |

| Section Heading | 2018 CMS QRDA IG | 2017 CMS QRDA IG |
|--|--|---|
| 5.1.6 documentationOf/serviceEvent | <p>This representedOrganization SHOULD contain zero or one [0..1] id (CONF:3265-16592).</p> <p>The id, if present, SHALL contain exactly one [1..1] @root="2.16.840.1.113883.4.2" Tax ID Number (CONF:3265-16593).</p> | <p>This representedOrganization SHALL contain exactly one [1..1] id (CONF:1140-16592_C01) such that it SHALL contain exactly one [1..1] @root="2.16.840.1.113883.4.2" Tax ID Number (CONF:1182-43).</p> |
| 5.3 HQR Validations | <p>New section added to list additional HQR validations contained in the 2017 CMS QRDA IG, and are updated for the 2018 reporting period.</p> | <p>Additional QRDA I Validation Rules for HQR Programs</p> <p>5.2.5 HQR Validation Rules Updates</p> <p>5.2.6 Date and Time Validation</p> |
| Appendix 7 Null Flavor Validation Rules for Data Types | <p>Updated with CMS conformance number assigned to each rule.</p> | <p>Null Flavor Validation Rules for Data Types</p> |
| Appendix 8 NPI and TIN Validation Rules | <p>New section added to list conformance statements for NPI and TIN validations.</p> | <p>n/a</p> |

11 Acronyms

This section describes acronyms used in this guide.

| Acronym | Literal Translation |
|---------|--|
| ASKU | Asked, but not known |
| CDA | Clinical Document Architecture |
| CMS | Centers for Medicare & Medicaid Services |
| CONF | conformance |
| CQM | Clinical Quality Measure |
| STU | Standard for Trial Use |
| eCQI | electronic Clinical Quality Improvement |
| eCQM | electronic Clinical Quality Measure |
| EHR | Electronic Health Record |
| FAP | Final Action Processing |
| HIC | Health Insurance Claim |
| HL7 | Health Level Seven |
| HL7 V3 | Health Level 7 Version 3 |
| HQMF | Health Quality Measure Format |
| HQR | Hospital Quality Reporting |
| ID | identifier |
| IP | Initial Population |
| IT | Information technology |
| LOINC | Logical Observation Identifiers Names and Codes |
| MBI | Medicare Beneficiary Identification Number |
| n/a | not applicable |
| NA | Not applicable |
| NLM | National Library of Medicine |
| NPI | National Provider Identification Number |
| OID | Object Identifier |
| ONC | Office of the National Coordinator for Health Information Technology |

| Acronym | Literal Translation |
|----------------|--|
| QDM | Quality Data Model |
| QRDA | Quality Reporting Data Architecture |
| QRDA I | Quality Reporting Data Architecture Category I |
| TIN | Tax Identification Number |
| UNK | Unknown |
| UTC | Coordinated Universal Time |
| VSAC | Value Set Authority Center |
| XML | Extensible Markup Language |

12 Glossary

| Term | Definition |
|--|--|
| Electronic health record (EHR) | Electronic records of patient health information gathered and/or generated in any care delivery setting. This information includes patient demographics, progress notes, medications, vital signs, past medical history, immunizations, laboratory data, and radiology reports. This provides the ability to pass information from care point to care point providing the ability for quality health management by physicians. |
| Electronic Clinical Quality Measure (eCQM) | A standardized performance measure in the Health Quality Measure Format (HQMF). |
| XML Path Language (XPath) | This notation provides a mechanism that will be familiar to developers for identifying parts of an XML document. XPath syntax selects nodes from an XML document using a path containing the context of the node(s). The path is constructed from node names and attribute names (prefixed by an '@') and concatenated with a '/' symbol. |

13 References

CMS, eCQM Library. http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html

Certified Health IT Product List. <https://chpl.healthit.gov/>

eCQI Resource Center. <https://ecqi.healthit.gov/>

HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture, Category I, Release 1, Standard for Trial Use Release 4 (QRDA I STU R4). January 2017.
http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35

ONC, Electronic Clinical Quality Measure issue reporting system.
<https://oncprojectracking.healthit.gov/>

U.S. National Library of Medicine, Value Set Authority Center. <https://vsac.nlm.nih.gov>