CMS Implementation Guide for Quality Reporting Document Architecture Category I

Hospital Quality Reporting

Implementation Guide for 2017

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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, Draft Standard for Trial Use (DSTU) Release 3.1, US Realm*, April 2016[1] for the 2017 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 DSTU R3.1 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 2017 CMS QRDA IG for HQR programs from the 2016 CMS QRDA IG, and validation rules for data types, NPI, and TIN.

[1] 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 the following figure, 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

```
1. SHALL contain exactly one [1..1] participant (CONF:2777).
     a. This participant SHALL contain exactly one [1..1]
        @typeCode="LOC" (CodeSystem: 2.16.840.1.113883.5.90
        HL7ParticipationType) (CONF:2230).
```

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

Figure 2: Constraints Format – only one like this allowed

```
1. SHALL contain exactly one [1..1] participant (CONF:2777) such that it
     a.  SHALL contain exactly one [1..1] @typeCode="LOC" (CodeSystem:
        2.16.840.1.113883.5.90 HL7ParticipationType) (CONF:2230).
```

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.

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 above list contains those null flavors that are commonly used in clinical documents. For the full list and descriptions, see the `nullFlavor` vocabulary domain in the 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 DSTU R3.1 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, DSTU Release 3.1 (published April, 2016)*, referred to as the *QRDA-I Implementation Guide* in this guide. This guide describes additional conformance statements and constraints for electronic health record (EHR) data submissions that are required for reporting information to the Centers for Medicare & Medicaid Services (CMS) for the Hospital Inpatient Quality Reporting Program 2017 Reporting Period.

The purpose of this guide is to serve as a companion to the base HL7 *QRDA-I Implementation Guide* 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 Hospital Quality Reporting in the 2017 reporting period must meet the conformance statements specified in this guide in addition to the conformance statements specified in the *QRDA-I Implementation Guide*. Only documents that are valid against the Clinical Document Architecture (CDA) Release 2 schema enhanced to support the sdtc namespace (CDA_SDTC.xsd) will be accepted for processing. Documents that are invalid against this rule will be rejected.

This guide is based on following rules:

1. The *QRDA-I Implementation Guide* 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, R3.1 standard is further constrained in this guide.
2. The original **SHALL**/**SHOULD**/**MAY** keywords along with conformance numbers from the *QRDA-I Implementation Guide* 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.

4 QRDA Category I Requirements

4.1 QRDA Category I Reporting

A QRDA-I document should be submitted for each patient who meets the Initial Population criteria of an eCQM. The QRDA-I base standard allows either one or multiple measures to be reported in a QRDA-I document. For Hospital Quality Reporting, 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 April 2016[2] must be used for the HQR programs.

The eCQM Value Sets published on April 6, 2016 at the Value Set Authority Center (VSAC)[3] must be used for the 2017 Reporting Period:

- eCQM Value Sets for Eligible Hospitals Update April 2016 must be used for the HQR programs.

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.)

4.3.2 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: CMS Certification Number (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 just 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.

4.3.3 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

[2] https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/eCQM_2014_EH_April2016.zip
[3] Value Set Authority Center. https://vsac.nlm.nih.gov/

4.4.1 eCQM Specified Value Sets Take Precedence

There are some cases where the value sets specified in electronic Clinical Quality Measures (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, 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. 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 is performed on the following elements:

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

There is one exception 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[@templateId="2.16.840.1.113883.10.20.17.3.8.1"][@extension="2016-03-01"]/effectiveTime/low
- act[@templateId="2.16.840.1.113883.10.20.17.3.8.1"][@extension="2016-03-01"]/effectiveTime/high

Figure 4: Time Zone Example

```
<encounter>
  <text>Encounter Performed: Hospital Measures-Encounter
    Inpatient</text>
  ...
  <effectiveTime>
    <!-- Attribute: admission datetime -->
    <low value="20160325090000-0500"/>
    <!-- Attribute: discharge datetime -->
    <high value="20160329103000-0500"/>
  </effectiveTime>
  ...
</encounter>
```

4.6 Submit eCQM Version Specific Measure Identifier ONLY

For the 2017 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 QRDAs. This is due to a known data type mismatch issue between the Health Level Seven (HL7) QRDA and HQMF standards for the *versionNumber* attribute. The QRDA-I standard is based on HL7 Clinical Document Architecture (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 (April 2016) generated by the Measure Authoring Tool (MAT) are string values such as 5.1.000 and 6.3.000 instead of integers such as 5 or 6. If a version number such as 5.1.000 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 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture Category I, Release 1, DSTU Release 3.1 and the CMS QRDA-I implementation guide have versioned the templates 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 QRDA-I, DSTU R3.1. For example, in QRDA-I DSTU R3.1, the previous Encounter Performed (V2) template is now Encounter Performed (V3), its template identifier is “2.16.840.1.113883.10.20.24.3.23:2016-02-01”. Both the @root and @extension are required as specified in the IG.

SHALL contain exactly one [1..1] **templateId** (CONF:2228-11861) such that it

a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.24.3.23" (CONF:2228-11862).
b. **SHALL** contain exactly one [1..1] **@extension**="2016-02-01" (CONF:2228-26552).

Correct template versions that are specified by both the base HL7 QRDA-I DSTU R3.1 and the 2017 CMS IG must be used for 2017 CMS QRDA-I submissions. For instance, if a QRDA-I file used Encounter Performed (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 DSTU R3.1 and the 2017 CMS 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 *QRDA-I Implementation Guide* are Clinical Document Architecture (CDA) templates.

5.1.1 General Header

This template describes header constraints that apply to the CMS Quality Reporting Document Architecture (QRDA) Category I document.

Table 2: QRDA Category I Report - CMS (V3) Constraints Overview
ClinicalDocument (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.1.3:2016-03-01)

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	2016-03-01
id	1..1	SHALL		1198-5363	
effectiveTime	1..1	SHALL		1198-5256	US Realm Date and Time (DTM.US.FIELDED) (identifier: urn:oid:2.16.840.1.113883.10.20.22.5.4
languageCode	1..1	SHALL		1198-5372	urn:oid:2.16.840.1.113883.1.11.11526 (Language)
@code	1..1	SHALL		CMS_0010	en
versionNumber	0..1	MAY		1198-5264	
component	1..1	SHALL		2239-28472	
structuredBody	1..1	SHALL		2239-28473	
component	1..*	SHALL		2239-28474	
section	1..1	SHALL		2239-28475	Reporting Parameters Section - CMS (identifier: urn:hl7ii:2.16.840.1.113883.10.20.17.2.1.1:2016-03-01
component	1..*	SHALL		2239-28476	

section	1..1	SHALL		2239-28477	Patient Data Section QDM (V3) - CMS (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.2.1.1:2016-03-01

1. Conforms to QDM-Based QRDA (V3) template `(identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.1.2:2016-02-01)`.
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=`**`"2016-03-01"` (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.FIELDED) (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:2239-28472).
   a. This component **SHALL** contain exactly one [1..1] **`structuredBody`** (CONF:2239-28473).
      i. This structuredBody **SHALL** contain at least one [1..*] **`component`** (CONF:2239-28474) 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:2239-28475).
      ii. This structuredBody **SHALL** contain at least one [1..*] **`component`** (CONF:2239-28476) such that it
         1. **SHALL** contain exactly one [1..1] Patient Data Section QDM (V3) - CMS `(identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.2.1.1:2016-03-01)` (CONF:2239-28477).

Figure 5: General Header Example

```
<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 (V3) -->
<templateId root="2.16.840.1.113883.10.20.24.1.2"
    extension="2016-02-01"/>
<!-- QRDA Category I Report - CMS (V3) -->
<templateId root="2.16.840.1.113883.10.20.24.1.3"
    extension="2016-03-01"/>

<!-- This is the globally unique identifier for this QRDA-I
    document -->
<id root="d651b289-c487-4436-95d2-4c816e50b447"/>
<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="20170110917150 4+0500"/>
<confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25"
    codeSystemName="HL7Confidentiality"/>
<languageCode code="en"/>
...
```

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:2.16.840.1.113883.10.20.24.1.3:2016-03-01)

XPath	Card.	Verb	Data Type	CONF#	Value
recordTarget	1..1	SHALL		2228-16598	
patientRole	1..1	SHALL		2228-16856	
id	0..1	SHOULD		2228-16857	
@root	1..1	SHALL		2228-16858	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	
addr	1..*	SHALL		1198-5271	US Realm Address (AD.US.FIELDED) (identifier: urn:oid:2.16.840.1.113883.10.20.22.5.2

XPath	Card.	Verb	Data Type	CONF#	Value
patient	1..1	SHALL		2228-27570	
name	1..1	SHALL		1198-5284_C01	US Realm Person Name (PN.US.FIELDED) (identifier: urn:oid:2.16.840.1.113883.10.20.22.5.1.1
administrativeGenderCode	1..1	SHALL		CMS_0011	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	urn:oid:2.16.840.1.114222.4.11.836 (Race)

1. **SHALL** contain exactly one [1..1] **recordTarget** (CONF:2228-16598).
   a. This recordTarget **SHALL** contain exactly one [1..1] **patientRole** (CONF:2228-16856).

HQR: 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:2228-16857) such that it
   1. **SHALL** contain exactly one [1..1] **@root="2.16.840.1.113883.4.572"** Medicare HIC number (CONF:2228-16858).

HQR: 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 than the OID for the Medicare HIC Number (2.16.840.1.113883.4.572).
   2. **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.

iii. This patientRole **SHALL** contain at least one [1..*] **US Realm Address (AD.US.FIELDED)** (identifier: urn:oid:2.16.840.1.113883.10.20.22.5.2) (CONF:1198-5271).

iv. This patientRole **SHALL** contain exactly one [1..1] **patient** (CONF:2228-27570).
   1. This patient **SHALL** contain exactly one [1..1] **US Realm Person Name (PN.US.FIELDED)** (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 (V3)

```
<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:2.16.840.1.113883.10.20.24.1.3:2016-03-01)

	XPath	Card.	Verb	Data Type	CONF#	Value
	custodian	1..1	SHALL		2228-16600	
	assignedCustodian	1..1	SHALL		2228-28239	
	representedCustodianOrganization	1..1	SHALL		2228-28240	
HQR	id	1..1	SHALL		2228-28241_C01	
HQR	@root	1..1	SHALL		2228-28244	2.16.840.1.113883.4.336
HQR	@extension	1..1	SHALL		2228-28245 CMS_0035	

1. **SHALL** contain exactly one [1..1] **custodian** (CONF:2228-16600).
    a. This custodian **SHALL** contain exactly one [1..1] **assignedCustodian** (CONF:2228-28239).
        i. This assignedCustodian **SHALL** contain exactly one [1..1] **representedCustodianOrganization** (CONF:2228-28240).

This representedCustodianOrganization id/@root='2.16.840.1.113883.4.336' coupled with the id/@extension represents the organization's Facility CMS Certification Number (CCN).

CCN is required for HQR.

1. **[HQR]** This representedCustodianOrganization **SHALL** contain exactly one [1..1] **id** (CONF:2228-28241_C01) such that it
    a. **[HQR] SHALL** contain exactly one [1..1] **@root="2.16.840.1.113883.4.336"** CMS Certification Number (CONF:2228-28244).
    b. **[HQR] SHALL** contain exactly one [1..1] **@extension** (CONF:2228-28245).
    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 (V3)

```
<!-- 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:2.16.840.1.113883.10.20.24.1.3:2016-03-01)

XPath	Card.	Verb	Data Type	CONF#	Value
informationRecipient	1..1	SHALL		2228-16703_C01	
intendedRecipient	1..1	SHALL		2228-16704	
id	1..1	SHALL		2228-16705_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:2228-16703_C01).
    a. This informationRecipient **SHALL** contain exactly one [1..1] **`intendedRecipient`** (CONF:2228-16704).
        i. This intendedRecipient **SHALL** contain exactly one [1..1] **`id`** (CONF:2228-16705_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** 2016-03-01 (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
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 (V3)

```
<!-- 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 IT Product List (CHPL) is the authoritative and comprehensive listing of Health IT certified through the 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 website.

Table 7: Participant Constraints Overview
ClinicalDocument (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.1.3:2016-03-01)

	XPath	Card.	Verb	Data Type	CONF#	Value
HQR	participant	1..1	SHALL		1198-10003_C01	
HQR	associatedEntity	1..1	SHALL		CMS_0004	

HQR	id	1..1	SHALL		CMS_0005	
HQR	@root	1..1	SHALL		CMS_0006	2.16.840.1.113883.3.2074.1
HQR	@extension	1..1	SHALL		CMS_0008	

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

CMS EHR Certification Identification Number is required for HQR.

   a. **[HQR]** This participant **SHALL** contain exactly one [1..1] **`associatedEntity`** (CONF:CMS_0004).
      i. **[HQR]** This associatedEntity **SHALL** contain exactly one [1..1] **`id`** (CONF:CMS_0005).
         1. **[HQR]** 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).
         2. **[HQR]** This id **SHALL** contain exactly one [1..1] **`@extension`** (CONF:CMS_0008).
            Note: The value of @extension is the CMS Certification Identification Number.

5.1.6 documentationOf/serviceEvent

Table 8: documentationOf/serviceEvent Constraints Overview

ClinicalDocument (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.1.3:2016-03-01)

	XPath	Card.	Verb	Data Type	CONF#	Value
	documentationOf	1..1	SHALL		2228-16579_C01	
	serviceEvent	1..1	SHALL		2228-16580	
HQR	performer	1..*	SHALL		2228-16583	
HQR	@typeCode	1..1	SHALL		2228-16584	PRF
HQR	assignedEntity	1..1	SHALL		2228-16586	
HQR	id	0..1	SHOULD		2228-16587	
HQR	@root	1..1	SHALL		2228-16588	2.16.840.1.113883.4.6
HQR	assignedPerson	0..1	MAY		CMS_0019	
HQR	name	0..1	MAY		CMS_0020	
HQR	representedOrganization	1..1	SHALL		2228-16591	
HQR	id	0..1	SHOULD		2228-16592	
HQR	@root	1..1	SHALL		2228-16593	2.16.840.1.113883.4.2
HQR	name	0..1	MAY		CMS_0022	

1. **SHALL** contain exactly one [1..1] **documentationOf** (CONF:2228-16579_C01) such that it
   a. **SHALL** contain exactly one [1..1] **serviceEvent** (CONF:2228-16580).
      i. **[HQR]** This serviceEvent **SHALL** contain at least one [1..*] **performer** (CONF:2228-16583).
         1. **[HQR]** Such performers **SHALL** contain exactly one [1..1] **@typeCode="PRF"** Performer (CONF:2228-16584).
         2. **[HQR]** Such performers **SHALL** contain exactly one [1..1] **assignedEntity** (CONF:2228-16586).

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

HQR: 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. (See Section 8 for specific NPI and TIN validation Rules.)

a. **[HQR]** This assignedEntity **SHOULD** contain zero or one [0..1] **id** (CONF:2228-16587) such that it
   i. **[HQR] SHALL** contain exactly one [1..1] **@root="2.16.840.1.113883.4.6"** National Provider ID (CONF:2228-16588).
b. **[HQR]** This assignedEntity **MAY** contain zero or one [0..1] **assignedPerson** (CONF:CMS_0019).
   i. **[HQR]** The assignedPerson, if present, **MAY** contain zero or one [0..1] **name** (CONF:CMS_0020).
      Note: This is the provider's name.
c. **[HQR]** This assignedEntity **SHALL** contain exactly one [1..1] **representedOrganization** (CONF:2228-16591).

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

HQR: For the 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:2228-16592).
1. The id, if present, **SHALL** contain exactly one [1..1] **@root="2.16.840.1.113883.4.2"** Tax ID Number (CONF:2228-16593).
ii. **[HQR]** 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 for HQR

```
<!-- 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 eMeasure or eMeasures being reported. It must contain entries with the identifiers of all the eMeasures so that corresponding QRDA Quality Data Model (QDM) data element entry templates to be instantiated in the Patient Data Section are identified. Each eMeasure for which QRDA QDM data elements are being sent must reference eMeasure version specific identifier (`QualityMeasureDocument/id`).

Table 9: Measure Section (eMeasure 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="40280381-4b9a-3825-014b-c11ae59d069b"/>
        </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	

XPath	Card.	Verb	Data Type	CONF#	Value
@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 2016 - 31 December 2016
    </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="20160101"/>
           <high value="20161231"/>
         </effectiveTime>
      </act>
  </entry>
</section>
```

5.2.3 Patient Data Section QDM (V3) - CMS

The Patient Data Section QDM (V3) - 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. So the Patient Data Section QDM (V3) - 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 QRDA-I standard.

Table 12: Patient Data Section QDM (V3) – CMS Constraints Overview

section (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.2.1.1:2016-03-01)

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	2016-03-01
entry	1..*	SHALL		CMS_0051	
entry	1..*	SHALL		2228-14430_C01	
observation	1..1	SHALL		2228-14431	Patient Characteristic Payer (identifier: urn:oid:2.16.840.1.113883.10.20.24.3.55

1. Conforms to Patient Data Section QDM (V3) template `(identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.2.1:2016-02-01).`
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=`**`"2016-03-01"` (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:2228-14430_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:2228-14431).

Figure 12: Patient Data Section QDM (V3) – CMS Example

```
<section>
    <!-- Patient Data Section -->
    <templateId root="2.16.840.1.113883.10.20.17.2.4" />
    <!-- Patient Data Section QDM (V3) -->
    <templateId root="2.16.840.1.113883.10.20.24.2.1"
      extension="2016-02-01" />
    <!-- Patient Data Section QDM (V3) - CMS-->
    <templateId root="2.16.840.1.113883.10.20.24.2.1.1"
      extension="2016-03-01" />
    <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"
              extension="2014-12-01" />
            <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="20170303" />
            </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, Order not done: Medical Reason", 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, R3.1 Implementation Guide*. To summarize, the following steps shall be followed:

- Set the containing act attribute negataionInd=”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 administered not done, patient refusal: Drug declined
by patient - reason unknown. No "Antibiotic Medications for
Pharyngitis" 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="2.16.840.1.113883.3.464.1003.196.12.1001">
            <originalText> None of value set: Antibiotic Medications
              for Pharyngitis</originalText>
          </code>
        </manufacturedMaterial>
      </manufacturedProduct>
    ...
    </substanceAdministration>
  </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 Validation Rules for CDAC Users

The following validation checks are made specifically for the Clinical Data Abstraction Center (CDAC) users.

i. The system SHALL reject QRDA-I files submitted by CDAC users when the CMS Program Name within the file is not CDAC_HQR_EHR (CONF: CMS_0064).

ii. The system SHALL reject QRDA-I files submitted by CDAC users when the QRDA is not submitted as a test file (CONF: CMS_0065).

iii. The system SHALL reject QRDA-I files submitted by non-CDAC users when the CMS Program Name within the file is CDAC_HQR_EHR (CONF: CMS_0080).

5.3.3 Other HQR Validations

Table 13: Other Validation Rules for HQR Programs

CONF. #	Validation Performed	Cause 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. Get this message if CCN is Null.
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).
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. Get this message if the upload date is outside the acceptable range(s), which for the 2017 Reporting Period is yet to be finalized.
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. Processing stops immediately on file.
CMS_0072	QRDA file does not pass XML schema validation (CDA_SDTC.xsd).	QRDA structure does not pass CDA_SDTC.XSD schema check. Processing continues on file to identify other Errors/Warnings.

CONF. #	Validation Performed	Cause of Error Message and File Rejection
CMS_0073	The document does not conform to QRDA document formats accepted by CMS	Document is not in QRDA Category 1 DSTU Release 3.1 format -- does not contain all four of the required header templateIds including both of the R3.1 templateIds and extensions: HL7 R3.1: <templateId root="2.16.840.1.113883.10.20.24.1.2" extension="2016-02-01"/> 2016 CMS QRDA IG: <templateId root="2.16.840.1.113883.10.20.24.1.3" extension="2016-03-01"/> This error is also produced for empty file or other non-XML file type (e.g., PDF). Processing stops immediately on file.
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 April 2016 version of the electronic specifications for the EH eCQMs will be accepted for the 2017 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_0078	QRDA file size exceeds (5) MB.	The maximum single QRDA-I file size accepted is 5MB, as determined by the receiving system.
CMS_0079	Reporting Period Effective Date Range does not match one of the Program's CY Discharge Quarters.	The Reporting Parameter Section effective date range must exactly match one of the HQR allowable calendar year discharge quarters.

5.3.4 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, 20160130113045+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 2016 or 201603 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, 20160930 is valid.
NA	Leap year calculation is validated.	For example, 20160229 is invalid because 2016 is not a leap year.

Attribute	Date and Time Format Validation Rules	Examples
NA	The UTC time shift range is -1300 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.

5.3.5 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"][@templateId="2.16.840.1.113883.10.20.17.2.1"|@extension="2015-07-01"]/entry/act/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"][@templateId="2.16.840.1.113883.10.20.17.2.1"|@extension="2015-07-01"]/entry/act/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:

- **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 the Office of the National Coordinator (ONC) for Health Information Technology for implementers to submit issues and request guidance on eCQM logic, specifications, and certification: https://www.healthit.gov/policy-researchers-implementers/certified-health-it-product-list-chpl
- **eCQI Resource Center** is the one-stop shop for the most current resources to support electronic clinical quality improvement: https://ecqi.healthit.gov/

6.2 Support

Table 16: Support Contact Information

Contact	Org.	Phone	Email	Role	Responsibility
CMS IT Service Desk	CMS	(410) 786-2580 (800) 562-1963	CMS_IT_Service_Desk@cms.hhs.gov	Help desk support	1st 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, DSTU Release 3.1 Comments page	HL7	http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=186	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

<table>
<tr><th>Data Type</th><th>CONF.#</th><th>Rules</th></tr>
<tr><td>Boolean (BL)</td><td>CMS_0105</td><td>Data types of BL SHALL have either @value or @nullFlavor but SHALL NOT have both @value and @nullFlavor (CONF:CMS_0105).</td></tr>
<tr><td>Coded Simple (CS)</td><td>CMS_0106</td><td>Data types of CS SHALL have either @code or @nullFlavor but SHALL NOT have both @code and @nullFlavor (CONF:CMS_0106).</td></tr>
<tr><td>Coded Descriptor (CD)</td><td rowspan="2">CMS_0107</td><td rowspan="2">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).</td></tr>
<tr><td>Coded With Equivalents (CE)</td></tr>
<tr><td>Instance Identifier (II)</td><td>CMS_0108</td><td>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).</td></tr>
<tr><td>Integer Number (INT)</td><td>CMS_0109</td><td>Data types of INT SHALL NOT have both @value and @nullFlavor (CONF:CMS_0109).</td></tr>
<tr><td>Physical Quantity (PQ)</td><td>CMS_0110</td><td>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).</td></tr>
<tr><td>Real Number (REAL)</td><td>CMS_0111</td><td>Data types of REAL SHALL NOT have both @value and @nullFlavor (CONF:CMS_0111).</td></tr>
<tr><td>String (ST)</td><td>CMS_0112</td><td>Data types of ST SHALL either not be empty or have @nullFlavor (CONF:CMS_0112).</td></tr>
<tr><td>Point in Time (TS)</td><td>CMS_0113</td><td>Data types of TS SHALL have either @value or @nullFlavor but SHALL NOT have @value and @nullFlavor (CONF:CMS_0113).</td></tr>
<tr><td>Universal Resource Locator (URL)</td><td>CMS_0114</td><td>Data types of URL SHALL have either @value or @nullFlavor but SHALL NOT have both @value and @nullFlavor (CONF:CMS_0114).</td></tr>
</table>

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 DSTU R3.1 Base Standard

This table lists all changes made to the base HL7 QRDA-I R3.1 contained in this 2017 guide. The "Base Standard" is the *HL7 Implementation Guide for CDA Release 2: Quality Report Document Architecture, Category I, DSTU Release 3.1,* (published April, 2016).

Table 21: Changes Made to the QRDA-I DSTU R3.1 Base Standard

CONF. #	Section	Base Standard	Changed To
CMS_0001	5.1.1	n/a	Conforms to QDM-Based QRDA (V3) template (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.1.2:2016-02-01). SHALL contain exactly one [1..1] templateId (CONF:CMS_0001) such that it
CMS_0002 CMS_0003	5.1.1	n/a	SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.24.1.3" (CONF:CMS_0002). SHALL contain exactly one [1..1] @extension="2016-03-01" (CONF:CMS_0003).
CMS_0010	5.1.1	n/a	This languageCode SHALL contain exactly one [1..1] @code="en" (CONF:CMS_0010).
CMS_0009 CMS_0053 CMS_0103	5.1.2	n/a	This patientRole SHALL contain exactly one [1..1] id (CONF:CMS_0009) such that it SHALL contain exactly one [1..1] @root (CONF:CMS_0053). Note: This is the provider's organization OID or other non-null value different than the OID for the Medicare HIC Number (2.16.840.1.113883.4.572). 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.

CONF. #	Section	Base Standard	Changed To
1098_5284_C01	5.1.2	This patient SHALL contain at least one [1..*] US Realm Person Name (PN.US.FIELDED) (identifier: urn:oid:2.16.840.1.113883.10.20.22.5.1.1) (CONF:1198-5284).	This patient SHALL contain exactly one [1..1] US Realm Person Name (PN.US.FIELDED) (identifier: urn:oid:2.16.840.1.113883.10.20.22.5.1.1) (CONF:1198-5284_C01).
CMS_0011 CMS_0029	5.1.2	This patient SHALL contain exactly one [1..1] administrativeGenderCode, which SHALL be selected from ValueSet Administrative Gender (HL7 V3) urn:oid:2.16.840.1.113883.1.11.1 DYNAMIC (CONF:1198-6394).	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). If the patient's administrative sex is unknown, nullFlavor="UNK" SHALL be submitted (CONF:CMS_0029).
1198_5300_C01	5.1.2	This patient SHALL contain exactly one [1..1] birthTime (CONF:1140-27571). SHOULD be precise to day (CONF:1198-5300).	This patient SHALL contain exactly one [1..1] birthTime (CONF:1140-27571). SHALL be precise to day (CONF:1198-5300_C01).
CMS_0013 CMS_0030 CMS_0031	5.1.2	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).	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). If the patient's race is unknown, nullFlavor="UNK" SHALL be submitted (CONF:CMS_0030). If the patient declined to specify his/her race, nullFlavor="ASKU" SHALL be submitted (CONF:CMS_0031).
CMS_0014	5.1.2	This patient MAY contain zero or more [0..*] sdtc:raceCode, 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..*] 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.

CONF. #	Section	Base Standard	Changed To
CMS_0032 CMS_0033	5.1.2	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).	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). If the patient's ethnicity is unknown, nullFlavor="UNK" SHALL be submitted (CONF:CMS_0032). If the patient declined to specify his/her ethnicity, nullFlavor="ASKU" SHALL be submitted (CONF:CMS_0033).
2228-28241_C01	5.1.3	This representedCustodianOrganization SHOULD contain zero or one [0..1] id (CONF:2228-28241) such that it	This representedCustodianOrganization SHALL contain exactly one [1..1] id (CONF:2228-28241_C01) such that it
CMS_0035	5.1.3	n/a	CCN SHALL be six to ten characters in length (CONF:CMS_0035).
2228_16703_C01	5.1.4	MAY contain zero or more [0..*] informationRecipient (CONF:2228-16703).	SHALL contain exactly one [1..1] informationRecipient (CONF:2228-16703_C01).
2228_16705_C01 CMS_0025 CMS_0026	5.1.4	This intendedRecipient SHALL contain at least one [1..*] id (CONF:2228-16705).	This intendedRecipient SHALL contain exactly one [1..1] id (CONF:2228-16705_C01). 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 2016-03-01 (CONF:CMS_0026). Note: The value of @extension is CMS Program Name.
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).

CONF. #	Section	Base Standard	Changed To
CMS_0004 CMS_0005 CMS_0006 CMS_0008	5.1.5		The participant, if present, SHALL contain exactly one [1..1] associatedEntity (CONF:CMS_0004). This associatedEntity SHALL contain exactly one [1..1] id (CONF:CMS_0005) such that it 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.
2228-16579_C01	5.1.6	MAY contain zero or one [0..1] documentationOf (CONF:2228-16579) such that it	SHALL contain exactly one [1..1] documentationOf (CONF:2228-16579_C01) such that it
CMS_0019 CMS_0020	5.1.6	n/a	This assignedEntity MAY contain zero or one [0..1] assignedPerson (CONF:CMS_0019). The assignedPerson, if present, MAY contain zero or one [0..1] name (CONF:CMS_0020). Note: This is the provider's name.
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
CMS_0040 CMS_0041 CMS_0042 CMS_0023 CMS_0024	5.2.2	n/a	Conforms to Reporting Parameters Section template (identifier: urn:oid:2.16.840.1.113883.10.20.17.2.1). SHALL contain exactly one [1..1] templateId (CONF:CMS_0040) such that it SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.17.2.1" (CONF:CMS_0041). SHALL contain exactly one [1..1] @extension="2015-07-01" (CONF:CMS_0042). SHALL contain exactly one [1..1] entry (CONF:CMS_0023) such that it 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).
CMS_0044 CMS_0045 CMS_0046	5.2.2.1	n/a	Conforms to Reporting Parameters Act template (identifier: urn:oid:2.16.840.1.113883.10.20.17.3.8). SHALL contain exactly one [1..1] templateId (CONF:CMS_0044) such that it SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.17.3.8" (CONF:CMS_0045). SHALL contain exactly one [1..1] @extension="2015-07-01" (CONF:CMS_0046).

CONF. #	Section	Base Standard	Changed To
CMS_0048 CMS_0027 CMS_0050 CMS_0028	5.2.2.1	SHALL contain exactly one [1..1] effectiveTime (CONF:23-3273). This effectiveTime SHALL contain exactly one [1..1] low (CONF:23-3274). This effectiveTime SHALL contain exactly one [1..1] high (CONF:23-3275).	SHALL contain exactly one [1..1] effectiveTime (CONF:23-3273). This effectiveTime SHALL contain exactly one [1..1] low (CONF:23-3274). This low SHALL contain exactly one [1..1] @value (CONF:CMS_0048). SHALL be precise to day (CONF:CMS_0027) This effectiveTime SHALL contain exactly one [1..1] high (CONF:23-3275). This high SHALL contain exactly one [1..1] @value (CONF:CMS_0050). SHALL be precise to day (CONF:CMS_0028)
CMS_0036 CMS_0037 CMS_0038	5.2.3	n/a	Conforms to Patient Data Section QDM (V3) template (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.2.1:2016-02-01). SHALL contain exactly one [1..1] templateId (CONF:CMS_0036) such that it SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.24.2.1" (CONF:CMS_0037). SHALL contain exactly one [1..1] @extension="2016-03-01" (CONF:CMS_0038).
CMS_0051 CMS_0039	5.2.3	n/a	SHALL contain at least one [1..*] entry (CONF:CMS_0051) such that it 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).
2228-14430_C01	5.2.3	MAY contain zero or more [0..*] entry (CONF:2228-14430) such that it	SHALL contain at least one [1..*] entry (CONF:2228-14430_C01) such that it SHALL contain at least one [1..*] Patient Characteristic Payer (identifier: urn:oid:2.16.840.1.113883.10.20.24.3.55) (CONF:2228_14431).

10 Change Log for 2017 CMS QRDA Implementation Guide from the 2016 CMS QRDA Implementation Guide

This appendix summarizes the changes made in this 2017 CMS QRDA Implementation Guide since the release of 2016 CMS QRDA Implementation Guide (July 8, 2015) and the 2016 CMS QRDA IG Appendix (February 26, 2016).

The table below lists the changes made for the QRDA-I DSTU R3.1 Implementation Guide for Hospital Quality Reporting of the 2017 CMS QRDA IG from the QRDA-I DSTU R3 CMS Implementation Guide for Hospital Quality Reporting of the 2016 CMS QRDA IG (and the 2016 CMS QRDA IG Appendix).

Table 22: Changes Made for 2017 CMS QRDA IG from 2016 CMS QRDA IG

	2017 CMS QRDA IG	2016 CMS QRDA IG
Base Standard	HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture Category I, Release 1, Draft Standard for Trial Use (DSTU) Release 3.1, US Realm, 2016 (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, Draft Standard for Trial Use (DSTU) Release 3, US Realm, June 2015
4 QRDA Category I Requirements	Language is updated to reflect the requirement updates for the 2017 reporting year.	n/a
5.1.1 General Header	QRDA Category I Report – CMS HQR (V3) (Note: this template is based on QRDA-I, DSTU R3.1)	QRDA Category I Report – CMS EP & HQR (V2) (Note: this template is based on QRDA-I, DSTU R3)
5.1.3 Custodian	Updated to remove: [HQR] SHALL NOT contain [0..0] @ nullFlavor (CONF:CMS_0034). (Because CONF:2228-28244 and 2228-28245 require the presence of both @root and @extension, hence @nullFlavor is not allowed.)	[HQR] SHALL NOT contain [0..0] @ nullFlavor (CONF:CMS_0034).

	2017 CMS QRDA IG	2016 CMS QRDA IG
5.1.4 informationRecipient	This intendedRecipient SHALL contain exactly one [1..1] id (CONF:2228-16705_C01). 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 2016-03-01 (CONF:CMS_0026).	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.
5.1.5 Participant (CMS Certification Identification Number)	(New section 5.1.5 Participant) SHALL contain exactly one [1..1] participant (CONF:1198-10003_C01). CMS EHR Certification Identification Number is required for HQR. This participant SHALL contain exactly one [1..1] associatedEntity (CONF:CMS_0004). This associatedEntity SHALL contain exactly one [1..1] id (CONF:CMS_0005). 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). This id SHALL contain exactly one [1..1] @extension (CONF:CMS_0008). Note: The value of @extension is the Certification Number.	(5.1.1 General Header) MAY contain zero or more [0..*] participant (CONF:1098-10003). CMS EHR Certification Number is optional. If it is submitted, it SHALL conform to the constraints specified for the CMS EHR Certification Number. The participant, if present, SHALL contain exactly one [1..1] associatedEntity (CONF:CMS_0004). 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.

	2017 CMS QRDA IG	2016 CMS QRDA IG
5.1.6 documentationOf/serviceEvent	This assignedEntity SHOULD contain zero or one [0..1] **id** (CONF:2228-16587) such that it SHALL contain exactly one [1..1] @root="2.16.840.1.113883.4.6" National Provider ID (CONF:2228-16588).	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).
5.1.6 documentationOf/serviceEvent	This assignedEntity SHALL contain exactly one [1..1] representedOrganization (CONF:2228-16591).	This assignedEntity SHALL contain exactly one [1..1] representedOrganization (CONF:1140-16591_C01).
5.1.6 documentationOf/serviceEvent	This representedOrganization SHOULD contain zero or one [0..1] id (CONF:2228-16592). The id, if present, SHALL contain exactly one [1..1] @root="2.16.840.1.113883.4.2" Tax ID Number (CONF:2228-16593).	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).
5.3 HQR Validations	New section added to list additional HQR validations contained in the 2016 CMS QRDA IG and 2016 CMS QRDA IG Appendix, and are updated for the 2017 reporting period.	Appendix 10. Additional QRDA-I Validation Rules for HQR Programs 2016 CMS QRDA IG Appendix 5.2.5 HQR Validation Rules Updates 5.2.6 Date and Time Validation
Appendix 7 Null Flavor Validation Rules for Data Types	Updated with CMS conformance number assigned to each rule.	Appendix 11 Null Flavor Validation Rules for Data Types
Appendix 8 NPI and TIN Validation Rules	New section added to list conformance statements for NPI and TIN validations.	n/a

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
DSTU	Draft 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 Measures Format
HQR	Hospital Quality Reporting
ID	identifier
IHTSDO	International Health Terminology Standard Development Organization
IP	initial population
LOINC	Logical Observation Identifiers Names and Codes
n/a	not applicable
NA	Not applicable
NLM	National Library of Medicine
NPI	National Provider Identification Number
OID	Oject Identifier
ONC	Office of the National Coordinator for Health Information Technology
PHDSC	Public Health Data Standards Consortium

Acronym	Literal Translation
QDM	Quality Data Model
QRDA	Quality Reporting Data Architecture
QRDA-I	Quality Reporting Data Architecture Category I
SNOMED CT	Systematized Nomenclature of Medicine, Clinical Terms
TIN	Taxpayer 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.
eMeasure	A standardized performance measure in the Health Quality Measures 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

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

HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture, Category I, Release 1, Draft Standard for Trial Use Release 3.1 (QRDA-I R3.1). March 2016. http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35

ONC, Electronic Clinical Quality Measure issue reporting system. https://www.healthit.gov/policy-researchers-implementers/certified-health-it-product-list-chpl

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