Centers for Medicare & Medicaid Services

CMS Implementation Guide for Quality Reporting Document Architecture Category I

Hospital Quality Reporting

Implementation Guide for 2020

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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 5.1, US Realm*, December 2018[1] for the 2020 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 R5 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

[1] HL7 QRDA I R1 STU R5.1. http://www.hl7.org/documentcenter/public/standards/dstu/CDAR2_IG_QRDA_I_R1_STU5.1_2018DEC.zip

Guide, a change log for the 2020 CMS QRDA IG for HQR programs from the 2019 CMS QRDA IG, and validation rules for data types, National Provider Identifier (NPI), and Tax Identification Number (TIN).

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

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 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

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. 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 R5.1 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, STU Release 5.1* (published December 2018), referred to as the HL7 QRDA I STU R5.1 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 2020 Reporting Period.

The purpose of this guide is to serve as a companion to the base HL7 QRDA I STU R5.1 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 2020 reporting period must meet the conformance statements specified in this guide in addition to the conformance statements specified in the HL7 QRDA I STU R5.1. 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 R5.1 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 R5.1 standard is further constrained in this guide.

[2] CDA_SDTC.xsd is available as part of the HL7 QRDA I STU R5.1 standard package (http://www.hl7.org/documentcenter/public/standards/dstu/CDAR2_IG_QRDA_I_R1_STU5.1_2018DEC.zip).

2. The original **SHALL**/**SHOULD**/**MAY** keywords along with conformance numbers from the HL7 QRDA I STU R5.1 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

The HL7 QRDA I STU R5.1 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 Hospital Quality Reporting May 2019[3], and any applicable addenda, must be used for the HQR programs for the 2020 Reporting Period.

The eCQM Value Sets for Eligible Hospitals May 2019[4], and any applicable addenda, published at the Value Set Authority Center (VSAC) must be used for the HQR programs for the 2020 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 five key elements identifying the file: CCN, CMS Program Name, EHR Patient ID, EHR Submitter ID[5], 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 five key identifiers are incorrect, the HQR system provides the user with the capability to delete a previously submitted file.

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[3] eCQI Resource Center, Eligible Hospital/Critical Access Hospital eCQMs web page. https://ecqi.healthit.gov/eligible-hospital/critical-access-hospital-ecqms. Select 2020 Reporting Period.
[4] Value Set Authority Center, VSAC Downloadable Resources web page. https://vsac.nlm.nih.gov/download/ecqm. Select 2020 Reporting/Performance Period eCQM Value Sets.
[5] The EHR Submitter ID is the ID that is assigned by QualityNet to submitter entities upon registering into the system and will be used to upload QRDA I files. It is not submitted as an element in the QRDA I report. For vendors, the EHR Submitter ID is the Vendor ID; for hospitals, the EHR Submitter ID is the hospital's CCN.

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) that is updated for the 2020 reporting period.

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, 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 value set "Intravenous route" (2.16.840.1.113883.3.117.1.7.1.222). In this case, the "Intravenous route" (2.16.840.1.113883.3.117.1.7.1.222) value set 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[@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

- The time zone validation rule is not performed on `birthTime/@value`

Figure 4: Time Zone Example

```
<!-- This is an example when timezone offset is provided -->
<encounter>
  <text>Encounter Performed: Hospital Measures-Encounter
    Inpatient</text>
  ...
  <effectiveTime>
    <!-- Attribute: admission datetime -->
    <low value="202003250930-0500"/>
    <!-- Attribute: discharge datetime -->
    <high value="202003291052-0500"/>
  </effectiveTime>
  ...
</encounter>
```

4.6 Submit eCQM Version Specific Measure Identifier ONLY

For the 2020 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 HL7 QRDA and Health Quality Measure Format (HQMF) 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 R1 Normative, however, is derived from HL7 RIM, Version 2.44, where *versionNumber* is specified as ST data type. The version numbers for eCQM Specifications for Hospital Quality Reporting for the 2020 reporting period generated by the Measure Authoring Tool (MAT) are string values such as 8.2.000 instead of integers such as 8. If a version number such as 8.2.000 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 HI7 QRDA I STU R5.1 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 R5.1. For example, in QRDA I STU R5.1, the previous `Procedure Performed (V4)` template is now `Procedure Performed (V5)`, its template identifier is

"`2.16.840.1.113883.10.20.24.3.64:2018-10-01`". Both the `@root` and `@extension` are required as specified in the IG.

SHALL contain exactly one [1..1] **`templateId`** (CONF:4388-11262) such that it

a. **SHALL** contain exactly one [1..1] **`@root`**="2.16.840.1.113883.10.20.24.3.64" (CONF:4388-11263).
b. **SHALL** contain exactly one [1..1] **`@extension`**="2018-10-01" (CONF:4388-27129).

Correct template versions that are specified by both the base HL7 QRDA I STU R5.1 and the 2020 CMS IG must be used for 2020 CMS QRDA I submissions. For instance, if a QRDA I file used `Procedure Performed (V4)` instead of `Procedure Performed (V5)`, this older version of the template will be ignored by the CMS receiving system. Data submitted using template versions that are not specifically required by the base HL7 QRDA I STU R5.1 and the 2020 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 R5.1 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 (V6) Constraints Overview
ClinicalDocument (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.1.3:2019-02-01)

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	2019-02-01
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

1. Conforms to `QDM-Based QRDA (V6)` template `(identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.1.2:2018-10-01)`.
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`**`="2019-02-01"` (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).

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 (V4) -->
    <templateId root="2.16.840.1.113883.10.20.24.1.1" extension="2017-
08-01"/>
    <!-- QDM-based QRDA (V6) -->
    <templateId root="2.16.840.1.113883.10.20.24.1.2" extension="2018-
10-01"/>
    <!-- QRDA Category I Report - CMS (V6) -->
    <templateId root="2.16.840.1.113883.10.20.24.1.3" extension="2019-
02-01"/>
    <!-- This is the globally unique identifier for this QRDA I
document -->
    <id root="fcae78c4-a122-4bfb-9aad-a9e7f33324d5"/>
    <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="20210201"/>
    <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:2.16.840.1.113883.10.20.24.1.3:2019-02-01)

XPath	Card.	Verb	Data Type	CONF. #	Value
recordTarget	1..1	SHALL		4388-16598	
patientRole	1..1	SHALL		4388-16856	
id	0..1	SHOULD		4388-16857_C01	
@root	1..1	SHALL		4388-16858	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	SHOULD		4388-28697_C01	

XPath	Card.	Verb	Data Type	CONF. #	Value
@root	1..1	SHALL		4388-28698	2.16.840.1.113883.4.927
addr	1..*	SHALL		1198-5271	US Realm Address (AD.US.FIELDED) (identifier: urn:oid:2.16.840.1.113883.10.20.22.5.2
patient	1..1	SHALL		4388-27570	
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 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:4388-16598).
    a. This recordTarget **SHALL** contain exactly one [1..1] **`patientRole`** (CONF:4388-16856).

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:4388-16857_C01) such that it
    1. **SHALL** contain exactly one [1..1] **`@root`**`="2.16.840.1.113883.4.572"` Medicare HIC number (CONF:4388-16858).

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) 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.

HQR: 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 **SHOULD** contain zero or one [0..1] **`id`** (CONF:4388-28697_C01) such that it
   1. **SHALL** contain exactly one [1..1] **`@root="`**`2.16.840.1.113883.4.927`**"** Medicare Beneficiary Identifier (MBI) (CONF:4388-28698).

iv. 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).

v. This patientRole **SHALL** contain exactly one [1..1] **`patient`** (CONF:4388-27570).
   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 (V6)

```
<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:2.16.840.1.113883.10.20.24.1.3:2019-02-01)

XPath	Card.	Verb	Data Type	CONF. #	Value
custodian	1..1	SHALL		4388-16600	
assignedCustodian	1..1	SHALL		4388-28239	
representedCustodianOrganization	1..1	SHALL		4388-28240	
id	1..1	SHALL		4388-28241_C01	
@root	1..1	SHALL		4388-28244	2.16.840.1.113883.4.336
@extension	1..1	SHALL		4388-28245 CMS_0035	

1. **SHALL** contain exactly one [1..1] **`custodian`** (CONF:4388-16600).
    a. This custodian **SHALL** contain exactly one [1..1] **`assignedCustodian`** (CONF:4388-28239).
        i. This assignedCustodian **SHALL** contain exactly one [1..1] **`representedCustodianOrganization`** (CONF:4388-28240).

HQR: 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. This representedCustodianOrganization **SHALL** contain exactly one [1..1] **`id`** (CONF:4388-28241_C01) such that it
    a. **SHALL** contain exactly one [1..1] **`@root="`**`2.16.840.1.113883.4.336`**`"`** CMS Certification Number (CONF:4388-28244).
    b. **SHALL** contain exactly one [1..1] **`@extension`** (CONF:4388-28245).
    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 (V6)

```
<!-- 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:2.16.840.1.113883.10.20.24.1.3:2019-02-01)

XPath	Card.	Verb	Data Type	CONF. #	Value
informationRecipient	1..1	SHALL		4388-16703_C01	
intendedRecipient	1..1	SHALL		4388-16704	
id	1..1	SHALL		4388-16705_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:4388-16703_C01).
    a. This informationRecipient **SHALL** contain exactly one [1..1] **`intendedRecipient`** (CONF:4388-16704).
        i. This intendedRecipient **SHALL** contain exactly one [1..1] **`id`** (CONF:4388-16705_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** 2019-02-01 (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_PI	CMS Program	urn:oid:2.16.840.1.113883.3.249.7	Hospital Quality Reporting for the Promoting Interoperability 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_PI_IQR	CMS Program	urn:oid:2.16.840.1.113883.3.249.7	Hospital Quality Reporting for the Promoting Interoperability Program and the Inpatient Quality Reporting 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

Figure 8: informationRecipient Example, QRDA Category I Report - CMS (V6)

```
<!-- This example shows the @extension attribute with a value of
"HQR_PI", which indicates that this QRDA I report is submitted to the
Hospital Quality Reporting for the Promoting Interoperability Program
-->

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

5.1.5 Participant (CMS EHR Certification ID)

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 ID 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[6].

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:2.16.840.1.113883.10.20.24.1.3:2019-02-01)

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).

HQR: 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 ID (CONF:CMS_0006).
         2. This id **SHALL** contain exactly one [1..1] **`@extension`** (CONF:CMS_0008).
            Note: The value of @extension is the CMS EHR Certification ID.

[6]Certified Health IT Product List. https://chpl.healthit.gov/

5.1.6 documentationOf/serviceEvent

Table 8: documentationOf/serviceEvent Constraints Overview
ClinicalDocument (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.1.3:2019-02-01)

XPath	Card.	Verb	Data Type	CONF. #	Value
documentationOf	0..1	MAY		4388-16579	
serviceEvent	1..1	SHALL		4388-16580	
performer	1..*	SHALL		4388-16583	
@typeCode	1..1	SHALL		4388-16584	PRF
assignedEntity	1..1	SHALL		4388-16586	
id	0..1	SHOULD		4388-16587	
@root	1..1	SHALL		4388-28497	2.16.840.1.113883.4.6
assignedPerson	0..1	MAY		CMS_0019	
name	0..1	MAY		CMS_0020	
representedOrganization	1..1	SHALL		4388-16591	
id	0..1	SHOULD		4388-16592	
@root	1..1	SHALL		4388-16593	2.16.840.1.113883.4.2
name	0..1	MAY		CMS_0022	

1. **MAY** contain zero or one [0..1] **`documentationOf`** (CONF:4388-16579) such that it
    a. **SHALL** contain exactly one [1..1] **`serviceEvent`** (CONF:4388-16580).
        i. This serviceEvent **SHALL** contain at least one [1..*] **`performer`** (CONF:4388-16583).
            1. Such performers **SHALL** contain exactly one [1..1] **`@typeCode="`**`PRF`**`"` Performer (CONF:4388-16584).
            2. Such performers **SHALL** contain exactly one [1..1] **`assignedEntity`** (CONF:4388-16586).

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.

a. This assignedEntity **SHOULD** contain zero or one [0..1] **`id`** (CONF:4388-16587) such that it
    i. **SHALL** contain exactly one [1..1] **`@root="`**`2.16.840.1.113883.4.6`**`"` National Provider ID (CONF:4388-28497).

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:4388-16591).

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 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:4388-16592).

1. The id, if present, **SHALL** contain exactly one [1..1] **`@root="`**`2.16.840.1.113883.4.2`**`"`** Tax ID Number (CONF:4388-16593).

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

```
<informationRecipient>
  <!-- CMS Program Name is "HQR_PI" -->
  <intendedRecipient>
    <id root="2.16.840.1.113883.3.249.7" extension="HQR_PI"/>
  </intendedRecipient>
</informationRecipient>
...
<documentationOf>
  <serviceEvent classCode="PCPR">
    ...
    <performer typeCode="PRF">
       <assignedEntity>
        <representedOrganization/>
      </assignedEntity>
    </performer>
  </serviceEvent>
</documentationOf>
```

5.1.7 component

Table 9: component Constraints Overview
ClinicalDocument (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.1.3:2019-02-01)

XPath	Card.	Verb	Data Type	CONF. #	Value
component	1..1	SHALL		4388-12973	
structuredBody	1..1	SHALL		4388-17081	
component	1..1	SHALL		4388-17090	

section	1..1	SHALL		CMS_0054	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		4388-17091	
section	1..1	SHALL		CMS_0055	Patient Data Section QDM (V6) - CMS (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.2.1.1:2019-02-01
component	1..1	SHALL		4388-17082	
section	1..1	SHALL		4388-17083	Measure Section QDM (identifier: urn:oid:2.16.840.1.113883.10.20.24.2.3

1. **SHALL** contain exactly one [1..1] **`component`** (CONF:4388-12973).
    a. This component **SHALL** contain exactly one [1..1] **`structuredBody`** (CONF:4388-17081).
        i. This structuredBody **SHALL** contain exactly one [1..1] **`component`** (CONF:CMS_0056) 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:CMS_0054).
        ii. This structuredBody **SHALL** contain exactly one [1..1] **`component`** (CONF:CMS_0057) such that it
            1. **SHALL** contain exactly one [1..1] **`Patient Data Section QDM (V6) - CMS`** `(identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.2.1.1:2019-02-01)` (CONF:CMS_0055).
        iii. This structuredBody **SHALL** contain exactly one [1..1] **`component`** (CONF:4388-17082) 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:4388-17083).

5.2 Section-Level Templates

5.2.1 Measure Section

This section contains information about the eCQM(s) 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 R5.1 standard for the full specification of Measure Section.

Table 10: 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 eCQM.
            2. **SHALL** contain exactly one [1..1] **`@extension`** (CONF:67-12813). Note: This @extension SHALL equal the version specific identifier for eCQM (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
    eCQM -->
```

```
  <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 eCQM version specific identifier -->
          <id root="2.16.840.1.113883.4.738"
              extension="40280382-68d3-a5fe-0169-35d2594e28b6"/>
        </externalDocument>
      </reference>
    </organizer>
  </entry>
  <entry>
    <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 11: 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 12: 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 2020 - 31 March 2020
    </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="20200101"/>
           <high value="20200331"/>
         </effectiveTime>
     </act>
  </entry>
</section>
```

5.2.3 Patient Data Section QDM (V6) - CMS

The Patient Data Section QDM (V6) - 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 (V6) - 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 R5.1 standard.

Table 13: Patient Data Section QDM (V6) – CMS Constraints Overview
section (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.2.1.1:2019-02-01)

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	2019-02-01
entry	1..*	SHALL		CMS_0051 CMS_0039	

XPath	Card.	Verb	Data Type	CONF. #	Value
entry	1..*	SHALL		4388-14430_C01	
observation	1..1	SHALL		4388-14431	Patient Characteristic Payer (identifier: urn:oid:2.16.840.1.113883.10.20.24.3.55

1. Conforms to `Patient Data Section QDM (V6)` template `(identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.2.1:2018-10-01)`.
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="`**`2019-02-01`**`"` (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:4388-14430_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:4388-14431).

Figure 12: Patient Data Section QDM (V6) – CMS Example

```
<section>
    <!-- Patient Data Section -->
    <templateId root="2.16.840.1.113883.10.20.17.2.4" />
    <!-- Patient Data Section QDM (V6) -->
    <templateId root="2.16.840.1.113883.10.20.24.2.1"
      extension="2018-10-01" />
    <!-- Patient Data Section QDM (V6) - CMS-->
    <templateId root="2.16.840.1.113883.10.20.24.2.1.1"
      extension="2019-02-01" />
    <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="a83777f2-0753-4638-9bb4-9d0d4a559a52"/>
            <code code="48768-6" codeSystem="2.16.840.1.113883.6.1"
              codeSystemName="LOINC" displayName="Payment source"/>
            <statusCode code="completed" />
            <effectiveTime>
                <low value="20200101"/>
                <high value="20201231"/>
            </effectiveTime>
            <value xsi:type="CD" code="1"
              codeSystem="2.16.840.1.113883.3.221.5"
              codeSystemName="Source of Payment Typology"
              displayName="Medicare"/>

        </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 Not Administered" with negation rationale attribute indicating it is due to patient reason, an **`entryRelationship`** to a Reason (V3) (templateId: `2.16.840.1.113883.10.20.24.3.88:2017-08-01`") 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, STU R5.1 Implementation Guide, Volume 1. To summarize, the following steps should be followed:

- Set the attribute `negataionInd`="true"
- Use `code/[@nullFlavor="NA"]`
    - If a value set is provided, specified code and code system will be ignored
- If QDM element in eCQM specification is defined using value set:
    - 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]"`
- If QDM element in eCQM specification is defined using direct referenced code:
  - Set code attribute code=`"[The Direct Referenced Code]"`

Figure 13: Not Done Example for QDM Element Defined with Value Set

```
<!--Medication not administered, patient refusal: Drug declined by
patient - reason unknown. No "Low Dose Unfractionated Heparin for VTE
Prophylaxis" were administered -->
<substanceAdministration classCode="SBADM" moodCode="EVN"
negationInd="true">
  <templateId root="2.16.840.1.113883.10.20.22.4.16" extension="2014-
06-09" />
  <templateId root="2.16.840.1.113883.10.20.24.3.42" extension="2017-
08-01" />
  <id root="48cb49dc-2bf7-43e9-9824-8538665158f8" />
  <statusCode code="completed" />
  ...
  <consumable>
    <manufacturedProduct classCode=”MANU”>
    <templateId root=”2.16.840.1.113883.10.20.22.4.23"
extension="2014-06-09" />
    <id root=”9a985c44-ced7-4323-a6ec-e2937563a6b6”/>
      <manufacturedMaterial>
        <code nullFlavor=”NA”
sdtc:valueSet=”2.16.840.1.113883.3.464.1003.196.12.1001”>
         <originalText>
            None of the value set: Antibiotic Medications for
Pharyngitis
         </originalText>
        </code>
      </manufacturedMateiral>
    </manufacturedProduct>
  </consumable>
  <entryRelationship typeCode=”RSON”>
     <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.24.3.88"
        extension="2017-08-01" />
      <code code="77301-0"
        codeSystem="2.16.840.1.113883.6.1"
        displayName="Reason care action performed or not"
        codeSystemName="LOINC" />
      <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"/>
    </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 14: Other Validation Rules for HQR Programs

CONF. #	Validation Performed	Description of Error Message and File Rejection
CMS_0066	CCN (NULL) cannot be validated.	CCN 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 2020 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. 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.
CMS_0073	The document does not conform to QRDA document formats accepted by CMS	Document is not in QRDA Category I STU Release 5.1 format -- does not contain all four of the required header templateIds including both of the R5 templateIds and

CONF. #	Validation Performed	Description of Error Message and File Rejection
		extensions: HL7 R5.1: <templateId root="2.16.840.1.113883.10.20.24.1.2" extension="2018-10-01"/> 2020 CMS QRDA IG: <templateId root="2.16.840.1.113883.10.20.24.1.3" extension="2019-02-01"/> 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.	The Version Specific Measure Identifier for an eCQM being reported is a required element in the QRDA file (i.e., XPath is QualityMeasureDocument/id/@root). The HQR eCQM receiving system will only accept the "2019 version" of eCQMs for the CY 2020 reporting period. Each eCQM has an associated Version Specific Measure Identifier corresponding to the 2020 eCQM specifications. Only those Version Specific Measure Identifiers for the current reporting year will be accepted. If any submitted version specific identifier does not match one of the defined set of the Version Specific Measure Identifier for the current reporting year, the file will be rejected.
CMS_0075	Admission Date is not properly formatted.	Fails validation check for Encounter Performed Admission Date (effectiveTime/low value) as specified in Table 15: 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 15: 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 (10) MB.	QRDA file size exceeds 10 MB.
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.
CMS_0082	CMS EHR Certification ID does not meet year/version criteria	The EHR system needs to be certified to 2015 Edition for CY2020/PY2022.

5.3.3 Date and Time Validation

Table 15: 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: YYYYMMDDHHMM YYYYMMDDHHMMSS 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, 202001301130
BirthTime	Valid Date/Time Format: YYYYMMDD YYYYMMDDHHMM 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	For example, 19910428 201809102223 (newborn)
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 2020 or 202003 are not allowed.

Attribute	Date and Time Format Validation Rules	Examples
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) x - plus or minus sign UUUU - UTC time shift -1300 thru+1400	For example, 20200130 is valid.
NA	Leap year calculation is validated.	For example, 20190229 is invalid because 2019 is not a leap year. 20200229 is valid, because 2020 is a leap year.
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 16: 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

Validation Item	CONF. #	CDA Template Name and CDA Element XPath
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/
- **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://oncprojectracking.healthit.gov/

6.2 Support

Table 17: Support Contact Information

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

6.3 Errata or Enhancement Requests

Table 18: Errata or Enhancement Request Location

Contact	Organization	URL	Purpose
HL7 QRDA I R1, STU Release 5.1 Comments page	HL7	http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=220	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 19: 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 but SHALL NOT have both @code 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 20: NPI Validation Rules and Table 21: TIN Validation Rules list the validation rules performed on the NPI and TIN.

Table 20: 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 21: 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 R5.1 Base Standard

This table lists all changes made to the base HL7 QRDA I STU R5.1 contained in this implementation guide. The "Base Standard" is the *HL7 Implementation Guide for CDA Release 2: Quality Report Document Architecture, Category I, STU Release 5.1,* (published December 2018).

Table 22: Changes Made to the QRDA I STU R5.1 Base Standard

CONF. #	Section	Base Standard	Changed To
CMS_0001	5.1.1	n/a	Conforms to `QDM-Based QRDA (V6) template` (`identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.1.2:2018-10-01`). **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**="`2019-02-01`" (CONF:CMS_0003).
CMS_0010	5.1.1	n/a	This **`languageCode`** **SHALL** contain exactly one [1..1] **`@code`**="en" (CONF:CMS_0010).
4388-16857_C01	5.1.2	This patientRole **MAY** contain zero or one [0..1] **`id`** (CONF:4388-16857) such that it **SHALL** contain exactly one [1..1] **`@root="`**`2.16.840.1.113883.4.572`**`"`** Medicare HIC number (CONF:4388-16858).	This patientRole **SHOULD** contain zero or one [0..1] **`id`** (CONF:4388-16857_C01) such that it **SHALL** contain exactly one [1..1] **`@root="`**`2.16.840.1.113883.4.572`**`"`** Medicare HIC number (CONF:4388-16858).

CONF. #	Section	Base Standard	Changed To
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). 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). **SHALL** contain exactly one [1..1] **@extension** (CONF:CMS_0103). Note:The value of @extension is the Patient ID.
4388-28697_C01	5.1.2	This patientRole **MAY** contain zero or one [0..1] **`id`** (CONF:4388-28697) such that it **SHALL** contain exactly one [1..1] **`@root="`**`2.16.840.1.113883.4.927`**"** Medicare Beneficiary Identifier (MBI) (CONF:4388-28698).	**HQR:** 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 **SHOULD** contain zero or one [0..1] **`id`** (CONF:4388-28697_C01) such that it **SHALL** contain exactly one [1..1] **`@root="`**`2.16.840.1.113883.4.927`**"** Medicare Beneficiary Identifier (MBI) (CONF:4388-28698).
1198_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).

CONF. #	Section	Base Standard	Changed To
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). For cases where information about newborn's time of birth needs to be captured. **MAY** be precise to the minute (CONF:1198-32418).	This patient **SHALL** contain exactly one [1..1] **`birthTime`** (CONF:1140-27571). **SHALL** be precise to day (CONF:1198-5300_C01). For cases where information about newborn's time of birth needs to be captured. **MAY** be precise to the minute (CONF:1198-32418).
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.
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).

CONF. #	Section	Base Standard	Changed To
4388-28241_C01	5.1.3	This representedCustodianOrganization **SHOULD** contain zero or one [0..1] **`id`** (CONF:4388-28241) such that it **SHALL** contain exactly one [1..1] **`@root="`**`2.16.840.1.113883.4.336`**`"`** CMS Certification Number (CONF:4388-28244).	This representedCustodianOrganization **SHALL** contain exactly one [1..1] **`id`** (CONF:4388-28241_C01) such that it **SHALL** contain exactly one [1..1] **`@root="`**`2.16.840.1.113883.4.336`**`"`** CMS Certification Number (CONF:4388-28244).
CMS_0035	5.1.3	n/a	CCN **SHALL** be six to ten characters in length (CONF:CMS_0035).
4388_16703_C01	5.1.4	**MAY** contain zero or more [0..*] **`informationRecipient`** (CONF:4388-16703).	**SHALL** contain exactly one [1..1] **`informationRecipient`** (CONF:4388-16703_C01).
4388_16705_C01 CMS_0025 CMS_0026	5.1.4	This intendedRecipient **SHALL** contain at least one [1..*] **`id`** (CONF:4388-16705).	This intendedRecipient SHALL contain exactly one [1..1] **`id`** (CONF:4388-16705_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 2018-02-01 (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).
CMS_0004 CMS_0005 CMS_0006 CMS_0008	5.1.5		**HQR:** CMS EHR Certification ID is required for HQR. The participant **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 ID (CONF:CMS_0006). **SHALL** contain exactly one [1..1] **`@extension`** (CONF:CMS_0008). Note: The value of @extension is the CMS EHR Certification ID.

CONF. #	Section	Base Standard	Changed To
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).
CMS_0054	5.1.7	n/a	**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:CMS_0054).
CMS_0055	5.1.7	n/a	**SHALL** contain exactly one [1..1] `Patient Data Section QDM (V6) - CMS (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.2.1.1:2019-02-01)` (CONF:CMS_0055).
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:2.16.840.1.113883.10.20.17.3.8.1:2016-03-01)` (CONF:CMS_0024).

CONF. #	Section	Base Standard	Changed To
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**="`2016-03-01`" (CONF:CMS_0046).
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 (V6)` template (`identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.2.1:2018-10-01)`. **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`**="`2019-02-01`" (CONF:CMS_0038).

CONF. #	Section	Base Standard	Changed To
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).
4388-14430_C01	5.2.3	**MAY** contain zero or more [0..*] **`entry`** (CONF:4388-14430) such that it	**SHALL** contain at least one [1..*] **`entry`** (CONF:4388-14430_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:4388_14431).

10 Change Log for 2020 CMS QRDA Implementation Guide from the 2019 CMS QRDA Implementation Guide

This appendix (Table 23) summarizes the changes made in this 2020 CMS QRDA Implementation Guide since the release of 2019 CMS QRDA Implementation Guide.

Table 23: Changes Made for 2020 CMS QRDA IG from 2019 CMS QRDA IG

Section Heading	2020 CMS QRDA IG	2019 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 5.1, US Realm, December 2018	HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture Category I, Release 1, Standard for Trial Use (STU) Release 5, US Realm, December 2017
4 QRDA Category I Requirements	Language is updated to reflect the requirement updates for the 2020 reporting year.	n/a
5.1.1 General Header	`QRDA Category I Report - CMS (V6)` (Note: this template is based on QRDA I, STU R5.1) **SHALL** contain exactly one [1..1] **templateId** (CONF:CMS_0001) such that it **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**="2019-02-01" (CONF:CMS_0003).	`QRDA Category I Report - CMS (V5)` (Note: this template is based on QRDA I, STU R5) **SHALL** contain exactly one [1..1] **templateId** (CONF:CMS_0001) such that it **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**="2018-02-01" (CONF:CMS_0003).
5.1.4 informationRecipient	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** 2019-02-01 (CONF:CMS_0026).	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** 2018-02-01 (CONF:CMS_0026).

Section Heading	2020 CMS QRDA IG	2019 CMS QRDA IG
5.1.4 informationRecipient	CMS Program Name: HQR_PI HQR_IQR HQR_PI_IQR HQR_IQR_VOL (Note: CDAC_HQR_EHR is removed)	CMS Program Name: HQR_PI HQR_IQR HQR_PI_IQR HQR_IQR_VOL CDAC_HQR_EHR
5.1.5 Participant (CMS EHR Certification ID)	Updated to use "CMS EHR Certification ID" consistently in this section. 5.1.5 Participant (CMS EHR Certification ID) This id **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.2074.1" CMS EHR Certification ID (CONF:CMS_0006).	5.1.5 Participant (CMS Certification Identification Number) This id **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).
5.1.7 component	This structuredBody **SHALL** contain exactly one [1..1] **component** (CONF:CMS_0057) such that it **SHALL** contain exactly one [1..1] Patient Data Section QDM (V6) - CMS (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.2.1.1:2019-02-01) (CONF:CMS_0055).	This structuredBody **SHALL** contain exactly one [1..1] **component** (CONF:CMS_0057) such that it **SHALL** contain exactly one [1..1] Patient Data Section QDM (V5) - CMS (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.2.1.1:2018-02-01) (CONF:CMS_0055).
5.2.3 Patient Data Section (V6) - CMS	Patient Data Section QDM (V6) – CMS Conforms to Patient Data Section QDM (V6) template (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.2.1:2018-10-01). **SHALL** contain exactly one [1..1] **templateId** (CONF:CMS_0036) such that it **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.24.2.1.1" (CONF:CMS_0037). **SHALL** contain exactly one [1..1] **@extension**="2019-02-01" (CONF:CMS_0038).	Patient Data Section QDM (V5) – CMS Conforms to Patient Data Section QDM (V5) template (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.2.1:2017-08-01). **SHALL** contain exactly one [1..1] **templateId** (CONF:CMS_0036) such that it **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.24.2.1.1" (CONF:CMS_0037). **SHALL** contain exactly one [1..1] **@extension**="2018-02-01" (CONF:CMS_0038).

Section Heading	2020 CMS QRDA IG	2019 CMS QRDA IG
5.3.2 Additional HQR Validations	Updated error description of CMS_0066 CCN value does not appear in HQR lookup of valid CCNs. CCN is Null, resulting in this message.	CMS_0066 CCN passes Schematron format check but the value does not appear in HQR lookup of valid CCNs. CCN is Null, resulting in this message.

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
IQR	Inpatient Quality Reporting
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
PI	Promoting Interoperability
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

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 5.1 (QRDA I STU R5.1). December 2018. 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