



Centers for Medicare & Medicaid Services

**CMS Implementation Guide for
Quality Reporting Document Architecture
Category I
Hospital Quality Reporting
Implementation Guide for 2025**

**DRAFT
03/07/2024**

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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 5.3, US Realm*, and any subsequent errata update¹, for the 2025 reporting period.

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 6 contain technical specifications for the QRDA I STU 5.3 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
- Chapter 6: Hybrid Measures/CCDE Submission — guidance on hybrid measures/core clinical data element submission.

APPENDIX

- Chapters 7-16 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 2025 CMS QRDA IG for HQR programs from the 2024 CMS

¹ HL7 QRDA I R1 STU 5.3 and any subsequent errata update.

http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35

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

- | |
|--|
| <p>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).</p> |
|--|

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

- | |
|--|
| <p>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).</p> |
|--|

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 measurable. 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 HL7 standard, *Clinical Document Architecture, Release 2.0*².

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`.

² HL7 CDA Release 2.0 Normative Edition
https://www.hl7.org/implement/standards/product_brief.cfm?product_id=496

QRDA I STU 5.3 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 5.3*, and any subsequent errata update, referred to as the HL7 QRDA I STU 5.3 in this guide. This guide describes additional conformance statements and constraints for EHR data submissions that are required for reporting to CMS for the Hospital Inpatient Quality Reporting Program, Hospital Outpatient Quality Reporting Program, and the Medicare Promoting Interoperability Program pertaining to the 2025 reporting period.

The purpose of this guide is to serve as a companion to the base HL7 QRDA I STU 5.3 for entities such as eligible hospitals (EHs), critical access hospitals (CAHs), and vendors to submit QRDA I data for consumption by CMS systems including for Hospital Quality Reporting (HQR).

Each QRDA Category I report³ 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 QRDA I reports originating from EHR systems. Submitted QRDA I reports for HQR in the 2025 reporting period must meet the conformance statements specified in this guide in addition to the conformance statements specified in the HL7 QRDA I STU 5.3. Only reports that are valid against the CDA Release 2 schema enhanced to support the *urn:hl7-org:sdtc* namespace (CDA_SDTC.xsd)⁴ will be accepted for processing. Reports that are invalid against this rule will be rejected.

This guide is based on following rules:

1. The HL7 QRDA I STU 5.3 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 5.3 standard is further constrained in this guide.
2. The original **SHALL/SHOULD/MAY** keywords along with conformance numbers from the HL7 QRDA I STU 5.3 for relevant data elements and attributes have been included in this

³ Note that the terms QRDA I report and QRDA I file are used interchangeably in this guide.

⁴ CDA_SDTC.xsd is available at <https://github.com/HL7/cda-core-2.0>.

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

4.2 eCQM, Hybrid Measure, and Value Set Specifications

The eCQM Specifications for Hospital Quality Reporting May 2024⁵, and any applicable addenda, must be used for the HQR programs for the 2025 reporting period.

The eCQM Value Sets for Hospital Quality Reporting May 2024⁶, and any applicable addenda, published at the Value Set Authority Center (VSAC) must be used for HQR programs for the 2025 reporting period.

For hybrid measures/core clinical data element (CCDE) submission, this guide must be used for reporting of 2025 - 2026 data (measurement period July 1, 2025 through June 30, 2026) and be submitted in 2026. The 2025 reporting period hybrid measure specifications must be used.⁷

4.3 Succession Management

This section describes the management of successive replacement files 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 ID⁸, 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.

⁵ eCQI Resource Center, Eligible Hospital/Critical Access Hospital eCQMs web page. <https://ecqi.healthit.gov/eh-cah>. Select the EH/CAH eCQMs tab, then select 2025 reporting period.

⁶ Value Set Authority Center, VSAC Downloadable Resources web page. <https://vsac.nlm.nih.gov/download/ecqm>. Select 2025 Reporting/Performance Period of eCQM & Hybrid Measure Value Sets.

⁷ eCQI Resource Center, Eligible Hospital/Critical Access Hospital eCQMs web page. <https://ecqi.healthit.gov/eh-cah>. Select 2025 reporting period and filter by Hybrid Measures.

⁸ 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 \(2.16.840.1.113883.3.249.14.103\)](#) for the 2025 reporting period specified in this guide.

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 the SPL Drug Route of Administration Terminology value set (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 "SPL Drug Route of Administration Terminology" (2.16.840.1.113883.3.88.12.3221.8.7) value set in constructing a QRDA I report.

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="202503250930-0500"/>
    <!-- Attribute: discharge datetime -->
    <high value="202503291052-0500"/>
  </effectiveTime>
  ...
</encounter>
```

4.6 Submit eCQM Version Specific Measure Identifier ONLY

For the 2025 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 QRDA submissions. 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 2025 reporting period generated by the Measure Authoring Tool (MAT) are string values such as 12.0.000 instead of integers such as 12. If a version number such as 12.0.000 were submitted, the QRDA reports 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 report will not be rejected, but the value will be ignored.

4.7 Templates Versioning and Validations

Both the base HL7 QRDA I STU 5.3 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 5.3. For example, in HL7 QRDA I STU 5.3, the previous `Procedure Performed (V6)` template is now `Procedure Performed (V7)`, and its template identifier is

"2.16.840.1.113883.10.20.24.3.64:2021-08-01". Both the @root and @extension are required as specified in the IG.

SHALL contain exactly one [1..1] **templateId** (CONF:4509-11262) such that it

- a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.24.3.64" (CONF:4509-11263).
- b. **SHALL** contain exactly one [1..1] @extension="2021-08-01" (CONF:4509-27129).

Correct template versions that are specified by both the base HL7 QRDA I STU 5.3 and the 2025 CMS IG must be used for 2025 CMS QRDA I submissions. For instance, if a QRDA I report used *Procedure Performed (V6)* instead of *Procedure Performed (V7)*, this older version of the template will be ignored by the HQR System. Data submitted using template versions that are not specifically required by the base HL7 QRDA I STU 5.3 and the 2025 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 are used and be 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 5.3 are Clinical Document Architecture (CDA) templates.

5.1.1 General Header

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

Table 2: QRDA Category I Report - CMS (V8) Constraints Overview
ClinicalDocument (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.1.3:2022-02-01)

| XPath | Card. | Verb | 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 | 2022-02-01 |
| id | 1..1 | SHALL | 1198-5363 1198-9991 | |
| effectiveTime | 1..1 | SHALL | 1198-5256 | US Realm Date and Time (DTM.US.FIELDDED) (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 (V8) template (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.1.2:2021-08-01).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:CMS_0001) such that it
 - a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.24.1.3" (CONF:CMS_0002).
 - b. **SHALL** contain exactly one [1..1] **@extension**="2022-02-01" (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.FIELDDED) (identifier: urn:oid:2.16.840.1.113883.10.20.22.5.4) (CONF:1198-5256).
5. **SHALL** contain exactly one [1..1] **languageCode**, which **SHALL** be selected from ValueSet Language urn:oid:2.16.840.1.113883.1.11.11526 **DYNAMIC** (CONF:1198-5372).
 - a. This languageCode **SHALL** contain exactly one [1..1] **@code**="en" (CONF:CMS_0010).

Figure 5: CMS 2025 QRDA I Document 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 (V8) -->
  <templateId root="2.16.840.1.113883.10.20.24.1.2"
extension="2021-08-01"/>
  <!-- QRDA Category I Report - CMS (V8) -->
  <templateId root="2.16.840.1.113883.10.20.24.1.3"
extension="2022-02-01"/>
  <!-- This is the globally unique identifier for this QRDA I
report -->
  <id root="be8eeafc-86b2-4d1f-881d-971def0c74ec"/>
  <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 report creation time -->
  <effectiveTime value="20250201"/>
  <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:2.16.840.1.113883.10.20.24.1.3:2022-02-01)

| XPath | Card. | Verb | CONF. # | Value |
|--------------|-------|--------|--------------------------------|-------------------------|
| recordTarget | 1..1 | SHALL | 4509-16598 | |
| patientRole | 1..1 | SHALL | 4509-16856 | |
| id | 0..1 | SHOULD | 4509-16857_C01 | |
| @root | 1..1 | SHALL | 4509-16858 | 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 | 4509-28697_C01 | |

| XPath | Card. | Verb | CONF. # | Value |
|--------------------------|-------|--------|--|--|
| @root | 1..1 | SHALL | 4509-28698 | 2.16.840.1.113883.4.927 |
| addr | 1..* | SHALL | 1198-5271 | US Realm Address (AD.US.FIELDDED) (identifier: urn:oid:2.16.840.1.113883.10.20.22.5.2) |
| telecom | 1..* | SHALL | 1198-5280 | |
| @use | 0..1 | SHOULD | 1198-5375 | urn:oid:2.16.840.1.113883.11.20.9.20 (Telecom Use (US Realm Header)) |
| telecom | 0..* | SHOULD | CMS_0130 | |
| @value | 1..1 | SHALL | CMS_0131 CMS_0132 | |
| telecom | 0..* | SHOULD | CMS_0133 | |
| @value | 1..1 | SHALL | CMS_0134 CMS_0135 | |
| patient | 1..1 | SHALL | 4509-27570 | |
| name | 1..1 | SHALL | 1198-5284_C01 | US Realm Person Name (PN.US.FIELDDED) (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) |
| sdct: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) |

6. **SHALL** contain exactly one [1..1] **recordTarget** (CONF:4509-16598).
- This **recordTarget** **SHALL** contain exactly one [1..1] **patientRole** (CONF:4509-16856).

HQR: Medicare Health Insurance Claim (HIC) Number (HICN) is not required for HQR but should be submitted if the payer is Medicare and the patient has an HIC number assigned.

Note that HICN is not required for hybrid measures submission.

- i. This patientRole **SHOULD** contain zero or one [0..1] `id` (CONF:4509-16857_C01) such that it
 - 1. **SHALL** contain exactly one [1..1]
 - `@root="2.16.840.1.113883.4.572"` Medicare HIC number (CONF:4509-16858).

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.

Note that for hybrid measures, the patient's MBI must be submitted.

- iii. This patientRole **SHOULD** contain zero or one [0..1] `id` (CONF:4509-28697_C01) such that it
 - 1. **SHALL** contain exactly one [1..1]
 - `@root="2.16.840.1.113883.4.927"` Medicare Beneficiary Identifier (MBI) (CONF:4509-28698).
- iv. This patientRole **SHALL** contain at least one [1..*] US Realm Address (AD.US.FIELDDED) (`identifier: urn:oid:2.16.840.1.113883.10.20.22.5.2`) (CONF:1198-5271).
- v. This patientRole **SHALL** contain at least one [1..*] `telecom` (CONF:1198-5280).
 - 1. Such telecoms **SHOULD** contain zero or one [0..1] `@use`, which **SHALL** be selected from ValueSet `Telecom Use (US Realm Header)` (`urn:oid:2.16.840.1.113883.11.20.9.20 DYNAMIC`) (CONF:1198-5375).
- vi. This patientRole **SHOULD** contain zero or more [0..*] `telecom` (CONF:CMS_0130) such that it
 - 1. **SHALL** contain exactly one [1..1] `@value` (CONF:CMS_0131).
 - a. This value **SHALL** begin with "mailto:" which is the email address of the patient (CONF:CMS_0132).
- vii. This patientRole **SHOULD** contain zero or more [0..*] `telecom` (CONF:CMS_0133) such that it
 - 1. **SHALL** contain exactly one [1..1] `@value` (CONF:CMS_0134).
 - a. This value **SHALL** begin with "tel:" which is the telephone of the patient (CONF:CMS_0135).
- viii. This patientRole **SHALL** contain exactly one [1..1] `patient` (CONF:4509-27570).

1. This patient **SHALL** contain exactly one [1..1] US Realm Person Name (PN.US.FIELDDED) (identifier: urn:oid:2.16.840.1.113883.10.20.22.5.1.1) (CONF:1198-5284_C01).
2. This patient **SHALL** contain exactly one [1..1] **administrativeGenderCode**, which **SHALL** be selected from ValueSet *ONC Administrative Sex* urn:oid:2.16.840.1.113762.1.4.1 **DYNAMIC** (CONF:CMS_0011).
 - a. If the patient's administrative sex is unknown, nullFlavor="UNK" **SHALL** be submitted (CONF:CMS_0029).
3. This patient **SHALL** contain exactly one [1..1] **birthTime** (CONF:1198-5298).
 - a. **SHALL** be precise to day (CONF:1198-5300_C01).

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

- b. **MAY** be precise to the minute (CONF:1198-32418).
4. This patient **SHALL** contain exactly one [1..1] **raceCode**, which **SHALL** be selected from ValueSet *Race* urn:oid:2.16.840.1.114222.4.11.836 **DYNAMIC** (CONF:CMS_0013).
 - a. If the patient's race is unknown, nullFlavor="UNK" **SHALL** be submitted (CONF:CMS_0030).
 - b. If the patient declined to specify his/her race, nullFlavor="ASKU" **SHALL** be submitted (CONF:CMS_0031).
5. This patient **MAY** contain zero or more [0..*] **sdct: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 sdct: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 (V8)

```

<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="HP" value="tel:+1(781)271-3000"/>
    <telecom use="HP" value="mailto:me@email.com"/>
    <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:2.16.840.1.113883.10.20.24.1.3:2022-02-01)

| XPath | Card. | Verb | CONF. # | Value |
|----------------------------------|-------|-------|--|-------------------------|
| custodian | 1..1 | SHALL | 4509-16600 | |
| assignedCustodian | 1..1 | SHALL | 4509-28239 | |
| representedCustodianOrganization | 1..1 | SHALL | 4509-28240 | |
| id | 1..1 | SHALL | 4509-28241_C01 | |
| @root | 1..1 | SHALL | 4509-28244 | 2.16.840.1.113883.4.336 |
| @extension | 1..1 | SHALL | 4509-28245 CMS_0035 | |

1. **SHALL** contain exactly one [1..1] **custodian** (CONF:4509-16600).
 - a. This custodian **SHALL** contain exactly one [1..1] **assignedCustodian** (CONF:4509-28239).
 - i. This assignedCustodian **SHALL** contain exactly one [1..1] **representedCustodianOrganization** (CONF:4509-28240).

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:4509-28241_C01) such that it
 - a. **SHALL** contain exactly one [1..1] **@root="2.16.840.1.113883.4.336"** CMS Certification Number (CONF:4509-28244).
 - b. **SHALL** contain exactly one [1..1] **@extension** (CONF:4509-28245).

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

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

Figure 7: CCN as Custodian Example, QRDA Category I Report - CMS (V8)

```
<!-- 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 report is created.

Table 5: informationRecipient Constraints Overview
 ClinicalDocument (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.1.3:2022-02-01)

| XPath | Card. | Verb | CONF. # | Value |
|----------------------|-------|-------|--------------------------------|---|
| informationRecipient | 1..1 | SHALL | 4509-16703_C01 | |
| intendedRecipient | 1..1 | SHALL | 4509-16704 | |
| id | 1..1 | SHALL | 4509-16705_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:4509-16703_C01).
 - a. This `informationRecipient` **SHALL** contain exactly one [1..1] `intendedRecipient` (CONF:4509-16704).
 - i. This `intendedRecipient` **SHALL** contain exactly one [1..1] `id` (CONF:4509-16705_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** 2022-02-

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 Medicare 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 Medicare Promoting Interoperability Program and the Inpatient Quality Reporting Program |
| HQR_OQR | CMS Program | urn:oid:2.16.840.1.113883.3.249.7 | Hospital Quality Reporting for the Outpatient Quality Reporting Program |

Figure 8: informationRecipient Example, QRDA Category I Report - CMS (V8)

```

<!-- 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 eligible hospital 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.⁹

⁹ Certified Health IT Product List. <https://chpl.healthit.gov/>

CMS EHR Certification ID is different from the CHPL product number. In the CHPL, this would be the number that is generated when select 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:2.16.840.1.113883.10.20.24.1.3:2022-02-01)

| XPath | Card. | Verb | 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.

5.1.6 component

Table 8: component Constraints Overview

ClinicalDocument (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.1.3:2022-02-01)

| XPath | Card. | Verb | CONF. # | Value |
|----------------|-------|-------|----------------------------|---|
| component | 1..1 | SHALL | 4509-12973 | |
| structuredBody | 1..1 | SHALL | 4509-17081 | |
| component | 1..1 | SHALL | CMS_0056 | |
| 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 | CMS_0057 | |
| section | 1..1 | SHALL | CMS_0055 | Patient Data Section QDM (V8) - CMS (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.2.1.1:2022-02-01) |
| component | 1..1 | SHALL | 4509-17082 | |
| section | 1..1 | SHALL | 4509-17083 | 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:4509-12973).
 - a. This component **SHALL** contain exactly one [1..1] **structuredBody** (CONF:4509-17081).
 - 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 \(V8\) - CMS](#) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.2.1.1:2022-02-01) (CONF:CMS_0055).
 - iii. This structuredBody **SHALL** contain exactly one [1..1] **component** (CONF:4509-17082) 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:4509-17083).

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 5.3 standard for the full specification of Measure Section.

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

| XPath | Card. | Verb | 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 9: 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="2c928083-8651-08a3-0186-754df8c706a4"/>
        </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 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 | 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:h17ii: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 | CONF. # | Value |
|----------------------------|-------|-------|--|----------------------------------|
| <code>templateId</code> | 1..1 | SHALL | CMS_0044 | |
| <code>@root</code> | 1..1 | SHALL | CMS_0045 | 2.16.840.1.113883.10.20.17.3.8.1 |
| <code>@extension</code> | 1..1 | SHALL | CMS_0046 | 2016-03-01 |
| <code>effectiveTime</code> | 1..1 | SHALL | 23-3273 | |
| <code>low</code> | 1..1 | SHALL | 23-3274 | |
| <code>@value</code> | 1..1 | SHALL | CMS_0048 CMS_0027 | |
| <code>high</code> | 1..1 | SHALL | 23-3275 | |
| <code>@value</code> | 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 10: 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 2025 - 31 March 2025</item>
    </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"/>
      <id root="67e84480-1f84-4d04-9be3-cc3e8c2c6933"/>
      <code code="252116004" codeSystem="2.16.840.1.113883.6.96"
displayName="Observation Parameters"/>
      <effectiveTime>
        <low value="20250101"/>
        <high value="20250331"/>
      </effectiveTime>
    </act>
  </entry>
</section>

```

5.2.3 Patient Data Section QDM (V8) - CMS

The Patient Data Section QDM (V8) - 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 (V8) - 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 5.3 standard with errata.

Table 12: Patient Data Section QDM (V8) – CMS Constraints Overview
section (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.2.1.1:2022-02-01)

| XPath | Card. | Verb | 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 | 2022-02-01 |

| XPath | Card. | Verb | CONF. # | Value |
|-------------|-------|-------|--|--|
| entry | 1..* | SHALL | CMS_0051 CMS_0039 | |
| entry | 1..* | SHALL | 4509-14430_C01 | |
| observation | 1..1 | SHALL | 4509-14431 | Patient Characteristic Payer (identifier: urn:oid:2.16.840.1.113883.10.20.24.3.55) |

1. **Conforms to Patient Data Section QDM (V8) template** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.2.1:2021-08-01).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:CMS_0036) such that it
 - a. **SHALL** contain exactly one [1..1] **@root="2.16.840.1.113883.10.20.24.2.1.1"** (CONF:CMS_0037).
 - b. **SHALL** contain exactly one [1..1] **@extension="2022-02-01"** (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:4509-14430_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:4509-14431).

Figure 11: Patient Data Section QDM (V8) – CMS Example

```

<section>
  <!-- Patient Data Section -->
  <templateId root="2.16.840.1.113883.10.20.17.2.4" />
  <!-- Patient Data Section QDM (V8) -->
  <templateId root="2.16.840.1.113883.10.20.24.2.1"
    extension="2021-08-01"/>
  <!-- Patient Data Section QDM (V8) - CMS-->
  <templateId root="2.16.840.1.113883.10.20.24.2.1.1"
    extension="2022-02-01"/>
  <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="20250101"/>
        <high value="20251231"/>
      </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

To report 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, the following steps must be followed:

1. Must set the attribute `negataionInd="true"`
2. If QDM in eCQM specification is defined using a value set, for example, ["Medication, Not Ordered": "Warfarin"]:
 - Must provide `code/[@nullFlavor="NA"]`
 - Must provide the value set OID instead of a specific code from the value set. Set the code attribute `code/sdct: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]"

3. If QDM element in eCQM specification is defined using direct referenced code:
 - Must not provide code/[@nullFlavor="NA"]
 - Must provide the direct referenced code. Set the code attribute code="[The Direct Referenced Code]"
4. Must provide the reason for negation, such as a medical reason or a patient reason
 - Provide 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. See Reason Template Placement When Specifying "Not Done" with a Reason for more details.

Figure 12: 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="2022-
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"/>
      <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>
      </manufacturedMaterial>
    </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>
</substanceAdministration>

```

5.2.3.2 Reporting "unit" for Result Value

If eCQM definition uses the "unit" in the measure logic for the "result" criteria, the patient QRDA report must report the result with the exact appropriate/required unit specified in the eCQM. For example, in the measure logic for maximum LDL-c result of less than 70 mg/dL, Unified Code

for Units of Measure (UCUM) code “mg/dL” is specified as “unit” by the eCQM definition.¹⁰ If the LDL-c result value is provided without the unit or with a different unit than specified by the eCQM, depending on the system processing the data, the case might not meet the measure’s requirement and fail the “result” logic.

If eCQM definition does not specify the “unit” in the measure logic for the “result” criteria, for example, ["Laboratory Test, Performed": "INR"] INRLabTest where INRLabTest.result > 3.0, then the laboratory test performed result must be reported using one of the two options:

- 1) represent INR result using data type REAL or Interval REAL (xsi:type="REAL" or xsi:type="IVL_REAL") for results such as INR=2.4 or INR>=4.5;
- 2) represent INR result using data type PQ and PQ.unit should be using UCUM annotations {ratio} or {INR}.

For guidance on reporting result value “unit” for hybrid measures, please see [6.2 Reporting Result “unit” for Hybrid Measures](#).

5.2.3.3 Reporting “result as type”

CQL supports Choice type, which is defined by a list of component types. In cases where result values are cast as a specific type in measure specification, such as “result as Integer”, “result as Quantity”, and “result as DateTime”, result values shall also be cast to their corresponding HL7 V3 data types when reporting in QRDA to ensure appropriate evaluation.

For example, the following definition specified in CMS334v5 has result cast as Integer:

```
Last(["Assessment, Performed": "[#] Births.preterm"] PretermBirth
  where Global."EarliestOf"(PretermBirth.relevantDatetime,
  PretermBirth.relevantPeriod)42 weeks or less before
  PCMaternal."LastTimeOfDelivery"(Encounter)
  and PretermBirth.result is not null
  sort by Global."EarliestOf"(relevantDatetime, relevantPeriod)
).result as Integer
```

In this case, when report Assessment Performed result in QRDA, observation/value shall be cast to the INT data type.

When report result as Quantity and as DateTime, they shall be submitted using the PQ and TS data types respectively.

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 HQR System.

¹⁰ The Clinical Quality Language (CQL) specification defines a number of built-in units for timing, such as “week”, “weeks”, and “year”. CQL logic for eCQMs uses these built-in units. For the 2025 reporting period, submitting either “week” and “weeks” or their corresponding UCUM representation “wk” will be accepted by the receiving system.

5.3.1 Validation Rules for Encounter Performed

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. The system **SHALL** reject QRDA I files if there are no Encounter Performed Discharge Dates within the reporting period found in the QRDA (CONF: CMS_0063).

When there are multiple diagnoses for an Encounter Performed, only one diagnosis shall be identified as principal diagnosis. The following validation rule from the QRDA I STU 5.3 is used to enforce that only one Encounter Diagnosis Quality Data Model (QDM) template with a rank attribute equal to 1, to indicate the principal diagnosis, within an Encounter Performed template.

If **entryRelationship to Encounter Diagnosis QDM (V2)** is present, **SHALL** contain at most one **Encounter Diagnosis QDM (V2)** of rank 1, as principal diagnosis (CONF:4509-32546).

5.3.2 Other HQR Validations

Table 13: Other Validation Rules for HQR Programs

| CONF. # | Validation Performed | Description of Error Message and File Rejection |
|----------|---|---|
| CMS_0066 | CCN (NULL) cannot be validated. | CCN 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 2025 Reporting |

| CONF. # | Validation Performed | Description of Error Message and File Rejection |
|----------|--|---|
| | | Period is yet to be finalized, this message is returned. |
| CMS_0071 | Data submitted is not a well formed QRDA XML. | File violates syntax rule in the XML specification, e.g., missing start/end tag or prime elements missing or not properly nested or not properly written. <u>Processing stops immediately on file.</u> |
| CMS_0072 | QRDA file does not pass XML schema validation (CDA_SDTC.xsd). | QRDA structure does not pass CDA_SDTC.XSD schema check. <u>Processing continues</u> on file to identify other Errors/Warnings. |
| CMS_0073 | The document does not conform to QRDA document formats accepted by CMS. | <p>File is not in QRDA Category I STU Release 5.3 format -- does not contain all four of the required header templateIds including both of the R5.3 templateIds and extensions:</p> <p>HL7 R5.3:</p> <pre><templateId root="2.16.840.1.113883.10.20.22.1.1" extension="2015-08-01"/></pre> <pre><templateId root="2.16.840.1.113883.10.20.24.1.1" extension="2017-08-01"/></pre> <pre><templateId root="2.16.840.1.113883.10.20.24.1.2" extension="2021-08-01"/></pre> <p>2025 CMS QRDA I IG:</p> <pre><templateId root="2.16.840.1.113883.10.20.24.1.3" extension="2022-02-01"/></pre> <p>This error is also produced for empty file or other non-XML file type (e.g., PDF). <u>Processing stops immediately on file.</u></p> |
| CMS_0074 | The Version Specific Measure Identifier is not valid for the Reporting Period and/or CMS Program Name. | <p>The Version Specific Measure Identifier is a required element in the QRDA file (XPath is QualityMeasureDocument/id/@root)</p> <p>The HQR System will only accept the correct version of eCQMs/CCDEs/linking variables for the current reporting period. Each inpatient eCQM, outpatient eCQM and inpatient Hybrid measure has an associated Version Specific Measure Identifier for the current reporting period.</p> <p>The QRDA file must have at least one Version Specific Measure Identifier for the current reporting period and must be supported by the CMS Program Name.</p> <p>If the QRDA file does not contain at least one Version Specific Measure Identifier for the CMS Program Name and/or reporting period, it will be rejected.</p> <p>If the QRDA file does contain at least one Version Specific Measure Identifier for the CMS Program Name and reporting period, Version Specific Measure Identifiers not associated with the CMS</p> |

| CONF. # | Validation Performed | Description of Error Message and File Rejection |
|----------|---|---|
| | | Program Name and /or reporting period within the same file will be ignored. |
| 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 (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 Cures Update for CY2025. The CMS EHR Certification ID must contain "15C" in the third, fourth, and fifth places. |
| CMS_0083 | CMS Certification ID format is not valid. | CMS EHR Certification ID must be 15 alpha numeric characters in length. |
| CMS_0084 | The Patient MBI is required for hybrid measure/Core Clinical Data Elements (CCDE) submissions. | QRDA files for hybrid measure/CCDE submissions must contain a MBI. |
| CMS_0087 | Low date is after high date. | Fails validation check. Low dates are after high dates. |
| CMS_0088 | Invalid DateTime has been provided. | Fails validation check for low and high date time format. |
| CMS_0089 | CMS Program Name conflicts with the file upload location. | CMS program name for inpatient Hybrid measures/CCDE submissions must be HQR_IQR. CMS program name for inpatient eCQM submissions must be HQR_IQR, HQR_PI_IQR or HQR_PI. CMS program name for outpatient eCQM submissions must be HQR_OQR. |

5.3.3 Date and Time Validation

Table 14: Valid Date/Time Format for HQR

| Attribute | Date and Time Format Validation Rules | Examples |
|---|--|--|
| <Encounter> <EffectiveTime> <low>(Admission Date) <high>(Discharge Date) | Valid Date/Time Format: 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 -1200 thru+1400 | For example, 202501301130 |
| BirthTime | Valid Date/Time Format: YYYYMMDD 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) HH - hour - range 0 to 23 MM - minutes - range 0-59 SS - seconds - range 0-59 | For example, 19910428 202504202115 (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 2025 or 202503 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 -1200 thru+1400 | For example, 20250130 is valid. |
| NA | Leap year calculation is validated. | For example, 20240229 is valid, because 2024 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 15: Validation XPath

| Validation Item | CONF. # | CDA Template Name and CDA Element XPath |
|-----------------------------|--|--|
| Admission Date | CMS_0062 CMS_0075 | Encounter Performed ../../encounter/effectiveTime/low |
| Discharge Date | CMS_0060 CMS_0061 CMS_0062 CMS_0063 CMS_0076 | Encounter Performed ../../encounter/effectiveTime/high |
| Reporting Period Start Date | CMS_0063 CMS_0077 CMS_0027 | /ClinicalDocument/component/structuredBody/component/section[@templateId="2.16.840.1.113883.10.20.17.2.1"]/entry/act[@templateId="2.16.840.1.113883.10.20.17.3.8.1"]/effectiveTime/low |

| 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) | 1198-5256 | /ClinicalDocument/effectiveTime |
| effectiveTime (Applies to all effectiveTime except Admission Date, Discharge Date, and Reporting Period Start and End Date) | CMS_0087 CMS_0088 | ../effectiveTime/high ../effectiveTime/low |
| | CMS_0088 | ../effectiveTime/value ../time/value |
| CMS Program Name | CMS_0089 | /ClinicalDocument/informationRecipient/intendedRecipient/id/@extension |

6 Hybrid Measures/CCDE Submission

This section provides guidance on how to submit the encounter id associated with a core clinical data element and report result “unit” for submissions for hybrid measures.

Hybrid Measures/CCDE submissions SHALL use the CMS Program Name HQR_IQR.

The hybrid measures available for submission are listed in Table 16.

Table 16: Hybrid Measures for Submission

| eCQM CMS# | eCQM Title | Short Name | Measurement Period |
|-----------|---|------------|------------------------------------|
| CMS529v5 | Core Clinical Data Elements for the Hybrid Hospital-Wide Readmission (HWR) Measure with Claims and Electronic Health Record Data. | Hybrid HWR | July 1, 2025 through June 30, 2026 |
| CMS844v5 | Core Clinical Data Elements for the Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure (HWM) | Hybrid HWM | July 1, 2025 through June 30, 2026 |

For each core clinical data element specified in the Hybrid HWM and Hybrid HWR measures, it is recommended to report values using one of the appropriate UCUM units of measurement listed in Table 17 for result “unit”.

Table 17: Hybrid HWM and Hybrid HWR UCUM Codes

| Core Clinical Data Element | UCUM Unit – Hybrid HWM | UCUM Unit – Hybrid HWR |
|----------------------------|---|------------------------|
| Bicarbonate | meq/L mmol/L | meq/L mmol/L |
| Creatinine | mg/dL umol/L | mg/dL umol/L |
| Glucose | <i>Not applicable</i> | mg/dL mmol/L |
| Heart rate | {Beats}/min | {Beats}/min |
| Hematocrit | % | % |
| Oxygen saturation | %{Oxygen} | %{Oxygen} |
| Platelet | 10 ³ /uL 10 ⁹ /L /mm ³ | <i>Not applicable</i> |
| Potassium | <i>Not applicable</i> | meq/L mmol/L |
| Respiratory rate | <i>Not applicable</i> | {Breaths}/min |
| Sodium | meq/L mmol/L | meq/L mmol/L |
| Systolic blood pressure | mm[Hg] | mm[Hg] |

| Core Clinical Data Element | UCUM Unit – Hybrid HWM | UCUM Unit – Hybrid HWR |
|----------------------------|---|---|
| Temperature | Cel [degF] | Cel [degF] |
| Weight | <i>Not applicable</i> | kg [lb_av] g |
| White blood cell count | {Cells}/uL 10 ³ /uL 10 ⁹ /L /mm ³ | {Cells}/uL 10 ³ /uL 10 ⁹ /L /mm ³ |

APPENDIX

7 Troubleshooting and Support

7.1 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 and hybrid measures: <https://vsac.nlm.nih.gov/>
- **The ONC Project Tracking System** is a tool offered by CMS and ONC for implementers to submit issues and request guidance on measure logic, specifications, and certification: <https://oncprojecttracking.healthit.gov/>

7.2 Support

Table 18: Support Contact Information

| Contact | Org. | Phone | Email | Role | Responsibility |
|---------------------|------|--------------|--|-------------------|--|
| CCSQ Service Center | CMS | 866-288-8912 | QNetSupport@cms.hhs.gov | Help desk support | 1 st level user support & problem reporting |

7.3 Errata or Enhancement Requests

Table 19: Errata or Enhancement Request Location

| Contact | Organization | URL | Purpose |
|------------------|--------------|---|--|
| HL7 Jira Tracker | HL7 | https://jira.hl7.org | Document errors or enhancement request to the HL7 standard. Create a Jira tracker by selecting project “CDA Specification Feedback” and specification “Quality Reporting Document Architecture Category I”. |

8 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 20: 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) Coded With Equivalents (CE) | 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). |
| 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). |

9 NPI and TIN Validation Rules

Table 21: NPI Validation Rules and Table 22: TIN Validation Rules list the validation rules performed on the NPI and TIN.

Table 21: 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 22: 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. |

10 Reason Template Placement When Specifying “Not Done” with a Reason

The Processing Consideration section in Volume 1 of the HL7 QRDA I STU 5.3 provides guidance on the placement of the Reason (V3) template when specify the reason for “Not Done”.

In summary, the Reason (V3) template will be nested directly within the element containing the **negationInd** attribute. When a parent template and a child template both allow negation, then the parent template must be negated and contain the Reason (V3) template. For example, for “Medication, Not Discharged”, the parent Discharge Medication (V6) template (2.16.840.1.113883.10.20.24.3.105:2021-08-01) must have **negationInd="true"** and contain the Reason (V3) template indicating reason for negation.

The table below provides detailed guidance for the location of the Reason (V3) template for each negated QDM data element that were used by the eCQM specifications for Hospital Quality Reporting for the 2025 reporting period.

Table 23: Placement of Reason (V3) Template for Negated QDM Data Element

| Negated QDM Data Element | QRDA Template(s) | Guidance |
|----------------------------|---|--|
| <p>Device, Not Ordered</p> | <p>Device Order Act (V4) (2.16.840.1.11388.3.10.20.24.3.130:2021-08-01)</p> <p>Device Order (V6) (2.16.840.1.11388.10.20.24.3.9:2021-08-01)</p> <p>Note: Reason (V3) for not done is contained directly within the Device Order Act (V4) template</p> | <p>XPath for "Device, Not Ordered" Reason Code:</p> <pre> ./act[templateId/@root="2.16.840.1.113883.10.20.24.3.130"][templateId/@extension="2021-08-01"][@negationInd="true"]/entryRelationship[@typeCode="RSON"]/observation[templateId/@root="2.16.840.1.113883.10.20.24.3.88"][templateId/@extension="2017-08-01"]/value[@xsi:type="CD"/> </pre> <p><!-- Device Order Act (V4) --> <act classCode="ACT" moodCode="EVN" negationInd="true"> <templateId root="2.16.840.1.113883.10.20.24.3.130" extension="2021-08-01"/> <code code="SPLY" codeSystem="2.16.840.1.1.113883.5.6" displayName="Supply"/> <!-- Device Order (V6) --> <entryRelationship typeCode="SUBJ"> <supply classCode="SPLY" moodCode="RQO"> <templateId root="2.16.840.1.113883.10.20.22.4.43" extension="2014-06-09"/> <templateId root="2.16.840.1.113883.10.20.24.3.9" extension="2021-08-01"/> ... </supply> </entryRelationship> <!-- Reason(V3) for device not ordered--> <entryRelationship typeCode="RSON"> <observation classCode="OBS" moodCode="EVN"> <templateId root="2.16.840.1.113883.10.20.24.3.88" extension="2017-08-01"/> ... </observation> </entryRelationship> </act> </p> |

| Negated QDM Data Element | QRDA Template(s) | Guidance |
|------------------------------|--|---|
| Medication, Not Administered | Medication Administered (V6) (2.16.840.1.113883.10.20.24.3.42:2021-08-01) | <p>XPath for "Medication, Not Administered" Reason Code:</p> <pre> ./substanceAdministration[templateId/@root="2.16.840.1.113883.10.20.24.3.42"][templateId/@extension="2021-08-01"][@negationInd="true"]/entryRelationship[@typeCode="RSON"]/observation[templateId/@root="2.16.840.1.113883.10.20.24.3.88"][templateId/@extension="2017-08-01"]/value[@xsi:type="CD"/> </pre> <p><!-- Medication Administered (V6) --> <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="2021-08-01"/> ... <!-- Reason (V3) for medication not administered --> <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" codeSystemName="LOINC" displayName="Reason care action performed or not"/> <value xsi:type="CD" code="397745006" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" displayName="Medical contraindication (finding)"/> </observation> </entryRelationship> </substanceAdministration> </p> |

| Negated QDM Data Element | QRDA Template(s) | Guidance |
|-----------------------------------|---|---|
| <p>Medication, Not Discharged</p> | <p>Discharge Medication (V6) (2.16.840.1.113883.10.20.24.3.105:2021-08-01) Note: Reason (V3) for not done is contained directly within the Discharge Medication (V6) template</p> | <p>XPath for "Medication, Not Discharged" Reason Code: <code>../act[templateId/@root="2.16.840.1.113883.10.20.24.3.105"][templateId/@extension="2021-08-01"][@negationInd="true"]/entryRelationship[@typeCode="RSON"]/observation[templateId/@root="2.16.840.1.113883.10.20.24.3.88"][templateId/@extension="2017-08-01"]/value[@xsi:type="CD"]/</code></p> <p><!-- Discharge Medication (V6) --> <code><act classCode="ACT" moodCode="RQO" negationInd="true"> <templateId root="2.16.840.1.113883.10.20.24.3.105" extension="2021-08-01"/> <code code="75311-1" codeSystem="2.16.840.1.1.113883.6.1" displayName="Discharge medications"/> <!-- Medication Activity (V2) --> <entryRelationship typeCode="SUBJ"> <substanceAdministration classCode="SBADM" moodCode="EVN"> <templateId root="2.16.840.1.113883.10.20.22.4.16" extension="2014-06-09"/> <id root="f8a9729a-ba09-4dc6-a430-bde2c6137d3c"/> ... </substanceAdministration > </entryRelationship> <!-- Reason (V3) for medication not discharged --> <entryRelationship typeCode="RSON"> <observation classCode="OBS" moodCode="EVN"> <templateId root="2.16.840.1.113883.10.20.24.3.88" extension="2017-08-01"/> ... </observation> </entryRelationship> </act></code></p> |

| Negated QDM Data Element | QRDA Template(s) | Guidance |
|--------------------------|---|---|
| Medication, Not Ordered | Medication Order (V7) (2.16.840.1.113883.10.20.24.3.47:2021-08-01) | <p>XPath for "Medication, Not Ordered" Reason Code:</p> <pre> ./substanceAdministration [templateId/@root="2.16.840.1.113883.10.20.24.3.47"] [templateId/@extension="2021-08-01"] [@negationInd="true"]/entryRelationship [@typeCode="RSON"]/observation [templateId/@root="2.16.840.1.113883.10.20.24.3.88"] [templateId/@extension="2017-08-01"] /value[@xsi:type="CD"]/ </pre> <p><!-- Medication Order (V7) --> <substanceAdministration classCode="SBADM" moodCode="RQO" negationInd="true"> <templateId root="2.16.840.1.113883.10.20.22.4.42" extension="2014-06-09"/> <templateId root="2.16.840.1.113883.10.20.24.3.47" extension="2021-08-01"/> <!-- Reason (V3) for medication not ordered --> <entryRelationship typeCode="RSON"> <observation classCode="OBS" moodCode="EVN"> <templateId root="2.16.840.1.113883.10.20.24.3.88" extension="2017-08-01"/> ... </observation> </entryRelationship> </substanceAdministration> </p> |

| Negated QDM Data Element | QRDA Template(s) | Guidance |
|---------------------------------|--|---|
| <p>Procedure, Not Performed</p> | <p>Procedure Performed (V7) (2.16.840.1.113883.10.20.24.3.64:2021-08-01)</p> | <p>XPath for "Procedure, Not Performed" Reason Code:</p> <pre> ./procedure [templateId/@root="2.16.840.1.113883.10.20.24.3.64"][templateId/@extension="2021-08-01"][@negationInd="true"]/entryRelationship[@typeCode="RSON"]/observation[templateId/@root="2.16.840.1.113883.10.20.24.3.88"][templateId/@extension="2017-08-01"]/value[@xsi:type="CD"]/ </pre> <p><!-- Procedure Performed (V7)--> <procedure classCode="PROC" moodCode="EVN" negationInd="true"> <templateId root="2.16.840.1.113883.10.20.22.4.14" extension="2014-06-09"/> <templateId root="2.16.840.1.113883.10.20.24.3.64" extension="2021-08-01"/> <!-- Reason (V3) for procedure not performed --> <entryRelationship typeCode="RSON"> <observation classCode="OBS" moodCode="EVN"> <templateId root="2.16.840.1.113883.10.20.24.3.88" extension="2017-08-01"/> ... </observation> </entryRelationship> </procedure></p> |

11 Ensuring Data Uniqueness

The presence of duplicated data in a QRDA I file not only could potentially lead to increased data processing time, but most importantly, might cause incorrect processing and therefore produce unexpected measure results when calculated by other entities. The Processing Consideration section in Volume 1 of the HL7 QRDA I STU 5.3 provides guidance for ensuring data uniqueness in a QRDA I file. Submitted QRDA I files for HQR in the 2025 reporting period should follow the ensuring data uniqueness guidance specified in the base standard.

- Each reported QDM data element contains all of the attributes (e.g., discharge status, facility location, etc.) required by all measures, which are reported in the file, in the same QRDA template for the same instance.
- Not to duplicate QDM data element by including `sdtc:valueSet`. (Note that `sdtc:valueSet` is still required for Not Done events where attribute `negationInd="true"` and should only be used when submitting a Not Done event.)

Table 24 lists the key elements for determining data uniqueness.

Table 24: Key Elements for Determining Data Uniqueness

| QDM Data Type | Key Elements |
|-----------------------------|--|
| Data types except Encounter | <p>Precondition: same QRDA template</p> <ul style="list-style-type: none"> • Id element—combination of <code>@root</code> and <code>@extension</code> (if <code>@extension</code> is present) <ul style="list-style-type: none"> ◦ <code>act/id</code> ◦ <code>observation/id</code> ◦ <code>procedure/id</code> ◦ <code>substanceAdministration/id</code> ◦ <code>supply/id</code> |
| Encounter, Performed | <p>Precondition: same QRDA template</p> <ul style="list-style-type: none"> • Encounter id element (<code>encounter/id</code>)— combination of <code>@root</code> and <code>@extension</code> (if <code>@extension</code> is present) • Encounter code (<code>encounter/code</code>) • Admission date time (<code>encounter/effectiveTime/low</code>) • Discharge date time (<code>encounter/effectiveTime/high</code>) <p>Each episode of care (EOC) shall have one unique inpatient encounter id and if there are other types of encounters present (e.g., ED) during the same episode of care, they shall have their own unique encounter ids. If there is data for multiple episodes of care within the same QRDA Category I file, then each episode of care shall have its own unique inpatient encounter id. Should there be another reference to an encounter/EOC in a QRDA Category I file, then users should reference the previously reported encounter id of that inpatient encounter instance or EOC.</p> |

12 CMS QRDA I Implementation Guide Changes to QRDA I STU 5.3 Base Standard

This table lists all changes made to the base HL7 QRDA I STU 5.3 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 5.3* and any subsequent errata update.

Table 25: Changes Made to the QRDA I STU 5.3 Base Standard

| CONF. # | Section | Base Standard | Changed To |
|----------------------------------|---------|--|--|
| n/a | 5.1.1 | n/a | Conforms to QDM-Based QRDA (V8) template (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.1.2:2021-08-01). |
| CMS_0001 CMS_0002 CMS_0003 | 5.1.1 | n/a | 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="2022-02-01" (CONF:CMS_0003). |
| CMS_0010 | 5.1.1 | n/a | This languageCode SHALL contain exactly one [1..1] @code="en" (CONF:CMS_0010). |
| 4509-16857_C01 | 5.1.2 | This patientRole MAY contain zero or one [0..1] id (CONF:4509-16857) such that it SHALL contain exactly one [1..1] @root="2.16.840.1.113883.4.572" Medicare HIC number (CONF:4509-16858). | This patientRole SHOULD contain zero or one [0..1] id (CONF:4509-16857_C01) such that it SHALL contain exactly one [1..1] @root="2.16.840.1.113883.4.572" Medicare HIC number (CONF:4509-16858). |

| CONF. # | Section | Base Standard | Changed To |
|----------------------------------|---------|---|--|
| CMS_0009 CMS_0053 CMS_0103 | 5.1.2 | n/a | <p>This patientRole SHALL contain exactly one [1..1] id (CONF:CMS_0009) such that it</p> <p>SHALL contain exactly one [1..1] @root (CONF:CMS_0053). Note: This is the provider's organization OID or other non-null value different from the OID for the Medicare HIC Number (2.16.840.1.113883.4.572) and the OID for the Medicare Beneficiary Identifier (2.16.840.1.113883.4.927).</p> <p>SHALL contain exactly one [1..1] @extension (CONF:CMS_0103). Note: The value of @extension is the Patient ID.</p> |
| 4509-28697_C01 | 5.1.2 | <p>This patientRole MAY contain zero or one [0..1] id (CONF:4509-28697) such that it</p> <p>SHALL contain exactly one [1..1] @root="2.16.840.1.113883.4.927" Medicare Beneficiary Identifier (MBI) (CONF:4509-28698).</p> | <p>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.</p> <p>This patientRole SHOULD contain zero or one [0..1] id (CONF:4509-28697_C01) such that it</p> <p>SHALL contain exactly one [1..1] @root="2.16.840.1.113883.4.927" Medicare Beneficiary Identifier (MBI) (CONF:4509-28698).</p> |
| CMS_0130 CMS_0131 CMS_0132 | 5.1.2 | n/a | <p>This patientRole SHOULD contain zero or more [0..*] telecom (CONF:CMS_0130) such that it</p> <p>SHALL contain exactly one [1..1] @value (CONF:CMS_0131).</p> <p>This value SHALL begin with "mailto:" which is the email address of the patient (CONF:CMS_0132).</p> |
| CMS_0133 CMS_0134 CMS_0135 | 5.1.2 | n/a | <p>This patientRole SHOULD contain zero or more [0..*] telecom (CONF:CMS_0133) such that it</p> <p>SHALL contain exactly one [1..1] @value (CONF:CMS_0134).</p> <p>This value SHALL begin with "tel:" which is the telephone of the patient (CONF:CMS_0135).</p> |

| CONF. # | Section | Base Standard | Changed To |
|----------------------------------|---------|---|---|
| 1198-5284_C01 | 5.1.2 | This patient SHALL contain at least one [1..*] US Realm Person Name (PN.US.FIELDDED) (identifier: urn:oid:2.16.840.1.113883.10.20.22.5.1.1) (CONF:1198-5284). | This patient SHALL contain exactly one [1..1] US Realm Person Name (PN.US.FIELDDED) (identifier: urn:oid:2.16.840.1.113883.10.20.22.5.1.1) (CONF:1198-5284_C01). |
| 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:1198-5298). 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:1198-5298). 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:2.16.840.1.114222.4.1.1.836 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). |

| CONF. # | Section | Base Standard | Changed To |
|----------------------|---------|--|---|
| CMS_0014 | 5.1.2 | This patient MAY contain zero or more [0..*] sdct: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..*] sdct:raceCode , which SHALL be selected from ValueSet Race urn:oid:2.16.840.1.114222.4.1.1.836 DYNAMIC (CONF:CMS_0014). Note: If a patient has more than one race category, one race is reported in raceCode, and additional races are reported using sdct: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:2.16.840.1.114222.4.1.11.837 DYNAMIC (CONF:1198-5323). | This patient SHALL contain exactly one [1..1] ethnicGroupCode , which SHALL be selected from ValueSet Ethnicity urn:oid:2.16.840.1.114222.4.1.1.837 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). |
| 4509-28241_C01 | 5.1.3 | This representedCustodianOrganization SHOULD contain zero or one [0..1] id (CONF:4509-28241) such that it SHALL contain exactly one [1..1] @root="2.16.840.1.113883.4.336" CMS Certification Number (CONF:4509-28244). | This representedCustodianOrganization SHALL contain exactly one [1..1] id (CONF:4509-28241_C01) such that it SHALL contain exactly one [1..1] @root="2.16.840.1.113883.4.336" CMS Certification Number (CONF:4509-28244). |
| CMS_0035 | 5.1.3 | n/a | CCN SHALL be six to ten characters in length (CONF:CMS_0035). |
| 4509-16703_C01 | 5.1.4 | MAY contain zero or more [0..*] informationRecipient (CONF:4509-16703). | SHALL contain exactly one [1..1] informationRecipient (CONF:4509-16703_C01). |

| CONF. # | Section | Base Standard | Changed To |
|--|---------|--|--|
| 4509-16705_C01 CMS_0025 CMS_0026 | 5.1.4 | This intendedRecipient SHALL contain at least one [1..*] id (CONF:4509-16705). | This intendedRecipient SHALL contain exactly one [1..1] id (CONF:4509-16705_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 2022-02-01 (CONF:CMS_0026). Note: The value of @extension is CMS Program Name. |
| 1198-10003_C01 CMS_0004 CMS_0005 CMS_0006 CMS_0008 | 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). 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 This id SHALL contain exactly one [1..1] @root ="2.16.840.1.113883.3.2074.1" CMS EHR Certification ID (CONF:CMS_0006). This id SHALL contain exactly one [1..1] @extension (CONF:CMS_0008). Note: The value of @extension is the CMS EHR Certification ID. |
| CMS_0056 CMS_0054 | 5.1.6 | n/a | This structuredBody SHALL contain exactly one [1..1] component (CONF:CMS_0056) such that it 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). |

| CONF. # | Section | Base Standard | Changed To |
|---|----------------|---------------|---|
| <p>CMS_0057 CMS_0055</p> | <p>5.1.6</p> | <p>n/a</p> | <p>This structuredBody SHALL contain exactly one [1..1] component (CONF:CMS_0057) such that it</p> <p>SHALL contain exactly one [1..1] Patient Data Section QDM (V8) - CMS (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.2.1.1:2022-02-01) (CONF:CMS_0055).</p> |
| <p>CMS_0040 CMS_0041 CMS_0042 CMS_0023 CMS_0024</p> | <p>5.2.2</p> | <p>n/a</p> | <p>Conforms to Reporting Parameters Section template (identifier: urn:oid:2.16.840.1.113883.10.20.17.2.1).</p> <p>SHALL contain exactly one [1..1] templateId (CONF:CMS_0040) such that it</p> <p>SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.17.2.1.1" (CONF:CMS_0041).</p> <p>SHALL contain exactly one [1..1] @extension="2016-03-01" (CONF:CMS_0042).</p> <p>SHALL contain exactly one [1..1] entry (CONF:CMS_0023) such that it</p> <p>SHALL contain exactly one [1..1] Reporting Parameters Act - CMS (identifier: urn:hl7ii:2.16.840.1.113883.10.20.17.3.8.1:2016-03-01) (CONF:CMS_0024).</p> |
| <p>CMS_0044 CMS_0045 CMS_0046</p> | <p>5.2.2.1</p> | <p>n/a</p> | <p>Conforms to Reporting Parameters Act template (identifier: urn:oid:2.16.840.1.113883.10.20.17.3.8).</p> <p>SHALL contain exactly one [1..1] templateId (CONF:CMS_0044) such that it</p> <p>SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.17.3.8" (CONF:CMS_0045).</p> <p>SHALL contain exactly one [1..1] @extension="2016-03-01" (CONF:CMS_0046).</p> |

| CONF. # | Section | Base Standard | Changed To |
|--|----------------|--|---|
| <p>CMS_0048 CMS_0027 CMS_0050 CMS_0028</p> | <p>5.2.2.1</p> | <p>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).</p> | <p>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)</p> |
| <p>CMS_0036 CMS_0037 CMS_0038</p> | <p>5.2.3</p> | <p>n/a</p> | <p>Conforms to Patient Data Section QDM (V8) template (identifier: urn:h17ii:2.16.840.1.113883.10.20.24.2.1:2021-08-01) . 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="2022-02-01" (CONF:CMS_0038).</p> |
| <p>CMS_0051 CMS_0039</p> | <p>5.2.3</p> | <p>n/a</p> | <p>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).</p> |
| <p>4509-14430_C01</p> | <p>5.2.3</p> | <p>MAY contain zero or more [0..*] entry (CONF:4509-14430) such that it</p> | <p>SHALL contain at least one [1..*] entry (CONF:4509-14430_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:4509_14431).</p> |

13 Change Log for 2025 CMS QRDA I Implementation Guide from the 2024 CMS QRDA Implementation Guide

Table 26 summarizes the changes made in this 2025 CMS QRDA I Implementation Guide since the release of 2024 CMS QRDA I Implementation Guide.

Table 26: Changes Made for 2025 CMS QRDA I IG from 2024 CMS QRDA I IG

| Section Heading | 2025 CMS QRDA I IG (DRAFT) | 2024 CMS QRDA I IG (Version 1.1) |
|--------------------------------|--|--|
| Base Standard | No change to the base standard. HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture Category I, Release 1, Standard for Trial Use (STU) Release 5.3, US Realm, and any subsequent errata update. | HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture Category I, Release 1, Standard for Trial Use (STU) Release 5.3, US Realm, and any subsequent errata update. |
| Overall Formatting | Removed the Data Type column from all Constrains Overview tables | Constrains Overview tables |
| 1 Introduction | Updated to 2025 reporting period. | 2024 reporting year. |
| 3 Overview | Updated to 2025 reporting period. | 2024 reporting year. |
| 3.1 Background | This guide describes additional conformance statements and constraints for EHR data submissions that are required for reporting to CMS for the Hospital Inpatient Quality Reporting Program, Hospital Outpatient Program, and the Medicare Promoting Interoperability pertaining to the Program 2025 reporting period. | This guide describes additional conformance statements and constraints for EHR data submissions that are required for reporting to CMS for the Hospital Inpatient Quality Reporting Program, Hospital Outpatient Program, and the Medicare Promoting Interoperability Program 2024 reporting period. |
| 4 QRDA Category I Requirements | Updated to reference the 2025 reporting period throughout. No changes to the requirements. | Section 4 |

| Section Heading | 2025 CMS QRDA I IG (DRAFT) | 2024 CMS QRDA I IG (Version 1.1) |
|--|---|--|
| 4.2 eCQM, Hybrid Measure, and Value Set Specifications | <p>The eCQM Value Sets for Hospital Quality Reporting May 2024, and any applicable addenda, published at the Value Set Authority Center (VSAC) must be used for HQR programs for the 2025 reporting period.</p> <p>For hybrid measures/core clinical data element (CCDE) submission, this guide must be used for reporting of 2025 – 2026 data (measurement period July 1, 2025 through June 30, 2026) and be submitted in 2026. The 2025 reporting period hybrid measure specifications must be used.</p> <p>Updated the footnote 7.</p> | <p>The eCQM Value Sets for eligible hospitals May 2023, and any applicable addenda, published at the Value Set Authority Center (VSAC) must be used for HQR programs for the 2024 reporting period.</p> <p>For hybrid measures/core clinical data element (CCDE) submission, this guide must be used for reporting of 2024 – 2025 data (measurement period July 1, 2024 through June 30, 2025) and be submitted in 2025. The 2024 reporting period hybrid measure specifications must be used.</p> |
| 5.1.4 recordTarget | <p>Medicare Health Insurance Claim (HIC) Number (HICN) is not required for HQR but should be submitted if the payer is Medicare and the patient has an HIC number assigned.</p> <p>Added “Note that HICN is not required for hybrid measure submissions”</p> | <p>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.</p> |
| 5.1.4 recordTarget | <p>Added “Note that for hybrid measures, the patient’s MBI must be submitted.”</p> | <p>n/a</p> |
| 5.1.4 informationRecipient | <p>Table 6: QRDA I CMS Program Name</p> <p>Updated the print name for HQR_PI, HQR_PI_IQR, and HQR_OQR</p> <p>HQR_PI: Hospital Quality Reporting for the Medicare Promoting Interoperability Program</p> <p>HQR_PI_IQR: Hospital Quality Reporting for the Medicare Promoting Interoperability Program and the Inpatient Quality Reporting Program</p> <p>HQR_OQR: Hospital Quality Reporting for the Outpatient Quality Reporting Program</p> | <p>Table 6: QRDA I CMS Program Name</p> <p>HQR_PI: Hospital Quality Reporting for the Promoting Interoperability Program</p> <p>HQR_PI_IQR: Hospital Quality Reporting for the Promoting Interoperability Program and the Inpatient Quality Reporting Program</p> <p>HQR_OQR: Hospital Outpatient Quality Reporting Program</p> |
| 5.2.1 Measure Section | <p>Figure 9: Measure Section Example (Will be updated to use a 2025 reporting period eCQM version specific UUID as an example when available).</p> | <p>Figure 10: Measure Section Example Example used is a 2024 reporting period eCQM version specific UUID.</p> |

| Section Heading | 2025 CMS QRDA I IG (DRAFT) | 2024 CMS QRDA I IG (Version 1.1) |
|--|--|--|
| 5.2.2.1 Reporting Parameters Act – CMS | <p>Figure 10: Reporting Parameters Section – CMS and Reporting Parameters Act – CMS Example</p> <p>Updated the example reporting period to 01 Jan 2025 – 31 March 2025</p> | <p>Figure 10: Reporting Parameters Section – CMS and Reporting Parameters Act – CMS Example</p> <p>Updated the example reporting period to 01 Jan 2024 – 31 March 2024</p> |
| 5.2.3.3 Reporting “result as type” | (Will be updated to use CMS334v6 as example when available) | Used CMS334v5 as example |
| 5.2.3 Patient Data Section (V8) - CMS | <p>Figure 11: Patient Data Section QDM (V8) – CMS Example</p> <p>Updated the example effectiveTime value</p> | Figure 11: Patient Data Section QDM (V8) – CMS Example |
| 5.3.2 Other HQR Validations | <p>Updated to reference the 2025 Reporting Period in the error description of CMS_0070</p> <p>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 2025 Reporting Period is yet to be finalized, this message is returned.</p> | <p>CMS_0070</p> <p>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 2024 Reporting Period is yet to be finalized, this message is returned.</p> |
| 5.3.2 Other HQR Validations | <p>Updated the error description of CMS_0082</p> <p>The EHR system needs to be certified to 2015 Edition Cures Update for CY2025. The CMS EHR Certification ID must contain “15C” in the third, fourth, and fifth places.</p> | <p>CMS_0082</p> <p>The EHR system needs to be certified to 2015 Edition Cures Update for CY2024/PY2026. The CMS EHR Certification ID must contain “15C” in the third, fourth, and fifth places.</p> |
| 5.3.2 Other HQR Validations | <p>Updated CMS_0084.</p> <p>Validation performed:</p> <p>The Patient MBI is required for hybrid measure/Core Clinical Data Elements (CCDE) submissions.</p> <p>Description of error message:</p> <p>QRDA files for hybrid measure/CCDE submissions must contain a MBI.</p> | <p>CMS_0084</p> <p>Validation performed:</p> <p>Either the Patient HICN or MBI is required for hybrid measure/Core Clinical Data Elements (CCDE) submissions.</p> <p>Description of error message:</p> <p>QRDA files for hybrid measure/CCDE submissions must contain a HICN or MBI.</p> |

| Section Heading | 2025 CMS QRDA I IG (DRAFT) | 2024 CMS QRDA I IG (Version 1.1) |
|-----------------------------------|---|--|
| 5.3.2 Other HQR Validations | <p>Corrected typo in CMS_0089 error description: HQR_IQR_PI should be HQR_PI_IQR</p> <p>CMS program name for inpatient Hybrid measures/CCDE submissions must be HQR_IQR. CMS program name for inpatient eCQM submissions must be HQR_IQR, HQR_PI_IQR or HQR_PI. CMS program name for outpatient eCQM submissions must be HQR_OQR.</p> | <p>CMS_0089</p> <p>CMS program name for inpatient Hybrid measures/CCDE submissions must be HQR_IQR. CMS program name for inpatient eCQM submissions must be HQR_IQR, HQR_IQR_PI or HQR_PI. CMS program name for outpatient eCQM submissions must be HQR_OQR.</p> |
| 6 Hybrid Measures/CCDE Submission | <p>Removed 6.1 Submitting the encounter id associated with a CCDE section, including the figure (Figure 13) and the table (Table 17) in that section.</p> <p>The content of reporting result “unit” for hybrid measures is directly under the heading 6. Hybrid Measures/CCDE Submission.</p> <p>Previous Table 18 is renumbered to Table 17. All subsequent tables are renumbered accordingly.</p> | <p>6.1 Submitting the encounter id associated with a CCDE</p> <p>Figure 13. Encounter Performed Example</p> <p>Table 17. Associating an Existing Encounter Id with a Core Clinical Data Element</p> <p>6.2 Reporting Result “unit” for Hybrid Measures</p> |
| 6 Hybrid Measures/CCDE Submission | <p>Table 16. Hybrid Measures for Submission</p> <p>Updated the eCQM version number</p> <p>Updated the measurement period to July 1, 2025 through June 30, 2026</p> | <p>Table 16. Hybrid Measures for Submission</p> <p>Measurement Period: July 1, 2024 through June 30, 2026</p> |

| Section Heading | 2025 CMS QRDA I IG (DRAFT) | 2024 CMS QRDA I IG (Version 1.1) |
|---------------------|--|---|
| <p>15. Glossary</p> | <p>Updated to use the definition from the eCQI Resource Center.</p> <p>An electronic clinical quality measure (eCQM) is a measure specified in a standard electronic format that uses data electronically extracted from electronic health records (EHR) and/or health information technology (IT) systems to measure the quality of health care provided.</p> | <p>An electronic clinical quality measure (eCQM) is a clinical quality measure that is expressed and formatted to use data from electronic health records (EHR) and/or health information technology systems to measure healthcare quality, specifically data captured in structured form during the process of patient care. So they can be reported from an EHR, the Health Quality Measure Format (HQMF) is used to format the eCQM content using the Quality Data Model (QDM) to define the data elements and Clinical Quality Language (CQL) to express the logic needed to evaluate a provider or organization’s performance.</p> |

14 Acronyms

The table below contains acronyms used in this guide.

Table 27: Acronyms

| Acronym | Literal Translation |
|---------|---|
| ASKU | Asked, but not known |
| CCDE | Core Clinical Data Element |
| CCN | CMS Certification Number |
| CCSQ | Center for Clinical Standards & Quality |
| CDA | Clinical Document Architecture |
| CMS | Centers for Medicare & Medicaid Services |
| CONF | conformance |
| 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 |
| HICN | Health Insurance Claim (HIC) Number |
| HL7 | Health Level Seven |
| HL7 V3 | Health Level 7 Version 3 |
| HWM | Core Clinical Data Elements for the Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure (HWM) |
| HWR | Core Clinical Data Elements for the Hybrid Hospital-Wide Readmission (HWR) Measure with Claims and Electronic Health Record Data |
| HQMF | Health Quality Measure Format |
| HQR | Hospital Quality Reporting |
| ID | identifier |
| IQR | Inpatient Quality Reporting |
| IT | Information technology |

| Acronym | Literal Translation |
|---------|--|
| 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 |
| PI | Promoting Interoperability |
| QDM | Quality Data Model |
| QRDA | Quality Reporting Document Architecture |
| QRDA I | Quality Reporting Document Architecture Category I |
| TIN | Tax Identification Number |
| UCUM | Unified Code for Units of Measure |
| UNK | Unknown |
| UTC | Coordinated Universal Time |
| VSAC | Value Set Authority Center |
| XML | Extensible Markup Language |

15 Glossary

| Term | Definition |
|--|---|
| Electronic health record (EHR) | Electronic Health Record (EHR) is also known as the electronic patient record, electronic medical record, or computerized patient record. As defined by Healthcare Information Management and Systems Society, “the electronic health record (EHR) is a longitudinal electronic record of patient health information generated by one or more encounters in any care delivery setting. Included in this information are patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data, and imaging reports.” |
| Electronic Clinical Quality Measure (eCQM) | An electronic clinical quality measure (eCQM) is a measure specified in a standard electronic format that uses data electronically extracted from electronic health records (EHR) and/or health information technology (IT) systems to measure the quality of health care provided. |
| Hybrid measure | A hybrid measure is a quality measure that uses more than one source of data for measure calculation. Current hybrid measures use claims data and electronic clinical data from EHRs to calculate measure results. |
| 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. |

16 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 5.3 (QRDA I STU 5.3), and subsequent errata update. http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35

HL7 Clinical Document Architecture (CDA) Release 2.0 Normative Edition.
https://www.hl7.org/implement/standards/product_brief.cfm?product_id=496

HL7 Jira Tracker system. <https://jira.hl7.org>

ONC, Project Tracking System. <https://oncprojecttracking.healthit.gov/>

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