Centers for Medicare & Medicaid Services

CMS Eligible Professionals Programs Quality Reporting Document Architecture Category III, Release 1

Implementation Guide for 2014 Volume 1 – Introductory Material

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1. Introduction

1.1 Organization of This Guide

This document is the first of two volumes of an implementation guide for CMS Eligible Professionals (EP) Programs to the HL7 CDA Release 2: QRDA Category III (QRDA-III), DSTU Release 1.

- Volume 1: Introductory Material — provides narrative explanations of QRDA-III as well as other important submission information for CMS EP programs
    - Chapter 1 — Introduction.
    - Chapter 2 — Submission Rules. This chapter includes guidelines for submissions under the Comprehensive Primary Care (CPC) Initiative, the Electronic Health Record (EHR) Incentive Program (Meaningful Use), and the Physician Quality Reporting System (PQRS) Program.
    - Chapter 3 — Business Rules. This chapter describes the formal representation of templates and additional information necessary to understand and correctly implement the content found in Volume 2 of this guide.
    - Chapter 4 — Troubleshooting and Support. This chapter lists additional information and where to go for support.
- Volume 2: Templates and Supporting Materials — includes the formal template definitions and submission criteria (business rules)
    - Chapter 1 — Document-Level Template. This chapter defines the QRDA Category III CMS EP Report template that defines the document type and header constraints specific to CMS EP program reporting.
    - Chapter 2 — Section-Level Templates. This chapter defines the section templates referenced within the QRDA Category III CMS EP Report document.
    - Chapter 3 — Entry-Level Templates. This chapter defines entry-level templates, called clinical statements. Machine-processable (coded) data are sent in the entry templates.
    - Chapter 4, 5, and 6 — These chapters provide summary information, including template IDs and value sets used in this guide.

Templates defined in this implementation guide are conformant with the *HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture – Category III, DSTU Release 1.* CMS EP Programs QRDA-III templates address aggregate reporting requirements for:

- Comprehensive Primary Care (CPC) initiative
- Electronic Health Record (EHR) Incentive program (Meaningful Use)
- Physician Quality Reporting System (PQRS)

This implementation guide describes CMS EP Programs reporting requirements using QRDA-III for the 2014 Reporting Year.

1.2 Background

A Clinical Quality Measure (CQM) is a mechanism for a user to quantify the quality of a selected aspect of care by comparing it to a criterion. A subtype of a quality measure is a clinical performance measure. A clinical performance measure is a mechanism for assessing the degree to which a provider competently and safely delivers clinical services that are appropriate for the patient in the optimal time period.

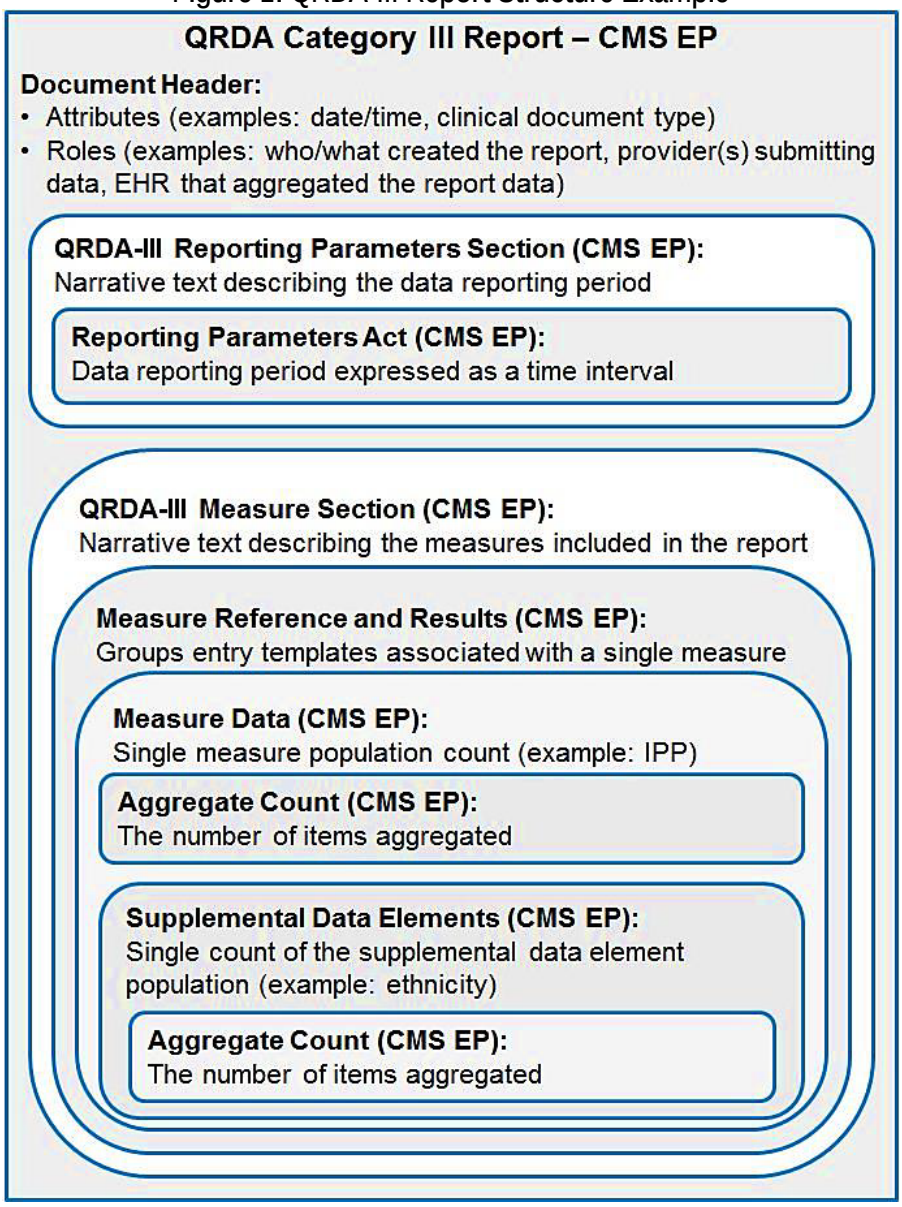
CQMs have three purposes:

- Quality improvement
- Accountability
- Research

Without the ability to accurately communicate the data in these quality measures to external agencies, the benefit of collecting the information is limited. This *CMS EP Programs QRDA-III Implementation Guide* standardizes the representation of measure-defined data elements for interoperability between stakeholder organizations.

A QRDA-III report is an aggregate quality report using data collected in patient-level QRDA-I reports. Each QRDA-III report contains calculated summary data for one or more measures for a specified population of patients within a particular health system over a specific period of time. Summary data in the QRDA-III report are defined in the HL7 Health Quality Measures Format (HQMF), which standardizes the representation of a health quality measure as an electronic document. The structure of a QRDA-III report is depicted in Figure 1.

Figure 1: QRDA-III Report Structure Example



2. Submission Rules

CMS will process CQM QRDA-III documents originating from EHR systems. Submitted QRDA-III documents for EPs in 2014 must meet the conformance statements specified in Volume 2 of this implementation guide.

2.1 Comprehensive Primary Care (CPC) Initiative Submissions

CPC QRDA-III submissions for the 2014 Measurement Year must contain all data for all measures recorded by a CPC practice site. Each CPC practice site is a single, physical (brick and mortar) location. The measures included in 2014 CPC QRDA-III submissions are the June 2013 versions of Meaningful Use (MU) EP CQMs and are a subset of the 64 MU EP CQMs outlined for reporting as part of the CMS EHR Incentive Program.

For CPC measures, the CQM population is inclusive of all patients seen at the CPC practice site location as follows:

1) If the CPC practice site is a solo-practitioner site, the CQM population includes all patients who had one or more visits at the CPC practice site in the Measurement Year and who meet the initial patient population criteria of the CQM.
2) If the CPC practice site includes multiple practitioners, the CQM population must include all patients who had one or more visits at the CPC practice site in the Measurement Year and who meet the initial patient population criteria of the CQM.
3) If the CPC practice site is part of a larger group practice that includes non-CPC practitioners, the CQM population of the CPC practice site must include all patients who had one or more visits at the CPC practice site **only.**
    a) The aggregate numbers must be a representation of those patients seen at the CPC practice site only.
        i) If the patient was seen at both a CPC practice site and a non-participating practice site within the same larger group practice, the aggregate CQM report for the CPC practice site includes this patient if the patient had one or more visits in the Measurement Year at the CPC practice site and who meets the initial patient population criteria for the measure.
        ii) If a patient is only seen at a non-participating practice site, but the data reside within the larger group practice's certified EHR, the patient is excluded from any CPC practice aggregate CQM report.
    b) Note that CPC practice sites on a shared EHR system with a non-CPC practice site may count quality criteria that were performed at the non-CPC practice site if the data are contained within the CPC practice site's certified EHR and the patient had one or more visits in the Measurement Year at the CPC practice site and meets the initial patient population criteria for the measure.
4) For CPC reporting, the **same TIN** (Tax Identification Number) has to be reported for all of the National Provider Identification (NPI) numbers listed for the CPC practice site. This TIN will be used for the PQRS aligned reporting option if the PQRS waiver is selected by the CPC practice site.
5) CPC practice sites are required to submit 12 months of data for all measures.

The measurement period for the CPC program begins on January 1, 2014 and ends on December 31, 2014. Data collected during the measurement period should be submitted from January 1, 2015 through February 28, 2015.

2.1.1 Summary of Measures for CPC Reporting

Table 1 lists the required CPC CQMs for Program Year 2014 as of 04/18/2014.

The CPC EHR CQM User Manual found under the Vendor Information section at http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/EducationalMaterials.html will be updated in the near future to reflect changes for Program Year 2014 EHR CQM requirements. Please check back frequently to see if the 2014 CPC EHR User Manual has been published. CPC practices will receive this manual in May/June 2014.

Table 1: CPC CQMs for Program Year 2014

NQF	CMS ID	Version	Measure	Version Specific ID	Version Neutral ID
0018	165	2	Controlling High Blood Pressure	40280381-3d61-56a7-013e-66bc02da4dee	abdc37cc-bac6-4156-9b91-d1be2c8b7268
0028	138	2	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	40280381-3d61-56a7-013e-5cd94a4d64fa	e35791df-5b25-41bb-b260-673337bc44a8
0031	125	2	Breast Cancer Screening	40280381-3d61-56a7-013e-66a5a5834990	19783c1b-4fd1-46c1-8a96-a2f192b97ee0
0034	130	2	Colorectal Cancer Screening	40280381-3d61-56a7-013e-5bff718b5a57	aa2a4bbc-864f-45ee-b17a-7ebcc62e6aac
0041	147	2	Preventive Care and Screening: Influenza Immunization	40280381-3d61-56a7-013e-57f49972361a	a244aa29-7d11-4616-888a-86e376bfcc6f
0059	122	2	Diabetes: Hemoglobin A1c Poor Control	40280381-3d61-56a7-013e-62240559256d	f2986519-5a4e-4149-a8f2-af0a1dc7f6bc
0064	163	2	Diabetes: Low Density Lipoprotein (LDL) Management	40280381-3d61-56a7-013e-5d5b19bf6dfb	0dac1dec-e011-493b-a281-7c28964872dd
0075	182	3	Ischemic Vascular Disease (IVD): Complete Lipid Panel and LDL Control	40280381-3f77-75c9-013f-7b481cea02fd	500e4792-7f94-4e34-8546-ee71c56fe463

NQF	CMS ID	Version	Measure	Version Specific ID	Version Neutral ID
0083	144	2	Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)	40280381-3d61-56a7-013e-666032b244f7	8439f671-2932-4d4c-88ca-ea5faeacc89a
0101	139	2	Falls: Screening for Future Fall Risk	40280381-3d61-56a7-013e-62684f542b66	bc5b4a57-b964-4399-9d40-667c896f31ea
0418	2	3	Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan	40280381-3e93-d1af-013e-9f642782222a	9a031e24-3d9b-11e1-8634-00237d5bf174

2.2 EHR Incentive Program (Meaningful Use) Submissions

EHR Incentive Program submissions must contain nine of the 64 EP CQMs outlined for reporting as part of the EHR Incentive Program (Meaningful Use). The nine CQMs selected for submission must cover at least three of the six National Quality Strategy domains. QRDA-III submissions for the EHR Incentive Program will contain June 2013 versions of EP CQMs. However, if reporting on National Quality Forum (NQF) 0387/CMS 140 EP CQM, the December 2012 version is used.

The EHR Incentive Program CQM populations include all patients seen by the EP during the reporting period, which is one full year (January 1, 2014 – December 31, 2014) or a calendar quarter within the calendar year (i.e., January 1, 2014 – March 31, 2014). EPs who are in their first year of participation in the EHR Incentive Program can also use any 90-day period within the calendar year 2014 as the data reporting period. Data collected during the reporting period may then be submitted January 1, 2015 through February 28, 2015. Please note that EPs who are in their first year of participation in the EHR Incentive Program must submit their CQMs via attestation by October 1, 2014 in order to avoid the EHR Incentive Program payment adjustment.

2.3 Physician Quality Reporting System (PQRS) Submissions

PQRS QRDA-III submissions must contain nine of the 64 EP CQMs outlined for reporting as part of the EHR Incentive Program (Meaningful Use). The nine CQMs selected for submission must cover at least three of the six National Quality Strategy domains. QRDA-III submissions for PQRS reporting programs will contain June 2013 versions of EP CQMs. However, if reporting on National Quality Forum (NQF) 0387/CMS 140 EP CQM, the December 2012 version is used.

For PQRS Group Practice Reporting Option (GPRO) QRDA-III submissions, a "group practice" consists of a physician group practice defined by a single TIN with two or more individual EPs

who have reassigned billing rights to the TIN. If the EP also reports through a different TIN that is not participating as a GRPO, then the EP may report individually through that alternate TIN.

The PQRS CQM populations include all Medicare patients seen by the EP during the reporting period, which begins on January 1, 2014 and ends on December 31, 2014. For PQRS GPRO, CQM populations include all unique Medicare patients from all practice sites in the group practice seen by the group during the reporting period beginning January 1, 2014 and ending December 31, 2014. Data for both individual EPs and GPROs is then submitted January 1, 2015 through February 28, 2015.

2.4 Identifiers

For all CMS EP program reporting, certain identifiers are **mandatory**, meaning that they must be present in the QRDA-III report and no nulls are allowed. Exceptions and considerations are noted where applicable. Mandatory identifiers for CMS EP program reporting include:

- National Provider Identifier (NPI)
    - Optional for PQRS GPRO reporting
- Tax Identification Number (TIN)
    - For a practice site with a single provider, the TIN is an organization ID
    - When a provider has more than one TIN, the provider is recorded for each NPI/TIN combination
      Note: The CPC program requires each CPC practice site, use only one TIN and this TIN shall be the **same** for all CPC Practice Site practitioners (NPIs) who are eligible professionals at that CPC practice site ID location.(See section 2.1 above)
- Each measure included in the QRDA-III report must reference the Version Specific ID.

2.5 Succession Management

This section describes the succession management for QRDA-III reports. (For example, a submitter notices an error in the submission and wants to replace it with a corrected version.) The document that replaces a previous document will have a replacement relationship and will have a new unique QRDA-III document/id. The document/id of the previous QRDA-III will be referenced in the current document's /ClinicalDocument/relatedDocument/parentDocument/id.

Currently, references to the 'id' of a parentDocument are not consistently used. A more reliable means of determining the current version of a QRDA-III document is used by the receiving system at CMS. For group practice reporting (except for the CPC program), it is the submission timestamp, the CMS program name, and the TIN combination. For individual reporting (except for the CPC program), it is the submission timestamp, the CMS program name, the NPI number, and the TIN combination. For QRDA-III documents that are submitted to the CPC program, it is the submission timestamp, the CMS program name, and the CPC practice site ID combination.

3. Business Rules

Conformance statements constraining the CDA Release 2 specification are used to standardize representations of measure-defined data elements. The conformance statements in Volume 2 of this implementation guide are generated from a template repository. An algorithm converts constraints recorded in the template repository to a printable presentation. Each constraint is uniquely identified by an conformance number at or near the end of the constraint (e.g., CONF:7345). Constraints unchanged from QRDA-III templates are identified by the same conformance number as labeled in the *HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture – Category III, DSTU Release 1.* Updated constraints for CMS EP Program QRDA-III reports are uniquely labeled. Only documents that are valid against the CDA Release 2 schema enhanced to support the sdtc namespace (CDA_SDTC.xsd) will be accepted for processing. Documents that are invalid against this rule will be rejected.

Bracketed information following each template title indicates the template type (section, observation, act, procedure, etc.), the templateId, and whether the template is open or closed.

Each section and entry template in the guide includes a contexts table. The "Contained By" column indicates which documents or sections use this template, and the "Contains" column indicates templates contained within this template. Each entry template also includes a constraints overview table to summarize the constraints following the table. Value set tables, where applicable, and brief Extensible Markup Language (XML) example figures are included with most explanations.

A typical template, as presented in this guide, is shown in the Constraints Format Example Figure 2. The next sections describe specific aspects of conformance statements—open vs. closed statements, conformance verbs (keywords), cardinality, and null flavors.

Figure 2: Constraints Format Example

3.7 Performance Rate for Proportion Measure (CMS EP)

[observation: templateId 2.16.840.1.113883.10.20.27.3.25 (open)]

Table 21: Performance Rate for Proportion Measure (CMS EP) Contexts

Contained By	Contains
Measure Reference and Results (CMS EP) (optional)	

This template is only used with proportion measures. The performance rate is a ratio of patients that meet the numerator criteria divided by patients in the denominator (after accounting for exclusions and exceptions). Performance Rate is calculated using this formula: Performance Rate = (NUMER) / (DENOM – DENOM EXCL – DENOM EXCEP).

Table 22: Performance Rate for Proportion Measure (CMS EP) Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Fixed Value
observation[templateId/@root = '2.16.840.1.113883.10.20.27.3.25']					
@classCode	1..1	SHALL		18395	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
@moodCode	1..1	SHALL		18396	2.16.840.1.113883.5.1001 (ActMood) = EVN
templateId	1..1	SHALL		711255	
@root	1..1	SHALL		711256	2.16.840.1.113883.10.20.27.3.25
code	1..1	SHALL		18397	
...					

1. Conforms to Performance Rate for Proportion Measure template (2.16.840.1.113883.10.20.27.3.14).
2. **SHALL** contain exactly one [1..1] **@classCode="OBS"** Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:18395).
3. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:18396).
4. ...

3.1 Open and Closed Templates

In open templates, all of the features of the CDA Release 2 base specification are allowed except as constrained by the templates. By contrast, a closed template specifies everything that is allowed and nothing further may be included. Templates defined in Volume 2 for CMS EP Program QRDA-III reports are open except as constrained for CMS EP program reporting.

3.2 Conformance Verbs (Keywords)

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

- **SHALL**: an absolute requirement for the particular element. Where a **SHALL** constraint is applied to an 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

3.3 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 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

3.4 Null Flavor

Information technology solutions store and manage data, but sometimes data are not available; an item may be unknown, not relevant, or not computable or measureable. In HL7, a flavor of null, or `nullFlavor`, describes the reason for missing data.

Figure 3: nullFlavor Example

```
<recordTarget>
  <patientRole>
    <id nullFlavor="NA"/>
  </patientRole>
</recordTarget>
<!-- data about a single patient is not applicable -->
```

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

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

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

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

3.5 XML Examples and Sample Documents

XML examples appear in the various figures throughout this implementation guide. Portions of the XML content may be omitted from the content for brevity, marked by an ellipsis (...) as shown in Figure 4.

Figure 4: Clinical Document Example

```
<ClinicalDocument xmls="urn:h17-org:v3">
  ...
</ClinicalDocument>
```

4. Troubleshooting and Support

4.1 Resources

The following are resources for additional information:

- **eCQM Library** contains resources for eCQMs including Measure Logic Guidance: http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html
- **National Library of Medicine (NLM) Value Set Authority Center (VSAC)** contains the official versions of the value sets used for eCQMs: https://vsac.nlm.nih.gov/
- **Electronic Clinical Quality Measure specification feedback system** is a tool offered by CMS and ONC for implementers to submit issues and request guidance on eCQM logic, specifications, and certification: http://oncprojecttracking.org/secure/Dashboard.jspa

4.2 Support

Table 2: Points of Contact

Contact	Organization	Phone	Email	Role	Responsibility
CMS IT Service Desk	CMS	(410) 786-2580 (800) 562-1963	CMS_IT_Service_Desk@cms.hhs.gov	Help desk support	1st level user support & problem reporting
QNet Help Desk	QualityNet	(866) 288-8912	qnetsupport@sdps.org	Help desk support	1st level user support & problem reporting
CPC Help Desk	CPC/Telligen	(800) 381-4724	cpcisupport@telligen.org	Help desk support	CPC support & problem reporting

4.3 Errata or Enhancement Requests

Table 3: Errata or Enhancement Request Location

Contact	Organization	URL	Purpose
HL7 QRDA III, DSTU Release 1 Comments page	HL7	http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=90	Document errors or request enhancments

Acronyms

This section describes the acronyms used in this implementation guide.

Table 4: Acronyms

Acronym	Literal Translation
CDA	Clinical Document Architecture
CMS	Centers for Medicare & Medicaid Services
CPC	Comprehensive Primary Care initiative
CQM	Clinical Quality Measure
DSTU	Draft Standard for Trial Use
eCQM	Electronic Clinical Quality Measure
EHR	Electronic Health Record
EP	Eligible Professional
GPRO	Group Practice Reporting Option
HL7	Health Level Seven
HQMF	Health Quality Measures Format
ID	Identifier
IPP	Initial patient population
MAT	Measure Authoring Tool
NLM	National Library of Medicine
NPI	National Provider Identification
NQF	National Quality Forum
ONC	Office of the National Coordinator for Health Information Technology
PQRS	Physician Quality Reporting System
QRDA	Quality Reporting Data Architecture
QRDA-III	Quality Reporting Data Architecture Category III
TIN	Tax Identification Number
XML	Extensible Markup Language

References

CMS, *Comprehensive Primary Care Initiative Instruction Guide for the Reporting of EHR Clinical Quality Measures, Version 1.0,* April 11, 2013. http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/CPC_CQM_InstructionGuide.pdf

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

HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture – Category III, DSTU Release 1 (2012). http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=90

HL7, *Clinical Document Architecture, Release 2.0*. (Normative Edition, May 2005.) http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7

NLM, Value Set Authority Center (VSAC). https://vsac.nlm.nih.gov/

ONC, Electronic Clinical Quality Measure issue reporting system. http://oncprojecttracking.org/secure/Dashboard.jspa