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Qualified Clinical Data Registry (QCDR) Measure Development For The Merit-Based Incentive Payment System (MIPS) Program

Thursday, February 13, 2025

WELCOME AND AGENDA

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Agenda

- QCDR Measure Overview and Requirements
- QCDR Measure Basics and Measure Development
- QCDR Measure Review and Tips for a Successful Submission
- QCDR Measure Testing
- Looking Ahead and Transitioning to MIPS Value Pathways (MVPs)
- Resources
- Question and Answer

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CMS PHILOSOPHY FOR QUALITY MEASURES

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QCDR MEASURE OVERVIEW AND REQUIREMENTS

Stacy Sams
MIPS QCDR/Registry Support Team (Practice Improvement and Measure Management System (PIMMS) Team)

QCDR Measure Development, Review, and Posting Process

1	Measure development (ongoing process)
2	Requirements and resources published to Quality Payment Program (QPP) Resource Library
3	QCDRs submit Self-Nomination and potential QCDR measures
4	CMS determines QCDR's eligibility to submit QCDR measures
5	CMS approves/rejects each QCDR measure
6	QCDRs submit edits/updates for rejected QCDR measures for reconsideration
7	QCDR measure specification files reconciled
8	CMS publishes approved QCDR measure specification file to QPP website
9	QCDRs publicly post QCDR measure specifications to individual websites

Requirements

QCDR measures should:

- Be beyond measure concept phase of development. [1]
- Address significant performance variation. [1]
- Focus on outcome rather than clinical process.[2]
- Meet face validity for initial MIPS performance period. [1]
  - Be fully developed and tested for subsequent performance periods.
- Avoid measure concepts already addressed.[1]

[1] § 42 CFR 414.1400(b)(4)(iii)(A)
[2] §42 CFR 414.1400(b)(4)(iii)(B)(1)

Approval Process/Evaluation

- QCDRs should be able to collect ALL measure data elements required and implement the measure by January 1 of performance period.[3]
- QCDR measures generally approved for one performance period. [4]
- Regardless of QCDR measure approval status, all QCDR measures are reviewed annually.

[3] 42 CFR 414.1400(b)(4)(iii)(A)(4)
[4] 42 CFR 414.1400(b)(4)(iii)(C)

Measure Posting

Posting Approved Measure Specifications

- At a minimum, measure specifications should include: [5]
  - Name/title of measure.
  - Consensus-Based Entity (CBE) number (if CBE-endorsed).
  - Descriptions of the denominator and numerator.
  - When applicable, denominator exceptions, denominator exclusions, numerator exclusions, or risk adjustment variables and algorithms.

- Publicly post CMS-approved specifications for each QCDR measure.
  - Within 15 calendar days following CMS posting. [5]
  - Include CMS-assigned QCDR measure ID.
  - Provide link to CMS.
  - Remain published through performance period until end of data submission period. [5]

[5] § 42 CFR 414.1400(b)(4)(i)(B)

Links to Improvement Activity, Cost Measure, or MVP

Link QCDR measures to at least one of the following:[6]

- Cost measure
- Improvement activity
- MVP

CMS may consider exceptions if there's no clear link.[6]

- **Examples**:
  - Specialty not reflected in cost measures inventory.
  - Indicate there were no cost measures during QCDR measure submission.

[6] § 42 CFR 414.1400(b)(4)(iii)(B)(7)

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QCDR MEASURE BASICS AND MEASURE DEVELOPMENT

Stacy Sams
MIPS QCDR/Registry Support Team (PIMMS Team)

QCDR Measure Basics

QCDR measures should:

- Measure a meaningful quality action (numerator).
  - Be evidence-based.
  - Be supported by clinical guidelines/recommendations from recent reputable sources.

- Preferably be outcome-oriented or being closely linked to an outcome measure concept could be acceptable.
  - Address health status change due to care, desirable or adverse.

- Not duplicate current/retired MIPS quality/QCDR measure concepts.[7]

- Measure performance with known variation and performance gap.[8]
  - Quantify performance gap and variation.
  - Demonstrate room for meaningful improvements.

[7] § 42 CFR 414.1400(b)(4)(iv)(A) through (C)
[8] § 42 CFR 414.1400(b)(4)(iv)(G)

QCDR Measure Development Recommendations

CMS considerations:

DO	DON'T
Focus on robust outcome quality action instead of checkbox/documentation only.	Only capture completed assessments or surveys WITHOUT follow up or plan of care to address abnormal findings.
Focus on outcome measure types. • Outcome, Intermediate Outcome, Patient-Reported Outcome-based Performance Measure (PRO-PM), etc.	Focus on clinical process with minimal link to an outcome.
Explore opportunities to combine as a composite/strata measure, providing a broader picture of quality.	Split single measure into several different measures.
Collaborate with existing measure stewards to cover broader patient population/clinical settings.	Duplicate existing/proposed/retired MIPS quality or QCDR measures.

QCDR Measure Development Recommendations

CMS considerations:

DO	DON'T
Focus on measures where performance variability between clinicians can be quantified.	Submit a 'never event' with no variability between clinician's performance.
Consider existing coding systems to efficiently capture patient population and quality action. Choose appropriate collection for your measure.	Be burdensome to the MIPS clinician.
Evaluate measure to determine need for denominator exclusions or denominator exceptions.	Have potential for unintended consequences.
Ensure a performance gap exists through testing. Investigate opportunities to revise measure to include a comprehensive and robust quality action.	Be a standard of care with the expectation it is performed consistently (low bar).

Duplicative Concepts

- Perform environmental scan for similar concepts in prior CMS reporting programs (i.e., Physician Quality Reporting System [PQRS]).[9]

- Identify similarities/differences in:
  - Clinical concept
  - Patient population
  - Clinician type
  - Quality action
  - Clinical setting
  - Other important factors

- Addressing areas of duplication:
  - Reduces burden
  - Improves scientific viability
  - Increases measure importance
  - Supports comparisons across larger cohort
  - Increases likelihood of benchmark creation

[9] § 42 CFR 414.1400(b)(4)(iii)(B)(9)(i)

Duplicative Concepts

- If a new QCDR measure duplicates an existing measure:
  - Obtain permission to use existing measure rather than self-nominating a duplicative, new QCDR measure.
  - CMS likely won't approve duplicative measure.

- If areas of duplication are unresolved:
  - Most robust of duplicative measures will be approved.

- Special circumstances:
  - Duplicative measures may be approved for one year, under the condition that areas of duplication must be resolved for subsequent year's consideration. [10]

[10] § 42 CFR 414.1400(b)(4)(iii)(A)(5)

Preferred Measure Types

Moving toward outcome-based measures in MIPS.

Preferred measure types:

- **Outcome Measure** – Focuses on health status of patient (or change in health status) resulting from healthcare—desirable or adverse.

- **PRO-PM** – Based on patient-reported outcome measure (PROM) data.
  - Data collected directly from patient using PROM tool(s).
  - Consideration for measures allowing use of more than one PROM tool.

- **Intermediate Outcome** – Assesses change produced by healthcare intervention.
  - Leads to long-term outcome.
  - Non-outcome measure closely linked to an outcome of interest.
  - Evidence showing intermediate outcome leads to desired health outcome.

- **Patient Experience** – Focuses on potential to improve person-centered care and family/ caregiver experiences.

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QCDR MEASURE REVIEW AND TIPS FOR A SUCCESSFUL SUBMISSON

Marla Throckmorton
MIPS QCDR/Registry Support Team (PIMMS Team)

Submission of Measure Specifications

- Review, submit all required specification components (owned and borrowed).
  - Testing data, performance data, measure recommendations, and rationale.
- Complete spelling and grammar check.
- Revisions limited to minor edits (e.g., grammar, punctuation, wordsmith).
- Can't add QCDR measures after Self-Nomination closes (only MIPS quality measures).[11]
- Check QPP Self-Nomination form often to ensure timeline compliance.
- If supporting QCDR measure(s) in an MVP:
  - Must be included in self-nominated QCDR measures tab.
  - Must include written permission to borrow QCDR measure.

11 § 414.1400(b)(4)(iv)(O)

Multiple Strata/Denominators/Patient Populations

- Collection and submission of data for multiple populations, often referred to as “multi-performance rate”.
  - Each denominator/patient population represents its own strata/subcomponent.
  - Each denominator/patient population is required for submission and reporting to CMS.

- QCDRs should carefully review specifications to identify if there are multiple patient population submissions (strata) and which performance rate(s) are used for reporting.

- Determining performance rate(s) being used for MIPS reporting:
  - Option 1 Example:
    - **Specific strata** as the "overall" or specifically selected rate to determine performance for the measure.
  - Option 2 Example:
    - **Simple average** of available strata performance rates in the measure.
  - Option 3 Example:
    - **Weighted average** of available strata performance rates in the measure.

Multiple Strata/Denominators/Patient Populations

This column indicates how many performance rates should be submitted to CMS for reporting.

This column indicates analytic or performance rate to be used for benchmarking.

Number of performance rates to be calculated and submitted	Performance Rate Description(s)	Indicate an Overall Performance Rate
1	Rate 1: Strata 1: FOR REPORTING All patients with closures after resection. Strata 2: Male patients with closures after resection. Strata 3: Female patients with closures after resection.	~~1st Performance Rate~~ Weighted Average

NOTE: If the measure requires only a single rate be submitted for multiple strata, it should be identified as a weighted OR simple average.

This column outlines the different strata/denominators needed for data aggregation OR performance rates needed for reporting.

Multiple Strata/Denominators/Patient Populations

Option 1 Example:

- Focuses on selected strata as performance rate:
  - QCDR must identify strata for required performance rate.
    - Example: “Overall” MIPS Performance Rate = Performance Rate 2
  - Submit one performance rate to CMS.
  - Completed by QCDR prior to submission:
    - Performance data aggregated
    - Performance rate calculated

Option 1 Example

Number of performance rates to be calculated and submitted	Performance Rate Description(s)	Indicate an Overall Performance Rate
2	The measure will be calculated with 2 performance rates for criteria 1 and criteria 2. Rate 1: NUMERATOR CRITERIA 1: Documentation by the provider who performed the surgery that an exam for recurrence of melanoma was performed on the patient within the reporting period. Rate 2: NUMERATOR CRITERIA 2: All patients that were diagnosed with a recurrent melanoma in the current reporting year.	2nd Performance Rate

Multiple Strata/Denominators/Patient Populations

Option 2 and 3 Examples:

- Indicate how CMS calculates performance rate for MIPS.
  - Weighted (sum of numerator values divided by sum of denominator values), OR
  - Simple average (sum of performance rates divided by number of performance rates).

- Submit measure data at each strata level (performance rate).

- CMS calculates overall performance rate.
  - Number of performance rates must be greater than or equal to 2.
  - Indicate if weighted or simple average for benchmarking.

Option 2 and 3 Examples

Number of performance rates to be calculated and submitted	Performance Rate Description(s)	Indicate an Overall Performance Rate
2	Rate 1: Male patients with closures after resection. Rate 2: Female patients with closures after resection.	Simple Average

Ownership and Eligibility of QCDR Measures

- Approved QCDR(s) must own or co-own the QCDR measure.

- Approved QCDR(s) must be active within MIPS.
  - Allows for continued use of QCDR measure when QCDR is no longer participating:
    - Inactive QCDR may transfer measure ownership/rights to active, MIPS-approved QCDR.
    - QCDR taking over ownership must be able to:
      - Continue to support measure for MIPS performance period.
      - Provide medical and measure expertise to be able to amend/manage the measure.
      - Permit other QCDRs to use the measure.

- Permission must be submitted and granted at time of Self-Nomination.

Ownership and Eligibility of QCDR Measures

- Participation plans:
  - Measure doesn't meet benchmarking thresholds 2 consecutive performance periods.[12]
  - Should include detailed plans/changes encouraging adoption.
    - Education/communication plan for clinicians.
    - Require clinicians to report on the measure.
    - Encourage submission of data for MIPS purposes.
    - Update specification to encourage broader participation.

[12] § 42 CFR 414.1400(b)(4)(iii)(B)(10)(i)

New Measure IDs

- Systematically assigned.
- For existing measures:
  - Will be considered a new measure and updated to '1st performance year'.
  - Can no longer be benchmarked against previous ID.
- Examples of measures receiving new IDs (not an all-inclusive list):
  - Changing the analytic of the measure.
    - Inverse to not inverse.
    - Proportional to ratio.
    - Adding risk-adjustment.
  - Adding a second quality action to the numerator.
  - Newly combined measures.

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QCDR MEASURE TESTING

Marla Throckmorton
MIPS QCDR/Registry Support Team (PIMMS Team)

Testing Requirements

New QCDR measures:

- Minimum of face validity prior to being self-nominated [13]

Subsequent performance periods:

- Fully developed and tested
- Complete testing results at clinician level
- Completed prior to submitting during Self-Nomination [13]

Fully developed and tested: [14]

- Empirical validity
- Measure score reliability
- Patient/encounter-level (data element) testing
- Feasibility

[13] § 42 CFR 414.1400(b)(4)(iii)(A)(3)
[14] Measure Selection | The Measures Management System

The Role of Testing Performance Measurement

Testing and Analysis:

- Critical to development of feasible, reliable, and valid measure.
- Conducted during measure development (alpha and beta testing).
- Enables developer's assessment of strengths, weaknesses of measure.
- Assesses reliability, validity, feasibility, usability, and scientific acceptability.
- Reduces provider reporting burden.
- Iterative process yielding more accurate/consistent data for program scoring.

Measure Testing: Validity

- The degree to which evidence, clinical judgment, and theory support interpretations of a measure's performance score for MIPS.
- Types of validity:
  - Face validity: A subjective assessment by experts based on experience about whether the measure reflects its intended assessment, and the research community.
  - Convergent validity: Demonstrates measure performance is associated with meaningful outcome, or other indicators of processes related to the target outcome.
  - Discriminant validity: Measure can differentiate between disparate groups that are expected to perform better (or worse).
  - Predictive validity: Measure performance can predict scores of other related measures or outcomes in the future.
- **NOTE: New QCDR measures require only face validity. After the initial year of implementation, existing measures should be fully tested with empirical validity.**

Measure Testing: Reliability

- Data elements should produce same results to the same phenomena.
- Addresses precision of measurement for the entity and to whom it applies.
- A lack of reliability/precision demonstrates 'random error.'
- Measures of reliability:
  - Signal-to-noise: Estimates the proportion of overall variability explained by the differences between entities.
    - Most common test for measure score reliability.
  - Temporal correlation: Assesses the correlation of data from adjacent time periods for each entity.
  - Random split-half correlation: Randomly splits data from each entity in half and estimates the correlation of the two halves across all entities.

Measure Testing: Patient/Encounter-Level Data Element Testing

- Building blocks for a quality measure should be assessed for reliability or validity.
- Required for meeting definition of fully developed measure.
- Testing may be empiric or reference external/previous testing.
  - Example: Empirical testing
    - Validity testing of data elements (i.e., criterion validity):
      - Verifies data elements against reference criterion determined to be valid.
    - Reliability testing of data elements:
      - Repeatability of testing findings.
      - Inter-rater or intra-rater reliability in data abstractor studies.
      - Internal consistency for multi-item tests or surveys.
      - Test-retest for survey items (measuring temporal reliability).

Measure Testing: Patient/Encounter-Level Data Element Testing (cont'd)

- Testing may be empiric or reference external/previous testing.
  - Example: External/previous testing
    - Established data element library
    - CMS Data Element Library (DEL), Electronic clinical quality measure (eCQM) Data Element Repository (DERep), or literature
- Elements already established as reliable, such as age, may be excluded.

Measure Testing: Feasibility

- Performed early in measure development.
- Follows identification of required data for measure calculation, before specification finalization.
- Goals:
  - Availability of required data, retrievable without undue burden
  - Extent data collection and processing without violation of patient confidentiality
  - Estimates costs/burden of data collection, data entry, and analysis
  - Impacts on clinician workflow, diagnostic thought processes, and patient-physician interaction
  - Identifies unintended consequences
  - Identifies possible barriers during implementation, data abstract, measure calculations, and performance reporting
- May also support validity of data elements using systematic surveys, conducting focus groups.

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LOOKING AHEAD AND TRANSITIONING TO MVPs

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MIPS QCDR/Registry Support Team (PIMMS Team)

Reduce Clinician Burden

- Focus on measures that reduce reporting burden:
  - Administrative Claims Outcome Measures
  - Digital Quality Measures (dQM)

- Measure alignment across programs where appropriate:
  - Measures included in Core Quality Measures Collaborative (CQMC)
  - Measures that can be implemented the same/similarly across programs

- Fast Healthcare Interoperability Resources (FHIR) data model:
  - Integrating new data interoperability

CMS Goals

- QCDRs/qualified registries support MVPs applicable to participants they submit MIPS data. [15]
- Move away from siloed reporting.
- MVPs offer connected measures and activities across all performance categories.
- Comparative performance data.
  - Valuable when evaluating clinician performance, making decisions about care.
- More cohesive participation experience.
- Create streamlined approach to MIPS reporting.

[15] § 42 CFR 414.1400(b)(1)(ii)

QCDRs Supporting MVPs

- Must support all measures and activities included in MVPs that are applicable to their clinicians.
- Exceptions:
  - If several specialties included in MVP:
    - QCDR is only expected to support measures pertinent to specialty of their clinicians.[16]
  - QCDR measures are required to be reported by the measure owner.
    - Only report QCDR measures with appropriate permissions from owner. [17]

Impact of transition to MVPs on current QCDR measures?

- QCDR measures will be reviewed as a component of current/future MVPs.
  - Align with current or future MVP topic?
  - Complement improvement activities and cost measures?
  - Align with goal of keeping MVPs stable year over year?

[16] § 414.1400(b)(1)(ii)(A)
[17] § 414.1400(b)(1)(ii)(B)

QCDRs Supporting MVPs

Requirements for QCDR measure inclusion in MVPs:

- Fully tested and developed at clinician level:
  - Proof of reliability, feasibility, and validity.
  - Avoids inadvertent submission, calculation, or scoring issues.

- Required during Self-Nomination period of July 1 – September 1:
  - Self-nominate as a QCDR.
  - Submit QCDR measure(s) for CMS consideration.
  - Submit all QCDR measure testing data.

- Active one year prior to Self-Nomination.

- Supporting another QCDR's measure in an MVP:
  - Must be included in QCDR measures tab.
  - Requires written permission from steward to borrow QCDR measure.

RESOURCES

QCDR Measure Preview Calls

Preview measure concepts before Self-Nomination.

- February 7, 2025 - May 30, 2025
- May 16, 2025, last day to request.
- First-come, first-served basis.
- Submit email request to QCDRVendorSupport@gdit.com.
  - Must include in request:
    - Multiple dates over 2-week period.
    - Names, email addresses of who should attend.
    - Submit specifications **at least 7 calendar days** prior to call.
    - Single Word or Excel document or use available measure template.
    - Subject to reschedule if not received on time.
- Measure decisions aren't made during QCDR measure preview calls.

Resources and Contact Information

- Medicare and Medicaid Programs: Calendar Year 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; Medicare Overpayments
  - https://www.federalregister.gov/public-inspection/2024-25382/medicare-and-medicaid-programs-calendar-year-2025-payment-policies-under-the-physician-fee-schedule

- 2025 QPP Policies Final Rule Fact Sheet
  - https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3057/2025-QPP-Policies-Final-Rule-Fact-Sheet.pdf

- 2024 Measures Management System (MMS) Blueprint:
  - https://mmshub.cms.gov/

Resources and Contact Information

- Measure Development Plan and Annual Reports:
  - https://www.cms.gov/Medicare/Quality-Payment-Program/Measure-Development/Measure-development
  - https://www.cms.gov/Medicare/Quality-Payment-Program/Measure-Development/2019-Quality-MDP-Annual-Report-and-Appendices.zip
- Measures Management System:
  - https://mmshub.cms.gov/about-quality/MMS-overview
- 2025 QCDR Measure Specification file:
  - https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3108/2025_QCDR_Measure_Specifications_PUB.xlsx
- 2025 Clinical Quality Measures Specification and Supporting Documents:
  - https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3093/2025-MIPS-CQM-Specifications-and-Supporting-Documents.zip

Resources to Support Electronic Clinical Quality Improvement

- eCQI Resource Center – Home Page:
  - https://ecqi.healthit.gov/
- eCQI Resource Center – Tools and Key Resources :
  - https://ecqi.healthit.gov/ecqm-tools-key-resources
- eCQI Resource Center – eCQM and eCQI Educational Resources:
  - https://ecqi.healthit.gov/ecqm-and-ecqi-education-resources
- eCQI Resource Center – Implementation Checklist:
  - https://ecqi.healthit.gov/ecqm-implementation-checklist

Resources to Support MVPs

- **Learn About MVP Reporting Option:** Helps to guide decision making and choosing to report MVPs.
  - https://qpp.cms.gov/mips/mvps/learn-about-mvp-reporting-option

- **MVP Implementation Guide:** Provides details about how to participate through an MVP.
  - https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2778/2024-MVPs-Implementation-Guide.pdf

- **Transition from Traditional MIPS to MVPs:** Timeline showing how CMS plans to transition from Traditional MIPS to MVPs.
  - https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2149/QPP%20Transition%20from%20Traditional%20MIPS%20to%20MVPs.pdf

- **Explore MVPs Webpage:** Learn about all the finalized MVPs, including the measures and activities in each MVP.
  - https://qpp.cms.gov/mips/explore-mips-value-pathways?py=2024

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QUESTION AND ANSWER

- To ask a question, raise your hand and we'll unmute your line, or submit via the Questions box.
- For those dialed in via phone, you must have your audio pin entered.
- If you're listening through your computer speakers and want to ask a question, you must have a working microphone.
- Speakers will address as many questions as time allows.


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