

2024 Qualified Clinical Data Registry (QCDR) Measure Development Handbook



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Introduction

QCDRs have the opportunity to develop and submit up to 30 QCDR measures for consideration during the self-nomination period. All submitted QCDR measures are reviewed by CMS for potential inclusion as QCDR measures in MIPS. This document provides guidance and suggestions to QCDR measure developers on QCDR measure structure, analytics, and measure testing. It also includes a QCDR measure development checklist, resources for QCDR measure development, and definitions used by CMS to communicate QCDR measure review decisions.

This QCDR Measurement Development Handbook has been updated from the May 2022 version to reflect policies finalized for inclusion and removal in the [CY2023 Medicare Physician Fee Schedule \(PFS\) Final Rule](#).

QCDR Measure Development, Review, and Posting Process

1	QCDRs create and collaborate to develop QCDR measures (ongoing process).
2	CMS annually publishes QCDR intermediary requirements and QCDR measure requirements/handbook.
3	QCDR submits self-nomination and potential QCDR measures.
4	CMS determines if a QCDR is eligible to submit QCDR measures on behalf of clinicians, groups, virtual groups, subgroups, or Alternative Payment Model (APM) Entities. ¹
5	CMS approves or rejects the potential QCDR measure for a specific performance period(s).
6	QCDRs have the opportunity to submit edits/updates to their potential QCDR measure for reconsideration.
7	QCDR measure specification files are reconciled.
8	CMS publishes the QCDR measure specification file to the Quality Payment Program (QPP) website.
9	QCDRs must publicly post the QCDR measure specifications to their individual intermediary websites.

QCDR Measure Development Checklist

QCDRs should be able to collect all that's required for the QCDR measure and feasibly implement the QCDR measure by January 1 of the performance period. Prior to submitting a QCDR measure for CMS consideration, the following checklist should be reviewed. CMS uses a similar checklist during the QCDR measure review process. For detailed information, please reference the third party intermediaries QCDR measures for the quality performance category

¹ Subgroups are only available through MVP reporting. All measure-specific criteria must be met by the subgroup.



section [42 CFR § 414.1400](#) for QPP policies in the CY2023 Medicare Physician Fee Schedule (PFS) Final Rule.

QCDR measures are required to²:

- Be beyond the measure concept phase of development.
- Address significant variation in performance.
- Meet face validity for the initial MIPS performance period for which it is approved.
- Be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination for subsequent performance periods after being initially approved.
- Collect data, appropriate to the measure type, prior to the submission of the QCDR measure for CMS consideration during the self-nomination period.
- Address areas of duplication if applicable.

Greater consideration is given to measures for which QCDRs:

- Used the [CMS Quality Measure Development Plan and Annual Report](#) and the measure development processes as defined within the Blueprint Measure Lifecycle content on the [CMS Measures Management System Hub \(CMS MMS Hub\)](#).
- Conducted an environmental scan of existing QCDR measures; MIPS quality measures; quality measures retired from the legacy Physician Quality Reporting System (PQRS).
- Aligned the measure to be clinically relevant and evidence-based with current clinical guidelines.
- Indicated accurate measure analytics (inverse, ratio, proportional, or continuous variable).
- Thoroughly vetted the QCDR measure to ensure proper spelling and grammar throughout the QCDR measure specification.
- Focused on measures that are outcome-based rather than clinical process measures.
- Focused on a quality action instead of documentation.
- Focused on an outcome rather than a clinical process.
- Demonstrated an opportunity for adequate patient population and measure adoption for the QCDR measure to have a more significant impact on quality improvement.
- Clearly defined the quality action and population in the description for clinician ease of understanding.
- Confirmed that they're able to abstract measure data according to the QCDR measure owner's specifications for QCDR measures that are being used by a QCDR that doesn't own the measure.

² [42 CFR 414.1400\(b\)\(4\)\(iii\)\(A\)](#)



QCDR measures shouldn't³:

- Duplicate an existing or proposed MIPS quality measure.
- Duplicate an existing QCDR measure (unless the new measure is a substantial improvement over the existing measure).
 - To reduce the number of duplicative QCDR measures in MIPS, CMS encourages QCDRs to share or resolve areas of duplication of QCDR measures that are similar in topic or concept. CMS likely won't approve measures that are duplicative or similar to one another since QCDR measures that don't have areas of duplication allow for a larger cohort on which clinicians can be compared. CMS strongly encourages QCDRs to perform an environmental scan prior to developing a QCDR measure.
- Duplicate a retired PQRS or MIPS quality measure, or previously rejected QCDR measure.
- Include measures that are considered topped-out. As defined, a topped-out non-process measure means a measure where the Truncated Coefficient of Variation is less than 0.10 and the 75th and 90th percentiles are within 2 standard errors.⁴ A topped-out process measure means a measure with a median performance rate of 95% or higher. This definition aligns with other CMS Value-Based Payment programs.
- Split a single or related clinical process or outcome into several QCDR measures. For example, the results of 3 different tests are required for a standard of care. Each test shouldn't be a single measure but all 3 should be combined into one comprehensive measure.
- Have the potential of unintended consequences. For example, a measure that discourages an oncology patient from receiving oxygen therapy or other comfort measures.
- Focus on the elimination of serious, preventable, and costly medical errors that are highly unlikely to occur (so-called "Never Events") For example, surgery performed on the wrong patient or a fire in the operating room.
- Be burdensome to the MIPS eligible clinician.
- Be a standard of care with the expectation it's performed consistently (low bar). While measures that are a standard of care represent important clinical topics, they don't provide value to a pay-for-performance program. Continued data capture for purposes outside of MIPS are encouraged.
- Be incidence measures.
- Have a quality action that isn't attributed to or isn't completed by the submitting clinician.
- Be documentation/check box measures.

³ [42 CFR 414.1400\(b\)\(4\)\(iv\)](#)

⁴ [§ 414.1305](#)



QCDR Measure Development

This section provides information on methods of constructing or structuring measures, the parts of a measure needed for analytics, methods of measure analytics, and measure types.

Measure Specification Components

Critical to the construction of a quality measure is the identification of the measure's target population (denominator) and quality clinical action (numerator), including any applicable exclusions or exceptions. The following components are used to create quality measures and include the analytic attributes used to calculate a measure.

- **Measure description:** This is a high-level summary of the target population and the quality action. The measure description should briefly describe the type of score (e.g., percentage, percentage rate, proportion, or number), the target population, and the focus of measurement. *For example, "Percentage of patients 65 years of age and older who were screened for future fall risk during the performance period."*
- **Denominator statement:** The lower portion of a fraction used to calculate a rate, proportion, or ratio. The denominator statement should describe the population to be evaluated by the measure. This should be defined precisely and include parameters such as age ranges, condition or diagnosis, procedures, setting, and timeframe (when applicable) or other qualifying events. *For example, "Patients aged 18 through 75 years with a diagnosis of diabetes."*
- **Denominator exclusion:** This is criteria that removes the patients or cases from the denominator before determining if the quality action (numerator) was completed. Denominator exclusions mean the quality action isn't applicable to those covered by the denominator exclusion and wouldn't be considered for the population. *For example, "Patients with bilateral lower extremity amputations" would be listed as a denominator exclusion for a measure requiring foot exams.*
 - Denominator exclusions aren't considered denominator-eligible and shouldn't be included in the data completeness and performance rate calculations.
- **Numerator statement:** The upper portion of a fraction used to calculate a rate, proportion, or ratio. The numerator statement should clearly detail the quality clinical action that's expected. The numerator statement describes the condition, process, event, or outcome that's the focus or intent of the measurement for each patient, procedure, or other unit of measurement established by the denominator (patients who received a particular service or clinicians that completed a specific outcome/process). *For example, "Patients whose most recent HbA1c level resulted during the performance period is well controlled."*
- **Numerator exclusion:** Applies only in ratio and proportional measures to define instances that shouldn't be included in the numerator data.
 - *Ratio Example: If the number of central line blood stream infections per 1,000 catheter days as to exclude infections with a specific bacterium, that bacterium would be listed as a numerator exclusion.*



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- **Denominator exception:** This is used only in proportional measures allowing the measured entity to get credit when the measured entity performs the quality action (numerator), but they're not penalized if it's not done for an appropriate reason. This allows the exercise of clinical judgment and implies that the treatment was at least considered or offered to each potentially eligible patient in the denominator. Denominator exceptions may be classified into medical, patient, or system reasons.

Measure Structure

There are several methods for structuring quality measures. The following are common measure structures with examples for constructing a more robust measure through creation of a composite or stratified quality measure:

- **Simple measure structure (non-stratified/non-composite measure):** This is the most common measure structure within MIPS. It contains a single target population with a single numerator. This produces one performance rate.
 - **MIPS clinical quality measure (CQM) example:** Quality Identifier (ID) #130: Documentation of Current Medications in the Medical Record.
- **Composite measure:** A combination of 2 or more individual performance measures, each of which individually reflects quality of care, resulting in a single performance measure with a single score.
 - *Composite measures* can provide a broader assessment in the measurement of comprehensive quality care. Examples:
 - All-or-none – Only those patients who received all indicated quality actions will be considered numerator compliant.
 - Any-or-none – Similar to all-or-none but is used for events that shouldn't occur. A patient is counted as failing if he or she experiences at least 1 adverse outcome from a list of 2 or more adverse outcomes.
 - Linear combinations – May be a simple average or a weighted average of individual measure scores.
 - Regression-based composite – The weight assigned to each item is directly related to its reliability and the strength of its association with the gold standard endpoint.
 - **MIPS CQM (All-or-none):** Quality ID #441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal control); Quality ID #394: Immunizations for Adolescents.
- **Multi-strata measure:** Multiple denominator options to reduce the number of measures addressing a similar condition, quality action, or topic. Reasons for stratification include but aren't limited to age groupings, specific condition, specific location, different complications of the same procedure, and vaccinations.
 - **Measure construction:**
 - Each denominator (patient population) can be limited to the appropriate patient population.



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- Each numerator (quality action) can be adjusted for the denominator-eligible patient population.
- **MIPS CQM example:** Quality ID #7 (Consensus-Based Entity [CBE] 0070): Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF $\leq$ 40%).

Measure Types

Measures are assigned a measure type based on the quality action defined in the measure numerator. Measures can be classified into the following measure types:

- **Outcome Measure:** A measure that focuses on the health status of a patient (or change in health status) resulting from health care (desirable or adverse).
 - **MIPS CQM example:** Quality ID #191 (CBE 0565): Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery.
- **Intermediate Outcome Measure:** A measure that assesses the change produced by a health care intervention that leads to a long-term health outcome.
 - An intermediate outcome is a (measured) change in physiologic state that leads to a longer-term health outcome.
 - **MIPS CQM example:** Quality ID #236: Controlling High Blood Pressure.
- **Patient-Reported Outcome-based Performance Measure (PRO-PM):** A type of outcome measure that's based on patient-reported outcome measure (PROM) data aggregated for an accountable health care entity. The patient directly self-reports the status of a health condition, health behavior, or experience with health care without interpretation of the patient's response by a clinician or anyone else.
 - The data is collected directly from the patient using the PROM tool, which can be an instrument, scale, or single-item measure.
 - Measures that only capture the distribution of survey assessments won't be approved.
 - PRO-PM measures should require positive outcome (improved pain score, improved functional status, patients are satisfied).
 - **MIPS CQM example:** Quality ID #470: Functional Status After Primary Total Knee Replacement.
- **Efficiency and Cost/Resource Use:** Measures of cost and resource use can be used to assess the variability of the cost of health care and to direct efforts to make health care more affordable.
 - **MIPS CQM example:** Quality ID #102: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients.
- **Patient Engagement/Experience:** Patient engagement measures involvement and strengthens person and family engagement as partners in their health care. The measure should address the experience of each person and their family and the extent to which they're engaged as partners in their care.



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- **MIPS CQM example:** Quality ID #304: Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery
- **Structure:** Measures that assess features of a health care organization or clinician relevant to its capacity to provide high-quality health care. These measures should have evidence that the specific structural elements are linked to improved care and improved health outcomes.
 - **MIPS CQM example:** Quality ID #137: Melanoma: Continuity of Care - Recall System.
- **Process Measure:** A measure that focuses on steps that should be followed to provide good care. There should be a scientific basis for believing that the process, when executed well, will increase the probability of achieving a desired outcome.
 - Process measures are supported by evidence that the clinical process—that's the focus of the measure—has led to improved outcomes.
 - CMS recognizes that process measures contribute to improving the clinical process to achieve the clinical outcome, but the intent is to prioritize outcome-based measures and move away from process-based measures.
 - **MIPS CQM example:** Quality ID #226 Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention.

Measure Analytics

Measures can be described as per the Blueprint Measure Lifecycle content on the [CMS MMS Hub](#) as proportional, non-proportional, continuous variable, ratio, or require multiple performance rate calculation, depending upon the methodology used to analyze the measure. The construction of the patient population and assessment of the quality action would determine the methodology.

- **Proportional:** The Blueprint Measure Lifecycle content on the [CMS MMS Hub](#) states that a proportional measure will produce a score (MIPS performance rate) derived by dividing the number of cases (denominator eligible encounters) that meet a criterion for quality (the numerator) by the number of denominator eligible cases within a given time frame (the denominator). The numerator cases are a subset of the denominator cases based on the performance of the quality action within the measure (e.g., percentage of eligible patients with a documented Body Mass Index (BMI) during the encounter or during the previous twelve months, AND when the BMI is outside of normal parameters, a follow-up plan is documented). The MIPS program requires the submission of 2 different measure calculations for each measure. QCDRs will need to submit a data completeness rate and a performance rate.
 - The performance rate of a proportion measure is defined as the number of patients meeting the quality action divided by the denominator-eligible population.
 - **MIPS CQM example:** Quality ID #128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: 321 patients received BMI screening and appropriate follow-up out of 401 patients. The



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performance rate would be 80%, in accordance with the measure specification.

- **Non-proportional:** A score that's derived from a variety of different data elements that are captured as numerator information. The variability in these data points makes decile creation based on a mathematical analysis unpredictable.
 - CMS prefers that the numerators are revised to establish an expected benchmark based on guidelines or national performance data. By comparing the observed data to the benchmark, this would allow for these measures to be converted into a proportional measure.
 - Continuous variable: Mean time from patient arrival to puncture time for those who undergo an endovascular stroke treatment.
 - Proportional: Door-to-puncture time of 90 minutes or less from patient arrival to puncture time for those who undergo an endovascular stroke treatment.
 - **MIPS CQM example:** Quality ID #413: Door to Puncture Time for Endovascular Stroke Treatment.
- **Continuous Variable:** A measure score in which each individual value for the measure can fall anywhere along a continuous scale and can be aggregated using a variety of methods such as the calculation of a mean or median (e.g., mean time to thrombolytics, which aggregates the time in minutes from a patient presenting with chest pain to the time of administration of thrombolytics).
- **Ratio:** A score that may have a value of zero or greater that's derived by dividing a count of one type of data by a count of another type of data. The key to the definition of a ratio is that the numerator and the denominator represent the count of different kinds of people, things, events, or objects (e.g., the number of patients with central lines who develop infection divided by the number of central line days).
 - Rates closer to one represent the expected outcome.
 - **Example:** Actual/Expected.
 - Length of Stay for Heart Failure
 - Actual: 5.5
 - Expected: 4.5 days
 - Ratio: 1.2
- **Inverse:** A lower calculated performance rate for this type of measure would indicate better clinical care or control. The "Performance Not Met" numerator option for an inverse measure is the representation of the better clinical quality or control. Submitting that numerator option will produce a performance rate that trends closer to 0%, as quality increases.
 - **MIPS CQM example:** Quality ID #1 (CBE 0059): Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%): Goal is to have a lower percentage of patients with diabetes with poor control.
- **Multiple performance rate calculation:** One performance rate should be identified that will be submitted for scoring purposes. QCDRs have the opportunity to provide stratified



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performance data to the clinicians, groups, virtual groups, or subgroups⁵ to provide meaningful feedback. CMS will use the overall or indicated performance rate for the scoring of quality measures. Options to determine the scored performance rate include but aren't limited to:

- Weighted Average:
 - Add the numerator counts of each submeasure and divide by the sum of the denominator counts of each submeasure.
 - **MIPS CQM example:** Quality ID #370 (CBE 0710): Depression Remission at Twelve Months.
- Simple Average:
 - Add the percentages for each submeasure and divide by the total number of component submeasure.
 - **MIPS electronic clinical quality measure (eCQM) example:** Quality ID #9: Anti-Depressant Medication Management.
- Indicated Performance Rate
 - Identify one of the performance rates that should be used for benchmarking/scoring purposes. This is often the more robust quality action.
 - **MIPS CQM example:** Quality ID #394: Immunizations for Adolescents.
- **Risk adjustment:** Risk adjustment is the statistical process used to identify and adjust for differences in patient characteristics (or risk factors) before examining outcomes of care.
- **Risk stratification:** Risk stratification is a method to separate outcomes for different groups, unadjusted by a risk model.
- **Electronically derived measure:** A QCDR measure that's being electronically derived/data mined from an electronic health record (EHR) (and the electronic QCDR measure is still benchmarked as a QCDR measure). EHR data mining is permitted without electronic clinical quality measure (eCQM) designation.

⁵ Subgroups are only available through MVP reporting. All measure-specific criteria must be met by the subgroup.



Measure Classification

- **High-Priority Measure:** Measures that meet the definition of high-priority should be flagged as such during self-nomination. CMS identifies the following as high priority ([§ 414.1305](#)):
 - **Outcome measures:** Outcome measures show how a health care service or intervention influences the health status of patients. (Outcome measures include outcome, intermediate outcome, and patient-reported outcome-based performance measure).
 - **Appropriate Use:** CMS wants to specifically focus on appropriate use measures. This means that the measure must address appropriate use of services, including measures of over-use.
 - **Patient Safety:** This means that the measure must address either an explicit structure or process intended to make care safer, or the outcome of the presence or absence of such a structure or process and harm caused in the delivery of care. This means that the structure, process, or outcome must occur as a part of or as a result of the delivery of care.
 - **Efficiency/Cost Reduction:** This means that the measure must address the affordability of health care including unnecessary health services, inefficiencies in health care delivery, high prices, or fraud. Measures should cause change in efficiency and reward value over volume.
 - **Person and caregiver-centered Experience and Outcomes:** Should address the experience of each person and their family; and the extent to which they are engaged as partners in their care. CMS wants to specifically focus on patient reported outcome measures (PROMs). This also includes person or family-reported experiences of being engaged as active members of the health care team and in collaborative partnerships with providers and provider organizations.
 - **Communication and Care Coordination:** This means that the measure must address the promotion of effective communication and coordination of care and the coordination of care and treatment with other providers.
 - **Opioid Related:** Opioid-related measures that measure opioid use, overuse, risks, monitoring, and education.
 - **Health Equity:** This means the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.



QCDR Measure Testing

The QCDR measure testing information summarized in this section can be found on the Blueprint Measure Lifecycle content on the [CMS MMS Hub](#). CMS gives greater consideration to measures for which QCDRs, among other things, utilized the [CMS Quality Measure Development Plan and Annual Report](#) and the Blueprint Measure Lifecycle content on the [CMS MMS Hub](#) to identify measurement gaps prior to measure development.⁶ The measure testing requirement has been implemented in an incremental manner beginning in the 2022 performance period.⁷ Beginning with the 2022 MIPS performance period/2024 MIPS payment year, CMS may approve a QCDR measure only if the QCDR measure meets face validity. Beginning with the 2024 MIPS performance period/2026 MIPS payment year, a QCDR measure approved for a previous performance year must be fully developed and tested, with complete testing results at the clinician level, prior to self-nomination.⁸

According to CMS, a fully developed measure contains the following criteria.⁹

- Patient/encounter-level testing for each critical data element has been completed and no changes to the measure specifications are needed based on the results.
- Reliability testing at the accountable entity level has been completed and no changes to the measure specifications are needed based on the results.
- Empiric validity testing at the accountable entity level has been completed, and no changes to the measure specifications are needed based on the results. (Completion of face validity testing as the sole type of validity testing doesn't meet the criteria for Fully Developed).
- For measures based on survey data or patient-reported tools, the survey or tool has been tested and no changes to the instrument are needed based on the results.

Role of Testing in Performance Measurement

- Testing assesses the scientific acceptability of QCDR measures to assure they're meaningful.
- Testing is fundamental in reducing the reporting burden on providers by assuring their effort isn't wasted in collecting data on measures that aren't feasible or informative.
- Testing provides the opportunity to refine draft measure specifications before they're implemented, so they'll yield accurate and consistent data for performance program scoring.

⁶ [§ 414.1400\(b\)\(4\)\(iii\)\(B\)\(9\)\(ii\)](#)

⁷ [§ 414.1400\(b\)\(4\)\(iii\)\(A\)\(3\)](#)

⁸ [§ 414.1400\(b\)\(4\)\(iii\)\(A\)\(3\)](#)

⁹ <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/selection>



Scientific Acceptability

The Blueprint Measure Lifecycle content on the [CMS MMS Hub](#) indicates that scientific acceptability of a measure refers to the extent to which the measure produces reliable and valid results about the quality of care when implemented. These attributes provide insight on whether the measure will produce meaningful data about the quality care within the defined denominator of a measure. The measure steward will need to provide evidence of reliability and validity for both the measure score and data elements. Below are ways to address common measure testing and reporting errors which can reduce scientific acceptability:

- Avoid descriptive statistics as they aren't able to support reliability or validity of a measure.
- If a measure is respecified, it may require retesting to obtain empirical data for reliability and validity.
- Attempt to identify and account for any missing data.
- Determine if there's a need for risk adjustment or stratification of the measure.

Measure Reliability

According to the Blueprint Measure Lifecycle content on the [CMS MMS Hub](#), the International Organization for Standardization (ISO) (1995) definition of reliability is "a metric is reliable in as much as it constantly provides the same result when applied to the same phenomena." Measure score is the observed situations for the desired clinical concept. Data elements are criteria such as demographic, health status, health care activity, or other patient, clinician, or encounter attributes. Refer to the Blueprint Measure Lifecycle content on the [CMS MMS Hub](#) for more information regarding measure reliability types, uses, and tests.

• Measure Score Reliability

- Conceptually, reliability is the measure of the ratio between signal to noise ($SNR = \bar{x}/s$) (where $\bar{x}$ =mean and s =standard deviation).
- Proportion of variability (signal) being the proportion of variability in a measure due to true differences in performance.
- Chance variation (noise) is the proportion of variability in measure performance due to measurement error.
- The measure must be able to distinguish differences between quality performance due to true differences in performance rather than chance, therefore reducing the probability of misclassification in comparative performance.
- CMS expects the measure developer to assess the reliability of the measure score during development using data derived from testing.
- Refer to the Blueprint Measure Lifecycle content on the [CMS MMS Hub](#) for more information regarding measure score differences.



- **Data Element Testing**

- CMS anticipates that measure developers will conduct data element reliability with clinician level data elements (e.g., numerator, denominator, denominator exclusions, and denominator exceptions) to ensure the correct data elements are abstracted consistently.
 - Although, per the CMS consensus-based entity (CBE), the measure developer may not need to perform data element reliability if data element validity was completed.
 - Additionally, data elements already established as reliable, like patient age, may be excluded from reliability testing.
- CMS recommends that measure developers should review all data elements prior to deciding which to include in reliability testing.
- Refer to the Blueprint Measure Lifecycle content on the [CMS MMS Hub](#) for more information regarding data element reliability assessment.

Measure Validity

Measure validity ensures that the measure accurately represents the concept being evaluated and achieves the purpose for which it's intended (i.e., to measure quality).

- Face Validity is the extent to which a test appears to cover the concept it purports to measure “at face value.” It’s a subjective assessment by experts of whether the measure reflects its intended assessment (for example, the use of a current clinical guideline to frame the measure, such as using the blood pressure guideline of < 140/90 is a marker of quality).
 - For QCDR measures to be approved for the 2024 performance period, all QCDR measures must meet face validity for the initial MIPS payment year for which it’s approved. For subsequent years, all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination.¹⁰
 - For future years, when a measure must be fully developed and tested, it must demonstrate validity at the clinician level for scientific acceptability, as well as reliability and feasibility on the same level (Blueprint Measure Lifecycle content on the [CMS MMS Hub](#)).
- Empirical Validity is an empirical demonstration of the ability of a measure to record or quantify what it purports to measure. Examples are construct validity, discriminant validity, predictive validity, convergent validity, and criterion validity.
 - Empirical validity, beyond face validity, is required for subsequent years after the measure is initially approved.

¹⁰ [§ 414.1400\(b\)\(4\)\(iii\)\(A\)\(3\)](#)



Measure Feasibility Assessment

Determine the extent to which the required data are available and retrievable without undue burden and the extent to which they can be implemented for performance measurement. The Blueprint Measure Lifecycle content on the [CMS MMS Hub](#) indicates feasibility assessments should address the following:

- Availability of data.
- Extent of missing data, measure susceptibility to inaccuracies, and the ability to audit data to detect problems.
- Estimate of the costs or burden of data collection, data entry, and analysis.
- Barriers encountered in implementing performance measure specifications, data abstraction, measure calculation, or performance reporting.
- Ability to collect information without violation of patient confidentiality, including circumstances where measures based on patient surveys, or the small number of patients may compromise confidentiality.
- Identification of unintended consequences.

Usability and Use

The Blueprint Measure Lifecycle content on the [CMS MMS Hub](#) indicates that usability and use include an analysis to demonstrate that the measure is meaningful and useful to the target audience. It's the extent to which potential audiences (e.g., consumers, purchasers, providers, and policymakers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare. This may be accomplished by a Technical Expert Panel (TEP) reviewing the measure results (e.g., means and detectable differences, dispersion of comparison groups). There are other methods a measure steward may use to analyze the understandability and decision-making utility of a measure such as:

- Focus group,
- Structured interview or
- Surveys of potential users.

QCDR Measure Review Process

Communication between CMS, Contractors, and QCDRs

- CMS welcomes the opportunity to meet with QCDRs to review measure concepts or specifications and provide feedback prior to self-nomination.
- During the QCDR measure review process, contractors may reach out for additional information related to the submitted QCDR measure specification (e.g., performance data, supporting clinical guidelines, or consideration of a denominator exclusion/exception).



CMS QCDR Measure Determinations

CMS and contractors review QCDR measures. The QCDR measure status is assigned to indicate whether the measure has been approved or rejected.

- **Approved** – The QCDR measure is approved for the given performance period.
- **Rejected** – The QCDR measure isn't approved for the given performance period. CMS will provide a rationale for the rejection based on the definitions outlined below.
- CMS may approve a QCDR measure for 2 years with annual review. CMS may revoke the second year's approval if the approved QCDR measure is found to be: Topped out; duplicative of a more robust measure; reflects an outdated clinical guideline; or if the QCDR self-nominating the QCDR measure is no longer in good standing.¹¹

If a QCDR measure fails to meet benchmarking thresholds for 2 consecutive performance periods (data submitted is insufficient in meeting the case minimum requirements and volume thresholds required for benchmarking), the QCDR may submit a participation plan for CMS consideration if the QCDR believes the QCDR measure is important and relevant to a specialist's practice.¹² To clarify, the submission of a QCDR measure participation plan doesn't guarantee the approval of a QCDR measure for the upcoming performance period.

- **QCDR Measure Participation Plan:** Detailed plan and methods to encourage clinicians, groups, or virtual groups to increase QCDR measure adoption.
 - As examples, a QCDR measure participation plan could include one or more of the following: Development of an education and communication plan; update the QCDR measure's specification with changes to encourage broader participation; require reporting on the QCDR measure as a condition of reporting through the QCDR.

QCDR Measure Review Terminology and Definitions

Below are the definitions for communications from CMS regarding QCDR measure feedback after review:

- **Standard of Care:** Standard of care is based on the typical practice of an average or below average clinician, e.g., what basic care would be expected of any clinician under similar circumstances. This includes the minimum that would be expected of any clinician treating a given patient related to the concept/recommendation/care dictated by the measure. *For example: obtaining informed consent prior to surgery.*
- **Low Bar:** The measure evaluates basic health care that should be done on a routine basis.
- **Topped Out:** Topped-out status shows high and unvarying performance which limits opportunity to improve clinical outcomes and as such doesn't allow for meaningful benchmarks to be established. A topped-out non-process measure means a measure where the Truncated Coefficient of Variation is less than 0.10 and the 75th and 90th

¹¹ [§ 414.1400\(b\)\(4\)\(iii\)\(C\)](#)

¹² [§ 414.1400\(b\)\(4\)\(iii\)\(B\)\(10\)\(i\)](#)



percentiles are within 2 standard errors.¹³ A topped-out process measure means a measure with a median performance rate of 95% or higher. This definition aligns with other CMS Value-Based Payment programs.

- **Performance Gap:** Data that shows the quality action isn't being performed as frequently as it should. This data is based on recent and relevant scientific evidence, reputable studies, or data from the QCDR which includes average performance rate, performance range, and number of clinicians, groups, virtual groups, subgroups, or APM Entities reporting on the measure.
- **Performance Variance:** Variance in performance allows for a range of deciles to be developed based on performance range. Regarding performance measurement, a high standard deviation or variance may indicate erratic data collection or an opportunity for improvement. CMS is requesting that performance data be assessed to determine if the variance is due to data collection (e.g., workflow, method of data abstraction, etc.) or actual performance differences. CMS encourages the development of measures with performance variance if it reflects opportunity for performance improvement, not data imperfections.
- **Resolve Areas of Duplication:** CMS encourages QCDRs to share or resolve areas of duplication of QCDR measures that are similar in topic or concept. CMS won't likely approve measures that are duplicative or similar to one another, as QCDR measures with resolved areas of duplication allow for a larger cohort on which clinicians can be compared.¹⁴
- **Combine Measure Concepts:** Measures that split a similar or related clinical outcome or process into individual measures should be combined. *For example: Improvement in toe pain: Pain in the fifth toe and a separate measure for the second toe.*
- **Documentation, Checkbox, or No Quality Action:** CMS has assessed that the focus of these measures isn't about providing quality care and improving outcomes.
 - For example, the quality action, as defined by the numerator statement, is the completion of an assessment or a survey but offers no follow-up or plan of care to address abnormal/unusual findings or the survey doesn't account for patient satisfaction with the care received.
 - Measure developers should avoid selecting or constructing measures that can be met primarily through documentation without evaluating the clinical quality of the activity—often satisfied with a checkbox, date, or code. *For example, a completed assessment, care plan, or delivered instruction.*
- **Clinician Attribution:** The quality action isn't under the direct control of the reporting clinician. The quality action is completed or dependent on others.

¹³ [§ 414.1305](#)

¹⁴ [§ 414.1400\(b\)\(4\)\(iii\)\(A\)\(5\)](#)



Scenarios

The following are common scenarios CMS and the contractors have encountered during the QCDR measure review process. CMS asks that QCDRs review the scenarios below and consider the likely CMS response prior to self-nominating a QCDR measure.

If New or Existing QCDR Measure Concept is:	Anticipated CMS Response:
Similar or identical to retired PQRS/MIPS clinical quality measure or QCDR measures.	CMS likely won't approve this measure.
Similar or identical to an existing MIPS clinical quality measure.	CMS likely won't approve this measure and will suggest the QCDR report the similar or identical existing MIPS quality measure.
Similar to a QCDR measure that was previously rejected.	CMS likely won't approve the measure, unless the measure was modified to address prior concerns, such as to have a more meaningful quality action or it demonstrates a performance gap.
Creating QCDR measures that disjoin a single quality action into individual steps OR delineates individual complications or outcomes of care associated with a specific procedure.	CMS may recommend that QCDRs consolidate the related series of measures into a single composite measure. Consolidating multiple similar measures into a single composite measure, will lead to a robust measure that will likely result in providing meaningful data to clinicians and groups on possible areas of improvement in the quality of care they provide.
A QCDR measure doesn't have a quality action.	CMS likely won't approve the measure. Documentation or "checkbox based" QCDR measures won't be approved. The measure must demonstrate a performance gap.
A QCDR measure that includes a CBE Measure ID, but the measure specification doesn't accurately reflect the version endorsed by the CBE.	CMS won't recognize the CBE ID, unless the exact measure specifications are used.
A QCDR measure isn't feasible, unable to be implemented, or the data can't be abstracted at the time of self-nomination or during the performance or submission periods.	CMS likely won't approve the measure. QCDR measures should be fully implemented and feasible beginning on January 1 of the performance period.



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If New or Existing QCDR Measure Concept is:	Anticipated CMS Response:
A QCDR measure that doesn't demonstrate room for quality improvement (topped out).	CMS won't approve the measure if the measure is topped out.
A QCDR measure that isn't attributable to the individual clinician.	CMS likely won't approve the measure. CMS acknowledges the value of pursuing facility-based quality improvement efforts, but the measure must fit within the constraints of MIPS quality measures, where attribution must be made to a single individual clinician or group.
Submitted by a QCDR that doesn't have permission to self-nominate a QCDR measure owned by another QCDR for the applicable performance period.	CMS likely won't approve the measure for use. Case-by-case review can occur.

MIPS Value Pathways (MVPs)

MVP reporting allows for a more cohesive MIPS participation experience. The MVP framework aims to make MIPS more focused on value by connecting activities and measures from all performance categories, reducing selection and reporting burden by requiring submission of fewer MIPS quality measures than the traditional MIPS participation method, and aims to provide meaningful data and feedback to clinicians and patients by comparing the performance of like clinicians who report on the same MVP. MVP development is a collaborative process during which interested parties are invited to submit MVP candidates for CMS consideration and potential implementation through future rulemaking. Additional information on this process is on the [MVP Candidate Development & Submission webpage](#). Third party intermediaries should identify and support MVPs that are relevant to the clinicians and groups they support.

Requirements for QCDR measure to be included in an MVP:

- QCDR measures must be fully developed and tested at the clinician level. They must be reliable, feasible, and valid so as not inadvertently cause a clinician or group an issue with submission, calculation, and scoring of a measure.
- CMS needs to receive QCDR measure testing data for review by the end of the QCDR self-nomination period, no later than September 1, to be eligible for proposal within an MVP.
- QCDRs must self-nominate as a QCDR and submit QCDR measures for CMS consideration within the 60-day self-nomination period that begins on July 1 of the calendar year prior to the applicable performance period and ends on September 1 of the same year.



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- Only QCDR measures that were approved in the previous year may be considered for inclusion within a candidate MVP.
- All QCDR measures are reviewed by CMS on an annual basis during the self-nomination period, regardless of the measure's inclusion in an MVP.

What impact will the transition to MVPs have on current QCDR measures?

- Fully tested QCDR measures may be considered for inclusion in MVPs. QCDR measures should align with current and future MVP topics and should complement improvement activities and cost measures.

QCDR Measure Development Resources

- QCDR Measure Preview Calls - CMS and the MIPS QCDR/Registry Support (PIMMS) Team welcome the opportunity to preview your QCDR measure concepts, offer constructive feedback, and have the opportunity to understand the QCDR measure's importance. These calls are for measure review discussions only.
 - To request a measure preview call, contact QCDRVendorSupport@gdit.com with the following information:
 - Please provide several options of availability during the timeframe you wish to meet.
 - Please provide email addresses of attendees from your QCDR who should be included in the meeting invitation.
 - Preview calls may occur through June 2, 2023.
 - May 19, 2023 is the last day you can request a preview call.
 - QCDRs must send (in a single Word or Excel document) the QCDR measure concepts and specifications to be discussed at the meeting at least one week prior to the scheduled meeting.
 - If QCDR measure concepts and specifications aren't received at least one week prior to the scheduled meeting, the meeting is subject to rescheduling.
- [2023 QCDR Measure Specification file.xlsx \(Size 679 KB\)](#) - Contains measure specifications for all approved 2023 QCDR measures.
- [2023 Clinical Quality Measure Specification and Supporting Documents](#) – Contains measure specifications and supporting documents for the 2023 MIPS clinical quality measures.
- [QPP Resource Library](#) – Provides access to all the educational resources created for the QPP.
- [Blueprint Measure Lifecycle Content on the CMS MMS Hub](#) - Provides a standardized system for developing and maintaining the quality measures used in CMS's various quality initiatives and programs. The primary goal is to provide guidance to measure developers



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to help them produce high-caliber health care quality measures and documents the core set of business processes and decision criteria used when developing, implementing, and maintaining measures.

- [Measure Development Plan](#) - Is a focused framework to help CMS build and improve quality measures that clinicians could report under MIPS and as participants in APMs (collectively known as QPP).
- [Developer Tools](#) - Offers assistance for developers building tools to integrate directly with CMS applications and data.
- Contact the Quality Payment Program Service Center at 1-866-288-8292 (Monday-Friday, 8 a.m. - 8 p.m. ET) or by email at: QPP@cms.hhs.gov. Customers who are hearing impaired can dial 711 to be connected to a TRS Communications Assistant.

