

2023 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 the Centers for Medicare & Medicaid Services (CMS) for potential inclusion as QCDR measures in the Merit-based Incentive Payment System (MIPS) program. This document provides guidance and suggestions to QCDR measure developers on QCDR measure structure, analytics, and types as well as a QCDR measure development check list, 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 2021 version to reflect policies finalized for inclusion and removal in the calendar year [\(CY\) 2022 Physician Fee Schedule Final Rule](#) for the Quality Payment Program (QPP).

QCDR Measure Development, Review, and Posting Process:

1	QCDRs create and/or 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, ¹ or Alternative Payment Model (APM) Entities.
5	CMS approves or rejects the potential QCDR measure for a specific performance period(s).
6	QCDRs have 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 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 is 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

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

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reference the third party intermediaries QCDR measures for the quality performance category section § 414.1400 of the [\(CY\) 2022 Physician Fee Schedule Final Rule](#) for the Quality Payment Program (QPP).

QCDR measures are required to:

- Be beyond the measure concept phase of development.
- Address significant variation in performance.
- Be face valid and in alignment with the incremental policy stated in the final rule.
- Collect data prior to the submission of the QCDR measure for CMS consideration during the self-nomination period.
- Address areas of duplication if applicable.

QCDR measures should:

- Be developed by using the measure development processes as defined in the most recent [Blueprint content on the CMS MMS Hub](#).
- Conduct an environmental scan of existing QCDR measures; MIPS quality measures; quality measures retired from the legacy Physician Quality Reporting System (PQRS).
- Be clinically relevant and evidence based (align with current clinical guidelines).
- Preference for measures that are outcome-based rather than clinical process measures.
- Focus on a quality action instead of documentation.
- Focus on an outcome rather than a clinical process.
- Address one or more Meaningful Measure Areas and National Quality Strategy (NQS) domains:
 - Focus on measures that address patient safety and adverse events.
 - Focus on measures that identify appropriate use of diagnosis and therapeutics.
 - Focus on measures that address the NQS domain of care coordination.
 - Focus on measures that address the NQS domain for patient and caregiver experience.
 - Focus on measures that address efficiency, cost, and resource use.
- Have opportunity for adequate patient population and measure adoption for the QCDR measure to have a more significant impact on quality improvement.
- Clearly define the quality action and population in the description for clinician ease of understanding.
- If a QCDR measure is being used by a QCDR that does not own the measure, the QCDR should confirm that it is able to abstract the data according to the QCDR measure owner's specifications.
- Indicate accurate measure analytics (inverse, risk-adjusted, ratio, proportional, or continuous variable).
- Be thoroughly vetted by the QCDR to ensure proper spelling and grammar throughout the QCDR measure specification.



QCDR measures should not:

- 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 and/or resolve areas of duplication of QCDR measures that are similar in topic and/or concept. CMS will likely not approve measures that are duplicative or very similar to one another since QCDR measures that do not have areas of duplication allow for a larger cohort on which clinicians can be compared. NOTE: 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 with performance rates at or near 100% (or 0% for inverse measures). Topped out measures are defined as above 95% or less than 5% for inverse measures. 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.² 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 three different tests are required for a standard of care. Each test should not be a single measure but all three 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 is performed consistently (low bar). While measures that are a standard of care represent important clinical topics, they do not provide value to a pay for performance program. Continued data capture for purposes outside of the MIPS program are encouraged.
- Be incidence measures.
- Have a quality action that is not attributed to or not completed by the submitting clinician.
- Be documentation/check box measures.

² § 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, 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 eligible population (or episodes of care) to be evaluated by the measure. This should indicate 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:** Criteria that removes the encounter/patient from the denominator before determining if the quality action was completed. Denominator exclusions are more absolute where the quality action is not applicable and would not 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 are **not** considered denominator eligible and should not 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 expected that satisfies the condition(s) and is the focus 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 measures to define instances that should not be included in the numerator data.
 - *Ratio Example: If the number of central line blood stream infections per 1,000 catheter days were to exclude infections with a specific bacterium, that bacterium would be listed as a numerator exclusion.*



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- **Denominator exception:** Used only in proportion measures to remove a patient, procedure, or unit of measurement from the denominator only if the numerator criteria are not met. This permits the exercise of clinical judgment and implies that the treatment was at least considered for each eligible patient. 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 two or more individual performance measures, each of which individually reflects quality of care, into a single performance measure with a single score. Appropriate denominator exceptions should be included for the quality action being measured. Composite measures promote a high standard of excellence generally representing comprehensive care.
 - *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 should not occur. A patient is counted as failing if he or she experiences at least one adverse outcome from a list of two 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 not limited to age groupings, specific condition, specific location, different complications of the same procedure, and vaccinations.
 - **Measure construction:**



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- Each denominator (patient population) can be limited to the appropriate patient population.
- Each numerator (quality action) can be adjusted for the denominator eligible patient population.
- **MIPS CQM example:** Quality ID #7 (National Quality Forum [NQF] 0070): Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 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 assesses the results of healthcare that are experienced by patients: clinical events, recovery and health status, experiences in the health system, and efficiency/cost.
 - **MIPS CQM example:** Quality ID #191 (National Quality Forum [NQF] 0565): Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery.
- **Intermediate Outcome Measure:** A measure that assesses the most recent assessment of quantity, quality, and consistency of the body of evidence that the measured intermediate clinical outcome leads to a desired 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 where the patient directly self-reports the status of a health condition, health behavior, or experience with healthcare without interpretation of the patient's response by a clinician or anyone else.
 - Measures that only capture the distribution of survey assessments will not 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 healthcare and to direct efforts to make healthcare 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 the involvement and strengthens person and family engagement as partners in their healthcare. The measure



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should address the experience of each person and their family and the extent to which they are engaged as partners in their care.

- **MIPS CQM example:** Quality ID #304: Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery
- **Structure:** Measures features of a healthcare organization or clinician relevant to its capacity to provide high-quality healthcare. 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 a process which may lead to a certain outcome, meaning that a scientific basis exists 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 is 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 (National Quality Forum [NQF] 0028): Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention.

Measure Analytics

Measures can be described as per the [Blueprint 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 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 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 two different measure calculations for each measure. QCDRs will need to submit a data completeness rate and a performance rate(s).
 - 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



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received appropriate BMI screening and follow-up out of 401. The performance rate would be 80% in accordance with the measure specification.

- **Non-proportional:** A score that is derived from a variety of different data elements that are captured as the numerator information. The variability in these data points make decile creation based on a mathematical analysis very 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 less than 2 hours 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 case presenting with chest pain to the time of administration of thrombolytics).
 - Aggregate scores for continuous variable measures are more complex than for proportion measures in that they are more than just the counts of individuals in each population.
 - **Ratio:** A score that may have a value of zero or greater that is 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 is not in the denominator (e.g., the number of patients with central lines who develop infection divided by the number of central line days).
 - Rates closer to 1 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 (National Quality Forum [NQF] 0059): Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%): Goal is to have a lower percentage of patients with diabetes with poor control.



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- **Multiple performance rate calculation:** One performance rate should be identified that will be submitted for scoring purposes. QCDRs have the opportunity to provide stratified performance data to the clinicians, groups, virtual groups, or subgroups³ to provide meaningful feedback. CMS will utilize the overall or indicated performance rate for the scoring of quality measures. Options to determine the scored performance rate include but not limited to:
 - **Weighted Average:**
 - Add the numerator counts of each sub-measure and divide by the sum of the denominator counts of each sub-measure.
 - **MIPS CQM example:** Quality ID #370 (National Quality Forum [NQF] 0710) Depression Remission at Twelve Months.
 - **Simple Average:**
 - Add the percentages for each sub-measure and divide by the total number of component sub-measures.
 - **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 #391 (National Quality Forum [NQF] 0576): Follow-Up After Hospitalization for Mental Illness (FUH).
- **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 is being electronically derived/data mined from an electronic health record (EHR), the electronic QCDR measure is still benchmarked as a QCDR measure. EHR data mining is permitted without electronic clinical quality measure (eCQM) designation.

³ Subgroups are only available through MVP reporting. All measure-specific criteria must be met by the subgroup.

Measure Classification

- **National Quality Strategy (NQS) domains:** [The National Quality Strategy Fact Sheet](#) provides a focus for addressing the abundance of clinical quality measures currently used in national programs. NQS focuses on six priorities:
 - Making care safer by reducing harm caused in the delivery of care
 - Ensuring that each person and family is engaged as partners in their care
 - Promoting effective communication and coordination of care
 - Promoting the most effective prevention and treatment practices for the leading causes of mortality, starting with cardiovascular disease
 - Working with communities to promote wide use of best practices to enable healthy living
 - Making quality care more affordable for individuals, families, employers, and governments by developing and spreading new health care delivery models
- **Meaningful Measures:** Meaningful Measures identify high priority areas for quality measurement and improvement that CMS considers most vital to providing high-quality care and improving patient outcomes. CMS intends to prioritize outcome-based measures and move away from process-based measures. Meaningful Measures 2.0 has five interrelated goals:
 - Empower consumers to make good health care choices through patient-directed quality measures and public transparency.
 - Leverage quality measures to promote health equity and close gaps in care.
 - Use the Meaningful Measures Initiative to streamline quality measurement.
 - Leverage measures to drive outcome improvement through public reporting and payment programs.
 - Improve quality measure efficiency by transitioning to digital measures and using advanced data analytics.
- **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).
 - **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). 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 coordination of care and treatment with other providers.
- **Opioid Related:** Opioid-related measures that measure opioid use, overuse, risks, monitoring, and education.

QCDR Measure Testing

The QCDR measure testing information summarized in this section can be found in the [Blueprint content on the CMS MMS Hub](#). We give greater consideration to measures for which QCDRs, among other things, utilized the CMS Quality Measure Development Plan Annual Report and the Blueprint for the CMS Measures Management System to identify measurement gaps prior to measure development.⁴ Note: The measure testing requirement will be implemented in an incremental manner beginning with the 2022 performance period⁵.

According to CMS, a fully tested measure contains the following criteria⁶:

- 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 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 does not 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.

⁴ 42 CFR 414.1400(b)(4)(iii)(B)(9)(ii)

⁵ 42 CFR 414.1400(b)(4)(iii)(A)(3)

⁶ <https://mmshub.cms.gov>

Role of Testing in Performance Measurement

- Testing assesses scientific acceptability, reliability, validity, feasibility, usability and use of QCDR measures to assure they are meaningful measures.
- Testing is fundamental in reducing the reporting burden on providers by assuring their effort is not wasted in collecting data on measures that are not feasible or informative.
- Testing provides the opportunity to refine draft measure specifications before they are implemented so they will yield accurate and consistent data for performance program scoring.

Scientific Acceptability

The [Blueprint 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 intended area of measurement. 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 are not 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.
- CMS recommends testing of commonly used data elements to support reliability and validity.
- Attempt to identify and account for any missing data.
- Determine if there is a need for risk adjustment or stratification of the measure.

Measure Reliability

According to [Blueprint 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 element is criteria such as demographic, health status, healthcare activity, or other patient, clinician, or encounter attributes. For a validated tool or assessment instrument, the observed situation by result in ‘satisfaction’ or ‘functional status.’ Refer to the [Blueprint 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).

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- 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.
- Important because the measure must be able to distinguish differences between quality performance due to true differences in performance rather than chance reducing the probability of misclassification in comparative performance.
- CMS expects the measure developer assess the reliability of the measure score during development using data from testing.
- Refer to the [Blueprint content on the CMS MMS Hub](#) for more information regarding measure score differences.
- **Data Element Reliability**
 - 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 NQF, 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, maybe 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 content on the CMS MMS Hub](#) for more information regarding data element reliability assessment.

Measure Validity

Measure accurately represents the concept being evaluated and achieves the purpose for which it is intended 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 is a subjective assessment by experts of whether the measure reflects the quality of care (for example, the utilization of a current clinical guideline to frame the measure, such as using the blood pressure guideline of < 140/90 is a marker of quality).
 - Self-nominated QCDR measures must be face valid.
 - To be approved for the 2023 performance period all QCDR measures must meet face validity for the initial MIPS payment year for which it is approved. For subsequent years after being initially approved, 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)⁷.

⁷ § 414.1400(b)(4)(iii)(A)(3)

- For future years, when a measure must be fully tested, it must demonstrate validity at the clinician level for scientific acceptability, as well as reliability and feasibility on the same level ([see the Blueprint content on the CMS MMS Hub](#)).
- Possible Obstacles for Validation and Reliability:
 - Complex specifications may make a measure more susceptible to varying data field interpretation by different users.
 - Small errors in the measure specifications, such as omission of codes for commonly documented concepts in value sets, can reduce the capture of appropriate patients in the measure's denominator.
 - Users may enter information into specified measure fields other than those from which the vendor extracts data for measure reporting.

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 content on the CMS MMS Hub indicates feasibility assessments 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 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 content on the CMS MMS Hub indicates that usability and use includes an analysis to demonstrate that the measure is meaningful and useful to the target audience. This may be accomplished by a TEP reviewing the measure results (e.g., means and detectable differences, dispersion of comparison groups). There are other methods in which a measure steward may use to analyze 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 (Performance data, supporting clinical guidelines, consideration of a denominator exclusion/exception).

CMS QCDR Measure Determinations

QCDR measures are reviewed by CMS and contractors. 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 is not 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 is⁸:
 - Topped out.
 - Duplicative of a more robust measure.
 - Reflects an outdated clinical guideline.
 - Requires areas of duplication to be resolved between 2 or more QCDR measures.
 - The QCDR self-nominating the QCDR measure is no longer in good standing.

If a QCDR measure fails to meet benchmarking thresholds for two consecutive performance periods (data submitted is insufficient in meeting the case minimum 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.⁹ Please note that the submission of a participation plan does not 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;

⁸ § 414.1400(b)(4)(iii)(C)

⁹ § 414.1400(b)(4)(iii)(B)(10)(i)



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 physician, e.g., what basic care would be expected of any physician under similar circumstances. This includes the minimum that would be expected of any physician 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 healthcare 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 does not allow for meaningful benchmarks to be established. For QCDR measures, this is typically defined as > 95% performance rate or < 5% performance rate for average for inverse analytics. 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.¹⁰ 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 is not 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, 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 and/or resolve areas of duplication of QCDR measures that are similar in topic and/or concept. CMS will not likely approve measures that are duplicative or very similar to one another, as QCDR

¹⁰ § 414.1305



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measures with resolved areas of duplication allow for a larger cohort on which clinicians can be compared.¹¹

- **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 is not 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 does not 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 is not under the direct control of the reporting clinician. The quality action is completed or dependent on others.

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 will likely not approve this measure.
Similar or identical to an existing MIPS clinical quality measure.	CMS will likely not approve this measure and suggest QCDR report the similar or identical existing MIPS I quality measure.
Similar to a QCDR measure that was previously rejected.	CMS will likely not approve the measure, unless the measure was modified to address prior concerns, such as have a more meaningful quality action or demonstrates a performance gap.

¹¹ § 414.1400(b)(4)(iii)(A)(5)

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If New or Existing QCDR Measure Concept is:	Anticipated CMS Response:
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 QCDRs to consolidate the related series of measures into a single composite measure. By 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 does not have a quality action.	CMS will likely not approve the measure. Documentation or “check box” based QCDR measures will not be approved. The measure must demonstrate a performance gap.
A QCDR measure that includes an NQF Measure ID, but the measure specification does not accurately reflect the version endorsed by the NQF.	CMS will not recognize the NQF ID, unless the exact measure specifications are used.
A QCDR measure is not feasible, unable to be implemented, or the data cannot be abstracted at the time of self-nomination or during the performance and/or submission periods.	CMS will likely not approve the measure. QCDR measures should be fully implemented and feasible beginning on January 1 of the performance period.
A QCDR measure that does not demonstrate room for quality improvement (topped out).	CMS will not approve the measure if the measure is topped out.
A QCDR measure that is not attributable to the individual clinician.	CMS will likely not 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 does not have permission to self-nominate a QCDR measure owned by another QCDR for the applicable performance period.	CMS will likely not approve the measure for use. Case by case review can occur.



Transition to MIPS Value Pathways (MVPs)

MVP reporting will allow 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 aiming to provide meaningful data and feedback to clinicians and patients by comparing the performance of like clinicians who report on the same MVP. MVPs are developed in coordination with stakeholders with an established process in which clinician and patient perspectives are incorporated. 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 tested at the clinician level: Reliable, feasible, and valid as to 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 end on September 1 of the same year.
- Only QCDR measures that were approved in the previous year may be considered for inclusion within a candidate MVP.
- QCDR measures included in MVPs, and finalized through notice-and-comment rulemaking, would be eligible for 2-year QCDR measure approval.

QCDR Measure Development Resources

- CMS and the MIPS QCDR/Registry Support Team welcome the opportunity to preview measure concepts and provide feedback.
 - To request a measure concept 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.



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- QCDR measure concepts and specifications to be discussed at the meeting should be sent at least one week prior to the scheduled meeting in a single Word or Excel document.
 - If information is not received at least one week prior to the scheduled meeting, the meeting is subject to be rescheduled.
- [2022 QCDR Measure Specification file](#) - Contains measure specifications for all approved 2022 QCDR measures.
- [QPP Resource Library](#) - Contains a list of MIPS CQMs and will be posted after the final rule is published.
- [Blueprint 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 to help them produce high-caliber healthcare quality measures and documents the core set of business processes and decisions criteria 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 Advanced Alternative Payment Models (collectively known as the Quality Payment Program).
- [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 e-mail at: QPP@cms.hhs.gov. To receive assistance more quickly, please consider calling during non-peak hours—before 10 a.m. and after 2 p.m. ET.
 - Customers who are hearing impaired can dial 711 to be connected to a TRS Communications Assistant.
 - E-mails must be sent directly, not forwarded or Cc'ed, and must utilize the QPP e-mail address (QPP@cms.hhs.gov) in the **"To" line**. Inquiries forwarded to QPP@cms.hhs.gov or sent via e-mail with QPP@cms.hhs.gov in the "Cc" line will not trigger the creation of a case number for your inquiry.

