

Qualified Clinical Data Registry (QCDR) Non-PQRS Measure Submittal Tool
Guidance to Measure Stewards/Owners
On Submitting Measures and Measure Specification Elements

Measure Owners / Stewards: Please consider the following non-mandatory guidance for each of the data elements defining a measure specification when submitting performance measures to CMS for incorporation into Physician Quality Reporting System (PQRS) as a non-PQRS measure from a Qualified Clinical Data Registry (QCDR).

General Guidance

Eligible Professionals must submit nine measures covering three National Quality Strategy (NQS) Domains to align with the Center for Medicare and Medicaid Services (CMS) standards for successful reporting in PQRS. Two measures must be Outcome Measures and the remaining seven measures may be Outcome or Process Measures. Therefore it is beneficial to submit measures from across the six National Quality Strategy domains and a mix of process and outcome measures, with a preference for outcome measures as there are currently fewer outcome measures as compared to process measures in the PQRS.

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.

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.

Specific Guidance on Individual Measure Specification Elements

Measure Title: The measure title should start with the clinical condition of focus (e.g. Adult Sinusitis) followed by a brief description of the measure's desired clinical action (for positive measures). If the measure is NQF-Endorsed use NQF-Endorsed title. Measure titles should use as few words as possible and should not be a repetition of the measure description. For measures based on Appropriate Use criteria addressing overuse of certain services there are three standardized title lead ins:

- Appropriate Use of . . .
- Appropriate Non Use of . . .
- Inappropriate Use of . . . (for inverse measures – the least desirable approach).

Examples:

- *Adult Sinusitis -Inappropriate Use of Antibiotic*
- *Post-Anesthetic Transfer of Care*

Measure Description: It is ideal if the measure description uses standardized phrases in a standard order: "The percentage of gender qualifier (if applicable, e.g. female) patients or individuals, age

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qualifier (e.g. aged 18 years and older), denominator definition (e.g. who are under the care of an anesthesia practitioner and are admitted to a PACU), numerator criteria (e.g. in which a post-anesthetic formal transfer of care protocol or checklist which includes key transfer of care elements is utilized). It is important that performance measures be positive – that is that the correct and proper clinical activity or health outcome is captured in the numerator if at all possible. It is also important that the measure be expressed as a percentage whenever possible (for standardization purposes do not use “proportion”, “percentage rate” or “rate” – use “percentage”). If the measure is NQF endorsed the NQF-Endorsed measure description should be used verbatim.

Example: Percentage of patients, regardless of age, who are under the care of an anesthesia practitioner and are admitted to a PACU in which a post-anesthetic formal transfer of care protocol or checklist which includes the key transfer of care elements is utilized.

National Quality Strategy (NQS) Domain: The categorization of the proposed measure into the proper National Quality Strategy (NQS) Domain is a critical element of the measure submittal process. Eligible professionals are required to report a measure from at least three of the six domains, thus having a variety of measures in each domain is important. Developing and submitting measures from multiple domains allows for greater diversity in measure selection for the Eligible Professional. To that end, CMS suggests the following algorithm for measure domain assignment with the caveat that the measure should be assigned to the domain that a patient, their families or the community would find most intuitive. If the measure could be classified as:

1. Person and Caregiver-Centered Experience and Outcomes – categorize it as such, if not:
2. If the measure could be classified as a Patient safety measure – categorize it as such, if not:
3. If the measure could be classified as Communication and Care Coordination – categorize it as such, if not:
4. If the measure could be classified as Community/Population Health - categorize it as such, if not:
5. If the measure could be classified as Efficiency and Cost Reduction – categorize it as such, if not:
6. Categorize it as Effective Clinical Care.

Defining elements of measures for each domain are presented below:

1. Person and Caregiver-Centered Experience and Outcomes Measures should meet the following criteria by capturing:
 - a. the experience of each person and their family; or,
 - b. the extent to which the person and their family are engaged as partners in their care.
2. Patient Safety Measures include:
 - a. structures or processes that are designed to reduce risk in the delivery of care; or,
 - b. an outcome that results from the presence or absence of structures or processes designed to reduce risk in the delivery of care.
3. Communication and Coordination of Care Measures address:
 - a. the promotion of effective communication and coordination of care; or
 - b. the communication and coordination of care
4. Community / Population Health Measures involve:

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- a. working with communities, a community being defined as a group of people who have a common characteristic such as geographic proximity, race, ethnicity, age, occupation or other similar bonds (but is distinct in that the denominator is community based rather than utilization based – those seeking care);
 - b. a practice to enable healthy living, an intervention to improve the health behaviors or health of a group of individuals;
 - c. measurement of a process focused on primary prevention of disease or general screening – examples include immunizations, smoking cessation and age based colon cancer screening.
5. Efficiency and Cost Reduction Measures include:
- a. Measures focused on the appropriateness of care; or,
 - b. Measures focused on the affordability of care for individuals, families, employers, or governments.
6. Effective Clinical Care
- a. Measures not otherwise categorized in the above described domains.

Numerators and Denominators

Most performance measures consist of two major components: Numerators (patients or individuals receiving a clinical action or experiencing a health outcome) and Denominators (the eligible population who should receive the clinical action or health outcome). A general rule of thumb in building performance measures is – if you are in the numerator you must be in the denominator, and if you are in the denominator you must be at risk of being in the numerator.

Denominator Description: A statement that describes the population evaluated by the performance measure. The lower part of a fraction used to calculate a percentage or ratio (albeit ratios are rarely used in performance measurement). The denominator is associated with a given patient population that may be counted as eligible to meet a measure's inclusion requirements. In the case of percentages if the person is in the denominator they must be at risk of being in the numerator. The denominator criteria define the population that should receive the numerator action or positive health outcome (assuming a positive measure, which is always most desirable). Denominator criteria may include the population within a certain age strata, or a population defined by having some disease state or code for services rendered. It may be helpful, for clarity sake; to start the denominator description with the phrase "Number of patients..." as this defines the denominator as a number and not a percentage.

Example: *Number of patients, regardless of age, who are cared for by an anesthesia practitioner and are transferred directly from the procedure room to the PACU upon completion of the anesthetic.*

Numerator Description: A statement of the measure's focus, it is the target process, procedure, condition, event or outcome on which the measure is focused. The upper portion of a fraction used to calculate the percentage or ratio (albeit ratios are rarely used). Numerator criteria are the processes or outcomes expected for each patient, procedure, or other unit of measurement defined in the

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denominator. A numerator statement describes the clinical action that satisfies the conditions of the performance measure. Ideally the numerator criteria statement would start with the phrase “Number of denominator eligible patients...” thereby eliminating the necessity of repeating the denominator criteria. This also clarifies that the numerator is simply a number and not a percentage until it is divided by the denominator. It then should state the clinical procedure, procedural step or health outcome which is the target of the performance measure, which in the case of our example is “for whom a checklist or protocol which includes the key transfer of care elements is used.” As mentioned above – whenever possible the numerator should capture the correct clinical procedure or desired health outcome thereby creating a positive measure that moves towards 100% as the ideal state. The criteria for numerator inclusion should be as precisely defined as possible, which in our example means the “key transfer of care elements” should be listed and carefully defined.

Example: Number of denominator eligible patients for whom a checklist or protocol which includes the key transfer of care elements (which should be listed) is utilized.

Denominator Exceptions: Exceptions fall into two general categories – positive exceptions and defensible exceptions. Positive denominator exceptions are include instances where the patient would be removed from the denominator as an exclusion but based on the clinical judgement of the EP did receive the numerator service and therefore remain in the measure as a performance met. Positive exceptions should remove a patient, procedure or unit of measurement from the denominator of the performance rate only if the numerator criteria are not met. Denominator exceptions allow for adjustment of the calculated score for those providers with higher risk populations. Denominator exceptions are used only in percentage measures. Denominator exceptions allow for the exercise of clinical judgment and should be specifically defined where capturing the information in a structured manner fits the clinical workflow.

Defensible denominator exceptions are where the numerator criteria are not met and the patient is removed from the denominator and hence the performance measure altogether. Like denominator exclusions these cases are removed from the denominator; however unlike denominator exclusions they are removed only after the numerator criteria are not met. The number of patients with valid exceptions may still be reported. Defensible Exceptions allow for the exercise of clinical judgment. Allowable reasons fall into three general categories: Medical reasons; Patients’ reasons; and, System reasons.

Denominator Exclusions: Patients with conditions who should be removed from the measure population and denominator before determining if numerator criteria are met. (For example, women having previously undergone a dual radical mastectomy would no longer be eligible for a bi-annual screening mammography). The idea behind a denominator exclusion is to make the risk of being in the numerator as homogeneous as possible across the population identified in the denominator, therefore those not at risk of being in the numerator (as in the example) must be excluded from the population.

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Measure Types: The Measure Type is similar to the Measure Domain but characterizes the measure on different characteristics. Measure Owners / Steward needs to identify the measure type from the categories listed below, only the most relevant type should be identified. This is an important categorization process because Eligible Professionals must report at least two Outcome Measures. The measure types and their definitions are detailed below; identify the most appropriate characterization of measure type reporting only one of the measure types presented below:

Process Measure: Refers to a measure that focuses on a process which leads 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. A process of care is a health care-related activity performed for, on behalf of, or by a patient. There should be a scientific basis for believing that the process, when executed well, will increase the probability of achieving a desired outcome.

Outcome Measure: A measure of an outcome of care, which is a health state of a patient resulting from health care. An [Outcome] measure assesses the results of health care as experienced by patients. Outcome Measures must be linked to processes of care which if improved will improve the outcome. This aspect of performance measurement is referred to as responsiveness.

Intermediate Outcome: A measure which aims to meet specific thresholds of health outcomes that may not be perceptible to the patient (e.g. having an HbA1C level < 9 and being diabetic).

Patient Reported Outcome: A measure that is based on any report of the status of a patient's health condition, health behavior or experience with health care that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else.

Structural Measures: A measure that assesses the aspects of the health care infrastructure, these are generally broad in scope, system wide (e.g. the presence of a CAT scan, staffing levels, etc.).

Composite Measure: A measure which contains two or more individual measures, resulting in a single measure and a single score. Composite measures may be composed of one or more process and/or one or more outcome measures.

Patient Engagement/Experience Measure: A measure that focuses on patients' or enrollees' report concerning observations of and participation in the health care system (e.g. a satisfaction survey)

Cost/Resource Use Measure: a measure of health services counts (in terms of units or dollars) applied to a population or event (broadly defined to include diagnoses, procedures, or encounters). A resource use measure which counts the frequency of defined health system resources; some may further apply a dollar amount (for example, allowable charges, paid amounts, or standardized prices) to each unit of

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resource use—that is, monetize the health service or resource use units per a defined population or group in the denominator.

Efficiency Measures: a measure of cost of care associated with a specified level of health outcome.

NQF Number: Enter the measure number assigned by the National Quality Forum. Enter "NA" if the measure does not have an NQF number.

eCQM Measure Number: Enter the measure number assigned if the measure has a formally developed eCQM. Enter "NA" if the measure does not have an eCQM number.

Rationale: This element should address the clinical rationale for the measure and most often would cite a clinical practice guideline or some other objective clinically based reference that would serve as the rationale for the measure. PQRS and non-PQRS performance measures should be well established in the literature and clinical practice guidelines. Measure should not be based on emerging or controversial clinical procedures. An analysis on the relevance of the measure and the purpose for implementation within the organization should be listed in this field. This should include studies and any other relevant information pertaining to the implementation of the measure.

Data Source: This measure specification element seeks to identify the data collection tool used, or the primary source of the data reported to the PQRS for the individual measure. The Data Source is equivalent to the submitted measure's reporting options and all of the sources that may be used should be reported. Choose all that apply (e.g., Claims/Paper Medical Record, Registry, EHR, and Survey). **Do not** select EHR as a data source if your measure is not an eCQM.

Electronic Health Record Data Source: Complete only if Electronic Health Record was selected as a Data Source. Note that CMS will verify if the measure is using the Measure Authoring Tool (MAT) and the Value Set Authority Center (VSAC). If the measure is using the MAT, you must provide the eMeasure identifier and the GUID.

Measure Steward: Refers to the primary (and secondary, if applicable) party responsible for updating and maintaining a measure. Note that documented confirmation of the steward's agreement to maintain an accepted measure must be submitted with all measure submission required documentation.

Number of Performance Rates to be submitted in the XML: Enter the number of performance rates that will be calculated for this measure and submitted to CMS.

Indicate an Overall Performance Rate if more than 1 performance rate is to be submitted: If more than one performance rate will be submitted, specify which rate will represent an overall performance rate

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for the measure or how an overall performance rate could be calculated based on the data submitted in the XML [for example, simple average of the performance rates submitted or weighted average (sum the numerators divided by the sum of the denominators), etc]. It is suggested that one of the performance rates submitted should reflect an overall performance rate for the measure

Inverse Measure: A simple yes / no response is required for this element. A principle of quality improvement science and hence performance measurement is that the positive or correct clinical care should be emphasized and captured in the numerator, with quality performance increasing toward a rate of 100% (perfect care – each patient receiving the care they need). Inverse measures function inversely from traditional performance measures, where a lower score in an inverse measure indicates better performance, with a rate of 0% indicating perfect care (e.g. the percentage of inappropriate imaging technology utilization). Inverse measures should be avoided if possible; however CMS does accept their use as PQRS and non-PQRS measures. It is important that inverse measures are clearly identified as such. The status of an inverse measure as such should be indicated within the measure specification. The measure owner / steward should consider flipping inverse measures and creating standard positive measures if at all possible (e.g. the percentage of appropriate imaging technology utilization).

- Yes (it is an inverse measure).
- No (it is NOT an inverse measure)

Proportion Measure Scoring – a Percentage Rate: Proportion Measures indicate a traditional performance measure, where the numerator is directly related to the denominator and will produce a percentage rate. In a traditional proportion measure, a higher score indicates better performance; a rate of 100% indicates perfect care. Inverse measures may also be proportion measures where a lower percentage rate indicates better care.

Selection from drop down list:

- Yes (this is a proportion measure expressed as a percentage rate)
- No (this is not a proportion measure expressed as a percentage rate)

Continuous Measure Scoring: Continuous measures compare a defined parameter (e.g. a test result) against a specified patient population, essentially capturing the average experience of the denominator population (the sum of the parameter for each individual divided by the number of denominator eligible individuals). These measures are not percentage measures and cannot be expressed as a percentage rate. Continuous measures are often difficult to interpret from a quality perspective as higher or lower rates may not always mean better performance. It may be appropriate to dichotomize a continuous measure using some standard cut point. For example, in diabetics the Hemoglobin A1c (HbA1c) test characterizes blood sugars over time and can range from 4 or 5 to over 10. For diabetics a HbA1c of 9 or less is generally considered acceptable control of blood sugar levels. Therefore, in order to dichotomize the continuous variable of HbA1c a threshold of less than or equal to 9 is used. Each measurement that is found to be below the threshold is in compliance with the numerator criteria, where values above 9

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are categorized as performance not met. In this manner the continuous variable of the results of HbA1c tests are dichotomized and therefore can be expressed as a percentage rate. Whenever possible, performance measures that are continuous variable should be dichotomized by establishing some threshold above or below which is indicative of quality. Another example of dichotomizing a continuous variable would be wait times in the Emergency Department. The average wait time can be transformed to the percentage of wait times of 15 minutes or less (or whatever wait-time goal is desirable). This then allows each individual measure to be characterized as meeting the numerator criteria and the measure can be presented as a percentage rate. CMS recognizes that there are some continuous variables for which quality thresholds are not yet established and therefore will accept continuous variables as potential PQRS and non-PQRS measures. However when possible thresholds should be established and measures dichotomized in order that they can be expressed as the more typical and easier to interpret percentage rates. Continuous variable measures can be either episode or patient-based.

Selection from drop down list:

- Yes (this is a continuous variable)
- No (this is not a continuous variable)

Risk Adjusted: Risk adjusted measures have been adjusted to compensate for the risk structure of the Eligible Professional's population of patients (i.e. the denominator of the measure). These measures can be a proportional measure or continuous and this information should be defined in the measure specification.

Selection from drop down list:

- Yes (measure is risk adjusted)
- No (measure is not risk adjusted)