Quality Payment PROGRAM

2021 Qualified Clinical Data Registry (QCDR) Fact Sheet

Overview

To become a QCDR for the Merit-based Incentive Payment System (MIPS) program under the Quality Payment Program, you must self-nominate and successfully complete a qualification process.

When is the self-nomination period?

You can self-nominate from:

July 1 – September 1 of the year prior to the applicable performance period. The self-nomination period will promptly open at **10 a.m. (Eastern Time) ET** on July 1st close at **8 p.m. ET** on September 1, 2020. Self-Nominations submitted after the deadline will not be considered.

Tips for successful self-nomination:

1. You must provide all required information at the time of self-nomination, and before the close of the self-nomination period via the CMS Quality Payment Program portal (https://qpp.cms.gov/login) for CMS consideration.

2. Self-nomination is an annual process. If you want to qualify as a QCDR for a given MIPS performance period, you will need to self-nominate for that MIPS performance period. Qualification and participation in a prior program year does not automatically qualify a vendor for subsequent MIPS performance periods.

   A simplified self-nomination form is available to reduce the burden of self-nomination for those existing QCDRs that have previously participated in MIPS and are in good standing (CMS did not take remedial action against or terminate the QCDR as a third party intermediaries). **Please note that the simplified self-nomination form must be successfully submitted during the self-nomination period to be considered for the given MIPS performance period.**

   A simplified self-nomination form is available **only** to existing QCDRs who are in good standing. Existing QCDRs in good standing should contact the MIPS QCDR/Registry Support Team (PIMMS Team) at QCDRVendorSupport@gdit.com if they cannot find or access the simplified self-nomination form instead of submitting a new self-nomination form.

3. Take advantage of QCDR measure concept preview calls available until June 30, 2020th. These preview calls allow CMS, the MIPS QCDR/Registry Support Team, and the QCDR to collaboratively discuss and provide feedback regarding new and existing QCDR measure(s)

prior to self-nomination. This may also provide an opportunity to discuss current provisionally approved QCDR measures with requested: revisions, measure harmonization, or requests to combine measures within a single QCDR. CMS may provide preliminary input that may be useful to revise QCDR measures. Please note, that final measure decisions will not be made during the call. To schedule a meeting, contact the QCDRVendorSupport@gdit.com by 5 p.m. ET on June 12, 2020. QCDR measure concepts and specifications to be discussed at the meeting must 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. In addition, a QCDR measure concept preview call does not qualify a QCDR as meeting the QCDR definition for a given self-nomination period.

What is a QCDR?

A QCDR is defined as an entity that demonstrates clinical expertise in medicine and quality measurement development that collect medical or clinical data on behalf of MIPS eligible clinicians to track patients and diseases and foster improvement in the quality of care provided to patients. A QCDR may include:

- An entity with clinical expertise in medicine. Clinicians must be on staff with the organization and lend their clinical expertise in the work carried out by the organization as a QCDR.
- An entity with stand-alone quality measurement development.
- An entity that collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients.
- An entity that uses an external organization for purposes of data collection, calculation, or transmission may meet the definition of a QCDR as long as the entity has a signed, written agreement that specifically details the relationship, roles and responsibilities of the entity with the external organization effective as of September 1 the year prior to the year for which the entity seeks to become a QCDR.

Entities without clinical expertise in medicine and quality measure development that want to become a QCDR, may collaborate with entities with such expertise.

As described in the CY 2018 Quality Payment Program final rule (82 FR 53809), changes to the QCDR's organizational structure (for example, if a specialty society wishes to partner with a different data submission platform vendor) are considered substantive and would need to be included as an update at the time of self-nomination. The roles and responsibilities of each organization should be specifically detailed within the self-nomination form.

Alternatively, entities may seek to qualify as another type of third-party intermediary, such as a Qualified Registry. Becoming a Qualified Registry does not require the level of measure development expertise that is needed to be a QCDR that develops measures.

The QCDR reporting option is different from a Qualified Registry because QCDRs are not limited to reporting only MIPS Quality Measures. A QCDR may also submit a maximum of 30 QCDR measures to CMS for consideration in the 2021 MIPS performance period.

Measures submitted by a QCDR may be from one or more of the following categories:

- Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CAHPS), which must be reported via CAHPS certified vendor. Although the CAHPS for MIPS survey is included in the MIPS measure set, the changes needed for reporting by individual eligible clinicians are significant enough to treat it as a QCDR measure for the purposes of reporting via a QCDR. Please note that submitting a subset of CAHPS survey measures as a QCDR measure will not count for credit towards completing the CAHPS for MIPS Survey.
- National Quality Forum (NQF) endorsed measures.
- Current 2021 MIPS Clinical Quality Measures.
- QCDR measures developed by boards or specialty societies with the appropriate documented permission to the QCDR measure.
- QCDR measures developed by regional quality collaborative with the appropriate documented permission to the QCDR measure.

What are the requirements to become a QCDR?

1. **Participants:** You must have at least 25 participants by January 1 of the year prior to the applicable performance period (January 1, 2020 for consideration for the 2021 MIPS performance period). These participants are not required to use the QCDR to report MIPS data to CMS, but they must submit data to the QCDR for quality improvement. **Please note that your system must be implemented and able to accept data from a clinician, group or virtual group should they wish to submit data** under any performance category **starting on January 1, 2021**. A system that is not "live" beginning with the start of the performance period is considered non-compliant with this requirement.

2. **Certification Statement:** During the data submission period, you must certify that data submissions are true, accurate, and complete to the best of your knowledge. This certification includes the acceptance of data exports directly from an EHR or other data sources. If you become aware that any submitted information is not true, accurate, and complete, you will correct such issues promptly prior to submission, or refrain from submitting it, and understand that the knowing omission, misrepresentation, or falsification of any submitted information may be punished by criminal, civil, or administrative penalties, including fines, civil damages, and/or imprisonment.

3. **Data Submission:** You must submit data via a CMS-specified secure method for data submission, such as a defined Quality Payment Program data format. Additional information regarding data submission methodologies can be found in the Developer Tools section of the Resource Library of the Quality Payment Program website: https://qpp.cms.gov/developers.

4. **Data Validation Plan (DVP):** During self-nomination, you must thoroughly explain your **process** for validation of data submitted on behalf of individual MIPS clinicians, groups and virtual groups through the development of a Data Validation Plan. **Execution of your Data Validation Plan must be completed prior to data submission for the 2021 performance period for all performance categories supported, so errors can be corrected prior to submitting.** All data that is eligible to be submitted for purposes of the MIPS program should be subject to validation, regardless of whether the clinician or group are MIPS eligible, voluntary, or are opting in. You are required to provide the following as a part of your Data Validation Plan:

   - ☐ Process of verifying Quality Payment Program eligibility of clinicians, groups, and virtual groups. QCDRs are required to identify and track their clinicians as MIPS eligible, opt-in, or voluntary reporters.
   - ☐ Process of verifying accuracy of tax identification numbers (TINs)-National Provider Identifier (NPIs).
   - ☐ Process of calculating reporting and performance rates.
   - ☐ Process of verifying that your system will only accept data (for purposes of MIPS) on the 2021 version of measures and activities during submission
     - 2021 MIPS Clinical Quality Measures (CQMs), electronic Clinical Quality Measures (eCQMs) and/or QCDR measures for the Quality performance categories.
     - 2021 Promoting Interoperability measures and objectives for the Promoting Interoperability performance categories.
     - 2021 Improvement Activities for the Improvement Activities performance categories
   - ☐ Process used for completion of randomized audit across the Quality, Promoting Interoperability, and/or Improvement Activities performance categories. At a minimum must meet the following sampling methodology to meet participation requirements: Sample 3% of the TIN/NPIs submitted to CMS, with a minimum of 10 TIN/NPIs or a maximum sample of 50 TIN/NPIs. At least 25% of the TIN/NPI's patients (with a minimum sample of 5 patients or a maximum sample of 50 patients) should be reviewed for all measures applicable to the patient).
   - ☐ Process used for completion of detailed audit for the Quality, Promoting Interoperability, and/or Improvement Activities performance categories. The Detailed Audit should include a description of the root cause analysis, how the error was corrected, and the percentage of your total clinicians impacted by the data error. Please note that the sample used for auditing in the Detailed Audit should be broadly selected, and should not only include clinicians and groups impacted by the error in question. The aspect of the audit that is considered "the detail" is the specific error you are auditing for. (*Note: The detailed audit is required if any errors are found through the randomized audit*).

   Your Data Validation Plan will be reviewed by CMS as a part of your self-nomination application and will need CMS approval prior to its implementation for the performance period.

5. **Data Validation Execution Report (DVER):** You must execute your 2021 Data Validation Plan and provide us with the **results** (i.e., Results of the randomized/detailed audits, identifying calculation issues, why they occurred and what was done to remediate). Execution of your Data Validation Plan, including the identification and correction of those errors must be completed **prior** to the submission of data for the 2021 MIPS performance period, for all performance categories supported.

   ☐ The 2021 Data Validation Execution Report that includes the results of our audit must be submitted to CMS by May 31, 2022.
   ☐ The following items should be addressed in the 2021 Data Validation Execution Report:

   - Name of QCDR
   - Was data submitted for any of the performance categories for the 2021 MIPS performance period?
   - Overall Data Error Rate - (Number of Clinicians with a Data Issue / Total Number of clinicians Supported)
     - The overall data error rate includes only data errors that were not corrected before submission to CMS.
   - Results of verifying MIPS eligibility of clinicians, groups, and virtual groups (i.e., were any issues identified when determining if clinicians, groups, and virtual groups meet the MIPS eligibility requirements? If so, please provide details and examples regarding the identified issues and how they were resolved).
   - Results of verifying the accuracy of TIN-NPI (i.e., were any issues identified when verifying TINs-NPIs? If so, please provide details and examples regarding the identified issues and how they were resolved).
   - Results of verifying that 2021 MIPS measures and activities were utilized for submission (i.e., were any issues identified?? If so, please provide details and examples regarding the identified issues and how they were resolved).
     - 2021 MIPS Clinical Quality Measures (CQMs), electronic Clinical Quality Measures (eCQMs) and/or QCDR measures for the Quality performance categories.
     - 2021 Promoting Interoperability measures and objectives for the Quality performance categories.
     - 2021 Improvement Activities for the Improvement Activities performance categories
   - Results of calculating data completeness and performance rates (i.e., were any issues identified with how the MIPS quality measure specifications and/or QCDR measure specifications (as applicable) were implemented in the system? If so, please provide details and examples regarding the identified issues and how they were resolved).
   - Results of the randomized audit (i.e., were there any data issues identified? If so, please provide details and examples regarding the identified issues).
   - Results of the detailed audit (i.e., provide details and examples regarding how the identified data issues were resolved (*Note: The detailed audit is required if any*

errors are found through the randomized audit). The Detailed Audit should include a description of the root cause analysis, how the error was corrected, and the percentage of your total clinicians impacted by the data error. Please note that the sample used for auditing in the Detailed Audit should be broadly selected, and should not only include clinicians and groups impacted by the error in question. The aspect of the audit that is considered "the detail" is the specific error you are auditing for.

We require QCDRs to utilize auditing processes to ensure the accuracy of all data submissions under all performance categories as QCDRs must be able to submit data for all performance categories; however, a third-party intermediary may be excepted from this requirement if all supported MIPS eligible clinicians, groups or virtual groups fall under the reweighting policies at §414.1380(c)(2)(i)(A)(4) or (5) or § 414.1380(c)(2)(i)(C)(1) through (7) or §414.1380(c)(2)(i)(C)(9)). In instances where some of the QCDR's participants do not fall under the reweighting policies described above, the QCDR will be expected to comply with the requirements.

QCDRs will certify, at the time of self-nomination that the data submitted for all performance categories is true, accurate, and complete to the best of their knowledge. This certification includes the acceptance of data exports directly from an EHR or other data sources. If you become aware that any submitted information is not true, accurate, and complete, you will correct such issues promptly prior to submission, or refrain from submitting it, and understand that the knowing omission, misrepresentation, or falsification of any submitted information may be punished by criminal, civil, or administrative penalties, including fines, civil damages, and/or imprisonment.

Please note, a late, incomplete, and/or absent submission of your Data Validation Execution Report from your QCDR will be seen as non-compliance with program requirements and may result in remedial action or termination of the QCDR for the current and possibly future program years of the MIPS program.

Please note: CMS will provide a sample Data Validation Execution Report template, which will be posted on the CMS Quality Payment Program Resource Library.

6. **Performance Category Feedback Reports:** QCDRs are required to provide performance category feedback at least four times a year, and provide specific feedback to all individual MIPS clinicians, groups and virtual groups on how they compare to other clinicians who have submitted data on a given measure for all individual MIPS clinicians, groups and virtual groups. Please note:
   - ☐ CMS does not provide a template for the performance feedback reports.
   - ☐ If a real-time feedback dashboard is available to clinicians, CMS asks that the QCDR e-mail clinicians, groups and virtual groups at least four times a year, to remind them the feedback is available.

- ☐ Exceptions to this requirement may occur if the QCDR does not receive the data from their clinician until the end of the performance period, as discussed at §414.1400(c)(2)(ii).

7. Attest that you understand the QCDR qualification criteria and program requirements, and will meet all program requirements (such as provide performance feedback at least 4 times a year, and provide specific feedback to clinicians and groups on how they compare to other clinicians who have submitted data on a given measure.

What information is required to self-nominate?

You must provide the following when you self-nominate:

- ☐ What is your QCDR's Vendor Name?
- ☐ Are you a new or existing QCDR (approved in a previous year of MIPS and/or Physician Quality Reporting System [PQRS])?
- ☐ Which MIPS performance categories do you intend to support? Please note QCDRs are required to support the Quality, Promoting Interoperability, and Improvement Activity performance categories. Third party intermediaries could be excepted from this requirement if ALL of its supported MIPS eligible clinicians, groups or virtual groups fall under the reweighting policies.
- ☐ Are you submitting a QCDR Measure Specifications (if submitting QCDR Measures)?
- ☐ Are you supporting MIPS CQMs? Please note that the reporting of MIPS CQMs must utilize the current measure specification for the performance period in which they will be used, and must be used as specified. Third party intermediaries are not permitted to alter or modify measure specifications.
- ☐ Are you supporting MIPS eCQMs? Please note that the reporting of MIPS eCQM must utilize the current measure specification for the performance period in which they will be used, and must be used as specified. Third party intermediaries are not permitted to alter or modify measure specifications.
- ☐ Which 2021 Improvement Activities are you supporting?
- ☐ Which 2021 Promoting Interoperability Objectives and Measures are you supporting?
- ☐ Please identify your vendor type (i.e., Collaborative, Health Information Exchange/Regional Health Information Organization, Health IT vendor, Regional Health Collaborative, Specialty Society, Other)
- ☐ Which data collection method(s) do you utilize (i.e., claims, EHR, practice management system, web-based tool, etc.)?
- ☐ Provide details of your Data Validation Plan (as described above).
- ☐ Confirm you will provide your 2021 performance period Data Validation Plan results by the deadline of May 31, 2022 (the Data Validation Execution Report)
- ☐ Available Performance Data
- ☐ Risk Adjustment Method for QCDR Measures (if applicable)
- ☐ Which reporting options do you intend to support (i.e., Individual MIPS eligible clinician, Group, Virtual Groups, APM Entity)?
- ☐ Specify the Cost (frequency (monthly, annual, per submission) and if the Cost is per provider/practice and Services Included in Cost

☐ Detailed information on quality measure development experience and clinical expertise

What are the QCDR measure specification requirements?

You must provide specifications for each QCDR measure that you would like to nominate for CMS consideration:

- Provide QCDR measure descriptions and narrative specifications for each QCDR measure with your submitted self-nomination application no later than the last day of the applicable self-nomination period (September 1, 2020), utilizing the QCDR measure submission template.
- Publicly post the QCDR measure specifications for each QCDR measure no later than 15 calendar days following CMS's approval of these QCDR measure specifications and provide CMS with the link to the posted information (via a comment in your approved self-nomination form).

QCDR Measures	MIPS Quality Measures
For QCDR Measures, QCDR measure specifications must include: • Measure Title and Description • QCDR measure ID for previously approved CMS measure • Denominator and numerator statements • Descriptions of the denominator exceptions, denominator exclusions, and numerator exclusions • National Quality Strategy (NQS) domain • Care setting • Meaningful measure area • Meaningful measure area rationale • Measure type • If the QCDR measure is a high priority measure and priority type (if applicable) • Primary data source used for abstraction • Concise summary of evidence to support performance gap • Performance data on the QCDR measure (number of months collected, average performance rate, performance range, and number of clinicians reporting the QCDR measure) • Measure owner, please note that permission to use another QCDR's measure should be obtained prior to the QCDR measure being submitted for CMS consideration. • National Quality Forum (NQF) ID number, if applicable • Number of performance rates required for QCDR measure • Overall performance rate information, if more than one is required • Clinical recommendation statements which summarize the clinical recommendation based on best practices • QCDR measure rationale which provides a brief statement describing the evidence base and/or intent for the measure • Traditional vs Inverse measure • Proportional, continuous variable, ratio measure indicator • If the QCDR measure is risk-adjusted and which score is risk-adjusted • Risk adjustment variables, and risk adjustment algorithms, when applicable • Indicate if the QCDR measure was tested at the individual clinician level • Describe link to Cost measure/Improvement Activity • Indicate which specialty/specialties apply to the QCDR measure • Preferred measure clinical category • Attestation of the feasibility of the QCDR measure at the time of self-nomination	**For MIPS Clinical Quality Measures**, only the MIPS Clinical Quality Measure IDs for individual measures and/or the specialty-measure set measures must be submitted.

What is considered a QCDR measure?

QCDR Measures may include:

- A measure that is not contained in the annual list of MIPS Quality Measures for the applicable performance period.
- A measure that may be in the annual list of MIPS Quality Measures but has substantive differences in the manner it is submitted by the QCDR.

- The CAHPS for MIPS survey, which can only be submitted using a CMS-approved survey vendor. Although the CAHPS for MIPS survey is included in the MIPS measure set, the changes needed for reporting by individual eligible clinicians are significant enough to treat it as a QCDR measure for the purposes of reporting via a QCDR. CMS will not approve patient survey measures that only measure whether the survey was distributed and/or completed. In addition, QCDRs will not receive CAHPS for MIPS survey credit for CAHPS for MIPS survey measures submitted as QCDR measures.

What are the QCDR measure consideration criteria?

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 additional information, please reference section §414.1400(b)(3) of the Physician Fee Schedule 2020 Final Rule.
QCDR measures should:

- Be developed using the measure development processes as defined in the most recent Blueprint for the CMS Measures Management System.
- Be clinically relevant and evidence based (align with current clinical guidelines).
- Include evidence of a performance gap. CMS encourages QCDRs to collect data for 12 months prior to submission which increases the likelihood the QCDR measure could be benchmarked. NOTE: CMS is delaying the implementation of the collection of data requirement for QCDR measures policy by one year. Beginning with the 2022 performance period, QCDRs are required to collect data on a QCDR measure, appropriate to the measure type, prior to submitting the QCDR measure for CMS consideration during the self-nomination period. Please reference CMS' most recent release of the Interim Final Rule with Public Comment: Medicare and Medicaid IFC: Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (CMS-5531 IFC).
- Address requested/required revisions made by CMS during the previous performance period of MIPS (Provisionally Approved measures) or provide rationale of why the CMS request is not clinically appropriate.
- 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 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 eligible clinician ease of understanding.
- Be fully developed and not just in the concept development phase. End to end testing or process validation should be performed to ensure data can be collected or extracted, received and calculations can occur.
    - If a QCDR measure is being used by a QCDR that does not own the measure, it is expected that the ability to abstract the data according to the QCDR measure owner's specifications is a condition of self-nominating the QCDR measure. Withdrawing of the QCDR measure during an active performance period is not acceptable.
- 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.
- Identify whether there are changes to the QCDR measure specification for the upcoming performance period of MIPS, if approved from a previous performance period of MIPS. Please note, substantive changes that alter the intent of the QCDR measure and may impact the performance score and benchmarking will result in a new QCDR measure ID being assigned.
- Identify linkage to a cost measure and improvement activity. (In cases where a QCDR measure does not have a clear link to a cost measure and an improvement activity, we would consider exceptions if the potential QCDR measure otherwise meets the QCDR measure requirements and considerations.)

QCDR measures should **not**:

- Duplicate an existing or proposed MIPS quality measure (CQM/eCQM).
- 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 harmonize 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 harmonized QCDR measures 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 Physician Quality Reporting System (PQRS) or MIPS quality measure (CQM/eCQM).
- 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. 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 eligible clinician.
- Be documentation/check box measures.

Beginning with the 2021 MIPS performance period, QCDR measures may be approved for 2 years, at CMS discretion. Upon annual review, CMS may revoke QCDR measure second year approval, if the QCDR measure is found to be: topped out; duplicative of a more robust measure; reflects an outdated clinical guideline; requires QCDR measure harmonization; or if the QCDR that is nominating the QCDR measure is no longer in good standing [§414.1400(b)(3)(iv)(J)(2)(vi)].

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. Please note that the submission of a participation plan does not guarantee the approval of a QCDR measure for the upcoming performance period.

- Participation Plan: Detailed plan and methods to encourage MIPS 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.

CMS recommends that QCDRs utilize the following when developing and self-nominating QCDR measures:

- Measure Development Plan

- QCDR Measure Development Handbook
- CMS Blueprint

What data submission functions must an approved QCDR perform?

Following the self-nomination and QCDR measure process, an approved QCDR must perform the following data submission functions:

1. **Indicate:**
   - ☐ Whether the QCDR is using CEHRT data source
   - ☐ End-to-end electronic reporting, if applicable.
   - ☐ Performance period start and end dates.
   - ☐ Report data on Quality measures, Promoting Interoperability objectives and measures and objectives or Improvement Activities, as applicable, to the standards and requirements of the respective performance categories.

2. **Submit:**
   - ☐ The data and results for all supported MIPS performance categories.
     - ✓ The data must include **all-payer data**, and not just Medicare Part B patients.
   - ☐ Results for at least six Quality Measures (MIPS CQMs, eCQMs, and/or QCDR measures), including one outcome measure, as applicable.
     - ✓ If an outcome measure is not available, use at least one other high priority measure.
     - ✓ Give entire distribution of measure results by decile, if available.
   - ☐ Appropriate measure and activity IDs for Quality Measures, Promoting Interoperability measures and objectives, and Improvement Activities.
   - ☐ Measure-level data completeness rates by TIN-NPI and/or TIN.
   - ☐ Measure-level performance rates by TIN-NPI and/or TIN.
   - ☐ The sampling methodology used for data validation.
   - ☐ Risk-adjusted results for any risk-adjusted measures.
   - ☐ Additional details for QCDR Measures:
     - ✓ Data elements and QCDR measure specifications.
     - ✓ Risk-adjusted results for QCDR quality data, if applicable.
     - ✓ Comparison of quality of care by measure, by clinician or group.

3. **Report on the number of:**
   - ☐ Eligible instances (eligible patient population).
   - ☐ Instances a quality action is performed (performance met).
   - ☐ Instances the applicable quality action was not met (performance not met).
   - ☐ Instances a performance exception/exclusion occurred (denominator exceptions/numerator exclusions).

4. **Verify and maintain eligible clinician information:**

- ☐ Signed verification of clinician names, contact information, services provided, costs charged to clinicians, Quality Measures (MIPS Quality Measures and/or QCDR Measures), and specialty-specific measure sets (if applicable).
- ☐ Business associate agreements must comply with HIPAA Privacy and Security Rules.
- ☐ Business agreement(s) with clinicians, groups or virtual groups who provide patient-specific data.
- ☐ Obtain and keep on file signed documentation that each holder of an NPI whose data are submitted to the QCDR, has authorized the QCDR to submit quality measure results, improvement activities measure and activity results, promoting interoperability results and numerator and denominator data or patient-specific data on Medicare and non-Medicare beneficiaries to CMS for the purpose of MIPS participation. This documentation should be obtained at the time the MIPS eligible clinician or group signs up with the QCDR to submit MIPS data to the QCDR and must meet the requirements of any applicable laws, regulations, and contractual business associate agreements. Groups participating in MIPS via a QCDR may have their group's duly authorized representative grant permission to the QCDR to submit their data to us. If submitting as a group, each individual MIPS eligible clinician does not need to grant their individual permission to the QCDR to submit their data to us.
- ☐ A practice administrator may give consent on behalf of a group or virtual group reporting as a group, but **not** for an individual MIPS-eligible clinician reporting as an individual. If you are submitting the individual MIPS-eligible clinician data as an individual, you must have a business associate agreement and consent in place for each individual clinician.
- ☐ Include disclosure of MIPS quality measure results and data on Medicare and non-Medicare beneficiaries.
- ☐ Clinician consent with signed authorization to submit results and data to CMS for MIPS.
- ☐ Certification statement that all data and results are true, accurate, and complete to the best of your knowledge.

5. Comply with:

- ☐ Any CMS request to review your submitted data. For the purposes of auditing, CMS may request any records or data retained for the purposes of MIPS for up to 6 years from the end of the MIPS performance period.
- ☐ Requirement to participate in the mandatory QCDR kickoff meeting and monthly support calls.
- ☐ Participation requirements (for example, and not limited to: Data Validation Execution Report, performance feedback to eligible clinicians, QCDR must be up and running by January 1 of the given performance period, etc.).
- ☐ A CMS-approved secure method for data submission.

What are the thresholds for data inaccuracies? What are considered data inaccuracies?

Data inaccuracies that affect MIPS clinicians, may result in:

- Remedial action, up to and including termination, may be taken against your QCDR due to the low data quality rating.
- The QCDR Qualified Posting updated for the performance period of MIPS to indicate the QCDR's data error rate on the CMS website until the data error rate falls below 3 percent and that remedial action or termination has been taken against the QCDR.

CMS will further evaluate the QCDR to determine if any inaccurate, unusable or otherwise compromised data affects MIPS eligible clinicians. Data inaccuracies affecting your total MIPS eligible clinicians may lead to remedial action/termination of the QCDR for future program year(s) based on CMS discretion.

CMS will evaluate each quality measure for data completeness and accuracy. The vendor will also attest that the data (quality measures, improvement activities, and promoting interoperability objectives and measures) results submitted are true, accurate, and complete to the best of their knowledge.

CMS will determine error rates calculated on data submitted to CMS for MIPS eligible clinicians.

CMS will evaluate data inaccuracies including, but not limited to:

- TIN/NPI Issues – Incorrect TINs, Incorrect NPIs, Submission of Group NPIs.
- Formatting Issues – Submitting files with incorrect file formats, Submitting files with incorrect element formats, Failure to update and resubmit rejected files.
- Calculation Issues – Incorrect qualities for measure elements, performance rates, and/or data completeness rates; Numerators larger than denominators.
- Data Audit Discrepancies – Since data audits are required to occur prior to data submission, QCDRs should correct all identified errors prior to submitting the data to CMS. QCDR acknowledgement of data discrepancies found post submission from clinician feedback reports.

What may cause remedial action to be taken or termination of third party intermediaries from the program?

The CY 2020 Physician Fee Schedule (PFS) Final Rule for Quality Payment Program (84 FR §414.1400(f)) provides CMS the ability to enforce remedial action or termination based on its determination that a third-party intermediary is non-compliant with any applicable criteria or if the third-party intermediary submits data that is inaccurate, unusable, or otherwise compromised.

QCDRs that have remedial action taken against them will be required to submit a corrective action plan (CAP) to address any deficiencies and detail any steps taken to prevent the deficiencies from reoccurring within a specified time period. The CAP must include the following:

- The issues that contributed to the non-compliance.
- The impact to the individual clinicians, groups and virtual groups.
- The corrective action implemented by the QCDR to ensure that the non-compliance issues have been resolved and will not be repeated in the future.
- The timeline from the issue identification to resolution.
- The resolution follow-up plan to communicate the final resolution and plan to monitor for future issues.

Failure to comply with the remedial action process may lead to termination of third party intermediaries for the current and/or subsequent performance year.

The QCDR Qualified Posting will be updated to reflect when remedial action has been taken and/or termination of third party intermediaries participating as a qualified QCDR.

What is the overall process to become a CMS-approved QCDR?

The list of CMS-approved QCDRs that have been approved to submit data to CMS as a QCDR for the 2021 MIPS performance period will be posted in the 2021 QCDR Qualified Posting on the QPP Resource Library of the CMS Quality Payment Program website.

The overall process includes these steps:

- The QCDR completes and submits the self-nomination form, supported measures (MIPS Quality Measures and/or QCDR Measures), and Data Validation Plan through the Quality Payment Program portal for CMS consideration.
- If the self-nomination form, MIPS Quality Measures, and Data Validation Plan are approved, all submitted QCDR measures are reviewed (if applicable). CMS may approve, provisionally approve, or reject the QCDR measures. The QCDR measure statuses are defined as:
    - Approved – The QCDR measure is approved for the given performance period.
    - Provisionally Approved – The QCDR measure is approved for the given performance period. However, CMS is requesting additional information or action if the QCDR measure is resubmitted for subsequent performance periods. CMS will provide a rationale for the provisional status. This may include performance data to assess performance gaps, revision or harmonization of the QCDR measure if it is to be submitted during the next self-nomination period.
    - Rejected – The QCDR measure is not approved for the given performance period. CMS will provide a rationale for the rejection.
- The Qualified Posting is developed for the approved QCDRs and include organization type, specialty, previous participation in MIPS (if applicable), program status (remedial action taken against the QCDR or terminated as a third part intermediary (if applicable)),

contact information, last date to accept new clients, virtual groups specialty parameters (if applicable), the approved quality measures, reporting options supported, performance categories supported, services offered, and costs incurred by clients. All approved QCDRs are included in the Qualified Posting that is posted on the CMS Quality Payment Program Resource Library.

- Approved QCDRs review and acknowledge the measure specifications for their approved QCDR measures.
- Approved QCDRs are required to support the performance categories, measures and activities listed on their Qualified Posting and meet all applicable approval criteria for the applicable performance period as a condition of participation in MIPS. Failure to do so may lead to remedial action or possible termination of the QCDR from future program years of MIPS. Prior to discontinuing services to any MIPS eligible clinician, group or virtual group during a performance period, the third party intermediary must support the transition of such MIPS eligible clinician, group, or virtual group to an alternate third party intermediary, submitter type, or, for any measure on which data has been collected, collection type according to a CMS approved transition plan.

Resources

- **QCDR Support Calls -** CMS will hold mandatory joint support calls for QCDRs and Qualified Registries that are approved to participate in the 2021 performance period. These support calls will be held approximately once a month, with the kick-off meeting (in-person or virtually) being the first of the monthly calls. The support calls address reporting requirements, steps for successful submission, and allow for a question and answer session. The monthly support calls are limited to only approved 2021 performance period QCDRs. Each QCDR must attend both the webinar and audio portion via computer or phone to receive credit for attending the support call. One representative, from a vendor supporting multiple QCDRs, will **NOT** be counted as attendance for multiple QCDRs.
- **Virtual Office Hours (VOHs) -** CMS will host joint VOHs to offer QCDRs and Qualified Registries an opportunity to ask CMS subject matter experts questions related to the assigned topics for those calls. Please note that only topic specific questions will be addressed during each call. All other questions will be referred to the Quality Payment Program. Participation in the VOHs is **not required** but is strongly encouraged.
- **Quality Payment Program ListServ -** The Quality Payment Program ListServ will provide news and updates on new resources, website updates, upcoming milestones, deadlines, CMS trainings, and webinars. To subscribe, visit the Quality Payment Program website and select “Subscribe to Updates” at the bottom of the page or in the footer.
- **Quality Payment Program Website -** Educational documents for QCDR participation will be available on the website to help support you in your submission process. In addition, lists with the criteria used to audit and validate data submitted in each of the MIPS performance categories will be available on the website.
- **Quality Payment Program -** If you have any questions, the Quality Payment Program is here to help and will be able to direct you to the appropriate staff to best meet your needs.

You can reach the Quality Payment Program at QPP@cms.hhs.gov or 1-866-288-8292 (Monday – Friday, 8 a.m. – 8 p.m. ET). Customers who are hearing impaired can dial 711 to be connected to a TRS Communications Assistant.

- **The Self-Nomination User Guide -** This guide provides step-by-step instructions for vendors looking to become an approved QCDR for the 2021 performance period of MIPS.
- **Blueprint for the CMS Measures Management System -** 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).
- **QCDR Measure Development Handbook -** 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.
- **QCDR Measure Development Google Group -** Provides a space for QCDRs to collaborate on QCDR measures and share ideas throughout the QCDR measure development process.
- **QCDR/Registry Google Calendar -** Will be used to share key milestones and activities for the annual self-nomination period.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-1314 (Expiration date: XX/XX/XXXX). The time required to complete this information collection is estimated to average 8 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. ****CMS Disclosure**** Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact QPP@cms.hhs.gov.