2019 Qualified Clinical Data Registry (QCDR) Fact Sheet

Overview

To become a QCDR for the Merit-based Incentive Payment System (MIPS) 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:

September 1 – November 1 of the year prior to the applicable performance period.

Tips for Successful Self-Nomination:

1. To become qualified for a given performance period, the vendor must exist by January 1 of the performance period and have 25 participants submitting data to the QCDR (not necessarily for purposes of MIPS). For example, to be eligible in the 2019 performance period, the vendor must exist by January 1, 2019.
2. You must provide all required information at the time of self-nomination, via the web-based tool, JIRA: https://oncprojectracking.healthit.gov/support/login.jsp, for CMS review and approval.
3. Self-nomination is an annual process. If you want to qualify as a QCDR, you will need to self-nominate for that year. Qualification and participation in a prior program year does not automatically qualify a vendor for subsequent performance periods. Beginning with the 2019 performance period, a simplified self-nomination process has been implemented to reduce the burden of self-nomination for those existing QCDRs that have previously participated in MIPS and are in good standing (not on probation or terminated). The simplified process is available **only** for existing QCDRs in good standing.

The list of vendors that have been qualified to submit data to CMS as a QCDR for purposes of MIPS will be posted on the CMS Quality Payment Program website.

What is a QCDR?

A QCDR is a CMS-approved vendor that collects clinical data on behalf of clinicians for data submission. Examples include, but are not limited to, regional collaboratives, specialty societies, or large healthcare systems. Please note that QCDRs cannot be owned or managed by an individual, locally-owned specialty group. Clinicians work directly with their chosen QCDR to submit data on the selected measures or specialty set of measures they have picked.

The QCDR reporting option is different from a Qualified Registry because QCDRs are not limited to reporting only MIPS Quality Measures within MIPS. A QCDR may submit a maximum of 30 QCDR developed measures

(known as QCDR Measures, and previously as non-MIPS measures) for CMS review and approval for reporting.

Quality Measures submitted by a QCDR may include measures 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 2019 MIPS Quality Measures.
- QCDR Measures developed by boards or specialty societies.
- QCDR Measures developed by regional quality collaboratives.

What are the requirements to become a QCDR?

1. **Participants:** You must have at least 25 participants by January 1, 2019. These participants are not required to use the QCDR to report data to CMS, but they must be submitting data to the QCDR for quality improvement. Please note that your system must be implemented and able to accept data should a clinician, group or virtual group wish to submit data on the approved MIPS Quality Measures and QCDR Measures by January 1, 2019.
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. If you become aware that any submitted information is not true, accurate, and complete, you will correct such information promptly; 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:** During self-nomination, you must provide information on your **process** for data validation for individual MIPS eligible clinicians, groups and virtual groups within a Data Validation Plan. You must provide the following to fulfill the requirements of the Data Validation Plan:

- Name of QCDR
- Benchmarking Capability
  - Process of verifying Quality Payment Program eligibility of MIPS eligible clinicians, groups, and virtual groups.
- Process of verifying accuracy of TIN/NPIs.
- Process of calculating reporting and performance rates.
  - Process of verifying that your system will only accept data (for purposes of MIPS) on 2019 MIPS Quality Measures and/or QCDR Measures (as applicable) during submission.

- Process used for completion of randomized audit.
- Process used for completion of detailed audit.

5. **Data Validation Execution Report:** You must execute your 2019 Data Validation Plan and provide us with the **results** (i.e., Results of the randomized/detailed audits? Were there any calculation issues? If so, why did they occur and what was done to remediate?).
   - The 2019 Data Validation Execution Report must be submitted to CMS by May 31, 2020.
   - The following items should be addressed in the 2019 Data Validation Execution Report:
     - Name of QCDR
     - Results of benchmarking capability (i.e., Were any issues identified with the benchmarking capability? If so, please provide the details regarding the identified issues and how they were resolved).
     - Results of verifying Quality Payment Program eligibility of MIPS eligible clinicians, groups, and virtual groups (i.e., Were any issues identified with the process to determine if MIPS eligible clinicians, groups, and virtual groups meet the Quality Payment Program eligibility requirements? If so, please provide the details regarding the identified issues and how they were resolved).
     - Results of verifying accuracy of Taxpayer Identification Number (TIN)/National Provider Identifier (NPI) (i.e., Were any issues identified with the process to verify TINs/NPIs? If so, please provide the details regarding the identified issues and how they were resolved).
     - Results of verifying 2019 MIPS Quality Measures and/or QCDR Measures are utilized for submission (i.e., Were any issues identified with verification process to ensure that only 2019 MIPS Quality Measures and/or QCDR Measures (as applicable) were submitted? If so, please provide the details regarding the identified issues and how they were resolved).
     - Results of calculating data completeness and performance rates (i.e., Were any issues identified with how the measure specifications (MIPS Quality Measures and/or QCDR Measures (as applicable) were implemented in the system? If so, please provide the details 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 the details regarding the identified issues).
     - Results of the detailed audit (i.e., Provide the details regarding how the identified data issues from the Randomized Audit were resolved (if applicable)).

For the purposes of QCDR participation, we do not require that you provide a written report on Promoting Interoperability or Improvement Activities, as our primary focus is Quality. However, we encourage QCDRs to utilize auditing processes to ensure the accuracy of data submissions under the Promoting Interoperability and Improvement Activities performance categories as QCDRs would have certified at the time of submission, that all data submitted (across all performance categories) is true, accurate, and complete to the best of their knowledge.

A late submission of your Data Validation Execution Report from your QCDR will be seen as non-compliance with program requirements and may result in probationary status or termination in future program years.

Please note that CMS will provide a specific template for the Data Validation Execution Reports. The Data Validation Execution Report template will be posted on the CMS Quality Payment Program Resource Library.

6. **Performance Category Feedback Reports:** Provide performance category feedback at least four times a year for all MIPS eligible clinicians.
   - CMS does not provide a template for the vendor feedback reports.
   - If a dashboard is available to clinicians with real-time feedback, CMS asks that the QCDR emails the clinicians four times per year to remind them the feedback is available.

What information is required to self-nominate?

You must provide the following when you self-nominate:

- Vendor Name
- New or Existing QCDR (Approved for a previous year of MIPS and/or Physician Quality Reporting System [PQRS])
- QCDR Measure Specifications (if submitting QCDR Measures)
- Supported MIPS Quality Measures
- Supported MIPS Performance Categories
- Improvement Activities Supported
- Promoting Interoperability Measures and Objectives Supported
- Performance Period
- Vendor Type
- Data Collection Method
- Method for Verifying TINs and NPIs
- Method for Calculating Performance Rates for Quality Measures (source of clinician's data)
- Randomized Audit Process
- Data Validation Process
- Ability to Provide Data Validation Plan Results by May 31st Following the Performance Period (Data Validation Execution Report)
- Available Performance Data
- Risk Adjustment Method for QCDR Measures
- Reporting Options
- Cost and Services Included in Cost

What are the measure specification requirements?

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

- Provide 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 (November 1).

- Publicly post the measure specifications for each QCDR measure no later than 15 calendar days following CMS's approval of these measure specifications and provide CMS with the link to the posted information (via a comment in your approved JIRA self-nomination form).

QCDR Measures	MIPS Quality Measures
For QCDR Measures (owned and developed by QCDRs), QCDR measure specifications must include: • Measure Title • National Quality Strategy (NQS) domain • Meaningful measure area • Meaningful measure area rationale • Measure type • Data source used for the measure • Concise summary of performance data or evidence to support performance gap • If the measure belongs to another vendor • National Quality Forum (NQF) number, if applicable • Descriptions of the denominator and numerator • Descriptions of the denominator exceptions, denominator exclusions, risk adjustment variables, and risk adjustment algorithms, when applicable • Number of performance rates required for measure • Overall performance rate information, if more than one is required • If the QCDR measure is a high priority measure and priority type (if applicable) • Traditional vs Inverse measure • Proportional, continuous variable, ratio measure indicator • If the QCDR measure is risk-adjusted • Indicate which specialty/specialties apply to the QCDR measure	**For MIPS Quality Measures**, you only need to submit the MIPS Quality Measure IDs for individual measures and/or the specialty-measure set measures.

CMS finalized that if QCDRs would like to use another QCDR's measure they be required to report on the measure using the same CMS-assigned QCDR measure ID. If a QCDR refuses to enter into such an agreement, the QCDR measure may be rejected and another QCDR measure of similar clinical concept or topic may be approved in its place.

What is considered a QCDR measure?

The following are QCDR Measures:

- 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?

Prior to self-nomination of a QCDR measure, the following checklist should be reviewed to increase the likelihood of approval of the QCDR measure. CMS and the contractor team use a similar checklist during the review of QCDR Measures.

QCDR Measures should:

- Be clinically relevant and evidence based (summary of current clinical guidelines).
- Include evidence of a performance gap and/or eligible clinician performance variation.
- Include requests made by CMS during the previous program year (Provisionally Approved Measures) or documentation of why the request is not clinically appropriate.
- Focus on a quality action instead of documentation.
- Focus on an outcome rather than a clinical process.
- Preferably fall within clinical workflows so data collection is not burdensome.
- Address one or more meaningful measure areas and National Quality Strategy domains.
- Be fully developed and not just in the concept development phase.
- Include accurate measure classification (inverse, risk-adjusted, ratio, proportional, or continuous variable).
- Include proper spelling and grammar throughout the specification.
- If approved for previous performance period, identify changes to the specification. Measures that undergo substantive changes will have a new QCDR measure ID assigned. Substantive changes alter the intent of the QCDR measure and may impact the performance score. In this instance, QCDR measure data would not be comparable across performance periods.

QCDR Measures should **not**:

- Duplicate an existing or proposed MIPS Quality Measure.
- Duplicate an existing QCDR measure (unless the new measure is a dramatic improvement over the existing measure).
- Duplicate a retired PQRS measure.
- Be topped out: have high, unvarying performance where there is little room for clinician improvement.
- Split a single or related clinical process or outcome into several QCDR Measures. For example: The results of 3 different tests are required for a standard of care. Each test should not be a single measure, but all included in one measure.

- Have the potential of unintended consequences. For example: the measure disqualifies a patient from receiving oxygen therapy or other comfort measures.
- Focus on the elimination of serious, preventable, and costly medical errors - “Never Events”. For example: Surgery performed on the wrong patient.
- Be a standard of care with the expectation it is performed consistently (low bar).
- Be incidence measures
- Be a rare occurrence
- Lack a quality action
- Have a quality action that is not attributed to the submitting eligible clinician.
- Be documentation/check box measures.

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

- Measure Development Plan
- QCDR Measure Guide Handbook
- CMS Blueprint

What data submission functions must an approved QCDR perform?

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

1. **Indicate:**

- CEHRT data source, if applicable.
- End-to-end electronic reporting, if applicable.
- Performance period start and end dates.
- Reporting on Promoting Interoperability measures and objectives or Improvement Activities, if it applies.

2. **Submit:**

- Data and results for all your MIPS performance categories.
  - ✓ Include all-payer data, not just Medicare Part B patients.
- Results for at least six Quality Measures, including one outcome measure.
  - ✓ 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.
    - Additional information about benchmarks can be found in the Quality Benchmarks zip file.
- Appropriate 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.
- Sampling methodology for data validation.
- Risk-adjusted results for any risk-adjusted measures.
- Additional details for QCDR Measures:
  - ✓ Data elements and measure specifications.

- ✓ Risk-adjusted results for QCDR quality data.
- ✓ Comparison of quality of care by measure, by clinician or group.
- ✓ Data from before the start of the performance period, if available.

3. **Submit the number of:**

- Eligible instances (reporting denominator).
- Times a quality action is performed (performance met).
- Times the applicable submission criteria were not met (performance not met).
- Times a performance exclusion occurred (denominator exceptions/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 agreement(s) with clinicians or groups who provide patient-specific data.
  - ✓ Ensure the business associate agreement complies with HIPAA Privacy and Security Rules.
  - ✓ Include disclosure of Quality Measure results and data on Medicare and non-Medicare beneficiaries.
- Signed NPI-holder authorization to:
  - ✓ Submit data and results 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.
- Requirement to participate in the mandatory QCDR kick-off meeting and monthly support calls. Failure to participate in the QCDR kick-off meeting will lead the QCDR to be placed on probation.
- Participation requirements (Data Validation Execution Report, performance feedback, etc.).
- A CMS-approved secure method for data submission.

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

If any data inaccuracies affect **more than 3%** of your total MIPS eligible clinicians, you:

- Will be placed on probation due to your low data quality rating.
- Will have the QCDR Qualified Posting updated for the performance period to indicate you are on probation.

Data inaccuracies affecting **more than 5%** of your total MIPS eligible clinicians may lead to you being precluded from participating in the following year.

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 measures and objectives, if applicable) and results submitted are true, accurate and complete.

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 mismatches, formatting issues, calculation errors, and data audit discrepancies affecting in excess of three percent of the total number of MIPS eligible clinicians, groups or virtual groups submitted. Examples of such errors include:

- TIN/NPI Issues – Incorrect Tax Identification Numbers (TINs), Incorrect National Provider Identifiers (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, Incorrect performance rates, Incorrect data completeness rates, Numerators larger than denominators.
- Data Audit Discrepancies – Vendor acknowledgement of data discrepancies found during data validation but not corrected in submissions, Vendor/clinician acknowledgement of data discrepancies found post submission from clinician feedback reports and our Quality Use Resource Use (QURU) reports.

What may cause an approved QCDR to be placed on probation or precluded from the program?

CMS may place QCDRs on probation for failing to meet certain standards and/or participation requirements. These requirements include, but are not limited to the following:

- QCDR support call absences,
- Delinquent deliverables like the Data Validation Execution Report,
- Submission of false, inaccurate or incomplete data.

If a QCDR is placed on probation, CMS will require that the QCDR take remedial action by submitting a corrective action plan to address any deficiencies or issues and prevent them from recurring. The corrective action plan must be received by CMS within 14 days from the date of the CMS probation notification for CMS review and approval. Failure to comply with the probation process may lead to termination for the current and/or subsequent performance year.

The QCDR Qualified Posting will be updated to reflect when a QCDR is placed on probation and/or terminated from participating as a qualified QCDR.

CMS may place the QCDR on probation or preclude the QCDR for the current performance year and/or the subsequent performance year, as applicable.

What if I do not meet the criteria to become a QCDR on my own?

QCDRs are welcome to collaborate with another vendor to meet the requirements and become a QCDR.

A vendor that uses an external vendor for data collection, calculation, or transmission may meet the definition of a QCDR if the vendor has a signed, written agreement that specifically details the relationship of the vendor with the external vendor. This agreement must be effective as of September 1 prior to the performance period.

What is the overall process to become an approved QCDR?

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 JIRA for CMS review and approval.
- 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 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 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 contact information, the approved measures, 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 website.
- Approved QCDRs are required to support the services and measures (MIPS Quality Measures and/or QCDR Measures) listed on their Qualified Posting as a condition of participation in MIPS. CMS expects each approved QCDR to support the services and measures (MIPS Quality Measures and/or QCDR Measures) listed on their Qualified Posting through the entirety of the performance and submission periods for which the QCDR is approved, as well as meet all participation and program requirements. Failure to do so will preclude the QCDR from future participation in MIPS.

Resources

- **QCDR Support Calls -** CMS will hold mandatory support calls for QCDRs that are approved to participate in the performance period they have self-nominated to be considered for. These support calls will be held approximately once a month, with the kick-off meeting being the first of the monthly calls. The support calls address reporting requirements, steps for successful submission, and a question and answer session. Attendance to all support calls is mandatory, and is a requirement of participation as an approved QCDR. 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.
- **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.

Disclaimer: The information noted with an asterisk (*) is subject to change based upon what is finalized in the CY 2019 Physician Fee Schedule Final Rule for the Quality Payment Program. If needed, this document will be updated to what is finalized in the final rule and reposted accordingly.

- **Quality Payment Program -** If you have any questions, the Quality Payment Program is here to help and will be able to direct your call 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 or 1-877-715-6222 (TTY) Monday – Friday, 8:00 AM – 8:00 PM Eastern Time.
- **The Self-Nomination User Guide -** This guide provides step-by-step instructions for vendors looking to become an approved QCDR for the 2019 MIPS program year.
- **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 the Merit-based Incentive Payment System 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 CMS availability for QCDR measure reconsideration calls (after the self-nomination period ends) and to track and highlight 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 12 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.

Disclaimer: The information noted with an asterisk (*) is subject to change based upon what is finalized in the CY 2019 Physician Fee Schedule Final Rule for the Quality Payment Program. If needed, this document will be updated to what is finalized in the final rule and reposted accordingly.