2022 Qualified Clinical Data Registry (QCDR) Fact Sheet

What is a QCDR?

A QCDR is defined as an entity that demonstrates clinical expertise in medicine and quality measurement development 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.[1] A QCDR may include:

- An entity with clinical expertise in medicine. Clinicians are 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 expertise.
- 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 responsibilities of the entity and the external organization. The written agreement must be effective as of September 1 of the year preceding the applicable performance period.[2].

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 calendar year (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.

As an alternative to becoming a QCDR, entities may seek to qualify as another type of third-party intermediary, such as a Qualified Registry. A Qualified Registry does not require quality measurement development experience.

A QCDR may request to report on up to 30 quality measures not in the annual list of Merit-based Incentive Payment System (MIPS) quality measures. Full specifications will need to be provided to Centers for Medicare & Medicaid Services (CMS) at the time of self-nomination. CMS will review the quality measures and determine if they are appropriate for QCDR reporting.[3]

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[1] §414.1305
[2] §414.1400(b)(2)(ii)
[3] 81 FR 77368

Measures submitted by a QCDR <u>may</u> 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 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 2022 MIPS Quality Measures.
- QCDR measures developed by the QCDR.
- QCDR measures developed by other entities such as boards or specialty societies or regional quality collaboratives 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, 2021 for consideration for the 2022 MIPS performance period).[4] 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.[5] **Please note CMS expects QCDRs would be up and running by January 1 of the performance period to accept and retain data, to allow clinicians to begin their data collection on January 1 of the performance period.**[6] A system that is not "live", beginning with the start of the performance period, is considered non-compliant with this requirement.

2. **Certification Statement:** You must certify that all data submissions to CMS on behalf of MIPS eligible clinicians, groups and virtual groups are true, accurate, and complete to the best of your knowledge.[7] This certification applies to data submissions based on the acceptance of data exports directly from an electronic health record (EHR) or other data sources. If you become aware that any submitted information is not true, accurate, and complete, corrected information may be submitted until the end of the data submission period. If false, inaccurate, or incomplete data are identified after the data submission period, you should immediately notify CMS.

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[4] §414.1400(b)(2)(i)
[5] 81 FR 77365
[6] 83 FR 59761
[7] §414.1400(a)(5)

3. **Data Submission:** You should submit data via a CMS-specified secure method for data submission, such as a defined Quality Payment Program data format.[8] 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. [Data submission is discussed in more detail below].

Except as provided in the Final Rule[9], QCDRs, qualified registries, and health information technology (IT) vendors must be able to submit data for all of the following MIPS performance categories:
- Quality, except:
  - The CAHPS for MIPS survey; and
  - For qualified registries and health IT vendors, QCDR measures;
- improvement activities; and
- Promoting Interoperability, if the eligible clinician, group, or virtual group is using Certified Electronic Health Record Technology (CEHRT); however, a third party intermediary may be excepted from this requirement if its MIPS eligible clinicians, groups or virtual groups fall under the reweighting policies.[10]

4. **Data Validation and Targeted Audits:** You must conduct Data Validation for the 2022 performance year prior to any data submission **for the 2022 performance period.[11] Your data validation must include all performance categories for which you will submit data and each submitter type for which you will submit data**, regardless of whether the clinician or group are MIPS eligible, voluntary, or are opting in.[12] You must use clinical documentation (provided by the clinicians they are submitting data for) to validate that the action or outcome measured actually occurred or was performed.[13] In addition, each data validation audit must include the following:

☐ Verification of the eligibility status of each eligible clinician, group, virtual group, opt-in participant, and voluntary participant.
☐ Verification of the accuracy of tax identification numbers (TINs) and National Provider Identifier (NPIs).
☐ Calculation of reporting and performance rates.
☐ Verification that only the MIPS quality measures and QCDR measures that are relevant for the reporting periods will be used for MIPS submission. For the 2022 performance year, this means:

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[8] 81 FR 77367 through 77369
[9] §414.1400(a)(2)(ii)
[10] §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)
[11] §414.1400(b)(2)(iv)(A)
[12] §414.1400(b)(2)(iv)(B) & (C)
[13] §414.1400(b)(2)(iv)(D)

- 2022 MIPS Clinical Quality Measures (CQMs), electronic CQMs (eCQMs) and/or QCDR measures for the quality performance category.
- 2022 Promoting Interoperability measures and objectives for the Promoting Interoperability performance category.
- 2022 improvement activities for the improvement activities performance category.

Each data validation audit (formerly known as "randomized audit") must use a sampling methodology that meets the following requirements for all performance categories for which you will submit data:
- Sample size of at least 3% of the TIN-NPIs submitted to CMS, except that the sample size must have a minimum of 10 TIN-NPIs and the sample size does not need to include more than 50 TIN-NPIs.
- Sample that includes at least 25% of the patients of each TIN-NPI in the sample, except that the sample size must have a minimum of 5 patients and does not need to include more than 50 patients.

Targeted Audits. If a data validation audit identifies one or more deficiency or data error, you must also conduct a targeted audit (formerly known as "detailed audit") into the impact and root cause of each such deficiency or data error for that MIPS payment year.[14] Any required targeted audits for the 2022 performance year and correction of any deficiencies or data errors identified through such audit must be completed prior to the submission of data for the 2022 performance year.[15]) The sample used for auditing in the targeted audit must be based on a sampling methodology that meets the requirements for data validation audits and must not include data from the sample used for the data validation audit in which the deficiency or data error was identified.[16] (*Note: The targeted audit is required if any errors or deficiencies are found through the data validation audit*).

5. **Data Validation Execution Report (DVER) and Targeted Audits:** You must execute your 2022 Data Validation and any required targeted audits **prior** to the submission of data for the 2022 MIPS performance period.

   ☐ The 2022 Data Validation Execution Report with the results of your data validation audit must be submitted to CMS by May 31, 2023.[17]
   ☐ The 2022 Data Validation Execution Report must include:
      o Name of QCDR
      o Was data submitted for any of the performance categories for the 2022 MIPS performance period?

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[14] §414.1400(b)(2)(v)(A)
[15] §414.1400(b)(2)(v)(B)
[16] §414.1400(b)(2)(v)(C)
[17] §414.1400(b)(2)(iv)(G)

- o Overall Data Deficiency or Data Error Rate - (Number of Clinicians with a Data Issue / Total Number of clinicians Supported)
- o For each type of deficiencies or data errors discovered you must provide (1) description and examples of the deficiency/error; (2) the percentage of clinicians impacted by the deficiency/error and (3) when and how each deficiency/error was corrected. Types of deficiencies or data errors include, but are not limited to, the following:
  - Errors or deficiencies related to verifying MIPS eligibility of clinicians, groups, and virtual groups.
  - Errors or deficiencies related to verifying the accuracy of TINs and NPIs.
  - Errors or deficiencies related to use of 2022 MIPS measures and activities were utilized for submission, namely
    - 2022 MIPS CQMs, eCQMs and/or QCDR measures for the quality performance category.
    - 2022 Promoting Interoperability measures and objectives for the Promoting Interoperability performance category.
    - 2022 improvement activities for the improvement activities performance category.
  - Errors or deficiencies in 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 you are required to conduct any targeted audits for performance year 2022, the corresponding 2022 Targeted Audit results should also be submitted to CMS by May 31, 2023.
- ☐ Your report with the results of each targeted audit must include:
  - o the overall deficiency or data error rate;
  - o the types of deficiencies or data errors discovered;
  - o how and when the error or deficiency was corrected; and
  - o the percentage of your total clinicians impacted by the data error.

Please note, late, incomplete, and/or absent submission of your Data Validation Execution Report or the results for a required targeted audit constitutes 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 for Data Validation and Targeted Audit results, 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 clinicians, groups, virtual groups, and Alternative Payment Model (APM) Entities on how they compare to other clinicians, groups, virtual groups, and AMP Entities who have submitted data on a given measure.
   - 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, virtual groups, and APM Entities 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 in the Final Rule.[18]

7. Attest that you understand the QCDR qualification criteria and program requirements and will meet all program requirements.

What data submission functions must an approved QCDR perform?

Following the self-nomination and QCDR measure process, an approved QCDR should be able to 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 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 claims 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 identifiers (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.

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[18] §414.1400(b)(2)(iii)

☐ 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 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 Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules (82 FR 53812).
   ☐ Business agreement(s) with clinicians, groups, virtual groups, or APM Entities 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 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 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 **<u>not</u>** for an individual clinician reporting as an individual. If you are submitting the individual 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 attend and complete training and support sessions.
    - ☐ Participation requirements (for example, and not limited to conducting data validation and submitting required reports, performance feedback to clinicians, QCDR would be up and running by January 1 of the given performance period, etc.).
    - ☐ A CMS-approved secure method for data submission.

What is the threshold for posting a QCDR's rate of data inaccuracies? What are considered data inaccuracies?

Data inaccuracies may result in:
- Remedial action, up to and including termination.
- 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% and to indicate that remedial action or termination has been taken against the QCDR.

CMS will further evaluate the QCDR to determine if any additional inaccurate, unusable, or otherwise compromised data has been submitted. Data inaccuracies may lead to remedial action/termination of the QCDR for future program year(s) based on CMS discretion.

CMS will evaluate data submitted for quality measures for data completeness and accuracy. The QCDR will also certify that all data submitted (including quality measures, improvement activities, and Promoting Interoperability objectives and measures) are true, accurate, and complete to the best of their knowledge.

CMS will determine error rates calculated on data submitted to CMS for clinicians, groups, virtual groups, and APM Entities.

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 will be taken into consideration by CMS.

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

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

The overall process includes these steps:

- The QCDR completes and submits the self-nomination form and supported measures (MIPS Quality Measures and/or QCDR Measures) through the Quality Payment Program website for CMS consideration (82 FR 53810).
- If the self-nomination form and MIPS Quality Measures 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.
    - 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 clinician, group, virtual group, or APM Entity during a performance period, the third party intermediary must support the transition of such clinician, group, virtual group, or APM Entity 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.

The list of CMS-approved QCDRs that have been approved to submit data to CMS as a QCDR for the 2022 MIPS performance period will be posted in the 2022 QCDR Qualified Posting on the [Resource Library](#) of the CMS Quality Payment Program website.

When is the self-nomination period?

You can self-nominate from:

July 1 – September 1 of the year prior to the applicable performance period. For the 2022 performance period, the self-nomination period will promptly open at **10 a.m. (Eastern Time) ET** on July 1st and close at **8 p.m. ET** on September 1, 2021. Self-Nominations submitted after the deadline were not 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 website (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 an entity 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 (i.e., 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.

What information is needed to self-nominate?

You should provide the following when you self-nominate:
- ☐ Your QCDR's entity name
- ☐ Whether you are a new applicant or previously approved QCDR (approved in a previous year of MIPS and/or Physician Quality Reporting System [PQRS]).
- ☐ MIPS performance categories you will 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 clinicians, groups, virtual groups, or APM Entities fall under the reweighting policies.
- ☐ Are you submitting one or more 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 2022 improvement activities are you supporting?
- [ ] Which 2022 Promoting Interoperability objectives and measures are you supporting?
- [ ] An entity seeking to become a QCDR must submit specifications for each measure, activity, and objective that the entity intends to submit for MIPS (including the information described in paragraphs §414.1400(b)(3)(ii)(A) and (B) of this section) at the time of self-nomination.
- [ ] Please identify your entity 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.)?
- [ ] Confirm you will conduct your 2022 data validation audits and any required targeted audits and correct any deficiencies or data errors identified through such audits prior to the submission of data for the MIPS payment year.
- [ ] Confirm you will submit reports with the results of each 2022 performance period Data Validation audit and targeted audit by the deadline of May 31, 2023.
- [ ] Available Performance Data
- [ ] Risk Adjustment Method for QCDR Measures (if applicable).
- [ ] Which reporting options do you intend to support (i.e., clinician, group, virtual group, 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 is 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 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.

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

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

What is required for nominating a QCDR measure?
QCDR measures should have the following:

- Be beyond the measure concept phase of development.
- Address significant variation in performance.
- Be face valid for 2022 performance period/2024 MIPS payment year. To be approved for the 2023 performance period/2025 MIPS payment year and future years, a QCDR measure must be face valid for the initial MIPS payment year for which it is approved and fully tested with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination for any subsequent MIPS payment year for which it is approved.
- 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.
- Address areas of duplication.

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

- Provide QCDR measure specifications for each QCDR measure. This should be submitted with your self-nomination application no later than the last day of the applicable self-nomination period, utilizing the QCDR measure submission template. See table 1 below.
- 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 (including the CMS-assigned QCDR measure ID) and provide CMS with the link to where this information is posted (via a comment in your approved self-nomination form).[19]

CMS delayed 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

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[19] §414.1400(3)(ii)

a QCDR measure, appropriate to the measure type, prior to submitting the QCDR measure for CMS consideration during the self-nomination period.

What are other QCDR measure approval considerations?

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.

In reviewing potential QCDR measures, we take into consideration the below. For additional information, please reference the Final Rule.[20]

- Be developed using the measure development processes as defined in the most recent Blueprint for the CMS Measures Management System.
- Conducted an environmental scan of existing QCDR measures; MIPS quality measures; quality measures retired from the legacy PQRS program.
- Be clinically relevant and evidence based (align with current clinical guidelines).
- Preference for measures that are outcome-based rather than clinical process measures.
- Focus on a quality action instead of documentation.
- Focus on an outcome rather than a clinical process.
- Address one or more Meaningful Measure Areas and National Quality Strategy 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 National Quality Strategy (NQS) domain of care coordination.
    - Focus on measures that address the NQS domain for patient and caregiver experience.
    - Focus on measures that address efficiency, cost, and resource use.
- Have opportunity for adequate patient population and measure adoption for the QCDR measure to have a more significant impact on quality improvement.
- Clearly define the quality action and population in the description for clinician ease of understanding.
- If a QCDR measure is being used by a QCDR that does not own the measure, 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.
- 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.

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[20] §414.1400(b)(3)(iv)

QCDR measure rejection criteria considerations include, but are not limited to, the following factors:

- Duplicative, or identical to other QCDR measures or MIPS quality measures that are currently in the program.
- Duplicative or identical to MIPS quality measures that have been removed from MIPS through rulemaking.
- Duplicative or identical to quality measures used under the legacy PQRS program, which have been retired.
- Meet the topped out definition. Topped out measures are defined as above 95% or less than 5% for inverse measures. As defined at §414.1305, a topped out non-process measure means a measure where the Truncated Coefficient of Variation is less than 0.10 and the 75th and 90th percentiles are within 2 standard errors. A topped out process measure means a measure with a median performance rate of 95% or higher. This definition aligns with other CMS Value Based Payment programs.
- Process-based, with consideration to whether the removal of the process measure impacts the number of measures available for a specific specialty.
- Whether the QCDR measure has potential unintended consequences to a patient's care.
- Considerations and evaluation of the measure's performance data, to determine whether performance variance exists.
- Whether the previously identified areas of duplication have been addressed as requested.
- Split a single clinical practice or action into several QCDR measures.
- "Check-box" with no actionable quality action.
- Do not meet the case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive years.
- No longer considered robust, in instances where new QCDR measures are considered to have a more vigorous quality actions, where CMS preference is to include the new QCDR measure rather than requesting QCDR measure harmonization.
- Clinician attribution issues, where the quality action is not under the direct control of the reporting clinician.
- Focus on rare events or "never events" in the measurement period.

QCDR Measure Approval

QCDR measures are generally approved annually for one 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; or if the QCDR that is nominating the QCDR measure is no longer in good standing.[21]

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[21] §414.1400(b)(3)(vi)

We place greater preference on QCDR measures that meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive performance periods. Those that do not meet reporting volumes required to establish benchmarks may not continue to be approved.[22]

In instances where a QCDR believes the low-reported QCDR measure that did not meet benchmarking thresholds is still important and relevant to a specialist's practice, that the QCDR may develop and submit a QCDR measure participation plan for our consideration. This QCDR measure participation plan must include the QCDR's detailed plans and changes to encourage clinicians, groups and virtual groups to submit data on the low-reported QCDR measure for purposes of the MIPS program.[23]

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.

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[22] §414.1400(b)(3)(iv)(J)
[23] §414.1400(b)(3)(iv)(J)(1)

Table 1: Measure Specifications

QCDR Measures	MIPS Quality Measures
For QCDR Measures, QCDR measure specifications include: • Measure Title • 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 • Includes Telehealth • 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 published clinical category • Attestation of the feasibility of the QCDR measure at the time of self-nomination • Validity, Feasibility, and Reliability testing summary • Participation Plan if QCDR measure has low adoption by clinicians	**For MIPS Clinical Quality Measures/eCQMs**, only the MIPS Clinical Quality Measure IDs for individual measures and/or the specialty-measure set measures must be submitted.

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

CMS has the authority to impose remedial action or termination based on its determination that a third party intermediary is non-compliant with one or more applicable criteria for approval, has submitted a false certification or has submitted data that is inaccurate, unusable, or otherwise compromised.[24]

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 third party intermediary is required to submit a CAP by a date specified by CMS. The CAP must address the following issues unless different or additional information is specified by CMS:
- The issues that contributed to the non-compliance.
- The impact to individual clinicians, groups, or virtual groups, regardless of whether they are participating in the program because they are MIPS eligible, voluntary participating, or opting in to participating in the MIPS program.
- The corrective actions to be implemented by the third party intermediary to ensure that the non-compliance has been resolved and will not recur in the future.
- The detailed timeline for achieving compliance with the applicable requirements.

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.

Resources

- **CY 2021 Payment Policies under the Physician Fee Schedule -** CMS provides an overview of the major policies we finalized for the 2021 performance period in the 2021 QPP Final Rule Resources zip file, which includes a table comparing the previous policy to the newly finalized policy and the Electronic Code of Federal Regulations.
- **QCDR Support Calls -** CMS will hold mandatory joint support calls for QCDRs and Qualified Registries that are approved to participate in the 2022 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 include approved 2022 performance period QCDRs. Each QCDR must attend both the webinar and audio portion via computer

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[24] §414.1400(f)

or phone to receive credit for attending the support call. One representative, from an entity 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 -** For additional questions related to the Quality performance category, please contact the Quality Payment Program Service Center at QPP@cms.hhs.gov or 1-866-288-8292 (Monday-Friday 8 a.m. - 8 p.m. ET). To receive assistance more quickly, please consider calling during non-peak hours—before 10 a.m. and after 2 p.m. ET. Customers who are hearing impaired can dial 711 to be connected to a TRS Communications Assistant.

- **The Self-Nomination User Guide -** This guide provides step-by-step instructions for entities looking to become an approved QCDR for the 2022 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.

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