Quality Payment PROGRAM

2021 Qualified Registry Fact Sheet

Overview

To become a Qualified Registry 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 and 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 website (https://qpp.cms.gov/login) for CMS consideration.

2. Self-nomination is an annual process. If you want to qualify as a Qualified Registry 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 Qualified Registries that have previously participated in MIPS and are in good standing (CMS did not take remedial action against or terminate the Qualified Registry as a third party intermediary). **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 Qualified Registries who are in good standing. Existing Qualified Registries in good standing should contact the MIPS QCDR/Registry Support Team (PIMMS Team) at RegistryVendorSupport@gdit.com if they cannot find or access the simplified self-nomination form instead of submitting a new self-nomination form.

What is a Qualified Registry?

A Qualified Registry is a vendor that collects clinical data from a clinician, group, virtual group, or Alternative Payment Model (APM) Entity and submits it to CMS on their behalf. Clinicians work directly with their chosen Qualified Registry to submit data on the selected measures or specialty set of measures they have selected.

What are the requirements to become a Qualified Registry?

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 Qualified Registry to report MIPS data to CMS, but they must submit data to the Qualified Registry for quality improvement. **Please note that your system must be implemented and able to accept data from a clinician, group, virtual group, or APM Entity 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 Section of the Quality Payment Program website: https://qpp.cms.gov/developers. Note: the APM Performance Pathway (APP) is a new data submission method starting in the 2021 performance period.
4. **Data Validation Plan (DVP):** During self-nomination, you must thoroughly explain your **process** for validation of data submitted on behalf of clinicians, groups, virtual groups, and APM Entities 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, virtual groups, and APM Entities. Qualified Registries are required to identify and track their clinicians as MIPS eligible, opt-in, or voluntary reporters.
- ☐ Process of verifying accuracy of tax identification number (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) and/or electronic Clinical Quality Measures (eCQMs) 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 data validation audit (formerly known as "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 targeted audit (formerly known as "detailed audit') for the Quality, Promoting Interoperability, and/or Improvement Activities performance categories. The targeted 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 targeted 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 targeted audit is required if any errors are found through the data validation 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. Data Validation Plans cannot be changed by the Qualified Registry once it is approved as a part of the self-nomination review.

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 data validation/targeted 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 your 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 Qualified Registry
    - 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) and/or electronic Clinical Quality Measures (eCQMs) 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 were implemented in the system? If so, please provide details and examples regarding the identified issues and how they were resolved).
    - Results of the data validation audit for the Quality, Promoting Interoperability, and/or Improvement Activities performance categories (i.e. were there any data issues identified? If so, please provide details and examples regarding the identified issues).
    - Results of the targeted audit for the Quality, Promoting Interoperability, and/or Improvement Activities performance categories (i.e., provide details and examples regarding how the identified data issues were resolved (*Note: The targeted audit is required if any errors are found through the data validation audit*). The targeted 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 targeted 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 Qualified Registries to utilize auditing processes to ensure the accuracy of all data submissions under all performance categories as Qualified Registries must be able to submit data for all performance categories; however, a third-party intermediary may be excepted from this requirement if all supported clinicians, groups, virtual groups, and APM Entities 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 Qualified Registry's participants do not fall under the reweighting policies described above, the Qualified Registry will be expected to comply with the requirements.

Qualified Registries 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 Qualified Registry will be seen as non-compliance with program requirements, and may result in remedial action or termination of the Qualified Registry 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:** Qualified Registries are required to provide performance categories feedback at least four times a year, and provide specific feedback to all clinicians, groups, virtual groups, and APM Entities on how they compare to other clinicians who have submitted data on a given measure for all clinicians, groups, virtual groups, and APM Entities. 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 Qualified Registry 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 Qualified Registry 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 Qualified Registry 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, groups, virtual groups, and APM Entities 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 Qualified Registry's Name?
- ☐ Are you a new or existing Qualified Registry (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 Qualified Registries 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 or virtual groups fall under the reweighting policies.
- ☐ 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 eCQMs 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)
- ☐ 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

What data submission functions must a Qualified Registry perform?

Following the self-nomination process, an approved Qualified Registry must perform the following data submission functions:

1. **Indicate:**
   - ☐ Whether the Qualified Registry 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 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 MIPS Quality Measures (MIPS CQMs and eCQMs), including one outcome measure, as applicable.
     - ✓ If an outcome measure is not available, use at least one other high-priority measure.
   - ☐ 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.
   - ☐ Risk-adjusted results for any risk-adjusted measures.
   - ☐ The sampling methodology used for data validation.

3. **Report on the number of:**
   - ☐ Eligible instances (eligible patient population).
   - ☐ Instances a quality service is performed (performance numerator).
   - ☐ 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, costs charged to clinicians, services provided, MIPS Quality Measures or specialty-specific measure sets (if applicable).
   - ☐ Business associate agreements must comply with HIPAA Privacy and Security Rules.
   - ☐ Business associate 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 Qualified Registry, has authorized the Qualified Registry 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 Qualified Registry to submit MIPS data to the Qualified Registry and must meet the requirements of any applicable laws, regulations, and contractual business associate agreements. Groups participating in MIPS via a Qualified Registry may have their group's duly authorized representative grant permission to the Qualified Registry to submit their data to us. If submitting as a group, each individual clinician does not need to grant their individual permission to the Qualified Registry 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 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 submitted to CMS 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 Qualified Registry kickoff meeting and monthly support calls.
   - ☐ Participation requirements (for example, and not limited to: Data Validation Execution Report, performance feedback to clinicians, registry must be up and running by January 1 of the given performance period, etc.).
   - ☐ CMS-approved secure method for data submission.

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

Data inaccuracies that affect clinicians, groups, virtual groups and APM Entities, may result in:

- Remedial action, up to and including termination, may be taken against your Qualified Registry due to the low data quality rating.
- The Qualified Registry posting updated for the performance period of MIPS to indicate the Qualified Registry'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 Qualified Registry.

CMS will further evaluate the Qualified Registry to determine if any inaccurate, unusable or otherwise compromised data affects clinicians. Data inaccuracies affecting your total clinicians may lead to remedial action/termination of the Qualified Registry 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 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, Qualified Registries should correct all identified errors prior to submitting the data to CMS. Qualified Registry 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.

Qualified Registries 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 clinicians, groups, virtual groups, and APM Entities.

- The corrective action implemented by the Qualified Registry 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 Qualified Registry Qualified Posting will be updated to reflect when remedial action has been taken and/or termination of third party intermediaries participating as a Qualified Registry.

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

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

The overall process includes these steps:

- The Qualified Registry completes and submits the self-nomination form, supported MIPS Quality 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, a Qualified Posting is developed for the Qualified Registry that includes organization type, specialty, previous participation in MIPS (if applicable), program status (remedial action taken against the Qualified Registry or terminated as a third party intermediary (if applicable)), contact information, last date to accept new clients, virtual groups specialty parameters (if applicable), approved MIPS Quality Measures, reporting options supported, performance categories supported, services offered, and costs incurred by clients. All approved Qualified Registries are included in the Qualified Posting that is posted on the CMS Quality Payment Program Resource Library.
- Approved Qualified Registries 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 Qualified Registry 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.

Resources

- **Qualified Registry Support Calls -** CMS will hold mandatory joint support calls for Qualified Registries and QCDRs 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 Qualified Registries. Each Qualified Registry 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 Qualified Registries, will **NOT** be counted as attendance for multiple Qualified Registries.
- **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 Qualified Registry 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 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 a Qualified Registry for the 2021 performance period of MIPS.

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 3 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.