

## Qualified Registry Self-Nomination Fact Sheet Calendar Year 2020 Final versus Calendar Year 2021 Final

**Burden impact:** The changes to this self-nomination fact sheet reflect proposals in the CY2021 Physician Fee Schedule (PFS) Final Rule for the Quality Payment Program and result in an estimated increase of 3 hours for each respondent required to submit a Corrective Action Plan (CAP).

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**Change #1:**

**Location:** Page 1

**Reason for Change:**

Alignment with current year

**CY 2020 Final Rule text:**

Section Header-  
2020 Qualified Registry Fact Sheet

**CY 2021 Final Rule text:**

Section Header-  
2021 Qualified Registry Fact Sheet

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**Change #2:**

**Location:** Page 1

**Reason for Change:**

Alignment with current year, Edited for clarity

**CY 2020 Final Rule text:**

NA

**CY 2021 Final Rule text:**

Section Header-  
Version 2  
Updated on April 6, 2021

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**Change #3:**

**Location:** Page 1

**Reason for Change:**

Removed Section, Edited for alignment with finalized requirements

**CY 2020 Final Rule text:**

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

**CY 2021 Final Rule text:**

NA

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**Change #4:****Location:** Page 1**Reason for Change:**

Edited for alignment with finalized requirements; edited for clarity.

**CY 2020 Final Rule text:**

Section Header - What is a Qualified Registry?

A Qualified Registry is a vendor that collects clinical data from an individual MIPS eligible clinician, group or virtual group 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.

**CY 2021 Final Rule text:**

Section Header - What is a Qualified Registry?

A Qualified Registry is a data intermediary that collects MIPS data from MIPS eligible clinicians and submits it to the Centers for Medicare & Medicaid Services (CMS) on their behalf.<sup>1</sup> Clinicians work directly with their chosen Qualified Registry to submit data on the selected measures or activities they have selected.

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**Change #5:****Location:** Page 1-5**Reason for Change:**

Edited for alignment with finalized requirements; edited for clarity.

**CY 2020 Final Rule text:**

Section Header - 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, 2019). 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, or virtual group should they wish to submit data on MIPS Quality Measures starting on January 1, 2020.
- 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, 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.

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<sup>1</sup> §414.1305

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>.
4. **Data Validation Plan:** During self-nomination, you must thoroughly explain your **process** for validation of data submitted on behalf of individual MIPS eligible clinicians, groups, and virtual groups through the development of a Data Validation Plan. You are required to provide the following as a part of your Data Validation Plan:
- Name of Qualified Registry
  - 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 2020 MIPS Clinical Quality Measures and/or electronic Clinical Quality Measures during submission.
  - Process used for completion of randomized audit.
  - Process used for completion of detailed audit.

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

5. **Data Validation Execution Report:** You must execute your 2020 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?). **Execution of your Data Validation Plan must be completed prior to the 2020 performance period data submission period, so errors can be corrected prior to data submission.**

The 2020 Data Validation Execution Report that includes the results of your audit, must be submitted to CMS by May 31, 2021.

The following items should be addressed in the 2020 Data Validation Execution Report:

- o Name of Qualified Registry
- o 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.)
- o Results of verifying the accuracy of Taxpayer Identification Number (TIN)/National Provider Identifier (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).
- o Results of verifying that 2020 MIPS Quality Measure specifications are utilized for submission (i.e. were any issues identified when verifying that only 2020 MIPS Quality Measures were submitted? If so, please provide details and examples regarding the identified issues and how they were resolved).

- o 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).
- o Results of the randomized audit (i.e. were there any data issues identified? If so, please provide details and examples regarding the identified issues).
- o Results of the detailed audit (i.e., provide details and examples regarding how the identified data issues were resolved (*Note: The detailed audit is required if errors are found through the randomized audit*)).

We require Qualified Registries to utilize auditing processes to ensure the accuracy of all data submissions under all performance categories. Qualified Registries would have certified, at the time of submission, that the data submitted for all performance categories is true, accurate, and complete to the best of their knowledge.

Please note, a late 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 in future program years.

**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 to all individual MIPS eligible clinicians, groups and virtual groups they are reporting for. 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 and virtual groups, at least four times a year, to remind them the feedback is available.

#### **CY 2021 Final Rule text:**

Section Header - 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 Merit-based Incentive Payment System (MIPS) performance period).<sup>2</sup> 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.<sup>3</sup> **Please note CMS expects Qualified Registries 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.**<sup>4</sup> 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. 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

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<sup>2</sup> §414.1400(c)(2)

<sup>3</sup> 81 FR 77383

<sup>4</sup> 83 FR 59761

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.

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.<sup>5</sup> 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 Alternative Payment Model (APM) Performance Pathway (APP) is a new data submission method starting in the 2021 performance period. [Data submission is discussed in more detail below]

Except as provided in the Final Rule,<sup>6</sup> 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:
  - o The CAHPS for MIPS survey; and
  - o 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.<sup>7</sup>

4. **Data Validation and Targeted Audits:** You must conduct Data Validation for the 2021 performance year prior to any data submission **for the 2021 performance period.**<sup>8</sup> **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.<sup>9</sup> 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.<sup>10</sup> 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 MIPS quality measures that are relevant for the reporting periods will be used for MIPS submission. For the 2021 performance year, this means:
    - o 2021 MIPS Clinical Quality Measures (CQMs) and/or electronic CQMs (eCQMs) for the Quality performance categories.

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<sup>5</sup> 81 FR 77384 through 77385

<sup>6</sup> §414.1400(a)(2)(ii)

<sup>7</sup> [§414.1380\(c\)\(2\)\(i\)\(A\)\(4\) or \(5\)](#) or [§414.1380\(c\)\(2\)\(i\)\(C\)\(1\) through \(7\)](#) or [§414.1380\(c\)\(2\)\(i\)\(C\)\(9\)](#)

<sup>8</sup> §414.1400(b)(2)(iv)(A)

<sup>9</sup> §414.1400(b)(2)(iv)(B) & (C)

<sup>10</sup> §414.1400(b)(2)(iv)(D)

- o 2021 Promoting Interoperability measures and objectives for the Promoting Interoperability performance categories.
- o 2021 Improvement Activities for the Improvement Activities performance categories

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.<sup>11</sup> Any required targeted audits for the 2021 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 2021 performance year.<sup>12</sup> 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.<sup>13</sup> (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 2021 Data Validation and any required targeted audits **prior** to the submission of data for the 2021 MIPS performance period.

- The 2021 Data Validation Execution Report that includes the results of your data validation audit, must be submitted to CMS by May 31, 2022.<sup>14</sup>
- The 2021 Data Validation Execution Report must include:
  - o Name of Qualified Registry
  - o Was data submitted for any of the performance categories for the 2021 MIPS performance period?
  - o Overall Data Deficiency and 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.
  - 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

<sup>11</sup> §414.1400(b)(2)(v)(A)

<sup>12</sup> §414.1400(b)(2)(v)(B)

<sup>13</sup> §414.1400(b)(2)(v)(C)

<sup>14</sup> §414.1400(b)(2)(iv)(G)

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 2021 MIPS measures and activities were utilized for submission, namely
  - 2021 MIPS CQMs, eCQMs and/or QCDR measures for the Quality performance categories.
  - 2021 Promoting Interoperability measures and objectives for the Quality performance categories.
  - 2021 Improvement Activities for the Improvement Activities performance categories.
- 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?)
- o If you are required to conduct any targeted audits for performance year 2021, the corresponding 2021 Targeted Audit results should also be submitted to CMS by May 31, 2022.
- o Your report with the results of each targeted audit must include:
  - the overall deficiency or data error rate;
  - the types of deficiencies or data errors discovered,
  - how and when the error or deficiency was corrected, and
  - 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 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 for Data Validation and Targeted Audit results, which will be posted on the [CMS Quality Payment Program Resource Library](#).**

- 6. Performance Category Feedback Reports:** Qualified Registries are required to provide performance category 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, groups, virtual groups, and APM 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 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 in the Final Rule.<sup>15</sup>

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<sup>15</sup> §414.1400(c)(2)(ii)

7. Attest that you understand the Qualified Registry qualification criteria and program requirements, and will meet all program requirements.

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### **Change #6**

**Location:** Page 5-7

### **Reason for Change:**

Edited for clarity.

### **CY 2020 Final Rule text:**

Section Header – 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 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, as applicable.
- Results for at least six MIPS Quality Measures (claims, MIPS CQMs, 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 (the 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 Clinical Quality Measures or specialty-specific measure sets (if applicable).
- Business associate agreement(s) with clinicians, groups or virtual groups who provide patient-specific data.
  - ✓ A practice administrator may give consent on behalf of a group or virtual group reporting as a group, but not for an individual MIPS eligible clinician reporting as an individual.



- ✓ Business associate agreements must comply with HIPAA Privacy and Security Rules.
- ✓ Include disclosure of MIPS quality measure results and data on Medicare and non-Medicare beneficiaries.
- Signed NPI-holder 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.
- Requirement to participate in the mandatory Qualified Registry kick-off meeting and monthly support calls.
- Participation requirements (Data Validation Execution Report, performance feedback to eligible clinicians, registry must be up and running by January 1 of the given performance period, etc.).
- CMS-approved secure method for data submission

### CY 2021 Final Rule text:

Section Header – What data submission functions must a Qualified Registry perform?

Following the self-nomination process, an approved Qualified Registry should be able to 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 claims patients
- Results for at least six 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.
  - ✓ 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.
- Risk-adjusted results for any risk-adjusted measures.

#### 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 or specialty-specific measure sets (if applicable).
- Business associate agreements must comply with HIPAA Privacy and Security Rules (82 FR 53812).
- 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 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, Qualified Registry would be up and running by January 1 of the given performance period, etc.).
- CMS-approved secure method for data submission.

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#### **Change #7**

**Location:** Page 7

#### **Reason for Change:**

Edited for alignment with finalized requirements; edited for clarity.

**2020 Final Rule text:**

Section Header – What are the thresholds for data inaccuracies? What are considered data inaccuracies?

Data inaccuracies that affect MIPS eligible clinicians, may result in:

- Remedial action may be taken against your Qualified Registry due to the low data quality rating.
- Will have 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 has been taken against the Qualified Registry.

Data inaccuracies affecting **more than 5%** of your total MIPS eligible clinicians may lead to termination of the Qualified Registry for future program years.

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

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

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

- TIN/NPI Issues – Incorrect 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, 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.

**2021 Final Rule text:**

Section Header – What is the threshold for posting a Qualified Registries' rate of data inaccuracies? What are considered data inaccuracies?

Data inaccuracies may result in:

- Remedial action, up to and including termination.
- 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% and to indicate that remedial action or termination has been taken against the Qualified Registry.

CMS will further evaluate the Qualified Registry to determine if any additional inaccurate, unusable or otherwise compromised data has been submitted. Data inaccuracies may lead to

remedial action/termination of the Qualified Registry for future program year(s) based on CMS discretion.

CMS will evaluate data submitted for quality measures for data completeness and accuracy. The Qualified Registry will also certify that all the 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, 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 will be taken into consideration by CMS.

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### **Change #8**

**Location:** Page 8

**Reason for Change:**

Edited for alignment with finalized requirements; edited for clarity.

**CY 2020 Final Rule Text:**

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

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, 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 and, 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 years of MIPS.

**CY 2021 Final Rule text:**

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

To become a Qualified Registry 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 Qualified Registry completes and submits the self-nomination form and supported Measures the Quality Payment Program website for CMS consideration (82 FR 53817).
- If the self-nomination form and MIPS Quality Measures are approved, a Qualified Posting is developed for the approved Qualified Registry and include 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), the approved 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.

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 Resource Library of the CMS Quality Payment Program website.

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## **Change #9**

**Location:** Page 8

### **Reason for Change:**

Edited for alignment with finalized requirements

### **CY 2020 Final Rule text:**

Section Header - When is the self-nomination period?

You can self-nominate from:

**July 1 – September 3** of the year prior to the applicable performance period. The Self-Nomination Period will promptly open at **10:00 am ET** on July 1<sup>st</sup> and close at **8:00 pm ET** on September 3rd. Self-Nominations submitted after the deadline will not be considered.

### **CY 2021 Final Rule text:**

Section Header - 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 2021 performance period, the self-nomination period was open at **10 a.m. (Eastern Time) ET** on July 1st and closed at **8 p.m. ET** on September 1, 2020. Self-Nominations submitted after the deadline were not considered.

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## **Change #10**

**Location:** Page 9

### **Reason for Change:**

Edited for alignment with finalized requirements

### **CY 2020 Final Rule text:**

Section Header - Tips for Successful Self-Nomination:

1. To become qualified for a given performance period, the vendor must have at least 25 participants by January 1 of the year prior to the applicable performance period. These participants do not need to use the Qualified Registry to report MIPS data to us; rather, they need to submit data to the Qualified Registry for purposes of quality improvement.
2. You must provide all required information at the time of self-nomination, and before the close of the self-nomination period via the CMS Quality Payment Program portal (<https://qpp.cms.gov/login>) for CMS consideration.
3. Self-nomination is an annual process. If you want to qualify as a Qualified Registry for a given performance period, you will need to self-nominate for that 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 registry as a third party intermediary).

A simplified self-nomination form is available to reduce the burden of self-nomination for those existing QCDRs that have previously participated in MIPS and are in good standing (CMS did not take remedial action against or terminate the QCDR as a third party intermediaries).

The simplified form is available **only** for existing QCDRs in good standing.

The list of vendors that have been approved to submit data to CMS as a Qualified Registry for the 2020 performance period of MIPS will be posted in the Resource Library of the CMS Quality Payment Program website.

### **CY 2021 Final Rule text:**

Section Header – 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 an entity 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 (i.e., CMS did not take remedial action against or terminate the Qualified Registry 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 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](mailto:RegistryVendorSupport@gdit.com) if they cannot find or access the simplified self-nomination form instead of submitting a new self-nomination form.

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## **Change #11**

**Location:** Page 9-10

### **Reason for Change:**

Edited for clarity.

### **CY 2020 Final Rule text:**

Section Header - What information is required to self-nominate?

You must provide the following when you self-nominate:

- What is your Qualified Registry's Vendor Name?
- Are you a new or existing Qualified Registry (approved in a previous year of MIPS and/or Physician Quality Reporting System [PQRS])?
- Are you supporting MIPS Clinical Quality Measures? Please note that the MIPS clinical quality measure must be used as specified. Measure specification changes are not permitted.
- Are you supporting MIPS electronic Clinical Quality Measures (eCQMs)? Please note that the MIPS eCQM must be used as specified. Measure specification changes are not permitted.
- Which MIPS performance categories do you intend to support? Please note Qualified Registries are required to support the Quality performance category.
- Which Improvement Activities are you supporting?
- Are you supporting the Promoting Interoperability Objectives and Measures set?
- Which data collection method(s) do you intend to support?
- Data Validation Plan
- Confirm you will provide your 2020 performance period Data Validation Plan results by May 31, 2021 (the Data Validation Execution Report)
- Which reporting options do you intend to support (i.e., Individual MIPS eligible clinician, Group, Virtual Groups)?
- Specify the Cost (frequency (monthly, annual, per submission) and if the Cost is per provider/practice) and Services Included in Cost

### **CY 2021 Final Rule text:**

Section Header - What information is needed to self-nominate?

You must provide the following when you self-nominate:

- Your Qualified Registry's entity name
- Whether you are a new applicant or previously approved Qualified Registry (approved in a previous year of MIPS and/or Physician Quality Reporting System [PQRS]).
- MIPS performance categories you will 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, virtual groups or APM Entities 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 eCQM must utilize the current measure specification for the performance period in which they will be



used, and must be used as specified. Third party intermediaries are not permitted to alter or modify measure specifications.

- Which 2021 Improvement Activities are you supporting?
- Which 2021 Promoting Interoperability Objectives and Measures are you supporting?
- An entity seeking to become a Qualified Registry 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 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.)?
- Confirm you will conduct your 2021 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 2021 performance period Data Validation audit and targeted audit by the deadline of May 31, 2022.
- 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.

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## **Change #12**

**Location:** Page 10-11

### **Reason for Change:**

Edited for alignment with finalized requirements; edited for clarity.

### **2020 Final Rule text:**

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

CMS may take remedial action for failing to meet applicable criteria for approval or submit data that is inaccurate, unusable, or otherwise compromised. 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.

### **2021 Final Rule text:**

Section Header – 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.<sup>16</sup>

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 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 implemented by the third party intermediary to ensure that the non-compliance issues have 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 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.

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### **Change #13**

**Location:** Page 11-12

**Reason for Change:**

Edited for clarity.

**CY 2020 Final Rule Text:**

Section Header - Resources

- **Qualified Registry Support Calls** - CMS will hold mandatory support calls for Qualified Registries that are approved to participate in the 2020 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 2020 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.
- **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

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<sup>16</sup> §414.1400(f)

process.

- **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](mailto: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 a Qualified Registry for the 2020 performance period of MIPS.
- [QCDR/Registry Google Calendar](#) - Will be used to track and highlight key milestones and activities for the annual self-nomination period.

## CY 2021 Final Rule Text:

### Section Header - 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.
- **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 an entity 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** – For additional questions related to the Quality performance category, please contact the Quality Payment Program Service Center at [QPP@cms.hhs.gov](mailto: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 Qualified Registry for the 2021 performance period of MIPS.