Quality Payment PROGRAM

Calendar Year (CY) 2021 Physician Fee Schedule Final Rule: Finalized (New and Updated) Qualified Clinical Data Registry (QCDR) and Qualified Registry Policies

February 22, 2021

- This fact sheet summarizes policy updates finalized in the CY 2021 Physician Fee Schedule Final Rule, available here, as it pertains to QCDRs and Qualified Registries for the 2021 performance period for the Merit-based Incentive Payment System (MIPS). For broader Quality Payment Program policy changes for 2021, including changes to the Quality, Improvement Activities, Promoting Interoperability, and Cost performance categories, readers may reference the 2021 final rule Fact Sheet, Executive Summary, and FAQs on the Quality Payment Program Resource Library.

2021 Performance Period/2023 MIPS Payment Year

- Highlights for 2021 include:
- Maintaining the data completeness threshold at 70%.
- Medicare Part B Claims measures: 70% sample of Medicare Part B patients for the performance period.
- QCDR measures, MIPS Clinical Quality Measures (CQMs), and electronic clinical quality measures (eCQMs): 70% sample of eligible clinician's or group's patients across all payers for the performance period.
- Continuing to remove clinically low-bar, standard of care, process measures.
- Continuing to use historical benchmarks for the 2021 performance period.
- Finalizing policies for MIPS Value Pathways (MVPs) beginning in the 2022 performance period.
- All policies in this Fact Sheet apply beginning with the 2021 performance period/2023 payment year, except for a handful of requirements under subsequent performance periods as indicated.

MIPS Quality Measures that are Added/Removed

- The following MIPS quality measures were added as new measures in the 2021 performance period (2 Total):

MIPS Quality ID	Indicator	Collection Type	Measure Type	MIPS Quality Measure Title
479	High Priority (Outcome)	Administrative Claims	Outcome	Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment System (MIPS) Groups
480	High Priority (Outcome)	Administrative Claims	Outcome	Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS)

- The following MIPS quality measures were removed in the 2021 performance period (11 Total):

MIPS Quality ID	Indicator	Collection Type	Measure Type	MIPS Quality Measure Title
069	N/A	MIPS CQMs Specifications	Process	Hematology: Multiple Myeloma: Treatment with Bisphosphonates
146	High Priority (Efficiency)	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Inappropriate Use of "Probably Benign" Assessment Category in Screening Mammograms
333	High Priority (Appropriate Use)	MIPS CQMs Specifications	Efficiency	Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse)
348	High Priority (Outcome)	MIPS CQMs Specifications	Outcome	Implantable Cardioverter-Defibrillator (ICD) Complications Rate

MIPS Quality ID	Indicator	Collection Type	Measure Type	MIPS Quality Measure Title
390	High Priority (Patient Experience)	MIPS CQMs Specifications	Process	Hepatitis C: Discussion and Shared Decision Making Surrounding Treatment Options
408	High Priority (Opioid)	MIPS CQMs Specifications	Process	Opioid Therapy Follow-up Evaluation
412	High Priority (Opioid)	MIPS CQMs Specifications	Process	Documentation of Signed Opioid Treatment Agreement
414	High Priority (Opioid)	MIPS CQMs Specifications	Process	Evaluation or Interview for Risk of Opioid Misuse
435	High Priority (Outcome)	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Patient Reported Outcome	Quality of Life Assessment for Patients With Primary Headache Disorders
437	High Priority (Outcome)	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Outcome	Rate of Surgical Conversion from Lower Extremity Endovascular Revascularization Procedure
458	High Priority (Outcome)	Administrative Claims	Outcome	All-Cause Hospital Readmission

- The following MIPS quality measures had specific collection types only removed in the 2021 performance period (6 Total):

MIPS Quality ID	Indicator	Collection Type	Measure Type	MIPS Quality Measure Title
012	N/A	Removed: Medicare Part B Claim Specifications, MIPS CQMs Specifications Retained: eCQM Specifications	Process	Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation

MIPS Quality ID	Indicator	Collection Type	Measure Type	MIPS Quality Measure Title
048	N/A	Removed: Medicare Part B Claims Measure Specifications Retained: MIPS CQMs Specifications	Process	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older
052	N/A	Removed: Medicare Part B Claims Measure Specifications Retained: MIPS CQMs Specifications	Process	Chronic Obstructive Pulmonary Disease (COPD): Long-Acting Inhaled Bronchodilator Therapy
141	High Priority (Outcome)	Removed: Medicare Part B Claims Measure Specifications Retained: MIPS CQMs Specifications	Outcome	Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care
268	N/A	Removed: Medicare Part B Claims Measure Specifications Retained: MIPS CQMs Specifications	Process	Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy
419	High Priority (Efficiency)	Removed: Medicare Part B Measure Specifications Retained: MIPS CQMs Specifications	Process	Overuse of Imaging for the Evaluation of Primary Headache

Program Impacts

- For further details on the items below, please consult the CY 2021 Physician Fee Schedule Final Rule.

Beginning with the 2021 Performance Period/2023 MIPS Payment Year

QCDRs

Data Validation Audit and Targeted Audit Requirements (§ 414.1440(b)(2)(iv) and (v))

- As condition of approval, each QCDR must conduct annual data validation audits (formerly known as “randomized audits”), and if one or more deficiencies or data errors are identified, also conduct targeted audits.
- Data validation audits are separate from targeted audits (formerly known as “detailed audits”).
- Data validation for the payment year must be conducted prior to submitting any data for that payment year to the Centers for Medicare & Medicaid Services (CMS) for purposes of the MIPS program, which will lead to data being more reliable and promote compliance with the requirement of data being true, accurate, and complete.
- Data validation must be conducted on data for each performance category for which the QCDR will submit data, including if applicable the Quality, Improvement Activities, and Promoting Interoperability performance categories and be attested to as true, accurate, and complete data for each performance category.
- Data validation audits must be conducted on data for each submitter type for which it will submit data, including if applicable MIPS eligible clinicians, groups, virtual groups, voluntary participants, and opt-in participants.
- Data validation audits should account for all types of submitters that are utilizing the QCDR to submit data to CMS for purposes of the MIPS program. All data the QCDR submits, regardless of its use for payment or public reporting, should be true, accurate, and complete.
- Clinical documentation must be used (provided by the clinicians they are submitting data for) to validate that the action or outcome measured actually occurred or was performed.
- Each data validation audit must use a sampling methodology that meets the following requirements:
    - Uses a sample size of at least 3 percent of the Tax Identifier Numbers-National Provider Identifiers (TIN-NPIs) for which the QCDR will submit data to CMS, except if a 3 percent sample size would result in fewer than 10 TIN-NPIs, the QCDR must use a

sample size of at least 10 TIN-NPIs, and if a 3 percent sample size would result in more than 50 TIN-NPIs, the QCDR may use a sample size of 50 TIN-NPIs.
    - Uses a sample that includes at least 25 percent of the patients of each TIN-NPI in the sample, except that the sample for each TIN-NPI must include a minimum of 5 patients and does not need to include more than 50 patients.
- Each QCDR data validation audit must include the following:
    - Verification of the eligibility status of each MIPS eligible clinician, group, virtual group, opt-in participant, and voluntary participant. This will help ensure the accuracy of data publicly posted on the Care Compare Website (or a successor website) of the CMS website.
    - Verification of the accuracy of TINs and NPIs.
    - Calculation of reporting and performance rates (for example, formulas included in the Quality measure specifications).
    - Verification that only MIPS Quality measures and QCDR measures relevant to the performance period will be utilized for MIPS submission.
- Data validation results must include the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by any deficiency or data error, and how and when each deficiency or data error type was corrected. False certification may subject the QCDR to remedial action or termination.
- If deficiencies or data errors are identified under a data validation audit, the QCDR must conduct a targeted audit into the impact and root cause of each such deficiency or data error for that MIPS payment year.
- The QCDR must correct any deficiencies or data errors identified through the targeted audit prior to the submission of data for that MIPS payment year and should determine the error's impact using a separate sample of clinicians and groups.
- The targeted audit must use the approved sampling methodology set forth in the regulations. The sample for the targeted audit must not include data from the sample used for the data validation audit in which the deficiency or data error was identified.
- The results of each targeted audit must be reported, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by each deficiency or data error, and how and when each deficiency or data error type was corrected.

QCDR Measures

Requirements for QCDR Measures

- QCDR measures are generally reviewed and approved on an annual basis; only under certain circumstances are they approved for two years at a time, and even then, they are still reviewed annually.
- Upon annual review, CMS may revoke a QCDR measure's 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 self-nominating the QCDR measure is no longer in good standing.

Duplicative QCDR Measures

- We revised previously codified policies that refer to measure harmonization with updated terminology.
- Specifically, beginning with the 2022 MIPS payment year, CMS may provisionally approve the individual QCDR measures for 1 year with the condition that QCDRs address certain areas of duplication with other approved QCDR measures or MIPS quality measures in order to be considered for the program in subsequent years. If such areas of duplication are not addressed, CMS may reject the duplicative QCDR measure[1].
- In addition, beginning with the 2023 MIPS payment year, QCDR measures may be approved for 2 years, at CMS discretion by attaining approval status by meeting QCDR measure considerations and requirements. Upon annual review, CMS may revoke a QCDR measure's 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 self-nominating the QCDR measure is no longer in good standing[2].
- We also removed two previously codified policies that we identified as areas of redundancy.

Requirements for Self-Nomination

- See the 2021 MIPS QCDR Self-Nomination Fact Sheet, which will be available on the Quality Payment Program Resource Library, for complete details on self-nomination requirements.

Qualified Registries

Data Validation Audit and Targeted Audit Requirements (§ 414.1440(c)(2)(iii) and (iv))

- As condition of approval, each Qualified Registry must conduct annual data validation audits, and if one or more deficiencies or data errors are identified, also conduct targeted audits.
- Data validation audits are separate from targeted audits.
- Data validation for the payment year must be conducted prior to submitting any data for the payment year to CMS for the purposes of the MIPS program, which will lead to the data being more reliable and promote compliance with the requirement of data being true, accurate, and complete.

[1] § 414.1400(b)(3)(v)(E)
[2] § 414.1400(b)(3)(vi)

- Data validation must be conducted on data for each performance category for which the Qualified Registry will submit data, including if applicable the Quality, Improvement Activities, and Promoting Interoperability performance categories and be attested to as true, accurate, and complete data for each performance category.
- Data validation audits must be conducted on data for each submitter type for which it will submit data, including if applicable MIPS eligible clinicians, groups, virtual groups, voluntary participants, and opt-in participants.
- Data validation audits should account for all types of submitters that are utilizing the Qualified Registry to submit data to CMS for purposes of the MIPS program. All data the Qualified Registry submits, regardless of its use for payment or public reporting, should be true, accurate, and complete.
- Clinical documentation must be used (provided by the clinicians they are submitting data for) to validate that the action or outcome measured actually occurred or was performed.
- Each data validation audit should use a sampling methodology that meets the following requirements:
    - Uses a sample size of at least 3 percent of the TIN-NPIs for which the Qualified Registry will submit data to CMS, except if a 3 percent sample size would result in fewer than 10 TIN-NPIs, the Qualified Registry must use a sample size of at least 10 TIN-NPIs, and if a 3 percent sample size would result in more than 50 TIN-NPIs, the Qualified Registry may use a sample size of 50 TIN-NPIs.
    - Uses a sample that includes at least 25 percent of the patients of each TIN-NPI in the sample, except that the sample for each TIN-NPI must include a minimum of 5 patients and does not need to include more than 50 patients.
- Each Qualified Registry data validation audit must include the following:
    - Verification of the eligibility status of each MIPS eligible clinician, group, virtual group, opt-in participant, and voluntary participant. This will help ensure the accuracy of data publicly posted on the Care Compare Website (or a successor website) of the CMS website.
    - Verification of the accuracy of TINs and NPIs.
    - Calculation of reporting and performance rates (for example, formulas included in the Quality measure specifications).
    - Verification that only MIPS Quality measures relevant to the performance period will be utilized for MIPS submission.
- Data validation results must include the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by any deficiency or data error, and how and when each deficiency or data error type was corrected. False certification may subject the Qualified Registry to remedial action or termination.
- If deficiencies or data errors are identified under a data validation audit, the Qualified Registry must conduct a targeted audit into the impact and root cause of deficiency or data error for that MIPS payment year.

- The Qualified Registry must correct any deficiencies or data errors identified through the targeted audit prior to the submission of data for that MIPS payment year and should determine the error's impact using a separate sample of clinicians and groups.
- The targeted audit must use the approved sampling methodology set forth in the regulations. The sample for the targeted audit must not include date from the sample used for the data validation audit in which the deficiency or data error was identified.
- The results of each targeted audit must be reported, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by each deficiency or data error, and how and when each deficiency and data error type was corrected.

All Third Party Intermediaries

New Alternative Payment Model (APM) Performance Pathway (APP)

- A new APP was finalized beginning with the 2021 performance period that will be complementary to MVPs.
- Third party intermediaries such as QCDRs, Qualified Registries, and Health IT vendors can support the APP.
- The APP is available only to participants in MIPS APMs and may be reported by the clinician, group (TIN), or APM Entity.
- The APP is composed of a fixed set of measures for each performance category.
- The Quality performance category has six measures focused on population health that should be widely available to all MIPS APM participants.
- Quality measures reported through the APP automatically would automatically be used for purposes of quality performance scoring under the Medicare Shared Savings Program.
- The addition of the CMS Web Interface measure set to the APP quality measure set was finalized for the 2021 performance period for ACOs only.

New Approval Considerations – Past Performance and Conduct

- The determination of whether to approve an entity as a third party intermediary for a payment year may take into account:
  1. whether the entity failed to comply with the requirements of this section for any prior MIPS payment year for which it was approved as third party intermediary; and
  2. whether the entity provided inaccurate information regarding the requirements of this subpart to any eligible clinician.
- Past performance and conduct information will be used to make these approval determinations, and the results of the audit will be reviewed to inform future approval of a third party intermediary.

Third Party Intermediary Training and Support

- Third Party Intermediaries must attend and complete training and support sessions in the form and manner, and at the times, specified by CMS.
- These meetings may be virtual when in-person meetings are not possible, for example, during a PHE.

Remedial Action and Termination of Third Party Intermediaries

- If placed on remedial action, CMS will require the third party intermediary to submit a corrective action plan (CAP) by a date specified by CMS. The CAP must address the following issues, unless different or additional information is specified by CMS:
  1. the issues that contributed to the non-compliance;
  2. 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;
  3. the corrective actions to be implemented by the third party intermediary to ensure that the non-compliance has been resolved will not recur in the future and
  4. the detailed timeline for achieving compliance with the applicable requirements.
- Corrective actions must be addressed by the third party intermediary to ensure that the non-compliance has been resolved and will not recur in the future. Follow through with the implementation of the corrective actions and to see that the issue has been corrected permanently is expected.

Policies Implemented Beginning with the 2022 Performance Period/ 2024 MIPS Payment Year

Policies Delayed in IFC

- CMS issued a COVID-19 Public Health Emergency Interim Final Rule with Comment Period (IFC) that appeared in the April 6, 2020 Federal Register (85 FR 19230) with an effective date of March 31, 2020.
- CMS heard from third party intermediaries, specifically QCDRs, that due to the COVID-19 pandemic they anticipated being unable to complete QCDR measure testing or collect data on QCDR measures for the 2021 MIPS performance period.
- As a result, in the COVID-19 IFC published in the 2021 Physician Fee Schedule final rule, CMS finalized the delay of its measure testing policy by 1 year, such that instead of requiring full development and testing for the 2021 performance period, that requirement was delayed until the beginning of the 2022 performance period and language was revised to state that beginning with the 2022 performance period, all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self nomination[3].

[3] § 414.1400(b)(3)(v)(C) and 85 FR 84939

- To clarify, this policy is effective from May 8, 2020 through the end of the 2022 performance period since CMS made further updates to implement the QCDR measure testing requirements in an incremental manner beginning with the 2022 performance period[4].

Requirements for QCDR Measures

- QCDR measures, whether previously approved or not, are required to, at a minimum, be face valid prior to being self-nominated for the 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 for any subsequent MIPS payment year for which it is approved.
- Face validity is a subjective assessment by experts of whether the measure reflects the quality of care.
- Full testing includes reliability, feasibility, and validity completed at the clinician level (see CMS Measures Management System Blueprint 16.0).
- To avoid any potential confusion, CMS clarified in the CY 2021 Physician Fee Schedule final rule that for purposes of QCDR measures, CMS would expect QCDR measures to complete beta testing to be considered fully tested[5].
    - Beta testing is defined in the CMS Measures Blueprint as the following: Beta testing (that is, field testing) generally occurs after initial technical specifications have been developed and is usually larger in scope than alpha testing.
    - In addition to gathering further information about feasibility, beta tests serve as the primary means to assess scientific acceptability and usability of a measure.
    - For example, beta testing allows for an enhanced evaluation of a measure's importance, including evaluation of performance thresholds, disparities analysis, and outcome variation. It helps in looking for opportunities for improvement in the population, which aids in measuring the QCDR measure's importance for reasons that include evidence collection to measure variability among comparison groups, to demonstrate the measure is not topped-out where most groups achieve similarly high performance levels approaching the measure's maximum possible value.
    - We referred readers to the CMS Blueprint for the CMS Measures Management System at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/ [*84940] Blueprint.pdf* for additional details regarding beta testing[6].
    - As defined in the CMS Measures Management System Blueprint, for a beta test, methods and analysis should address these evaluation criteria:

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[4] 85 FR 84939 and 85 FR 84937
[5] 85 FR 84940
[6] 85 FR 84939-84940

- Importance—including analysis of opportunities for improvement such as reducing variability in comparison groups or disparities in healthcare related to race, ethnicity, age, or other classifications
- Scientific acceptability—including analysis of reliability, validity, and exclusion appropriateness
- Feasibility—including evaluation of reported costs or perceived burden, frequency of missing data, and description of data availability
- Usability and Use—including planned analyses to demonstrate the measure is meaningful and useful to the target audience. The TEP may accomplish this by reviewing the measure results (e.g., means and detectable differences, dispersion of comparison groups)

Requirements for Self-Nomination

- Beginning with the 2022 performance period, QCDRs are required to collect data on a QCDR measure, appropriate to the measure type, prior to submitting the QCDR measure for CMS consideration during the self-nomination period.

QCDR Measures and MVPs

- QCDRs may support MVPs beginning with the 2022 performance period.
- To be included in an MVP for the 2022 performance period and future years, a QCDR measure must be fully tested.

Qualified Registries and MVPs

- Qualified Registries may support MVPs beginning with the 2022 performance period.

Data Submission

- QCDRs, qualified registries, and Health 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 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[7].

  Health IT vendors that do not support MVPs, must be able to submit data for at least one of the MIPS performance categories for the 2024 MIPS payment year[8].

[7] § 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))
[8] 85 FR 85033