

Supporting Statement – Part B
Quality Payment Program/Merit-Based Incentive Payment System (MIPS)
CMS-10621, OMB 0938-1314
Collections of Information Employing Statistical Models

Introduction

The Merit-based Incentive Payment System (MIPS), is one of two paths for clinicians available through the Quality Payment Program authorized by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). The Quality Payment Program replaced three precursor Medicare reporting programs with a flexible system that allows clinicians to choose from two paths that link quality to payments: the Merit-Based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs). The MIPS measures MIPS eligible clinicians and groups on four performance categories: quality, cost, improvement activities, and Promoting Interoperability (related to meaningful use of certified EHR technology or CEHRT). Under the APM path, clinicians participating in certain types of APMs (Advanced APMs) may become Qualifying APM participants (QPs) and excluded from MIPS. QPs will receive lump-sum APM incentive payments equal to 5 percent of their estimated aggregate payment amounts for Medicare covered professional services in the preceding year.

The primary purpose of this collection is to generate data on a MIPS eligible clinician or group so that CMS can assess MIPS eligible clinician performance in the four performance categories, calculate the final score, and apply performance-based payment adjustments. We will also use this information to provide regular performance feedback to MIPS eligible clinicians and eligible entities. This information will also be made available to beneficiaries, as well as to the general public, on the Physician Compare website. In addition, the data collected under this PRA will be used for research, evaluation, and measure assessment and refinement activities.

Specifically, CMS uses the data to produce annual statistical reports that provide a comprehensive representation of the overall experience of MIPS eligible clinicians as a whole and subgroups of MIPS eligible clinicians. The data will also be utilized to fulfill a MACRA requirement in which the GAO must perform a MIPS evaluation to submit to Congress by October 1, 2021.¹ Further, CMS has processes to monitor and assess measures to ensure their soundness and appropriateness for continued use in the MIPS. As required by the MACRA, the ongoing measure assessment and monitoring process will be used to refine, add, and drop measures as appropriate, as shown in the finalized changes to the measure sets discussed in the

¹ MACRA mandates that the GAO evaluate and make recommendations regarding the final scores and the impact of technical assistance.

CY 2020 PFS final rule and the proposed changes in the CY 2021 PFS proposed rule. Part B characterizes the respondents of this collection and any sampling used in data collection so that, when grouped/aggregated data are presented, the inferences that can be drawn from those data are clear.

There are 19 information collections in the CY 2021 PFS proposed rule requirements and burden estimates. The discussion in this Supporting Statement Part B focuses on the 5 information collections for which we plan to conduct statistical reporting and analyses: quality performance category data submitted via Medicare Part B claims, eCQM, and MIPS CQM and QCDR collection types, and data submitted for the Promoting Interoperability and improvement activities performance categories.

Describe (including a numerical estimate) the potential respondent universe and any sampling or other respondent selection method to be used. Data on the number of entities (e.g., establishments, State and local government units, households, or persons) in the universe covered by the collection and in the corresponding sample are to be provided in tabular form for the universe as a whole and for each of the strata in the proposed sample. Indicate expected response rates for the collection as a whole. If the collection had been conducted previously, include the actual response rate achieved during the last collection.

Quality Performance Category Data Submission

Potential respondent universe and response rates

We anticipate that two groups of clinicians will submit quality data under MIPS: those who submit as MIPS eligible clinicians and other eligible clinicians who submit data voluntarily. We estimate the potential respondent universe and response rates for MIPS eligible clinicians and clinicians excluded from MIPS using data from the 2018 MIPS performance period and other CMS sources. To determine which QPs should be excluded from MIPS, we used the QP List for the 2019 third snapshot that contains participation in Advanced APMs as of August 31, 2019, that could be connected into our respondent data and are the best estimate of future expected QPs. From this data, we calculated the QP determinations as described in the Qualifying APM Participant (QP) definition at § 414.1305 for the 2021 QP Performance Period. We assumed that all Partial QPs will participate in MIPS data collections. Due to data limitations, we could not identify specific clinicians who have not yet enrolled in APMs, but who may become QPs in the future 2021 QP Performance Period (and therefore will no longer need to submit data to MIPS); hence, our model may underestimate or overestimate the fraction of clinicians and allowed charges for covered professional services that will remain subject to MIPS after the exclusions.

We assume that 100 percent of ACO APM Entities will submit quality data to CMS as required under their models. While we do not believe there is additional reporting for ACO APM entities, consistent with assumptions used in the CY 2019 and CY 2020 PFS final rules (83 FR 60000 through 60001 and 84 FR 63122), we include all quality data voluntarily submitted by MIPS APM participants made at the individual or TIN-level in our respondent estimates. As stated in section VI.4.a.(4) of the CY 2021 PFS proposed rule, we assume non-ACO APM Entities will participate through traditional MIPS and submit as an individual or group rather than as an entity. To estimate who will be a MIPS APM participant in the 2021 MIPS performance period, we used the latest QP List for the third snapshot data of the 2019 QP performance period and supplemented with clinicians who are in an APM in 2018 but not in the 2019 snapshot. This file was selected to better reflect the expected increase in the number of MIPS APMs in future years compared to previous APM eligibility files. If a MIPS eligible clinician is determined to not be scored as a MIPS APM, then their reporting assumption is based on their reporting for the CY 2018 MIPS performance period.

As discussed in Supporting Statement A, we explain that we assume 931,050 MIPS eligible clinicians will submit quality data as individual clinicians, or as part of groups or APM entities. We also estimate that 20,059 clinicians or 33 percent of clinicians who exceed at least one but not all low-volume threshold and submitted data in the CY 2018 MIPS performance period will elect to opt-in to MIPS.

CMS annual statistical reports about MIPS will be able to provide estimates of the numbers and percentages of MIPS eligible clinicians submitting quality that can be generalized to the entire population of MIPS eligible clinicians, and to relevant subpopulations (such as eligible clinicians participating in MIPS APMs).

Sampling for quality data submission

In the CY 2020 PFS final rule, we finalized to adopt a higher data completeness threshold for the 2020 MIPS performance period, such that MIPS eligible clinicians and groups submitting quality measure data on Medicare Part B claims, QCDR measures, MIPS CQMs, and eCQMs must submit data on at least 70 percent of the MIPS eligible clinician or group's patients that meet the denominator criteria, regardless of payer for the 2022 MIPS payment year. We further finalized that if quality data are submitted selectively such that the data are unrepresentative of a MIPS eligible clinician or group's performance, any such data would not be true, accurate, or complete. We believe this clarification emphasizes to all parties that the data submitted on each measure is expected to be representative of the clinician's or group's performance and free of selection bias. The data submission and data completeness requirements at §§ 414.1335 and 414.1340 and the guidance we provide in the 2019 MIPS Quality User Guide on the QPP Resource Library (<https://qpp-cm-prod-content.s3.amazonaws.com/uploads/558/2019%20MIPS%20Quality%20User%20Guide.pdf>) provides guidance as to how clinicians can submit in a consistent manner. We do not specify a methodology for how eligible clinicians can select the patients they want to report on because we believe some operational flexibility is appropriate provided the approach adopted is consistent with our regulations and guidance and does not allow "cherry picking" of data. Tables 1a and 1b summarize the data completeness criteria for the 2021 MIPS performance period.

TABLE 1a: Summary of Data Completeness Requirements and Performance Period by Collection Type for the 2021 MIPS Performance Period

Collection Type	Performance Period	Data Completeness
Medicare Part B Claims measures	Jan 1- Dec 31	70 percent sample of individual MIPS eligible clinician’s, or group’s Medicare Part B patients for the performance period.
Administrative claims measures	Jan 1- Dec 31	100 percent sample of individual MIPS eligible clinician’s Medicare Part B patients for the performance period.
QCDR measures, MIPS CQMs, and eCQMs	Jan 1- Dec 31	70 percent sample of individual MIPS eligible clinician’s, or group’s patients across all payers for the performance period.
CAHPS for MIPS survey measure	Jan 1- Dec 31	Sampling requirements for the group’s Medicare Part B patients

TABLE 1b: Summary of Quality Data Submission Criteria for the 2021 MIPS Performance Period for Individual Clinicians and Groups

Clinician Type	Submission Criteria	Measure Collection Types (or Measure Sets) Available
Individual Clinicians	Report at least six measures including one outcome measure, or if an outcome measure is not available report another high priority measure; if less than six measures apply then report on each measure that is applicable. Clinicians would need to meet the applicable data completeness standard for the applicable performance period for each collection type.	Individual MIPS eligible clinicians select their measures from the following collection types: Medicare Part B claims measures (individual clinicians in small practices only), MIPS CQMs, QCDR measures, eCQMs, or reports on one of the specialty measure sets if applicable.

Clinician Type	Submission Criteria	Measure Collection Types (or Measure Sets) Available
Groups	Report at least six measures including one outcome measure, or if an outcome measure is not available report another high priority measure; if less than six measures apply then report on each measure that is applicable. Clinicians would need to meet the applicable data completeness standard for the applicable performance period for each collection type.	<p>Groups select their measures from the following collection types: Medicare Part B claims measures (small practices only), MIPS CQMs, QCDR measures, eCQMs, or the CAHPS for MIPS survey - or reports on one of the specialty measure sets if applicable.</p> <p>Groups of 16 or more clinicians who meet the case minimum of 200 will also be automatically scored on the administrative claims based all-cause hospital readmission measure.</p>

Data Submission for Promoting Interoperability and Improvement Activities Performance Categories

During the 2021 MIPS performance period, eligible clinicians and groups can submit Promoting Interoperability and improvement activities data through direct, log in and upload, or log in and attest submission types.

Based on data from the 2018 MIPS performance period and 2020 MIPS eligibility data, we estimate that 62,746 individual MIPS eligible clinicians and 14,753 groups will submit Promoting Interoperability data. These estimates reflect that under the policies finalized in CY 2017 and CY 2018 Quality Payment Program final rules and the CY 2019 PFS final rule, certain MIPS eligible clinicians will be eligible for automatic reweighting of the Promoting Interoperability performance category to zero percent, including MIPS eligible clinicians that are hospital-based, ambulatory surgical center-based, non-patient facing clinicians, physician assistants, nurse practitioners, clinician nurse specialists, certified registered nurse anesthetists, physical therapists, occupational therapists, qualified speech-language pathologists or qualified audiologist, clinical psychologists, and registered dietitians or nutrition professionals (81 FR 77238 through 77245, and 82 FR 53680 through 53687, and 83 FR 59819 through 59820, respectively). These estimates already account for the reweighting policies finalized in the CY 2017 and CY 2018 Quality Payment Program final rules, including exceptions for MIPS eligible clinicians who have experienced a significant hardship (including clinicians who are in small practices), as well as exceptions due to decertification of an EHR. In the CY 2020 PFS final

rule, we finalized to revise the definition of a hospital-based MIPS eligible clinician under § 414.1305 to include groups and virtual groups. We finalized that, beginning with the 2022 MIPS payment year, a hospital-based MIPS eligible clinician under § 414.1305 means an individual MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in an inpatient hospital, on-campus outpatient hospital, off campus outpatient hospital, or emergency room setting based on claims for the MIPS determination period, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, meet the definition of a hospital-based individual MIPS eligible clinician during the MIPS determination period. We also finalized to specify that for the Promoting Interoperability performance category to be reweighted for a MIPS eligible clinician who elects to participate in MIPS as part of a group or virtual group, all of the MIPS eligible clinicians in the group or virtual group must qualify for reweighting, or the group or virtual group must meet the finalized revised definition of a hospital-based MIPS eligible clinician or the definition of a non-patient facing MIPS eligible clinician as defined in § 414.1305.

As discussed in Supporting Statement A, a variety of organizations will submit Promoting Interoperability data on behalf of clinicians. Clinicians not participating in a MIPS APM may submit data as individuals or as part of a group. In the CY 2017 Quality Payment Program final rule (81 FR 77258 through 77260, 77262 through 77264) and CY 2019 PFS final rule (83 FR 59822-59823), we established that eligible clinicians in MIPS APMs (including the Shared Savings Program) may report for the Promoting Interoperability performance category as an APM Entity group, individuals, or a group.

As discussed in Supporting Statement A, we estimate 85,760 clinicians will submit improvement activities as individuals, and an estimated 16,714 groups virtual groups will submit improvement activities on behalf of clinicians during the 2021 MIPS performance period.

Describe the procedures for the collection of information including:

- **Statistical methodology for stratification and sample selection,**
- **Estimation procedure,**
- **Degree of accuracy needed for the purpose described in the justification,**
- **Unusual problems requiring specialized sampling procedures, and**
- **Any use of periodic (less frequent than annual) data collection cycles to reduce burden.**

There are 19 information collections in the 2021 PRA package. Prior to the CY 2021 PFS proposed rule, one of the 19 information collections in this information collection request involved sampling conducted by CMS: quality data submission using the CMS Web Interface collection type. As a result of the proposal in the CY 2021 PFS proposed rule to sunset the CMS Web Interface measures as a quality performance category collection type/submission type, we

will no longer perform sampling for any information collections included in this PRA. The requirements for the other quality data submission mechanism, CAHPS for MIPS survey, are discussed in a separate information collection request submitted under OMB control number 0938-1222. We do not anticipate using sampling or statistical estimation in the remaining information collections.

Describe methods to maximize response rates and to deal with issues of non-response. The accuracy and reliability of information collected must be shown to be adequate for intended uses. For collections based on sampling, a special justification must be provided for any collection that will not yield 'reliable' data that can be generalized to the universe studied.

Quality Performance Category Data Submission

We expect additional experience with submissions under MIPS to clarify optimal data completeness thresholds and submission criteria for use in future performance periods. We will continually evaluate our policies and notify the public through future notice and comment rulemaking if we make substantive changes. As we evaluate our policies, we plan to continue a dialogue with stakeholders to discuss opportunities for program efficiency and flexibility.

The previously discussed proposal to sunset the CMS Web Interface measures as a quality performance category collection type/submission type will reducing reporting requirements by no longer requiring groups and virtual groups to have to completely report on all pre-determined 10 CMS Web Interface measures; groups and virtual groups would be able to select their own measures to report, would be reporting data on at least 6 measures, and data completeness threshold would be 70 percent for each measure, which is a reduction in program requirements compared to completed reporting required for all CMS Web Interface measures. In addition, the 10 CMS Web Interface measures that are required for reporting under the 2020 performance period have an eCQM and MIPS CQM equivalent measure and for the 2021 performance period, there are 10 eCQMs and 9 CQMs that are equivalent to the 10 CMS Web Interface measures. We believe that groups and virtual groups would be able to identify at least 6 equivalent eCQMs or MIPS CQMs (or a combination) that capture the same type of data collected for the measures used in the CMS Web Interface. Also, such transition for groups and virtual groups could potentially be more beneficial. For example, if a measure from a different collection type (for example, MIPS CQMs) meets data completeness but may not meet case minimum, the measure would receive a score of 3; whereas, under the CMS Web Interface, any measure that did not meet reporting requirements would receive a score of 0.

We believe that by continuing to provide virtual group participation as an option we will experience continued improvement in response rates due to the ability to better pool resources from participating as part of a virtual group, allowing for reporting on 6 quality measures.

Promoting Interoperability Performance Category Data Submission

The revised scoring methodology finalized in the CY 2019 PFS final rule (83 FR 59791) has provided a simpler, more flexible, less burdensome structure, allowing MIPS eligible clinicians to put their focus back on patients. This scoring methodology encourages MIPS eligible clinicians to push themselves on measures that are most applicable to how they deliver care to patients, instead of focusing on measures that may not be as applicable to them. We believe the increased flexibility to MIPS eligible clinicians that enables them to focus more on patient care and health data exchange through interoperability will continue to help to maximize response rates for the Promoting Interoperability performance category.

In the CY 2020 PFS final rule, we finalized to require QCDRs and qualified registries to be able to submit data for each of the quality, improvement activities, and Promoting Interoperability performance categories with the stipulation that based on the amendment to § 414.1400(a)(2)(iii) a third party could be excepted from this requirement if its MIPS eligible clinicians, groups or virtual groups 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)). As a result, MIPS reporting for clinicians who utilized qualified registries or QCDR that have not previously offered the ability to report performance categories other than quality will be able to report MIPS data in a more streamlined and less burdensome manner.

Improvement Activities Performance Category Data Submission

User experiences from the 2018 MIPS performance period reflect that the majority of users submit improvement activities data as part of the login and upload or direct submission types which allow multiple performance categories (i.e. quality and promoting interoperability) worth of data to be submitted at once. This results in less additional required time to submit improvement activities data which consists of manually attesting that certain activities were performed. In addition, the same improvement activity may be reported across multiple performance periods so many MIPS eligible clinicians may submit the same information for the 2021 MIPS performance period as they did for previous MIPS performance periods. There is also financial incentive to submit improvement activities data, as clinicians would not receive credit in their MIPS final score otherwise. We believe a less burdensome user experience combined with the financial incentives for submitting improvement activities data will continue to improve response rates in the 2021 and future MIPS performance periods.

Describe any tests of procedures or methods to be undertaken. Testing is encouraged as an effective means of refining collections of information to minimize burden and improve utility. Tests must be approved if they call for answers to identical questions from 10 or more respondents. A proposed test or set of tests may be submitted for approval separately or in combination with the main collection of information.

We are refining our procedures, methods and testing over time to be more efficient. We do not have any additional testing to describe in this section, including no additional tests that call for answers to identical questions from 10 or more respondents.

As stated above, we expect that additional experience with MIPS will clarify optimal reporting thresholds and submission criteria for use in future performance periods across the quality, Promoting Interoperability, and improvement activities performance categories. We will continually evaluate our policies based on our analysis of MIPS and other data.

Provide the name and telephone number of individuals consulted on statistical aspects of the design and the name of the agency unit, contractor(s), grantee(s), or other person(s) who will actually collect and/or analyze the information for the agency.

We do not anticipate any additional statistical reporting on data other than that presented here for the quality or Promoting Interoperability and improvement activities performance categories.

Quality Performance Category Data

We anticipate that a contractor will analyze information collected from individual MIPS eligible clinicians and groups submitting data to the quality, Promoting Interoperability and improvement activities performance categories.