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 path measures MIPS eligible clinicians and groups on the following performance areas: quality – a set of evidence-based, specialty-specific standards; improvement activities that focus on practice-based improvements; cost; and use of certified Electronic Health Record Technology (CEHRT) to support interoperability and advanced quality objectives in a single, cohesive program that avoids redundancies. Under the APM path, clinicians participating in certain types of APMs (Advanced APMs) may become Qualifying APM participants (QPs) and be excluded from MIPS.

The primary purpose of this collection is to generate data on a MIPS eligible clinician, group, or subgroup 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 care compare tool hosted by the U.S. Department of Health and Services. 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. 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 proposed changes to the measure sets discussed in the CY 2023 PFS proposed rule. Supporting Statement 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 23 information collections in the CY 2023 PFS proposed rule requirements and burden estimates. The discussion in this Supporting Statement Part B focuses on the 6 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, the quality performance category submissions for MVPs, and data submitted for the Promoting Interoperability and improvement activities performance categories.

1. **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 CY 2019 performance period/2021 MIPS payment year and other CMS sources. To determine which QPs should be excluded from MIPS, we used Advanced APM payment and patient percentages from the APM Participant List for the third snapshot date for the 2019 QP Performance Period. From this data, we calculated the QP determinations as described in the Qualifying APM Participant definition at § 414.1305 for the CY 2023 performance period/2025 MIPS payment year. Due to data limitations, we could not identify specific clinicians who may become QPs in the CY 2023 performance period/2025 MIPS payment year; 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 2022 PFS final rule (86 FR 65577), 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 the CY 2022 PFS final rule (86 FR 65577), 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 that can report using the APM performance pathway (APP) in the CY 2023 performance period/ 2025 MIPS payment year, we used the final snapshot data from the 2019 QP performance period. We elected to use this data source because the APM participant list for the 2019 final snapshot can reliably be used for MIPS APM participant projections.

As discussed in Supporting Statement A, we explain that we assume 865,116 MIPS eligible clinicians would submit data as individual clinicians (both required and voluntary), or as part of groups or APM entities in the CY 2023 performance period/2025 MIPS payment year. Included in this number, we estimate that 10,933 clinicians who exceeded at least one but not all low-volume threshold criteria, elected to opt-in and submitted data in the CY 2019 performance period/2021 MIPS payment year would elect to opt-in to MIPS in the CY 2023 performance period/2025 MIPS payment year. While this is the estimated number of MIPS eligible clinicians, the number of respondents that actually submit data varies significantly due to differences in individual, group, virtual group, and APM entity reporting and by the requirements and policies for each performance category.

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 2023 PFS proposed rule, we are proposing to continue the 70 percent data completeness threshold for the CY 2023 performance period/2025 MIPS payment year. Tables 1a and 1b summarize the proposed data completeness criteria for the CY 2023 performance period/ 2025 MIPS payment year.

TABLE 1a: Summary of Data Completeness Requirements and Performance Period by Collection Type for the CY 2023 Performance Period/2025 MIPS payment year

Collection Type	Performance Period	Data Completeness
Medicare Part B Claims measures	Jan 1- Dec 31	For the CY 2023 performance period/ 2025 MIPS payment year, 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	For the CY 2023 performance period/2025 MIPS payment year, 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 CY 2023 Performance Period/2025 MIPS Payment Year for Individual Clinicians and Groups

Clinician Type	Submission Criteria	Measure Collection Types (or Measure Sets) Available for Submission (Excludes Administrative Claims)
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 for Submission (Excludes Administrative Claims)
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.	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.
MVP Participant	An MVP Participant must select and report 4 quality measures, including 1 outcome measure (or, if an outcome measure is not available, 1 high priority measure, included in the MVP.	MVP Participants (individual MIPS eligible clinician, single specialty group, multispecialty group, subgroup, or APM Entity that is assessed on an MVP) report on the applicable measures and activities in MVPs included in the MVP Inventory.

Data Submission for Promoting Interoperability and Improvement Activities Performance Categories

During the CY 2023 performance period/2025 MIPS payment year, eligible clinicians, groups, subgroups and APM Entities 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 CY 2019 performance period/2021 MIPS payment year and CY 2020 performance period/2022 MIPS payment year eligibility data, we estimate that 43,117 individual MIPS eligible clinicians, 11,633 groups, and 20 subgroups would submit Promoting Interoperability data for the CY 2023 performance period/2025 MIPS payment year. These estimates reflect that under the policies finalized in CY 2017 and CY 2018 Quality Payment Program final rules and the CY 2019, CY 2020, and CY 2021 PFS final rules, certain MIPS eligible clinicians would 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, nurse practitioners, physician assistants, certified registered nurse anesthetists, and certified clinical nurse specialists, occupational therapists, qualified speech-language pathologists or qualified audiologist, clinical

psychologists, registered dieticians or nutrition professionals and clinical social workers (81 FR 77238 through 77245, 82 FR 53680 through 53687, 83 FR 59819 through 59820, 84 FR 63003 through 63006, and 85 FR 84894 through 84895, respectively). In the CY 2023 PFS proposed rule, we are proposing not to continue the automatic reweighting of the Promoting Interoperability performance category for nurse practitioners (NPs), physician assistants (PAs), certified registered nurse anesthetists (CRNAs), and certified clinical nurse specialists (CNSs) for the CY 2023 performance period/2025 MIPS payment year. Additionally, the Promoting Interoperability performance category would be automatically reweighted for eligible clinicians who meet the criteria for certain special status designations such as hospital-based, non-patient facing, etc. In the CY 2020 PFS final rule, we revised the definition of a hospital-based MIPS eligible clinician under § 414.1305 to include groups and virtual groups. We finalized that, beginning with the CY 2020 performance period/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 specified 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 finalized in the CY 2022 PFS final rule, small practices receive an automatic hardship exception beginning in the CY 2022 performance period/2024 MIPS payment year (86 FR 65486).

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 78,239 clinicians would submit improvement activities as individuals, an estimated 17,721 groups and virtual groups, and 20 subgroups will submit improvement activities on behalf of clinicians during the CY 2023 performance period/2025 MIPS payment year.

2. **Describe the procedures for the collection of information including:**

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

There are 23 information collections in the 2023 PRA package. We do not anticipate using sampling or statistical estimation in the information collections.

3. **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 interested parties to discuss opportunities for program efficiency and flexibility.

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 2023 PFS proposed rule, we are proposing for the Public Health and Clinical Data Exchange Objective, in addition to submitting responses for the required measures and any optional measures a MIPS eligible clinician chooses to report, we propose to require MIPS

eligible clinicians to submit their level of active engagement, either Pre-production and Validation or Validated Data Production, for each measure they report beginning with the CY 2023 performance period/2025 MIPS payment year.

In the CY 2020 PFS final rule, we required 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 CY 2019 performance period/2021 MIPS payment year reflect that the majority of users submit improvement activities data as part of the login and upload or direct submission types which allow data for multiple performance categories (i.e., quality and Promoting Interoperability) 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 CY 2023 performance period/2025 MIPS payment year as they did for previous MIPS performance periods/MIPS payment years. 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 CY 2023 performance period/2025 MIPS payment year.

4. **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.

5. **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, Promoting Interoperability, and Improvement Activities 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.