

Supporting Statement – Part B
Quality Payment Program/Merit-Based Incentive Payment System (MIPS)
CMS-10621, OCN 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 combines parts of the Physician Quality Reporting System (PQRS), the Value Modifier (VM), and the Medicare EHR Incentive Program into one single program in which MIPS eligible clinicians and groups will be measured on four performance categories: quality, cost, improvement activities, and Promoting Interoperability (related to meaningful use of certified EHR technology or CEHRT). For the 2019 MIPS performance year, we finalized a weight of 15 percent for the cost performance category. For the 2020 MIPS performance year, we are proposing a weight of 20 percent for the cost performance category. 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.¹ 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

¹ The initial Quality Payment Program Experience Report was published on qpp.cms.gov on March 20, 2019.

October 1, 2021.² Further, CMS has built on existing PQRS processes to monitor and assess measures and will continue to do so on an ongoing basis 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 2020 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 2020 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, MIPS CQM and QCDR collection types, the CMS Web Interface, 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 2017 MIPS performance period and other CMS sources except for CMS Web Interface respondents, which is based on the number of groups who registered to submit MIPS data via the CMS Web Interface during the 2018 MIPS performance period. Respondent data from the 2018 MIPS performance period was unavailable in time for publication of the CY 2020 PFS proposed rule; assuming updated respondent data is available, we will revise our burden estimates in the final rule. To determine which QPs should be excluded from MIPS, we used the QP List for the 2019 predictive file that contains current participation in Advanced APMs as of January 15, 2019 that could be connected into our respondent data and are the best estimate of future expected QPs. From this data, we calculated

² MACRA mandates that the GAO evaluate and make recommendations regarding the final scores and the impact of technical assistance.

the QP determinations as described in the Qualifying APM Participant definition at § 414.1305 for the 2020 QP performance period. We assumed that all partial QPs would participate in MIPS data collections. Due to data limitations, we could not identify specific clinicians who may become QPs in the 2020 Medicare QP Performance Period (and therefore would no longer need to submit data to MIPS); hence, our model may under estimate or overestimate the number of respondents.

We assume that 100 percent of APM Entities in MIPS APMs will submit quality data to CMS as required under their models. Consistent with assumptions used in the CY 2019 PFS final rule (83 FR 60000 through 60001), we include all quality data voluntarily submitted by MIPS APM participants made at the individual or TIN-level in our respondent estimates. Therefore, we are not making any adjustments to our respondent estimates as a result of the proposal discussed in section III.K.3.c.(5)(c)(i)(A) of the CY 2020 PFS proposed rule, which allows MIPS eligible clinicians participating in MIPS APMs to elect to report MIPS quality measures at either the individual or TIN-level under the APM scoring standard beginning in the 2020 MIPS performance period. To estimate who will be a MIPS APM participant in the 2020 MIPS performance period, we used the latest 2019 predictive file that contains current participation in MIPS APMs as of January 15, 2019, using all available data. 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 2017 MIPS performance period. For clinicians who participated in an APM in 2017, were not in an APM in 2019, and did not report MIPS quality data in 2017, we assume they will elect to report to MIPS via the MIPS CQM collection type.

As discussed in Supporting Statement A, we explain that we assume 818,391 MIPS eligible clinicians will submit quality data as individual clinicians, or as part of groups or APM entities. We also estimate that 31,246 clinicians or 33 percent of clinicians who exceed at least one but not all low-volume threshold and submitted data in the CY 2017 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 proposed rule, we are proposing 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 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 2020 MIPS performance period. We are further proposing 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 will emphasize to all parties that the data submitted on each measure is expected to be representative of the clinician’s or group’s performance. Tables 1a and 1b summarize the data completeness criteria for the 2020 MIPS performance period.

TABLE 1a: Summary of Data Completeness Requirements and Performance Period by Collection Type for the 2020 MIPS Performance Period

Collection Type	Performance Period	Data Completeness
Medicare Part B Claims measures	Jan 1- Dec 31	70 percent 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 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 of individual MIPS eligible clinician’s, or group’s patients across all payers for the performance period.
CMS Web Interface measure	Jan 1- Dec 31	Sampling requirements for the group’s Medicare Part B patients: populate data fields for the first 248 consecutively ranked and assigned Medicare beneficiaries in the order in which they appear in the group’s sample for each module/measure. If the pool of eligible assigned beneficiaries is less than 248, then the group would report on 100 percent of assigned beneficiaries.

Collection Type	Performance Period	Data Completeness
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 2020 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.
Groups (non-CMS Web Interface)	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. 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.

Clinician Type	Submission Criteria	Measure Collection Types (or Measure Sets) Available
Groups (CMS Web Interface for group of at least 25 clinicians)	<p>Report on all measures included in the CMS Web Interface collection type and optionally the CAHPS for MIPS survey.</p> <p>Clinicians would need to meet the applicable data completeness standard for the applicable performance period for each collection type.</p>	<p>Groups report on all measures included in the CMS Web Interface measures collection type and optionally the CAHPS for MIPS survey.</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>

For the CMS Web Interface, organizations (groups, Shared Savings Program ACOs, and Next Generation ACOs) will submit data on samples of the organization’s fee-for-service (FFS) Medicare beneficiaries that will be selected by CMS. CMS plans to use a Medicare beneficiary sampling method similar to that employed in the 2019 MIPS performance period. The sample will be drawn in the fourth quarter of the performance period (e.g. in October of 2020 for the 2020 MIPS performance period).

The first step in the CMS Web Interface quality measure sampling methodology is to identify the beneficiaries eligible for quality measurement. The assigned patient population is the foundation from which to measure quality performance. CMS will assign a Medicare beneficiary to an ACO or group based on current program rules. For ACOs, CMS will use beneficiaries assigned using the ACO assignment/alignment methodology.^{3,4} For groups, CMS will use beneficiaries assigned using the MIPS assignment methodology.⁵ Using Medicare administrative data from January 1, 2019, through October 31, 2019, CMS will exclude the following beneficiaries from eligibility:

- Beneficiaries with fewer than two primary care services⁶ within the ACO or group, as applicable, during the performance period.

³ The Shared Savings Program uses beneficiaries assigned in the third quarter of 2019. The Shared Savings Program beneficiary assignment methodology can be found here: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Financial-and-AssignmentSpecifications.html>

⁴ For Next Generation ACOs, the most recent exclusions (generally second quarter) are applied to aligned beneficiaries. The Next Generation ACO Model methodology can be found at <https://innovation.cms.gov/Files/x/nextgenaco-methodology.pdf>.

⁵ The MIPS assignment methodology for the CMS Web Interface and CAHPS for MIPS Survey document can be found on the CMS website at: <https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/Resource-library.html>.

⁶ As defined by the Healthcare Common Procedure Coding System (HCPCS) codes.

- Beneficiaries with part-year eligibility in Medicare FFS Part A and Part B
- Beneficiaries in hospice.
- Beneficiaries who died.
- Beneficiaries who did not reside in the United States.

The remaining beneficiaries will be considered eligible for quality measurement.

The second step in the CMS Web Interface quality measure sampling methodology is to identify beneficiaries eligible for sampling into each measure. For beneficiaries identified as eligible for quality measurement, we further determine if they are eligible for any of the specific quality measures on the basis of the denominator criteria for each measure using the 2019 CMS Web Interface Measure Specifications and Supporting Documents. Due to limitations in the Medicare claims data, some denominator exclusion and exception criteria must be applied by organizations using medical record data. Diagnostic data from all claims for each assigned beneficiary are used to determine whether that beneficiary has a particular condition such as diabetes, congestive heart failure, coronary artery disease, or a range of other chronic conditions. A beneficiary may be counted in one or more of each of those categories based on the number of conditions s/he has. The clinical measure denominator criteria, such as age, gender, hospitalization, etc. are further applied to each diagnostic sub-group of beneficiaries to determine which patients are eligible for data submission on the measure.

CMS will select an initial random sample of 900 beneficiaries eligible for quality measurement and populate them into the measures for which they are eligible until a sample size of 616 is reached. If, after this step, a measure has fewer than 616 beneficiaries, CMS will randomly sample additional eligible beneficiaries until the measure has the required 616 or until there are no additional eligible beneficiaries available. Note that CMS will rank the same beneficiary across measures when the beneficiary is eligible for multiple measures. Therefore, when it is possible, the beneficiaries in each sample will not be unique. This reduces the administrative burden for organizations by minimizing the total number of beneficiaries for whom data need to be collected. For all measures, beneficiaries will be assigned a rank between 1 and 616 based on the order in which they are populated into each measure-specific sample. We will also attempt to evenly distribute the risk categories throughout the sample.

Organizations will be required to consecutively complete a minimum of 248 beneficiaries (or all beneficiaries in the sample if there are fewer than 248). If an organization is unable to report data on a particular beneficiary, the organization must indicate a reason the data cannot be reported. The organization must not skip a beneficiary without providing a valid reason. The valid reasons are listed in the Web Interface measure specifications and will be available for selection in the CMS Web Interface. For each beneficiary that is skipped, the organization must completely report on the next consecutively ranked beneficiary until the target sample of 248 is reached or until the sample has been exhausted. Although this sampling methodology does not guarantee that beneficiaries will have the same rank across measures, it does increase the likelihood that a beneficiary will have a similar rank across measures. Therefore, a beneficiary with a low rank in one measure will likely have a low rank in other measures for which he or she is eligible. The intent of this approach is to reduce reporting burden for the ACOs and groups.

Data Submission for Promoting Interoperability and Improvement Activities Performance Categories

During the 2020 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 2017 MIPS performance period and 2019 MIPS eligibility data, we estimate that 81,358 individual MIPS eligible clinicians and 12,569 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). These estimates also 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. As discussed in sections III.K.3.c.(4)(f)(iii) and (iv) of the CY 2020 PFS proposed rule, we propose to assign a zero percent weight for the Promoting Interoperability performance category and the points for Promoting Interoperability performance category will be redistributed if: (1) all the TIN/NPIs were eligible for reweighting, or 2) the group met the proposed revised definition of a hospital-based MIPS eligible clinician as proposed in section III.K.3.c.(4)(f)(iii) (or the definition of a non-patient facing MIPS eligible clinician, as proposed in section III.K.3.c.(4)(f)(iv)). This proposal would only require the group or virtual group to meet a threshold of more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, to meet the definition of a hospital-based or non-patient facing individual MIPS eligible clinician instead of a threshold of all of the MIPS eligible clinicians in the group or virtual group. In section III.K.3.c.(4)(f)(iii) we also propose 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. Finally, in section III.K.3.c.(4)(f)(iv), we propose revisions to account for a group or virtual group that meets the definition of a non-

patient facing MIPS eligible clinician such that the group or virtual group only has to meet a threshold of more than 75 percent.

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 59823), we established that eligible clinicians in MIPS APMS (including the Shared Savings Program) may report as members of an APM Entity Group for the Promoting Interoperability performance category or as individuals or as part of a group.

As discussed in Supporting Statement A, we estimate 102,754 clinicians will submit improvement activities as individuals, and an estimated 15,761 groups virtual groups will submit improvement activities on behalf of clinicians during the 2020 MIPS performance period.

2 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 2020 PRA package. Only 1 of the 19 information collections in this information collection request involves sampling conducted by CMS. This information collection is for the quality data submission using the CMS Web Interface and is described below. Table 1 (above) provides information regarding the performance period, sampling, and completeness criteria for all but one of the data submission mechanisms for MIPS eligible clinicians and groups to submit quality measures data for the 2020 MIPS performance period. 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.

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 sample sizes and submission criteria for use in future performance periods. We will continually evaluate our policies on sampling 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.

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 sections III.K.3.g.(3)(a)(i) and III.K.3.g.(4)(a)(i) of the CY 2020 PFS proposed rule, beginning with the 2021 performance period and for future years, we are proposing to require QCDRs and qualified registries to support three performance categories: quality, improvement activities, and Promoting Interoperability. . Currently, qualified registries and QCDRs are only required to support the quality performance category while supporting Promoting Interoperability and improvement activity performance categories are optional. If finalized, this will simplify MIPS reporting for clinicians who currently utilize qualified registries or QCDR that have not previously offered the ability to report performance categories other than quality.

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 2020 MIPS performance period as they did for the 2019 MIPS performance period. 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 2020 and future MIPS performance periods.

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.

Quality Performance Category

As stated above, we expect that the initial experience with MIPS will clarify optimal sample sizes and submission criteria for use in future performance periods. We will continually evaluate our policies based on our analysis of MIPS and other data. For group submission through the CMS Web Interface, we note that the methodology was derived from commercially available methods used to compute quality measures in the commercial and Medicare managed care environments and was previously used under the PQRS GPRO Web Interface.

Promoting Interoperability and Improvement Activities Performance Categories

As stated above, we expect that our initial experience with MIPS will clarify optimal data submission criteria for use in future performance periods. We will continually evaluate our policies based on our analysis of the 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 Performance Category Data

We anticipate that a contractor will analyze information collected from individual MIPS eligible clinicians and groups submitting data to the quality performance category.

CMS Web Interface Quality Performance Category Submission

As noted above, we expect that the statistical methods for the CMS Web Interface data submission option will be very similar to those developed for the GPRO Web Interface data submission option. The methods were adopted from the PGP demonstration; the National Committee for Quality Assurance (NCQA) and RTI International were consulted on the development of the sampling methodology. A contractor will administer the sampling methodology for the CMS Web Interface.

Promoting Interoperability and Improvement Activities Performance Category

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