**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 2018 MIPS performance year, we finalized a weight of 10 percent for the cost performance category. For the 2019 MIPS performance year, we are proposing a weight of 15 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 plans to use the data to produce annual statistical reports that will describe the data submission 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

[1] The MIPS annual statistical reports will be modeled after two existing annual reports, the PQRS Experience Report and the Value Modifier Report.

which the GAO must perform a MIPS evaluation to submit to Congress by 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 changes to the measure sets discussed in the CY 2019 Quality Payment Program 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 2019 Quality Payment Program 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 the claims, eCQM, MIPS CQM and QCDR collection types, the CMS Web Interface submission mechanism, 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 clinicians who opt to 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 2016 PQRS and other CMS sources except for CMS Web Interface respondents, which is based on the number of groups who submitted MIPS data via the CMS Web Interface during the 2019 MIPS performance period. Although the submission period for the 2017 MIPS performance period ended in April 2018, the participation and performance data was not available at the time of writing the proposed rule; we intend to update these burdens in the final rule using actual MIPS data if technically feasible. Given that the majority of MIPS quality performance category measures will have been previously used under PQRS, we assume that clinicians who previously submitted quality

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

measures under PQRS will continue to do so under MIPS, either as voluntary reporters or as MIPS eligible clinicians required to report. For the CY 2019 Quality Payment Program proposed rule, we are proposing to revise the eligibility criteria to expand MIPS to additional clinician types. If this policy is finalized, it would expand the number of potential MIPS eligible clinicians, but we do not anticipate an incremental increase in the total number of respondents because the affected clinicians were assumed to be voluntary reporters in prior rules. In the CY 2018 Quality Payment program final rule, clinicians who participated in 2016 PQRS and who were not QPs in Advanced APMs and were not MIPS eligible were assumed to be voluntary reporters. Therefore, the expansion in eligibility does not change the total number of respondents, but instead shifts a certain number of voluntary reporters to MIPS eligible clinicians.

As discussed in Supporting Statement A, we explain that we assume 650,165 MIPS eligible clinicians will submit quality data as individual clinicians, or as part of groups or APM entities. We also estimate that 42,025 clinicians or 33 percent of the clinicians not subject to a MIPS payment adjustment in CY 2019 will voluntarily submit quality data as individual clinicians, or as part of groups or APM entities.

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*

The proposed rule continues implementing criteria from Quality Payment Program Year 2 designed to ensure that data submitted on quality measures are complete enough to accurately assess MIPS eligible clinicians' quality performance (see Table 1 below for further detail). MIPS eligible clinicians or groups that do not meet the data completeness criteria for quality measure data will not receive the maximum score for the applicable quality measure for the quality performance category. Individual MIPS eligible clinicians and groups submitting quality measures data using the QCDR, MIPS CQM, or eCQM collection types must submit data on at least 60 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment year 2021. Individual MIPS eligible clinicians submitting data on quality measures via claims will be required to submit data on at least 60 percent of the applicable Medicare Part B patients seen during the performance period to which the measure applies, beginning with MIPS payment year 2021. Tables 1a and 1b summarize the data completeness criteria for MIPS payment year 2021.

**TABLE 1a: Summary of Data Completeness and Performance Period by Collection Type**

| Collection Type | Performance Period | Data Completeness |
|---|---|---|
| Medicare Part B Claims | Jan 1- Dec 31 (or 90 | 60 percent of individual MIPS |

| | | |
|---|---|---|
| measures | days for selected measures) | eligible clinician'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 (or 90 days for selected measures) | 60 percent of individual MIPS eligible clinician's, or group's patients across all payers for the performance period. |
| CMS Web Interface measure specifications | 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. |
| CAHPS for MIPS Survey | Jan 1- Dec 31 | Sampling requirements for the group's Medicare Part B patients |

**TABLE 1b: Summary of Quality Data Submission Criteria for MIPS Payment Year 2021 for Individuals and Groups**

| Clinician Type | Submission Criteria | Measure Collection Types (or Measure Sets) Available |
|---|---|---|
| Individuals | 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, 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: MIPS CQMs, QCDR measures, eCQMs, or CAHPS for MIPS survey, or reports on one of the specialty measure sets if applicable.<br><br>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. |
| Groups (CMS Web Interface for group of at least 25 clinicians) | Report on all measures includes in the CMS Web Interface collection type and optionally the CAHPS for MIPS survey.<br><br>Clinicians would need to meet the applicable data completeness standard for the applicable performance period for each collection type. | Groups report on all measures included in the CMS Web Interface collection type and optionally the CAHPS for MIPS survey.<br><br>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. |

For the CMS Web Interface, organizations (groups, Shared Savings Program ACOs, and Next Generation ACOs) will submit data on samples of their assigned Medicare beneficiaries that will be selected by CMS. CMS plans to use a Medicare beneficiary sampling method similar to that employed in the 2018 MIPS. The sample will be drawn in the fourth quarter of the performance period (e.g. in October of 2019 for the 2019 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. For ACOs, CMS will use beneficiaries assigned using the ACO assignment algorithm.[3] For groups, CMS will use beneficiaries assigned using the assignment algorithm developed under the VM and adopted under MIPS.[4] Under the beneficiary assignment algorithms for groups and ACOs, Medicare

[3] The Shared Savings Program beneficiary assignment methodology can be found here: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/SharedSavings-Losses-Assignment-Spec-v2.pdf

[4] The PQRS assignment methodology document and training presentation can be found on this page: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-AssessmentInstruments/PQRS/GPRO_Web_Interface.html

fee-for-service patients are assigned to a group or ACO if the group or ACO provides the plurality of primary care services to the patient during the performance period.[5]

The second step in the CMS Web Interface quality measure sampling methodology is to identify assigned beneficiaries eligible for sampling into each measure. 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.

The third step in the sampling methodology is to randomly sample eligible beneficiaries into each measure. Claims-based measures are derived from the full subpopulation of assigned beneficiaries who meet the clinical criteria for the measure, and do not require any additional burden. For measures that are not claims-based, the CMS Web Interface provides a rank-ordered sample of assigned beneficiaries that meet the denominator criteria for the measure. The sample is selected as follows: CMS selects an initial random sample of 900 quality eligible beneficiaries and populates 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 uses the same beneficiary across measures, where possible. This reduces the administrative burden for ACOs and groups by minimizing the total number of beneficiaries on which data need to be collected. In other words, to the extent possible, the beneficiaries in each measure sample will not be unique. Beneficiaries will be assigned a rank between 1 and 616 based on the order in which they are populated into each measure-specific sample.

In order to meet data submission criteria for the MIPS, organizations (groups or ACOs) will complete the number of confirmed patients in rank order and may only exclude beneficiaries if the organization cannot confirm the diagnosis or if they meet one of the exclusion criteria for the measure. If the organization is unable to provide data on a particular beneficiary, the organization must indicate a reason the data cannot be provided. The organization cannot skip a beneficiary without providing a valid reason. The valid reasons will be available as drop-down options in the CMS Web Interface. Only a percentage of records may be skipped and clinicians are alerted to the skip rate while they are using the tool. 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. If the pool of eligible assigned beneficiaries is less than 248, then entities must report on 100 percent of assigned beneficiaries.[6]

---

[5] Section II.E.5.e.(3)(a)(i) of the final rule includes some modifications to the primary care services definition used in the CMS Web Interface attribution methodology to align with policies adopted under the Shared Savings Program.

[6] As noted above, the CMS Web Interface will use similar sampling specifications as under the PQRS GPRO Web Interface. For additional information on sampling under the PQRS GPRO Web Interface Reporting Option, see https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/GPRO_Web_Interface.html

Data Submission for Promoting Interoperability and Improvement Activities Performance Categories

During the 2019 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 2016 Medicare and Medicaid EHR Incentive Programs, the 2016 PQRS data, and 2017 MIPS eligibility data, we estimate that 50,878 individual MIPS eligible clinicians and 2,998 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 as well as policies proposed in the CY 2019 Quality Payment Program proposed 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, physician assistants, nurse practitioners, clinician nurse specialists, certified registered nurse anesthetists, physical therapists, occupational therapists, clinical social workers, and clinical psychologists. These estimates also account for the reweighting exceptions finalized in the CY 2017 and CY 2018 Quality Payment Program final rules and our policies for significant hardship exceptions, including for MIPS eligible clinicians in small practices, as well as exceptions due to insufficient internet connectivity, extreme and uncontrollable circumstances, lack of control over the availability of CEHRT, and decertified EHR technology.

As discussed in Supporting Statement A, MIPS APM participants will be required to submit Promoting Interoperability data, but not improvement activities data. We finalized in the 2017 Quality Payment Program final rule that except for participants in the Shared Savings Program, participants in MIPS APMS should have either the group or the individual clinician submit Promoting Interoperability data on behalf of clinicians in MIPS APMs. According to our current policies, for the Shared Savings Program, the group TINs had to submit the Promoting Interoperability data as a group. In the CY 2019 Quality Payment Program proposed rule, we propose to extend this flexibility to allow for both individual and group reporting to participants in the Shared Savings Program. We anticipate that the 460 Shared Savings Program Track 1 ACOs will submit data at the ACO participant TIN-level, for a total of 13,537 group TINs. We anticipate that the three APM Entities electing the one-sided track in the CEC model will submit data at the group TIN-level, for a total of 17 group TINs submitting data. And finally, we anticipate that the 192 APM Entities in the OCM (one-sided risk arrangement) will submit data at APM Entity level. The total estimated number of respondents is estimated at 67,622.

As discussed in Supporting Statement A, we estimate 387,347 clinicians will submit improvement activities as individuals, and an estimated 5,575 groups and 16 virtual groups will submit improvement activities on behalf of clinicians during the 2019 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 2019 PRA package. Only 1 of the 19 information collections in this information collection request involves sampling. 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 2021 MIPS payment year. 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

We anticipate the Promoting Interoperability performance category will have a higher response rate for MIPS eligible clinicians than its predecessor, the Medicare EHR Incentive Program, because it allows clinicians to participate as part of a group or virtual group as well as individual MIPS eligible clinician data submission.

We believe that the new proposed scoring methodology for the 2019 MIPS performance period which moves away from the base, performance, and bonus score methodology currently in place for the 2018 MIPS performance period will provide a simpler, more flexible, less burdensome structure, allowing MIPS eligible clinicians to put their focus back on patients. The introduction of this new scoring methodology would continue to encourage 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 help to maximize response rates for the Promoting Interoperability performance category.

Improvement Activities Performance Category Data Submission

In the CY 2017 Quality Payment Program final rule, we finalized that MIPS eligible clinicians would be required to submit data for a minimum of three MIPS clinical quality measures and that one of the measures must be an outcome measure, and one must be a patient experience measure. In the CY 2019 Quality Payment Program proposed rule, we are proposing that at least one of the minimum of three measures must be a high priority measure to reflect the requirements of MIPS and the Quality Payment Program. We believe that focusing on outcome and high priority measures, rather than patient experience measures, is important at this time, because it better aligns with the MIPS quality data submission criteria and will improve response rates due to the additional flexibility in reporting for the improvement activities performance category.

**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.