

Supporting Statement – Part B
Quality Payment Program/Merit-Based Incentive Payment System (MIPS)
CMS- 10621, OCN 0938-1314

Collections of Information Employing Statistical Methods

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 advancing care information (related to meaningful use of certified EHR technology or CEHRT). During the transition year we finalized that the cost performance category would have a zero percent weight so that cost performance could not contribute to the MIPS eligible clinician’s final score. We are proposing for the 2018 MIPS performance year the same, that the cost performance category would be weighted at zero percent. 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 incentive payments equal to 5 percent of their prior year’s payments.

The primary purpose of this collection is to generate data on a MIPS eligible clinician or group level 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 which the GAO must perform a MIPS evaluation to submit to Congress by October 1, 2021.² Further, CMS

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

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

will build on existing PQRS processes to monitor and assess measures 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. 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 15 information collections in the 2018 PRA package. 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, EHR, qualified registry and QCDR, and CMS Web Interface submission mechanisms, and data submitted for the advancing care information 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

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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 2015 PQRS and other CMS sources. 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 measures under PQRS will continue to do so under MIPS, either as voluntary reporters or as MIPS eligible clinicians required to report.

Based on 2015 data from the PQRS and other sources, we estimate that approximately 92 percent of the universe of 573,000 MIPS eligible clinicians will submit quality data. This includes MIPS eligible clinicians submitting data as individuals, or participating as a part of a group, virtual group or MIPS APM Entity. This is considerably higher than the most recently available estimate of the PQRS participation rate (63 percent) because many clinicians eligible to participate in

technical assistance.

PQRS would not be required to participate in MIPS (i.e., the denominator is smaller).

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 the transition year 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. As in the transition year, individual MIPS eligible clinicians or groups submitting data on quality measures using QCDRs, qualified registries, or via EHR will still be required to report on at least 50 percent of the patients for MIPS eligible clinician or groups, including virtual groups, that meet the measure’s denominator criteria, regardless of payer for the performance period in the 2018 MIPS performance period. In other words, under the quality data submission criteria, except for submission via the CMS Web Interface, we would expect to receive quality data for both Medicare and non-Medicare patients which is the same policy as in the CY 2017 final rule. Table 1 summarizes the data completeness criteria for the 2018 performance period MIPS payment year 2020). Starting with the 2018 MIPS performance period, multiple submission mechanisms may be used for the quality performance category.

TABLE 1: Summary of Proposed Quality Data Submission Criteria for MIPS Payment Year 2020 via Part B Claims, QCDR, Qualified Registry, EHR, CMS Web Interface, and the CAHPS for MIPS Survey

Performance period	Clinician Type	Submission mechanism	Submission criteria	Data completeness
Jan 1–Dec 31	Individual MIPS eligible clinicians	Part B Claims	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. Individual MIPS eligible clinicians would have to select their measures from either the set of all MIPS measures listed or referenced in Table A or one of the specialty measure sets listed in Table B of the Appendix in this proposed rule.	50 percent of individual MIPS eligible clinician’s Medicare Part B patients for the performance period.

Jan 1–Dec 31	Individual MIPS eligible clinicians, groups or virtual groups	QCDR, Qualified Registry, & EHR	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. Individual MIPS eligible clinicians, groups, or virtual groups would have to select their measures from either the set of all MIPS measures listed or referenced in Table A or one of the specialty measure sets listed in Table B of the Appendix in this proposed rule.	50 percent of individual MIPS eligible clinician's, group's, or virtual group's patients across all payers for the performance period.
Jan 1–Dec 31	Groups or virtual groups	CMS Web Interface	Report on all measures included in the CMS Web Interface; AND populate data fields for the first 248 consecutively ranked and assigned Medicare beneficiaries in the order in which they appear in the group's or virtual group's sample for each module/measure. If the pool of eligible assigned beneficiaries is less than 248, then the group or virtual group would report on 100 percent of assigned beneficiaries.	Sampling requirements for the group's or virtual group's Medicare Part B patients.
Jan 1 – Dec 31	Groups or virtual groups	CAHPS for MIPS Survey	CMS-approved survey vendor would need to be paired with another reporting mechanism to ensure the minimum number of measures is reported. CAHPS for MIPS survey would fulfill the requirement for one patient experience measure towards the MIPS quality data submission criteria. CAHPS for MIPS survey would only count for one measure under the quality performance category.	Sampling requirements for the group's or virtual group's Medicare Part B patients.

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 PQRS GPRO Web Interface. The sample will be drawn in the third quarter of the performance period (e.g. in the third quarter of 2018 for the 2018 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 PQRS.⁴ Under the beneficiary assignment algorithms for groups and ACOs, Medicare 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

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

⁵ Section II.E.5.e.(3)(a)(i) of the proposed 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

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

Program.

⁶As 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 Advancing Care Information and Improvement Activities Performance Categories

During the 2018 MIPS performance period, eligible clinicians and groups can submit advancing care information and improvement activities data through qualified registry, QCDR, EHR, CMS Web Interface, and attestation data submission methods. Starting with the 2018 MIPS performance period, multiple submission mechanisms may be used for the advancing care information performance category.

Based on 2015 data from the Medicare EHR Incentive Program and the data prepared to support the 2017 performance period initial determination of clinician eligibility and special status determination (available via the NPI lookup on qpp.cms.gov) using a date range of September 1, 2015 – August 31, 2016, we estimate that 265,895 individual MIPS eligible clinicians and 301 groups or virtual groups, representing 106,406 MIPS eligible clinicians, will submit advancing care information data. These estimates reflect that under the policies finalized in CY 2017 Quality Payment Program final rule, certain MIPS eligible clinicians will be eligible for automatic reweighting of their advancing care information performance category score to zero, including MIPS eligible clinicians that practice primarily in the hospital, physician assistants, nurse practitioners, clinician nurse specialists, certified registered nurse anesthetists, and non-patient facing clinicians. These estimates also account for the significant hardships finalized in the CY 2017 Quality Payment Program final rule and our proposed policies for significant hardship exceptions, including for MIPS eligible clinicians in small practices, as well as exceptions due to decertification of an EHR.

As discussed in Supporting Statement A, MIPS APM participants will be required to submit advancing care information data, but not improvement activities data. MIPS APMs will submit advancing care information data at the group TIN level. We estimate that 15,945 group TINs within the Shared Savings Program ACOs, 100 group TINs within the APM Entity participating in CECs in the one-sided risk track, and 6,478 group TINs within the OCM (one-sided risk arrangement), and 2 CPC+ group TINs will submit advancing care information performance category data.

As discussed in Supporting Statement A, we estimate 520,654 clinicians will submit improvement activities as individuals during the 2018 MIPS performance period, and an estimated 3,818 groups and 16 virtual groups to submit improvement activities on behalf of clinicians during the 2018 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 15 information collections in the 2018 PRA package. Only 1 of the 15 information collections in this information collection request involve 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 2019 MIPS payment adjustment. 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 believe that in addition to being eligible for payment adjustments through MIPS, providing MIPS eligible clinicians and groups with multiple submission options will help to maximize response rates. 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 adding virtual group participation as an option we will improve 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. We expect individual MIPS eligible clinicians and groups that furnish services in an in-patient hospital or emergency room will also more fully participate by electing to participate in facility-based measurement during the performance period, and to be given a MIPS score in the quality and cost performance category based on their facility's data submission for the hospital value-based purchasing program.

Data Submission for Advancing Care Information Performance Category

We believe that in addition to being eligible for payment adjustments through MIPS, providing MIPS eligible clinicians, groups, and virtual groups with multiple submission options will help to maximize response rates in the advancing care information and improvement activities performance categories. Further, we anticipate the advancing care information 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 the ability to continue to use EHR technology certified to either the 2014 or 2015 Edition certification criteria, or a combination of the two for the CY 2018 performance period will also help to maximize response rates for the advancing care information 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 overtime 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 the 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 environment and was previously used under the PQRS GPRO Web Interface.

QCDR or Qualified Registry Self-nomination

We are using a web-based tool to support the QCDR and qualified registry self-nomination process and have eliminated the submission method of email. This process was successfully tested in 2017 and there were no issues with functionality. The web-based tool will be used for the CY

2018 self-nomination process which we believe will help streamline the process. This is reflected in our burden estimates for self-nomination by a QCDR or qualified registry.

Advancing Care Information 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 other than the data presented here for the quality, advancing care information and improvement performance data.

Quality Performance Category Data

We anticipate that a contractor will analyze information collected from individual MIPS eligible clinicians, groups, and virtual 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.

Advancing Care Information and Improvement Activities Performance Category

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