

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

Collections of Information Employing Statistical Methods

**Introduction**

The Centers for Medicare & Medicaid Services (CMS) seeks approval to collect, process, and analyze data for the purposes of implementing the Merit-based Incentive Payment System (MIPS), one of two paths for providers available through the Quality Payment Program authorized by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). The Quality Payment Program would replace a patchwork system of Medicare reporting programs with a flexible system that allows MIPS eligible clinicians to choose from two paths that link quality to payments: the Merit-Based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APM). The MIPS is a new program that combines parts of the Physician Quality Reporting System (PQRS), the Value Modifier (VM or Value-based Payment Modifier), and the Medicare Electronic Health Record (EHR) incentive program into one single program in which MIPS eligible clinicians and groups will be measured on four performance categories. The four performance categories are quality, cost, improvement activities, and advancing care information (related to meaningful use of certified EHR technology). During the transition year, MIPS eligible clinicians will not be scored on the cost performance category. Under the APM path, clinicians participating in certain kinds 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.<sup>1</sup> 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.<sup>2</sup> Further, CMS will build on existing PQRS processes to monitor and assess measures on an ongoing basis to

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

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

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.

This Supporting Statement Part B discusses eight Information Collections (ICs) related the evaluation and implementation of the MIPS:

- Four ICs related to MIPS quality performance category submission by MIPS eligible clinicians:
  - o Quality measures--Claims submission method
  - o Quality measures-- Qualified registry and Qualified Clinical Data Registry (QCDR) submission method
  - o Quality measures-- EHR submission method
  - o Quality measures—CMS Web Interface submission method
- Qualified Registry or QCDR self-nomination
- Advancing care information performance category\*
- Improvement activities performance category\*
- Partial QP election

\*In the CY 17 Quality Payment Program final rule, we finalized the policy to allow MIPS eligible clinicians or groups to submit advancing care information performance category data and improvement activities performance category data via qualified registry, QCDR, EHR, CMS Web Interface, or attestation data submission mechanisms.

This Supporting Statement Part B is organized as follows: each section below discusses the relevant statistical information for all eight ICs. The ~~four quality~~~~four-quality~~ performance category submission mechanisms are generally discussed as a group under the quality performance category header, whereas the remaining four ICs are discussed individually under separate headers.

**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. Because the MIPS program has not yet been implemented, 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 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 up to 611,876 (approximately 88 percent) of the universe of 698,486 MIPS eligible clinicians will submit quality data.<sup>3</sup> This includes MIPS eligible clinicians submitting data as individuals, participating as groups or part of a Shared Savings Program ACO. This is considerably higher than the most recently available estimate of the PQRS participation rate (63 percent) because many clinicians eligible to participate in PQRS would not be required to participate in MIPS (i.e., the denominator is smaller).

We estimate that 296,776 clinicians, or approximately 44 percent of the 668,090 clinicians excluded from MIPS, will submit MIPS quality data voluntarily. The universe of 668,090 clinicians permitted to voluntarily submit data includes 199,308 ineligible clinician types, 85,268 newly enrolled Medicare clinicians, and 383,514 low-volume clinicians.<sup>4</sup> Voluntary reporters will be scored and receive feedback on their performance, but will not be subject to payment adjustments.

We assume clinicians will continue to submit quality data under the same submission mechanisms that they used under the 2015 PQRS. Specifically, we assume that the number of clinicians using different quality data submission mechanisms will include:

- 332,729 clinicians submitting as individuals through the claims mechanism.
- 258,993 clinicians submitting as individuals or groups through qualified registry or QCDR mechanisms.
- 105,987 clinicians submitting as individuals and groups through EHR mechanisms.
- 107,884 clinicians submitting as 299 groups through the CMS Web Interface.
- 140,341 clinicians participating in 433 Shared Savings Program ACOs and submitting through the CMS Web Interface.

The numbers of clinicians that submit data through the various quality submission mechanisms are not mutually exclusive; some clinicians submit data under more than one.

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<sup>3</sup> Based on CMS projections of QPs participating in Advanced APMs and excluded from MIPS, the number of MIPS eligible clinicians in the transition year may be considerably smaller ---592,119-642,119 clinicians. Due to data limitations, the data source we used to estimate the participation rate cannot identify participants in Advanced APMs that were implemented after 2015. Hence, the sample we use to estimate our participation rate includes 698,486 MIPS eligible clinicians.

<sup>4</sup> See the CY 17 Quality Payment Program final rule's Regulatory Impact Analysis for additional details on the estimated counts of clinicians excluded from or ineligible for MIPS.

In addition, we include participants in an Advanced APM in our burden estimates for quality data submission under the CMS Web Interface

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 CY 17 Quality Payment Program final rule established criteria 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 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 or groups submitting data on quality measures using QCDRs, qualified registries, or via EHR will be required to report on at least 50 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for the performance period. In other words, under the quality data submission criteria for these submission mechanisms, we would expect to receive quality data for both Medicare and non-Medicare patients. (Under the PQRS, eligible professionals and group practices reporting via qualified registries for individual measures were only required to report on Medicare patients, and were not required to submit data on non-Medicare patients). Individual MIPS eligible clinicians submitting data on quality measures using Medicare Part B claims, would report on at least 50 percent of the Medicare Part B patients seen during the performance period to which the measure applies. For claims, EHR, QCDR, and qualified registry submission mechanisms, the MIPS eligible clinicians are responsible for submitting data that meets the data completeness criteria of 50 percent described in Table 1 below.

**TABLE 1: Summary of Quality Data Submission Criteria for MIPS via Part B Claims, QCDR, Qualified Registry, EHR and CMS Web Interface**

<b>Performance Period</b>	<b>Measure Type</b>	<b>Submission Mechanism</b>	<b>Submission Criteria,</b>	<b>Data Completeness</b>
A minimum of any continuous 90 day period during CY2017	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. MIPS eligible clinicians and groups will have to select their measures from either the list of all MIPS Measures in Table A or a set of specialty specific measures in Table E.	50 percent of MIPS eligible clinician's Medicare Part B patients seen during the performance period to which the measure applies.
A minimum of any continuous 90 day period during CY2017	Individual MIPS eligible clinicians or 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. MIPS eligible clinicians and groups will have to select their measures from either the list of all MIPS Measures in Table A or a set of specialty-specific measures in Table E.	50 percent of MIPS eligible clinician's or groups' patients seen during the performance period to which the measure applies
Jan 1 – Dec 31	Groups of 25 or more eligible clinicians	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 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.	sampling requirements for their 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 2017 for the 2017 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.<sup>5</sup> For groups, CMS will use beneficiaries assigned using the assignment algorithm developed under the PQRS.<sup>6</sup> 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.<sup>7</sup>

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 need to complete the tool for 248 of the assigned beneficiaries in rank order and may only exclude beneficiaries if the organization cannot confirm the diagnosis or if they meet one of the

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<sup>5</sup> 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>

<sup>6</sup> 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](http://www.cms.gov/Medicare/Quality-Initiatives-Patient-AssessmentInstruments/PQRS/GPRO_Web_Interface.html)

<sup>7</sup> Section II.E.5.e.(3)(a)(i) of the CY 17 Quality Payment Program 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 Program.

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. 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.<sup>8</sup>

### QCDR or Qualified Registry Self-nomination

We anticipate that the 114 qualified registries and 69 QCDRs qualified to report quality measures data for the 2016 PQRS will self-nominate to submit data on behalf of MIPS eligible clinicians and groups.<sup>9</sup> In the CY 17 Quality Payment Program final rule, we finalized our proposal to expand qualified registries' and QCDRs' capabilities by allowing them to submit data on measures, activities, or objectives for any of the following MIPS performance categories:

- Quality;
- Improvement activities; or
- Advancing care information, if the MIPS eligible clinician or group is using certified EHR technology.

### Data Submission for Advancing Care Information and Improvement Activities Performance Categories

During the transition year, 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. Given the limitations of historical 2015 EHR Incentive Program data, our estimates of the potential respondent universe for those two performance categories are based on 2015 PQRS data. We anticipate that the rates of participation in the advance care information and improvement activities performance category data submission will be comparable to those of quality performance category data submission. Specifically, we assume that the number of individual clinicians and groups submitting advancing care information and improvement activities data will be the same as the number of individual clinicians and groups submitting data under the 2015 PQRS. Hence, we assume 503,457 clinicians will submit as

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<sup>8</sup>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](https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/GPRO_Web_Interface.html)

<sup>9</sup> The full list of qualified registries for 2016 is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2016QualifiedRegistries.pdf> and the full list of QCDRs is available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2016QCDRPosting.pdf>

individuals and 3,880 groups submitting data on behalf of 194,192 clinicians.

As discussed in the Supporting Statement, 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 billing TIN level. For the Shared Savings Program ACOs we estimate that 14,384 billing TINS representing 433 Shared Savings Programs ACOs will submit data. We anticipate that two other MIPS APMs will submit data. We anticipate that the single APM Entity in the Comprehensive End Stage Renal Disease (ESRD) Care (CEC) (non-Large Dialysis Organization (LDO) arrangement) model will submit data at the billing TIN level, for an estimated total of 33 billing TINS submitting data. Finally, we anticipate that the 195 APM Entities in the Oncology Care Model (OCM) one-sided risk arrangement model will submit at the billing TIN level, for an estimated 6,478 billing TINs submitting data.

#### Data Submission for Partial QP Election for Advanced APM participants

We do not anticipate using sampling for the data submission for Partial QP Elections for APMs. One representative from each APM Entity will make an election on behalf of all APM Entity participants meeting the partial QP threshold. In addition, Affiliated Practitioners participating as gain sharers in the Comprehensive Care for Joint Replacement (CJR) that meet the partial QP threshold would submit partial QP elections data at the participant level.

#### **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.**

#### Quality Performance Category

For the quality performance category data submission, 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, are discussed in a separate PRA package.

#### QCDR or Qualified Registry Self-nomination

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We do not anticipate using sampling for the web-based submission of the QCDR and qualified registry self-nomination email or if technically feasible online form. One representative from each QCDR or qualified registry will submit the email or if technical feasible online form.



## Data Submission for Advancing Care Information and Improvement Activities Performance Categories

We do not anticipate using sampling for the advancing care information and improvement activities performance categories. For MIPS eligible clinicians submitting data as groups, one representative from each group will submit data on behalf of the entire group.

## Data Submission for Partial QP Election for Advanced APM participants

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We do not anticipate using sampling for the data submission for Partial QP Elections for APMs. If an Advanced APM Entity is notified of that one or more participants meet the Partial QP threshold, a representative from the APM Entity will log into the MIPS portal to indicate whether clinicians meeting the partial QP threshold wish to participate in MIPS. In addition, Affiliated Practitioners participating as gain sharers in the Comprehensive Care for Joint Replacement (CJR) that meet the partial QP threshold would submit partial QP elections data at the participant level.

**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

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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.

## QCDR or Qualified Registry Self-nomination

We assume that QCDRs and qualified registries that self-nominated for PQRS in the past will self-nominate to submit data on behalf of MIPS eligible clinicians and groups. We believe our policy to allow qualified registries and QCDRs to submit data for three MIPS performance categories will result in their continued engagement under the MIPS.

## Data Submission for Advancing Care Information and Improvement Activities Performance Categories

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 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 for groups as well as individual MIPS eligible clinician data submission.

## Data Submission for Partial QP Election for Advanced APM participants

We believe that the opportunity to opt into MIPS data submission and payment adjustments will maximize Advanced APM Entities' response rates for partial QP elections on behalf of their model participants.

**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.**

## Quality Performance Category

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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

As noted above, we plan to modify the QCDR and qualified registry self-nomination process so that they can submit data on behalf of MIPS eligible clinicians and groups for three performance categories: quality, improvement activities, and advancing care information performance category data (if the MIPS eligible clinician or group is using certified EHR technology).

If technically feasible for the first MIPS performance period, qualified registries and QCDRs will submit self-nomination forms via web-based user interface. If a web-based interface is not technically feasible, self-nomination information will be submitted via email. Prior to any implementation of the modified QCDR and qualified registry self-nomination process via web-based user interface, testing with fewer than 10 respondents will be completed to ensure that the self-nomination process is functioning as designed.

#### 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.

#### Partial QP Election for Advanced APM Entities

Prior to the implementation of the Partial QP election data via a web-based user interface, testing with fewer than 10 respondents will be completed to ensure that the data submission tool is functioning as designed.

**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.**

#### Quality, Advancing Care Information, and Improvement Activities Performance Category Data

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

#### 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 (TBD) will administer the sampling methodology for the CMS Web Interface.

#### QCDR or Qualified Registry Self-nomination

Because a statistical design will not be used, no statistical experts were consulted on the QCDDR or Qualified Registry self-nomination process.

Data Submission for Partial QP Election for Advanced APM Entities

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Because a statistical design will not be used, no statistical experts were consulted on the partial QP Election for Advanced APMs.