Supporting Statement – Part A
Merit-Based Incentive Payment System (MIPS)
CMS-10621, OCN XXXX-XXXX

A. Background

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 proposed Quality Payment Program (QPP) authorized by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). The QPP 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 (APMs). 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 eligible clinicians and groups will be measured on four performance categories: quality, resource use, clinical practice improvement activities (CPIA), and advancing care information (related to meaningful use of certified EHR technology). Under the APM path, eligible 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 implementation of MIPS requires the collection of quality, advancing care information, and CPIA performance category data.[1] MIPS eligible clinicians will submit data using multiple mechanisms, including Medicare claims, CMS Web Interface, qualified registries, qualified clinical data registries (QCDRs), EHR mechanisms, and CMS-approved survey vendors.[2] The implementation of MIPS requires the collection of additional data beyond performance category data submission. Qualified registries and QCDRs must submit self-nomination forms to CMS before they can submit data on behalf of eligible clinicians. Further, under MIPS, a CMS contractor will conduct a data validation survey in order to identify and address problems with data handling, data accuracy, and incorrect payments for the MIPS program. Advanced APMs will submit forms that indicate whether their model participants would elect to participate in MIPS if they meet the partially qualifying APM participant (partial QP) threshold.

This supporting statement provides a comprehensive approach to requesting approval for

[1] Resource use performance category measures do not require the collection of additional data because they are derived from the Medicare Parts A and B claims.

[2] The use of CMS-approved survey vendors is not included in this PRA package. CMS will request approval for the collection of CAHPS for MIPS data via CMS-approved survey vendors in a separate PRA package, that will be a revision of the currently approved CAHPS Survey of Physician Quality Reporting PRA (OMB Control Number 0938-1222).

information collection, rather than the piecemeal approach used for information collections submitted under the PQRS and EHR-MU programs. The PRA package includes nine ICRs, seven of which represent a change in purpose for seven existing ICRs contained in three previously submitted PRA packages approved or under review by OMB. Two of the nine ICRs are new, representing new data collections introduced under MIPS. Given that the MIPS PRA represents a combination of previously submitted and new ICRs, we are proposing that the PRA package be approved under a new OMB control number.

The information to be collected will not duplicate similar information currently collected by CMS. The MIPS is a new reporting program which supersedes and incorporates features of the PQRS, the Medicare Electronic Health Record (EHR) Incentive Program , and the VM. Pursuant to MACRA, the payment adjustments under these three programs will sunset at the end of 2018 along with their associated reporting requirements and will be replaced by and aligned within the MIPS performance categories.

TABLE 1: Information Collection Requests (ICRs) in MIPS PRA and Related Previous ICRs and PRA Packages

IC under MIPS	New or change in purpose	ICR under PQRS/EHR MU Incentive Programs	OMB control number (OCN) for PRA package under PQRS/ EHR MU	Expiration Date for Current OMB Approval
Quality performance category: claims submission mechanism	Change in Purpose: • Most MIPS quality measures are the same as PQRS; quality measure scoring and its relationship to payment adjustments differs between MIPS and PQRS. • Assume increased burden in first performance year per MIPS eligible clinician becoming familiar with new reporting requirements. • After first performance year, assume reduction in burden per MIPS eligible clinician because MIPS requires fewer measures than PQRS (six rather than nine). • Smaller number of entities reporting due to shift to other quality data submission mechanisms.	PQRS: claims-based reporting mechanisms	0938-1059	01/31/2018*
Quality performance category : Qualified registry and QCDR submission mechanisms	Change in Purpose: • Most MIPS quality measures are the same as PQRS; quality measure scoring and its relationship to payment adjustments differs between MIPS and PQRS. • Assume increased burden in first performance year per eligible clinician	PQRS: Qualified registry-based and QCDR-based reporting mechanisms	0938-1059	01/31/2018*

IC under MIPS	New or change in purpose	ICR under PQRS/EHR MU Incentive Programs	OMB control number (OCN) for PRA package under PQRS/ EHR MU	Expiration Date for Current OMB Approval
	or group becoming familiar with new reporting requirements. • After first performance year, assume reduction in burden per eligible clinician or group because MIPS requires fewer measures than PQRS (six rather than nine). • Retain flexibility for group reporting as under PQRS. • Slightly larger number of entities reporting due to reflect increased participation.			
Quality performance category EHR submission mechanism	Change in Purpose: • Most MIPS quality measures are the same as PQRS; quality measure scoring and its relationship to payment adjustments differs between MIPS and PQRS. • Assume increased burden per MIPS eligible clinician or group in first performance year due to becoming familiar with new reporting requirements. • After first performance year, assume reduction in burden per MIPS eligible clinician or group because MIPS requires fewer measures than PQRS (six rather than nine). • Retain flexibility for group reporting as under PQRS. • Larger number of entities reporting due to reflect increased participation. • Added incentives for using EHR submission of quality measures.	PQRS: EHR-based reporting mechanisms	0938-1059	01/31/2018*
Quality performance category CMS Web interface submission mechanism	Change in Purpose: • Most MIPS quality measures are the same as PQRS; quality measure scoring and its relationship to payment adjustments differs between MIPS and PQRS. • In first performance year, assume same burden per reporting entity as PQRS because similar number of measures. • Larger number of entities reporting due to reflect increased participation in APMs.	PQRS: GPRO Web interface submission	0938-1059	01/31/2018*
QCDR or registry self-nomination	Change in Purpose: • Change in purpose because self-nominate for MIPS rather than PQRS.	PQRS: QCDR or registry self-nomination	0938-1059	01/31/2018*

IC under MIPS	New or change in purpose	ICR under PQRS/EHR MU Incentive Programs	OMB control number (OCN) for PRA package under PQRS/ EHR MU	Expiration Date for Current OMB Approval
	• Self-nomination process substantively the same across MIPS and PQRS.			
MIPS Data Validation	Change in Purpose: • Number of respondents expected to increase, number of questions expected to stay the same. • Expanding survey topics beyond PQRS (quality measures) to include CPIA and potentially advancing care information performance categories.	PQRS Data Validation	0938-1255	11/30/2017**
Advancing Care Information Performance Category	Change in Purpose: • Change in purpose: advancing care information data now used for scoring and payment adjustment calculations under MIPS, rather than Medicare Electronic Health Record (EHR) Incentive Program. • Advancing care information has fewer measures and objectives than Medicare Electronic Health Record (EHR) Incentive Program, lower expected burden per respondent. • MIPS eliminates duplicative electronic clinical quality (eCQM) measures reporting that existed under PQRS and EHR Incentive Program. MIPS eligible clinicians get credit for reporting eCQMs under quality performance category, not the advancing care information performance category.	EHR-MU Health Record Incentive Program: ICR (Objectives/Measures EPs)	0938-1278	EHR MU Incentive Program Stage 3 PRA received in OIRA on 10/30/2015 is still under review
CPIA Performance Category	New	None	None	None
Partial QP Election	New • Related to APM portion of the rule	None	None	None

* Current expiration date is for PQRS PRA package received in OIRA in 2015. A revised package received in OIRA on 3/23/2016 is still under review.

** Current expiration date is for PQRS Data Validation package received in OIRA in 2015. A revised package received in OIRA on 2/09/2016 is still under review.

1. Data Collection for MIPS

a. Quality Performance Category Reporting

In selecting measures for adoption for the quality performance category, we strive to achieve several objectives. First, the measures should take into account national priorities such as those established by the HHS National Quality Strategy (NQS) and the CMS Quality Strategy. Second, the measures should be tailored to achieving improved quality of care. Third, the burden

of measure reporting should be weighed against the potential for improvements in patient health and well-being resulting from the measures' collection.

The majority of quality measures currently proposed for MIPS are extracted from PQRS quality measures and therefore require a substantially equivalent effort as these measures for the purposes of PQRS. Under MIPS, the quality performance category reporting requirements are as follows: MIPS eligible clinicians must submit a minimum of six measures with at least one cross-cutting measure (for patient-facing MIPS eligible clinicians) and an outcome measure if available. If an outcome measure is not available, then the MIPS eligible clinician would report one other high priority measure (an appropriate use, patient safety, efficiency, patient experience, or care coordination measure) in lieu of an outcome measure. MIPS eligible clinicians can meet this criterion by selecting measures either individually or from a specialty-specific measure set. The proposed quality performance category measures are listed in Appendix A.

b. Advancing Care Information Performance Category

Under MIPS, the meaningful use of certified EHR technology is referred to as "advancing care information." In accordance with sections 1848(o)(2) of the Act, a MIPS eligible clinician must submit, using CEHRT, information on the measures selected by the Secretary in order to demonstrate they are meaningful users of CEHRT for an EHR for a performance period, as defined in section 1848(o)(2) of the Act. Appendix B provides a list of proposed advancing care information performance category measures.

The MIPS has reduced the complexity and burden associated with reporting applicable quality measures through the use of CEHRT compared to previous programs. Prior to MIPS, the submission of applicable quality measures through a CEHRT was counted towards the requirements of the EHR Incentive Program for eligible professionals, but did not satisfy PQRS requirements. Under the MIPS, eligible clinicians who report under the quality performance category through the use of CEHRT with respect to a performance period shall be treated as satisfying the clinical quality measures (CQMs) reporting requirement under section 1848(o)(2)(A)(iii) of the Act for that performance period. Therefore, CQMs will not be calculated as part of the burden for reporting the advancing care information performance category, but will be associated with the burden for the quality performance category.

We are proposing that under MIPS, each eligible clinician would be required to attest to yes/no statements related to a subset of measures adopted by the Medicare EHR Incentive Program for EPs listed in Appendix C of the 2015 Medicare EHR Incentive Program's Final Rule.[3]

c. Clinical Practice Improvement Activities (CPIAs)

[3] https://www.federalregister.gov/articles/2015/10/16/2015-25595/medicare-and-medicaid-programs-electronic-health-record-incentive-program-stage-3-and-modifications

MACRA defines CPIA as "an activity that relevant eligible professional organizations and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes." We are encouraging, but not requiring, a minimum number of CPIAs, conducted at the group or the individual level, be reported via attestation or a similar method during performance period 2017. We do not anticipate in the first performance period that we will receive measurable data for the majority of activities. Rather, 2017 reporting will involve provider attestation of having engaged in an activity.

To implement the MIPS program, we created an inventory of proposed CPIAs. We created a broad list of activities that may be used by multiple practice types to demonstrate CPIAs. In addition, we choose activities that may lend themselves to being measured for improvement in future years. For the first performance period the MIPS eligible clinician must choose activities from the CPIA Inventory (Appendix C).

d. Resource Use Performance Category

Resource use performance category measures are derived from the Medicare Parts A and B claims submission process. As required by section 1848(q)(2)(B)(ii), future resource use measures will include Part D drug costs as feasible and applicable. Resource use measures do not result in any reporting burden because individual MIPS eligible clinicians are not asked to provide any documentation beyond the claims submission process.

e. Data Collection for MIPS Data Validation

Under MIPS, a CMS contractor will conduct a data validation survey in order to identify and address problems with data handling, data accuracy, and incorrect payments for the MIPS program. Because the data that will be submitted by, or on behalf of, MIPS eligible clinicians to the MIPS program and will be used to calculate incentive payments and payment adjustments, it is critical that this data be accurate. Additionally, the data will be used to generate Feedback Reports for MIPS eligible clinicians and, in some cases, will be posted publicly on the CMS website, further supporting the need for accurate and complete data. The ultimate use of the clinical quality reporting data is to improve the quality of care for Medicare beneficiaries. The CMS data validation contractor will conduct surveys of groups, qualified registries, QCDRs, MIPS eligible clinicians submitting data via an EHR vendor, and claims reporting options in support of evaluating the data submitted for MIPS.

The MIPS data validation survey will be similar in length to the PQRS data validation survey. The PQRS data validation survey uses a series of approximately thirty questions, arranged by category, to gather information about data handling practices, training, and quality assurance, as well as the challenges that stakeholders may face. Under MIPS, the survey's topics will be expanded beyond validation of quality measures to include CPIA and potentially advancing care information performance category data in the future. The MIPS data validation

survey instrument is included in Appendix E.

The MIPS data validation survey will build on other core elements of the PQRS data validation survey. The PQRS data validation survey is completely automated and was designed with simplicity as a core requirement – it does not require a login and can be accessed via a link provided in a survey invitation email. There is no Protected Health Information (PHI) or Personally Identifiable Information (PII) submitted in the survey. In order to minimize the burden on the participant community, the number of questions in a survey will not exceed 33. The majority of the questions in the survey are "point and click", allowing the participant to complete the survey quickly. There is a feedback section included in the survey, which allows for free-form text entry and document upload; however, document uploads are not required. In very isolated instances, additional follow-up may be required. The preferred method of contact for the follow-up interview is a second electronic survey, which will contain the necessary questions. In the event there are issues making contact electronically or there are other technical challenges that cannot be overcome, the survey may be administered via telephone.

2. Data Collection for APMs

Advanced APM Entities will face a reporting burden under MIPS related to Partial Qualifying APM Professional (Partial QP) elections. Partial QPs will have the option to elect whether or not to report under MIPS, which determines whether or not they will be subject to MIPS scoring and payment adjustments. In QP Performance Period 2017, we define Partial QPs to be Advanced APM participants that have at least 20 percent, but less than 25 percent, of their Medicare Part B payments for covered professional services through an Advanced APM Entity, or at least 10 percent, but less than 20 percent, of their Medicare patients served through an Advanced APM Entity. The partial QP election will be made at any time during the MIPS performance period, before Advanced APM participants will be notified about whether they qualify as partial QPs for that performance period. A representative from each Advanced APM Entity will log into a web-based user interface to indicate whether the eligible clinicians participating in the Advanced APM would wish to report to MIPS if they are later deemed to be partial QPs.

B. Justification

1. Need and Legal Basis

Authority for collection of this information is provided under sections 1848(q), 1848(k), 1848(m), 1848(o), 1848(p), and 1833(z) of the Act.

Section 1848(q) of the Act requires the establishment of the MIPS beginning with payments for items and services furnished on or after January 1, 2019, under which the Secretary is required to: (1) develop a methodology for assessing the total performance of each MIPS eligible clinician according to performance standards for a performance period; (2) using the

methodology, provide a composite performance score (CPS) for each MIPS eligible clinician for each performance period; and (3) use the CPS of the MIPS eligible clinician for a performance period to determine and apply a MIPS adjustment factor (and, as applicable, an additional MIPS adjustment factor) to the MIPS eligible clinician for a performance period. Under section 1848(q)(2)(A) of the Act, a MIPS eligible clinician's CPS is determined using four performance categories: (1) quality; (2) resource use; (3) clinical practice improvement activity (CPIA), and (4) the advancing care information.

2. Information Users

We will use this data to assess MIPS eligible clinician performance in the MIPS performance categories, calculate the CPS, and apply performance-based payment differentials. We also use this information to provide regular feedback reports to MIPS eligible clinicians and eligible entities. This information is made available to beneficiaries, as well as to the public, on the Physician Compare website. The data will be used to produce annual statistical reports that will describe the reporting experience of MIPS eligible clinicians as a whole and subgroups of MIPS eligible clinicians. The MIPS annual statistical reports will be modeled after two existing annual reports, the PQRS Experience Report and the Value Modifier Report.

3. Use of Information Technology

All the proposed information collection described in this form is to be conducted electronically.

4. Duplication of Efforts

The information to be collected is not duplicative of similar information collected by the CMS. Table 2 shows the timing of data collections for the final PQRS and EHR-MU reporting periods and the first MIPS performance period. The data collection and associated burden for the PQRS, PQRS data validation survey, and Medicare Electronic Health Record (EHR) Incentive Program will occur in 2017 with respect to reporting period 2016. The data submission requirements for MIPS will begin in performance period 2017, which will affect reporting and burden that will occur in 2018.

TABLE 2: Timing of Data Collection During Transition from Legacy Programs to MIPS

What program(s) in effect?	**What period will data pertain to?**	**When will data collection/submission burden be experienced?**	**When will applicable payment adjustments be**

			applied?
Final reporting period for PQRS, PQRS Data Validation Survey, and Medicare Electronic Health Record (EHR) Incentive Program	Reporting period 2016	2017	2018
1st performance period for MIPS	Performance period 2017	2018	2019

5. Small Businesses

Because the vast majority of Medicare providers (well over 90 percent) are small entities within the definition in the Regulatory Flexibility Act (RFA), HHS's normal practice is to assume that all affected clinicians are "small" under the RFA. In this case, most Medicare and Medicaid eligible clinicians are either non-profit entities or meet the Small Business Administration's size standard for small business. In the Notice of Proposed Rulemaking's Regulatory Impact Analysis (Section P of the Preamble) estimates that between approximately 716,613 and 775,613 (among the 1,009,623 clinicians in MIPS eligible specialties) will be subject to MIPS performance requirements. The proposed low-volume threshold is designed to limit burden to eligible clinicians who do not have a substantive business relationship with Medicare. We estimate that approximately 225,615 clinicians in eligible specialties will be excluded from MIPS data submission requirements because they meet the proposed low-volume threshold of less than $10,000 in Medicare allowable charges and fewer than 100 Medicare patients. Further, we propose to exclude newly enrolled Medicare professionals to reduce data submission burden to those professionals, and estimate that 79,739 would be excluded. Clinicians who meet the low-volume threshold or who are not in MIPS eligible specialties may opt to submit MIPS data.[4] Medicare professionals voluntarily participating in MIPS would receive feedback on their performance, but would not be subject to payment adjustments.

Based on historical PQRS and Medicare Electronic Health Record (EHR) Incentive Program data, we assume that more clinicians will submit data under the quality than the advancing care information performance category. In the first MIPS performance period, we assume that 822,810 MIPS eligible clinicians will submit data under the quality and 436,500 MIPS eligible clinicians will submit advancing care information data. Further detail on those estimates is provided below. Because attestation of CPIA activities involves limited burden, we assume that eligible clinicians who submit quality data will also submit CPIA data.

Additionally, we estimate that between roughly 30,658 and 90,000 clinicians will

[4] For further detail on MIPS exclusions, see Supporting Statement B and the Regulatory Impact Analysis Section of the Notice of Proposed Rulemaking.

participate in the MIPS APM path.

6. Less Frequent Collection

If data on the quality, advancing care information, and CPIA performance categories are not collected from individual MIPS eligible clinicians or groups annually, we will have no mechanism to: (1) determine whether a MIPS eligible clinician or group meets the performance criteria for a payment adjustment under MIPS, (2) calculate for payment adjustments to MIPS eligible clinicians or groups, and (3) publicly post provider performance information on the *Physician Compare* website.

If qualified registries and QCDRs are not required to submit a self-nomination statement, we will have no mechanism to determine which registries and QCDRs will participate in submitting quality measures, CPIAs, or advancing care information measures, objectives and activities. As such, we would not be able to post the annual list of qualified registries which MIPS eligible clinicians use to select qualified registries and QCDRs to use to report quality measures, CPIA, or advancing care information measures, objectives, and activities to CMS.

If the MIPS data validation survey were not conducted, it would limit CMS' ability to detect and address problems with data handling, data accuracy, and incorrect payments for the MIPS program.

7. Special Circumstances

There are no special circumstances that would require an information collection to be conducted in a manner that requires respondents to:

- Report information to the agency more often than quarterly;
- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register/Outside Consultation

The proposed rule serves as the 60-day Federal Register notice which published on May 9, 2016 (81 FR, RIN 0938-AS69, CMS-5517-P). The proposed rule was placed on public inspection on April 27, 2016 and ICR related comments are due July 8, 2016.

9. Payments/Gifts to Respondents

There will be no payments/gifts to respondents.

10. Confidentiality

Consistent with federal government and CMS policies, CMS will protect the confidentiality of the requested proprietary information. Specifically, any confidential information (as such terms are interpreted under the Freedom of Information Act, the Privacy Act of 1974, and other applicable Federal government rules and regulations) will be protected from release by CMS under 5 U.S.C. § 552a(b).

Additional confidentiality provisions apply to the MIPS Data Validation survey. All respondents to the MIPS Data Validation survey will be assured of confidentiality and told the purposes for which the information is collected; any identifiable information about them will not be used or disclosed for any purpose. If a respondent's identity is needed, the information collection will comply completely with all aspects of the Privacy Act of 1974.

11. Sensitive Questions

Other than requested proprietary information noted above in section 10, there are no sensitive questions included in the information request.

12. Burden Estimates (Hours & Wages)

Burden Estimates for the MIPS: (CY 2017)

To derive wage estimates, we used data from the U.S. Bureau of Labor Statistics' May 2014 National Occupational Employment and Wage Estimates and the December 2015 Employer Costs for Employee Compensation. In this regard, Table 3 presents the mean hourly wage, the cost of fringe benefits and overhead, and the adjusted hourly wages for Billing and Posting Clerks, Computer Systems Analysts and Physicians. We are adjusting our employee hourly wage estimates by a factor of 100 percent to reflect current HHS department-wide guidance on estimating the cost of time spent by employees of regulated entities. These are necessarily rough adjustments, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that these are reasonably accurate estimation methods.

TABLE 3: Adjusted Hourly Wages Used in Burden Estimates

Occupation Title	Occupational Code	Mean Hourly Wage ($/hr.)	Fringe Benefits and Overhead ($/hr.)	Adjusted Hourly Wage ($/hr.)
Billing and Posting Clerks	43-3021	17.10 [i]	17.10	34.20
Computer Systems Analysts	15-1121	41.98[i]	41.98	83.96
Physicians	29-060	91.23 [i]	91.23	182.46

[i]nsource: "Occupational Employment and Wage Estimates May 2014," U.S. Department of Labor, Bureau of Labor Statistics. http://www.bls.gov/oes/current/oes_nat.htm

12.1 Framework for Understanding the Burden of MIPS Data Submission

Because the entities permitted to submit MIPS data on behalf of eligible clinicians will vary based on APM participation and the type of data, Table 4 presents a framework for understanding the entities facing the burden of MIPS data submission. We are proposing that the MIPS eligible clinician have the flexibility to submit information individually or via a group; however, the MIPS eligible clinician would use the same identifier for all performance categories. Hence, Table 4 shows that, MIPS eligible clinicians who are not in APMs will submit data either as individuals or groups to the quality, advancing care information, and CPIA performance categories.

For APMs, the entities submitting data on behalf of model participants will vary across categories of data and APM. For performance year 2017, the quality data submitted by Shared Savings Program Accountable Care Organizations (ACOs) and Next Generation ACOs on behalf of their model participants will be used to fulfill the requirements of their APMs, in addition to fulfilling to any applicable MIPS submission requirements for the quality performance category. Many APM participants will be scored on advancing care information and CPIA performance categories, and the submitting entity for those categories differs between the Shared Savings Program and other APMs. For the Shared Savings Program, billing TINs (or groups) will submit advancing care information and CPIA performance category data on behalf of individual eligible clinicians participating in the model. In other APMs, MIPS eligible clinicians will submit data as individuals to the advancing care information and CPIA performance categories. For Advanced APMs, Partial Qualifying APM Participant (Partial QP) election data will be submitted by Advanced APM Entities on behalf of all their participants.

TABLE 4: Entities Submitting MIPS Data On Behalf of Clinicians, by Type of Data and Category of Clinician

	Type of Data Submitted			
Category of Clinician	**Quality Performance Category**	**Advancing Care Information Performance Category**	**CPIA Category**	**Partial QP Election**
MIPS Eligible Clinicians (not in APMs)	As groups or individuals	As groups or individuals.	As groups or individuals.	Not applicable
MIPS Eligible Clinicians participating in the Shared Savings Program	Shared Savings Program participants report at the ACO level.	Shared Savings Program participants will report at Billing TIN level.	Shared Savings Program participants will report at Billing TIN level.	For Shared Savings Program Tracks 2 and 3 (which are Advanced APMs), Shared Savings Program ACOs will make election for participating MIPS eligible clinicians.
MIPS Eligible Clinicians in the Next Generation ACO Model	Next Generation ACO Model participants report at the ACO level	Next Generation ACO Model participants will report as individuals clinicians.	Next Generation ACO Model participants will report as individuals clinicians..	For Next Generation ACO Model(which is an Advanced APM), Next Generation ACOs will make election for participating MIPS eligible clinicians.
MIPS Eligible Clinicians participating in APMs (other than the Shared Savings Program or Next Generation ACO Model)	APM participants will report at APM level.	APM participants in APMs other than Shared Savings Program will report as individuals.	APM participants in APMs other than Shared Savings Program will report as individuals.	Advanced APM Entities will make election for participating MIPS eligible clinicians.

12.2 Burden Estimate for Quality Performance Category Reporting by Individual MIPS Eligible Clinicians and Groups: Reporting in General

Based on historical data in the 2014 PQRS Experience Report, we estimate that up to

822,810 professionals will submit quality performance category data including those participating as groups or APM participants. Historically, the PQRS has never experienced 100 percent participation; the participation rate for 2014 was 63 percent. We assume that professionals who reported quality data to PQRS in 2014 will continue to report quality data to MIPS , either as voluntary reporters or as MIPS eligible clinicians required to report. We anticipate that the professionals submitting data voluntarily will include Medicare professionals not in MIPS eligible specialties and clinicians that meet the proposed low-volume threshold.

We assume that the number of MIPS eligible clinicians who will submit through claims mechanisms (299,169), qualified registry or QCDR-mechanisms (214,590), EHR mechanisms (77,241), and as groups, Shared Savings Program ACOs, or Next Generation ACOs through CMS Web Interface (276,532) will be the same as the numbers submitting data through those mechanisms under the 2014 PQRS.[5] We also assume that the number of groups and ACOs that will submit quality performance category data through the CMS Web Interface will be the same as the number submitting PQRS data through the GRPO Web Interface in 2014. Specifically, we assume 300 groups will submit on behalf of 112,467 MIPS eligible clinicians; 332 Shared Savings Program ACOs will submit on behalf of 139,921 model participants, and 20 Next Generation ACOs will submit on behalf of 24,144 model participants.[6]

For MIPS eligible clinicians or groups, the burden associated with the requirements of the MIPS quality performance category is the time and effort associated with MIPS eligible clinicians identifying applicable quality measures for which they can report the necessary information, collecting the necessary information, and reporting the information needed to submit the MIPS eligible clinician's measures. We believe it is difficult to quantify the burden accurately because MIPS eligible clinicians and groups may have different processes for integrating quality reporting into their practices' work flows. Moreover, the time needed for a MIPS eligible clinician to review the quality measures and other information, select measures applicable to his or her patients and the services he or she furnishes to them, and incorporate the use of quality data codes into the office work flows is expected to vary, along with the number of measures that are potentially applicable to a given clinician's practice.

For MIPS eligible clinicians and groups, we estimate a total of six hours as the amount of time needed for a billing clerk to review the quality measures list, review the various submission options, select the most appropriate submission option, identify the applicable measures or specialty-specific measure sets for which they can report the necessary information, review the measure specifications for the selected measures, and incorporate submission of the selected measures or specialty-specific measure sets into the office work flows. The six hour estimate for the billing clerk is comprised of reviewing the performance criteria (up to two hours) and reviewing measure specifications (up to four hours). Assuming the MIPS eligible clinician has

[5] The most recently available counts of eligible clinicians submitting to PQRS are from 2014.

[6] We are assuming that the number of Next Generation ACOs and model participants in MIPS performance period 2017 will be the same as the number of Pioneer ACOs and model participants in PQRS reporting period 2014. The Pioneer ACO model, which is ending in 2016, is the predecessor to the Next Generation ACO model, which was launched in 2015.

received no training from his or her specialty society, we estimate it will take a billing clerk up to two hours to review the measure list, review the submission method, and select a submission method and measures on which to report. If a MIPS eligible clinician has received training, then we believe this would take less time. We believe four hours is a reasonable estimate for a billing clerk to review the measure specifications of measures they select to report and to develop a mechanism for incorporating submission of the selected measures into the office work flows.

Further, we estimate that it will take a physician up to one hour to review MIPS quality performance category measure specifications for each clinician, group, or APM Entity submitting data.[7] Therefore, we believe that the start-up cost for a billing clerk to report measures data may be calculated as: 6 hours x $34.20/hour = $205.20, and the start-up cost for a physician to review quality performance category measure specifications to be calculated as 1 hour x $182.46/hour = $182.46.[8] These start-up costs pertain to the specific quality submission methods below, and hence appear in the burden estimate table.[9]

We believe the burden associated with actually submitting the quality measures will vary depending on the submission method selected by the MIPS eligible clinician. As such, we break down the burden estimates by MIPS eligible clinicians and groups according to the submission method used.

12.2.1 Burden for Quality Performance Category: Claims Submission Mechanism

We anticipate the claims submission process for MIPS will be operationally similar to the PQRS submission process. MIPS eligible clinicians must gather the required information, select the appropriate quality data codes (QDCs), and include the appropriate QDCs on the claims they submit for payment. MIPS eligible clinicians will collect QDCs as additional (optional) line items on the CMS-1500 claim form or the electronic equivalent HIPAA transaction 837-P, approved by OMB under control number 0938-0999.

The total estimated burden will vary along with the volume of claims on which the quality data is reported. Based on our experience with the PQRS, we estimate that the total burden for submission of quality data will range from 0.22 hours to 10.8 hours of computer system analyst's time per MIPS eligible clinician. The wide range of estimates for the time required for a MIPS eligible clinician to submit quality measures via claims reflects the wide variation in complexity of submission across different clinician quality measures. Therefore, as shown in Table 5 we also estimate that the cost of quality data submission will range from $18.47 (.22 hours X $83.96) to $906.77 (10.8 hours X $83.96).

[7] Lawrence P. Casalino *et al*, "US Physician Practices Spend More than $15.4 Billion Annually to Report Quality Measures," *Health Affairs*, 35, no. 3 (2016): 401-406.

[8] Because MIPS has different reporting requirements than PQRS, the assumptions for the burden of startup costs of reporting are higher than they were under the most recently approved PQRS PRA package (OMB Control Number (OCN) 0938-105). The PQRS burden estimate was based on the assumption that startup costs involved five hours at a clerk's labor rate, and 0 hours of a physician's time.

[9] The one exception is the start-up cost for a billing clerk to submit data is not listed in the CMS Web Interface Reporting Burden.

The burden will also involve becoming familiar with MIPS data submission requirements. Therefore, we believe that the start-up cost for a billing clerk to report measures data may be calculated as: 6 hours x $34.20/hour = $205.20, and the start-up cost for a MIPS eligible clinician to review quality performance category measure specifications to be calculated as 1 hour x $182.46/hour=$182.46.

Considering both data submission and start-up costs, the total estimated burden hours per clinician ranges from a minimum of 7.22 hours (0.22 + 6 + 1) to maximum of 17.8 hours (10.8 + 6 + 1). The total estimated annual cost per MIPS eligible clinician ranges from the minimum burden estimate of $406.13 ($18.47 + $205.20 + $182.46) to a maximum burden estimate of $1,294.43 (($906.77 + $205.20 + $182.46).

Therefore, total annual burden cost is estimated to range from a minimum burden estimate of $121,501,865 (299,169 X $406.13) to a maximum burden estimate of $387,252,730 (299,169 X $1294.43).

TABLE 5: Burden Estimate for Quality Performance Category: MIPS Eligible Clinicians Using the Claims Submission Mechanism[10]

	Minimum Burden Estimate	**Median Burden Estimate**	**Maximum Burden Estimate**
Estimated # of Participating MIPS Eligible Clinicians (a)	299,169	299,169	299,169
Burden Hours Per MIPS Eligible Clinician to Report Quality Data (b)	0.22	1.58	10.80
Estimated # of Hours Per MIPS Eligible Clinician's billing clerk to Prepare for MIPS Participation (c)	6	6	6
Estimated # of Hours Per MIPS Eligible Clinician to Review Measure Specifications (d)	1	1	1
Estimated Annual Burden hours per MIPS Eligible Clinician (e) = (b) + (c) + (d)	**7.22**	**8.58**	**17.8**
Estimated Total Annual Burden Hours (f) = (a)*(e)	**2,160,000**	**2,566,870**	**5,325,208**
Estimated Cost Per MIPS Eligible Clinician to Report Quality Data (@ computer systems analyst's labor rate of $83.96/hr.) (g)	$18.47	$132.66	$906.77
Estimated Cost Per MIPS Eligible Clinician to Prepare for MIPS Participation (@ clerk's labor rate	$205.20	$205.20	$205.20

[10] In Tables 47-56, the numbers have been truncated to two decimals for readability.

	Minimum Burden Estimate	Median Burden Estimate	Maximum Burden Estimate
of $34.20/hr.) (h)			
Estimated Cost Per MIPS Eligible Clinician to Review Measure Specifications (@ physician's labor rate of $182.46/hr.) (i)	$182.46	$182.46	$182.46
Estimated Total Annual Cost Per Eligible Clinician (j) = (g)+(h)+(i)	$406.13	$520.32	$1,294.43
Estimated Total Annual Burden Cost (k) = (a)*(j)	**$121,501,865**	**$155,662,657**	**$387,252,730**

12.2.2 Burden for Quality Performance Category: Qualified Registry or QCDR Data Submission Mechanism

For qualified registry and QCDR data submissions, we estimate a time burden for MIPS eligible clinicians and groups to become familiar with MIPS submission requirements and in some cases, new specialty-specific measure sets. Therefore, we believe that the start-up cost for a MIPS eligible clinician's billing clerk to report measures data may be calculated as: 6 hours x $34.20/hour = $205.20, and the start-up cost for a MIPS eligible clinician to review quality performance category measure specifications to be calculated as 1 hour x $182.46/hour=$182.46. These start-up costs pertain to the specific quality submission methods below, and hence appear in the burden estimate table.

Little, if any, additional data will need to be reported to the qualified registry or QCDR solely for purposes of participation in MIPS. However, MIPS eligible clinicians and groups will need to authorize or instruct the qualified registry or QCDR to submit quality measures results and numerator and denominator data on quality measures to CMS on their behalf. We estimate that the time and effort associated with this will be approximately five minutes (0.083 hours) per MIPS eligible clinician for a total burden cost of $6.97, at a computer systems analyst's labor rate. We also estimate it will take three hours per clinician to submit quality data to the registry. Hence, we estimated 10.083 burden hours per MIPS eligible clinician, with annual total burden hours of 2,163,711 (10.083 burden hours X 214,590 MIPS eligible clinicians). The total estimated annual cost per MIPS eligible clinician is estimated to be approximately $646.51. Therefore, total annual burden cost is estimated to be $138,734,298 (214,590 X $646.51). Based on these burden requirements and the number of eligible clinicians historically using the qualified registry and QCDR submissions, we have calculated a burden estimate for quality performance category reporting for these submissions:

TABLE 6: Burden Estimate for Quality Performance Category: MIPS Eligible Clinicians (Participating Individually or as Part of a Group) Using the Qualified Registry/QCDR Submission

	Burden Estimate
Estimated # of Participating MIPS Eligible Clinicians (a)	214,590
Estimated Burden Hours Per MIPS Eligible Clinician to Report Quality Data (b)	3
Estimated # of Hours Per MIPS Eligible Clinician to Prepare for MIPS Participation (c)	6
Estimated # of Hours Per MIPS Eligible Clinician to Review Measure Specifications (d)	1
Estimated # of Hours Per MIPS Eligible Clinician to Authorize Qualified Registry to Report on Eligible Clinician's Behalf) (e)	0.083
Estimated Annual Burden hours per MIPS Eligible Clinician (f) = (b) + (c) + (d) +(e)	10.083
Estimated Total Annual Burden Hours (g) = (a)*(f)	**2,163,711**
Estimated Cost Per MIPS Eligible Clinician to Report Quality Data (@ computer systems analyst's labor rate of $83.96/hr.) (h)	$251.88
Estimated Cost Per MIPS Eligible Clinician to Prepare for MIPS Participation (@ clerk's labor rate of $34.20/hr.) (i)	$205.20
Estimated Cost Per MIPS Eligible Clinician to Review Measure Specifications (@ physician's labor rate of $182.46/hr.) (j)	$182.46
Estimated Burden for Submission Tool Registration etc. (@ computer systems analyst's labor rate of $83.96/hr.) (k)	$6.97
Estimated Total Annual Cost Per MIPS Eligible Clinician (l) = (h)+(i) +(j)+(k)	$646.51
Estimated Total Annual Burden Cost (m) = (a)*(l)	**$138,734,298**

12.2.3 Burden for Quality Performance Category: EHR Submission Mechanism

Under EHR submission mechanism, the individual eligible clinician or group may either submit the quality measures data directly to CMS from their EHR or utilize an EHR data submission vendor to submit the data to CMS on the eligible clinician's or group's behalf.

Based on our experience with the PQRS, we estimate that he time needed to perform all the steps necessary for MIPS eligible clinicians to submit quality performance measures via EHR includes the time to prepare for participating in quality performance category submissions for MIPS (calculated at six hours plus one hour of the MIPS eligible clinician's time for reviewing specifications plus one hour for the MIPS eligible clinician to obtain an account in the CMS identify management system, plus one hour for submission of a test data file), and an additional two hours for data submission.

To prepare for the EHR submission mechanism, the MIPS eligible clinician or group must review the quality measures on which we will be accepting MIPS data extracted from CEHRT, select the appropriate quality measures, extract the necessary clinical data from his or

her CEHRT, and submit the necessary data to the CMS-designated clinical data warehouse or use a health IT vendor to submit the data on behalf of the MIPS eligible clinician or group. We assume the burden for submission of quality measures data via EHR is similar for providers who submit their data directly to CMS from their CERHT and providers who use an EHR data submission vendor to submit the data on their behalf. To submit data to CMS directly from their CEHRT, MIPS eligible clinicians must have access to a CMS-specified identity management system. Once a MIPS eligible clinician has an account for this CMS-specified identity management system, he or she will need to extract the necessary clinical data from his or her CEHRT, and submit the necessary data to the CMS-designated clinical data warehouse. We estimate that obtaining access to a CMS-specified identity management system will require one hour per MIPS eligible clinician cost of $83.96 (1 X $83.96), and that submitting a test data file to CMS will also require one hour for a per MIPS eligible clinician for a cost of $83.96. With respect to submitting the actual data file for the respective reporting period, we believe that this will take an MIPS eligible clinician or group no more than two hours for a per MIPS eligible clinician cost of submission of $167.92 (2 X $83.96). The burden will involve becoming familiar with MIPS submission. In addition, we believe that the start-up cost for a MIPS eligible clinician's billing clerk to report measures data may be calculated as: 6 hours x $34.20/hour = $205.20, and the start-up cost for a MIPS eligible clinician to review quality performance category measure specifications to be calculated as 1 hour x $182.46/hour=$182.46. Hence, we estimated eleven burden hours per MIPS eligible clinician, with annual total burden hours of 849,651 (11 burden hours X 77,241 MIPS eligible clinicians). The total estimated annual cost per MIPS eligible clinician is estimated to be $723.50. Therefore, total annual burden cost is estimated to be $55,883,864 (77,241 X $723.50).

Based on these burden requirements and the number of MIPS eligible clinicians historically using the EHR submission mechanism, we have calculated a burden estimate for quality performance category reporting for this submission mechanism:

TABLE 7: Burden Estimate for Quality Performance Category: MIPS Eligible Clinicians (Reporting Individually or as Part of a Group) Using the EHR Submission Mechanism

	Burden Estimate
Estimated # of Participating MIPS Eligible Clinicians (a)	77,241
Estimated Burden Hours Per MIPS Eligible Clinicians to Obtain Account in CMS-Specified Identity Management System (b)	1
Estimated Burden Hours Per MIPS Eligible Clinicians to Submit Test Data File to CMS (c)	1
Estimated Burden Hours Per MIPS Eligible Clinicians to Submit MIPS Quality Data File to CMS (d)	2
Estimated # of Hours Per MIPS Eligible Clinicians to Prepare for MIPS Participation (e)	6
Estimated # of Hours Per MIPS Eligible Clinician to Review Measure Specifications (f)	1
Estimated Annual Burden hours per MIPS Eligible Clinicians (g) = (b) + (c) + (d) +(e)+(f)	11
Estimated Total Annual Burden Hours (h) = (a)*(g)	**849,651**
Estimated Cost Per MIPS Eligible Clinicians to Obtain Account in CMS-specified identity management system (@ computer systems analyst's labor rate of $83.96/hr.) (i)	$83.96
Estimated Cost Per MIPS Eligible Clinicians to Submit Test Data File to CMS (@ computer systems analyst's labor rate of $83.96/hr.) (j)	$83.96
Estimated Cost Per MIPS Eligible Clinicians to Report Quality Data (@ computer systems analyst's labor rate of $83.96/hr.) (k)	$167.92
Estimated Cost Per MIPS Eligible Clinicians to Prepare for MIPS Participation (@ clerk's labor rate of $34.20/hr.) (l)	$205.20
Estimated Cost Per MIPS Eligible Clinicians to Review Measure Specifications (@ physician's labor rate of $182.46/hr.) (l)	$182.46
Estimated Total Annual Cost Per MIPS Eligible Clinicians (m) = (i)+ (j)+(k)+(l)	$**723.50**
Estimated Total Annual Burden Cost (m) = (a)*(l)	**$55,883,864**

12.2.4 Burden for Quality Performance Category Data Submission via CMS Web Interface

Based on 2014 PQRS data, we assume that 652 entities will submit quality data via the CMS Web Interface in the 2017 performance period (300 groups, 332 Shared Savings Program ACOs, and 20 Next Generation ACOs). Approximately 276,532 clinicians will be represented (112,467 MIPS eligible clinicians not participating in ACOs; 139,921 Shared Savings Program participants, and 24,144 Next Generation ACO participants). . Groups interested in participating in the MIPS program using the CMS Web Interface must complete a registration process, whereas Shared Savings Program ACOs and Next Generation ACOs do not need to complete a separate registration process. We estimate that the registration process for groups under MIPS involves approximately one hour of administrative staff time per group. The weighted average of the time required to register for the CMS Web Interface across all entities is 0.46 hours (1

hour for each of the 300 groups and zero hours for each of the 352 SSP ACOs or Next Generation ACOs.) We assume that the administrative staff involved in the group registration process has an average labor cost of $34.20 per hour. Therefore, assuming the weighted total burden hours per entity (group, Shared Savings ACO, or Next Generation ACO) associated with the group registration process is 0.46 hours, we estimate the total cost to an entity associated with the group registration process to be approximately $15.74 ($34.20 per hour x 0.46 hours per entity).

The burden associated with submission of quality measures via the CMS Web Interface is the time and effort associated with completing the CMS Web Interface. Based on experience with PQRS GPRO Web Interface reporting mechanism, we estimate that, on average, it will take each entity 79 hours to submit quality measures data via the CMS Web Interface at a cost of $83.96 per hour, for a total cost of $6,6632.84 (79 X $83.96). We also estimate that a for each reporting entity, a physician will need to spend one hour per year to review quality performance measure specifications, for a total cost of $182.46. As mentioned above, we estimate it will take an average of 0.46 hours for each entity to register to submit through the CMS Web Interface, for a total of cost of $15.74 (0.46 X $34.20). The cost of these 1.46 hours is included in the total estimated annual cost per reporting entity ($6831). The total annual burden hours are estimated to be $52,460 (652 reporting entities X 80.46 annual hours), and the total annual burden cost is estimated to be $ 4,453,833 (652 X $6831.03).

Based on the assumptions discussed above we have calculated the following burden estimate for groups, Shared Savings Program ACOs, and Next Generation ACOs submitting data to MIPS via the CMS Web Interface.

TABLE 8: Burden Estimate for Quality Performance Category Group, Shared Savings ACO, and Next Generation ACO Submission via the CMS Web Interface

	Burden Estimate
Estimated # of Groups (a)	652
Estimated # of Burden Hours Per Reporting Entity to Register for CMS Web Interface (b)	0.46
Estimated # of Burden Hours Per Reporting Entity to Review Measure Specifications (c)	1
Estimated # of Burden Hours Per Reporting Entity to Submit (d)	79
Estimated Total Annual Burden Hours Per Reporting Entity (e) = (b)+ (c)+(d)	80.46
Estimated Total Annual Burden Hours (f) = (a)*(e)	**52,460**
Estimated Cost Per Reporting Entity to Register to Participate in MIPS Under the CMS Web Interface Submission Option (@ clerk's labor rate of $34.20/hr.) (g)	$15.73

Estimated Cost Per Reporting Entity to Submit (@ computer systems analyst's labor rate of $83.96/hr.) (h)	$6,632.84
Estimated Cost Per Reporting Entity to Review Measure Specifications (@ physician's labor rate of $182.46/hr.) (i)	$182.46
Estimated Total Annual Cost Per Reporting Entity (j) = (g)+(h)+(i)	$6831.03
Estimated Total Annual Burden Cost (k) = (a)*(j)	**$ 4,453,833**
	By Provider
Estimated # of Participating MIPS Eligible Clinicians (l)	276,532
Average Burden Hours Per MIPS Eligible Clinician (m) = (f) ÷ (l)	0.19
Estimated Cost Per MIPS Eligible Clinician to Submit Quality Data (n) = (k) ÷ (l)	$16.11

12.3 Burden for Qualified Registry and QCDR Self-Nomination

For CY 2015, 98 qualified registries and 49 QCDRs were qualified to report quality measures data to CMS for purposes of the PQRS.[11] Under MIPS we believe that the number of QCDRs and qualified registries will increase because (1) many MIPS eligible clinicians will be able to use the qualified registry and QCDR for all MIPS submission (not just for quality submission), and (2) QCDRs will be able to provide innovative measures that address practice needs. Qualified registries or QCDRs interested in submitting quality measures results and numerator and denominator data on quality measures to CMS on their MIPS eligible clinicians' behalf will need to complete a self-nomination process in order to be considered qualified. We estimate that the self-nomination process for qualifying additional qualified registries or QCDRs to submit on behalf of MIPS eligible clinicians or groups for MIPS will involve approximately one hour per qualified registry or QCDR to complete the online self-nomination process.

Please note that the self-nomination statement is an online form that entities will use to provide information on their business, and is included as Appendix K. The self-nomination statement will be available at https://jira.oncprojectracking.org/login.jsp.

In addition to completing a self-nomination statement, qualified registries and QCDRs will need to perform various other functions, such as meet with CMS officials when additional information is needed. In addition, QCDRs must benchmark and calculate their measure results. The time it takes to perform these functions may vary depending on the sophistication of the entity, but we estimate that a qualified registry or QCDR will spend an additional nine hours performing various other functions, such as benchmarking and calculating measure results, related to being a MIPS qualified registry or QCDR.

We estimate that the staff involved in the qualified registry or QCDR self-nomination process will mainly be Computer Systems Analysts or the equivalent, at an average labor cost of $83.96/hour. Therefore, assuming the total burden hours per qualified registry or QCDR

[11] The full list of qualified registries for 2015 is available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2015QualifiedRegistries.pdf and the full list of QCDRs is available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2015QCDRPosting.pdf.

associated with the self-nomination process is ten hours, the annual burden hours is 1,500 (150 QCDRs X 10 hours). We estimate that the total cost to a qualified registry or QCDR associated with the self-nomination process will be approximately $839.60 ($83.96 per hour x 10 hours per qualified registry). We also estimate that 150 new qualified registries or QCDRs will go through the self-nomination process leading to a total burden of $125,940 ($839.60 x 150).

The burden associated with the qualified registry and QCDR submission requirements in MIPS will be the time and effort associated with the qualified registry calculating quality measures results from the data submitted to the qualified registry or QCDR by its participants and submitting the quality measures results, the numerator and denominator data on quality measures, and the advancing care information performance category and CPIA data to CMS on behalf of the MIPS eligible clinician. We expect that the time needed for a qualified registry or QCDR to review the quality measures and other information, calculate the measures results, and submit the measures results and numerator and denominator data on the quality measures and the advancing care information performance category and CPIA data on their MIPS eligible clinicians' behalf will vary along with the number of MIPS eligible clinicians submitting data to the qualified registry or QCDR and the number of applicable measures. However, we believe that qualified registries and QCDRs already perform many of these activities for their MIPS eligible clinicians. We believe the estimate above represents the upper bound of QCDR burden, with the potential for less additional MIPS burden if the QCDR already provides similar reporting services.

Based on the assumptions previously discussed, we provide an estimate of total annual burden hours and total annual cost burden associated with a qualified registry or QCDR self-nominating to be considered "qualified" for the purpose of submitting quality measures results and numerator and denominator data on MIPS eligible clinicians.

TABLE 9: Burden Estimate for QCDR and Registry Self Nomination

	Burden Estimate
Estimated # of Qualified registries or QCDRs Self-Nominating for the MIPS (a)	150
Estimated Total Annual Burden Hours Per Qualified registry or QCDR (b)	10
Estimated Total Annual Burden Hours For Qualified registries or QCDRs (c) = (a)*(b)	**1,500**
Estimated Cost Per Qualified registry or QCDR (d) (@ computer systems analyst's labor rate of R83.96/hr.)	$839.60
Estimated Total Annual Burden Cost For Qualified registries or QCDRs (e) = (a)*(d)	**$125,940**

12.4 Burden for MIPS Data Validation Survey

Under MIPS, a CMS contractor will conduct a data validation survey in order to identify and address problems with data handling, data accuracy, and incorrect payments for the MIPS program. Because the data that will be submitted by, or on behalf of, MIPS eligible clinicians to

the MIPS program and will be used to calculate payment adjustments, it is critical that this data be accurate. Additionally, the data will be used to generate Feedback Reports for MIPS eligible clinicians and groups and, in some cases, is posted publicly on the CMS website, further supporting the need for accurate and complete data. The CMS data validation contractor will conduct surveys of groups, qualified registries, QCDRs, health IT vendors, and MIPS eligible clinicians in support of evaluating the data submitted for MIPS. The MIPS data validation survey will be similar to the PQRS data validation survey. The PQRS data validation survey uses a series of approximately thirty questions, arranged by category, to gather information about data handling practices, training, and quality assurance, as well as the challenges that stakeholders faced in participating in the PQRS program. Under MIPS, the survey's topics will be expanded beyond validation of quality measures to include CPIA and potentially advancing care information performance category data.

The MIPS data validation survey for performance period 2017 will be conducted in late 2018 for data reported in early 2018. Because the MIPS verification process is still under development, the precise sample size for respondents has not yet been determined. We anticipate that at most 500 entities would be contacted for MIPS data verification for performance period 2017. Based on the most recent reporting period of the PQRS data validation survey, we will assume that the response rate will be 86 percent. Hence, we estimated the total number of respondents for the first performance period will be 430 (500 entities contacted X 86 percent response rate).

Based on the PQRS Data Validation survey burden we estimate the total annual burden for the ongoing MIPS data validation will be up to 750 hours each performance period (500 responses X 1.5 hours), and the data validation will be conducted at a clerk's labor rate of $34.20 per hour for a total burden cost of $25,650 ($34.20 X 1.5).

TABLE 10: Total Estimated Burden for MIPS Data Validation

Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost ($)	Total Burden Cost ($)
430	430	1.5	645	$34.20	$22,059

12.5 Burden for Advancing Care Information Performance Category Data Submission

Advancing care information performance category data will not be submitted separately by MIPS eligible clinicians in most cases as was required under the Medicare EHR Incentive Program. MIPS eligible clinicians and groups will submit this data using the same submission mechanism, or a similar submission mechanism they have selected for the other MIPS performance categories. For the purpose of submission of advancing care information performance category objectives and measures under MIPS, we proposed in the NPRM to allow MIPS eligible clinicians to submit advancing care information performance category data

through the qualified registry, EHR, QCDR, and CMS Web Interface data submission methods. We have also streamlined the submission requirements for advancing care information as part of the MIPS program. In comparison to the reporting requirements in the 2015 Medicare EHR Incentive Program Final Rule, two objectives and their associated measures (Clinical Decision Support and Computerized Provider Order Entry) will no longer be required for submission purposes. We are aligning the advancing care information performance category with other MIPS performance categories, such as submitting CQMs to the quality performance category, which will streamline submission requirements and reduce MIPS eligible clinician confusion. Hence, a MIPS eligible clinician's estimated burden for the advancing care information performance category is lower than the estimated seven hours per MIPS eligible clinician in the Medicare EHR Incentive Program –Stage 3 PRA (OMB control number 0938-1278) currently under review at OMB. We are requesting that effective January 1, 2017, the MIPS Collection of Information Requirements replace those for MIPS eligible clinicians in the Medicare EHR Incentive Program Stage 3 PRA.[12]

As noted above in Section B, a variety of third-party intermediaries will report advancing care information performance category data on behalf of MIPS eligible clinicians. Based on historical data and 2015 Medicare EHR Incentive Program attestation, we estimate that approximately 436,500 MIPS eligible clinicians not participating in APMs would submit advancing care information performance category data to MIPS.

TABLE 11: Estimated Numbers of Entities Submitting Advancing Care Information Performance Category Data on Behalf of MIPS Eligible Clinicians

Category of Clinician	Available Mechanisms for Submission	Estimated Number of Entities Submitting Data
MIPS Eligible Clinicians (not in APMs)	As groups or individuals.	436,500 MIPS eligible clinicians submitting as individuals
MIPS Eligible Clinicians participating in the Shared Savings Program Tracks 1, 2, and 3	Shared Savings Program participants will report at Billing TIN level.	25,925 Billing TINs representing 140,341 MIPS eligible clinicians participating in 434 Shared Savings Program ACOs
MIPS Eligible Clinicians participating in APMs that are not Advanced APMs (other than Shared Savings Program Track 2 and 3)	APM participants in APMs other than the Shared Savings Program will report as individuals.	55,000 APM participants
Total number of entities submitting		517,425 submitting entities representing 631,931 MIPS eligible clinicians

Because the 2017 performance period will be the first time for MIPS eligible clinicians to report the advancing care information performance category data as groups, there is considerable

[12]We do not anticipate any changes in the CERHT process for EHR vendors as we transition to MIPS. Hence, EHR vendors are not included in these burden estimates.

uncertainty about what number of MIPS eligible clinicians will report as part of a groups. For the purposes of our burden estimate, we conservatively estimate that all the MIPS eligible clinicians that reported as individuals under the 2015 Medicare EHR Incentive Program will continue to report as individuals in the first MIPS performance period, but may transition to group submission in future years. Because some participants in MIPS APMs will be required to report advancing care information performance category data to fulfill the requirements of submitting to MIPS, we have included them in our burden estimate for the advancing care information performance category. Further we anticipate that the 434 Shared Savings Program ACOs will submit data at the ACO participant billing TIN level, for a total of 25,925 submitting entities, and approximately 55,000 other APM participants will report as MIPS eligible clinicians. Hence, as shown in Table 12, we estimate that up to approximately 517,425 entities will be submitting data under the advancing care information performance category (436,100 MIPS eligible clinicians + 25,925 billing TINs within the Shared Savings Program ACOs + 55,000 APM participants). The total burden hours for a MIPS eligible clinician or group to report on the objectives and measures specified for the advancing care information performance category will be four hours. The total estimated burden hours are 1,552,275 (517,425 X 4). At a clinician's hourly rate, the total burden cost is $283,228,097 (1,552,275,300 X $182.46).

TABLE 12: Total Estimated Burden for Advancing Care Information Performance Category Data Submission

Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost ($)	Total Burden Cost ($)
517,425	517,425	4	2,069,700	$182.46	$377,637,462

12.6 Burden for CPIA Performance Category Data Submission

Requirements for submitting CPIAs are new and we do not have historical data which is directly relevant. As noted in the NPRM a variety of entities will report advancing care information performance category data on behalf of MIPS eligible clinicians. For MIPS eligible clinicians who are not part of APMs, we assume that the number of MIPS eligible clinicians submitting as part of a group will be approximately the same as the number of MIPS eligible clinicians submitting PQRS data through the GPRO Web Interface in 2014. We estimate that that there could be as many as 595,100 MIPS eligible clinicians submitting CPIA category data as individuals, which is equal to the number of EPs who used administrative claims, QCDR, qualified registry, or EHR submission mechanisms under the 2014 PQRS reporting period.[13] We

[13] Because of the lack of historical data on CPIA submission, our estimate of 595,100 eligible clinicians submitting CPIA data is based on 2014 PQRS historical data (595,100 eligible clinicians = 299,169 eligible clinicians submitting quality data through claims + 214,590 eligible clinicians submitting quality data through QCDR or qualified registry + 77,241 eligible clinicians submitting quality data through EHR).

estimate that approximately 112,500 MIPS eligible clinicians comprising 300 groups may report at the group level.

TABLE 13: Estimated Numbers of Entities Submitting CPIA Performance Category Data on Behalf of MIPS Eligible Clinicians

Category of Clinician	Available mechanisms for submission	Estimated number of entities submitting data
MIPS Eligible Clinicians (not in APMs)	As groups or individuals.	300 groups representing 112,500 MIPS eligible clinicians 595,100 MIPS eligible clinicians submitting individually
MIPS Eligible Clinicians participating in Shared Savings Program Tracks 1, 2, and 3	Shared Savings Program participants will report at Billing TIN level.	25,925 Billing TINs representing 140,341 MIPS eligible clinicians participating in 434 Shared Savings Program ACOs
MIPS Eligible Clinicians participating in APMs (other than Shared Savings Program Track 2 and 3)	APM participants in models other than the Shared Savings Program will report as individual clinicians.	55,000 APM participants
Total number of entities submitting		676,325 Entities submitting on behalf of 903,031 MIPS eligible clinicians

Because some APM Entities and participants will be required to report CPIA data to fulfill the requirements of submitting to MIPS, we have included them in our burden estimate for CPIA data submission. As with the advancing care information performance category, participants in Shared Savings Program ACOs will report at the ACO participant billing TIN level, and other APM participants will report as individual MIPS eligible clinicians. We anticipate MIPS eligible clinicians, groups, and APM billing TINs, will submit CPIA data using the same mechanism, or a similar mechanism as they select for submitting quality data. In addition to collecting necessary supporting documentation, each MIPS eligible clinician, group, ACO participant billing TIN, or APM participant will provide a yes/no attestation submitted during the data submission period for successfully completed CPIAs. We estimate that up to approximately 676,325 entities will submit data for CPIAs. We estimate it will take no longer than three hours per entity to submit data for the CPIA performance category. The total estimated burden is 2,028,975 (676,325 entities X 3 hours each). At a MIPS eligible clinician's hourly rate, the total estimated burden cost is $370,206,779 (2,028,975 X $182.46).

TABLE 1: Total Estimated Burden for CPIA Submission

Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost ($)	Total Burden Cost ($)
676,325	676,325	3	2,028,975	$182.46	$370,206,779

12.7 Burden for Resource Use Performance Category Data Submission

The resource use performance category relies on administrative claims data. For claims-based reporting, the Medicare Parts A and B claims submission process is used to collect data on resource measures from MIPS eligible clinicians. MIPS eligible clinicians are not asked to provide any documentation by CD or hardcopy. Therefore, we do not anticipate any new or additional reporting burden for MIPS eligible clinicians as a result of the resource use performance category.

12.8 Burden for partial Qualifying Professional (QP) Election for APMs

The NPRM discusses the MIPS-related submission requirements for participants in the Shared Savings Program and certain APMs. MIPS APMs participating in Advanced APMs will face an additional submission requirement under MIPS related to Partial Qualifying APM Participant (QP) elections. A representative from each APM Entity will log into a web-based user interface to indicate whether MIPS eligible clinicians would wish to participate in MIPS if the eligible clinicians participating in the APM Entity are later deemed to be Partial QPs. We estimate it will take each MIPS APM representative 15 minutes to make this election, and an additional 15 minutes to register for the web-based user interface. We estimate that 543 APM Entities will make this election via a web-based user interface, for a total burden estimate of 272 hours (543 X .5). At a computer systems analyst's hourly labor cost, the total burden cost is estimated to be $22,795 (272 X $83.96). For partial QPs that elect to submit MIPS data, burden for the actual data submission is included in the burden estimates for the quality, advancing care information, and CPIA performance categories.

TABLE 15: Total Estimated Burden for Partial QP Election

Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost ($)	Total Burden Cost ($)
543	543	.5	272	83.96	22,795

13. Capital Costs (Maintenance of Capital Costs)

The costs for implementation and complying with the advancing care information performance category requirements could potentially lead to higher operational expenses for MIPS eligible clinicians. However, we believe that the combination of payment incentives and long-term overall gains in efficiency will likely offset the initial expenditures. Additionally, because we are proposing above to reweight the advancing care information performance category scores for eligible clinicians that were exempt from the Medicare Electronic Health Record (EHR) Incentive Program or received hardship exemptions, these proposals would not impose additional requirements for EHR adoption during the first MIPS performance period. As we have stated with respect to the Medicare EHR Incentive Program, we believe that future retrospective studies on the costs to implement CEHRT and the return on investment (ROI) will demonstrate efficiency improvements that offset the actual costs incurred by MIPS eligible clinicians participating in MIPS and specifically in the advancing care information performance category, but we are unable to quantify those costs and benefits at this time.

Similarly, the costs for implementation and complying with the CPIA performance category requirements could potentially lead to higher expenses for MIPS eligible clinicians. Costs per full-time equivalent MIPS eligible clinician for CPIA will vary across practices, including for some activities or patient-centered medical home practices, in incremental costs per encounter, and in estimated costs per member per month. Costs may vary based on panel size and location of practice among other variables, and given the lack of historical data for CPIA, we are unable to quantify those costs at this time.

14. Cost to Federal Government

Because MIPS replaces three existing programs (the PQRS, the Value Modifier, and the EHR Incentive Program), there will be an initial cost to consolidating systems and building the MIPS scoring capabilities. CMS intends to leverage existing infrastructure to the extent feasible and annual operating costs for the existing systems will be replaced by those of the MIPS. Aside from program administrative and implementation costs, MIPS payment incentives and penalties are budget-neutral and present no cost to the federal government, with respect to the application of the MIPS payment adjustments.

15. Program or Burden Changes

The total gross burden estimate includes the total burden of recordkeeping and data submission under MIPS. Table 16 provides an estimate of the total annual burden of MIPS of 12,492,122 hours and a total annual burden cost of $1,328,891,951. Some of the information collection burden under MIPS does not represent an additional burden to the public, but replaces information collection burden that existed under two of its predecessor programs, the PQRS and the Medicare EHR Incentive Program. Due to programmatic changes, seven of the nine MIPS ICs replace existing ICs. The MIPS ICs related to including quality data submission via claims,

qualified registry or QCDR, EHR, or CMS Web Interface submission mechanisms replace similar submission mechanisms under PQRS. The MIPS Advancing Care Information IC replaces the EHR Incentive Program IC and the MIPS Data Validation IC replaces the PQRS Data Validation IC. Two MIPS ICs are new: the CPIA performance category data submission and the partially qualifying APM participant election. The estimated total existing burden approved for existing information collections related to PQRS and the Medicare EHR Incentive Program (for EPs) was 9,955,484 hours for a total annual burden cost of $1,198,322,907. The net burden estimate of 2,536,638 hours (and associated net burden cost of $130,569,044) reflects only the incremental burden associated with this rule, and excludes the burden of existing recordkeeping and data submission under the PQRS, the Medicare EHR Incentive Program, and PQRS data validation survey.Mindful of the combined data submission burden of MIPS, we have sought to avoid duplication of data submission efforts and simplified data submission structures within the unified program.

TABLE 16: Proposed Annual Recordkeeping and Reporting Requirements

Section(s) in title 42 of the CFR and Section of Rule	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting ($)	Total Annual Burden Cost ($)
§414.1330 and §414.1335 (Quality Performance Category) Claims Submission Mechanism	299,169	299,169	17.8	5,325,208	Varies (see Table 5)	387,252,730
§414.1330 and §414.1335 (Quality Performance Category) Qualified Registry or QCDR Submission Mechanisms	214,590	214,590	10	2,163,711	Varies (see Table 6)	$138,734,298
§414.1330 and §414.1335 (Quality Performance Category) EHR- Submission Mechanism	77,241	77,241	11	849,651	Varies (See Table 7)	55,883,864
§414.1330 and §414.1335 (Quality Performance Category) CMS Web Interface Submission Mechanism	652	652	80.4	52,460	Varies (See Table 8)	4,453,833
§414.1400 (QCDR and Registries) QCDR and qualified registry self nomination	150	10	1500	1,500	83.96	125,940
§414.1390 (Data Validation and Auditing)	430	430	1.5	645	34.20	22,059
§414.1375 (Advancing Care Information Performance Category)	517,425	517,425	4	2,069,700	182.46	377,637,462
§414.1360 (CPIA)	676,325	676,325	3	2,028,975	182.46	370,206,779
$414.1430 (Partial Qualifying APM Participant (QP) election)	543	543	.5	272	83.96	22,795
Total Gross Burden		1,786,525		12,492,122		1,328,891,951
Total Approved Burden Under Previous Programs		1,221,750		9,955,484		1,198,322,907
Total Net Burden		564,775		2,563,638		130,569,044

16. Publication and Tabulation Dates

To ensure that MIPS results are useful and accurate, CMS plans to provide performance feedback to MIPS eligible clinicians. Beginning July 1, 2017, we propose to include information on the quality and resource use performance categories in the performance feedback. Initially, we propose to provide performance feedback on an annual basis. In future years, we may consider providing performance feedback on a more frequent basis as well as adding feedback on the CPIA and advancing care information performance categories. In the NPRM we propose to make performance feedback available using a CMS designated system.

We plan to publicly report MIPS information through the *Physician Compare* website. The public reporting is anticipated to start in late 2018 for the 2017 performance period. We plan public reporting of a MIPS eligible clinician's MIPS data; in that for each performance period, we will post on a public website (for example, *Physician Compare*), in an easily understandable format, information regarding the performance of MIPS eligible clinicians or groups under the MIPS.

17. Expiration Date

We would like approval for this information collection for a period of 3 years. There are no paper forms involved in this data collection activity, but the expiration date will be displayed on the MIPS Data Validation survey and respondent letters.

18. Certification Statement

There are no exceptions to the certification statement.