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

A. <u>Background</u>

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 (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 EHR Incentive Program into one single program in which eligible clinicians and groups will be measured on four performance categories: quality, cost, improvement activities, and advancing care information (related to meaningful use of certified EHR technology). During the transition year, MIPS eligible clinicians will not be scored on the cost performance category.

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. Advanced APMs will submit forms that indicate whether their model participants who meet the partially qualifying APM participant (partial QP) threshold elect to participate in MIPS.

The implementation of MIPS requires the collection of quality, advancing care information, and improvement activities performance category data.¹ MIPS eligible clinicians will have the option to submit data using various 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.

This supporting statement provides a comprehensive approach to requesting approval for information collection, rather than the piecemeal approach used for information collections submitted under the PQRS and Medicare EHR Incentive Program. This PRA package includes

¹ Cost 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 has requested approval for the collection of CAHPS for MIPS data via CMS-approved survey vendors in a separate PRA package, that is a revision of the currently approved CAHPS Survey of Physician Quality Reporting PRA (OMB Control Number 0938-1222).

eight information collections (ICs), six of which represent a change in purpose for seven preexisting ICs contained in three previously submitted PRA packages approved or under review by OMB. Two of the eight ICs are new, representing new data collections introduced under MIPS. Given that the MIPS PRA represents a combination of previously approved and new instruments; this PRA package has been submitted for approval under a new OMB control number. The PRA packages related to the PQRS will be discontinued in calendar year 2017 after Medicare eligible professionals (EPs) have completed data submission for the 2016 reporting period. The Medicare EHR Incentive Program for Eligible Professionals information collection related to EPs will be discontinued in calendar year 2017 after Medicare EPs have completed data submission for the 2016 reporting period. The ICs in the EHR Incentive Program—Stage 3 PRA package related to hospitals and critical access hospitals (CAHs) and the Medicaid EHR Incentive Program for Eligible Professionals information data be collected simultaneously for the MIPS and the programs that it is replacing, the PQRS Program and Medicare EHR Incentive Program.

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 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 data submission requirements and will be replaced by and aligned within the MIPS performance categories.

	Packages	- ·	l	L
IC under MIPS	New or change in purpose	IC under PQRS/Medicare EHR Incentive Programs	OMB control number (OCN) for PRA package under PQRS/ EHR Medicare EHR Incentive Program	Expiration Date for Current OMB Approval
Quality performance category: claims submission mechanism	5 I	PQRS: claims-based submission mechanisms	0938-1059	07/31/2019
Quality performance category: Qualified registry and QCDR submission mechanisms		PQRS: Qualified registry-based and QCDR-based submission mechanisms	0938-1059	07/31/2019

TABLE 1: Information Collection (ICs) now in MIPS and Related Previous Freestanding PRA Packages

IC under MIPS	New or change in purpose	IC under PQRS/Medicare EHR Incentive Programs	OMB control number (OCN) for PRA package under PQRS/ EHR Medicare EHR Incentive	Expiration Date for Current OMB Approval
	Burden estimate now assumes that the respondent is the group or individual clinician submitting data. The PQRS burden estimate assumed that the respondent was always the individual clinician, even if the clinician was submitting data as part of a group. The PQRS burden estimate did adequately		Program	
Quality performance category EHR submission mechanism	 reflect efficiencies for group reporting. 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. Assumptions about time needed for measure review reflect the reduction from 9 measures under PQRS to 6 measures under MIPS. Retain flexibility for group or individual submission as under PQRS. Larger number of respondents submitting data due to increased participation in this submission mechanism Added incentives for using EHR submission of quality measures. Change Due to Adjustment in Estimate: In response to public comments and based on review of recent research, we have updated our assumptions about the amount of time needed to review the new quality measure specifications in in the claims, registry, QCDR, and EHR submission Burden estimate now assumes that the respondent is the group or individual clinician submitting data. The PQRS burden estimate assumed that the respondent was always the individual clinician, even if the clinician was submitting data as part of a group. The PQRS burden estimate did adequately reflect efficiencies for group reporting. 		0938-1059	07/31/2019
Quality performance category CMS Web interface submission mechanism	Change in Purpose:		0938-1059	07/31/2019

IC under MIPS	New or change in purpose	IC under PQRS/Medicare EHR Incentive Programs	OMB control number (OCN) for PRA package under PQRS/ EHR Medicare EHR Incentive Program	Expiration Date for Current OMB Approval
	 number of measures. Larger number of entities submitting data due to increased participation in APMs. 			
QCDR or registry self-nomination	 Change in Purpose: Change in purpose because self-nominate for MIPS rather than PQRS. Self-nomination process substantively the same across MIPS and PQRS. Increase in burden due to growth in numbers of QCDRs and registries over time. 	PQRS: QCDR or registry self-nominatior	0938-1059	07/31/2019
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 EHR Incentive Program. Lower expected burden per respondent due to reduction in measures and objectives relative to Medicare EHR Incentive Program. MIPS eliminates duplicative electronic clinical quality measures (eCQM) submission that existed under PQRS and the Medicare EHR Incentive Program for Eligible Professionals. MIPS eligible clinicians get credit for submission of eCQMs or other electronically submitted measures under the quality performance category, not the advancing care information performance category. Lower burden estimate due to availability of group reporting under MIPS. Under the Medicare EHR Incentive Program. group reporting was not available Burden estimate now assumes that the respondent is the group or individual clinician submitting data. 	ÈPS) e	0938-1278	12/31/2019
Improvement Activities Performance Category	New	None	None	None
Partial QP Election	New • Related to APM portion (II.F) of the CY 17 Quality Payment Program final rule	None	None	None

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 submission 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 required for the purposes of PQRS. Under MIPS, the quality performance category performance requirements are as follows: the MIPS eligible clinician or group will report at least six measures including at least one outcome measure if available; if an applicable outcome measure is not available, then the MIPS eligible clinician or group will report a high priority measure (appropriate use, patient safety, efficiency, patient experience, and care coordination measures) in lieu of an outcome measure. If fewer than six measures apply to the individual MIPS eligible clinician or group, then the MIPS eligible clinician or group will be required to report on each measure that is applicable. MIPS eligible clinicians can meet this criterion by selecting measures either individually or from a specialty-specific measure set. The finalized 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 final advancing care information performance category measures.

The MIPS has reduced the complexity and burden associated with submission of applicable quality measures through the use of CEHRT compared to previous programs. Prior to the 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) submission 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 submission the advancing care information performance category, but will be associated with the burden for the quality performance category.

Under the MIPS, each eligible clinician will be required to submit the required measures

listed in Appendix B (and at <u>https://qpp.cms.gov/measures/aci</u>) to achieve a 50 percent base score, with the option to submit additional measures to receive a higher score. The number of base measures and optional additional measures depends on whether the eligible clinician elects to use the Advancing Care Information Measures or the 2017 Advancing Care Information Transition Measures. During the transition year. MIPS eligible clinicians and groups can submit advancing care information data via qualified registry, QCDR, EHR, CMS Web Interface, or attestation data submission mechanisms.

c. Improvement Activities Performance Category

Under MIPS, clinical practice improvement activities are referred to as improvement activities. MACRA defines an improvement activity 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 improvement activities, conducted at the group or the individual level. During the transition year MIPS eligible clinicians and groups can submit data via qualified registry, QCDR, EHR, CMS Web Interface, or attestation data submission mechanisms.

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

d. Cost Performance Category

Under MIPS, we are referring to the resource use performance category as "cost." Cost 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 cost measures will include Part D drug costs as feasible and applicable. Cost performance category measures do not result in any submission burden because individual MIPS eligible clinicians are not asked to provide any documentation beyond the claims submission process. During the transition year, MIPS eligible clinicians will not be scored on the cost performance category.

2. Data Collection for APMs

Advanced APM Entities will face a submission 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. Early in QP Performance Period 2017, Advanced APM participants will be notified about whether they qualify as partial QPs based on data from the previous year. If an Advanced APM Entity is notified 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 gainsharers in the Comprehensive Care for Joint Replacement CJR model may face a data submission requirement for Partial QP elections. CMS has recently finalized changes to the CJR model in the final Advancing Care Coordination Through Episode Payment Models rule (82 FR 180 through 651 that will allow the CJR model to meet the Advanced APM criteria. Because CMS will assess Affiliated Practitioners in the CJR model individually, they must make a partial QP election at the participant level.

If the Advanced APM Entity or CJR model participant chooses not to make the election, the default is for the clinicians meeting the partial QP threshold to opt out of MIPS.

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 final score for each MIPS eligible clinician for each performance period; and (3) use the final score 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 final score is determined using four performance categories: (1) quality; (2) cost; (3) improvement activities, 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 final score, and calculate positive and negative payment adjustments based on the final score. We also use this information to provide performance feedback to MIPS eligible clinicians and eligible entities. Some of the information collected will

be made available to the public on the Physician Compare website. We anticipate that the data will also be used to produce annual statistical reports that will describe the participation experience of MIPS eligible clinicians as a whole and subgroups of MIPS eligible clinicians. We anticipate that the MIPS annual statistical reports will be modeled after two existing annual reports, the PQRS Experience Report and the Value Modifier Report.

3. <u>Use of Information Technology</u>

All the 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 Medicare EHR-Incentive Program reporting periods and the first MIPS performance period. The data collection and associated burden for the PQRS, PQRS data validation survey, and Medicare (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 data submission burden that will occur in 2018.

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 Medicare EHR Incentive Program	For most participants, Reporting period 2016	For most participants, late calendar year 2016 and early calendar year 2017 First time participants can avoid payment adjustment if they attest by October 1, 2017	Payment year 2018
MIPS transition year	Performance period 2017 For CMS Web Interface and CAHPS quality data submission mechanisms, Performance period is January 1-December 31, 2017 For other quality, improvement activities and advancing care information data submissions, performance period is a minimum of any continuous 90 day period during CY2017.	Timing varies; during calendar year 2017 or early calendar year 2018	Payment year 2019

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

5. <u>Small Businesses</u>

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. The CY 17 Quality Payment Program final Regulatory Impact Analysis (Section P of the Preamble) estimates that between rule's approximately 592,119 and 642,119 (among the 1,060,901-1,110,901 clinicians in MIPS eligible specialties) will be subject to MIPS performance requirements. The 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 383,514 clinicians in eligible specialties will be excluded from MIPS data submission requirements because they meet the low-volume threshold of less than or equal to \$30,000 in Medicare allowable charges or less than or equal to 100 Medicare patients. Further, we exclude newly enrolled Medicare professionals to reduce data submission burden to those professionals, and estimate that 85,268 would be excluded. Clinicians who meet the low-volume threshold, who are not in MIPS eligible specialties, or who are newly enrolled Medicare clinicians may opt to submit MIPS data.³ Medicare professionals voluntarily participating in MIPS would receive feedback on their performance, but would not be subject to payment adjustments.

Based on historical PQRS data, we assume that 611,876 MIPS eligible clinicians will submit quality data as individual clinicians, or as part of groups or Shared Savings Program ACOs. We also assume that 296,766 clinicians excluded from MIPS will voluntarily submit quality data as individual clinicians, or as part of groups or Shared Savings Program ACOs. Due to limitations of historical Medicare EHR Program data, we base our estimates of the numbers of clinicians submitting advancing care information data on 2015 PQRS data. Because attestation of improvement activities involves limited burden, we assume that eligible clinicians who submit quality data will also submit data on improvement activities. Further detail on those estimates is provided below.

Additionally, we estimate that between roughly 70,000 and 120,000 clinicians will participate in the QPP program through the Advanced APMs Path.

6. Less Frequent Collection

If data on the quality, advancing care information, and improvement activities 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, improvement activities, or advancing care information measures,

³ For further detail on MIPS exclusions, see Supporting Statement B and the Regulatory Impact Analysis Section of the CY 17 Quality Payment Program final rule.

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, improvement activities, 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. <u>Special Circumstances</u>

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 CY 17 Quality Payment Program proposed rule served as the 60-day Federal Register notice which posted for public inspection on April 27, 2016 and published on May 9, 2016 (81 FR, RIN 0938-AS69, CMS-5517-P). We received several comments regarding to our burden estimates. Several commenters were supportive of the streamlining and simplification of data submission requirements under MIPS, and several commenters recommended further streamlining and simplification. Several commenters believed that the burden estimates should be higher to reflect the time required to become familiar with the new data collection requirements, and two commenters noted that more skilled staff were needed to review the quality measure specifications than assumed in the proposal.

The CY 17 Quality Payment Program final rule served as the 30-day Federal Register notice

which posted for public inspection on October 14, 2016 and published on November 4, 2016 (81 FR 77008 through 77831, RIN 0938-AS69, CMS-5517-P). The CY 17 Quality Payment Program final rule's data submission requirements were further streamlined and simplified in response to public comments. As a result of this additional streamlining and simplification of data submission requirements and adjustments in estimates to better reflect this rule's emphasis on group reporting, the total burden estimate has been reduced between the CY 17 Quality Payment Program proposed rule and CY 17 Quality Payment Program final rule. In addition, the several key assumptions were updated in response to public comments, including increasing the amount of clinician time needed to review new quality measure specifications, and factoring in the need for more skilled staff to review measure specifications. No additional comments were received regarding the burden estimates in the CY 17 Quality Payment Program final rule.

9. Payments/Gifts to Respondents

There will be no payments/gifts to respondents. We will use this data to assess MIPS eligible clinician's performance in the MIPS performance categories, calculate the final score, and calculate positive and negative payment adjustments based on the final score.

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 and the Privacy Act of 1974), and will be protected from release by CMS to the extent allowable by law and consistent with 5 U.S.C. § 552a(b).

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' (BLS) May 2015 National Occupational Employment and Wage Estimates. 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, physicians, practice administrators, and licensed practical nurses as derived from this data. We believe these are the primary positions that will be

involved in the collection and reporting of information under this regulation. We have adjusted these employee hourly wage estimates by a factor of 100 percent to reflect current HHS department-wide guidance on estimating the cost of fringe benefits and overhead. 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 reasonable estimation methods. In addition, to calculate beneficiary time costs, we have used wage estimates for Civilian, all occupations, using the same BLS data discussed above. We have not adjusted these costs for fringe benefits and overhead because direct wage costs represent the "opportunity cost" to beneficiaries themselves for time spent in health care settings.

Occupation Title	Occupational Code	Mean Hourly Wage (\$/hr.)	Fringe Benefits and Overhead (\$/hr.)	Adjusted Hourly Wage (\$/hr.)
Billing and Posting Clerks	43-3021	\$17.60	\$17.60	\$35.20
Computer Systems Analysts	15-1121	\$43.36	\$43.36	\$86.72
Physicians	29-060	\$97.33	\$97.33	\$194.66
Practice Administrator	11-91111	\$50.99	\$50.99	\$101.98
Licensed Practical Nurse (LPN)	29-2061	\$21.17	\$21.17	\$42.34
Civilian, All Occupations	Not applicable	\$23.23	N/A	\$23.23

TABLE 3: Adjusted Hourly Wages Used in Burden Estimates

Source: "Occupational Employment and Wage Estimates May 2015," U.S. Department of Labor, Bureau of Labor Statistics. <u>http://www.bls.gov/oes/current/oes_nat.htm</u>

<u>12.1 Framework for Understanding the Burden of MIPS Data Submission</u>

Because of the wide range of information collection requirements under MIPS, Table 4 presents a framework for understanding how the organizations permitted or required to submit data on behalf of clinicians varies across the types of data, and whether the clinician is a MIPS eligible clinician, MIPS APM participant, or an Advanced APM participant. As shown in the first row of Table 4, MIPS eligible clinicians that are not in MIPS APMs and other clinicians voluntarily submitting data will submit data either as individuals or groups to the quality, advancing care information, and improvement activities performance categories, either on their own or through the services of a qualified registry, QCDR or EHR.

For MIPS APMs, the organizations submitting data on behalf of participating MIPS eligible clinicians will vary across categories of data, and in some instances across APMs. For the performance period in 2017, the quality data submitted by Shared Savings Program Accountable Care Organizations (ACOs) and Next Generation ACOs on behalf of their participants will fulfill both MIPS submission requirements for the quality performance category. For the advancing care information performance category, billing TINs will submit data on behalf of participants who are MIPS eligible clinicians. For the improvement activities performance category, we will assume no reporting burden for MIPS APM participants because CMS will assign the improvement activities performance category score at the MIPS APM level and all APM Entity groups in the same MIPS APM will receive the same score. Advanced APM participants who are determined to be Partial QPs will be required to submit elections as to whether they will participate in MIPS.

	Type of Data Submitted			
Category of	Quality Performance	Advancing Care	Improvement	Partial QP
Clinician	Category	Information	Activities	Election
		Performance	Performance	
		Category	Category	
MIPS Eligible	As groups or	As groups or	As groups or	Not applicable.
Clinicians (not in	individuals.	individuals.	individuals.	
MIPS APMs)				
And other				
clinicians				
voluntarily				
submitting data				
Eligible	ACOs submit to the	Each TIN in the	CMS will assign the	Advanced APM
Clinicians	CMS Web Interface	APM Entity reports	same improvement	Entities will make
participating in	on behalf of their	advancing care	activities performance	election for
the Shared	participating MIPS	information to	category score to each	participating MIPS
Savings Program	eligible clinicians.	$MIPS^4$	APM Entity based on	eligible clinicians.
			the activities involved	
			in participation in the	
			Shared Savings	
			Program. *	
			[The burden estimates	
			assume no	
			improvement activity	
			reporting burden for	
			APM participants]	
			- F	

TABLE 4: Clinicians or Organizations Submitting MIPS Data On Behalf of Clinicians, byType of Data and Category of Clinician

⁴ For MIPS APMs other than the Shared Savings Program, both group and individual clinician advancing care information data will be accepted. If both group and individual scores are submitted for the same MIPS APM Entity, CMS would take the higher score for each TIN/NPI. The TIN/NPI scores are then aggregated for the APM Entity score.

	Type of Data Submitted			
Category of	Quality Performance	Advancing Care	Improvement	Partial QP
Clinician	Category	Information	Activities	Election
		Performance	Performance	
		Category	Category	
Eligible	ACOs submit to the	Each MIPS eligible	CMS will assign the	Advanced APM
Clinicians in the	CMS Web Interface	clinician in the	same improvement	Entities will make
Next Generation	on behalf of their	APM Entity reports	activities performance	election for
ACO Model	participating MIPS	advancing care	category score to each	participating
	eligible clinicians	information to	APM Entity based on	eligible clinicians.
		MIPS through either	the activities involved	
		group TIN or	in participation in the	
		individual reporting	Next Generation ACO	
		[The burden	Model. *	
		estimates assume	[The burden estimates	
		TIN-level	assume no	
		reporting.]	improvement activities	
		1 0 -	reporting burden for	
			APM participants]	
Eligible	The APM Entity	Each MIPS eligible	CMS will assign the	Advanced APM
Clinicians	would not be assessed	clinician in the	same improvement	Entities will make
participating in	on quality under	APM Entity reports	activities performance	election for
MIPS APMs	MIPS in the first	advancing care	category score to each	participating
other than the	performance period.	information to	APM Entity based on	eligible clinicians.
Shared Savings	The APM Entity	MIPS through either	the activities involved	
Program or Next	would submit quality	group TIN or	in participation in the	
Generation ACO	measures to CMS	individual reporting	MIPS APM.*	
Model	required by the APM.	[The burden	[The burden estimates	
		estimates assume	assume no	
	[No burden for	TIN-level	improvement activities	
	submitting MIPS	reporting.]	performance category	
	quality data]		reporting burden for	
			APM participants]	
			FPuntol	
	imata far Ovality Dat			l

<u>12.2</u> Burden Estimate for Quality Data Submission by Individual MIPS Eligible Clinicians and Groups: Reporting in General

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 in, but will not be subject to MIPS payment adjustments. Based on 2015 data from the PQRS and other CMS sources⁵, we estimate that up to 611,876 (or 88 percent of) MIPS eligible clinicians will submit quality performance category data including those participating as groups. Historically, the PQRS has never experienced 100 percent participation; the participation rate for 2014 was 63 percent. For purposes of these analyses, we assume that clinicians who participated in the 2015

⁵ The other data sources include 2014 QRUR data, NPPES, and Medicare Part B claims data from 2014 and 2015.

PQRS will continue to submit quality data under MIPS as either MIPS eligible clinicians or voluntary reporters. We also assume that the number of MIPS eligible clinicians will be the same in the transition year as it was in our estimate based on 2015 data. Similarly, we assume that the population of clinicians excluded from MIPS will be the same size in 2017 as it was in our 2015 data. We anticipate that the professionals submitting data voluntarily will include Medicare clinicians that are ineligible clinician. ⁶ Based on those assumptions, we estimate that an additional 296,776 clinicians, or 44 percent of clinicians excluded from MIPS, will submit MIPS quality data voluntarily.

Our burden estimates for quality data submission combine the burden for MIPS eligible clinicians and other clinicians submitting data voluntarily. We assume clinicians will continue to submit quality data under the same submission mechanisms that they used under the 2015 PQRS. Using the 2015 PQRS counts of individuals and groups submitting through various mechanisms, we assume that 332,729 clinicians will submit as individuals through claims submission mechanisms; 258,993 clinicians will submit as individuals or groups through qualified registry or QCDR submission mechanisms; 105,987 clinicians will submit as individuals or groups through EHR submission mechanisms; and 107,884 clinicians will submit as groups through CMS Web Interface. We also assume that clinicians that submitted quality data as groups under the 2015 PQRS will continue to do so under the MIPS first performance year. Specifically, we assume that 2,678 groups will submit data via QCDR and registry submission mechanisms on behalf of 139,772 clinicians; 903 groups will submit via EHR submission mechanisms on behalf of 54,460 eligible clinicians; and 299 groups will submit data via the CMS Web Interface on behalf of 107,884 clinicians. For CMS Web Interface submission by Shared Savings Program ACOs and Next Generation ACOs, we assume that the 2017 counts of APM Entities and their participants will be the same as the 2016 counts. Specifically, we assume that 433 Shared Savings Program ACOs will submit on behalf of 140,341 participants and 18 Next Generation ACOs will submit on behalf of 24,144 participants.⁷

For clinicians or groups, the burden associated with the requirements of the MIPS quality performance category is the time and effort associated with clinicians identifying applicable quality measures, and submission of the measures.

The burden estimates were revised to reflect differences between the policies established in the CY 17 Quality Payment Program final rule and those proposed in the CY 17 Quality Payment Program proposed rule. In addition, the burden estimates were revised in response to public comments about the underlying assumptions, which are discussed at the end of this subsection. As a result of these revisions, the gross burden estimate in the CY 17 Quality Payment Program proposed rule was 12,493,654 burden hours with an associated burden cost of

⁶ The category 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. See Table 57 in Regulatory Impact Analysis section of the CY 17 Quality Payment Program final rule for additional details on the estimated counts of clinicians excluded from or ineligible for MIPS.

⁷ he counts of clinicians submitting quality data through the various submission mechanisms are not mutually exclusive because some clinicians submit through more than one mechanism.

\$1,327,177,693 (81 FR 28362). The finalized burden estimates are 10,903,147 burden hours with an associated burden cost of \$1,310,208,850. These finalized burden estimates are exclusive of the CAHPS for MIPS survey which was submitted for approval under OMB Control Number 0938-1222.

Several differences between the revised policies set forth in the CY 17 Quality Payment Program final rule and the policies in the CY 17 Quality Payment Program proposed rule are reflected in the burden estimates, including the reduction in the number of required advancing care information measures from eleven to five and the reduction in the number of recommended improvement activities from six to four. The burden estimates also reflect a simplification of the data submission requirements for MIPS APM participants. Specifically, the CY 17 Quality Payment Program final rule does not generally require MIPS APM participants to submit improvement activities data, whereas the CY 17 Quality Payment Program proposed rule did. For the advancing care information performance category, the CY 17 Quality Payment Program final rule establishes the capability for participants in MIPS APMs other than the Shared Savings Program to submit data at the billing TIN level. In contrast, we had proposed that participants in Shared Savings Program ACOs submit advancing care information data at the billing TIN level and participants in other MIPS APMs submit advancing care information data at the individual clinician level.

Finally, under the revised policy set forth in the CY 17 Quality Payment Program final rule, Advanced APM participants will be notified about their QP or Partial QP status before the end of the performance period, whereas in the CY 17 Quality Payment Program proposed rule, Advanced APM participants would not have been notified of their QP or Partial QP status until after the end of the submission period. Due to the timing of the QP and Partial QP status data, the CY 17 Quality Payment Program proposed rule's burden estimates assumed that all Advanced APM Entities would be required to submit Partial QP election data. In the CY 17 Quality Payment Program final rule, we assume the vast majority of Advanced APM participants will not be required to submit Partial QP election data.

In addition to policy differences between the CY 17 Quality Payment Program proposed rule and CY 17 Quality Payment Program final rule, the burden estimates also reflect changes in methods. In response to public comments, we have changed our assumptions about the number of hours and skill mix of labor needed to review quality measure specifications. We have also changed our assumptions to more accurately reflect the efficiency gains from group reporting. In the CY 17 Quality Payment Program proposed rule, we assumed that the burden per clinician was the same whether they submitted as an individual or as part of a group. In the CY 17 Quality Payment Program final rule's burden estimates, we calculate the burden at the level of the respondent (group or individual clinician) submitting data, and assume the average burden per respondent is the same.

These burden estimates have some limitations. We believe it is difficult to quantify the burden accurately because clinicians and groups may have different processes for integrating quality data submission into their practices' work flows. Moreover, the time needed for a clinician to review quality measures and other information, select measures applicable to their patients and the services they furnish, and incorporate the use of quality data codes into the office workflows is expected to vary along with the number of measures that are potentially applicable to a given clinician's practice. Further, the final burden estimates are based on historical rates of participation in the PQRS program, and the rate of participation in MIPS are expected to differ.

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

We anticipate that clinicians and groups using claims, QCDR and registry, and EHR submission mechanisms will have the same start-up costs related to reviewing measure specifications. As such, we estimate for clinicians and groups using any of these three submission mechanisms a total of 8 staff hours needed to review the quality measures list, review the various submission options, select the most appropriate submission option, identify the applicable measures or specialty measure sets for which they can report the necessary information, review the measure specifications for the selected measures or measures group, and incorporate submission of the selected measures or specialty measure sets into the office work flows. Building on data in a recent Health Affairs article (Casalino et al, 2016) http://content.healthaffairs.org/content/35/3/401.abstract we assume that a range of expertise is needed to review quality measures: 3 hours of an administrator's time, 2 hours of a clinician's time, 1 hour of a LPN/medical assistant's time, 1 hour of a computer systems analyst's time, and 1 hour of a billing clerk's time.⁸ We estimate that the start-up cost for a MIPS eligible clinician's practice to review measure specifications is \$730.40, including 3 hours of an practice administrator's time (3 hours X \$101.98 = \$305.94), 2 hours of a clinician's time (2 hours X \$182.46/hour = \$346.92), 1 hour of a LPN/medical assistant's time (1 hour X \$42.34), and 1 hour of a billing clerk's time (1 hour X \$35.20/hour = \$35.20). These start-up costs pertain to the specific quality submission methods below, and hence appear in the burden estimate tables.⁹

For the purposes of our burden estimates for the claims, registry and QCDR, and EHR submission mechanisms, we also assume that, on average, each clinician or group will submit six quality measures. Given the lack of historical data on MIPS, it is difficult to estimate the number of physicians who will voluntary elect to test this system by submitting fewer than the six measures required for many clinicians. We believe that the number of clinicians and groups that submit fewer than six measures as they gain experience with the new system may be balanced out by the number of clinicians and groups that continue to submit more than six measures because they were required to submit nine measures under the PQRS.

⁸ Our burden estimates are based on prorated versions of the estimates for reviewing measure specifications in 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. The estimates were annualized to 50 weeks per year, and then prorated to reflect that Medicare revenue is 30% of all revenue paid by insurers, and then adjusted d to reflect that the decrease from 9 required quality measures under PQRS to 6 required measures under MIPS. 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 because the CMS Web Interface measures are very similar to the GPRO Web Interface measures used in the 2016 PQRS.

The revised quality performance requirements and burden estimates were submitted along with all other ICRs listed below under a new OMB control number (0938-1314). Given that in the first year of implementation CAHPS for MIPS is replacing and using the same questions as CAHPS for the PQRS, the CAHPS for MIPS performance requirements and burden estimates were submitted as a request for continuation of OMB control number (0938-1222), CAHPS for PQRS.

12.2.1 Burden for Quality Data Submission by Clinicians: Claims-Based Submission

As noted above, we assume that 332,729 individual clinicians will submit quality data via claims based on 2015 PQRS data. We anticipate the claims submission process for MIPS will be operationally similar to the way it functioned under the PQRS. Specifically, clinicians will need to gather the required information, select the appropriate quality data codes (QDCs), and include the appropriate QDCs on the claims they submit for payment. 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 of claims-based submission will vary along with the volume of claims on which the submission is based. Based on our experience with the PORS, we estimate that the burden for submission of quality data will range from 0.22 hours to 10.8 hours per clinician. The wide range of estimates for the time required for a clinician to submit quality measures via claims reflects the wide variation in complexity of submission across different clinician quality measures. As shown in Table 5, we also estimate that the cost of quality data submission using claims will range from \$19.08 (0.22 hours X \$86.72) to \$936.58 (10.8 hours X \$86.72). The total estimated annual cost per clinician ranges from the minimum burden estimate of \$878.60 to a maximum burden estimate of \$1,796.10. The burden will involve becoming familiar with MIPS data submission requirements. We believe that the start-up cost for a clinician's practice to review measure specifications total 8, which includes 3 hours of a practice administrator's time (3 hours X \$101.98 = \$305.94), 2 hours of a clinician's time (2 hours X \$194.66/hour = \$389.32), 1 hour of a LPN/medical assistant's time (1 hour X \$42.34 = \$42.34), 1 hour of a computer systems analyst's time (1 hour X \$86.72 = \$86.72), and 1 hour of a billing clerk's time (1 hour X \$35.20/hour = \$35.20). These start-up costs pertain to the specific quality submission methods below, and hence appear in the burden estimate tables.

Considering both data submission and start-up costs, the total estimated burden hours per clinician ranges from a minimum of 8.22 hours (0.22 + 3 + 2 + 1 + 1 + 1) to a maximum of 18.8 hours (10.8 + 3 + 2 + 1 + 1 + 1). The total estimated annual cost per clinician ranges from the minimum estimate of \$878.60 (\$19.08 + \$305.94 + \$389.32 + \$42.34 + \$86.72 + \$35.20) to a maximum estimate of \$1,796.10 (\$936.58 + \$305.94 + \$389.32 + \$42.34 + \$86.72 + \$35.20). Therefore, total annual burden cost is estimated to range from a minimum burden estimate of \$292,335,167 (332,729 X \$878.60) to a maximum burden estimate of \$597,613,226 (332,729 X \$1,796.10).

Based on the assumptions discussed above, Table 5 summarizes the range of total annual burden associated with clinicians using the claims submission mechanism.

TABLE 5: Burden Estimate for Quality Performance Category: Clinicians Using theClaims Submission Mechanism¹⁰

	Minimum Burden Estimate	Median Burden Estimate	Maximum Burden Estimate
Estimated # of Participating Clinicians (a)	332,729	332,729	332,729
Burden Hours Per Clinician to Submit Quality Data (b)	0.22	1.58	10.8
Estimated # of Hours Practice Administrator Review Measure Specifications (c)	3	3	3
Estimated # of Hours Computer Systems Analyst Review Measure Specifications (d)	1	1	1
Estimated # of Hours LPN Review Measure Specifications (e)	1	1	1
Estimated # of Hours Billing Clerk Review Measure Specifications (f)	1	1	1
Estimated # of Hours Physician Review Measure Specifications (g)	2	2	2
Estimated Annual Burden hours per Clinician (h) = (b)+(c)+(d)+(e)+(f)+(g)	8.22	9.58	18.8
Estimated Total Annual Burden Hours (i) = (a)*(h)	2,735,032	3,187,544	6,255,305
Estimated Cost Per Clinician to Submit Quality Data (@ computer systems analyst's labor rate of \$86.72/hr.) (j)	\$19.08	\$137.02	\$936.58
Estimated Cost Practice Administrator Review Measure Specifications (@ practice administrator's labor rate of \$101.98/hr.) (k)	\$305.94	\$305.94	\$305.94
Estimated Cost Computer System's Analyst Review Measure Specifications (@ computer systems analyst's labor rate of \$86.72/hr.) (1)	\$86.72	\$86.72	\$86.72
Estimated Cost LPN Review Measure Specifications (@ LPN's labor rate of \$42.34/hr.) (m)	\$42.34	\$42.34	\$42.34
Estimated Cost Billing Clerk Review Measure Specifications (@ clerk's labor rate of \$35.2/hr.) (n)	\$35.20	\$35.20	\$35.20
Estimated Cost Physician Review Measure Specifications (@ physician's labor rate of \$194.66/hr.) (p)	\$389.32	\$389.32	\$389.32
Estimated Total Annual Cost Per Eligible Clinician (q) = $(j)+(k)+(l)+(m)+(n)+(p)$	\$878.00	\$996.54	\$1,796.10
Estimated Total Annual Burden Cost (r) = (a)*(q)	\$292,335,167	\$331,576,959	\$597,613,226

¹⁰ In Tables 5-15, the numbers have been truncated to two decimals for readability.

<u>12.2.2 Burden for Quality Data Submission by Clinicians and Groups Using Qualified Registry</u> and QCDR Submissions

As noted above, we assume that 258,993 clinicians will submit quality data as individuals or groups via qualified registry or QCDR submissions based on 2015 PQRS data. Of these, we expect 119,201 clinicians to submit as individuals and 2,678 groups are expected to submit on behalf of the remaining 139,792 clinicians. Given that the number of measures required is the same for clinicians and groups, we expect the burden to be the same for each respondent submitting data via qualified registry or QCDR, whether the clinician is participating in MIPS as an individual or group.

We estimate that burdens associated with QCDR submissions are similar to the burdens associated with qualified registry submissions. Therefore, we discuss the burden for both data submissions together below. For qualified registry and QCDR submissions, we estimate an additional time burden for respondents (clinicians and groups) to become familiar with MIPS submission requirements and, in some cases, new specialty measure sets. Therefore, we believe that the start-up cost for an individual clinician or group to review measure specifications and report quality data to total \$1,126.88. This total includes 3 hours per respondent to submit quality data (3 hours X \$86.72/hour = \$260.16), 3 hours of a practice administrator's time (3 hours X \$101.98/hour = \$\$305.94), 2 hours of a clinician's time (2 hours X \$194.66/hour=\$389.32), 1 hour of a computer systems analyst's time (1 hour X \$86.72/hour = \$86.72), 1 hour of LPN/medical assistant's time, (1 hour X \$42.34/hour = \$42.34), and 1 hour of a billing clerk's time (1 hour X \$35.20/hour = 35.20). 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 authorizing or instructing the quality registry or QCDR to submit this data will be approximately 5 minutes (0.083 hours) per clinician or group (respondent) for a total burden cost of \$7.20, at a computer systems analyst's labor rate (.083 hours X \$86.72/hour). Hence, we estimate 11.083 burden hours per respondent, with annual total burden hours of 1,350,785 (11.083 burden hours X 121,879 respondents). The total estimated annual cost per respondent is estimated to be approximately \$1,126.88. Therefore, total annual burden cost is estimated to be \$137,342,735 (121,879 X \$1,126.88). Based on these burden requirements and the number of clinicians and groups historically using the Qualified Registry and QCDR submissions, we have calculated a burden estimate for these submissions:

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

	Burden Estimate
# of Clinicians submitting via QCDR or registry (a)	258,933
# of Clinicians submitting as individuals (b)	119,201
# of Groups submitting via QCDR or registry on behalf of individual	
clinicians (c)	2,678
# of Respondents (groups plus clinicians submitting as individuals)	
(d)=(b)+(c)	121,879
Estimated Burden Hours Per Respondent to Submit Quality Data (e)	3
Estimated # of Hours Practice Administrator Review Measure	3
Specifications (f)	3
Estimated # of Hours Computer Systems Analyst Review Measure	1
Specifications (g)	1
Estimated # of Hours LPN Review Measure Specifications (h)	1
Estimated # of Hours Billing Clerk Review Measure Specifications (i)	1
Estimated # of Hours Physician Review Measure Specifications (j)	2
Estimated # of Hours Per Respondent to Authorize Qualified Registry	0.083
to Report on Respondent's Behalf) (k)	0.005
Estimated Annual Burden Hours Per Respondent (l)= (e)+(f)+(g)	11.083
+(h)+(i)+(j)+(k)	11.005
Estimated Total Annual Burden Hours (m) = (d)*(l)	1,350,785
Estimated Cost Per Respondent to Submit Quality Data (@ computer	\$260.16
systems analyst's labor rate of \$86.72/hr.) (n)	\$200:10
Estimated Cost Practice Administrator Review Measure	
Specifications (@ practice administrator's labor rate of \$101.98/hr.)	\$305.94
(p)	
Estimated Cost Computer System's Analyst Review Measure	
Specifications (@ computer systems analyst's labor rate of	\$86.72
\$86.72/hr.) (q)	
Estimated Cost LPN Review Measure Specifications (@ LPN's labor	\$42.34
rate of \$42.34/hr.) (r)	ψτ2.3τ
Estimated Cost Billing Clerk Review Measure Specifications (@	\$35.20
clerk's labor rate of \$35.2/hr.) (s)	\$55.20
Estimated Cost Physician Review Measure Specifications (@	\$389.32
physician's labor rate of \$194.66/hr.) (t)	\$00 3. 52
Estimated Burden for Submission Tool Registration etc. (@ computer	\$7.20
systems analyst's labor rate of \$86.72/hr.) (u)	\$7.20
Estimated Total Annual Cost Per Respondent (v) = $(n)+(p)+(q)+(r)+$	\$1,126.88
(s)+(t)+(u)	
Estimated Total Annual Burden Cost (m) = (a)*(v)	\$137,342,735

12.2.3 Burden for Quality Data Submission by Clinicians and Groups: EHR Submission

As noted above, based on 2015 PQRS data, we assume that 105,987 clinicians will submit quality data as individuals or groups via EHR submissions; 51,527 clinicians are expected to submit as individuals; and 903 groups are expected to submit on behalf of 54,460 clinicians. We expect the burden to be the same for each respondent submitting data via qualified registry or QCDR, whether the clinician is participating in MIPS as an individual or group.

Under the EHR submission mechanism, the individual 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 clinician's or group's behalf.

Based on our experience with the PQRS, we estimate that the time needed to perform all the steps necessary for clinicians or groups to submit quality performance measures includes the time to prepare for participating in quality performance category submissions for MIPS calculated at 8 hours of time to for reviewing specifications: (3 hours of a practice administrator's time, 2 hours of clinician's time, 1 hour of a LPN/medical assistant's time, plus 1 hour of a billing clerk's time). The time preparing for participating in EHR data submission also includes 1 hour for the respondent to obtain an account in the CMS identity management system plus 1 hour for submission of a test data file. This means the final step for quality data via an EHR submission mechanism is an additional 2 hours for data submission.

To prepare for the EHR submission mechanism, the clinician or group must review the quality measures on which we will be accepting MIPS data extracted from EHRs, select the appropriate quality measures, extract the necessary clinical data from their EHR, 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 clinician or group. We assume the burden for submission of quality measures data via EHR is similar for clinicians and groups who submit their data directly to CMS from their CERHT and clinicians and groups who use an EHR data submission vendor to submit the data on their behalf. To submit data to CMS directly from their CEHRT, clinicians and groups must have access to a CMS-specified identity management system which we believe takes less than 1 hour to obtain. Once a clinician or group has an account for this CMS-specified identity management system, they will need to extract the necessary clinical data from their EHR, and submit the necessary data to the CMS-designated clinical data warehouse. We estimate that obtaining a CMS-specified identity management system will require 1 hour per respondent for a cost of \$86.72 (1 hour X \$86.72/hour), and that submitting a test data file to CMS will also require 1 hour per respondent for a cost of \$86.72. With respect to submitting the actual data file, we believe that this will take clinicians or groups no more than 2 hours per respondent for a cost of submission of \$173.44 (2 hours X \$86.72/hour). The burden will involve becoming familiar with MIPS submission. We believe that the start-up cost for a clinician or group to review measure specifications total 8 hours, which includes 3 hours of a practice administrator's time (3 hours X \$101.98/hour =\$305.94), 2 hours of a clinician's time (2 hours X \$194.66/hour=\$389.32), 1 hour of a computer systems analyst's time (1 hour X \$86.72/hour = \$86.72), 1 hour of a LPN/medical assistant's time (1 hour X \$42.34/hour = \$42.34), and 1 hour of a billing clerk's time (1 hour X \$35.20/hour = \$35.20). Hence, we estimated 12 total burden hours per respondent with annual total burden hours of 629,160 (12 burden hours X 52,430 respondents). The total estimated annual cost per respondent is estimated to be \$1,206.40. Therefore, total annual burden cost is estimated to be \$63,251,552 (52,430 X \$1,206.40).

Based on these burden requirements and the number of clinicians and groups historically using the EHR submission mechanism, we have calculated a burden estimate for the quality data submission using EHR submission mechanism:

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

	Burden Estimate
# of Clinicians submitting via EHR (a)	105,987
# of Clinicians submitting as individuals (b)	51,527
# of Groups submitting via EHR on behalf of individual clinicians (c)	903
# of Respondents (groups plus clinicians submitting as individuals)	
(d)=(b)+(c)	52,430
Estimated Burden Hours Per Respondent to Obtain Account in CMS-	1
Specified Identity Management System (e)	1
Estimated Burden Hours Per Respondents to Submit Test Data File to	1
CMS (f)	I
Estimated Burden Hours Per Respondent to Submit MIPS Quality	2
Data File to CMS (g)	۷
Estimated # of Hours Practice Administrator Review Measure	3
Specifications (h)	5
Estimated # of Hours Computer Systems Analyst Review Measure	1
Specifications (i)	1
Estimated # of Hours LPN Review Measure Specifications (j)	1
Estimated # of Hours Billing Clerk Review Measure Specifications	1
(k)	
Estimated # of Hours Physician Review Measure Specifications (l)	2
Estimated Annual Burden Hours Per Respondent (m)=(e)+(f)+(g)	12
+(h)+(i)+(j)+(k)+(l)	
Estimated Total Annual Burden Hours (n)=(d)*(m)	629,160
Estimated Cost Per Respondent to Obtain Account in CMS-specified	
identity management system (@ computer systems analyst's labor	\$86.72
rate of \$86.72/hr.) (p)	
Estimated Cost Per Respondent to Submit Test Data File to CMS (@	\$86.72
computer systems analyst's labor rate of \$86.72/hr.) (q)	•
Estimated Cost Per Respondent to Submit Quality Data (@ computer	\$173.44
systems analyst's labor rate of \$86.72/hr.) (r)	
Estimated Cost Practice Administrator Review Measure	¢205.04
Specifications (@ practice administrator's labor rate of \$101.98/hr.)	\$305.94
(s)	
Estimated Cost Computer System's Analyst Review Measure	
Specifications (@ computer systems analyst's labor rate of $\frac{996}{72}$ (hp) (c)	¢06 70
\$86.72/hr.) (t) Estimated Cost LPN Review Measure Specifications (@ LPN's labor	\$86.72
rate of \$42.34/hr.) (u)	\$42.34
Estimated Cost Billing Clerk Review Measure Specifications (@	ψ42.04
clerk's labor rate of \$35.2/hr.) (v)	\$35.20
Estimated Cost Physician Review Measure Specifications (@	ψυυ.20
physician's labor rate of \$194.66/hr.) (w)	\$389.32
Estimated Total Annual Cost Per Respondent (x)=(p)+(q)+(r)+(s)	φυσυισε
+(t)+(u)+(v)+(w)	\$1,206.40
Estimated Total Annual Burden Cost (y)=(d)*(x)	\$63,251,552
	400,201,002

12.2.4 Burden for Quality Data Submission via CMS Web Interface

Based on 2015 PQRS data and 2016 Shared Savings Program and Next Generation ACO participation data, we assume that 750 organizations will submit quality data via the CMS Web Interface in the 2017 performance period (299 groups, 433 Shared Savings Program ACOs, and 18 Next Generation ACOs). Approximately 272,369 clinicians will be represented (107,885 clinicians not participating in ACOs; 140,341 Shared Savings Program participants, and 24,144 Next Generation ACO participants). Groups interested in participating in MIPS 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 1 hour of administrative staff time per group. The weighted average of the time required to register for the CMS Web Interface across all organizations is 0.40 hours (1 hour for each of the 299 groups and zero hours for each of the 433 Shared Savings Program ACOs or 18 Next Generation ACOs). We assume that a billing clerk will be responsible for registering the group and that therefore, this process has an average labor cost of \$35.20 per hour. Therefore, assuming the total burden hours per group associated with the group registration process is 1 hour, we estimate the total cost to a group associated with the group registration process to be approximately \$14.08. (\$35.20 per hour X 0.40 hours per group).

The burden associated with the group submission requirements under the CMS Web Interface is the time and effort associated with submitting data on a sample of the organization's beneficiaries that is prepopulated in the CMS Web Interface. Based on experience with PQRS GPRO Web Interface submission mechanism, we estimate that, on average, it will take each group 79 hours of a computer system analyst's time to submit quality measures data via the CMS Web Interface at a cost of \$86.72 per hour, for a total cost of \$6,850.88 (79 hours X \$86.72/hour).

Our estimate of 79 hours for submission includes the time needed for each group to populate data fields in the web interface with information on approximately 248 eligible assigned Medicare beneficiaries and then submit the data (CMS will partially pre-populate the CMS Web Interface with claims data from their Medicare Part A and B beneficiaries). The patient data can either be manually entered or uploaded into the CMS Web Interface via a standard file format, which can be populated by CEHRT. Because each group must provide data on 248 eligible assigned Medicare beneficiaries (or all eligible assigned Medicare beneficiaries if the pool of eligible assigned beneficiaries is less than 248), we are assuming that entering or uploading data for one Medicare beneficiary requires 19 minutes of a computer systems analyst's time (79 hours \div 248 patients).

We also estimate that for each organization (group or ACO) submitting data, a clinician will need to spend 1 hour per year to review quality measure specifications, for a total cost of \$194.66. The estimated time for reviewing quality measure specifications is lower than under the quality submission mechanisms because the CMS Web Interface measures are very similar to the GPRO Web Interface measures used in the 2016 PQRS. As mentioned above, we estimate it will

take an average of 0.40 hours for each organization to register to submit through the CMS Web Interface, for a total of cost of \$14.03 (0.40 X \$35.20). The cost of these 1.40 hours is included in the total estimated annual cost per organization of \$7,059.57. The total annual burden hours are estimated to be 60,299 (750 organizations X 80.40 annual hours), and the total annual burden cost is estimated to be \$5,294,680 (750 organizations X \$7.059.57).

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

-	
	Burden Estimate
Estimated # of Eligible Group Practices (a)	750
Estimated # of Burden Hours Per Group Practice to Self-Nominate to Participate in MIPS Under the Group Reporting Option (b)	0.40
Estimated # of Burden Hours Per Group to Report (c)	79
Estimated # of Burden Hours for Physician Familiarizing Self with MIPS Measures (d)	1
Estimated Total Annual Burden Hours Per Group (e) = $(b)+(c)+(d)$	80.40
Estimated Total Annual Burden Hours (f) = (a)*(e)	60,299
Estimated Cost Per Group Practice to Self-Nominate to Participate in MIPS Under the Group Reporting Option (@ clerk's labor rate of \$35.2/hr.) (g)	\$14.08
Estimated Cost Per Group to Report (@ computer systems analyst's labor rate of \$86.72/hr.) (h)	\$6,850.88
Estimated Cost for Physician Familiarizing Self with MIPS Measures (@ physician's labor rate of \$194.66/hr.) (i)	\$194.66
Estimated Total Annual Cost Per Group (j) = (g)+(h)+(i)	\$7,059.57
Estimated Total Annual Burden Cost (k) = (a)*(j)	\$5,294,680
	By Provider
Estimated # of Participating Eligible Professionals (l)	272,369
Average Burden Hours Per Eligible Professional (m) = (f) \div (l)	0.22
Estimated Cost Per Eligible Professional to Submit Quality Data (n) = $(k) \div (l)$	\$19

TABLE 8: Burden Estimate for Quality Performance CategoryGroup Submission via the CMS Web Interface

12.3 Burden for Qualified Registry and QCDR Self-Nomination¹¹

For CY 2016, 114 qualified registries and 69 QCDRs were qualified to report quality measures data to CMS for purposes of the PQRS, an increase from 98 qualified registries and 49 QCDRs in CY2015.¹² Under MIPS we believe that the number of QCDRs and qualified registries will continue to 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

¹¹ We do not anticipate any changes in the CEHRT process for health IT vendors as we transition to MIPS. Hence, health IT vendors are not included in the burden estimates for MIPS

¹² The full list of qualified registries for 2016 is available at <u>https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2016QualifiedRegistries.pdf</u> and the full list of QCDRs is available at <u>https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2016QCDRPosting.pdf</u>.

registries or QCDRs interested in submitting quality measures results and numerator and denominator data on quality measures to CMS on their participants' behalf will need to complete a self-nomination process in order to be considered qualified to submit on behalf of MIPS eligible clinicians or groups, unless the qualified registry or QCDR was qualified to submit on behalf of MIPS eligible clinicians or groups for prior program years and did so successfully.

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 1 hour per qualified registry or QCDR to complete the online self-nomination process. If technically feasible for the first MIPS performance period, qualified registries and QCDRs will submit self-nomination forms via web-based user interface. If web-based interface submission is not technically feasible, self-nomination information will be submitted via email. We estimate that either of these mechanisms will require the same amount of time for respondents. Appendix D is a screen shot of the online self-nomination form for qualified registries and QCDRs.

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 9 hours performing various other functions 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 their equivalent, who have an average labor cost of \$86.72/hour. Therefore, assuming the total burden hours per qualified registry or QCDR associated with the self-nomination process is 10 hours, the annual burden hours is 1,830 (183 QCDRs or qualified registries X 10 hours). We estimate that the total cost to a qualified registry or QCDR associated with the self-nomination process will be approximately \$867.20 (\$86.72 per hour X 10 hours per qualified registry). We also estimate that 183 new qualified registries or QCDRs will go through the self-nomination process leading to a total burden of \$158,697.60 (\$867.20 X 183).

The burden associated with the qualified registry and QCDR submission requirements in MIPS will be the time and effort associated with calculating quality measure results from the data submitted to the qualified registry or QCDR by its participants and submitting these results, the numerator and denominator data on quality measures, the advancing care information performance category, and improvement activities data to CMS on behalf of their participants. We expect that the time needed for a qualified registry to accomplish these tasks 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 participants. 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 data submission 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 selfnominating to be considered "qualified" for the purpose of submitting quality measures results and numerator and denominator data on MIPS eligible clinicians.

	Burden Estimate
Estimated # of Qualified registries or QCDRs Self-Nominating for the PQRS (a)	183
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)	1,830
Estimated Cost Per Qualified registry or QCDR (@ computer systems analyst's labor rate of	\$867.20
\$86.72/hr.) (d)	
Estimated Total Annual Burden Cost for Qualified registries or QCDRs (e) = (a)*(d)	\$158,697.60

TABLE 9: Burden Estimate for QCDR and Registry Self Nomination

12.4 Burden for Advancing Care Information Performance Category Data Submission

During the transition year, clinicians and groups can submit advancing care information data through qualified registry, QCDR, EHR, CMS Web Interface, and attestation data submission methods. Also, we have streamlined the submission requirements for advancing care information under the MIPS. Compared 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 have also worked to align the advancing care information performance category with other MIPS performance categories, such as submitting eCQMs to the quality category, which will streamline submission requirements and reduce MIPS eligible clinician confusion. In addition, as part of our efforts to align and streamline submission requirements, we are providing a group reporting option (which did not exist under the Medicare EHR Incentive Program). Hence, a MIPS eligible clinician's estimated burden for the advancing care information performance category is lower than the estimated 7 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 eligible clinicians in the Medicare EHR Incentive Program Stage 3 PRA.¹³

As noted, billing TINs may report advancing care information performance category data on behalf of MIPS eligible clinicians in MIPS APMs, or, except for participants in the Shared Savings Program, MIPS eligible clinicians in MIPS APMs may report advancing care information performance category data individually. Because billing TINs in APM Entities will be report advancing care information performance category data to fulfill the requirements of submitting to MIPS, we have included MIPS APMs in our burden estimate for the advancing care information performance category. Consistent with the proposed list of APMs that are MIPS APMs in the CY 17 Quality Payment Program proposed rule, we assume that three MIPS

¹³We 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.

APMs that do not also qualify as Advanced APMs will operate in the first performance period: Track 1 of the Shared Savings Program, Comprehensive ESRD Care Initiative (CEC) (non-LDO track), and OCM (Oncology Care Model).

Performance Category Data on Benalf of Eligible Clinicians						
Category of Clinician	Available Mechanisms for	Estimated Number of				
	Submission	Organizations Submitting Data				
MIPS Eligible Clinicians (not in APMs)	As groups or individuals.	503,457 clinicians submitting as individuals. 3,880 groups submitting on behalf of 194,192 clinicians				
MIPS Eligible Clinicians participating in the Shared Savings Program	Each TIN in the APM Entity group reports advancing care information to MIPS through group TIN reporting	14,384 billing TINs representing 140,341 participants in 433 Shared Savings Program ACOs.				
MIPS Eligible Clinicians participating in MIPS APMs other than the Shared Savings Program	Each MIPS eligible clinician in the APM Entity group reports advancing care information to MIPS through either group TIN or individual reporting [The burden estimates assume TIN- level reporting.]	 33 Billing TINs representing 1 APM Entity in CEC (non-LDO arrangement) 6,478 Billing TINS representing 195 APM Entities in OCM 				
Total Number of Organizations and Individuals Submitting Data		528,231 respondents				

TABLE 10 Estimated Numbers of Organizations Submitting Advancing Care InformationPerformance Category Data on Behalf of Eligible Clinicians

Because performance year 2017 will be the first year for clinicians to report the advancing care information performance category data as groups, there is considerable uncertainty about what number of clinicians will report as part of a groups. Given the limitations of historical 2015 EHR Incentive Program data, some of our burden estimate's assumptions are based on 2015 PQRS data. Specifically, we assume that the number of individual clinicians and groups submitting advancing care information 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 individuals and 3,880 groups submitting data on behalf of 194,192 clinicians. Further we anticipate that the 433 Shared Savings Program ACOs will submit data at the ACO participant billing TIN level, for a total of 14,384 billing TINS representing 140,341 participants. We anticipate that the APM Entity in the CEC model non-LDO track (at the time of publication, there is only one APM Entity in this track) 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 OCM will submit at the billing TIN level, for an estimated 6,478 billing TINs submitting data. Hence, as shown in Table 11, we estimate that up to approximately 528,231 respondents will be submitting data under the advancing care information performance category (503,457 MIPS eligible clinicians + 3,880 groups submitting on behalf of clinicians +

14,384 billing TINs within the Shared Savings Program ACOs + 33 billing TINs within the APM Entity participating in CEC non-LDO arrangement and 6,578 billing TINs within the OCM. The total burden hours for a clinician or group to report on the specified Advancing Care Information Objectives and Measures will be 3 hours. The total estimated burden hours are 1,584,694 (528,231 responses X 3 hours). At a clinician's hourly rate, the total burden cost is \$304,476,511 (1,584,694 hours X \$194.66/hour).

TABLE11: Total Estimated Burden for Advancing Care Information Performance
Category Data Submission

		Burden			
		per		Hourly	
		Response	Total Annual	Labor	
Respondents	Responses	(hours)	Burden (hours)	Cost (\$)	Total Burden Cost (\$)
528,231	528,231	3	1,584,694	\$194.66	\$308,476,511

Our burden estimates also reflect that some MIPS eligible clinicians will not need to submit advancing care information performance category measures. Clinicians who are hospital based, non-patient facing, Nurse Practitioners, Physician Assistants, Clinical Nurse Specialists, and Certified Registered Nurse Anesthetists are not required to submit information to have the category re-weighted to zero. Clinicians who have insufficient internet connectivity, extreme and uncontrollable circumstances, or lack of control over CEHRT availability can submit a brief application for reweighting providing information that has been defined in the CY 17 Quality Payment Program final rule. We assume that that individual clinicians or groups submitting reweighting applications would face a burden of three hours related to fulfilling the submission requirements for that application.

12.6 Burden for Improvement Activities Data Submission

Requirements for submitting improvement activities are new, and we do not have historical data which is directly relevant. As noted, a variety of organizations and in some cases, individual clinicians, will report improvement activity performance category data. For clinicians who are not part of APMs, we assume that the number of clinicians submitting improvement activities as part of a group will be approximately the same as the number of clinicians submitting PQRS data as part of a group through the QCDR and registry, EHR, and GPRO Web Interface submission mechanisms in 2015. As noted above, MIPS eligible clinicians participating in MIPS APMs do not need to report improvement activities data unless the CMS-assigned improvement activities score is below the maximum improvement activities score. We estimate that there could be as many as 503,547 clinicians submitting improvement activities performance category data as individuals, which is equal to the number of clinicians submitting as individuals using the claims, QCDR or qualified registry, or EHR submission mechanisms under the 2015 PQRS.¹⁴ We estimate that approximately 194,192 clinicians comprising 3,880

¹⁴ Because of the lack of historical data on improvement activities submission, our estimate of 595,100 eligible clinicians submitting improvement activities 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

groups may submit at the group level. The burden estimates assume no improvement activities reporting burden for MIPS APM participants. CMS will assign the improvement activities performance category score at the APM level; each APM Entity within the same MIPS APM will be assigned the same score.

TABLE 12: Estimated Numbers of Organizations Submitting Improvement Activities
Performance Category Data on Behalf of Eligible Clinicians

Category of Clinician	Available Mechanisms for	Estimated Number of Entities	
	Submission	Submitting Data	
MIPS Eligible Clinicians (not in APMs)	As groups or individuals.	3,880 groups representing 302,076 eligible clinicians. 503,337 eligible clinicians submitting individually.	
MIPS APM participants	No reporting burden	0	

During the transition year, clinicians and groups can submit data via qualified registry, QCDR, EHR, CMS Web Interface, or attestation data submission mechanisms. In addition to collecting necessary supporting documentation, each clinician and group, will provide a yes/no attestation submitted during the data submission period for successfully completed improvement activities. We estimate that up to approximately 507,457 groups or individuals (3,880 groups and + 503,337 individual clinicians) will be submitting data for improvement activities. We estimate it will take no longer than 2 hours per group or individual to submit data for the improvement activities performance category. The total estimated burden is 1,014,674 hours (507,337 groups or individuals X 2 hours each). At a physician's hourly rate, the total estimated burden cost is \$197,516,441(1,014,674 hours X \$194.66).

 TABLE 13: Total Estimated Burden for Improvement Activities Submission

		Burden			
		per		Hourly	
		Response	Total Annual	Labor	
Respondents	Responses	(hours)	Burden (hours)	Cost (\$)	Total Burden Cost (\$)
507,337	507,337	2	1,014,674	\$194.66	\$197,516,441

12.7 Burden for Cost Performance Category Data Submission

The cost performance category relies on administrative claims data. For claims-based submitting, the Medicare Parts A and B claims submission process is used to collect data on

data through QCDR or qualified registry + 77,241 eligible clinicians submitting quality data through EHR).

resource measures from MIPS eligible clinicians. MIPS eligible clinicians are not asked to provide any documentation by CD or hardcopy. Therefore, under the cost performance category, we do not anticipate any new or additional submission requirements for MIPS eligible clinicians.

12.8 Burden for Partial Qualifying Professional (QP) Election for Advanced APMs

Advanced APM Entities may face an additional submission requirement under MIPS related to Partial QP elections. The CY 17 Quality Payment Program final rule has changed the timing of when eligible clinicians in Advanced APMs receive notification about their Partial QP status, which reduced the burden estimates. Under the revised policy set forth in the CY 17 Quality Payment Program final rule, Advanced APM participants will be notified about their QP or Partial QP status before the end of the performance period, whereas in the CY 17 Quality Payment Program proposed rule, Advanced APM participants would not have been notified of their QP or Partial QP status until after the end of the submission period. If an Advanced APM Entity is notified its eligible clinicians are determined as a group to be Partial QPs, a representative from the Advanced APM Entity will log into the MIPS portal to indicate whether MIPS eligible clinicians determined to be Partial QPs wish to participants would meet the QP threshold, and that no participants would be determined as a group to be Partial QPs. Hence, we assume that no Advanced APM Entities will face the data submission requirement in the 2017 performance period.

In addition, Affiliated Practitioners participating as gainsharers in the CJR model and assessed individually for purposes of the QP determination may face a data submission requirement for Partial QP elections. Under the CY 17 Quality Payment Program proposed rule, we did not discuss the CJR model as potentially contributing to the burden for Partial QP elections. However, CMS has recently finalized changes to the CJR model in the final Advancing Care Coordination Through Episode Payment Models rule (82 FR 180 through651) that will allow the CJR model to meet the Advanced APM criteria. Because CMS will assess Affiliated Practitioners in the CJR model individually, Affiliated Practitioners must make a Partial QP election at the individual eligible clinician level if they are determined to be Partial QPs. We also estimate that CJR participants are much more likely to be Partial QPs than participants in other Advanced APMs. We therefore estimate that up to 12,800 individual participants in the CJR model may submit partial QP election data.

We estimate it will take each Advanced APM Entity representative or CJR model participant 15 minutes to make this election, and an additional 15 minutes to register for the MIPS Portal. As noted above, we assume that 12,800 participants in the CJR model and no Advanced APM Entities will make this election. Hence, we assume that 12,800 APM Entities' participants will make this election on the MIPS Portal, for a total burden estimate of 6,400 hours (12,800 participants X 0.5 hours). At a computer systems analyst's hourly labor cost, the total

¹⁵ If the Advanced APM Entity or CJR model participant chooses not to make the election, the default is for the clinicians meeting the partial QP threshold to opt out of MIPS.

burden cost of these elections is collectively estimated to be \$ 555,008 (6,400 X \$86.72/hour).

				-	
		Burden per	Total Annual	Hourly	
		Response	Burden	Labor	Total Burden
Respondents	Responses	(Hours)	(Hours)	Cost (\$)	Cost (\$)
12,800	12,800	0.5	6,400	\$86.72	\$555,008

TABLE 14: Total Estimated Burden for Partial QP Election

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 reweighting the advancing care information performance category scores for eligible clinicians that were exempt from the Medicare EHR Incentive Program or received hardship exemptions, additional requirements for EHR adoption would not be imposed during the first MIPS performance period. As we have stated with respect to the Medicare EHR Incentive Program for Eligible Professionals, 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 improvement activities performance category requirements could potentially lead to higher expenses for MIPS eligible clinicians. Costs per full-time equivalent MIPS eligible clinician for improvement activities 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 improvement activities, 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. Summary of Annual Burden Estimates

The total gross burden estimate includes the total burden of recordkeeping and data submission under MIPS. Table 15 provides an estimate of the total annual burden of MIPS of 10,903,147 hours and a total labor cost of reporting of \$1,310,208,8501. 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. The estimated total existing burden approved for information collections related to PQRS and the Medicare EHR Incentive Program (for EPs) was 11,914,510hours for a total labor cost of reporting of \$1,317,767,850. The net burden estimate reflects only the incremental burden associated with this CY 17 Quality Payment Program final rule, and excludes the burden of existing recordkeeping and data submission under the PQRS, the Medicare EHR Incentive Program, and CAHPS for PQRS,¹⁶ 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. The streamlining and simplification of data submission structures is reflected in our net burden estimates, which show a reduction in burden of --1,007,131 burden hours and -\$7,460,683 labor cost of reporting compared to the existing information collections.

¹⁶ The previously approved data collections OMB control numbers were as follows: PQRS (OCN 0938-1059), CAHPS for PQRS (OCN 0938-1222), and the Objectives/Measures (EP) ICR in the EHR Incentive Program Stage III PRA (OCN 0938-1278).

Section(s) in title 42 of	Respondents	Responses	Burden	Total	Labor	Total Annual
the CFR and Section of			per	Annual	Cost of	Burden Cost
Rule			Response	Burden	Reporting	(\$)
			(hours)	(hours)	(\$)	
§414.1330 and	332,729	332,729	18.8	6,255,305	Varies (see	597,613,226
§414.1335 (Quality					Table 5)	
Performance Category)						
Claims Submission						
Mechanism						
§414.1330 and	121,879	121,879	11.1	1,350,785	Varies (see	137,342,735
§414.1335 (Quality					Table 6)	
Performance Category)						
Qualified Registry or						
QCDR Submission Mechanisms						
§414.1330 and	52,430	52,430	12.0	629,160	Varies (See	63,251,552
§414.1335 (Quality	52,450	52,450	12.0	029,100		03,231,332
Performance Category)					Table 7)	
EHR- Submission						
Mechanism						
§414.1330 and	750	750	80.4	60,299	Varies (See	5,294,680
§414.1335 (Quality					Table 8)	
Performance Category)					rubic 0)	
CMS Web Interface						
Submission Mechanism						
§414.1400 (QCDR and	183	183	10.0	1,830	86.72	158,698
Registries) QCDR and						
qualified registry self-						
nomination						
§414.1375 (Advancing	528,231	528,231	3.0	1,584,694	194.66	308,476,511
Care Information						
Performance Category)					101.00	
§414.1360 (Improvement	507,337	507,337	2.0	1,014,674	194.66	197,516,441
Activities)	12,000	12,000	0.5	C 400	86.72	
\$414.1430 (Partial Qualifying APM	12,800	12,800	0.5	6,400	86.72	555,008
Participant (QP)						
election)						
§414.1400	132,307	132,307	0.3	43,661	23.23	1,014,252
(Quality Performance	102,007	102,007				1,017,202
Category)						
CAHPS for MIPS						
Total Gross Burden				10,947,453		
		1,556,339		10,903,147		1,310,208,850
Total Approved						1,317,767,850
Burden Under Previous		1,221,750		11,914,510		
Programs Tetel Net Develop						
Total Net Burden		-334 580		-1 011 262		-7 550 000
		-334,589		-1,011,363		-7,559,000

16. Publication and Tabulation Dates

To ensure that MIPS results are useful and accurate, CMS plans to provide performance feedback to MIPS eligible clinicians. No later than July 1, 2017, CMS will provide the first MIPS performance feedback which will provide historical quality and cost data.¹⁷. For year 2 of the Quality Payment Program, CMS intends to provide performance feedback for MIPS data collected in 2017. This data could potentially include all applicable data reflecting CY 2017 performance, including data on the quality and cost performance categories. This reflects our commitment to providing as timely information as possible to eligible clinicians in order to help them predict their performance in in MIPS.

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 some measures in 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 are requesting approval for this information collection for a period of 3 years. There are no paper forms involved in this data collection activity. The expiration date will be displayed on web-based data collection forms, including the CMS Web Interface, the web-based QCDR and qualified registry self-nomination form, and the web-based partial QP election form.

18. Certification Statement

There are no exceptions to the certification statement.

¹⁷ We may have MIPS eligible clinicians that will not have historical data available to produce performance feedback by July 1, 2017. For those eligible clinicians we will not be able to produce performance feedback, until these eligible clinicians submit data through the Quality Payment Program.