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

A. Background

The Merit-based Incentive Payment System (MIPS) is a program for certain eligible clinicians that makes Medicare payment adjustments based on performance on quality, cost and other measures and activities, and that consolidates components of three precursor programs—the Physician Quality Reporting system (PQRS), the Value Modifier (VM), and the Medicare Electronic Health Record (EHR) Incentive Program for eligible professionals. As prescribed by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), MIPS focuses on the following: quality – both a set of evidence-based, specialty-specific standards as well as practice-based improvement activities; cost; and use of Certified Electronic Health Record Technology (CEHRT) to support interoperability and advanced quality objectives in a single, cohesive program that avoids redundancies.

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), EHRs, and CMS-approved survey vendors.[2]

The CY 2018 Quality Payment Program proposed rule proposes several new flexibilities in terms of data collection. We are proposing to allow individual MIPS eligible clinicians, groups, and virtual groups to submit measures and activities through multiple submission mechanisms within a category as available and applicable to meet the requirements of the quality, advancing care information, and improvement activities performance categories. We do not anticipate the proposal for multiple submission mechanisms would result in an increase in burden in the quality performance category relative to the baseline continued transition year policies. We assume that the majority of MIPS eligible clinicians will submit using the mechanisms they have historically used to submit quality data under PQRS.

We are also proposing to add a virtual group participation option, which would be composed of solo practitioners and groups of 10 or fewer eligible clinicians who come together "virtually" with at least 1 such other practitioner or group to participate in MIPS for a

[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 (OMB Control Number 0938-1222).

performance period of a year. We expect an overall reduction in burden due to the formation of virtual groups because TINs or solo practitioners that would have had to independently submit data for all of the performance categories that are now part of a virtual group will be able to assign their data submission to just one virtual group representative.

For the quality and cost performance categories, we propose certain individual MIPS eligible clinicians and groups that furnish services in an in-patient hospital or emergency room may elect to participate in facility-based measurement during the performance period, and to be given a MIPS score in the quality and costs performance category based on their facility's data submission for the hospital value-based purchasing program. We anticipate an overall reduction in burden for clinicians and groups that elect facility-based measurement because we believe they will not submit additional measures under the quality performance category.

For the advancing care information performance category for the 2018 MIPS performance period, we are proposing two additional policies that we anticipate will reduce burden of data submission. We are proposing to allow MIPS eligible clinicians in small practices faced with a significant hardship to apply for a significant hardship exception and have the performance category reweighted to zero. We are also proposing to allow assigning a scoring weight of zero percent for the advancing care information performance category for MIPS eligible clinicians who are determined to be based in ambulatory surgical centers (ASCs).

The implementation of MIPS requires the collection of additional data beyond performance category data submission. Qualified registries and QCDRs must submit an online self-nomination form to CMS before they can submit data on behalf of eligible clinicians. Virtual group representatives must make an election on behalf of the members of their virtual group, regarding the formation of the virtual group prior to the start of the MIPS performance period. Facility-based clinicians and groups that opt to participate via facility-based measurement must make an online election. Clinicians, groups, and other relevant stakeholders may nominate new improvement activities using a nomination form provided on the Quality Payment Program website at qpp.cms.gov, and send their proposed new improvement activities to CMS via email. In addition, this information collection request includes two information collections relating to Advanced APMs.

We are requesting approval of 15 information collections associated with the CY 2018 Quality Payment Program proposed rule (other than virtual group election and Consumer Assessment of Healthcare Providers and Systems (CAHPS)-related data collection) as a revision to currently approved information requests submitted under OMB control number 0938-1314. CMS is requesting approval for two additional information collection requests associated with the CY 2018 Quality Payment Program proposed rule under separate OMB control numbers. CMS is requesting approval to collect a revised CAHPS for MIPS survey (version 2.0) via CMS-approved survey vendors in the revised CAHPS for MIPS Paperwork Reduction Act (PRA)

package (0938-1222). CMS is requesting approval for collection of information associated with the virtual group election process via a separate virtual group PRA package under a new OMB control number. We have invited public comments on the virtual group election process under a separate Federal Register Notice (82 FR 27257) published on June 14, 2017. Information collection comments related to virtual group election are due on or before August 14, 2017.

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 consider 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.

Most of the quality measures currently proposed for the CY 2018 MIPS performance period are the same as the CY 2017 quality measures and therefore we anticipate clinicians will be more familiar with the measures and submission processes in this second year. Under MIPS, the quality performance category performance requirements are as follows: the MIPS eligible clinician or group will report at least 6 measures including at least 1 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 6 measures apply to the individual MIPS eligible clinician, group, or virtual group, then the MIPS eligible clinician, group, or virtual group will be required to report on each measure that is applicable. MIPS eligible clinicians, groups, and virtual groups can meet this criterion by selecting measures either individually or from a specialty-specific measure set. The quality measures as finalized in the CY 2017 Quality Payment Program final rule are at https://qpp.cms.gov/measures/quality. The proposed changes to the quality performance category measures are listed in Appendix Tables Group A, Group B, C.1, C.2, D and E of the proposed rule.

b. Advancing Care Information Performance Category

Under MIPS, the use of CEHRT 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 to demonstrate they are meaningful users of CEHRT for a performance period, as defined in section 1848(o)(2) of the Act. Table 7 of the proposed rule provides a list of proposed advancing care information performance category objectives and measures.

Under the MIPS, each MIPS eligible clinician will be required to submit the required measures listed in Table 7 of the 2018 Quality Payment Program proposed rule (and at https://qpp.cms.gov/measures/aci) 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 2018 Advancing Care Information Transition Objective and Measure set. MIPS eligible clinicians and groups can submit advancing care information data via qualified registry, QCDR, EHR, CMS Web Interface, or attestation data submission mechanisms for the 2018 MIPS performance period.

As described in the proposed rule, we are proposing to allow MIPS eligible clinicians to apply for an exception due to a significant hardship or as a result of a decertified EHR and subsequently have their advancing care information performance category reweighted to zero. In the CY 2017 Quality Payment Program final rule (81 FR 77240 through 77243), we recognized that there may not be sufficient measures applicable and available under the advancing care information performance category to MIPS eligible clinicians facing a significant hardship, such as those who lack sufficient internet connectivity, face extreme and uncontrollable circumstances, lack control over the availability of CEHRT, or do not have face-to-face interactions with patients. We are proposing a new hardship exception for small practices with 15 or fewer clinicians.

In addition, we propose that MIPS eligible clinicians who are determined to practice primarily in a hospital or are based in an ASC will be assigned a scoring weight of zero percent for the category. We are proposing to rely on section 1848(o)(2)(D) of the Act, as amended by section 4002(b)(1)(B) of the 21st Century Cures Act, as our authority for these exemptions.

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. MIPS eligible clinicians and groups can submit data via qualified registry, QCDR, EHR, CMS Web Interface, or attestation submission mechanisms.

We created an inventory of improvement activities that includes 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.

MIPS eligible clinicians and groups must attest to improvement activities performed during the performance period that are selected from the proposed new improvement activities in Appendix Tables F and G in CY 2018 Quality Payment Program proposed rule, and https://qpp.cms.gov/measures/ia, which is the Improvement Activities Inventory that we finalized in the CY 2017 Quality Payment Program final rule

d. Cost Performance Category

Under MIPS, we refer to the resource use performance category as "cost." The 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.

e. Additional Data Collection

Under MIPS, there are information collections beyond performance category data submission. Other data submitted on behalf of MIPS eligible clinician include virtual group election, election for facility, based measurement, and registration for groups that are first-time uses of CMS Web Interface, and partial QP election.

The policies finalized in the CY 2017 Quality Payment Program final rule and proposed in this rule create some additional data collection requirements not listed in Table 2. These additional data collections, one of which was previously approved by OMB under control number 0938-1314, are as follows:

- Self-nomination of new and returning QCDRs and registries (0938-1314)
- Call for new improvement activities
- Other Payer Advanced APM identification: other payer initiated process
- Opt out of performance data display on Physician Compare for voluntary reporters under MIPS.

2. Data Collection related to Advanced APMs

This information request includes two information collections related to Advanced APMs. Advanced APM Entities will face a submission burden under MIPS related to Partial QP elections. Partial QPs will have the option to elect whether to report under MIPS, which determines whether they will be subject to MIPS scoring and payment adjustments. In the 2018 MIPS performance period, 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 2018, 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.

We are also proposing a payer-initiated identification process for identifying payment arrangements that qualify as Other Payer Advanced APMs. We are also proposing that in the 2019 Quality Payment Program performance year, we will allow clinicians the option of becoming QPs through a combination of Medicare participation and participation in Other Payer Advanced APMs.

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) 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 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. The 2015 PQRS Experience Report for example includes data on types of data submission problems or other data issues experienced and can be found at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2015_PQRS_Experience_Report.pdf

3. Use of Information Technology

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. The final data collection and associated burden for the PQRS and the Medicare EHR Incentive Programs for eligible professionals 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.

With respect to participating in MIPS for MIPS APMs, CMS has set forth requirements that limit duplication of effort. Quality measures submitted by MIPS APM Entities to fulfill the requirements of their MIPS APMs will also be used to fulfill their data submission requirements under MIPS.

The proposed rule introduces a provision that may limit duplication of effort with the Hospital Value Based Purchasing (VBP) Program. Certain clinicians who meet requirements of providing 75 percent or more of their services in certain facilities may elect to be considered facility-based clinicians, and be scored based on their facility's data submitted under the Hospital VBP Program.

5. Small Businesses

Because the vast majority of Medicare providers (well over 90 percent) are small entities within the definition in the Regulatory Flexibility Act (RFA), HHS's normal practice is to assume that all affected clinicians are "small" under the RFA. In this case, most Medicare and Medicaid eligible clinicians are either non-profit entities or meet the Small Business Administration's size standard for small business. The CY 2018 Quality Payment Program proposed rule Regulatory Impact Analysis estimates that approximately 572,000 clinicians in MIPS (among the 1.5 million clinicians billing Part B) will be subject to MIPS performance

requirements.[3] When we restrict to the clinicians types that are eligible for the 2020 MIPS payment year, we exclude approximately 233,000 clinicians. Further, we exclude newly enrolled Medicare professionals to reduce data submission burden to those professionals, and estimate that 82,000 would be excluded. 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 586,00 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 $90,000 in Medicare allowable charges or less than or equal to 200 Medicare patients. 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. Medicare professionals voluntarily participating in MIPS would receive feedback on their performance, but would not be subject to payment adjustments. (82 FR 30235)

Our estimates assume clinicians who participated in the 2015 PQRS and who are not QPs in Advanced APMs in the 2017 Quality Payment Program performance period will continue to submit quality data as either MIPS eligible clinicians or voluntary reporters in the 2018 Quality Payment Program performance period. We estimate that 36 percent of the 975,723 ineligible or excluded clinicians are expected to report voluntarily because they reported under PQRS. We expect them to continue to submit because (a) the collection and submission of quality data has been integrated into their clinician practice; and (b) the clinician types that were ineligible from MIPS in years 1 and 2 may potentially become eligible in the future. 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 180,000 and 245,000 eligible clinicians will participate in the Quality Payment Program through the Advanced APM Path. (82 FR 30233).

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 clinician performance information on the Physician Compare website.

[3] For further detail on MIPS exclusions, see Supporting Statement B and the Regulatory Impact Analysis Section of the CY 18 Quality Payment Program proposed rule (82 FR 30231 through 30246).

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, 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.

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 3 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. <u>Federal Register/Outside Consultation</u>

The proposed rule is serving as the 60-day Federal Register notice which was published on June 30, 2017 (82 FR 30010 through 30500, RIN 0938-AS69, CMS-5517-P). The proposed rule was placed on public inspection on June 20, 2017 whereby comments are due August 21, 2017.

9. <u>Payments/Gifts to Respondents</u>

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.

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 (Total Hours & Wages)

12.1 *Wage Estimates*

To derive wage estimates, we used data from the U.S. Bureau of Labor Statistics' (BLS) May 2016 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). Table 1 presents the mean hourly wage (calculated at 100 percent of salary), the cost of fringe benefits and overhead, and the adjusted hourly wage.

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, 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 doubling the hourly wage to estimate total cost is a reasonably accurate estimation method. We have selected the occupations in the table below based on a study (Casalino et al, 2016) that collected data on the staff in physician's offices involved in the quality data submission process.[4]

In addition, to calculate time costs for beneficiaries who elect to complete the CAHPS for MIPS survey, we have used wage estimates for Civilian, All Occupations, using the same BLS data. 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

[4]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.

completing the survey. To calculate time costs for virtual groups to prepare their written formal agreements, we have used wage estimates for Legal Support Workers, All Others.

TABLE 1: Adjusted Hourly Wages Used in Burden Estimates

Occupation Title	Occupational Code	Mean Hourly Wage ($/hr.)	Fringe Benefits and Overhead ($/hr.)	Adjusted Hourly Wage ($/hr.)
Billing and Posting Clerks	43-3021	$18.06	$18.06	$36.12
Computer Systems Analysts	15-1121	$44.05	$44.05	$88.10
Physicians	29-1060	$101.04	$101.04	$202.08
Practice Administrator (Medical and Health Services Managers)	11-9111	$52.58	$52.58	$105.16
Licensed Practical Nurse (LPN)	29-2061	$21.56	$21.56	$43.12
Legal Support Workers, All Other	23-2099	31.81	31.81	63.62
Civilian, All Occupations	Not applicable	$23.86	N/A	$23.86

Source: Occupational Employment and Wage Estimates May 2016, U.S. Department of Labor, Bureau of Labor Statistics. https://www.bls.gov/oes/current/oes_nat.htm

12.2 *Framework for Understanding the Burden of MIPS Data Submission*

Because of the wide range of information collection requirements under MIPS, Table 2 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 2, MIPS eligible clinicians that are not in MIPS APMs and other clinicians voluntarily submitting data will submit data either as individuals, groups, or virtual groups to the quality, advancing care information, and improvement activities performance categories. 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 2018 MIPS performance period, the quality data submitted by Shared Savings Program ACOs, Next Generation ACOs, and Other MIPS APMs on behalf of their participant eligible clinicians will fulfill any MIPS submission requirements for the quality performance category.

For the advancing care information performance category, group TINs will submit data on behalf of MIPS APM participants who are MIPS eligible clinicians. For the improvement

activities performance category, we will assume no reporting burden for MIPS APM participants because we 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 may incur additional burden if they elect to participate in MIPS.

TABLE 2: Clinicians or Organizations Submitting MIPS Data on Behalf of Clinicians, by Type of Data and Category of Clinician

	Type of Data Submitted			
Category of Clinician	**Quality Performance Category**	**Advancing Care Information Performance Category**	**Improvement Activities Performance Category**	**Other Data submitted on behalf of MIPS eligible clinician**
MIPS Eligible Clinicians (not in MIPS APMs) and other clinicians voluntarily submitting data	As group, virtual groups, or individual clinicians	As group, virtual groups, or individuals. Clinicians who practice primarily in a hospital, ambulatory surgical center based clinicians, non-patient facing clinicians, PAs, NPs, CNSs and CRNAs are automatically eligible for a zero percent weighting for the advancing care information performance category. Clinicians approved for significant hardship exceptions are also eligible for a zero percent weighting.	As group, virtual groups, or individual clinicians	Groups electing to use a CMS-approved survey vendor to administer CAHPS must register. Groups electing to submit via CMS Web Interface for the first time must register. Virtual groups must register via email.
Facility-based clinicians and groups that elect facility-based measurement	Clinicians and groups electing facility-based measurement will receive a quality score based on their facility's Hospital VBP data submission. The burden has been previously counted under the Hospital	Facility-based clinicians may be eligible for a zero percent weighting for the advancing care information category.	As groups, virtual groups, or individual clinicians.	Facility-based clinicians that elect facility-based measurement make the election online.

	VBP rule, and is not included in burden estimates here.			
Eligible Clinicians participating in the Shared Savings Program or Next Generation ACO Model (both MIPS APMs)	ACOs submit to the CMS Web Interface on behalf of their participating MIPS eligible clinicians. [Not included in burden estimate because quality data submission to fulfill requirements of the Shared Savings Program and Next Generation ACO models are not subject to PRA].[5]	Each group TIN in the APM Entity reports advancing care information to MIPS.[6]	CMS will assign the same improvement activities performance category score to each APM Entity group based on the activities involved in participation in the Shared Savings Program.[7] [The burden estimates assume no improvement activity reporting burden for APM participants.]	Advanced APM Entities will make election for participating MIPS eligible clinicians.
Eligible Clinicians participating in Other MIPS APMs	MIPS APM Entities submit to MIPS on behalf of their participating MIPS eligible clinicians [Not included in burden estimate because quality data submission to fulfill requirements of Innovation Center models are not subject to the PRA].	Each MIPS eligible clinician in the APM Entity reports advancing care information to MIPS through either group TIN or individual reporting. [The burden estimates assume group TIN-level reporting].	CMS will assign the same improvement activities performance category score to each APM Entity based on the activities involved in participation in the MIPS APM. [The burden estimates assume no improvement activities performance category reporting burden for APM participants].	Advanced APM Entities will make election for participating eligible clinicians.

The policies finalized in the CY 2017 Quality Payment Program final rule and the CY 2018 Quality Payment Program proposed rule create some additional data collection

[5]Sections and 3021 and 3022 of the Affordable Care Act state the Shared Savings Program and testing, evaluation, and expansion of Innovation Center models are not subject to the PRA (42 U.S.C. §1395jjj and 42 U.S.C. §1315a(d)(3), respectively)

[6]For MIPS APMs other than the Shared Savings Program, both group TIN and individual clinician advancing care information data will be accepted. If both group TIN 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.

[7] APM Entities participating in MIPS APMs do not need to submit improvement activities data unless the CMS-assigned improvement activities scores is below the maximum improvement activities score

requirements not listed in Table 2. These additional data collections, one of which was previously approved by OMB under control number 0938-1314, are as follows:

- Self-nomination of new and returning QCDRs and registries (0938-1314)
- Call for new improvement activities
- Other Payer Advanced APM identification: other payer initiated process
- Opt out of performance data display on Physician Compare for voluntary reporters under MIPS.

12.3 *Burden for Election of Facility-Based Measurement*

In the CY 2018 Quality Payment program proposed rule, we propose that for the 2020 MIPS payment year (2018 MIPS performance period), we would allow facility-based MIPS eligible clinicians to be given a MIPS score in the quality and cost performance categories that is based on the performance of the facility in which they provide services. We propose that a MIPS eligible clinician is eligible for facility-based measurement under MIPS if they furnish 75 percent or more of their covered professional services (as defined in section 1848(k)(3)(A) of the Act) in sites of service identified by the place of service codes used in the HIPAA standard transaction as an inpatient hospital, as identified by place of service code 21, and the emergency room, as identified by place of service code 23, based on claims for a period prior to the performance period as specified by CMS.

These MIPS eligible clinicians may elect to participate in facility-based measurement during the performance period. For the 2020 MIPS payment year (2018 MIPS performance period), we will base our assumptions for these eligible clinicians on the Hospital VBP Program.

In Table 3, we estimate participation in facility-based measurement, based on 2015 data from the PQRS and the first 2019 payment year MIPS eligibility and special status file as described in 81 FR 77069 and 77070.[8] We estimate 18,207 respondents (17,943 MIPS eligible clinicians who practice primarily in the hospital electing as individuals and 264 groups with 75 percent or more of their clinicians qualifying as clinicians who practice primarily in the hospital) will elect facility-based measurement in the 2018 MIPS performance period. We estimate that the 17,943 individual clinicians electing facility-based measurement are comprised of 20 percent (10,353) of a total of the approximately 51,767 of clinicians who practice primarily in the hospital that previously submitted as individuals in the 2017 MIPS performance period; 80 percent (7,590) of a total of 9,488 clinicians who practice primarily in the hospital that we estimate will not have submitted in the 2017 MIPS performance period.

[8] The data used for our estimates defined facility-based clinicians as those who furnish 75 percent or more of their covered professional service in sites of service identified by place service codes 21, 22, or 23. The proposal defines facility-based clinicians as those who furnish 75 percent or more of their covered professional service in sites of service identified by place service codes 21 and 23.

We believe that the 80 percent (7,590) of the total 9,488 would not have submitted in the 2017 MIPS performance period because of the additional effort required to report MIPS measures in addition to measures required for the Hospital VBP Program. We have heard this from hospitalists and other clinicians and we believe that the inclusion of this opportunity within MACRA was in response to this concern. We estimate that 20 percent (or 264) of groups that would have previously submitted on behalf of clinicians in the 2017 MIPS performance period will elect facility-based measurement on behalf of their 12,125 clinicians.

TABLE 3: Estimated Number of Individual Clinicians and Groups Who Practice Primarily in the Hospital to Elect Facility-Based Measurement

	Counts
Estimated # of clinicians who practice primarily in the hospital that previously submitted as individuals under the 2017 MIPS performance period to elect facility-based measurement in the 2018 MIPS performance period (a)	10,353
Estimated # of clinicians who practice primarily in the hospital that did not submit under the 2017 MIPS performance period to elect facility-based measurement as individuals in the 2018 MIPS performance period (b)	7,590
Estimated # of clinicians who practice primarily in the hospital to elect facility-based measurement as individuals in the 2017 MIPS performance period (c)= (a)+ (b)	17,943
Estimated # of clinicians who practice primarily in the hospital that previously submitted as groups under the 2017 MIPS performance period to elect facility-based measurement in the 2018 MIPS performance period (d)	12,125
Estimated # of groups who practice primarily in the hospital that previously submitted on behalf of clinicians as groups under the 2017 MIPS performance period to elect facility-based measurement in the 2018 MIPS performance period (e)	264
Estimated # of respondents that elect facility-based measurements (including individual clinicians who practice primarily in the hospital electing facility-based measurement and groups electing facility-based measurement) (f)=(c)+(e)	**18,207**

Although the election of facility-based measurement generates burden, it will also result in the reduction of burden in the quality performance category because certain clinicians and groups will no longer be required to submit data for this category. Hence, our burden estimates for the quality performance category consider the reduction in burden for clinicians who practice primarily in the hospital that previously submitted data for this performance category and elected to use facility-based measurement. The reduction in burden is described in the quality performance category section below. We assume that there will be no reduction in burden related to the advancing care information performance category because MIPS eligible clinicians who practice primarily in the hospital are not required to submit data for this performance category.

As shown in Table 4, we estimate that the election to participate via facility-based measurement will take 1 hour of staff time, comparable to the CMS Web Interface registration process. We assume that the staff involved in the election process to participate via facility-based measurement will mainly be billing clerks or their equivalent, who have an average labor cost of $36.12/hour. Therefore, assuming the total burden hours per group or individual clinician associated with the election process is 1 hours, the total annual burden hours are 18,207 (18,207 groups or individual clinicians X 1 hour). We estimate that the total cost to groups and individual clinicians associated with the election process will be approximately $36.12 ($36.12 per hour X 1 hour per group or eligible clinician). We also assume that 18,207 individual clinicians or groups will go through the election process leading to a total burden of $657,637 ($36.12 X 18,207 clinicians).

TABLE 4: Estimated Burden for Election to Participate in Facility-Based Measurement

	Burden Estimate
Estimated # of respondents to elect facility-based measurements (including individual clinicians who practice primarily in the hospital electing facility-based measurement and groups electing facility-based measurement) (a)	18,207
Estimated # of Burden Hours Per Group or Eligible Clinician to Elect Facility-based Measurement (b)	1
Estimated Total Annual Burden Hours (c) = (a)*(b)	18,207
Estimated Cost Per Clinician or Group Practice to Elect Facility-Based Measurement (@ billing clerk's labor rate of $36.12/hr.) (d)	$36.12
Estimated Total Annual Burden Cost (e) = (c)*(d)	$657,637

12.4 *Burden for Third Party Reporting*

Under MIPS, quality, advancing care information, and improvement activities performance category data may be submitted via relevant third party intermediaries, such as qualified registries, QCDRs and health IT vendors. The CAHPS for MIPS survey data, which counts as one quality performance category measure, can be submitted via CMS-approved survey vendors. The burdens associated with qualified registry and QCDR self-nomination and the CAHPS for MIPS survey vendor applications are discussed below.

12.4.1. Burden for Qualified Registry and QCDR Self-Nomination[9]

For the 2017 MIPS performance period, 120 qualified registries and 113 QCDRs were qualified to report quality measures data for purposes of the PQRS, an increase from 114

[9]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.

qualified registries and 69 QCDRs in CY 2016.[10] 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 registries or QCDRs interested in submitting quality measures results and numerator and denominator data on quality measures to us on their participants' behalf will need to complete a self-nomination process 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. The self-nomination form is submitted electronically using a web-based tool. We are proposing to eliminate the option of submitting the self-nomination form via email that was available in the transition year.

In addition to completing a self-nomination statement, qualified registries and QCDRs will need to perform various other functions, such as meeting with CMS officials when additional information is needed. In addition, QCDRs calculate their measure results. QCDRs must possess benchmarking capability (for non-MIPS quality measures) that compares the quality of care a MIPS eligible clinician provides with other MIPS eligible clinicians performing the same quality measures. For non-MIPS measures the QCDR must provide to us, if available, data from years prior (for example, 2016 data for the 2018 MIPS performance period) before the start of the performance period. In addition, the QCDR must provide to us, if available, the entire distribution of the measure's performance broken down by deciles. As an alternative to supplying this information to us, the QCDR may post this information on their website prior to the start of the performance period, to the extent permitted by applicable privacy laws. 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.

As shown in Table 5, 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 $88.10/hour. Therefore, assuming the total burden hours per qualified registry or QCDR associated with the self-nomination process is 10 hours, the annual

[10] The full list of qualified registries for 2017 is available at https://qpp.cms.gov/docs/QPP_MIPS_2017_Qualified_Registries.pdf and the full list of QCDRs is available at https://qpp.cms.gov/docs/QPP_2017_CMS_Approved_QCDRs.pdf.

burden hours is 2,330 (233 (113 + 120) 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 $881.00 ($88.10 per hour X 10 hours per qualified registry). We also estimate that 233 qualified registries or QCDRs will go through the self-nomination process leading to a total burden of $205,273 ($881.00 X 233).

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 us 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 noted in this section 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 self-nominating to be considered "qualified" to submit quality measures results and numerator and denominator data on MIPS eligible clinicians.

TABLE 5: Estimated Burden for QCDR and Qualified Registry Self-Nomination

	Burden Estimate
Estimated # of Qualified registries or QCDRs Self-Nominating (a)	233
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)	**2,330**
Estimated Cost Per Qualified Registry or QCDR (@ computer systems analyst's labor rate of $88.10/hr.) (d)	$881.00
Estimated Total Annual Burden Cost for Qualified registries or QCDRs (e) = (a)*(d)	**$205,273**

12.5 *Burden Estimate for the Quality Performance Category*

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 but will not be subject to MIPS payment adjustments.

Historically, the PQRS has never experienced 100 percent participation; the participation rate for 2015 was 69 percent. For purposes of these analyses, we assume that clinicians who participated in the 2015 PQRS and who are not QPs in Advanced APMs in the 2017 Quality Payment Program performance period will continue to submit quality data as either MIPS eligible clinicians. We assume that most clinicians excluded from or ineligible for MIPS will submit data voluntarily in the 2018 MIPS performance period if they submitted quality measures under the 2015 PQRS. We acknowledge that these assumptions have some important limitations because they are based on data from the legacy PQRS program.

In addition, as shown in Table 4, regarding our burden estimates for election of facility-based measurement, we assume that approximately 18,207 individual clinicians or groups will elect to participate in facility-based measurement for the 2018 MIPS performance period and will not be required to submit any additional quality performance category data under MIPS. Based on 2015 data from the PQRS, the data prepared to support the 2017 performance period initial determination of clinician and special status eligibility (available via the NPI lookup on qpp.cms.gov), using a date range of September 1, 2015 – August 31, 2016, and a version of the file used for the predictive qualifying APM participants analysis made available on qpp.cms.gov on June 2, 2017, and prepared using claims for services between January 1, 2016 through August 31, 2016. We estimate that at least 92 percent of MIPS eligible clinicians not participating in MIPS APMs will submit quality performance category data including those participating as individual clinicians, groups, or virtual groups. We assume that 100 percent of MIPS APM Entities will submit quality data to CMS as required under their models.[11] We anticipate that the professionals submitting data voluntarily will include clinicians that are ineligible for the Quality Payment Program, clinicians that do not exceed the low-volume threshold, and newly enrolled Medicare clinicians. Based on those assumptions, using data from the 2015 PQRS, the data prepared to support the 2017 performance period initial determination of clinician and special status eligibility (available via the NPI lookup on qpp.cms.gov), and a preliminary version of the file used for the predictive QP analysis made available on qpp.cms.gov on June 2, 2017, we estimate that an additional 292,351 clinicians, or 36 percent of clinicians excluded from or ineligible from MIPS, will submit MIPS quality data voluntarily. Because in the projected growth in the number of QPs over time, we are predicting a decline in the rate of voluntary quality data submission among clinicians excluded from or ineligible for MIPS relative to our estimated voluntary reporting rate of 45 percent in the CY 2017 Quality Payment Program final rule. Historically, clinicians who are expected to be QPs in 2018 MIPS performance period were much more likely to have submitted quality data under the 2015 PQRS than other clinicians excluded from or ineligible from MIPS. Due to data limitations, our assumptions about quality performance category participation for the

[11]We estimate that 110,159 clinicians that participated in the 2015 PQRS will be QPs who will not be not required to submit MIPS quality performance category data under MIPS, and are not included in the numerator or denominator of our participation rate.

purposes of our burden estimates differs from our assumptions about quality performance category participation in the impact analysis.

Our burden estimates for data submission combine the burden for MIPS eligible clinicians and other clinicians submitting data voluntarily. Apart from clinicians who practice primarily in the hospital electing facility-based measurement, we assume that clinicians will continue to submit quality data under the same submission mechanisms that they used under the 2015 PQRS. As discussed in more detail in the section of this Supporting Statement describing the burden for facility-based measurement, we assume that some eligible clinicians who practice primarily in the hospital will elect facility-based measurement, rather than submit quality data via other mechanisms. Further, as discussed in more detail in the section of this Supporting Statement describing the burden for the virtual group application process (III.C.), we assume that the approximately 80 TINs that elect to form the approximately 16 virtual groups will continue to use the same submission mechanism as under the 2015 PQRS, but the submission will be at the virtual group, rather than group level. Our burden estimates for the quality performance category do not include the burden for the quality data that MIPS APM Entities submit to fulfill the requirement of their models. Sections 3021 and 3022 of the Affordable Care Act state the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models are not subject to the PRA (42 U.S.C. §1395jjj and 42 U.S.C. §1315a(d)(3), respectively).[12] Tables 6-a, 6-b, and 6-c explain our revised estimates of the number of organizations (including groups, virtual groups, and individual MIPS eligible clinicians) submitting data on behalf of clinicians via each of the quality submission mechanisms. The proposed policies related to both virtual groups and facility-based measurement are reflected, as is the proposed policy to score quality measures submitted via multiple submission mechanisms.

Table 6-a provides our estimated counts of clinicians that will submit quality performance category data as MIPS individual clinicians, groups, or virtual groups in the 2018 MIPS performance period. The first step was to estimate the number of clinicians to submit as an individual clinician or group via each mechanism during the 2017 MIPS performance period using 2015 PQRS data on individuals and groups submitting through various mechanisms. The second step was to subtract out the estimated number of clinicians who practice primarily in the hospital to elect facility-based measurement as groups or individuals in the 2018 MIPS performance period. . Further detail on our methods to estimate the number of clinicians who practice primarily in the hospital to elect facility-based scoring as individual clinicians or groups is provided on the burden for the election of facility-based measurement.

Based on these methods, Table 6-a shows that in the 2018 MIPS performance period, an estimated 364,002 clinicians will submit as individuals via claims submission mechanisms;

[12]Our estimates do reflect the burden that MIPS APM participants of submitting advancing care information data, which is outside the requirements of their models.

225,569 clinicians will submit as individuals, or as part of groups or virtual groups via qualified registry or QCDR submission mechanisms; 115,241 clinicians will submit as individuals, or as part of groups or virtual groups via EHR submission mechanisms; and 101,939 clinicians will submit as part of groups via the CMS Web Interface.

Our estimated numbers of clinicians to submit as individual clinicians, groups, or virtual groups via each submission mechanism account for the proposed policy that individual clinicians, groups, and virtual groups can be scored on data submitted via multiple submission mechanisms. Hence, the estimated numbers of individual clinicians, groups, and virtual groups to submit via the various submission mechanisms are not mutually exclusive, and reflect the occurrence of individual clinicians or groups that submitted data via multiple mechanism under the 2015 PQRS.

TABLE 6-a: Estimated Number of Clinicians Submitting Quality Performance Category Data by Mechanism

	Claims	**QCDR/ registry**	**EHR**	**CMS Web Interface**
Estimated number of clinicians to submit via mechanism (as individual clinicians, groups, or virtual groups) in Quality Payment Program Year 1 (excludes QPs) (a)	371,987	236,908	118,395	101,939
Subtract out: Estimated number of clinicians to submit via mechanism (as individual clinicians, groups or virtual groups) in Quality Payment Program Year 1 that will opt for facility-based scoring in Quality Payment Program Year 2 (b)	7,985	11,339	3,154	0
Estimated number of clinicians to submit via mechanism (as individual clinicians or groups) in Quality Payment Program Year 2 (excludes QPs and facility-based measurement) (c) = (a)-(b)	364,002	225,569	115,241	101,939

Table 6-a provides estimates of the number of clinicians to submit quality measures via each mechanism, regardless of whether they decide to submit as individual clinicians or as part of groups or virtual groups. Because our burden estimates for quality data submission assume that burden is reduced when clinicians elect to submit as part of a group or virtual group, we also separately estimate the expected number of clinicians to submit as individuals or part of groups or virtual groups.

Table 6-b uses methods similar to those described for Table 6-a to estimate the number

of clinicians to submit as individual clinicians via each mechanism in Quality Payment Program Year 2. We estimate that approximately 364,002 clinicians will submit as individuals via claims submission mechanisms; approximately 86,046 clinicians will submit as individuals via qualified registry or QCDR submission mechanisms; and approximately 60,253 clinicians will submit as individuals via EHR submission mechanisms. Individual clinicians cannot elect to submit via CMS Web Interface. Consistent with the proposed policy to allow individual clinicians to be scored on quality measures submitted via multiple mechanisms, our columns in Table 6-b are not mutually exclusive.

TABLE 6-b: Estimated Number of Clinicians Submitting Quality Performance Category Data as Individuals

	Claims	**QCDR/registry**	**EHR**	**CMS Web Interface**
Estimated number of Clinicians to submit data as individuals in Quality Payment Program Year 1 (excludes QPs) (a)	371,987	88,078	60,589	0
Subtract out: Estimated number of clinicians to submit via mechanism as individuals in Quality Payment Program Year 1 that will opt for facility-based scoring in Quality Payment Program Year 2 (b)	7,985	2,032	336	0
Estimated number of clinicians to submit via mechanism as individuals in Quality Payment Program Year 2 (excludes QPs and facility-based measurement) (c)=(a)-(b)	364,002	86,046	60,253	0

Table 6-c provides our estimated counts of groups or virtual groups to submit quality data on behalf of clinicians via each mechanism in the 2018 MIPS performance period and reflects our assumption that the formation of virtual groups will reduce burden. Except for groups who practice primarily in the hospital electing facility-based measurement and groups comprised entirely of QPs, we assume that groups that submitted quality data as groups under the 2015 PQRS will continue to submit quality data either as groups or virtual groups via the same submission mechanisms in the 2018 MIPS performance period. The first step in estimating the numbers of groups or virtual groups to submit via each mechanism in the 2018 MIPS performance period was to estimate the number of groups to submit on behalf of clinicians via each mechanism in the 2017 MIPS performance period. We used 2015 PQRS data on groups submitting on behalf of clinicians via various mechanisms. The second step was to subtract out the estimated number of groups who practice primarily in the hospital that will elect facility-based measurement. Further detail on our methods to estimate the number of groups who practice primarily in the hospital to elect facility-based scoring on behalf of clinicians is provided in in the discussion of the burden for the election of facility-based measurement. The third and fourth steps in Table 6-c reflect our assumption that virtual groups

will reduce the burden for quality data submission by reducing the number of organizations to submit quality data on behalf of clinicians. We assume that 40 groups that previously submitted on behalf of clinicians via QCDR or qualified registry submission mechanisms will elect to form 8 virtual groups that will submit via QCDR and qualified registry submission mechanisms. We assume that another 40 groups that previously submitted on behalf of clinicians via EHR submission mechanisms will elect to form another 8 virtual groups via EHR submission mechanisms. Hence, the third step in Table 6-c is to subtract out the estimated number of groups under each submission mechanism that will elect to form virtual groups, and the fourth step in Table 6-c is to add in the estimated number of virtual groups that will submit on behalf of clinicians via each submission mechanism.

Specifically, we assumed that 2,455 groups and virtual groups will submit data via QCDR/registry submission mechanisms on behalf of 146,676 clinicians; 817 groups and virtual groups will submit via EHR submission mechanisms on behalf of 56,772 eligible clinicians; and 298 groups will submit data via the CMS Web Interface on behalf of 102,914 clinicians. Groups cannot elect to submit via the claims submission mechanism.

TABLE 6-c: Estimated Number of Groups and Virtual Groups Submitting Quality Performance Category Data by Mechanism on Behalf of Clinicians

	Claims	**QCDR/registry**	**EHR**	**CMS Web Interface**
Estimated number of groups to submit via mechanism (on behalf of clinicians) in Quality Payment Program Year 1 (excludes QPs) (a)	0	2,672	928	298
Subtract out: Estimated number groups to submit via mechanism on behalf of clinicians in Quality Payment Program Year 1 that will opt for facility-based scoring in Quality Payment Program Year 2 (b)	0	185	79	0
Subtract out: Estimated number groups to submit via mechanism on behalf of clinicians in Quality Payment Program Year 1 that will submit as Virtual Groups in Quality Payment Program Year 2 (c)	0	40	40	0
Add in: Estimated number of virtual groups to submit via mechanism on behalf of clinicians in Quality Payment Program Year 2 (d)	0	8	8	0
Estimated number groups to submit via mechanism on behalf of clinicians in Quality Payment Program Year 2 (e)=(a)-(b)-(c)+(d)	0	2,455	817	298

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, these 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 submitting the quality measures will vary depending on the submission method selected by the clinician, group, or virtual group. As such, we break down the burden estimates by clinicians, groups, and virtual groups by the submission method used.

We anticipate that clinicians and groups using QCDR, qualified registry, and EHR submission mechanisms will have the same start-up costs related to reviewing measure specifications. As such, we estimate for clinicians, groups, and virtual groups using any of these three submission mechanisms a total of 7 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 article, Casalino et. al. (2016), we assume that a range of expertise is needed to review quality measures: 2 hours of an office administrator's time, 1 hour of a clinician's time, 1 hour of an LPN/medical assistant's time, 1 hour of a computer systems analyst's time, and 1 hour of a billing clerk's time.[13] In the CY 2017 Quality Payment Program final rule, we estimated 3 hours for an administrator's time for data submission. Because the new CMS Application Programming Interface (API) will be available for EHR, registry and QCDR, and CMS Web Interface submission mechanisms, we have reduced our estimate to 2 hours of an office administrator's time for data submission. This CMS API will streamline the process of reviewing measure specifications and submitting measures for third party submission mechanisms. (We have also reduced our burden estimate for CMS Web Interface to reflect the new CMS API in a separate section below.).[14]

[13]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 percent of all revenue paid by insurers, and then adjusted to reflect that the decrease from 9 required quality measures under PQRS to 6 required measures under MIPS.
[14]CMS: New API Will Automate MACRA Quality Measure Data Sharing. http://healthitanalytics.com/news/cms-new-api-will-automate-macra-quality-measure-data-sharing.

For the claims submission mechanism, we estimate that the start-up cost for a MIPS eligible clinician's practice to review measure specifications is $596.80, including 3 hours of a practice administrator's time (3 hours X $105.16=$315.48), 1 hour of a clinician's time (1 hour X $202.08/hour=$202.08), 1 hour of an LPN/medical assistant's time (1 hour X $43.12), and 1 hour of a billing clerk's time (1 hour X $36.12/hour = $36.12). These start-up costs pertain to the specific quality submission methods below, and hence appear in the burden estimate tables.

For the purposes of our burden estimates for the claims, qualified registry and QCDR, and EHR submission mechanisms, we also assume that, on average, each clinician, group, or virtual group will submit 6 quality measures.

Our estimated number of respondents for the claims and EHR submission mechanisms increased relative to the estimates in the CY 2017 Quality Payment Program final rule because our estimates now reflect the proposed policy to allow individual clinicians and groups to be scored on quality measures submitted via multiple mechanisms. Our estimated number of respondents for the QCDRs and qualified registries submission mechanisms has declined relative to the CY 2017 Quality Payment final rule because our estimates now reflect the proposed policies allowing certain eligible clinicians who practice primarily in the hospital to elect facility-based measurement, as well as the proposed policy to allow practices of 10 or fewer eligible clinicians to participate as part of a virtual group. The number of respondents for CMS Web Interface has declined relative to the estimates in the CY 2017 Quality Payment Program final rule because our estimates now exclude the CMS Web Interface data submitted by Shared Savings Program and Pioneer ACOs to fulfill the requirement of their models. As noted above, information collections associated with the Shared Savings Program and the testing, evaluation, and expansion of CMS Innovation Center models are not subject to the PRA.

12.5.1 *Burden for Quality Data Submission by Clinicians: Claims-Based Submission*

As noted in Table 6-a, based on 2015 PQRS data, the data prepared to support the 2017 performance period initial determination of clinician and special status eligibility (available via the NPI lookup on qpp.cms.gov) using a date range of September 1, 2015 – August 31, 2016, and a preliminary version of the file used for the predictive qualifying APM participants analysis made available on qpp.cms.gov on June 2, 2017, and prepared using claims for services between January 1, 2016 through August 31, 2016, we assume that 364,002 individual clinicians will submit quality data via claims. We anticipate the claims submission process for MIPS will be operationally similar to the way the claims submission process 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 0938-1197.

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 PQRS, 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 7, we also estimate that the cost of quality data submission using claims will range from $19.38 (0.22 hours X $88.10) to $951.48 (10.8 hours X $88.10). The total estimated annual cost per clinician ranges from the minimum burden estimate of $704.28 to a maximum burden estimate of $1,636.38. The burden will involve becoming familiar with MIPS data submission requirements. As noted in Table 7, we believe that the start-up cost for a clinician's practice to review measure specifications totals 7 hours, which includes 3 hours of a practice administrator's time (3 hours X $105.16 = $315.48), 1 hour of a clinician's time (1 hour X $202.08/hour = $202.08), 1 hour of an LPN/medical assistant's time (1 hour X $43.12 = $43.12), 1 hour of a computer systems analyst's time (1 hour X $88.10 = $88.10), and 1 hour of a billing clerk's time (1 hour X $36.12/hour = $36.12).

Considering both data submission and start-up costs, the total estimated burden hours per clinician ranges from a minimum of 7.22 hours (0.22 + 3 + 1 + 1 + 1 + 1) to a maximum of 17.8 hours (10.8 + 3 + 1 + 1 + 1 + 1). The total estimated annual cost per clinician ranges from the minimum estimate of $704.28 ($19.38 + $315.48 + $88.10 + $43.12 + $36.12 + $202.08) to a maximum estimate of $1,636.38 ($951.48 + $315.48 + $88.10 + $43.12 + $36.12 + $202.08). Therefore, total annual burden cost is estimated to range from a minimum burden estimate of $256,359,329 (364,002 X $704.28) to a maximum burden estimate of $595,645,593 (364,002 X $1,636.38).

Based on the assumptions discussed above, Table 7 summarizes the range of total annual burden associated with clinicians using the claims submission mechanism.

TABLE 7: Burden Estimate for Quality Performance Category: Clinicians Using the Claims Submission Mechanism

	Minimum Burden	**Median Burden**	**Maximum Burden Estimate**
Estimated # of Clinicians (a)	364,002	364,002	364,002
Burden Hours Per Clinician to Submit Quality Data (b)	0.22	1.58	10.8
Estimated # of Hours Office Administrator Review Measure Specifications (c)	3	3	3
Estimated # of Hours Computer	1	1	1

	Minimum Burden	**Median Burden**	**Maximum Burden Estimate**
Systems Analyst Review Measure Specifications (d)			
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 Clinician Review Measure Specifications (g)	1	1	1
Estimated Annual Burden hours per Clinician (h) = (b)+(c)+(d)+(e)+(f)+(g)	7.22	8.58	17.8
Estimated Total Annual Burden Hours (i) = (a)*(h)	**2,628,094**	**3,123,137**	**6,479,236**
Estimated Cost to Submit Quality Data (@ computer systems analyst’s labor rate of $88.10/hr.) (j)	$19.38	$139.20	$951.48
Estimated Cost to Review Measure Specifications (@ practice administrator's labor rate of $105.16/hr.) (k)	$315.48	$315.48	$315.48
Estimated Cost to Review Measure Specifications (@ computer systems analyst’s labor rate of $88.10/hr.) (l)	$88.10	$88.10	88.10
Estimated Cost to Review Measure Specifications (@ LPN's labor rate of $43.12/hr.) (m)	$43.12	$43.12	$43.12
Estimated Cost to Review Measure Specifications (@ billing clerk’s labor rate of $36.12/hr.) (n)	$36.12	$36.12	$36.12
Estimated Cost to Review Measure Specifications (@ physician’s labor rate of $202.08/hr.) (o)	$202.08	$202.08	$202.08
Estimated Total Annual Cost Per Clinician (p) = (j)+(k)+(l)+(m)+(n)+(o)	$704.28	$824.10	$1,636.38
Estimated Total Annual Burden Cost (q) = (a)*(p)	**$256,359,329**	**$299,974,048**	**$595,645,593**

12.5.2 *Burden for Quality Data Submission by Individuals, Groups, and Virtual Groups Using Qualified Registry and QCDR Submissions*

As noted in Table 6-a and based on 2015 PQRS data, the data prepared to support the 2017 performance period initial determination of clinician and special status eligibility (available via the NPI lookup on qpp.cms.gov) using a date range of September 1, 2015 – August 31, 2016, we assume that 225,569 clinicians will submit quality data as individuals, groups, or virtual groups via qualified registry or QCDR submissions. Of these, we expect 86,046 clinicians, as shown in Table 6-b, to submit as individuals and 2,455 groups, as shown in Table 6-c, are expected to submit on behalf of the remaining 139,523 clinicians. Given that the number of measures required is the same for clinicians, groups, and virtual 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, group or virtual 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 (individual clinicians, groups, and virtual groups) to become familiar with MIPS submission requirements and, in some cases, specialty measure sets and QCDR measures. Therefore, we believe that the start-up cost for an individual clinician or group to review measure specifications and submit quality data to total $851.35. For review costs, this total includes 3 hours per respondent to submit quality data (3 hours X $88.10/hour = $264.00), 3 hours of a practice administrator's time (2 hours X $105.16/hour = $210.32), 1 hour of a clinician's time (1 hours X $202.08/hour =$202.08), 1 hour of a computer systems analyst's time (1 hour X $88.10/hour = $88.10), 1 hour of an LPN/medical assistant's time, (1 hour X $43.12/hour = $43.12), and 1 hour of a billing clerk's time (1 hour X $36.12/hour = $36.12). Clinicians, groups, and virtual 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 us 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 $7.31, at a computer systems analyst's labor rate (.083 hours X $88.10/hour). Hence, and as shown in Table 8, we estimate 9.083 burden hours per respondent, with annual total burden hours of 803,855 (9.083 burden hours X 88,501 respondents). The total estimated annual cost per respondent is estimated to be approximately $851.05. Therefore, total annual burden cost is estimated to be $75,318,776 (88,501 X $851.05). Based on these assumptions, we have estimated the burden for these submissions.

TABLE 8: Burden Estimate for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group or Virtual Group) Using the Qualified Registry/QCDR Submission

	Burden Estimate
# of clinicians submitting as individuals (a)	86,046
# of groups or virtual groups submitting via QCDR or registry on behalf of individual clinicians (b)	2,455
# of Respondents (groups and virtual groups plus clinicians submitting as individuals) (c)=(a)+(b)	88,501
Estimated Burden Hours Per Respondent to Report Quality Data (d)	3
Estimated # of Hours Office Administrator Review Measure Specifications (e)	2
Estimated # of Hours Computer Systems Analyst Review Measure Specifications (f)	1
Estimated # of Hours LPN Review Measure Specifications (g)	1
Estimated # of Hours Billing Clerk Review Measure Specifications (h)	1
Estimated # of Hours Clinician Review Measure Specifications (i)	1
Estimated # of Hours Per Respondent to Authorize Qualified Registry to Report on Respondent's Behalf) (j)	0.083
Estimated Annual Burden Hours Per Respondent (k)= (d)+(e)+(f)+(g)+(h)+(i)+(j)	9.083
Estimated Total Annual Burden Hours (l) = (c)*(k)	803,855
Estimated Cost Per Respondent to Submit Quality Data (@ computer systems analyst’s labor rate of $88.10/hr.) (m)	$264.00
Estimated Cost to Review Measure Specifications (@ practice administrator's labor rate of $105.16/hr.) (n)	$210.32
Estimated Cost Computer System’s Analyst Review Measure Specifications (@ computer systems analyst’s labor rate of $88.10/hr.) (o)	$88.10
Estimated Cost LPN Review Measure Specifications (@ LPN's labor rate of $43.12/hr.) (p)	$43.12
Estimated Cost Billing Clerk Review Measure Specifications (@ clerk’s labor rate of $36.12/hr.) (q)	$36.12
Estimated Cost Clinician Review Measure Specifications (@ physician’s labor rate of $202.08/hr.) (r)	$202.08
Estimated Burden for Submission Tool Registration etc. (@ computer systems analyst’s labor rate of $88.1/hr.) (s)	$7.31
Estimated Total Annual Cost Per Respondent (t) = (m)+(n)+(o)+(p)+(q)+(r)+(s)	$851.05
Estimated Total Annual Burden Cost (u) = (c)*(t)	$75,318,776

12.5.3 *Burden for Quality Data Submission by Clinicians, Groups, and Virtual Groups: EHR Submission*

As noted in Tables 6-a, 6-b and 6-c , based on our analysis of 2015 PQRS data, data prepared to support the 2017 performance period initial determination of clinician and special status eligibility (available via the NPI lookup on qpp.cms.gov) using a date range of September 1, 2015 – August 31, 2016, we assume that 115,241 clinicians will submit quality data as individuals or groups via EHR submissions; 60,253 clinicians are expected to submit as individuals; and 817 groups are expected to submit on behalf of 56,772 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 us from their EHR or utilize an EHR data submission vendor to submit the data to us on the clinician's or group's behalf.

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, groups, and virtual groups who submit their data directly to us from their CEHRT and clinicians, groups, and virtual groups who use an EHR data submission vendor to submit the data on their behalf. To submit data to us directly from their CEHRT, clinicians, groups, and virtual 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 an account on a CMS-specified identity management system will require 1 hour per respondent for a cost of $88.10 (1 hour X $88.10/hour), and that submitting a test data file to us will also require 1 hour per respondent for a cost of $88.10 (1 hour X $88.10/hour). For 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 $176.20 (2 hours X $88.10/hour). The burden will involve becoming familiar with MIPS submission. We believe that the start-up cost for a clinician or group to submit the test data file and review measure specifications is a total 7 hours, 1 hour for the test data submission and 6 hours for reviewing measuring which includes 2 hours of a practice administrator's time (2 hours X $105.16/hour = $210.32), 1 hour of a clinician's time (1 hour X $202.08/hour = $202.08), 1 hour of a computer systems analyst's time (1 hour X $88.10/hour = $88.10), 1 hour of an LPN/medical assistant's

time (1 hour X $43.12/hour = $43.12), and 1 hour of a billing clerk's time (1 hour X $36.12/hour = $36.12). Hence, and as shown in Table 9, we estimated 10 total burden hours per respondent with annual total burden hours of 610,700 (10 burden hours X 61,070 respondents). The total estimated annual cost per respondent is estimated to be $932.14. Therefore, total annual burden cost is estimated to be $56,925,790 = (61,070 respondents X $932.14).

Based on the assumptions discussed above, we have estimated the burden for the quality data submission using EHR submission mechanism below.

TABLE 9: Burden Estimate for Quality Performance Category: Clinicians (Submitting Individually or as Part of a Group or Virtual Group) Using the EHR Submission Mechanism

	Burden estimate
# of clinicians submitting as individuals (a)	60,253
# of Groups and Virtual Groups submitting via EHR on behalf of individual clinicians (b)	817
# of Respondents (Groups and Virtual Groups plus clinicians submitting as individuals) (c)=(a)+(b)	61,070
Estimated Burden Hours Per Respondent to Obtain Account in CMS-Specified Identity Management System (d)	1
Estimated Burden Hours Per Respondents to Submit Test Data File to CMS (e)	1
Estimated Burden Hours Per Respondent to Submit MIPS Quality Data File to CMS (f)	2
Estimated # of Hours Office Administrator Review Measure Specifications (g)	2
Estimated # of Hours Computer Systems Analyst Review Measure Specifications (h)	1
Estimated # of Hours LPN Review Measure Specifications (i)	1
Estimated # of Hours Billing Clerk Review Measure Specifications (j)	1
Estimated # of Hours Clinicians Review Measure Specifications (k)	1
Estimated Annual Burden Hours Per Respondent (l)=(d)+(e)+(f)+(g)+(h)+(i)+(j)+(k)	10
Estimated Total Annual Burden Hours (m)=(c)*(l)	610,700
Estimated Cost Per Respondent to Obtain Account in CMS-specified identity management system (@ computer systems analyst's labor rate of $88.10/hr.) (n)	$88.10
Estimated Cost Per Respondent to Submit Test Data File to CMS (@ computer systems analyst's labor rate of $88.10/hr.) (o)	$88.10
Estimated Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of $88.10/hr.) (p)	$176.20

	Burden estimate
Estimated Cost to Review Measure Specifications (@ practice administrator's labor rate of $105.16/hr.) (q)	$210.32
Estimated Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $88.10/hr.) (r)	$88.10
Estimated Cost to Review Measure Specifications (@ LPN's labor rate of $43.12/hr.) (s)	$43.12
Estimated Cost to Review Measure Specifications (@ clerk's labor rate of $36.12/hr.) (t)	$36.12
Estimated Cost to D21Review Measure Specifications (@ physician's labor rate of $202.08/hr.) (u)	$202.08
Estimated Total Annual Cost Per Respondent (v)=(n)+(o)+(p)+(q)+(r)+(s)+(t)+(u)	$932.14
Estimated Total Annual Burden Cost (w)=(c)*(v)	$56,925,790

12.5.4 *Burden for Quality Data Submission via CMS Web Interface*

Based on 2015 PQRS data and as shown in Table 10, we assume that 298 groups will submit quality data via the CMS Web Interface in the 2018 MIPS performance period. We anticipate that approximately 252,808 clinicians will be represented.

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 74 hours of a computer systems analyst's time to submit quality measures data via the CMS Web Interface at a cost of $88.10 per hour, for a total cost of $6,519 (74 hours X $88.10/hour). Our estimate of 74 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 (we will partially pre-populate the CMS Web Interface with claims data from their Medicare Part A and B beneficiaries). The patient data either can be manually entered or uploaded into the CMS Web Interface via a standard file format, which can be populated by CEHRT. Because the CMS API will streamline the measure submission process for many groups, we have reduced our estimate of the computer system's analyst time needed for submission from 79 hours in the CY 2017 Quality Payment Program final rule to 74 hours. 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 assume that entering or uploading data for one Medicare beneficiary requires approximately 18 minutes of a computer systems analyst's time (74 hours ÷ 248 patients).

The total annual burden hours are estimated to be 22,052 (298 groups X 74 annual

hours) and the total annual burden cost is estimated to be $1,942,662 (298 groups X $6,519).

Based on the assumptions discussed above, we have calculated the following burden estimate for groups submitting to MIPS with the CMS Web Interface.

TABLE 10: Burden Estimate for Quality Data Submission via the CMS Web Interface

	Burden Estimate
Estimated # of Eligible Group Practices (a)	298
Estimated Total Annual Burden Hours Per Group to Submit (b)	74
Estimated Total Annual Burden Hours (c) = (a)*(b)	22,052
Estimated Cost Per Group to Report (@ computer systems analyst's labor rate of $88.10/hr.) (d)	$88.10
Estimated Total Annual Cost Per Group (e) = (b)*(d)	$6,519
Estimated Total Annual Burden Cost (f) = (a)*(e)	$1,942,662
	By Eligible Clinician or Group
Estimated # of Participating Eligible Professionals (g)	252,808
Average Burden Hours Per Eligible Professional (h) = (c) ÷ (g)	0.09
Estimated Cost Per Eligible Professional to Report Quality Data (i) = (f) ÷ (g)	$7.68

12.5.5 *Burden for Group Registration for CMS Web Interface*

Groups interested in participating in MIPS using the CMS Web Interface for the first time must complete an on-line registration process. After first time registration, groups will only need to opt out if they are not going to continue to submit via the CMS Web Interface. In Table 11, we estimate that the registration process for groups under MIPS involves approximately 1 hour of administrative staff time per group. We assume that a billing clerk will be responsible for registering the group and that, therefore, this process has an average computer systems analyst labor cost of $88.10 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 $88.10 ($88.10 per hour X 1 hour per group). We assume that approximately 10 groups will elect to use the CMS Web Interface submission mechanism in the 2018 MIPS performance period. The total annual burden hours are estimated to be 10 (10 groups X 1 annual hour), and the total annual burden cost is estimated to be $881.00 (10 groups X $88.10).

TABLE 11: Total Estimated Burden for Group Registration for CMS Web Interface

	Burden Estimate
Estimated Number of New Groups Registering for CMS Web Interface (a)	10
Estimated Annual Burden Hours Per Group (b)	1

Estimated Total Annual Burden Hours (c) = (a)*(b)	**10**
Estimated Cost per Group to Register for CMS Web Interface @ computer systems analyst's labor rate of $88.10/hr.) (d)	$88.10
Estimated Total Annual Burden Cost for CMS Web Interface Group Registration (e) = (a)*(d)	**$881**

12.6 *Burden for Advancing Care Information Data*

During the 2018 MIPS performance period, clinicians, groups, and virtual groups can submit advancing care information data through qualified registry, QCDR, EHR, CMS Web Interface, and attestation data submission methods. We have worked to further align the advancing care information performance category with other MIPS performance categories. We anticipate that most organizations will use the same data submission mechanism for the advancing care information and quality performance categories, and that the clinicians, practice managers, and computer systems analysts involved in supporting the quality data submission will also support the advancing care information data submission process. Hence, the burden estimate for the submission of advancing care information data below shows only incremental hours required above and beyond the time already accounted for in the quality data submission process. While this analysis assesses burden by performance category and submission mechanism, we emphasize that MIPS is a consolidated program and submission analysis and decisions are expected to be made for the program as a whole.

12.6.1 *Burden for Advancing Care Information Application*

As stated in the CY 2017 Quality Payment Program final rule, some MIPS eligible clinicians may not have sufficient measures applicable and available to them for the advancing care information performance category, and as such, they may apply to have the advancing care information category re-weighted to zero in the following circumstances: insufficient internet connectivity, extreme and uncontrollable circumstances, lack of control over the availability of CEHRT (81 FR 77240 through 77243). We are proposing to allow MIPS eligible clinicians to apply to have their advancing care information performance category re-weighted to zero through the Quality Payment Program due to a significant hardship exception or exception for decertified EHR technology. We are also proposing that MIPS eligible clinicians who are in small practices (15 or fewer clinicians) may, beginning with the 2018 performance period and 2020 MIPS payment year, request a reweighting to zero for the advancing care information category due to a significant hardship. We are proposing to rely on section 1848(o)(2)(D) of the Act, as amended by section 4002(b)(1)(B) of the 21st Century Cures Act, as our authority for the significant hardship exceptions.

Table 12 shows the estimated annualized burden for clinicians to apply for a reweighting

to zero of their advancing care information performance category due to a significant hardship exception or as a result of a decertification of an EHR, as well as an application for significant hardship by small practices. Based on 2016 data from the Medicare EHR Incentive Program and the first 2019 payment year MIPS eligibility and special status file, we assume 50,689 respondents (eligible clinicians, groups, or virtual groups) will submit a request for reweighting to zero of their advancing care information category due to a significant hardship exception, decertification of an EHR or significant hardship for small practices through the Quality Payment Program. We estimate that 6,699 respondents (eligible clinicians, groups, or virtual groups) will submit a request for a reweighting to zero for the advancing care information performance category due to extreme and uncontrollable circumstances or as a result of a decertification of an EHR, and 43,990 respondents will submit a request for a reweighting to zero for the advancing care information performance category as a small practice. The application to request a reweighting to zero for the advancing care information performance category due to significant hardship is a short online form that requires identifying which type of hardship or if decertification of an EHR applies and a description of how the circumstances impair the ability to submit the advancing care information data, as well as some proof of circumstances beyond the submitter's control. The estimate to submit this application is 0.5 hours of a computer system analyst's time. Given that we expect 50,689 applications per year, the annual total burden hours are estimated to be 25,345 hours (50,689 respondents X 0.5 burden hours per respondent). The estimated total annual burden is $2,232,850 (50,689 X $44.05).

TABLE 12: Burden Estimate for Application for Advancing Care Information Reweighting

	Burden estimate
# of Eligible Clinicians, Groups, or Virtual Groups Applying Due to Significant Hardship and Other Exceptions (a)	6,699
# of Eligible Clinicians, Groups, or Virtual Groups Applying Due to Significant Hardship as Small Practice (b)	43,990
Total respondents Due to Hardships, Other Exceptions and Hardships for Small Practices (c)	50,689
Estimated Burden Hours Per Applicant for Advancing Care Information (d)	0.5
Estimated Total Annual Burden Hours (e)=(a)*(c)	25,345
Estimated Cost Per Applicant for Advancing Care Information (@ computer systems analyst's labor rate of $88.10/hr.) (f)	$44.05
Estimated Total Annual Burden Cost (g)=(a)*(f)	$2,232,850

12.6.2 *Number of Organizations Submitting Advancing Care Information Data on Behalf of Eligible Clinicians*

A variety of organizations will submit advancing care information data on behalf of clinicians. Clinicians not participating in a MIPS APM can submit as individuals or as part of a group or virtual group. Group TINs may submit advancing care information data on behalf of clinicians in MIPS APMs, or, except for participants in the Shared Savings Program, clinicians in MIPS APMs may submit advancing care information performance category data individually. Because group TINs in APM Entities will be submitting advancing care information 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 list of APMs that are MIPS APMs on the QPP website,[15] we assume that 5 MIPS APMs that do not also qualify as Advanced APMs will operate in the 2018 MIPS performance period: Track 1 of the Shared Savings Program, CEC (one-sided risk arrangement), OCM (one-sided risk arrangement), and the Comprehensive Primary Care Plus Model (CPC+). Further, we assume that group TINs will submit advancing care information data on behalf of Partial QPs that elect to participate in MIPS.

As shown in Table 13, based on 2015 data from the Medicare EHR Incentive Program and the data prepared to support the 2017 performance period initial determination of clinician eligibility and special status determination (available via the NPI lookup on qpp.cms.gov) using a date range of September 1, 2015 – August 31, 2016, we estimate that 265,895 individual MIPS eligible clinicians and 301 groups or virtual groups, representing 106,406 MIPS eligible clinicians, will submit advancing care information data. These estimates reflect that under the policies finalized in CY 2017 Quality Payment Program final rule, certain MIPS eligible clinicians will be eligible for automatic reweighting of their advancing care information performance category score to zero, including MIPS eligible clinicians that practice primarily in the hospital, physician assistants, nurse practitioners, clinician nurse specialists, certified registered nurse anesthetists, and non-patient facing clinicians. These estimates also account for the significant hardships finalized in the CY 2017 Quality Payment Program final rule and our proposed policies for significant hardship exceptions, including for MIPS eligible clinicians in small practices, as well as exceptions due to decertification of an EHR. Due to data limitations, our estimate of the number of clinicians to submit advancing care information data does not account for our proposal to rely on section 1848(o)(2)(D) of the Act, as amended by section 4002(b)(1)(B) of the 21st Century Cures Act, to assign a scoring weight of zero percent for the advancing care information performance category for MIPS eligible clinicians who are determined to be based in ASCs.

Further, we anticipate that the 480 Shared Savings Program ACOs will submit data at the ACO participant group TIN-level, for a total of 15,945 group TINs. We anticipate that the three APM Entities electing the one-sided track in the CEC model will submit data at the group TIN-level, for an estimated total of 100 group TINs submitting data. We anticipate that the 195 APM

[15] https://qpp.cms.gov/docs/QPP_Advanced_APMs_in_2017.pdf

Entities in the OCM (one-sided risk arrangement) will submit data at the APM Entity level, for an estimated total of 6,478 group TINs. Based on a preliminary version of the file used for the predictive qualifying APM participants analysis made available on qpp.cms.gov on June 2, 2017, and prepared using claims for services between January 1, 2016 through August 31, 2016, we estimate 2 APM Entities in the CPC+ model will submit at the group TIN-level, for an estimated total of 2 group TINs submitting data. Based on preliminary data, we assume that 1 CPC+ APM entity will submit data because one or more of its participants is a partial QP, and that 1 CPC+ APM Entity will submit data because some of its participants qualify as either as QPs or partial QPs. The total estimated number of respondents is estimated at 288,721.

TABLE 13: Estimated Number of Respondents to Submit Advancing Care Information Performance Data on Behalf of Clinicians

	Estimated # of Respondents	**Estimated # of APM Entities**
Number of Individual clinicians to submit advancing care information (a)	265,895	Not applicable
Number of groups or virtual groups to submit advancing care information (b)	301	Not applicable
Shared Savings Program ACO Group TINs (c)	15,945	480
CEC one-sided risk track participants[16] (d)	100	3
OCM one-sided risk arrangement Group TINs (e)	6,478	195
CPC+ TINs (f)	2	2
Total (g) = (a) + (b) + (c) + (d) + (e) + (f)	288,721	680

12.6.3 *Burden for Submission of Advancing Care Information Data*

In Table 14, we estimate that up to approximately 288,721 respondents will be submitting data under the advancing care information performance category, 265,895 clinicians, 301 groups or virtual groups, 15,945 group TINs within the Shared Savings Program ACOs, 100 group TINs within the APM Entity participating in CECs in the one-sided risk track, and 6,478 group TINs within the OCM (one-sided risk arrangement), and 2 CPC+ group TINs. We estimate this is a significant reduction in respondents from the 2017 MIPS performance period as a result of our proposed policy to provide significant hardship exceptions, including for MIPS eligible clinicians in small practices, as well as for situations due to decertification of an EHR, and our proposed policy to allow eligible clinicians to participate as part of a virtual group.

We account for multiple submission mechanisms in our improvement activities burden

[16] The 3 CEC APM Entities reflected in the burden estimate are the non-large dialysis organizations participating in the one-sided risk track.

estimate by assuming that clinicians, groups, and virtual groups that submit via multiple submission mechanisms for the quality performance category will also submit via multiple submission mechanisms for the advancing care information performance category.

In the CY 2017 Quality Payment Program final rule, our burden estimates assumed all clinicians who submitted quality data would also submit under advancing care information. For the proposed rule, MIPS special status eligibility data were available to model exceptions. The majority (214,302) of the difference in our estimated number of respondents is due to the availability of MIPS special status data to identify clinicians and groups that would also not need to report advancing care information data under transition year policies, including facility-based eligible clinicians, clinician types eligible for automatic reweighting of their advancing care information performance category score, non-patient facing clinicians, and clinicians facing a significant hardship. The remaining decline in respondents is due to policies proposed in this rule, including 25,881 respondents who would be excluded under the new proposed significant hardship exception for small practices.

Our burden estimates in the CY 2017 Quality Payment Program final rule assumed that during the transition year, 3 hours of clinician time would be required to collect and submit advancing care information performance category data. We anticipate that the year-over-year consistency of data submission processes, measures, and activities and the further alignment of the advancing care information performance category with other performance categories will reduce the clinician time needed under this performance category in the 2018 MIPS performance period. Further, for some practices the staff mix requirements in the 2018 MIPS performance period may be driven more by transition to 2015 CEHRT. Therefore, as shown in Table 15, the total burden hours for an organization to submit data on the specified Advancing Care Information Objectives and Measures is estimated to be 3 incremental hours of a computer analyst’s time above and beyond the clinician, practice manager, and computer system’s analyst time required to submit quality data. The total estimated burden hours are 866,163 (288,721 respondents X 3 hours). At a computer systems analyst’s hourly rate, the total burden cost is $76,308,960 (288,721 X $264.30/hour).

TABLE 14: Estimated Burden for Advancing Care Information Performance Category Data Submission

	Burden Estimate
# of respondents submitting advancing care information data on behalf of clinicians (a)	288,721
Estimated Total Annual Burden Hours Per Respondent (b)	3
Estimated Total Annual Burden Hours (c) = (a)*(b)	866,163

Estimated Cost Per Respondent to Submit Advancing Care Information data (@ computer systems analyst's labor rate of $88.10/hr.) (d)	$264.30
Estimated Total Annual Burden Cost (e) = (a)*(d)	$76,308,960

12.7 *Burden for Improvement Activities Submission*

Requirements for submitting improvement activities did not exist in the legacy programs replaced by MIPS, and we do not have historical data which is directly relevant. A variety of organizations and in some cases, individual clinicians, will submit improvement activity performance category data. For clinicians who are not part of APMs, we assume that clinicians submitting quality data as part of a group or virtual group through the QCDR and registry, EHR, and CMS Web Interface submission mechanisms will also submit improvement activities data. Further, we assume that clinicians and groups that practice primarily in the hospital that elect facility-based measurement for the quality performance category will also submit improvement activities data. MIPS eligible clinicians participating in MIPS APMs do not need to submit improvement activities data unless the CMS-assigned improvement activities score is below the maximum improvement activities score. As represented in Table 15, we estimate 520,654 clinicians will submit improvement activities as individuals during the 2018 MIPS performance period, an estimated 3,818 groups to submit improvement activities on behalf of clinicians during the 2018 MIPS performance period, and an additional 16 virtual groups to submit improvement activities, resulting in 524,488 total respondents. The burden estimates assume there will be no improvement activities burden for MIPS APM participants. We 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.

We account for multiple submission mechanisms in our improvement activities burden estimate by assuming that clinicians, groups, and virtual groups that submit via multiple submission mechanisms for the quality performance category will also submit via multiple submission mechanisms for the improvement activities performance category.

TABLE 15: Estimated Numbers of Organizations Submitting Improvement Activities Performance Category Data on Behalf of Clinicians

	Count
Estimated # of clinicians to participate in Improvement Activities data submission as individuals during the 2018 MIPS performance period (a)	520,654
Estimated # of Groups to submit improvement activities on behalf of clinicians during the 2018 MIPS performance period (b)	3,818
Estimated # of Virtual Groups to submit improvement activities on behalf of clinicians during the 2018 MIPS performance period (c)	16

Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the 2018 MIPS performance period (d) = (a) + (b) + (c)	524,488

In Table 16, we estimate that approximately 524,488 respondents will be submitting data under the improvement activities performance category. Our burden estimates in the CY 2017 Quality Payment Program final rule assumed that during the transition year, 2 hours of clinician time would be required to submit data on the specified improvement activities. For the proposed rule, our burden estimate has been revised to assume that the total burden hours to submit data on the specified improvement activities will be 1 hour of computer system analyst time in addition to time spent on other performance categories. Our revised estimate is based on feedback from stakeholders that these are activities they have already been doing and tracking so there is no additional development of material needed. Additionally, the same improvement activity may be reported across multiple performance periods so many MIPS eligible clinicians will not have any additional information to develop for the 2018 MIPS performance period. The total estimated burden hours are 524,488 (524,488 responses X 1 hour). At a computer systems analyst's hourly rate, the total burden cost is $46,207,393 (524,488 X $88.10/hour).

TABLE 16: Estimated Burden for Improvement Activities Submission

	Burden Estimate
Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the 2018 MIPS performance period (a)	524,488
Estimated Total Annual Burden Hours Per Respondent (b)	1
Estimated Total Annual Burden Hours (c)	524,488
Estimated Cost Per Respondent to Submit Improvement Activities (@ computer systems analyst's labor rate of $88.10/hr.) (d)	$88.10
Estimated Total Annual Burden Cost (e) = (a)*(d)	$46,207,393

12.8 *Burden for Nomination of Improvement Activities*

For the 2018 MIPS performance period, we are also proposing to allow clinicians, groups, and other relevant stakeholders to nominate new improvement activities using a nomination form provided on the Quality Payment Program website at qpp.cms.gov, and to send their proposed new improvement activities to us via email. As shown in Table 17, based on response to an informal call for new proposed improvement activities during the transition year, we estimate that approximately 150 organizations (clinicians, groups or other relevant stakeholders) will nominate new improvement activities. We estimate it will take an estimated 0.5 hours per organization to submit an activity to us, including an estimated 0.3 hours per

practice for a practice administrator to identify and submit an activity to us via email at a rate of $105.16/hour for a total of $31.55 per activity and clinician review time of 0.2 hours at a rate of $202.08/hour for a total of $40.42 per activity. We estimate that the total annual burden cost is $10,796 (150 x $71.96).

TABLE 17: Estimated Burden for Nomination of Improvement Activities

	Burden estimate
# of Organizations Nominating New Improvement Activities (a)	150
Estimated # of Hours Per Practice Administrator to Identify and Propose Activity (b)	0.30
Estimated # of Hours Per Clinician to Identify Activity (c)	0.20
Estimated Annual Burden Hours Per Respondent (d)= (b) + (c)	0.50
Estimated Total Annual Burden Hours (e) = (a)*(d)	75.00
Estimated Cost to Identify and Submit Activity (@ practice administrator's labor rate of $105.16/hr.) (f)	$31.55
Estimated Cost to Identify Improvement Activity (@ physician’s labor rate of $202.08/hr.) (g)	$40.42
Estimated Total Annual Cost Per Respondent (h)=(f)+(g)	$71.97
Estimated Total Annual Burden Cost (i)=(a)*(h)	$10,796

12.9 *Burden for Cost*

The cost performance category relies on administrative claims data. The Medicare Parts A and B claims submission process is used to collect data on cost 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.

12.10 *Burden for Partial QP Elections*

APM Entities may face a data submission burden under MIPS related to Partial QP elections. Advanced APM participants will be notified about their QP or Partial QP status before the end of the performance period. For Advanced APMs the burden of Partial QP election would be incurred by a representative of the participating APM Entity. For the purposes of this burden estimate, we assume that all MIPS eligible clinicians determined to be Partial QPs will participate in MIPS.

Based on our analyses of a preliminary version of the file used for the predictive qualifying APM participants analysis made available on qpp.cms.gov on June 2, 2017, and prepared using claims for services between January 1, 2016 through August 31, 2016, we assume that approximately 17 APM Entities will face the data submission requirement in the 2018 performance period.

As shown in Table 18, we assume that 17 APM Entities will make the election to participate as a partial QP in MIPS. We estimate it will take the APM Entity representative 15 minutes to make this election. Using a computer systems analyst's hourly labor cost, we estimate a total burden cost of just $375 (17 participant X $22.03).

TABLE 18: Estimated Burden for Partial QP Election

	Burden Estimate
# of APM Entities Electing Partial QP Status on behalf of their Participants (a)	17
Estimated Burden Hours Per Respondent to Elect to Participate as Partial QP (d)	0.25
Estimated Total Annual Burden Hours (e)= (c)*(d)	4.25
Estimated Cost Per Respondent to Elect to Participate as Partial QP (@ computer systems analyst's labor rate of $88.10/hr.) (f)	$22.03
Estimated Total Annual Burden Cost (g) = (c)*(f)	$375

12.11 *Burden for Other Payer Advanced APM Identification: Payer-Initiated Process*

Beginning in Quality Payment Program Year 3, the All-Payer Combination Option will be an available pathway to QP status for eligible clinicians participating sufficiently in Advanced APMs and Other Payer Advanced APMs. The All-Payer Combination Option allows for eligible clinicians to achieve QP status through their participation in both Advanced APMs and Other Payer Advanced APMs. In order to include an eligible clinician's participation in Other Payer Advanced APMs in their QP threshold score, we will need to determine if certain payment arrangements with other payers meet the criteria to be Other Payer Advanced APMs. To provide eligible clinicians with advanced notice prior to the start of the 2019 QP performance period, and to allow other payers to be involved prospectively in the process, the proposed rule has outlined a payer-initiated identification process for identifying payment arrangements that qualify as Other Payer Advanced APMs. This payer-initiated identification process of Other Payer Advanced APMs will begin in CY 2018, and determinations would be applicable for the Quality Payment Program Year 3.

As shown in Table 19, we estimate that 300 other payer arrangements will be submitted

(50 Medicaid payers, 150 MA Organizations, and 100 Multi-payers) for identification as Other Payer Advanced APMs. The estimated burden to apply is 10 hours per payment arrangement, for a total annual burden hours of 3,000 (300 X 100). We estimate a total cost per payer of $881.00 using a computer system analyst's rate of $88.10/hour (10 X 81.10). The total annual burden cost for all other payers is $264,300 (300 X $881.00).

TABLE 19: Burden for Prospective Identification of Other Payer Advanced APMs

	Burden Estimate
Estimated # of other payer payment arrangements (50 Medicaid, 150 MA Organizations, 100 Multi-payers) (a)	300
Estimated Total Annual Burden Hours Per other payer payment arrangement (b)	10
Estimated Total Annual Burden Hours (c) = (a)*(b)	3,000
Estimated Cost Per Other Payer (@ computer systems analyst's labor rate of $88.10/hr.) (d)	$881.00
Estimated Total Annual Burden Cost for Identifying Other Payer Advanced APMs (e) = (a)*(d)	$264,300

12.13 *Burden Estimate for Voluntary Participants to Elect Opt Out of Performance Data Display on Physician Compare*

We estimate 22,400 clinicians and groups who will voluntarily participate in MIPS but will also elect not to participate in public reporting. Table 20 shows that for these voluntary participants, they may submit a request to opt out which is estimated at 0.25 hours of a computer system analyst's labor rate of $88.10. The total annual burden hours for opting out is estimated at 5,600 hours (22,400 X 0.25). The total annual burden cost for opting out for all requesters is estimated at $493,472 (22,400 X $22.03).

TABLE 20: Burden for Voluntary Participants to Elect Opt Out of Performance Data Display on Physician Compare

	Burden Estimate
Estimated # of Voluntary Participants Opting Out of Physician Compare (a)	22,400
Estimated Total Annual Burden Hours Per Opt-out Requester (b)	0.25
Estimated Total Annual Burden Hours for Opt-out Requester (c) = (a)*(b)	5,600
Estimated Cost Per Physician Compare Opt-out Request@ computer systems analyst's labor rate of $88.10/hr.) (d)	$22.03
Estimated Total Annual Burden Cost for Opt-out Requester (e) = (a)*(d)	$493,472

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

15. Program or Burden Changes

The total estimated burden associated with the information collections submitted for approval as a revision of OMB control number 0938-1314 is 9,361,065 hours with a total labor cost of $856,214,758.

TABLE 21: Proposed Annual Recordkeeping and Submission Requirements

	Respondents/ responses	Hours per response	Total annual burden hours	Labor cost of submission	Total annual burden cost
§414.1345 Election of Facility-Based Measurement	18,207	1.0	18,207	$36.12	$657,637
§414.1400 QCDR and Registries self- nomination	233	10.0	2,330	$88.10	205,273
§414.1330 and §414.1335 (Quality Performance Category) Claims Submission Mechanism	364,002	17.8	6,479,236	Varies (See Table 7)	$595,645,593
§414.1330 and §414.1335 (Quality Performance Category) Qualified Registry or QCDR Submission Mechanisms	88,501	9.1	803,855	Varies (See Table 8)	$75,318,776
§414.1330 and §414.1335 (Quality Performance Category) EHR-Submission Mechanism	61,070	10.0	610,700	Varies (See Table 9)	$56,925,790
§414.1330 and §414.1335 (Quality Performance Category) CMS Web Interface Submission Mechanism	298	74.0	22,052	$88.10	$1,942,662
§414.1330 and §414.1335 (Quality Performance Category) Registration and Enrollment for CMS Web Interface	10	1.0	10	$88.10	$881
§414.1375 (Advancing Care Information Performance Category) Significant Hardships, including for small practices and decertification of EHRs	50,689	0.5	25,345	$88.10	$2,232,850
§414.1375 (Advancing Care Information Performance Category) Data Submission	288,721	3.0	866,163	$88.10	$76,308,960
§414.1360 (Improvement Activities Performance Category) Data Submission	524,488	1.00	524,488	$88.10	$46,207,393
§414.1360 (Improvement Activities Performance Category) Call for Activities	150	0.5	75	Varies (See Table 17)	$10,796
§414.1430 Partial Qualifying APM Participant (QP) Election	17	0.3	4	$88.10	$375
§414.1440 Other Payer Advanced APM Identification: Other Payer Initiated Process	300	10.0	3,000	$88.10	$264,300

	Respondents/ responses	Hours per response	Total annual burden hours	Labor cost of submission	Total annual burden cost
§414.1395 (Physician Compare) Opt Out for Voluntary Participants	22,400	0.3	5,600	$88.10	$493,472
Total for this PRA Package (0938-1314)	1,419,086		9,361,065		$856,214,758

To understand the burden implications of the proposals in the proposed rule, we have also estimated a baseline burden of continuing the policies and information collections set forth in the CY 2017 Quality Payment Program final rule into the 2018 MIPS performance period. The baseline burden estimates employ the improved data and methods also used for our year CY 2018 burden estimates. Because information collection requests related the CAHPS for MIPS survey and virtual groups elections information collection are submitted under separate OMB control numbers, the burden calculations do not include the CAHPS for MIPS and virtual groups elections

In order to accurately model changes in burden due to the policies in the proposed rule, we have estimated baseline a burden of 9,611,390 hours and a total labor cost of $879,892,319 of continuing transition year policies into a second year of implementation. This baseline burden estimate is lower than the burden approved for information collection related to the CY 2017 Quality Payment Program final rule due to updated data and assumptions, and because it does not include the burden for CAHPS for MIPS.[17] As shown in Table 22, our baseline estimate assumes decreased respondent time due to greater familiarity with the measures and data submission methods in their second year of participation. Further, our estimated baseline burden estimates reflect the recent availability of data sources to more accurately reflect the number of the organizations exempt from the advancing care information performance category in the transition year, and the recent availability of preliminary data that identifies clinicians that will be excluded from MIPS in the transition year because they are QPs.

Our baseline burden estimates have also been revised to assume that MIPS eligible clinicians and groups that reported via multiple mechanism under the 2015 PQRS would continue to do so in the transition year. We do not anticipate the proposal for multiple submission mechanisms would change behavior and result in an increase in burden in the quality performance category relative to the baseline of continued transition year policies. Specifically, we assume that MIPS eligible clinicians and groups that reported via multiple mechanisms during the transition year would continue to report that way for the 2018 MIPS performance period as they did under PQRS; the proposed change in policy is that they will receive credit for

[17] The burden estimate for the CY 2017 Quality Payment Program final rule was 10,940,417 hours for a total labor cost of $1,349,763,999. For comparability for the burden estimate in the proposed rule, the burden estimate for the CY 2017 Quality Payment Program final rule has been updated using 2016 wages.

that existing behavior. The previously approved information collection burden for the transition year did not take into account the burden of multiple submission mechanisms because our burden estimates used methods consistent with those used for the legacy PQRS program.

We estimate that the proposed rule will reduce burden by 250,325 hours and $23,677,561 in labor costs relative to the estimated baseline of continued transition year policies. The reduction in burden for the 2018 MIPS performance period is reflective of several proposed policies, including a new significant hardship exception for small practices for the advancing care information performance category. Our burden estimates also reflect our proposal to allow clinicians that practice primarily in the hospital to elect to use facility-based measurements, thereby eliminating the need for additional quality data submission processes; and our proposal to allow MIPS eligible clinicians to form virtual groups, which would create efficiencies in data submission.

Table 22 provides the reasons for changes in the estimated burden for information collections between the CY 2017 Quality Payment Program final rule and CY 2018 Quality Payment Program proposed rule. We have divided the reasons for our change in burden into those related to new policies in the CY 2018 proposed rule, and those related to changes in the baseline burden of continued Year 1 policies that reflect updated data and methods.

TABLE 22: Reasons for Change in Burden Compared to the Currently Approved CY 2017 Information Collection Burdens

Table in PRA Package	Changes in burden due to proposed Year 2 policies	Changes to "baseline" of burden continued Year 1 policy (*italics are changes in number of respondents due to updated data)*
TABLE 4: Election to Participate in Facility-based Measurement	Reflects new policy in Year 2 proposed rule.	None
TABLE 5: QCDR and Registry Self-Nomination	None	*Increase in the number of respondents as the number of QCDRs and qualified registries enrolling increases.*
TABLE 7: Quality Performance Category: Clinicians Using the Claims Submission Mechanism	Decrease in number of respondents due to facility-based measurement proposals.	*Increased number of respondents due to taking into account burden of multiple submission mechanisms.* . Decrease in time needed due to familiarity with measures (-1 hr. clinician time).
TABLE 8: Quality Performance Category: Qualified Registry/QCDR Submission	Decrease data submissions due to facility-based measurement proposals. Decrease due to consolidated reporting opportunity in virtual group proposals.	Decrease in time needed due to familiarity with measures (-1 hr. clinician time). *Increased number of respondents due to updated method of taking into account burden of multiple submission mechanisms.*
TABLE 9: Quality Performance Category: Clinicians (Submitting Individually or as Part of a Group) Using the EHR Submission Mechanism	Decrease data submissions due to facility-based measurement proposals. Decrease due to consolidated reporting opportunity in virtual group proposals.	Decrease in time needed due to familiarity with measures (-1 hr. clinician time).
TABLE 10: Quality Data Submission via the CMS Web Interface	None	Decrease in time needed due to familiarity with measures (-1 hr. clinician time). Decrease in time needed due to new API (- computer systems' analyst time from 79 to 74 hrs.) *Decrease in respondents by not including Shared Savings Program and Next Generation ACOs. Assumption updated from Year 1 burden estimate to accurately reflect that quality measures submitted for the purposes of fulfilling the Shared Savings Program and Next Generation ACO requirements are not subject to the PRA.*

Table in PRA Package	**Changes in burden due to proposed Year 2 policies**	**Changes to "baseline" of burden continued Year 1 policy (*italics are changes in number of respondents due to updated data)***
TABLE 11: Registration for CMS Web Interface	None	In the Year 1 Rule burden estimate, CMS Web Interface registration was folded in with CMS Web Interface data submission; assumed all groups using Web Interface would have to register. This has been updated to more accurately show that only new CMS Web Interface submitters are required to register.
TABLE 12: Application for Advancing Care Information Reweighting	Increase in the number of clinicians applying for the hardship exception due to the proposal for a hardship exception for small practices.	Decrease in the time spent by hardship applicants, as hardship data was not available for the Year 1 model, so hardship applicants received the standard ACI burden estimate of 3 hours. *In the Year 2 model, hardship applicants are identified using data from the EHR incentive program and are estimated to need 1 hour to apply for the exception.*
TABLE 14: Advancing Care Information Performance Category Data Submission	Decrease in participants due the proposed hardship exception for small practices. Not included due to unavailable data: Decrease in participants due to the automatic exclusion for ASC.	*Decrease in the number of respondents (and decrease in eligible clinician population) due to availability of data on 2017 QPs.* *Increase in respondents due to the increase in MIPS APM participants.* Decreased costs as labor mix changes from 3 hours of clinician time to 3 hours of computer system's analyst time because this category is typically submitted via same submission mechanism as quality (and quality has a mix of labor categories), and because in the second year this effort may be driven more by transition to 2015 CEHRT. *Reduced number of participants in advancing care information performance category using newly available of MIPS special status data identifying hospital-based; non-patent facing clinicians; and certain clinician types.* *Increased number of responses due to taking into account burden of multiple submission mechanisms.*

Table in PRA Package	**Changes in burden due to proposed Year 2 policies**	**Changes to "baseline" of burden continued Year 1 policy (*italics are changes in number of respondents due to updated data)***
TABLE 16: Improvement Activities Submission	None	*Decrease in the eligible clinician population due to growth in QPs.* Decrease in time and labor category needed from 3 hours of clinician time to 1 hour of computer system's analyst time to reflect that improvement activities data submission burden minimal due to attestation, and greater clinician familiarity with activities and submission process in second year of program. *Increased number of responses due to taking into account burden of multiple submission mechanisms.*
TABLE 17: Nomination of Improvement Activities	Increase due to new proposed policy for annual call for activities process for improvement activities via a form. The Year 1 Rule asked for comments on the development of a process, and during Year 1 CMS made an informal call for activities to be submitted by e-mail (not subject to PRA).	None
TABLE 18: Partial QP Election	None	Reduction in hours from 0.5 to 0.25 and change in labor category from clinician to computer systems analyst due to greater practice familiarity with QPP portal in Year 2.
TABLE 19: Prospective Identification of Other Payer Advanced APMs	Reflects new policy in Year 2 proposed rule.	None
TABLE 20: Voluntary Participants to Elect to Opt Out of Performance Data Display on Physician Compare	Reflects new policy in Year 2 proposed rule.	None

16. Publication and Tabulation Dates

To ensure that MIPS results are useful and accurate, CMS proposes to provide performance feedback to MIPS eligible clinicians that includes MIPS quality and cost data and if technically feasible to also include improvement activities and advancing care information data. CMS plans to work collaboratively with stakeholders to design feedback reports, and to make feedback available through multiple mechanisms including qpp.cms.gov and third-party vendors. CMS also proposes to provide performance feedback to MIPS eligible clinicians who participate in MIPS APMs in 2018 and future years as technically feasible. This reflects our commitment to providing as timely information as possible to eligible clinicians 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 2019 for the 2018 MIPS 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. The Physician Compare performance year 2016 measures will be available for preview at the Physician Compare website https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/physician-compare-initiative/

17. Expiration Date

There are no paper forms involved in this data collection activity. The expiration date will be displayed on all web-based data collection forms.

18. Certification Statement

There are no exceptions to the certification statement.