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

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. MIPS and Advanced Alternative Payment Models (AAPMs) are the two paths for clinicians available through the Quality Payment Program authorized by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). As prescribed by 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.

Under the AAPM path, eligible clinicians may become Qualifying APM Participants (QPs) and are excluded from MIPS. Partial Qualifying APM Participants (Partial QPs) may opt to report and be scored under MIPS. Where Partial QP status is earned at the APM Entity level the burden of Partial QP election would be incurred by a representative of the participating APM Entity. For Advanced APMs where Partial QP status is earned at the eligible clinician level, the burden of Partial QP election would be incurred by the eligible clinician. For the 2020 MIPS performance period, we finalized that APM Entities or eligible clinicians must submit all of the required information about the Other Payer Advanced APMs in which they participate, including those for which there is a pending request for an Other Payer Advanced APM determination, as well as the payment amount and patient count information sufficient for us to make QP determinations by December 1 of the calendar year that is 2 years to prior to the payment year, which we refer to as the QP Determination Submission Deadline (82 FR 53886). This data collection will first occur during the 2019 MIPS performance period.

The implementation of MIPS requires the collection of quality, Promoting Interoperability (previously advancing care information), and improvement activities performance category data.[1] For the quality performance category, MIPS eligible clinicians and groups will have the option to submit data using various submission types, including Medicare claims, direct, log in and upload, CMS Web Interface, and CMS-approved survey vendors.[2] Virtual groups are subject to the same requirements as groups, therefore we will refer only to groups as an inclusive term for both unless otherwise noted. For the improvement activities and Promoting Interoperability, clinicians and groups can submit data through direct, log in and upload, or log in and attest submission types. With the exception of submitters who elect to use the log in and attest submission type for the Promoting Interoperability and improvement activities performance

[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).

categories which is not available for the quality performance category and clinicians who use Medicare Part B claims, administrative claims, or the CMW Web Interface which are not available for the Promoting Interoperability and improvement activities performance categories, we anticipate that most organizations will use the same data submission type for all three of these performance categories and that the clinicians, practice managers, and computer systems analysts involved in supporting the quality data submission will also support the Promoting Interoperability and improvement activities data submission processes.

In the CY 2019 Physician Fee Schedule (PFS) final rule, we have finalized several scoring and measurement policies that would bring the Promoting Interoperability performance category to a new phase of EHR measurement with an increased focus on interoperability and improving patient access to health information. To better reflect this focus, we are renaming the advancing care information performance category to the Promoting Interoperability (PI) performance category. In addition to policies finalized in the CY 2017 and CY 2018 Quality Payment Program final rules, for the 2019 MIPS performance period, we have finalized to automatically reweight the Promoting Interoperability performance category for clinician types new to MIPS: physical therapists, occupational therapists, qualified speech-language pathologists or qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals. We have also finalized for the 2019 MIPS performance period a net reduction of 3 Promoting Interoperability measures (6 removed measures and 3 new measures) for which clinicians are required to submit data.

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. In order to use either the log in and upload or log in and attest submission types or to access feedback reports, clinicians, groups, virtual groups, or third-parties who do not already have CMS Enterprise Portal user accounts must register for one. Clinicians, groups, and other relevant stakeholders may nominate new improvement activities, Promoting Interoperability measures, and quality measures using nomination forms provided on the Quality Payment Program website at qpp.cms.gov, and in the case of quality measures must also submit a completed Peer Review Journal Article form also provided on the Quality Payment Program website.

In addition, this Quality Payment Program information collection request includes one new information collections relating to Advanced APMs. This collection request is to enable us to make QP determinations under the All-Payer Combination Option by requiring submission of payment amount or patient count information (1) attributable to an eligible clinician or APM Entity through every Other Payer Advanced APM; and (2) for all other payments or patients, except from excluded payers, made or attributed to the eligible clinician during the QP performance period (82 FR 53885).

We are requesting approval of 19 information collections associated with the CY 2019 PFS final rule (not including the separate request for 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-10621). CMS is requesting

approval for updated burden and respondent estimates in the revised CAHPS for MIPS Paperwork Reduction Act (PRA) package (0938-1222; CMS-10450). CMS has already received approval for collection of information associated with the virtual group election process via a separate virtual group PRA package under OMB control number 0938-1343 which expires 9/30/2020.

1. Data Collection for MIPS

i. Quality Performance Category

While we have finalized in the CY 2019 PFS final rule revisions to the terminology used to describe the submission processes available for MIPS eligible clinicians, groups, and third-party intermediaries to submit data, the processes themselves are generally the same as in the CY 2018 MIPS performance period; therefore, we anticipate clinicians will be more familiar with the submission processes in this third year. We have also finalized to limit the Medicare Part B claims collection type, and therefore, the Medicare Part B claims measures, to MIPS eligible clinicians in small practices and allow clinicians in small practices to report Medicare Part B claims as a group or individuals. 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, care coordination, or opioid-related measures) in lieu of an outcome measure. If fewer than 6 measures apply to the individual MIPS eligible clinician or group, then the MIPS eligible clinician or group will be required to report on each measure that is applicable. MIPS eligible clinicians and groups can meet this criterion by selecting measures either individually or from a specialty-specific measure set.

Previously finalized MIPS quality measures can be found in the CY 2018 Quality Payment Program final rule (82 FR 53966 through 54174) and in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77816). The new MIPS quality measures finalized for inclusion in MIPS for the 2019 MIPS performance period and future years are found in Table A of the Appendix 1 of the final rule. Previously finalized specialty measure sets can be found in the CY 2018 Quality Payment Program final rule (82 FR 53976 through 54146). The new and modified quality measure specialty sets can be found in Table B of Appendix 1 of the CY 2019 PFS final rule and include new measures, previously finalized measures with modifications, and previously finalized measures with no modifications.

As established in the CY 2018 Quality Payment Program final rule, we allow MIPS eligible clinicians to apply for a redistribution of the weights for the quality, cost, and improvement activities performance categories hardship exceptions such as a natural disaster (82 FR 53783 through 53785). We 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.

ii. Promoting Interoperability Performance Category

Section 1848(q)(2)(A) of the Act includes the meaningful use of CEHRT as a performance category under the MIPS. In prior rulemaking, we referred to this performance category as the advancing care information performance category but starting with this year's rule are now calling it the "Promoting Interoperability" performance category. It is reported by MIPS eligible clinicians as part of the overall MIPS program. As required by sections 1848(q)(2) and (5) of the Act, the four performance categories of the MIPS shall be used in determining the MIPS final score for each MIPS eligible clinician. In general, MIPS eligible clinicians will be evaluated under all four of the MIPS performance categories, including the Promoting Interoperability performance category. Beginning with the 2019 MIPS performance period, MIPS eligible clinicians must use EHR technology certified to the 2015 Edition certification criteria. 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. Table N-DD6 of the final rule provides a list of Promoting Interoperability performance category objectives and measures for the MIPS Performance Period in 2019.

Beginning with the 2019 performance period, we have finalized a new scoring methodology as shown in Table N-DD2 of the final rule, to include a combination of new measures, as well as the existing Promoting Interoperability performance category measures, broken into a smaller set of four objectives and scored based on performance. Under the finalized scoring methodology, MIPS eligible clinicians will be required to report certain measures from each of the four objectives, with performance-based scoring occurring at the individual measure-level. Each measure will be scored based on the MIPS eligible clinician's performance for that measure, based on the submission of a numerator and denominator, except for the measures associated with the Public Health and Clinical Data Exchange objective, which require "yes or no" submissions. Each measure would contribute to the MIPS eligible clinician's total Promoting Interoperability performance category score. The scores for each of the individual measures would be added together to calculate the Promoting Interoperability performance category score of up to 100 possible points for each MIPS eligible clinician. For Promoting Interoperability measures, clinicians and groups can submit data through direct, log in and upload, or log in and attest submission types.

As established in the CY 2017 and CY 2018 Quality Payment Program final rules, we 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 Promoting Interoperability performance category reweighted to zero (81 FR 77240 through 77243, 82 FR 53680 through 53682). MIPS eligible clinicians with significant hardships include those who lack sufficient internet connectivity, face extreme and uncontrollable circumstances, lack control over the availability of CEHRT, do not have face-to-face interactions with patients, or clinicians in small practices with 15 or fewer professionals. We 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.

iii. 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 through direct, log in and upload, or log in and attest submission types.

In the CY 2018 Quality Payment Program final rule (82 FR 53660), we finalized that we would add new improvement activities to the Improvement Activities Inventory through notice-and-comment rulemaking. Our previously finalized Improvement Activities Inventory is found in Table H in the Appendix of the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77199) and Table F and G in the Appendix of the CY 2018 Quality Payment Program final rule (82 FR 54175 through 54229). In the CY 2019 PFS final rule, we have finalized 6 new improvement activities, 5 modifications to existing activities for CY 2019 and future years, and removal of one existing improvement activity for CY 2019 and future years. We refer readers to the Improvement Activities Inventory in Tables A and B of Appendix 2 of the final rule for further details.

iv. 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. 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.

v. Additional Data Collection

Under MIPS, there are information collections beyond performance category data submission. Other data submitted on behalf of MIPS eligible clinicians include virtual group election, CMS Web Interface registration, CAHPS for MIPS registration and reweighting application.

The policies finalized in the CY 2017 and CY 2018Quality Payment Program final rules and the CY 2019 PFS final rule create some additional data collection requirements not listed in Table 2. These additional data collections, some of which were previously approved by OMB under control number 0938-1314, are as follows:

- Self-nomination of new and returning QCDRs
- Self-nomination of new and returning qualified registries
- QPP Identity Management Application Process
- Reweighting Applications for Promoting Interoperability and Other Performance Categories

- Call for quality measures
- Nomination of new improvement activities
- Call for Promoting Interoperability measures
- 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 four information collections related to Advanced APMs. These four additional data collections are as follows:

- Partial Qualifying APM Participant (Partial QP) election
- Other Payer Advanced APM determinations: Payer Initiated Process
- Other Payer Advanced APM determinations: Eligible Clinician Initiated Process
- Submission of Data for All-Payer QP Determinations

Advanced APM Entities will face a data 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 2019 Medicare QP performance period, we define Partial QPs to be eligible clinicians in Advanced APMs who have at least 40 percent, but less than 50 percent, of their payments for Part B covered professional services through an Advanced APM Entity or furnish Part B covered professional services to at least 20 percent, but less than 35 percent, of their Medicare beneficiaries through an Advanced APM Entity. If an Advanced APM Entity is notified that they meet the Partial QP threshold, a representative from the APM Entity will log into the MIPS portal to indicate whether all eligible clinicians participating in the APM Entity meeting the Partial QP threshold wish to participate in MIPS.

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 a given performance period, and to allow other payers to be involved prospectively in the process, the CY 2018 Quality Payment Program final rule provided a payer-initiated process for identifying payment arrangements that qualify as Other Payer Advanced APMs (82 FR 53844). The Payer-Initiated Process for Other Payer Advanced APM determinations began in CY 2018 for Medicaid, Medicare Health Plans, and payers participating in CMS multi-payer models. Determinations made in 2018 are applicable for the Quality Payment Program Year 3. Also, in the CY 2018 Quality Payment Program final rule we established that remaining other payers, including commercial and other private payers, may request that we determine whether other payer arrangements are Other Payer Advanced APMs starting prior to the 2020 QP performance period and each performance period thereafter (82 FR 53867). As a result, we have finalized to eliminate the Payer Initiated Process that is specifically for CMS Multi-Payer Models. We believe that payers aligned with CMS

Multi-Payer Models can submit their arrangements through the Payer Initiated Process for Remaining Other Payers discussed in the final rule, or through the Medicaid or Medicare Health Plan payment arrangement submission processes.

In the same rule, under the Eligible Clinician Initiated Process, APM Entities and eligible clinicians participating in other payer arrangements would have an opportunity to request that we determine for the year whether those other payer arrangements are Other Payer Advanced APMs (82 FR 53857 - 53858). However, to appropriately implement the statutory requirement to exclude from the All Payer Combination Option QP threshold calculations certain Title XIX payments and patients, we determined it would be problematic to allow APM Entities and eligible clinicians to request determinations for Title XIX payment arrangements after the conclusion of the QP performance period because any late-identified Medicaid APM or Medicaid Medical Home Model that meets the Other Payer Advanced APM criteria could unexpectedly affect QP threshold calculations for every other clinician in that state (or county). Thus, the CY 2018 Quality Payment Program final rule provided that APM Entities and eligible clinicians may request determinations for any Medicaid payment arrangements in which they are participating at an earlier point, prior to the start of a given QP performance period (82 FR 53858). This would allow all clinicians in a given state or county to know before the beginning of the performance period whether their Title XIX payments and patients would be excluded from the all-payer calculations that are used for QP determinations for the year under the All-Payer Combination Option. This Medicaid specific eligible clinician-initiated determination process for Other Payer Advanced APMs also began in CY 2018, and determinations made in 2018 are applicable for the Quality Payment Program Year 3.

The CY 2017 Quality Payment Program final rule provided that either APM Entities or individual eligible clinicians must submit by a date and in a manner determined by us: (1) payment arrangement information necessary to assess whether each other payer arrangement is an Other Payer Advanced APM, including information on financial risk arrangements, use of CEHRT, and payment tied to quality measures; (2) for each payment arrangement, the amounts of payments for services furnished through the arrangement, the total payments from the payer, the numbers of patients furnished any service through the arrangement (that is, patients for whom the eligible clinician is at risk if actual expenditures exceed expected expenditures), and (3) the total number of patients furnished any service through the arrangement (81 FR 77480). The rule also specified that if we do not receive sufficient information to complete our evaluation of another payer arrangement and to make QP determinations for an eligible clinician using the All-Payer Combination Option, we would not assess the eligible clinicians under the All-Payer Combination Option (81 FR 77480).

In the CY 2018 Quality Payment Program final rule, we explained that in order for us to make QP determinations under the All-Payer Combination Option using either the payment amount or patient count method, we would need to receive all of the payment amount and patient count information: (1) attributable to the eligible clinician or APM Entity through every Other Payer Advanced APM; and (2) for all other payments or patients, except from excluded payers, made or attributed to the eligible clinician during the QP performance period (82 FR 53885). We also finalized that eligible clinicians and APM Entities will not need to submit Medicare payment or patient information for QP determinations under the All-Payer Combination Option (82 FR 53885).

The CY 2018 Quality Payment Program final rule noted that APM Entities or eligible clinicians must submit all of the required information about the Other Payer Advanced APMs in which they participate, including those for which there is a pending request for an Other Payer Advanced APM determination, as well as the payment amount and patient count information sufficient for us to make QP determinations by December 1 of the calendar year that is 2 years to prior to the payment year, which we refer to as the QP Determination Submission Deadline (82 FR 53886).

In the CY 2019 PFS final rule, we have finalized to add a third alternative to allow QP determinations at the TIN level in instances where all clinicians who have reassigned billing rights to the TIN participate in a single APM Entity. This option will be available to all TINs participating in Full TIN APMs, such as the Medicare Shared Savings Program. It will also be available to any other TIN for which all clinicians who have reassigned billing rights to the TIN are participating in a single APM Entity. To make QP determinations under the All-Payer Combination Option at the TIN level as finalized using either the payment amount or patient count method, we will need to receive, by December 1 of the calendar year that is 2 years to prior to the payment year, all of the payment amount and patient count information: (1) attributable to the eligible clinician, TIN, or APM Entity through every Other Payer Advanced APM; and (2) for all other payments or patients, except from excluded payers, made or attributed to the eligible clinician(s) during the QP performance period for the periods January 1 through March 31, January 1 through June 30, and January 1 through August 31 sufficient for us to make QP determinations.

A. 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 for exceptional performance) 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) Promoting Interoperability.

2. Information Users

CMS will use this data to assess MIPS eligible clinician performance in the MIPS performance categories, calculate the final score (including whether or not requirements for certain performance categories can be waived), and calculate positive and negative payment adjustments based on the final score, and to provide feedback to the clinicians. This information may also be used for administrative purposes such as determining third party intermediaries and measures appropriate for the MIPS program or which additional payment arrangements qualify as Other Payer Advanced APM models. In order to administer the Quality Payment Program, the data will be used by agency contractors and consultants, and may be used by other federal and state agencies.

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 or on data.medicare.gov. The data also may be used by CMS authorized entities participating in health care transparency projects. 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. Relevant data will be provided to federal and state agencies, Quality Improvement Networks, Quality Improvement Organizations (QIOs), the Small, Underserved, and Rural Support (SURS) technical assistance contractors, and the Practice Transformation Networks (PTNs) under the Transforming Clinical Practice Initiative (TCPI) and parties assisting consumers, for use in administering or conducting federally-funded health benefit programs, payment and claims processes, quality improvement outreach and reviews, and transparency projects. In addition, this data may be used by the Department of Justice, a court, or adjudicatory body, another federal agency investigating fraud, waste, and abuse, appropriate agencies in the case of a system breach, or the U.S. Department of Homeland Security in the event of a cybersecurity incident.

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 CY 2018 Quality Payment Program will occur in 2019 with respect to the 2018 MIPS performance period. The data submission requirements for the CY 2019 Quality Payment Program will begin in the 2019 MIPS performance period, which will affect data submission burden that will occur in 2020.

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. In addition, as discussed in later sections, many APM Entities will not need to submit improvement activities because participants receive improvement activity credit based on the requirements of the model. For CY 2019 MIPS performance period, we expect virtually all MIPS APMs to qualify for the maximum improvement activity performance category score.

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 2019 PFS final rule's Regulatory Impact Analysis estimates that approximately 797,990 MIPS eligible clinicians will be subject to MIPS performance requirements.[3] 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 77,617 clinicians in eligible specialties will be excluded from MIPS data submission requirements because they have no charges under the PFS and thus do not meet opt-in volume criteria. Further, we exclude an additional 209,403 clinicians who are either QPs, newly enrolled Medicare professionals (to reduce data submission burden to those professionals), or practice non-eligible specialties. 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.

In section VII of the CY 2019 PFS final rule, we explain that we assume 797,990 MIPS eligible clinicians will submit quality data as individual clinicians, or as part of groups or as APM entities. Included in this number, we estimate 27,903 clinicians or 33 percent of clinicians who exceed one component of the threshold (but not all) and who submitted data to PQRS in 2016 will choose to opt-in and submit data to MIPS. We selected a random sample of 33 percent of clinicians without accounting for performance. We believe this assumption of 33 percent is reasonable because some clinicians may choose not to submit data due to performance, practice size, or resources or alternatively, some may submit data, but elect to be a voluntary reporter and not be subject to a MIPS payment adjustment based on their performance.

Additionally, we estimate that between 165,000 and 220,000 eligible clinicians will participate in the Quality Payment Program through the Advanced APM Path.

6. Less Frequent Collection

If data on the quality, Promoting Interoperability, 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.

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 Promoting Interoperability measures, objectives and activities. As such, we would not be able to post the annual list of qualified registries which

[3] For further detail on MIPS exclusions, see Supporting Statement B and the Regulatory Impact Analysis Section of the CY 2019 PFS final rule.

MIPS eligible clinicians use to select qualified registries and QCDRs to use to report quality measures, improvement activities, or Promoting Interoperability measures, objectives, and activities to CMS.

7. Special Circumstances

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

- Report information to the agency more often than quarterly;
- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than 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. Federal Register/Outside Consultation

Serving as the 60-day notice, the CY 2019 PFS proposed rule (RIN 0938-AT31, CMS-1693-P) published in the Federal Register on July 27, 2018 (83 FR 35704). The rule was placed on display for public inspection on July 3, 2018. Comments were received. A summary of the comments and our response is attached to this PRA package.

The CY 2019 PFS final rule published on November 23, 2018 (83 FR 59452).

In the proposed rule, we estimated a total of 5,566,944 hours with a total cost of $526,034,969. In the final rule, we revised our estimate to 5,109,042 hours and $482,416,597. This is a decrease in burden of 457,902 hours and a decrease of $43,618,372 in the labor cost.

The change is due to updated data becoming available from the 2017 MIPS performance period which changed the number of participants included for all performance categories as well as updated respondent estimates for the Other Payer Advanced APM Identification Determinations: Payer-Initiated Process and Submission of Data for All-Payer QP Determinations ICRs.

9. Payments/Gifts to Respondents

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. For the APM data collections, the Partial QP election will also be used to determine MIPS eligibility for receiving payment adjustments based on a final score. For the Other Payer Advanced APM determinations, no gift or payment is provided via MIPS; however, information from these determinations may be used to assess whether a clinician participating in Other Payer Advanced APMs meets the thresholds under the All-Payer Combination Option required to receive QP status and the associated APM incentive payment.

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

11. Sensitive Questions

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

12. Burden Estimates (Hours & Wages)

i. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2017 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, Table 1 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage. The adjusted hourly wage is used to calculate the labor costs associated with our finalized requirements.

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. Therefore, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method. With regard to respondents, we selected BLS occupations Billing and Postal Clerks, Computer Systems Analysts, Physicians, Practice Administrator, and Licensed Practical Nurse based on a study (Casalino et al., 2016) that collected data on the staff in physician's practices involved in the quality data submission process.[4]

TABLE 1: National Occupational Employment and Wage Estimates

Occupation Title	Occupational Code	Mean Hourly Wage ($/hr.)	Fringe Benefits and Overhead costs ($/hr)	Adjusted Hourly Wage ($/hr)
Billing and Posting Clerks	43-3021	18.49	18.49	36.98
Computer Systems Analysts	15-1121	44.59	44.59	89.18

[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.

Occupation Title	Occupational Code	Mean Hourly Wage ($/hr.)	Fringe Benefits and Overhead costs ($/hr)	Adjusted Hourly Wage ($/hr)
Licensed Practical Nurse (LPN)	29-2061	21.98	21.98	43.96
Physicians	29-1060	103.22	103.22	206.44
Practice Administrator (Medical and Health Services Managers)	11-9111	53.69	53.69	107.38

ii. 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 vary across the types of data, and whether the clinician is a MIPS eligible clinician or other eligible clinician voluntarily submitting data, 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 or groups for the quality, Promoting Interoperability, and improvement activities performance categories. Because MIPS eligible clinicians are not required to submit any additional information for assessment under the cost performance category, the administrative claims data used for the cost performance category is not represented in Table 2.

For MIPS eligible clinicians participating in MIPS APMs, the organizations submitting data on behalf of MIPS eligible clinicians will vary between performance categories and, in some instances, between MIPS APMs. For the 2019 MIPS performance period, the quality data submitted by Shared Savings Program ACOs, Next Generation ACOs, and other APM Entities on behalf of their participant MIPS eligible clinicians will fulfill any MIPS submission requirements for the quality performance category.

For the Promoting Interoperability performance category, group TINs may submit data on behalf of eligible clinicians in MIPS APMs, or eligible clinicians in MIPS APMs may submit data individually. For the improvement activities performance category, we will assume no reporting burden for MIPS APM participants. In the CY 2017 Quality Payment Program final rule, we describe that for MIPS APMs, we compare the requirements of the specific MIPS APM with the list of activities in the Improvement Activities Inventory and score those activities in the same manner that they are otherwise scored for MIPS eligible clinicians (81 FR 77185). Although the policy allows for the submission of additional improvement activities if a MIPS APM receives less than the maximum improvement activities performance category score, to date all MIPS APMs have qualified for the maximum improvement activities score. Therefore, we assume that no additional submission will be needed. Advanced APM participants who are determined to be Partial QPs may incur additional burden if they elect to participate in MIPS, which is discussed in more detail in the CY 2018 Quality Payment Program final rule (82 FR 53841 through 53844), but other than the election to participate in MIPS, we do not have data to estimate that burden.

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**	**PI Performance Category**	**Improvement Activities Performance Category**	**Other Data Submitted on Behalf of MIPS Eligible Clinicians**
MIPS Eligible Clinicians (not in MIPS APMs) and Other Eligible Clinicians Voluntarily Submitting Data[5]	As group or individual clinicians	As group or individual clinicians. Clinicians who are hospital-based, ambulatory surgical center-based, non-patient facing, physician assistants, nurse practitioners, clinician nurse specialists, certified registered nurse anesthetists, physical therapists, occupational therapists, qualified speech-language pathologists, qualified audiologists, and registered dieticians or nutrition professionals are automatically eligible for a zero percent weighting for the Promoting Interoperability performance category. Clinicians who submit an application and are approved for significant hardship or other exceptions are also eligible for a zero percent weighting.	As group 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.
Eligible Clinicians participating in the Shared Savings Program or Next Generation ACO Model (both MIPS APMs)	ACOs submit to the CMS Web Interface and CAHPS for ACOs on behalf of their participating MIPS eligible clinicians. [These submissions are not included in burden estimates	Each MIPS eligible clinician in the APM Entity reports data for the Promoting Interoperability performance category to MIPS through either group TIN or individual reporting. [Burden estimates assume group TIN-level reporting].[7]	CMS will assign the improvement activities performance category score to each APM Entity group based on the activities involved in participation in the Shared Savings Program.[8] [The burden	Advanced APM Entities will make election for participating MIPS eligible clinicians.

[5] Virtual group participation is limited to MIPS eligible clinicians, specifically, solo practitioners and groups consisting of 10 eligible clinicians or fewer.

	Type of Data Submitted			
Category of Clinician	**Quality Performance Category**	**PI Performance Category**	**Improvement Activities Performance Category**	**Other Data Submitted on Behalf of MIPS Eligible Clinicians**
	because quality data submission to fulfill requirements of the Shared Savings Program and for purposes of testing and evaluating the Next Generation ACO model Next Generation ACO models are not subject to the PRA].[6]		estimates assume no improvement activity reporting burden for APM participants because we assume the MIPS APM model provides a maximum improvement activity performance category score.]	
Eligible Clinicians participating in Other MIPS APMs	APM Entities submit to MIPS on behalf of their participating MIPS eligible clinicians. [These submissions are not included in burden estimates because quality data submission for purposes of testing and evaluating Innovation Center models tested under Section 1115A of the Social Security Act (or Section 3021 of the Affordable Care Act) are not subject to the	Each MIPS eligible clinician in the APM Entity reports data for the Promoting Interoperability performance category 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 no improvement activities performance category reporting burden for APM participants because we assume the MIPS APM model provides a maximum improvement activity score.]	Advanced APM Entities will make election for participating eligible clinicians.

[6] Sections 1899 and 1115A of the Act (42 U.S.C. 1395jjj and 42 U.S.C. 1315a, respectively) state the Shared Savings Program and testing, evaluation, and expansion of Innovation Center models are not subject to the PRA.

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

[7] Both group TIN and individual clinician PI data will be accepted. If both group TIN and individual scores are available for the same APM Entity, CMS will take the higher score for each TIN/NPI. The TIN/NPI scores are then aggregated for purposes of calculating the APM Entity score.

	Type of Data Submitted			
Category of Clinician	**Quality Performance Category**	**PI Performance Category**	**Improvement Activities Performance Category**	**Other Data Submitted on Behalf of MIPS Eligible Clinicians**
	PRA.]			

* Because the cost performance category relies on administrative claims data, MIPS eligible clinicians are not required to provide any additional information, and therefore the cost performance category is not represented in this table.

The policies finalized in the CY 2017 and CY 2018 Quality Payment Program final rules and CY 2019 PFS final rule create some additional data collection requirements not listed in Table 2. These additional data collections, some of which were previously approved by OMB under the control numbers 0938-1314 (Quality Payment Program), are as follows:

- Self-nomination of new and returning QCDRs
- Self-nomination of new and returning qualified registries
- Quality Payment Program Identity Management Application Process
- Reweighting Applications for Promoting Interoperability and Other Performance Categories
- Call for quality measures
- Nomination of new improvement activities
- Call for Promoting Interoperability measures
- Opt out of performance data display on Physician Compare for voluntary reporters under MIPS
- Partial Qualifying APM Participant (Partial QP) election
- Other Payer Advanced APM determinations: Payer Initiated Process
- Other Payer Advanced APM determinations: Eligible Clinician Initiated Process
- Submission of Data for All-Payer QP Determinations Framework for Understanding the Burden of MIPS Data Submission

iii. Burden for Third Party Reporting

Under MIPS, quality, Promoting Interoperability, and improvement activities, performance category data may be submitted via relevant third-party intermediaries, such as qualified registries, QCDRs, and health IT vendors. In the CY 2018 Quality Payment Program final rule, we combined the burden for self-nomination of qualified registries and QCDRs (82 FR 53906). For CY 2019 PFS final rule, we determined that requirements for self-nomination for qualified registries were sufficiently different from QCDRs that it is necessary to estimate the two independently. The change will align the burden more closely to the requirements for QCDRs and qualified registries to self-nominate, not because of any change in policy, but because of changes in our initial assumptions. Specifically, while the processes for self-nomination are similar, QCDRs have the option to submit QCDR measures for the quality performance category. Therefore, differences between QCDRs and registries self-nomination are associated with the preparation of QCDR measures for approval. The burden associated with qualified registry self-nomination, QCDR self-nomination, and the CAHPS for MIPS survey vendor applications follow:

1. Burden for Qualified Registry Self-Nomination

Qualified registries interested in submitting MIPS data to us on their participants' behalf need to complete a self-nomination process to be considered qualified to submit on behalf of MIPS eligible clinicians or groups (82 FR 53815).

In the CY 2018 Quality Payment Program final rule, previously approved qualified registries in good standing (that are not on probation or disqualified) that wish to self-nominate using the simplified process can attest, in whole or in part, that their previously approved form is still accurate and applicable (82 FR 53815). In the same rule, qualified registries in good standing that would like to make minimal changes to their previously approved self-nomination application from the previous year, may submit these changes, and attest to no other changes from their previously approved qualified registry application for CMS review during the self-nomination period, from September 1 to November 1 (82 FR 53815). This simplified self-nomination process will begin for the 2019 MIPS performance period.

We have adjusted the number of respondents (from 120 to 150) based on more recent data and a revised definition of "respondent" to account for self-nomination applications received but not approved. We have also adjusted our per respondent time estimate (from 10 hours to 3 hours) based on our review of the current burden estimates against the existing policy. Finally, we have provided a range of time estimates (from 10 hours to 0.5 hours) which reflect the availability of a simplified self-nomination process for previously approved qualified registries.

For the 2017 MIPS performance period, we received 138 applications for nomination to be a qualified registry and 145 applications for the 2018 MIPS performance period. In continuance of this trend for the 2019 MIPS performance period, we estimate 150 nomination applications will be received from qualified registries desiring approval to report MIPS data, an increase of 30 respondents from our currently approved estimate.

The burden associated with qualified registry self-nomination will vary depending on the number of existing qualified registries that will elect to use the simplified self-nomination process in lieu of the full self-nomination process as described in the CY 2018 Quality Payment Program final rule (82 FR 53815). The self-nomination form is submitted electronically using the web-based tool JIRA. For the 2018 MIPS performance period, 141 qualified registries were approved to submit MIPS data.

In the CY 2019 PFS final rule, we have finalized to modify the definition of a QCDR to be an entity with clinical expertise in medicine and in quality measurement development that collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. This revised definition of a QCDR may result in previously approved QCDRs who no longer meet the new definition to decide to instead seek approval as qualified registries. However, we have not received any notifications of intent and do not have data to support changing our estimate of 150 qualified registries who will submit applications during the self-nomination period for the CY 2020 performance period.

In the CY 2018 Quality Payment Program final rule, we estimated the burden associated with self-nomination of a qualified registry to be 10 hours, similar to PQRS (82 FR 53907). In the

CY 2019 PFS final rule, we reduced our estimate to 3 hours because registries no longer provide an XML submission, calculated measure, or measure flow as part of the self-nomination process and are not subject to a mandatory interview, which were done previously as part of the PQRS qualified registry self-nomination process, upon which the previous assumption of 10 hours was based. As described in the CY 2017 Quality Payment Program final rule, the full self-nomination process requires the submission of basic information, a description of the process the qualified registry will use for completion of a randomized audit of a subset of data prior to submission, and the provision of a data validation plan along with the results of the executed data validation plan by May 31 of the year following the performance period (81 FR 77383 through 77384). For the simplified self-nomination process, we have estimated 0.5 hours per qualified registry to submit a nomination, a reduction of 9.5 hours from currently approved estimates.

As shown in Table 3, we estimate that the staff involved in the qualified registry self-nomination process will be mainly computer systems analysts or their equivalent, who have an adjusted labor cost of $89.18/hour. Assuming that the time associated with the self-nomination process ranges from a minimum of 0.5 hours (for the simplified self-nomination process) to 3 hours (for the full self-nomination process) per qualified registry, we estimate that the annual burden will range from 97.5 hours ([141 qualified registries x 0.5 hr] + [9 qualified registries x 3 hr]) to 450 hours (150 qualified registries x 3 hr) at a cost ranging from $8,695 (97.5 hr x $89.18/hr) to $40,131 (450 hr x $89.18/hr), respectively (see Table 3). Independent of the change to our per response time estimate, the decrease in the number of respondents results in an adjustment of 300 hours and $26,754 (30 registries x 10 hr x $89.18/hr). Accounting for the change in the number of qualified registries, the change in time per qualified registry to self-nominate results in an adjustment of between -1,402.5 hours and -125,075 ([(141 registries x -9.5 hr)] + [(9 registries x -7 hr)] at $89.18/hr) and -1,050 hours and -$93,639 (150 registries x -7 hr x $89.18/hr). When these two adjustments are combined, the net impact ranges between -1,102.5 (1,402.5 – 300) and -750 (1,050 – 300) hours and -$98,321 (-$125,075 + $26,754) and -$66,885 (-$93,639 + $26,754).

Qualified registries must comply with requirements on the submission of MIPS data to CMS. The burden associated with the qualified registry submission requirements will be the time and effort associated with calculating quality measure results from the data submitted to the qualified registry by its participants and submitting these results, the numerator and denominator data on quality measures, the Promoting Interoperability performance category, and improvement activities data to us on behalf of their participants. These requirements are currently approved by OMB under control number 0938-1314 (CMS-10621). 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 and the number of applicable measures. However, we believe that qualified registries already perform many of these activities for their participants. We believe the estimates discussed above and shown in Table 3 represents the upper bound of registry burden, with the potential for less additional MIPS burden if the registry already provides similar data submission services.

Based on the assumptions previously discussed, we provide an estimate of the total annual burden associated with a qualified registry self-nominating to be considered “qualified” to submit quality measures results and numerator and denominator data on MIPS eligible clinicians.

TABLE 3: Estimated Burden for Qualified Registry Self-Nomination

Burden and Respondent Descriptions	Minimum Burden	Maximum Burden
# of Qualified Registry Simplified Self-Nomination Applications submitted (a)	141	0
# of Qualified Registry Full Self-Nomination Applications submitted (b)	9	150
Total Annual Hours Per Qualified Registry for Simplified Process (c)	0.5	0.5
Total Annual Hours Per Qualified Registry for Full Process (d)	3	3
Total Annual Hours for Qualified Registries (e) = (a)*(c)+(b)*(d)	**97.5**	**450**
Cost Per Simplified Process Per Registry (@ computer systems analyst's labor rate of $89.18/hr.) (f)	$44.59	$44.59
Cost Per Full Process Per Registry (@ computer systems analyst's labor rate of $89.18/hr.) (g)	$267.54	$267.54
Total Annual Cost for Qualified Registries (h) = (a)*(f)+(b)*(g)	**$8,695**	**$40,131**

2. Burden for QCDR Self-Nomination[9]

QCDRs interested in submitting quality, Promoting Interoperability, and improvement activities performance category data 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.

In the CY 2018 Quality Payment Program final rule, previously approved QCDRs in good standing (that are not on probation or disqualified) that wish to self-nominate using the simplified process can attest, in whole or in part, that their previously approved form is still accurate and applicable (82 FR 53808). Existing QCDRs in good standing that would like to make minimal changes to their previously approved self-nomination application from the previous year, may submit these changes, and attest to no other changes from their previously approved QCDR application, for CMS review during the self-nomination period, from September 1 to November 1 (82 FR 53808). This simplified self-nomination process will begin for the 2019 MIPS performance period. The burden associated with QCDR self-nomination will vary depending on the number of existing QCDRs that will elect to use the simplified self-nomination process in lieu of the full self-nomination process as described in the CY 2018 Quality Payment Program final rule (82 FR 53808 through 53813). The self-nomination form is submitted electronically using the web-based tool JIRA. For the 2018 MIPS performance period, 150 QCDRs were approved to submit MIPS data.

We have adjusted the number of respondents (from 113 to 200) based on more recent data and a revised definition of "respondent" to account for self-nomination applications received but not approved. We have also adjusted the time burden estimates per respondent based on our review of the current burden estimates against the existing policy as well as provided a range of time burden estimates which reflect the availability of a simplified self-nomination process for previously approved QCDRs.

For the 2017 MIPS performance period, we received 138 self-nomination applications from QCDRs and for the 2018 MIPS performance period, we received 176 self-nomination applications. In continuance of this trend for the 2019 MIPS performance period, we estimate

[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.

200 self-nomination applications will be received from QCDRs desiring approval to report MIPS data, an increase of 87 respondents.

In the CY 2019 PFS final rule, we have finalized to modify the definition of a QCDR to be an entity with clinical expertise in medicine and in quality measurement development that collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. This revised definition of a QCDR may result in previously approved QCDRs who no longer meet the new definition to decide to instead seek approval as qualified registries or collaborate with another previously approved QCDR to meet the requirements of the new definition. However, we have not received any notifications of intent and do not have data to support changing our estimate of 200 QCDRs who will submit applications during the self-nomination period for the CY 2020 performance period. In addition, we have not accounted for any costs associated with QCDRs collaborating to meet the requirements of the new definition as electing to do so would be a business decision made by individual entities which is not required or endorsed by CMS and considering the alternate path of seeking to be a qualified registry would be available for entities seeking to continue participating in MIPS.

We estimate that the self-nomination process for QCDRs to submit on behalf of MIPS eligible clinicians or groups for MIPS will involve approximately 3 hours per QCDR to submit information required at the time of self-nomination as described in the CY 2017 Quality Payment Program final rule including basic information about the QCDR, describing the process it will use for completion of a randomized audit of a subset of data prior to submission, providing a data validation plan, and providing results of the executed data validation plan by May 31 of the year following the performance period (81 FR 77383 through 77384). However, for the simplified self-nomination process, we estimate 0.5 hours per QCDR to submit this information. The aforementioned modification to the definition of a QCDR is not expected to affect the estimated time for submitting the full or simplified self-nomination. The self-nomination form is submitted electronically using the web-based tool JIRA.

In addition, QCDRs calculate their measure results. QCDRs must possess benchmarking capabilities (for QCDR measures) that compare the quality of care a MIPS eligible clinician provides with other MIPS eligible clinicians performing the same quality measures. For QCDR measures, the QCDR must provide to us, if available, data from years prior (for example, 2017 data for the 2019 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 QCDR will spend an additional 1 hour performing these activities per measure and assume that each QCDR will submit information for 9 QCDR measures, for a total burden of 9 hours per QCDR (1 hr per measure x 9 measures). The estimated average of 9 measures per QCDR is based on the number of QCDR measure submissions received in the 2017 and 2018 MIPS performance periods and is the same for each QCDR regardless of whether they elect to use the simplified or full self-nomination process. In the 2017 MIPS performance period, we received over 1,000 QCDR measure submissions. In the 2018 MIPS performance period, we received over 1,400 QCDR

measure submissions. For the 2019 MIPS performance period, we anticipate this trend will continue, and therefore, estimate we will receive a total of approximately 1,800 QCDR measure submissions, resulting in an average of 9 measure submissions per QCDR (1,800 measure submissions / 200 QCDRs).

In the CY 2018 Quality Payment Program final rule, the burden associated with self-nomination of a QCDR was estimated to be 10 hours (82 FR 53907). We are increasing the burden associated with self-nomination to 12 hours. Because QCDRs are no longer required to provide an XML submission and are not subject to a mandatory interview; both of which were completed as part of the PQRS QCDR self-nomination process upon which the previous assumption of 10 hours was based, we are eliminating 1 hour from our previous burden assumption. Simultaneously, we are increasing our burden assumption by 3 hours to account for an increase in the number of QCDR measure submissions being submitted. These two adjustments result in a net increase of 2 hours per respondent from our previously approved burden estimates.

As shown in Table 4, we estimate that the staff involved in the QCDR self-nomination process will continue to be computer systems analysts or their equivalent, who have an average labor cost of $89.18/hr. Assuming that the hours per QCDR associated with the self-nomination process ranges from a minimum of 9.5 hours (for the simplified self-nomination process) to 12 hours (for the full self-nomination process), we estimate that the annual burden will range from 2,025 hours ([150 QCDRs x 9.5 hr] + [50 QCDRs x 12 hr]) to 2,400 hours (200 QCDRs x 12 hr) at a cost ranging between $180,590 (2,025 hr x $89.18/hr) and $214,032 (2,400 hr x $89.18/hr), respectively (see Table 4). Independent of the change to our per response time estimate, the increase in the number of respondents results in an adjustment of 870 hours and $77,587 (87 registries x 10 hr x $89.18/hr). Accounting for the change in the number of qualified registries, the change in time per QCDR to self-nominate results in an adjustment of between 25 hours and $2,230 ([150 registries x -0.5 hr] + [50 registries x 2 hr] at $89.18/hr) and 400 hours and $35,672 (200 registries x 2 hr x $89.18/hr). When these two adjustments are combined, the net impact ranges between 895 (870 + 25) hours at $79,817 ($77,587 + $2,230) and 1,270 (870 + 400) hours at $113,259 ($77,587 + $35,672).

QCDRs must comply with requirements on the submission of MIPS data to CMS. The burden associated with the QCDR submission requirements will be the time and effort associated with calculating quality measure results from the data submitted to the QCDR by its participants and submitting these results, the numerator and denominator data on quality measures, the Promoting Interoperability performance category, and improvement activities data to us on behalf of their participants. These requirements are currently approved by OMB under control number 0938-1314 (CMS-10621). We expect that the time needed for a QCDR to accomplish these tasks will vary along with the number of MIPS eligible clinicians submitting data to the QCDR and the number of applicable measures. However, we believe that 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.

We finalized in the CY 2018 Quality Payment Program final rule that QCDR vendors may seek permission from another QCDR to use an existing measure that is owned by the other QCDR (82 FR 53813). However, some QCDR measure stewards charge a fee for the use of their QCDR measures. We have not accounted for QCDR measure licensing costs as part of our burden

estimate due to the election to license a QCDR measure being a business decision made by individual QCDRs which is not required or endorsed by CMS for participation in MIPS.

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

TABLE 4: Estimated Burden for QCDR Self-Nomination

Burden and Respondent Descriptions	**Minimum Burden**	**Maximum Burden**
# of QCDR Simplified Self-Nomination Applications submitted (a)	150	0
# of QCDR Full Self-Nomination Applications submitted (b)	50	200
Total Annual Hours Per QCDR for Simplified Process (c)	9.5	9.5
Total Annual Hours Per QCDR for Full Process (d)	12	12
Total Annual Hours for QCDRs (e) = (a)*(c) + (b)*(d)	**2,025**	**2,400**
Cost Per Simplified Process Per QCDR (@ computer systems analyst's labor rate of $89.18/hr.) (f)	$847.21	$847.21
Cost Per Full Process Per QCDR (@ computer systems analyst's labor rate of $89.18/hr.) (g)	$1,070.16	$1,070.16
Total Annual Cost for QCDRs (h) = (a)*(f)+(b)*(g)	**$180,590**	**$214,032**

iv. Burden Estimate for the Quality Performance Category

Under our current policies, two groups of clinicians will submit quality data under MIPS: those who submit as MIPS eligible clinicians and other eligible clinicians who opt to submit data voluntarily but will not be subject to MIPS payment adjustments. Although the finalized expansion of the definition of a MIPS eligible clinician to new clinician types and the opt-in process for MIPS participation discussed in the 2019 PFS final rule could affect respondent counts, all of the new potential respondents had the opportunity to participate in PQRS and as a voluntary reporter in MIPS. Therefore, consistent with our assumptions in the CY 2017 and CY 2018 Quality Payment Program final rules that PQRS participants that are not QPs will have participated in MIPS as voluntary respondents (81 FR 77501 and 82 FR 53908, respectively), we anticipate that this rule's finalized expansion of the definition of a MIPS eligible clinician will not have any incremental effect on any of our currently approved burden estimates. For the purpose of the following analyses, we assume that clinicians who participated in MIPS and who are not QPs in Advanced APMs in the 2017 MIPS performance period will continue to submit quality data in the 2019 MIPS performance period. We assume that 100 percent of APM Entities in MIPS APMs will submit quality data to CMS as required under their models. We estimate a total of 964,246 clinicians participated as individuals or groups in the 2017 MIPS performance period; this number differs from the currently approved estimate (OMB 0938-1314, CMS-10621) of 758,267 due to the availability of updated data.

As discussed in the CY2019 PFS final rule, we have finalized to replace the term "submission mechanism" with the terms "collection type" and "submission type." "Submission mechanism" is presently used to refer not only to the mechanism by which data is submitted, but also to certain types of measures and activities on which data are submitted to the entities submitting such data in the Quality Payment Program.

We assume that clinicians and groups will continue to submit quality data for the same collection types they used during the CY 2017 performance period. In addition, we assume that the 80 TINs that elect to form 16 virtual groups will continue to collect and submit MIPS data using the same collection and submission types as they did during the 2017 MIPS performance period, 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 APM Entities submit to fulfill the requirements of their models. The burden is excluded as sections 1899(e) and 1115A(d)(3) of the Act (42 USC 1395jjj(e) and 1315a(d)(3), respectively) state the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models tested under section 1115A of the Act (or section 3021 of the Affordable Care Act) are not subject to the PRA.[10] Tables 5, 6, and 7 explain our revised estimates of the number of organizations (including groups, virtual groups, and individual MIPS eligible clinicians) submitting data on behalf of clinicians segregated by collection type.

Table 5 provides our estimated counts of clinicians that will submit quality performance category data as MIPS individual clinicians or groups in the 2019 MIPS performance period based on data from the 2017 MIPS performance period.

For the 2019 MIPS performance period, respondents will have the option to submit quality performance category data via Medicare Part B claims, direct, and log in and upload submission types, and CMS Web Interface. We also receive data via administrative claims but there is no reporting burden associated with this collection type. At the time of the CY 2019 PFS proposed rule, participation data by submission type and user research data to inform burden assumptions was not available to estimate burden by submission type. As a result, we estimate the burden for collecting data via collection type: claims, QCDR and MIPS CQMs, eCQMs, and the CMS Web Interface. While we have more information about MIPS submissions, we believe it is important to continue to estimate burden by collection type because the public was able to comment on our assumptions using this framework.

For the Medicare Part B claims collection type, in the CY 2019 PFS final rule, we finalized limiting the Medicare Part B claims collection type to small practices beginning with the 2021 MIPS payment year and allowing clinicians in small practices to report Medicare Part B claims as a group or as individuals. We assumed in our currently approved burden analysis that any clinician that submits quality data codes to us for the Medicare Part B claims collection type is intending to do so for the Quality Payment Program. We made this assumption originally in the CY 2017 Quality Payment Program final rule to ensure that we fully accounted for any burden that may have resulted from our policies (81 FR 77501 through 77504). In some cases, however, clinicians may be submitting quality data codes not only for the Medicare Part B claims collection type, but also for MIPS CQM and QCDR collection types. Some registries and QCDRs utilize data from claims to populate their datasets when submitting on behalf of clinicians. We are not able to separate out when a clinician submits a quality data code solely for the Medicare Part B claim collection type or when a clinician is also submitting these codes for MIPS CQM or QCDR collection types. In addition, we see a large number of voluntary reporters for the Medicare Part B claims collection type. Approximately 70 percent of the 257,260 clinicians we estimate will submit quality data via Medicare Part B claims (see Table 5)

[10] Our estimates do reflect the burden on MIPS APM participants of submitting Promoting Interoperability performance category data, which is outside the requirements of their models.

are MIPS eligible clinicians while the other 30 percent are voluntary reporters which means our burden include estimates for a large number of voluntary reporters. Of these clinicians who are not scored as part of an APM, approximately 55 percent are in practices with more than 15 clinicians; however, over 91 percent of the number in practices larger than 15 clinicians are either voluntary reporters, group reporters, or are also reporting quality data through another collection type. Approximately 10,700 clinicians in non-small practices are both MIPS eligible and scored based only on Medicare Part B claims data and of these, 52 percent also qualify for facility-based reporting, and therefore, will not be required to submit quality data. It is unclear why many clinicians are submitting quality data via an alternate collection type, and we currently lack data to accurately estimate both the number of clinicians who will be impacted by these finalized policies and the potential behavioral response of those clinicians who will be required to switch to another collection type. As a result, we will continue using the assumption that all clinicians (except QPs) who submitted data via the Medicare Part B claims collection type in the 2017 MIPS performance period will continue to do so for MIPS in order to avoid overstating the impact of the change.

Using our revised terminology, clinicians who used a QCDR or Registry will now collect measures via QCDR or MIPS CQM collection type; clinicians who used the EHR submission type will elect the eCQM collection type, and groups that elected the CMS Web Interface for MIPS will continue to elect the CMS Web Interface for MIPS.

Table 5 shows that in the 2019 MIPS performance period, an estimated 257,260 clinicians will submit data as individuals for the Medicare Part B claims collection type; 324,693 clinicians will submit data as individuals or as part of groups for the MIPS CQM or QCDR collection types; 243,062 clinicians will submit data as individuals or as part of groups via eCQM collection types; and 139,231 clinicians will submit as part of groups via the CMS Web Interface.

Table 5 provides estimates of the number of clinicians to collect quality measures data via each collection type, regardless of whether they decide to submit as individual clinicians or as part of groups. Because our burden estimates for quality data submission assume that burden is reduced when clinicians elect to submit as part of a group, we also separately estimate the expected number of clinicians to submit as individuals or part of groups.

TABLE 5: Estimated Number of Clinicians Submitting Quality Performance Category Data by Collection Type

Data Description	Claims	QCDR/MIPS CQM	eCQM	CMS Web Interface	Total
Number of clinicians to collect data by collection type (as individual clinicians or groups) in Quality Payment Program Year 3 (excludes QPs) (a)	257,260	324,693	243,062	139,231	964,246
*Number of clinicians to collect data by collection type (as individual clinicians or groups) in Quality Payment Program Year 2 (excludes QPs) (b)	278,039	255,228	131,133	93,867	758,267
Difference between Year 3 and Year 2 (c)=(a)-(b)	-20,779	+69,465	+111,929	+45,364	+205,979

*Currently approved by OMB under control number 0938-1314 (CMS-10621).

In the CY 2018 Quality Payment Program final rule (82 FR 53625 through 53626), beginning with the 2019 MIPS performance period, we allowed MIPS eligible clinicians to submit data for multiple collection types for a single performance category. Therefore, we captured the burden of any eligible clinician that may have historically collected via multiple collection types, as we assume they will continue to collect via multiple collection types and that our MIPS scoring methodology will take the highest score where the same measure is submitted via multiple collection types. Hence, the estimated numbers of individual clinicians and groups to collect via the various collection types are not mutually exclusive and reflect the occurrence of individual clinicians or groups that collected data via multiple collection types during the MIPS 2017 performance period.

Table 6 uses methods similar to those described for Table 5 to estimate the number of clinicians to submit data as individual clinicians via each collection type in Quality Payment Program Year 3. We estimate that approximately 257,260 clinicians will submit data as individuals using the Medicare Part B claims collection type; approximately 71,439 clinicians will submit data as individuals using MIPS CQMs or QCDR collection types; and approximately 47,557 clinicians will submit data as individuals using eCQMs collection type.

TABLE 6: Estimated Number of Clinicians Submitting Quality Performance Category Data as Individuals by Collection Type

Data Description	Claims	QCDR/MIPS CQM	eCQM	CMS Web Interface	Total
Number of Clinicians to submit data as individuals in Quality Payment Program Year 3 (excludes QPs) (a)	257,260	71,439	47,557	0	376,256
*Number of Clinicians to submit data as individuals in Quality Payment Program Year 2 (excludes QPs) (b)	278,039	104,281	52,709	0	435,029
Difference between Year 3 and Year 2 (c)=(a)-(b)	-20,779	-32,842	-5,152	0	-58,773

*Currently approved by OMB under control number 0938-1314 (CMS-10621).

To be consistent with the policy in the CY 2018 Quality Payment Program final rule that for MIPS eligible clinicians who collect measures via Medicare Part B claims, MIPS CQM, eCQM, or QCDR collection types and submit more than the required number of measures (82 FR 53735 through 54736), we will score the clinician on the required measures with the highest assigned measure achievement points, our columns in Table 6 are not mutually exclusive.

Table 7 provides our estimated counts of groups or virtual groups that will submit quality data on behalf of clinicians for each collection type in the 2019 MIPS performance period and reflects our assumption that the formation of virtual groups will reduce burden. We assume that groups that submitted quality data as groups in the 2017 MIPS performance period will continue to submit quality data either as groups or virtual groups for the same collection types as they did as a group or TIN within a virtual group for the 2019 MIPS performance period. First, we estimated the number of groups or virtual groups that will collect data via each collection type during the 2019 MIPS performance period using data from the 2017 MIPS performance period. The second and third steps in Table 7 reflect our currently approved assumption that virtual groups will reduce the burden for quality data submission by reducing the number of organizations that will submit quality data on behalf of clinicians. We assume that 40 groups that previously collected on behalf of clinicians via QCDR or MIPS CQM collection types will elect to form 8 virtual groups that will collect via QCDR and MIPS CQM collection types. We assume that another 40 groups that previously collected on behalf of clinicians via eCQM collection types will elect to form another 8 virtual groups that will collect via eCQM collection types. Hence, the second step in Table 7 is to subtract out the estimated number of groups under each collection type that will elect to form virtual groups, and the third step in Table 7 is to add in the estimated number of virtual groups that will submit on behalf of clinicians for each collection type.

Specifically, we assume that 10,542 groups and virtual groups will submit data for the QCDR or MIPS CQM collection types on behalf of 253,254 clinicians; 4,304 groups and virtual groups will submit for eCQM collection types on behalf of 195,505 eligible clinicians; and 286 groups will submit data via the CMS Web Interface on behalf of 139,231 clinicians. Because we are using 2017 MIPS performance period participation data to estimate participation for the 2019 MIPS performance period, our estimates do not account for the finalized policy to allow only groups that meet the definition of a small practice to submit quality data via the Medicare Part B claims collection type. Due to a lack of historic data identifying which clinicians in small practices would want to submit via the Medicare Part B claims collection type and elect to be measured as part of a group, we continue to assume these clinicians submitting Medicare Part B claims will participate as individuals but will review this assumption for future performance periods.

TABLE 7: Estimated Number of Groups and Virtual Groups Submitting Quality Performance Category Data by Collection Type on Behalf of Clinicians

Data Description	Claims	QCDR/ MIPS CQM	eCQM	CMS Web Interface	Total
Number of groups to collect data by collection type (on behalf of clinicians) in Quality Payment Program Year 3 (excludes QPs) (a)	0	10,574	4,336	286	15,196
Subtract out: Number of groups to collect data by collection type on behalf of clinicians in Quality Payment Program Year 3 that will submit as virtual groups in Quality Payment Program Year 3 (b)	0	40	40	0	80
Add in: Number of virtual groups to collect data by collection type on behalf of clinicians in Quality Payment Program Year 3 (c)	0	8	8	0	16
Number of groups to collect data by collection type on behalf of clinicians in Quality Payment Program Year 3 (d)=(a)-(b)+(c)	0	10,542	4,304	286	15,132
*Number of groups to collect data by collection type on behalf of clinicians in Quality Payment Program Year 2 (e)	0	2,936	1,509	296	4,741
Difference between Year 3 and Year 2 (f)=(d)-(e)	0	+7,606	+2,795	-10	+10,391

*Currently approved by OMB under control number 0938-1314 (CMS-10621).

The burden estimates associated with submission of quality performance category data 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 measures into the practice workflows is expected to vary along with the number of measures that are potentially applicable to a given clinician's practice and by the collection type. For example, clinicians submitting data via the Medicare Part B claims collection type need to integrate the capture of quality data codes for each encounter whereas

clinicians submitting via the eCQM collection types may have quality measures automated as part of their EHR implementation.

We believe the burden associated with submitting quality measures data will vary depending on the collection type selected by the clinician, group, or third-party. As such, we separately estimated the burden for clinicians, groups, and third parties to submit quality measures data by the collection type used. For the purposes of our burden estimates for the Medicare Part B claims, MIPS CQM and QCDR, and eCQM collection types, we also assume that, on average, each clinician or group will submit 6 quality measures. In terms of the quality measures available for clinicians and groups to report for the 2019 MIPS performance period, the total number of quality measures will be 257. These measures are stratified by collection type in Table 8 below as well as counts of new, removed, and substantively changed measures.

TABLE 8: Summary of Quality Measures for the 2019 MIPS Performance Period

Collection Type	# measures finalized as new	# measures finalized for removal	# measures finalized with a substantive change	# measures remaining for CY 2019
Medicare Part B Claims Specifications	0	7	1	64
MIPS CQMs Specifications	6	21	0	233
eCQM Specifications	2	6	0	50
Survey - CSV	0	0	0	1
CMS Web Interface Measure Specifications	0	1	4	10
Administrative Claims	0	0	0	1
Total	**8**	**26***	**5**	**257***

*A measure may be applicable to more than one collection type but will only be counted once in the total.

For the 2019 MIPS performance period, there is a net reduction of 18 quality measures across all collection types. We do not anticipate that removing these measures will increase or decrease the reporting burden on clinicians and groups.

1. Burden for Quality Payment Program Identity Management Application Process

In the CY 2018 Quality Payment Program final rule, the time associated with the Identity Management Application Process was described as "Obtain Account in CMS-Specified Identity Management System" and included in the ICR for Quality Data Submission by Clinicians and Groups: EHR Submission for a total burden of 54,218 hours (1 hr x 54,218 respondents) (82 FR 53914). After our review of the quality data submission process, we determined the burden associated with the application process (3,741 hours) should be accounted for in a separate ICR. Our per respondent burden estimate remains unchanged at 1 hour per response. For an individual, group, or third-party to submit MIPS quality, improvement activities, or Promoting

Interoperability performance category data using either the log in and upload or the log in and attest submission type or to access feedback reports, the submitter must have a CMS Enterprise Portal user account. Once the user account is created, registration is not required again for future years.

Based on the number of new TINs registered in the 2017 MIPS performance period, we estimate 3,741 eligible clinicians, groups, or third-parties will register for new accounts for the 2019 MIPS performance period. As shown in Table 9 it would take 1 hour at $89.18/hr for a computer systems analyst (or their equivalent) to obtain an account for the CMS Enterprise Portal. In aggregate we estimate an annual burden of 3,741 hours (3,741 registrations x 1 hr/registration) at a cost of $333,622 (3,741 hr x $89.18/hr) or $89.18 per registration.

TABLE 9: Estimated Burden for Quality Payment Program Identity Management Application Process

Burden and Respondent Descriptions	**Burden Estimate**
# of New TINs completing the Identity Management Application Process (a)	3,741
Total Hours Per Application (b)	1
Total Annual Hours for completing the Identity Management Application Process (c) = (a)*(b)	3.741
Cost Per Application @ computer systems analyst's labor rate of $89.18/hr.) (d)	$89.18
Total Annual Cost for completing the Identity Management Application Process (e) = (a)*(d)	$333,622

2. Burden for Quality Data Submission by Clinicians: Medicare Part B Claims-Based Collection Type

As noted in Table 5, based on 2017 MIPS performance period data, we assume that 257,260 individual clinicians will collect and submit quality data via the Medicare Part B claims collection type. We continue to anticipate that the Medicare Part B claims submission process for MIPS is 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 QDCs, and include the appropriate QDCs on the Medicare Part B 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 CY 2019 PFS final rule's provisions do not necessitate the revision of either form.

We have adjusted the number of respondents based on more recent data and adjusted our per respondent time estimates so that they correctly align with the number of required measures for which MIPS data must be submitted (6 measures) in comparison to the number of measures previously required under PQRS (9 measures).

The total estimated burden of Medicare Part B claims-based submission will vary along with the volume of Medicare Part B claims on which the submission is based. Based on our experience with PQRS, we estimate that the burden for submission of MIPS quality data will range from 0.15 to 7.2 hours per clinician, a reduction from the range of 0.22 to 10.8 hours as set out in the CY 2018 Quality Payment Program final rule (82 FR 53912). In the same rule, the 33 percent reduction in the number of measures (from 9 to 6) was erroneously omitted from our burden

calculations; it is reflected in these burden estimates. The wide range of estimates for the time required for a clinician to submit quality measures via Medicare Part B claims reflects the wide variation in complexity of submission across different clinician quality measures. As shown in Table 10, we estimate that the cost of quality data submission using Medicare Part B claims will range from $13.38 (0.15 hr x $89.18/hr) to $642.10 (7.2 hr x $89.18/hr). The burden will involve becoming familiar with MIPS data submission requirements. We believe that the start-up cost for a clinician's practice to review measure specifications is 7 hours, consisting of 3 hours at $107.38/hr for a practice administrator, 1 hour at $206.44/hr for a clinician, 1 hour at $43.96/hr for an LPN/medical assistant, 1 hour at $89.18/hr for a computer systems analyst, and 1 hour at $36.98/hr for a billing clerk. The estimate for reviewing and incorporating measure specifications for the claims collection type is higher than that of QCDRs/Registries or eCQM collection types due to the more manual, and therefore, more burdensome nature of claims measures.

Considering both data submission and start-up requirements, the estimated time (per clinician) ranges from a minimum of 7.15 hours (0.15 hr + 7 hr) to a maximum of 14.2 hours (7.2 hr + 7 hr). In this regard the total annual burden rages from 1,819,082 hours (7.15 hr x 254,417 clinicians) to 3,612,721 hours (14.2 hr x 254,417 clinicians). The estimated annual cost (per clinician) ranges from $712.08 ($13.38 + $322.14 + $89.18 + $43.96 + $36.98 + $206.44) to a maximum of $1,340.80 ($642.10 + $322.14 + $89.18 + $43.96 + $36.98 + $206.44). The total annual burden ranges from a minimum of $183,189,701 (257,260 clinicians x $712.08) to a maximum of $344,934,208 (257,260 clinicians x $1,340.80). Table 10 summarizes the range of total annual burden associated with clinicians submitting quality data via Medicare Part B claims. Independent of the change in the number of respondents, the change in estimated time per clinician results in a burden adjustment of between -19,463 hours at -$1,860,081 (278,039 clinicians x -0.07 hr x $89.18/hr) and -1,000,941 hours at -$89,261,641 (278,039 clinicians x -3.6 hr x $89.18/hr). Accounting for the change in the time burden per respondent, the decrease in number of respondents results in a total adjustment of between -148,713 hours at -$14,810,552 (-20,799 respondents x $712.08/respondent) and -295,346 hours at -$27,887,299 (-20,779 respondents x $1,340.80/respondent). When these two adjustments are combined, the net adjustment ranges between -168,176 (-19,463 – 148,713) hours at -$16,670,633 (-$1,860,081 - $14,810,552) and -1,296,287 (-1,000,941 – 295,346) hours at -$117,148,940 (-$89,261,641 - $27,887,299).

TABLE 10: Estimated Burden for Quality Performance Category: Clinicians Using the Claims Collection Type

Burden and Respondent Descriptions	Minimum Burden	Median Burden	Maximum Burden Estimate
# of Clinicians (a)	257,260	257,260	257,260
Hours Per Clinician to Submit Quality Data (b)	0.15	1.05	7.2
# of Hours Practice Administrator Review Measure Specifications (c)	3	3	3
# of Hours Computer Systems Analyst Review Measure Specifications (d)	1	1	1

Burden and Respondent Descriptions	Minimum Burden	Median Burden	Maximum Burden Estimate
# of Hours LPN Review Measure Specifications (e)	1	1	1
# of Hours Billing Clerk Review Measure Specifications (f)	1	1	1
# of Hours Clinician Review Measure Specifications (g)	1	1	1
Annual Hours per Clinician (h) = (b)+(c)+(d)+(e)+(f)+(g)	7.15	8.05	14.2
Total Annual Hours (i) = (a)*(h)	**1,839,409**	**2,070,943**	**3,653,092**
Cost to Submit Quality Data (@ computer systems analyst's labor rate of $89.18/hr.) (j)	$13.38	$93.64	$642.10
Cost to Review Measure Specifications (@ practice administrator's labor rate of $107.38/hr.) (k)	$322.14	$322.14	$322.14
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $89.18/hr.) (l)	$89.18	$89.18	$89.18
Cost to Review Measure Specifications (@ LPN's labor rate of $43.96/hr.) (m)	$43.96	$43.96	$43.96
Cost to Review Measure Specifications (@ billing clerk's labor rate of $36.98/hr.) (n)	$36.98	$36.98	$36.98
Cost to Review Measure Specifications (@ physician's labor rate of $206/44/hr.) (o)	$206.44	$206.44	$206.44
Total Annual Cost Per Clinician (p) = (j)+(k)+(l)+(m)+(n)+(o)	$712.08	$792.34	$1,340.80
Total Annual Cost (q) = (a)*(p)	**$183,189,701**	**$203,837,388**	**$344,934,208**

3. Burden for Quality Data Submission by Individuals and Groups: MIPS CQM and QCDR Collection Types

As noted in Tables 5, 6, and 7 and based on 2017 MIPS performance period data, we assume that 324,693 clinicians will submit quality data as individuals or groups using MIPS CQM or QCDR collection types. Of these, we expect 71,439 clinicians, as shown in Table 6, will submit as individuals and 10,542 groups, as shown in Table 7, are expected to submit on behalf of the remaining 253,254 clinicians. Given that the number of measures required is the same for clinicians and groups, we expect the burden to be the same for each respondent collecting data via MIPS CQM or QCDR, whether the clinician is participating in MIPS as an individual or group.

Under the MIPS CQM and QCDR collection types, the individual clinician or group may either submit the quality measures data directly to us, log in and upload a file, or utilize a third-party intermediary to submit the data to us on the clinician's or group's behalf.

We estimate that the burden associated with the QCDR collection type is similar to the burden associated with the MIPS CQM collection type; therefore, we discuss the burden for both together below. For MIPS CQM and QCDR collection types, we estimate an additional time for respondents (individual clinicians and groups) to become familiar with MIPS submission requirements and, in some cases, specialty measure sets and QCDR measures. Therefore, we believe that the burden for an individual clinician or group to review measure specifications and submit quality data total 9.083 hours at $858.86. This consists of 3 hours at $89.18/hr for a computer systems analyst (or their equivalent) to submit quality data along with 2 hours at $107.38/hr for a practice administrator, 1 hour at $89.18/hr for a computer systems analyst, 1 hour at $43.96/hr for a LPN/medical assistant, 1 hour at $36.98/hr for a billing clerk, and 1 hour at $206.44/hr for a clinician to review measure specifications. Additionally, clinicians and groups will need to authorize or instruct the qualified registry or QCDR to submit quality measures' results and numerator and denominator data on quality measures to 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 cost of $7.40 (0.083 hr x $89.18/hr for a computer systems analyst). In aggregate, we estimate an annual burden of 744,633 hours (9.083 hr/response x 81,981 groups plus clinicians submitting as individuals) at a cost of $71,016,861 (81,981 responses x $866.26/response). The decrease in number of respondents results in a total adjustment of -229,219 hours at -$21,860,937 (-25,236 respondents x $866.26/respondent). Based on these assumptions, we have estimated in Table 11 the burden for these submissions.

TABLE 11: Estimated Burden for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the MIPS CQM/QCDR Collection Type

Burden and Respondent Descriptions	Burden Estimate
# of clinicians submitting as individuals (a)	71,439
# of groups submitting via QCDR or MIPS CQM on behalf of individual clinicians (b)	10,542
# of Respondents (groups and clinicians submitting as individuals) (c)=(a)+(b)	81,981
Hours Per Respondent to Report Quality Data (d)	3
# of Hours Practice Administrator Review Measure Specifications (e)	2
# of Hours Computer Systems Analyst Review Measure Specifications (f)	1
# of Hours LPN Review Measure Specifications (g)	1
# of Hours Billing Clerk Review Measure Specifications (h)	1
# of Hours Clinician Review Measure Specifications (i)	1
# of Hours Per Respondent to Authorize Qualified Registry to Report on Respondent's Behalf (j)	0.083
Annual Hours Per Respondent (k)= (d)+(e)+(f)+(g)+(h)+(i)+(j)	9.083
Total Annual Hours (l) = (c)*(k)	744,633
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of $89.18/hr.) (m)	$267.54

Burden and Respondent Descriptions	Burden Estimate
Cost to Review Measure Specifications (@ practice administrator's labor rate of $107.38/hr.) (n)	$214.76
Cost Computer System's Analyst Review Measure Specifications (@ computer systems analyst's labor rate of $89.18/hr.) (o)	$89.18
Cost LPN Review Measure Specifications (@ LPN's labor rate of $43.96/hr.) (p)	$43.96
Cost Billing Clerk Review Measure Specifications (@ clerk's labor rate of $36.98/hr.) (q)	$36.98
Cost Clinician Review Measure Specifications (@ physician's labor rate of $206.44/hr.) (r)	$206.44
Cost for Respondent to Authorize Qualified Registry/QCDR to Report on Respondent's Behalf (@ computer systems analyst's labor rate of $89.18/hr.) (s)	$7.40
Total Annual Cost Per Respondent (t) = (m)+(n)+(o)+(p)+(q)+(r)+(s)	$866.26
Total Annual Cost (u) = (c)*(t)	$71,016,861

4. Burden for Quality Data Submission by Clinicians and Groups: eCQM Collection Type

As noted in Tables 5, 6, and 7, based on 2017 MIPS performance period data, we assume that 243,062 clinicians will elect to use the eCQM collection type; 47,557 clinicians are expected to submit eCQMs as individuals; and 4,304 groups are expected to submit eCQMs on behalf of the remaining 195,505 clinicians. We expect the burden to be the same for each respondent using the eCQM collection type, whether the clinician is participating in MIPS as an individual or group.

In the CY 2018 Quality Payment Program final rule, the time required for users to obtain an account for the CMS Enterprise Portal was included in this Quality Data Submission by Clinicians and Groups: eCQM Collection Type ICR (82 FR 53914). However, we now have a separate ICR for this activity (now described as the Quality Payment Program Identity Management Application Process; see Table 9) and therefore, reduce (by 1 hour) our per respondent burden estimate for this ICR commensurately. We have also adjusted the number of respondents based on more recent data. Under the eCQM collection type, the individual clinician or group may either submit the quality measures data directly to us from their eCQM, log in and upload a file, or utilize a health IT vendor to submit the data to us on the clinician's or group's behalf.

To prepare for the eCQM collection type, the clinician or group must review the quality measures on which we will be accepting MIPS data extracted from eCQMs, select the appropriate quality measures, extract the necessary clinical data from their CEHRT, and submit the necessary data to the CMS-designated clinical data warehouse or use a health IT vendor to submit the data on behalf of the clinician or group. We assume the burden for collecting quality measures data via eCQM is similar for clinicians and groups who submit their data directly to us from their CEHRT and clinicians and groups who use a health IT vendor to submit the data on

their behalf. This includes extracting the necessary clinical data from their CEHRT and submitting the necessary data to the CMS-designated clinical data warehouse.

We continue to estimate that it will take no more than 2 hours at $89.18/hr for a computer systems analyst to submit the actual data file. The burden will also involve becoming familiar with MIPS submission. In this regard, we estimate it will take 6 hours for a clinician or group to review measure specifications. Of that time, we estimate 2 hours at $107.38/hr for a practice administrator, 1 hour at $206.44/hr for a clinician, 1 hour at $89.18/hr for a computer systems analyst, 1 hour at $43.96/hr for a LPN/medical assistant, and 1 hour at $36.98/hr for a billing clerk. In aggregate we estimate an annual burden of 414,888 hours (8 hr x 51,861 groups and clinicians submitting as individuals) at a cost of $39,916,374 (51,861 responses x $769.68/response) (see Table 12). Independent of the change in the number of respondents, removing the time burden associated with completing the Quality Payment Program Identity Management Application Process results in an adjustment to the total burden of -54,218 hours and -$4,835,161 (54,218 respondents x -1 hr x $89.18/hr). Accounting for the change in the per respondent time estimate, the decrease in number of respondents results in a total adjustment of -18,856 hours at -$1,814,136 (-2,357 respondents x $769.68/respondent). When these two adjustments are combined, the net adjustment is -73,074 (-54,218 – 18,856) hours at -$6,649,297 (-$4,835,161 - $1,814,136).

TABLE 12: Estimated Burden for Quality Performance Category: Clinicians (Submitting Individually or as Part of a Group) Using the eCQM Collection Type

Burden and Respondent Descriptions	Burden estimate
# of clinicians submitting as individuals (a)	47,557
# of Groups submitting via EHR on behalf of individual clinicians (b)	4,304
# of Respondents (groups and clinicians submitting as individuals) (c)=(a)+(b)	51,861
Hours Per Respondent to Submit MIPS Quality Data File to CMS (d)	2
# of Hours Practice Administrator Review Measure Specifications (e)	2
# of Hours Computer Systems Analyst Review Measure Specifications (f)	1
# of Hours LPN Review Measure Specifications (g)	1
# of Hours Billing Clerk Review Measure Specifications (h)	1
# of Hours Clinicians Review Measure Specifications (i)	1
Annual Hours Per Respondent (j)=(d)+(e)+(f)+(g)+(h)+(i)	8
Total Annual Hours (k)=(c)*(j)	414,888
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of $88.10/hr.) (l)	$178.36
Cost to Review Measure Specifications (@ practice administrator's labor rate of $105.16/hr.) (m)	$214.76
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $88.10/hr.) (n)	$89.18
Cost to Review Measure Specifications (@ LPN's labor rate of $43.12/hr.) (o)	$43.96
Cost to Review Measure Specifications (@ clerk's labor rate of $36.12/hr.) (p)	$36.98

Cost to D21Review Measure Specifications (@ physician's labor rate of $202.08/hr.) (q)	$206.44
Total Cost Per Respondent (r)=(l)+(m)+(n)+(o)+(p)+(q)	$769.68
Total Annual Cost (s) = (c)*(r)	$39,916,374

5. Burden for Quality Data Submission by CMS Web Interface

As discussed in the CY 2019 PFS final rule, we have finalized a 33 percent reduction in the number of measures (from 15 to 10 measures) for which clinicians are required to submit quality data via the CMS Web Interface. To account for the decrease in measures, we have also finalized a decrease to our per respondent time estimate.

We assume that 286 groups will submit quality data via the CMS Web Interface based on the number of groups who registered for using the CMS Web Interface during the 2018 MIPS performance period. This is a decrease of 10 groups from the currently approved number provided in the CY 2018 Quality Payment Program final rule (82 FR 53915) due to receipt of more current data. We estimate that approximately 91,757 clinicians will submit via this method.

The burden associated with the group submission requirements 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. In the CY 2018 Quality Payment Program final rule, we estimated that it would take, on average, 74 hours for each group to submit quality measures data via the CMS Web Interface (82 FR 53915). Of those hours, approximately half (or 37 hr) are unaffected by the number of required measures while the other half (37 hr) are affected proportionately by the number of required measures (37 hr x 33 percent reduction = 24.67 hr). Accounting for the finalized reduction in required measures, our revised estimate for the time to submit data via the CMS Web Interface for the 2019 MIPS performance period is 61.67 hours (37 hr + 24.67 hr), a reduction of 12.33 hours or approximately 18 percent of the currently approved 74 hour time estimate. Considering only the time which varies based on the number of required measures, the process of entering or uploading data requires approximately 2.74 hours of a computer systems analyst's time per measure (24.67 hr / 9 measures). Our estimate 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 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, uploaded into the CMS Web Interface via a standard file format, which can be populated by CEHRT, or submitted directly. 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) for each measure. In aggregate, we estimate an annual burden of 17,637 hours (286 groups x 61.67 hr) at a cost of $1,572,837 (17,637 hr x $89.18/hr).

Independent of the change in the number of respondents, the decrease in total burden resulting from the decrease in required measures is -3,650 hours at -$325,566 (296 groups x -12.33 hr x $89.18/hr). Accounting for the decrease in total time, the decrease in number of respondents results in a total adjustment of -616.7 hours at -$54,994 (-10 respondents x 61.67 hr x $89.18/hr).

When these adjustments are combined, the net adjustment is -4,267 (-3,650 – 617) hours at -$380,560 (-$325,566 - $54,994).

Based on the assumptions discussed in this section, Table 13 summarizes the burden for groups submitting to MIPS via the CMS Web Interface.

TABLE 13: Estimated Burden for Quality Data Submission via the CMS Web Interface

Burden and Respondent Descriptions	Burden Estimate
# of Eligible Group Practices (a)	286
Total Annual Hours Per Group to Submit (b)	61.67
Total Annual Hours (c) = (a)*(b)	17,637
Cost Per Group to Report (@ computer systems analyst's labor rate of $89.18/hr.) (d)	$5,499
Total Annual Cost (e) = (a)*(d)	$1,572,837

6. Burden for Group Registration for CMS Web Interface

We have adjusted the number of respondents based on more recent data and adjusted our per response time estimate based on our review of the currently approved estimates against the existing registration process.

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 14, we estimate that the registration process for groups under MIPS involves approximately 0.25 hours at $89.18/hr for a computer systems analyst (or their equivalent) to register the group. Although the registration process remains unchanged from the CY 2018 Quality Payment Program final rule, a review of the steps required for registration warranted a reduction of 0.75 hours in estimated burden per group (82 FR 53917). We assume that approximately 67 groups will elect to use the CMS Web Interface for the first time during the 2019 MIPS performance period based on the number of new registrations received during the CY 2018 registration period; an increase of 57 compared to the number of groups currently approved by OMB under control number 0938-1314 (CMS-10621). In aggregate, we estimate a burden of 16.75 hours (67 new registrations x 0.25 hr/registration) at a cost of $1,494 (16.75 hr x $89.18/hr). Independent of the decrease in time burden per group, the increase in the number of groups registering to submit MIPS data via the CMS Web Interface results in an adjustment to the total time burden of 57 hours at $5,083 (57 groups x 1 hr x $89.18/hr). Accounting for the increase in the number of groups, the decrease in time burden per group to register results in an adjustment to the total burden of -50.25 hours at -$4,481 (67 groups x -0.75 hrs x $89.18/hr). When these adjustments are combined, the net adjustment is 6.75 hours (57 - 50.25) at $602 ($5,083 - $4,481).

TABLE 14: Estimated Burden for Group Registration for CMS Web Interface

Burden and Respondent Descriptions	Burden Estimate
Number of New Groups Registering for CMS Web Interface (a)	67
Annual Hours Per Group (b)	0.25
Total Annual Hours (c) = (a)*(b)	**16.75**

Labor Rate to Register for CMS Web Interface @ computer systems analyst's labor rate) (d)	$89.18/hr
Total Annual Cost for CMS Web Interface Group Registration (e) = (a)*(d)	**$1,494**

v. Burden Estimate for the Nomination of Quality Measures

We have adjusted our currently approved estimates based on more recent data. We have also accounted for burden associated with policies that have been finalized but whose burden were erroneously excluded from our estimates.

As discussed in the CY 2019 PFS rule, quality measures are selected annually through a call for quality measures under consideration, with a final list of quality measures being published in the Federal Register by November 1 of each year. Under section 1848(q)(2)(D)(ii) of the Act, the Secretary must solicit a "Call for Quality Measures" each year. Specifically, the Secretary must request that eligible clinician organizations and other relevant stakeholders identify and submit quality measures to be considered for selection in the annual list of MIPS quality measures, as well as updates to the measures. Under section 1848(q)(2)(D)(ii) of the Act, eligible clinician organizations are professional organizations as defined by nationally recognized specialty boards of certification or equivalent certification boards.

As we described in the CY 2017 Quality Payment Program final rule (81 FR 77137), we will accept quality measures submissions at any time, but only measures submitted during the timeframe provided by us through the pre-rulemaking process of each year will be considered for inclusion in the annual list of MIPS quality measures for the performance period beginning 2 years after the measure is submitted. This process is consistent with the pre-rulemaking process and the annual call for measures, which are further described at (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rule-Making.html).

To identify and submit a quality measure, eligible clinician organizations and other relevant stakeholders use a one-page online form that requests information on background, gap analysis which includes evidence for the measure, reliability validity, endorsement and a summary which includes how the proposed measure relates to the Quality Payment Program and the rationale for the measure. In addition, proposed measures must be accompanied by a completed Peer Review Journal Article form.

As shown in Table 15, we estimate that approximately 140 organizations, including clinicians, CEHRT developers, and vendors, will submit measures for the Call for Quality Measures process; an increase of 100 compared to the number of organizations currently approved by OMB. In keeping with the focus on clinicians as the primary source for recommending new quality measures, we are using practice administrators and clinician time for our burden estimates. We also estimate it will take 0.5 hours per organization to submit an activity to us, consisting of 0.3 hours at $107.38/hr for a practice administrator to make a strategic decision to nominate and submit a measure and 0.2 hours at $206.44/hr for clinician review time. The 0.5 hour estimate assumes that submitters will have the necessary information to complete the nomination form readily available, which we believe is a reasonable assumption. Additionally, some submitters familiar with the process or who are submitting multiple measures may require

significantly less time, while other submitters may require more if the opposite is true; on average we believe 0.5 hours is a reasonable average across all submitters.

Consistent with the CY 2017 Quality Payment Program final rule, we also estimate it will take 4 hours at $206.44/hr for a clinician (or equivalent) to complete the Peer Review Journal Article Form (81 FR 77153 through 77155). This assumes that measure information is available and testing is complete in order to have the necessary information to complete the form, which we believe is a reasonable assumption. While the requirement for completing the Peer Review Journal Article was previously included in the CY 2017 Quality Payment Program final rule, the time required for completing the form was erroneously excluded from our burden estimates.

As shown in Table 15, in aggregate we estimate an annual burden of 630 hours (140 organizations x 4.5 hr/response) at a cost of $125,896 (140 x [(0.3 hr x $107.38/hr) + (4.2 hr x $206.44/hr)]. Independent of the change in time per organization, the change in the number of organizations nominating new quality measures results in an adjustment of 50 hours at $7,350 (100 organizations x [(0.3 hr x $107.38/hr) + (0.2 hr x $206.44/hr)]). When accounting for the change in respondents, the change in burden to nominate a quality measure results in an adjustment of 560 hours at $115,606 (140 organizations x 4 hr x $206.44/hr). When these adjustments are combined, the total adjustment is 610 hours (560 + 50) at $122,956 ($7,350 + $115,606).

TABLE 15: Burden Estimates for Call for Quality Measures

Burden and Respondent Descriptions	**Burden estimate**
# of Organizations Nominating New Quality Measures (a)	140
# of Hours Per Practice Administrator to Identify and Propose Measure (b)	0.30
# of Hours Per Clinician to Identify Measure (c)	0.20
# of Hours Per Clinician to Complete Peer Review Article Form (d)	4.00
Annual Hours Per Response (e)= (b) + (c) + (d)	4.50
Total Annual Hours (f) = (a)*(e)	630
Cost to Identify and Submit Measure (@ practice administrator's labor rate of $107.38/hr.) (g)	$32.21
Cost to Identify Quality Measure and Complete Peer Review Article Form (@ physician's labor rate of $206.44/hr.) (h)	$867.05
Total Annual Cost Per Respondent (i)=(g)+(h)	$899.26
Total Annual Cost (j)=(a)*(i)	$125,896

vi. Burden Estimate for the Promoting Interoperability Performance Category

For the 2019 MIPS performance period, clinicians and groups can submit Promoting Interoperability data through direct, log in and upload, or log in and attest submission types. We have worked to further align the Promoting Interoperability performance category with other MIPS performance categories. With the exception of submitters who elect to use the log in and attest submission type for the Promoting Interoperability performance category which is not available for the quality performance category, we anticipate that most organizations will use the same data submission type for the both of these performance categories and that the clinicians, practice managers, and computer systems analysts involved in supporting the quality data submission will also support the Promoting Interoperability data submission process. Hence, the

following burden estimates show only incremental hours required above and beyond the time already accounted for in the quality data submission process. Although this analysis assesses burden by performance category and submission type, we emphasize that MIPS is a consolidated program and submission analysis and decisions are expected to be made for the program as a whole.

1. Burden for Reweighting Applications for Promoting Interoperability and Other Performance Categories

As established in the CY 2017 and CY 2018 Quality Payment Program final rules, MIPS eligible clinicians who meet the criteria for a significant hardship or other type of exception may submit an application requesting a zero percent weighting for the Promoting Interoperability performance category in the following circumstances: insufficient internet connectivity, extreme and uncontrollable circumstances, lack of control over the availability of CEHRT, clinicians who are in a small practice, and decertified EHR technology (81 FR 77240 through 77243 and 82 FR 53680 through 53686). In addition, as finalized in the CY 2018 Quality Payment Program final rule, MIPS eligible clinicians and groups citing extreme and uncontrollable circumstances may also apply for a reweighting of the quality, cost, and/or improvement activities performance categories (82 FR 53783 through 53785). Respondents who apply for a reweighting for any of these performance categories have the option of applying for reweighting for the Promoting Interoperability performance category on the same online form. Since we do not have data on the number of reweighting applications submitted for the 2018 MIPS performance period, we assume that respondents applying for a reweighting of the Promoting Interoperability performance category due to extreme and uncontrollable circumstances will also request a reweighting of at least one of the other performance categories simultaneously and not submit multiple reweighting applications. As data availability allows, we will estimate the reporting burden for each reweighting application under separate ICRs in future rulemaking.

Table 16 summarizes the burden for clinicians to apply for reweighting the Promoting Interoperability performance category to zero percent due to a significant hardship exception (including a significant hardship exception for small practices) or as a result of a decertification of an EHR. Based on the number of reweighting applications received for the 2017 MIPS performance period, we assume 6,041 respondents (eligible clinicians or groups) will submit a request to reweight the Promoting Interoperability performance category to zero percent due to a significant hardship (including clinicians in small practices) or EHR decertification. We estimate that 3,344 respondents (eligible clinicians or groups) will submit a request for reweighting the Promoting Interoperability performance category to zero percent due to extreme and uncontrollable circumstances, insufficient internet connectivity, lack of control over the availability of CEHRT, or as a result of a decertification of an EHR. An additional 2,697 respondents will submit a request for reweighting the Promoting Interoperability performance category to zero percent as a clinician in a small practice experiencing a significant hardship. In total, this represents a decrease of 34,604 from the number of respondents currently approved by OMB. The application to request a reweighting to zero percent only for the Promoting Interoperability performance category is a short online form that requires identifying the type of hardship experienced or whether decertification of an EHR has occurred and a description of how the circumstances impair the clinician or group's ability to submit Promoting

Interoperability data, as well as some proof of circumstances beyond the clinician's control. The application for reweighting of the quality, cost, Promoting Interoperability, and/or improvement activities performance categories due to extreme and uncontrollable circumstances requires the same information with the exception of there being only one option for the type of hardship experienced.

We estimate it will take 0.25 hours at $89.18/hr for a computer system analyst to submit the application; a reduction from the 0.5 hours estimated in the CY 2018 Quality Payment Program final rule (82 FR 53918). This adjustment is due to a revised assessment of the application process which requires limited basic information about the clinician or submitter, a small number of check boxes and drop-down selections, and if the reason cited is extreme and uncontrollable circumstances, one free text field. In addition, we believe increased familiarity with the process in its second year also reduces the average time across all respondents. As shown in Table 16, in aggregate, we estimate an annual burden of 1,510.25 hours (6,041 applications x 0.25 hr/application) at a cost of $134,684 (1,510.25 hr x $89.18/hr). Independent of the change to the number of respondents, the decrease in the amount of time to submit a reweighting application results in an adjustment of -10,161.25 hours at -$906,180 (40,645 respondents x -0.25 hr x $89.18/hr). Accounting for the decrease in time per respondent, the decrease in the number of respondents submitting reweighting applications results in an adjustment of -8,651 hours at -$771,496 (-34,604 respondents x 0.25 hr x $89.18hr). When these adjustments are combined, the total adjustment is -18,812.25 hours (-10,161.25 – 8,651) at $1,677,676 (-$906,180 -$771,496).

TABLE 16: Estimated Burden for Reweighting Applications for Promoting Interoperability and Other Performance Categories

Burden and Respondent Descriptions	**Burden estimate**
# of Eligible Clinicians and Groups Applying Due to Significant Hardship and Other Exceptions (a)	3,344
# of Eligible Clinicians and Groups Applying Due to Significant Hardship for Small Practice (b)	2,697
Total Respondents Due to Hardships, Other Exceptions and Hardships for Small Practices (c)	6,041
Hours Per Applicant per application submission (d)	0.25
Total Annual Hours (e)=(a)*(c)	1,510.25
Labor Rate for a computer systems analyst (f)	$89.18/hr
Total Annual Cost (g)=(a)*(f)	$134,684

2. Burden for Submitting Promoting Interoperability Data

A variety of organizations will submit Promoting Interoperability data on behalf of clinicians. Clinicians not participating in a MIPS APM may submit data as individuals or as part of a group. In the CY 2017 Quality Payment Program final rule (81 FR 77258 through 77260, 77262 through 77264), we established that eligible clinicians in MIPS APMS other than the Shared Savings Program may submit data for the Promoting Interoperability performance category as individuals or as part of a group, whereas eligible clinicians participating in the Shared Savings Program are limited to submitting data through the ACO participant TIN. In the CY 2019 PFS

final rule, we have finalized to extend this flexibility to allow for both individual and group reporting by eligible clinicians participating in the Shared Savings Program.

As shown in Table 17, based on data from the 2017 MIPS performance period, we estimate that a total of 93,933 respondents consisting of 81,456 individual MIPS eligible clinicians and 12,413 groups will submit Promoting Interoperability data. Similar to the process shown in Table 7 for groups reporting via QCDR/MIPS CQM and eCQM collection types, we have adjusted the group reporting data from the 2017 MIPS performance period to account for virtual groups, as the option to submit data as a virtual group was not available until the 2018 MIPS performance period. These estimates reflect that under the policies in the CY 2017 Quality Payment Program final rule and in the CY 2018 Quality Payment Program final rule, certain MIPS eligible clinicians will be eligible for automatic reweighting of the Promoting Interoperability performance category to zero percent, including MIPS eligible clinicians that are hospital-based, ambulatory surgical center-based, non-patient facing clinicians, physician assistants, nurse practitioners, clinician nurse specialists, and certified registered nurse anesthetists (81 FR 77238 through 77245 and 82 FR 53680 through 53687). As discussed in the CY 2019 PFS final rule, starting with the 2021 MIPS payment year, we have finalized to automatically reweight the Promoting Interoperability performance category for clinician types new to MIPS: physical therapists, occupational therapists, qualified speech-language pathologists or qualified audiologist, clinical psychologists, and registered dieticians or nutrition professionals. These estimates also account for the reweighting policies finalized in the CY 2017 and CY 2018 Quality Payment Program final rules, including exceptions for MIPS eligible clinicians who have experienced a significant hardship (including clinicians who are in small practices), as well as exceptions due to decertification of an EHR.

Further, we assume that Shared Savings Program Track 1 ACOs will submit data at the ACO participant TIN-level, APM Entities electing the one-sided track in the CEC model will submit data at the group TIN-level, and APM Entities in the OCM (one-sided risk arrangement) will submit data at APM Entity level; these entities are included in our estimate of the number of groups submitting data. Our respondent estimate is based on existing data and does not consider policies finalized in the CY 2019 PFS final rule, as well as additional policies that have been proposed in the CY 2019 Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations--Pathways to Success proposed rule and may be finalized in a future rule, which may change the number of Shared Saving Program ACOs that are required to submit Promoting Interoperability data for future years (83 FR 41786).[11]

[11] https://www.gpo.gov/fdsys/pkg/FR-2018-08-17/pdf/2018-17101.pdf

TABLE 17: Estimated Number of Respondents to Submit Promoting Interoperability Performance Data on Behalf of Clinicians

Respondent Descriptions	# of Respondents
Number of individual clinicians to submit Promoting Interoperability (a)	81,456
Number of groups to submit Promoting Interoperability(b)	12,477
Subtract out: Number of groups to submit Promoting Interoperability on behalf of clinicians in Quality Payment Program Year 3 that will submit as virtual groups in Quality Payment Program Year 3 (c)	80
Add in: Number of virtual groups to submit Promoting Interoperability on behalf of clinicians in Quality Payment Program Year 3 (d)	16
Number of groups to submit Promoting Interoperability on behalf of clinicians in Quality Payment Program Year 3 (e)=(b)-(c)+(d)	12,413
Total (f) = (a) + (e)	93,869

In the CY 2018 Quality Payment Program final rule, we estimated it takes 3 hours for a computer system analyst to collect and submit Promoting Interoperability performance category data (82 FR 53920). We estimate the time required to submit such data should be reduced by 20 minutes to 2.67 hours due to the reduction in the number of measures for which clinicians are required to submit data, which we have finalized as discussed in the CY 2019 PFS final rule. As shown in Table 18, the total time for an organization to submit data on the specified Promoting Interoperability objectives and measures is estimated to be 250,317 hours (93,869 respondents x 2.67 incremental hours for a computer analyst's time above and beyond the clinician, practice manager, and computer system's analyst time required to submit quality data) at a cost of $22,323,300 (250,317 hr x $89.18/hr). Independent of the change in the number of respondents, the reduction in estimated time to submit Promoting Interoperability data results in a decrease in burden of -72,738.33 hours at -$6,486,805 (218,215 respondents x -0.33 hr x $89.18/hr). Accounting for the decreased per respondent time, the decrease in the number of respondents results in an adjustment to the total burden of -331,589.33 hours at -$29,571,137 (-124,346 respondents x 2.67 hrs x $89.18/hr). When these adjustments are combined, the total adjustment is -404,327.67 hours (-72,738.33 – 331,589.33) at -$36,057,941 (-$6,486,805 - $29,571,137).

TABLE 18: Estimated Burden for Promoting Interoperability Performance Category Data Submission

Burden and Respondent Descriptions	Burden Estimate
Number of individual clinicians to submit Promoting Interoperability (a)	81,456
Number of groups to submit Promoting Interoperability (b)	12,413
Total (c) = (a) + (b)	93,869
Total Annual Hours Per Respondent (b)	2.67
Total Annual Hours (c) = (a)*(b)	250,317
Labor rate for a computer systems analyst to submit Promoting Interoperability data/hr.) (d)	$89.18/hr
Total Annual Cost (e) = (a)*(d)	$22,323,300

vii. Burden Estimate for the Nomination of Promoting Interoperability Measures

Consistent with our requests for stakeholder input on quality measures and improvement activities, we also request potential measures for the Promoting Interoperability performance category that measure patient outcomes, emphasize patient safety, support improvement activities and the quality performance category, and build on the advanced use of CEHRT using 2015 Edition standards and certification criteria. Promoting Interoperability measures may be submitted via a designated submission form that includes the measure description, measure type (if applicable), reporting requirement, and CEHRT functionality used (if applicable).

We estimate 47 organizations will submit Promoting Interoperability measures, based on the number of organizations submitting measures during the CY 2017 nomination period. This is an increase of 7 from the estimate currently approved by OMB under the aforementioned control number. We estimate it will take 0.5 hours per organization to submit an activity to us, consisting of 0.3 hours at $107.38/hr for a practice administrator to make a strategic decision to nominate that activity and submit an activity to us via email and 0.2 hours at $206.44/hr for a clinician to review the nomination. As shown in Table 19, in aggregate, we estimate an annual burden of 235 hours (47 organizations x 0.5 hr/response) at a cost of $3,455 (47 x [(0.3 h x $107.38/hr) + (0.2 hr x $206.44/hr)]. The increase in the number of respondents results in an adjustment of 3.5 hours and $514.50 (7 respondents x 0.5 hrs x $73.50 per respondent).

TABLE 19: Estimated Burden for Call for Promoting Interoperability Measures

Burden and Respondent Descriptions	**Burden estimate**
# of Organizations Nominating New Promoting Interoperability Measures (a)	47
# of Hours Per Practice Administrator to Identify and Propose Measure (b)	0.30
# of Hours Per Clinician to Identify Measure (c)	0.20
Annual Hours Per Respondent (d)= (b) + (c)	0.50
Total Annual Hours (e) = (a)*(d)	23.50
Cost to Identify and Submit Measure (@ practice administrator's labor rate of $107.38/hr.) (f)	$32.21
Cost to Identify Improvement Measure (@ physician's labor rate of $206.44/hr.) (g)	$41.29
Total Annual Cost Per Respondent (h)=(f)+(g)	$73.50
Total Annual Cost (i)=(a)*(h)	$3,455

viii. Burden Estimate for the Submission of Improvement Activities Data

The CY 2018 Quality Payment Program final rule provides: (1) that for activities that are performed for at least a continuous 90 days during the performance period, MIPS eligible clinicians must submit a "yes" response for activities within the Improvement Activities Inventory (82 FR 53651); (2) that the term "recognized" is accepted as equivalent to the term "certified" when referring to the requirements for a patient-centered medical home to receive full credit for the improvement activities performance category for MIPS (82 FR 53649); and (3) that for the 2020 MIPS payment year and future years, to receive full credit as a certified or recognized patient-centered medical home or comparable specialty practice, at least 50 percent of the practice sites within the TIN must be recognized as a patient-centered medical home or comparable specialty practice (82 FR 53655).

In the CY 2017 Quality Payment Program final rule, we describe how we determine MIPS APM scores (81 FR 77185). We compare the requirements of the specific MIPS APM with the list of activities in the Improvement Activities Inventory and score those activities in the same manner that they are otherwise scored for MIPS eligible clinicians (81 FR 77817 through 77831). If, by our assessment, the MIPS APM does not receive the maximum improvement activities performance category score, then the APM Entity can submit additional improvement activities, although, as we noted, we anticipate that MIPS APMs in the 2019 MIPS performance period will not need to submit additional improvement activities as the models will already meet the maximum improvement activities performance category score (81 FR 77185).

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 through direct, log in and upload submission types, and CMS Web Interface will also submit improvement activities data. As finalized in the CY 2017 Quality Payment Program final rule (81 FR 77264), APM Entities only need to report improvement activities data if the CMS-assigned improvement activities score is below the maximum improvement activities score. Our CY 2018 Quality Payment Program final rule burden estimates assumed that all APM Entities will receive the maximum CMS-assigned improvement activities score (82 FR 53921 through 53922).

As represented in Table 20, based on 2017 MIPS performance period data, we estimate that 125,713 clinicians will submit improvement activities as individuals during the 2019 MIPS performance period and 16,478 groups will submit improvement activities on behalf of clinicians. Similar to the process shown in Table 17 for groups submitting Promoting Interoperability data, we have adjusted the group reporting data from the 2017 MIPS performance period to account for virtual groups, as the option to submit data as a virtual group was not available until the 2018 MIPS performance period.

Our 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. We also assume that the MIPS APM models for the 2019 MIPS performance period will qualify for the maximum improvement activities performance category score and the APM Entities will not need to submit any additional improvement activities.

TABLE 20: Estimated Numbers of Organizations Submitting Improvement Activities Performance Category Data on Behalf of Clinicians

Respondent Descriptions	**Count**
# of clinicians to participate in improvement activities data submission as individuals during the 2019 MIPS performance period (a)	119,956
# of Groups to submit improvement activities on behalf of clinicians during the 2019 MIPS performance period (b)	16,112
Subtract out: # of groups to submit improvement activities on behalf of clinicians in Quality Payment Program Year 3 that will submit as virtual groups during the 2019 MIPS performance period (c)	80
Add in: # of Virtual Groups to submit improvement activities on behalf of clinicians during the 2019 MIPS performance period (d)	16
# of Groups and Virtual Groups to submit improvement activities on behalf of clinicians during the 2019 MIPS performance period (e)	16,048

Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the 2019 MIPS performance period (f) = (a) + (b) + (e)	136,004
Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the 2018 MIPS performance period (g)	439,786
Difference between 2019 MIPS performance period and 2018 MIPS performance period (h)=(g)-(f)	-303,782

As described in the CY 2019 PFS final rule, for purposes of the 2021 MIPS payment year, we have finalized §414.1360(a)(1) to more accurately reflect the data submission process for the improvement activities performance category. In particular, instead of "via qualified registries; EHR submission mechanisms; QCDR, CMS Web Interface; or attestation," as currently stated, we have revised the first sentence to state that data will be submitted "via direct, log in and upload, and log in and attest." The revision will more closely align with the actual submission experience users have. In the CY 2018 Quality Payment Program final rule, we estimated it would take 1 hour for a computer system analyst to submit data on the specified improvement activities (82 FR 53922). Accordingly, we have decreased this burden estimate to reflect the actual submission experience of the user. User experiences from the 2017 MIPS performance period reflect that the majority of users submit improvement activities data as part of the login and upload or direct submission types which allow multiple performance categories (i.e. quality and promoting interoperability) worth of data to be submitted at once. This results in less additional required time to submit improvement activities data which consists of manually attesting that certain activities were performed. In addition, as previously stated in the CY 2018 Quality Payment Program final rule, the same improvement activity may be reported across multiple performance periods so many MIPS eligible clinicians will not have any additional information to submit for the 2019 MIPS performance period, further reducing the average time spent reporting improvement activities data across all MIPS eligible clinicians (82 FR 53921). As a result, we estimate that the per response time required per individual or group is 5 minutes at $89.18/hr for a computer system analyst to submit by logging in and manually attesting that certain activities were performed in the form and manner specified by CMS with a set of authenticated credentials. We have also finalized for CY 2019 and future years to: add 6 new improvement activities, modify 5 existing improvement activities, and remove 1 existing improvement activity. Because MIPS eligible clinicians are still required to submit the same number of activities, we do not expect these provisions to affect our collection of information burden estimates. In addition, in order for an eligible clinician or group to receive credit for being a patient-centered medical home or comparable specialty practice, the eligible clinician or group must attest in the same manner as any other improvement activity.

As shown in Table 21, we estimate an annual burden of 11,333.7 hours (136,004 responses x 5 minutes/60) at a cost of $1,010,736 (11,333.7 hr x $89.18/hr). Independent of the change to our per response time estimate, the decrease in the number of respondents results in an adjustment of -303,782 hours at -$27,091,279 (-303,782 respondents x 1 hr x $89.18/hr). Accounting for the change in number of respondents, the decrease in the time to submit improvement activities data results in an adjustment of -124,670.33 hours at -$11,118,100.33 (136,004 respondents x 55 minutes/60 x $89.18/hr). When these adjustments are combined, the total adjustment is -428,452.33 hours (-303,782 – 124,670.33) hours at -$38,209,379.33 (-$27,091,279 - $11,118,100.33).

TABLE 21: 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 2019 MIPS performance period (a)	136,004
Total Annual Hours Per Respondent (b)	5 minutes
Total Annual Hours (c)	11,333.7
Labor rate for a computer systems analyst to submit improvement activities (d)	$89.18/hr
Total Annual Cost (e) = (a)*(d)	$1,010,736

ix. Burden Estimate for the Nomination of Improvement Activities

We previously submitted our burden estimate for the nomination of new improvement activities as part of the currently approved PRA but did not previously include the Call for Improvement Activities Submission Form. Our currently approved estimate is based on the previously finalized requirement to complete the Call for Measures submission form, therefore we are not making changes to our burden estimate as a result of any new requirements. We are providing the submission form for approval for the first time as part of this PRA submittal.

We have adjusted the number of respondents based on more recent data and adjusted our per response time estimate based on our review of our currently approved burden estimates against the existing process for nomination of improvement activities. We have also finalized to adopt one new criteria and remove one existing criteria for nominating new improvement activities beginning with the CY 2019 performance period and future years. Furthermore, we have made clarifications to: (1) considerations for selecting improvement activities for the CY 2019 performance period and future years; and (2) the weighting of improvement activities. We believe these policy changes will not affect our currently approved burden estimates since they do not substantively impact the level of effort previously estimated to nominate an Improvement Activity. We have finalized a change to the performance year for which the nominations will apply, such that improvement activities nominations received in a particular year will be vetted and considered for the next year's rulemaking cycle for possible implementation in the following year. Also, we have finalized changing the submission timeframe for the Call for Activities from February 1st through March 1st to February 1st through June 30th, providing approximately four additional months for stakeholders to submit nominations. We believe these policy changes will not affect our currently approved burden estimates since we believe that the number of nominations is unlikely to change, but the quality of the nominations is likely to increase given the additional time provided.

For the 2018 MIPS performance period, we provided opportunity for stakeholders to propose new activities formally via the Annual Call for Activities nomination form that was posted on the CMS website (82 FR 53657). The 2018 Annual Call for Activities lasted from March 2, 2017 through March 1, 2018, for which we received 72 nominations consisting of a total of 125 activities which were evaluated for the Improvement Activities Under Consideration (IAUC) list for possible inclusion in the CY 2019 Improvement Activities Inventory. Based on the number of activities being evaluated during the 2018 Annual Call for Activities (125 activities), we estimate that the total number of nominations we will receive for the 2019 Annual Call for

Activities will continue to be 125, unchanged from the number of activities evaluated in CY 2018, which is a decrease from the 150 nominations currently approved by OMB.

In the CY 2018 Quality Payment Program final rule, we estimated that it takes 0.5 hours to nominate an improvement activity (82 FR 53922). As shown in Table 22, due to a review of the nomination process, the information required to complete the nomination form, and the criteria required to nominate an improvement activity, we now estimate it will take 2 hours (per organization) to submit an activity to us. Of those hours, we estimate it will take 1.2 hours at $107.38/hr for a practice administrator or equivalent to make a strategic decision to nominate and submit that activity and 0.8 hours at $206.44/hr for a clinician's review. In aggregate, we estimate an annual burden of 250 hours (125 nominations x 2 hr/nomination) at a cost of $36,751 (125 x [(1.2 hr x $107.38/hr) + (0.8 hr x $206.44/hr)]). The percentage of practice administrator and clinician labor in relation to the total is unchanged from the CY 2018 Quality Payment Program final rule (82 FR 53922). Independent of the change to our per response time estimate, the decrease in the number of nominations results in an adjustment of -12.5 hours and -$1,837 (-25 activities x [(0.3 hr x $107.38/hr) + (0.2 hr x $206.44/hr)]). Accounting for the decrease in the number of nominated improvement activities, the increase in time per nominated improvement activity results in an adjustment of 187.5 hours and $27,563 (125 activities x [(0.9 hr x $107.38/hr) + (0.6 hr x $206.44/hr)]). When these adjustments are combined, the total adjustment is 175 hours (187.5 – 12.5) and $25,726 ($27,563 - $1,837).

TABLE 22: Burden Estimates for Nomination of Improvement Activities

Burden and Respondent Descriptions	Burden estimate
# of Organizations Nominating New Improvement Activities (a)	125
# of Hours Per Practice Administrator to Identify and Propose Activity (b)	1.2
# of Hours Per Clinician to Identify Activity (c)	0.8
Annual Hours Per Respondent (d)= (b) + (c)	2
Total Annual Hours (e) = (a)*(d)	250
Cost to Identify and Submit Activity (@ practice administrator's labor rate of $107.38/hr.) (f)	$128.86
Cost to Identify Improvement Activity (@ physician's labor rate of $206.44/hr.) (g)	$165.15
Total Annual Cost Per Respondent (h)=(f)+(g)	$294.01
Total Annual Cost (i)=(a)*(h)	$36,751

x. Burden Estimate for the Cost Performance Category

The cost performance category relies on administrative claims data. The Medicare Parts A and B claims submission process (OMB control number 0938-1197) is used to collect data on cost measures from MIPS eligible clinicians. MIPS eligible clinicians are not required to provide any documentation by CD or hardcopy. Moreover, the provisions of the CY 2019 PFS final rule do not result in the need to add or revise or delete any claims data fields. Therefore, we do not anticipate any new or additional submission requirements and/or burden for MIPS eligible clinicians resulting from the cost performance category.

xi. Burden Estimate 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 as soon as possible after each QP determination. Where Partial QP status is earned at the APM Entity level, the burden of Partial QP election will be incurred by a representative of the participating APM Entity. Where Partial QP status is earned at the eligible clinician level, the burden of Partial QP election will be incurred by the eligible clinician. 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 predictive QP analysis for the 2019 QP performance period, we estimate that 6 APM Entities and 75 eligible clinicians will make the election to participate as a Partial QP in MIPS (see Table 23), an increase of 64 from the 17 elections currently approved by OMB under the aforementioned control number. We estimate it will take the APM Entity representative or eligible clinician 15 minutes (0.25 hr) to make this election. In aggregate, we estimate an annual burden of 20.25 hours (81 respondents x .25 hr/election) at a cost of $1,805.90 (20.25 hours x $89.18/hr). The increase in the number of Partial QP elections results in an adjustment of 16 hours and $1,431 (64 elections x 0.25 hrs x $89.18/hr).

TABLE 23: Estimated Burden for Partial QP Election

Burden and Respondent Descriptions	**Burden Estimate**
# of respondents making Partial QP election (6 APM Entities, 75 eligible clinicians) (a)	81
Total Hours Per Respondent to Elect to Participate as Partial QP (b)	0.25 hours
Total Annual Hours (c) = (a)*(b)	20.25 hours
Labor rate for computer systems analyst (d)	$89.18/hr
Total Annual Cost (d) = (c)*(d)	$1,805.90

xii. Burden Estimate for Other-Payer Advanced APM Determinations

1. 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 advance notice prior to the start of a given performance period, and to allow other payers to be involved prospectively in the process, the 2018 CY Quality Payment Program final rule established a payer-initiated process for identifying payment arrangements that qualify as Other Payer Advanced APMs (82 FR 53844). The payer-initiated process for Other Payer Advanced APM determinations began in CY 2018 for Medicaid, Medicare Health Plans, and payers participating in CMS multi-payer models. Payers seeking to submit payment arrangement information for Other Payer Advanced APM determination through the payer-

initiated process are required to complete a Payer Initiated Submission Form, instructions for which can be found at https://qpp.cms.gov/. Determinations made in 2018 are applicable for the Quality Payment Program Year 3.

Also, in the CY 2018 Quality Payment Program final rule we established our intent to finalize that the remaining other payers, including commercial and other private payers, may request that we determine whether other payer arrangements are Other Payer Advanced APMs starting prior to the 2020 QP performance period and each performance period thereafter (82 FR 53867). As a result, in the CY 2019 PFS final rule, we have finalized to eliminate the Payer Initiated Process that is specifically for CMS Multi-Payer Models. We believe that payers aligned with CMS Multi-Payer Models can submit their arrangements through the Payer Initiated Process for Remaining Other Payers discussed in the final rule, or through the Medicaid or Medicare Health Plan payment arrangement submission processes.

As shown in Table 24, we estimate that in 2019 for the 2020 QP performance period 215 payer-initiated requests for Other Payer Advanced APM determinations will be submitted (15 Medicaid payers, 100 Medicare Advantage Organizations, and 100 remaining other payers), a decrease of 85 from the 300 total requests currently approved by OMB under the aforementioned control number. We estimate it will take 10 hours at $89.18/hr for a computer system analyst per arrangement submission. In aggregate, we estimate an annual burden of 2,150 hours (215 submissions x 10 hr/submission) at a cost of $191,737 (2,150 hr x $89.18/hr). The decrease in the number of payer-initiated requests results in an adjustment of -850 hours and -$75,803 (-85 requests x 10 hr x $89.18/hr).

TABLE 24: Estimated Burden for Other Payer Advanced APM Identification Determinations: Payer-Initiated Process

Burden and Respondent Descriptions	Burden Estimate
# of other payer payment arrangements (15 Medicaid, 100 Medicare Advantage Organizations, 100 remaining other payers) (a)	215
Total Annual Hours Per other payer payment arrangement (b)	10
Total Annual Hours (c) = (a)*(b)	2,150
Labor rate for a computer systems analyst (d)	$89.18/hr
Total Annual Cost for Other Payer Advanced APM determinations (e) = (a)*(d)	$191,737

2. Eligible Clinician-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 a given performance period, and to allow other payers to be involved prospectively in the process, the CY 2018

Quality Payment Program final rule provided a payer-initiated identification process for identifying payment arrangements that qualify as Other Payer Advanced APMs (82 FR 53854). In the same rule, under the Eligible Clinician Initiated Process, APM Entities and eligible clinicians participating in other payer arrangements will have an opportunity to request that we determine for the year whether those other payer arrangements are Other Payer Advanced APMs (82 FR 53857 - 53858). However, to appropriately implement the statutory requirement to exclude from the All Payer Combination Option QP threshold calculations certain Title XIX payments and patients, we determined it will be problematic to allow APM Entities and eligible clinicians to request determinations for Title XIX payment arrangements after the conclusion of the QP performance period because any late-identified Medicaid APM or Medicaid Medical Home Model that meets the Other Payer Advanced APM criteria could unexpectedly affect QP threshold calculations for every other clinician in that state (or county). Thus, the CY 2018 Quality Payment Program final rule provided that APM Entities and eligible clinicians may request determinations for any Medicaid payment arrangements in which they are participating at an earlier point, prior to the start of a given QP performance period (82 FR 53858). This will allow all clinicians in a given state or county to know before the beginning of the performance period whether their Title XIX payments and patients will be excluded from the all-payer calculations that are used for QP determinations for the year under the All-Payer Combination Option. This Medicaid specific eligible clinician-initiated determination process for Other Payer Advanced APMs also began in CY 2018, and determinations made in 2018 are applicable for the Quality Payment Program Year 3. Eligible clinicians or APM Entities seeking to submit payment arrangement information for Other Payer Advanced APM determination through the Eligible Clinician-Initiated process are required to complete an Eligible Clinician Initiated Submission Form, instructions for which can be found at https://qpp.cms.gov/.

As shown in Table 25, we estimate that 150 other payer arrangements will be submitted by APM Entities and eligible Other Payer Advanced APM determinations, an increase of 75 from the 75 total requests currently approved by OMB under the aforementioned control number.

We estimate it would take 10 hours at $89.18/hr for a computer system analyst per arrangement submission. In aggregate we estimate an annual burden of 1,500 hours (150 submissions x 10 hr/submission) at a cost of $133,770 (1,500 hr x $89.18/hr). The increase in the number of clinician-initiated requests results in an adjustment of 750 hours and $66,885 (75 requests x 10 hrs x $89.18/hr).

TABLE 25: Estimated Burden for Other Payer Advanced APM Determinations: Eligible Clinician Initiated Process

	Burden Estimate
# of other payer payment arrangements from APM Entities and eligible clinicians	150
Total Annual Hours Per other payer payment arrangement (b)	10
Total Annual Hours (c) = (a)*(b)	1,500
Labor rate for a computer systems analyst (d)	$89.18/hr
Estimated Total Annual Cost for Other Payer Advanced APM determinations (e) = (a)*(d)	$133,770

3. *Submission of Data for QP Determinations under the All-Payer Combination Option*

The following reflects the burden associated with the first year of data collection resulting from policies set out in the CY 2018 Quality Payment Program final rule. Because no collection of data was required prior to the CY 2019 performance period, the requirements and burden were not submitted to OMB for approval.

The CY 2017 Quality Payment Program final rule provided that either APM Entities or individual eligible clinicians must submit by a date and in a manner determined by us: (1) payment arrangement information necessary to assess whether each other payer arrangement is an Other Payer Advanced APM, including information on financial risk arrangements, use of CEHRT, and payment tied to quality measures; (2) for each payment arrangement, the amounts of payments for services furnished through the arrangement, the total payments from the payer, the numbers of patients furnished any service through the arrangement (that is, patients for whom the eligible clinician is at risk if actual expenditures exceed expected expenditures), and (3) the total number of patients furnished any service through the arrangement (81 FR 77480). The rule also specified that if we do not receive sufficient information to complete our evaluation of another payer arrangement and to make QP determinations for an eligible clinician using the All-Payer Combination Option, we will not assess the eligible clinicians under the All-Payer Combination Option (81 FR 77480).

In the CY 2018 Quality Payment Program final rule, we explained that in order for us to make QP determinations under the All-Payer Combination Option using either the payment amount or patient count method, we will need to receive all of the payment amount and patient count information: (1) attributable to the eligible clinician or APM Entity through every Other Payer Advanced APM; and (2) for all other payments or patients, except from excluded payers, made or attributed to the eligible clinician during the QP performance period (82 FR 53885). We also finalized that eligible clinicians and APM Entities will not need to submit Medicare payment or patient information for QP determinations under the All-Payer Combination Option (82 FR 53885).

The CY 2018 Quality Payment Program final rule noted that we will need this payment amount and patient count information for the periods January 1 through March 31, January 1 through June 30, and January 1 through August 31 (82 FR 53885). We noted that the timing may be challenging for APM Entities or eligible clinicians to submit information for the August 31 snapshot date. If we receive information for either the March 31 or June 30 snapshots, but not the August 31 snapshot, we will use that information to make QP determinations under the All-Payer Combination Option. This payment amount and patient count information is to be submitted in a way that allows us to distinguish information from January 1 through March 31, January 1 through June 30, and January 1 through August 31 so that we can make QP determinations based on the two finalized snapshot dates (82 FR 30203 through 30204).

The CY 2018 Quality Payment Program final rule specified that APM Entities or eligible clinicians must submit all of the required information about the Other Payer Advanced APMs in which they participate, including those for which there is a pending request for an Other Payer Advanced APM determination, as well as the payment amount and patient count information

sufficient for us to make QP determinations by December 1 of the calendar year that is 2 years to prior to the payment year, which we refer to as the QP Determination Submission Deadline (82 FR 53886).

In the CY 2019 PFS final rule, we have finalized the addition of a third alternative to allow QP determinations at the TIN level in instances where all clinicians who have reassigned billing rights to the TIN participate in a single APM Entity. This option will therefore be available to all TINs participating in Full TIN APMs, such as the Medicare Shared Savings Program. It will also be available to any other TIN for which all clinicians who have reassigned billing rights to the TIN participating in a single APM Entity. To make QP determinations under the All-Payer Combination Option at the TIN level as finalized using either the payment amount or patient count method, we will need to receive, by December 1 of the calendar year that is 2 years to prior to the payment year, all of the payment amount and patient count information: (1) attributable to the eligible clinician, TIN, or APM Entity through every Other Payer Advanced APM; and (2) for all other payments or patients, except from excluded payers, made or attributed to the eligible clinician(s) during the QP performance period for the periods January 1 through March 31, January 1 through June 30, and January 1 through August 31 sufficient for us to make QP determinations..

As shown in Table 26, we assume that 4 APM Entities, 225 TINs, and 80 eligible clinicians will submit data for QP determinations under the All-Payer Combination Option in 2019. We estimate it will take the APM Entity representative, TIN representative, or eligible clinician 5 hours at $107.38/hr for a practice administrator to complete this submission. In aggregate, we estimate an annual burden of 1,545 hours (309 respondents x 5 hr) at a cost of $165,902 (1,545 hr x $107.38/hr).

TABLE 26: Estimated Burden for the Submission of Data for All-Payer QP Determinations

Burden and Respondent Descriptions	**Burden Estimate**
# of APM Entities submitting data for All-Payer QP Determinations (a)	4
# of TINs submitting data for All-Payer QP Determinations (b)	225
# of eligible submitting data for All-Payer QP Determinations (c)	80
Hours Per respondent QP Determinations (d)	5
Total Hours (g) = [(a)*(d)]+[(b)*(d)]+[(c)*(d)]	1,545
Labor rate for a Practice Administrator ($107.38) (h)	$107.38/hr
Total Annual Cost for Submission of Data for All-Payer QP Determinations (i) = (g)*(h)	$165,902

xiii. Burden Estimate for Voluntary Participants to Elect Opt-Out of Performance Data Display on Physician Compare

We estimate that 10 percent of the total clinicians and groups who will voluntarily participate in MIPS will also elect not to participate in public reporting. This results in a total of 11,617 (10 percent x 116,174 voluntary MIPS participants), a decrease of 10,783 from the total respondents currently approved by OMB under the aforementioned control number due to the reduction in voluntary participation in MIPS overall. As we discussed earlier in this section of the final rule, voluntary respondents are clinicians that are not QPs and are expected to be excluded from MIPS

after applying the eligibility requirements discussed in the CY 2019 PFS final rule, but have elected to submit data to MIPS. In implementing the finalized opt-in policy, we estimate that 33 percent of clinicians that exceed 1 of the low-volume criteria, but not all 3, will elect to opt-in to MIPS, become MIPS eligible, and no longer be considered a voluntary reporter. Table 27 shows that for these voluntary participants, we estimate it will take 0.25 hours at $89.18/hr for a computer system analyst to submit a request to opt-out. In aggregate, we estimate an annual burden of 2,904.25 hours (11,617 requests x 0.25 hr/request) at a cost of $259,001 (2,904.25 hr x $89.18/hr).

The decrease in the number of respondents due to policies finalized in this rule results in a decrease of -2,695.75 hours (-10,783 respondents x 0.25 hr) and -$240,407 (-2,695.75 hours x $89.18/hr).

TABLE 27: Estimated Burden for Voluntary Participants to Elect Opt Out of Performance Data Display on Physician Compare

Burden and Respondent Descriptions	Burden Estimate
# of Voluntary Participants Opting Out of Physician Compare (a)	11,617
Total Annual Hours Per Opt-out Requester (b)	0.25
Total Annual Hours for Opt-out Requester (c) = (a)*(b)	2,904.25
Labor rate for a computer systems analyst (d)	$89.18/hr
Total Annual Cost for Opt-out Requests (e) = (a)*(d)	$259,001

Burden Summary

Regulation Section(s) Under Title 42 of the CFR	Requirement	Table # (see above)	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting ($/hr)	Total Cost ($)*
§414.1400	Qualified Registry Self-Nomination	3	150	3	450	89.18	40,131
§414.1400	QCDR self-nomination	4	200	12	2,400	89.18	214,032
§414.1325 and 414.1335	QPP Identity Management Application Process	9	3,741	1	3,741	89.18	333,622
§414.1325 and 414.1335	(Quality Performance Category) Claims Collection Type	10	257,260	14.2	3,653,092	Varies (see table 10)	344,934,208
§414.1325 and 414.1335	(Quality Performance Category) QCDR/MIPS CQM Collection	11	81,981	9.083	744,633	Varies (see table 11)	71,016,861

Regulation Section(s) Under Title 42 of the CFR	Requirement	Table # (see above)	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting ($/hr)	Total Cost ($)*
	Type						
§414.1325 and 414.1335	(Quality Performance Category) eCQM Collection Type	12	51,861	8.0	414,888	Varies (see table 12)	39,916,374
§414.1325 and 414.1335	(Quality Performance Category) CMS Web Interface Submission Type	13	286	61.7	17,637	89.18	1,572,837
§414.1325 and 414.1335	(Quality Performance Category) Group Registration for CMS Web Interface	14	67	0.25	16.75	89.18	1,494
	(Quality Performance Category) Call for Quality Measures	15	140	4.5	630	Varies (see table 15)	125,896
§414.1375 and 414.1380	(PI Performance Category) Reweighting Applications for Promoting Interoperability and Other Performance Categories	16	6,041	0.25	1,510.3	89.18	134,684
§414.1375	(PI Performance Category) Data Submission	18	93,869	2.67	250,317.3	89.18	22,323,300
	(PI Performance Category) Call for Promoting Interoperability Measures	19	47	0.5	23.5	Varies (see table 19)	3,455
§414.1360	(Improvement Activities Performance	21	136,004	0.083	11,333	89.18	1,010,736

Regulation Section(s) Under Title 42 of the CFR	Requirement	Table # (see above)	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting ($/hr)	Total Cost ($)*
	Category) Data Submission						
§414.1360	(Improvement Activities Performance Category) Nomination of Improvement Activities	22	125	2.0	250	Varies (see table 22)	36,751
§414.1430	Partial Qualifying APM Participant (QP) Election	23	81	0.25	20.25	89.18	1,806
§414.1440	Other Payer Advanced APM Identification: Payer Initiated Process	24	215	10	2,150	89.18	191,737
§414.1445	Other Payer Advanced APM Identification: Clinician Initiated Process	25	150	10	1,500	89.18	133,770
§414.1440	Submission of Data for All-Payer QP Determinations under the All-Payer Combination Option	26	309	5	1,545	107.38	165,902
§414.1395	(Physician Compare) Opt Out for Voluntary Participants	27	11,617	0.25	2,904	89.18	259,001
TOTAL			**644,144**	**Varies**	**5,109,042**	**Varies**	**482,416,597**

Information Collection Instruments/Instructions

Appendix A (See Table 3): 2019 Qualified Registry Fact Sheet (No Changes)

Appendix B (See Table 4): 2019 Qualified Clinical Data Registry (QCDR) Fact Sheet (No Changes)

Appendix C (See Table 14): 2018 Registration Guide for the CMS Web Interface and CAHPS for MIPS Survey (No Changes)

Appendix D (See Table 25): Submission Form for Eligible Clinician and APM Entity Requests for Other Payer Advanced Alternative Payment Model Determinations (Eligible Clinician Initiated Submission Form) (No Changes)

Appendix E (See Table 24): Submission Form for Other Payer Requests for Other Payer Advanced Alternative Payment Model Determinations (Payer Initiated Submission Form) (No Changes)

Appendix F (See Table 26): Submission Form for Requests for Qualifying Alternative Payment Model Participant (QP) Determinations under the All-Payer Combination Option (New)

Appendix G (See Table 15): JIRA Measures under Consideration 2018, Data Template for Candidate Measures (Revised)

Appendix H (See Table 19): Promoting Interoperability Performance Category, Call for Measures Submission Form (Revised)

Appendix I (See Table 22): Improvement Activities Performance Category, Call for Activities Submission Form (English) (No Changes)

Appendix J (See Table 15): Peer Reviewed Journal Article Requirement Template (New)

13. Capital Costs

In the CY 2019 PFS final rule, we discuss the requirement to use EHR technology certified to the 2015 Edition beginning with the 2019 MIPS performance period for the Promoting Interoperability performance category. With respect to these costs, although this requirement would require some investment in systems updates, our policy prior to this regulation as reflected in §414.1305, is that 2015 Edition CEHRT will be required beginning with the 2019 MIPS performance period/2021 MIPS payment year (82 FR 53671). Therefore, we do not anticipate any additional costs due to this regulation.

Under the policies established in the CY 2017 Quality Payment Program final rule, the costs for complying with the improvement activities performance category requirements could have potentially led to higher expenses for MIPS eligible clinicians. Costs per full-time equivalent primary care clinician for improvement activities will vary across practices, including for some activities or certified patient-centered medical home practices, in incremental costs per encounter, and in estimated costs per (patient) member per month. Costs for compliance with previously finalized policies may vary based on panel size (number of patients assigned to each care team) and location of practice among other variables. For example, Magill (2015) conducted a study of certified patient-centered medical home practices in two states. That study found that costs associated with a full-time equivalent primary care clinician, who was associated with certified patient-centered medical home practices, varied across practices. Specifically, the study found an average cost of $7,691 per month in Utah practices, and an average of $9,658 in Colorado practices. Consequently, incremental costs per encounter were $32.71 for certified patient-centered medical home practices in Utah and $36.68 in Colorado (Magill, 2015). The study also found that the average estimated cost per patient member, per month, for an assumed panel of 2,000 patients was $3.85 in Utah and $4.83 in Colorado. However, given the lack of comprehensive historical data for improvement activities, we are unable to quantify those costs in detail at this time. The findings presented in these papers have not changed. We have improvement activities information from the 2017 performance period that is now available, but additional analysis is required to report the costs and benefits of implementing the improvement activities. We have considered factors that also contribute to the difficulty of identifying compliance costs for the improvement activities performance category in the CY 2018 Quality Payment Program final rule (82 FR 53845).

We believe that because we finalized an opt-in policy (as described in the CY 2019 PFS final rule), we would add approximately 28,000 additional clinicians to the MIPS eligible clinicians. In the final rule, we assumed that those who have elected to opt-in have already been voluntary reporters in MIPS and would not have additional compliance costs as a result of the regulation. Thus, we believe the overall potential cost of compliance would not increase because of the CY 2019 PFS final rule.

Further, we anticipate that the vast majority of clinicians submitting improvement activities data to comply with existing MIPS policies could continue to submit the same activities. Previously finalized improvement activities continue to apply for the current and future years unless otherwise modified per rule-making (82 FR 54175). We refer readers to Table H in the Appendix of the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77199) and Tables F and G in the Appendix of the CY 2018 Quality Payment Program final rule (82 FR 54175 through 54229) for our previously finalized 112 improvement activities established in the Improvement Activities Inventory. In the CY 2019 PFS final rule, we finalized 6 new improvement activities, 5 modifications and 1 removal of an existing activity.

Similarly, we believe that third parties who submit data on behalf of clinicians who prepared to submit data in the transition year will not incur additional costs as a result of policies finalized in the CY 2019 PFS final rule.

14. Cost to Federal Government

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

We have updated the appendices included in this PRA submittal to reflect changes due to finalized requirements, revised terminology, and to reflect dates starting with the CY 2019 performance period. None of these updates require changes to our currently approved burden estimates beyond those associated with any finalized requirements.

In addition, we have provided three new appendices: the All-Payer QP Data Submission form, the Improvement Activities Call for Activities Submission form, and the Peer Reviewed Journal Article Requirement form. The All-Payer QP Data Submission form is associated with a new burden estimate for the CY 2019 performance period while the IA Call for Activties Submission form was not previously available and the Peer Reviewed Journal Article Requirement form was previously included as part of the Advancing Care Information (now Promoting Interoperability) Measures Submission form.

Table 28 includes our final rule burden estimates for the Quality Payment Program. The total estimated burden is 5,109,042 hours at a cost of $482,416,597 (see Tables 28 and 29).

In order to understand the burden implications of the policies finalized in CY 2019 PFS final rule, we have also estimated a baseline burden of continuing the policies and information collections set forth in the CY 2018 Quality Payment Program final rule into the 2019 MIPS performance period. Our estimated baseline burden estimates reflect the recent availability of

data sources to more accurately reflect the number of the organizations exempt from the Promoting Interoperability performance category and to more accurately reflect the exclusion of QPs from all MIPS performance categories. The baseline burden estimates employ the improved data and methods also used for our year CY 2019 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 this Supporting Statement A.

The baseline burden estimate is 5,145,009 hours at a cost of $485.6 million. This baseline burden estimate is lower than the burden approved for information collection related to the CY 2018 Quality Payment Program final rule due to updated data and assumptions. As shown in Table 29, our baseline estimate reflects adjustments to our burden assumptions due to a review of the processes currently in place for submission of data and required MIPS information as well as estimates of respondents that more accurately account for all potential respondents.

As shown in Table 28, this Supporting Statement A reflects a total of 644,144 responses with an associated hours burden of 5,109,042, this is a reduction of 35,968 hours. As shown in Table 29, we estimate a total burden of approximately $482.4 million, a reduction of $3.2 million. The reduction in burden for the 2019 MIPS performance period is reflective of several finalized policies, including reduction in the number of measures for which clinicians are required to submit quality data via the CMS Web Interface, a reduction in the number of measures for which clinicians are required to submit data for the Promoting Interoperability performance category, and the reduced number of voluntary participants resulting from finalized eligibility requirements. Our burden estimates also reflect the first year of data collection associated with our previously finalized policy to require APM Entities or eligible clinicians to submit all of the required information about the Other Payer Advanced APMs in which they participate.

TABLE 28: Annual Recordkeeping and Submission Requirements

Requirement	Currently Approved Respondents	Finalized Respondents	Change in Respondents	Currently Approved Total Burden Hours	Finalized Total Burden Hours	Change in Total Burden Hours
§414.1400 Registry self-nomination*	120	150	30	1,200	450	-750
§414.1400 QCDR self-nomination*	113	200	87	1,130	2,400	1,270
§414.1325 and 414.1335 CMS Quality Payment Program Identity Management Application Process	0	3,741	3,741	0	3,741	3,741
§414.1325 and 414.1335 (Quality Performance Category) Claims Collection Type	278,039	257,260	-20,779	4,949,094	3,653,092	-1,196,002
§414.1325 and 414.1335 (Quality Performance Category) QCDR/MIPS CQM Collection Type	107,217	81,981	-25,236	973,852	744,633	-229,219

Requirement	Currently Approved Respondents	Finalized Respondents	Change in Respondents	Currently Approved Total Burden Hours	Finalized Total Burden Hours	Change in Total Burden Hours
§414.1325 and 414.1335 (Quality Performance Category) eCQM Collection Type	54,218	51,861	-2,357	487,962	414,888	-73,074
§414.1325 and 414.1335 (Quality Performance Category) CMS Web Interface	296	286	-10	21,904	17,636.7	-4,267.3
§414.1325 and 414.1335 (Quality Performance Category) Registration and Enrollment for CMS Web Interface	10	67	57	10	16.75	6.75
(Quality Performance Category) Call for Quality Measures	40	140	100	20	630	610
§414.1375 and 414.1380 (PI Performance Category) Reweighting Applications for Promoting Interoperability and Other Performance Categories	40,645	6,041	-34,604	20,323	1,510	-18,813
§414.1375 (PI Performance Category) Data Submission	218,215	93,869	-124,346	654,645	250,317	-404,328
(PI Performance Category) Call for Promoting Interoperability Measures	40	47	7	20	23.5	3.5
§414.1360 (Improvement Activities Performance Category) Data Submission	439,786	136,004	-303,782	439,786	11,334	-428,452
§414.1360 (Improvement Activities Performance Category) Nomination of Improvement Activities	150	125	-25	75	250	-175
§414.1430 Partial Qualifying APM Participant (QP) Election	17	81	64	4.25	20.25	16
§414.1440 Other Payer Advanced APM Identification: Payer Initiated Process	300	215	-85	3,000	2,150	-850
§414.1445 Other Payer Advanced APM Identification: Eligible Clinician Initiated Process	75	150	75	750	1,500	750
§414.1440 Submission of Data for All-Payer QP Determinations under the All-Payer Combination Option	0	309	309	0	1,545	1,545
§414.1395 (Physician Compare) Opt Out for Voluntary Participants	22,400	11,617	-10,783	5,600	2,904.25	-2,695.75
TOTAL	**1,161,681**	**644,144**	**-517,537**	**7,559,375**	**5,109,042**	**-2,450,333**

*These two ICRs were combined in a single ICR in the CY 2018 Quality Payment Program final rule (82 FR 53906 through 53907).

Table 29 summarizes the ICRs for the Quality Payment Program for which we have finalized changes to the burden estimates currently approved by OMB under control number 0938-1314 (CMS-10621). For each ICR we have noted the total burden adjustment due to changes in policy and the total burden adjustment due to changes assumptions.

TABLE 28: Annual Requirements and Burden

Regulation Section(s) Under Title 42 of the CFR	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting ($/hr)	Total Cost ($)*	Total Cost Adjustments due to Policy Changes ($)*	Total Cost Adjustments due to change in assumptions ($)*
§414.1400 (Registry self-nomination)	150	3	450	89.18	40,131	0	40,131
§414.1400 (QCDR self-nomination)	200	12	2,400	89.18	214,032	0	6,243
§414.1325 and 414.1335 (QPP Identity Management Application Process)	3,741	1	3,741	89.18	333,622	0	333,622
§414.1325 and 414.1335 [(Quality Performance Category) Claims Collection Type]	257,260	14.2	3,653,092	Varies (see table 10)	344,934,208	0	-117,122,124
§414.1325 and 414.1335 [(Quality Performance Category) QCDR/MIPS CQM Collection Type]	81,981	9.083	744,633	Varies (see table 11)	71,016,861	0	-21,860,937
§414.1325 and 414.1335 [(Quality Performance Category) eCQM Collection Type]	51,861	8.0	414,888	Varies (see table 12)	39,916,374	0	-6,649,297
§414.1325 and 414.1335 [(Quality Performance Category) CMS Web Interface Submission Type]	286	61.7	17,637	89.18	1,572,837	-314,569	-65,993
§414.1325 and 414.1335	67	0.25	16.75	89.18	1,494	0	602

Regulation Section(s) Under Title 42 of the CFR	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting ($/hr)	Total Cost ($)*	Total Cost Adjustments due to Policy Changes ($)*	Total Cost Adjustments due to change in assumptions ($)*
[(Quality Performance Category) Registration and Enrollment for CMS Web Interface]							
[(Quality Performance Category) Call for Quality Measures]	140	4.5	630	Varies (see table 15)	125,896	0	122,956
§414.1375 and 414.1380[(PI Performance Category) Reweighting Applications for Promoting Interoperability and Other Performance Categories	6,041	0.25	1,510.3	89.18	134,684	0	-1,677,677
§414.1375 [(PI Performance Category) Data Submission]	93,869	2.67	250,317.3	89.18	22,323,300	-2,790,412	-33,267,529
[(PI Performance Category) Call for Promoting Interoperability Measures]	47	0.5	23.5	Varies (see table 19)	3,455	0	515
§414.1360 [(Improvement Activities Performance Category) Data Submission]	136,004	0.083	11,333.7	89.18	1,010,736	0	-38,209,379
§414.1360 [(Improvement Activities Performance Category) Nomination of Improvement Activities]	125	2.0	250	Varies (see table 22)	36,751	0	25,726
§414.1430 [Partial	81	0.25	20.25	89.18	1,806	0	1,427

Regulation Section(s) Under Title 42 of the CFR	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting ($/hr)	Total Cost ($)*	Total Cost Adjustments due to Policy Changes ($)*	Total Cost Adjustments due to change in assumptions ($)*
Qualifying APM Participant (QP) Election]							
§414.1440 [Other Payer Advanced APM Identification: Payer Initiated Process]	215	10	2,150	89.18	191,737	0	-75,803
§414.1445 [Other Payer Advanced APM Identification: Clinician Initiated Process]	150	10	1,500	89.18	133,770	0	66,885
§414.1440 [Submission of Data for All-Payer QP Determinations under the All-Payer Combination Option]	309	5	1,545	107.38	165,902	165,902	0
§414.1395 [(Physician Compare) Opt Out for Voluntary Participants]	11,617	0.25	2,904.3	89.18	259,001	-240,407	0
TOTAL	**644,144**	**Varies**	**5,109,042**	**Varies**	**482,416,597**	**-3,179,486**	**-218,330,632**

*With respect to the PRA, this rule would not impose any non-labor costs.

Table 29 provides the reasons for changes in the estimated burden for information collections in the CY 2019 PFS final rule. We have divided the reasons for our change in burden into those related to new policies and those related to changes in the baseline burden of continued Quality Payment Program Year 2 policies that reflect updated data and methods.

TABLE 29: Reasons for Change in Burden Compared to the Currently Approved CY 2018 Information Collection Burdens

Table in Collection of Information	**Changes in burden due to finalized Year 3 policies**	**Changes to "baseline" of burden continued Year 2 policy (*italics are changes in number of respondents' due to updated data)***
Table 3: Qualified Registry Self-Nomination	None	After a review of the self-nomination process, we determined it is more accurate to separately assess the burden of Qualified Registry and QCDR self-nomination rather than aggregate them in the same ICR. Review of self-nomination process resulted in a decrease in estimated time needed to complete simplified self-nomination (-9.5 hr. computer system analyst time) and full self-nomination (-7 hr. computer system analyst time). *Increase in the number of respondents as the number of qualified registries enrolling increases and the basis for estimating the number of respondents is updated to reflect the number of self-nomination applications received in place of the number of qualified registries being approved.*
Table 4: QCDR Self-Nomination	None	After a review of the self-nomination process, we determined it is more accurate to separately assess the burden of Qualified Registry and QCDR self-nomination rather than aggregate them in the same ICR. Review of self-nomination process resulted in an increase in estimated time needed to complete simplified self-nomination (-0.5 hr. computer system analyst time) and full self-nomination (+2 hr. computer system analyst time). *Increase in the number of respondents as the number of QCDRs enrolling increases and the basis for estimating the number of respondents is updated to reflect the number of self-nomination applications received in place of the number of QCDRs being approved.*
Table 9: Quality Payment Program Identity Management Application Process	None	*Decreased number of respondents due to updates to the identity management system being used for data submission in the 2018 MIPS performance period; only new respondents submitting quality data using the CMS Enterprise Portal need to create a new account, versus system where all respondents submitting via EHR needed to register for user account annually.*

Table in Collection of Information	**Changes in burden due to finalized Year 3 policies**	**Changes to "baseline" of burden continued Year 2 policy (*italics are changes in number of respondents' due to updated data)***
Table 10: Quality Performance Category Claims Collection Type	None	*Decreased number of respondents due to updated data from 2017 MIPS performance period.* Correction to estimate to account for reduced number of required measures compared to PQRS (6 in MIPS; 9 in PQRS) reduced estimated time to submit data.
Table 11: Quality Performance Category QCDR/MIPS CQM Collection Type	None	*Decreased number of respondents due to updated data from 2017 MIPS performance period.*
Table 12: Quality Performance Category eCQM Collection Type	None	*Decreased number of respondents due to updated data from 2017 MIPS performance period.*
Table 13: Quality Performance Category CMS Web Interface	Decrease in number of required measures resulted in reduction in estimated time needed to submit data (-12.33 hrs computer system analyst time).	*Decrease in the number of respondents due to updated data from the 2018 MIPS performance period as fewer eligible group practices elected to submit data using the CMS Web Interface.*
Table 14: Registration for CMS Web Interface	None	*Increase in the number of respondents due to updated data from the 2018 MIPS performance period as more groups register to submit data using the CMS Web Interface.* Review of registration process resulted in decrease in estimated time to register. (-0.75 hr. computer system analyst time).
Table 15: Call for Quality Measures	None	*Increase in the number of new quality measures being nominated.* Inclusion of time required to complete Peer Review Journal Article Form resulted in increase in time to nominate a quality measure. This was a requirement in the CY 2017 Quality Payment Program final rule (81 FR 77153 through 77155) but was not included in burden estimates. (+4 hrs Physician time).
Table 16: Reweighting Applications for Promoting Interoperability and Other Performance Categories	None	*Decrease in the number of respondents due to updated data from 2017 MIPS performance period.* Review of application process resulted in decrease in estimated time to apply (-0.25 hr computer system analyst time).
Table 18: Promoting Interoperability Performance Category Data Submission	Decrease in number of required measures resulted in reduction in estimated time needed to submit data (-.33 hr computer system analyst time).	*Decrease in the number of respondents due to updated data from 2017 MIPS performance period.*

Table in Collection of Information	**Changes in burden due to finalized Year 3 policies**	**Changes to "baseline" of burden continued Year 2 policy (*italics are changes in number of respondents' due to updated data)***
Table 19: Call for Promoting Interoperability Measures	None.	*Increase in the number of new Promoting Interoperability measures being nominated.*
Table 21: Improvement Activities Submission	None.	*Decrease in the number of respondents due to updated data from 2017 MIPS performance period.* Review of submission process resulted in decrease in estimated to submit (-0.92 hr computer system analyst time).
Table 22: Nomination of Improvement Activities	None	Review of nomination process resulted in increase in estimated time to nominate a new improvement activity (+0.9 hrs Practice Administrator time; +0.6 hrs Physician time).
Table 23: Partial QP Election	None	*Increase in the number of respondents due to additional APM Entities and eligible clinicians electing to participate as a Partial QP in MIPS.*
Table 24: Other Payer Advanced APM Identification: Other Payer Initiated Process	None	None
Table 25: Other Payer Advanced APM Identification: Eligible Clinician Initiated Process	None	*Increase in the number of anticipated other payer arrangements submitted by APM Entities and eligible clinicians for identification as Other Payer Advanced APMs.*
Table 26: Submission of Data for All-Payer QP Determinations under the All-Payer Combination Option	Reflects new policy in the final rule.	None.
Table 27: Voluntary Participants to Elect to Opt Out of Performance Data Display on Physician Compare	*Decrease in the number of respondents due to updated data from the 2017 MIPS performance period.*	None.

Table 30 summarizes the annual burden estimates for finalized requirements for all ICRs being submitted for OMB approval under control number 0938-1314 (CMS-10621).

TABLE 30: Annual Requirements and Burden

Regulation Section(s) Under Title 42 of the CFR	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting ($/hr)	Total Cost ($)*
Quality Payment Program (See Subtotal Under Table 89)	**	(517,537)	varies	(2,450,334)	varies	(221,510,118)

* With respect to the PRA, the final rule would not impose any non-labor costs.
** We are unable to accurately calculate a total number of respondents for the Quality Payment Program. In many cases, individuals, groups, and entities have responded to multiple data collections and there is no unified way to identify unique respondents.

16. Publication and Tabulation Dates

To provide expert feedback to clinicians and third party data submitters in order to help clinicians provide high-value, patient-centered care to Medicare beneficiaries; we provide performance feedback to MIPS eligible clinicians that includes MIPS quality, cost data, improvement activities and Promoting Interoperability data. These reports were made available starting in July 2018 at qpp.cms.gov. We have also finalized 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 MIPS.

We plan to publicly report MIPS information through the Physician Compare website either on public profile pages or via the Downloadable Database housed on data.medicare.gov for the purpose of promoting more informed health care choices by for people with Medicare. The public reporting is anticipated to start in late 2020 for the 2019 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/

We plan to provide relevant data to other federal and state agencies, Quality Improvement Networks, and parties assisting consumers, for use in administering or conducting federally-funded health benefit programs, payment and claims processes, quality improvement outreach and reviews, and transparency projects.

17. Expiration Date

The expiration date will be displayed on all web-based data collection forms.

18. Certification Statement

There are no exceptions to the certification statement.