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. APM Entities and eligible clinicians must also 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).

The implementation of MIPS requires the collection of quality, Promoting Interoperability, 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 categories which is not available for the quality performance category and clinicians who use Medicare Part B claims, administrative

[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).

claims, or the CMS Web Interface, 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 2019 and prior MIPS performance periods, individuals and groups submitting data for the quality performance category via a qualified registry or QCDR that did not also support reporting of data for the Promoting Interoperability or improvement activity performance categories would be required to submit data for these performance categories using an alternate submission type. The proposals discussed in sections III.K.3.g.(3)(a)(i) and III.K.3.g.(4)(a)(i) of the CY 2020 PFS proposed rule requiring qualified registries and QCDRs to support the reporting of quality, improvement activities, and Promoting Interoperability performance categories alleviates this issue.

For the Promoting Interoperability performance category, in addition to policies finalized in the CY 2019 PFS final rule and CY 2017 and CY 2018 Quality Payment Program final rules, we are making a number of proposals in the CY 2020 PFS proposed rule: (1) to attempt to reweight the performance categories, if technically and operationally feasible, for a MIPS eligible clinician who we determine has been affected by compromised data issues outside of their control (otherwise we would provide a score of zero for the relevant performance category); (2) to assign a zero percent weight for the Promoting Interoperability performance category for groups defined as hospital-based and non-patient facing, and redistribute the points associated with the Promoting Interoperability performance category to another performance category or categories and to require the group or virtual group to meet a threshold of more than 75 percent (instead of 100 percent) of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, to meet the definition of a hospital-based or non-patient facing; (3) that a hospital-based MIPS eligible clinician means an individual MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in an inpatient hospital, on-campus outpatient hospital, off campus outpatient hospital, or emergency room setting based on claims for the MIPS determination period, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group’s TIN or virtual group’s TINs, as applicable, meet the definition of a hospital-based individual MIPS eligible clinician; and (4) revisions to account for a group or virtual group that meets the definition of a non-patient facing MIPS eligible clinician such that the group or virtual group only has to meet a threshold of more than 75 percent.

For the improvement activities performance category, as discussed in section III.K.3.c.(3)(d)(iii) of the CY 2020 PFS proposed rule, we are proposing, beginning with the 2020 MIPS performance period and for future years, to increase the minimum number of clinicians in a group or virtual group who are required to perform an improvement activity from at least one clinician to at least 50 percent of the NPIs billing under the group’s TIN or virtual group’s TINs, as applicable; and these NPIs must perform the same activity for the same continuous 90 days in the performance period. In addition, in section III.K.3.c.(3)(e)(i), we are proposing for the CY 2020 performance period and future years to: add 2 new improvement activities, modify 7 existing improvement activities, and remove 15 existing improvement activities.

The implementation of MIPS requires the collection of additional data beyond performance category data submission. Qualified registries and QCDRs must complete a self-nomination form submitted electronically using a web-based tool 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.

We are requesting approval of 19 information collections associated with the CY 2020 PFS proposed rule as a revision to currently approved information requests submitted under OMB control number 0938-1314 (CMS-10621). CMS has already received approval for collection of information associated with the CAHPS for MIPS survey via a separate Paperwork Reduction Act (PRA) package under OMB control number 0938-1222 which expires 1/31/2022. CMS has already received approval for collection of information associated with the virtual group election process via a separate PRA package under OMB control number 0938-1343 which expires 9/30/2020.

1. Data Collection for MIPS

i. Quality Performance Category

The processes for reporting quality performance category data will be generally the same for the 2020 MIPS performance period as they were in the 2019 MIPS performance period; therefore, we anticipate clinicians will be more familiar with the submission processes in this fourth year. Under MIPS, the quality performance category performance requirements are as follows: the MIPS eligible clinician or group will report at least 6 measures including at least 1 outcome measure if available; if an applicable outcome measure is not available, then the MIPS eligible clinician or group will report a high priority measure (appropriate use, patient safety, efficiency, patient experience, 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. As discussed in section III.K.3.c.(1)(c)(ii) of the CY 2020 PFS proposed rule, we are proposing to adopt a higher data completeness threshold (the percentage of eligible patients the clinician must check to see whether the measure applies to) for the 2020 MIPS performance period, such that MIPS eligible clinicians and groups submitting quality measure data on QCDR measures, MIPS CQMs, and eCQMs must submit data on at least 70 percent of the MIPS eligible clinician or group's patients that meet the denominator criteria, regardless of payer for the 2020 MIPS performance period.

Previously finalized MIPS quality measures can be found in the CY 2019 Physician Fee Schedule (PFS) final rule (83 FR 60097 through 60285); 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 proposed for inclusion in MIPS

for the 2020 MIPS performance period and future years are found in Table Group A of Appendix 1 in the CY 2020 PFS proposed rule; MIPS quality measures with proposed substantive changes can be found in Table Group D of Appendix 1 in the CY 2020 PFS proposed rule; and MIPS quality measures proposed for removal can be found in Table Group C of Appendix 1 in the CY 2020 PFS proposed rule. Previously finalized specialty measure sets can be found in the CY 2019 PFS final rule corrections notice (84 FR 566) and CY 2018 Quality Payment Program final rule (82 FR 53990 and 82 FR 54098 through 54099). Proposals for modifications to existing specialty measure sets and new specialty sets can be found in Table Group B of Appendix 1 in the CY 2020 PFS proposed rule. Also, as shown in Table Group AA of Appendix 1 of the CY 2020 PFS proposed rule, we are proposing the inclusion of a population health based quality measure (*The All-Cause Unplanned Admission for Patients with Multiple Chronic Conditions measure*) beginning with the 2021 MIPS performance period. We are proposing this measure with a delayed implementation until the 2021 performance period of MIPS, to allow for time to work through operational factors of implementing the measure. In total, we are proposing 4 new measures, removal of 55 existing measures, and 95 measures with a substantive change. The total number of measures remaining for the 2020 performance period and future years is 206, a reduction of 51 from the 257 measures finalized for the 2019 performance period (83 FR 60003)

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 due to 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, and it was reported by MIPS eligible clinicians as part of the overall MIPS program. In 2018, we renamed the Advancing Care Information performance category as the Promoting Interoperability performance category (83 FR 35912). 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 were required to 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 41 of the CY 2020 PFS proposed rule provides a list of Promoting Interoperability performance category objectives and measures for the 2020 MIPS Performance Period.

For the 2020 MIPS performance period, we are proposing a new scoring methodology as shown in Table 42 of the CY 2020 PFS proposed rule, which reflects our proposals to: (1) make the Query of PDMP measure optional and eligible for five bonus points in CY 2020; (2) make the e-

Prescribing measure worth up to 10 points in the event the proposal for the Query of PDMP measure is finalized; and (3) remove the Verify Opioid Treatment Agreement measure beginning in 2020. 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, furnish 75 percent or more of covered professional services in hospital-based settings, or clinicians in small practices with 15 or fewer professionals. As discussed in sections III.K.3.c.(4)(f)(iii) and (iv) of the CY 2020 PFS proposed rule , we are proposing to require a group or virtual group to meet a threshold of more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, to meet the definition of a hospital-based or non-patient facing individual MIPS eligible clinician instead of a threshold of all of the MIPS eligible clinicians in the group or virtual group. 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 section III.K.3.c.(3)(d)(iii) of the CY 2020 PFS proposed rule, we are proposing, beginning with the 2020 MIPS performance period, to increase the group reporting threshold from at least one clinician to at least 50 percent of the group and to require that at least 50 percent of a group's NPIs must perform the same improvement activity for the same continuous 90 days in the performance period for the entire group to receive credit.

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), Tables F and G in the Appendix of the CY 2018 Quality Payment Program final rule (82 FR 54175 through 54229), and Tables X and G in Appendix 2 of the CY 2019 PFS final rule (83 FR 60286 through 60303). In the CY 2020 proposed rule, we are proposing 2 new improvement activities, 7 modifications to existing activities for CY 2020 and future years, and removal of 15 existing improvement activities for CY 2020 and future years. We refer readers to the Improvement Activities Inventory in Appendix 2 of the CY 2020 PFS proposed 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 elections, CMS Web Interface registrations, CAHPS for MIPS registrations, and reweighting applications.

The policies finalized in the CY 2017 and CY 2018 Quality Payment Program final rules and the CY 2019 PFS final rule and proposed in the CY 2020 PFS proposed rule create some additional data collection requirements not listed in Table 2. These additional data collections 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

APM Entities may 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. For the 2020 Medicare QP performance period, we define Partial QPs to be eligible clinicians in Advanced APMs who collectively have at least 40 percent, but less than 50 percent, of their payments for Part B covered professional services through an APM Entity, or collectively furnish Part B covered professional services to at least 25 percent, but less than 35 percent, of their Medicare beneficiaries through an 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. If the Partial QP elects to be scored under MIPS, they would be subject to all MIPS requirements. If an eligible clinician does not meet either the QP or Partial QP thresholds, and does not meet any another exemption category, the eligible clinician would be subject to MIPS and would report to MIPS.

As detailed in CMS 5522-FC, beginning in Quality Payment Program Year 3, the All-Payer Combination Option is an available pathway to QP or Partial 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. 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, in the CY 2019 PFS final rule, we 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, or through the Medicaid or Medicare Health Plan payment arrangement submission processes, as applicable.

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.

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 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 (83 FR 59936). 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, 2020, 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. We expect to publicly report 2018 MIPS performance period data and final scores on Physician Compare in late CY 2019. The data also may be used by CMS authorized entities participating in health care transparency projects. The data is used to produce the annual Quality Payment Program Experience Report which provides a comprehensive representation of the overall experience of MIPS eligible clinicians and subgroups of MIPS eligible clinicians. The initial Quality Payment Program Experience Report was published on qpp.cms.gov on March 20, 2019.

Relevant data will be provided to federal and state agencies, Quality Improvement Networks, , the Small, Underserved, and Rural Support (SURS) technical assistance contractors, 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 2019 Quality Payment Program will occur in 2020 with respect to the 2019 MIPS performance period. The data submission requirements for the CY 2020 Quality Payment Program will begin in the 2020 MIPS performance period, which will affect data submission burden that will occur in 2021.

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 2020 MIPS performance period, we assume that MIPS APM models will qualify for the maximum improvement activities performance category score and the APM Entities will not need to submit any additional improvement activities.

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 2020 PFS proposed rule's Regulatory Impact Analysis estimates that approximately 818,391 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 77,450 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 202,684 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 the Regulatory Impact Analysis section (section VI) of the CY 2020 PFS proposed rule, we explain that we assume 818,391 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 31,246 clinicians or 33 percent of clinicians who exceed at least one but not all low-volume threshold and submitted data in the CY 2017 MIPS performance period will elect to opt-in 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 175,000 and 225,000 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 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.

[3] For further detail on MIPS exclusions, see Supporting Statement B and the Regulatory Impact Analysis Section of the CY 2020 PFS proposed rule.

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

The CY 2020 PFS proposed rule is serving as the 60-day Federal Register notice which published on August 14, 2019 (84 FR 40482, RIN 0938–AT72, CMS-1715-P). The rule filed for public inspection on July 29, 2019.

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 2018 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	19.00	19.00	38.00
Computer Systems Analysts	15-1121	45.01	45.01	90.02
Licensed Practical Nurse (LPN)	29-2061	22.62	22.62	45.24
Physicians	29-1060	101.43	101.43	202.86
Practice Administrator (Medical and Health Services Managers)	11-9111	54.68	54.68	109.36

[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.

ii. Summary of Quality Payment Program Changes

Two information collection requests (ICRs) show an increase in burden due to proposed changes in policies: QCDR self-nomination applications and Call for Quality Measures. For the QCDR self-nomination applications ICR, we have increased our estimate of the time required to submit a QCDR measure by 1.5 hour due to the proposal to require QCDRs to identify a linkage between their QCDR measures to related cost measures, Improvement Activities, and MIPS Value Pathways starting with the 2021 self-nomination period (+1 hour); and the proposal to require QCDR measure stewards to submit measure testing data as part of the self-nomination process for each QCDR measure (+0.5 hours). For this same ICR, we have increased our estimate of the time required for a QCDR to submit their self-nomination by 0.25 due to the proposal to require QCDRs to include a description of the quality improvement services they intend to support. For the Call for Quality Measures, we have increased our estimate of the time required to nominate a quality measure for consideration by 1 hour due to the proposal to require that MIPS quality measure stewards link their MIPS quality measures to existing and related cost measures and improvement activities and provide rationale for the linkage. The remaining changes to currently approved burden estimates are adjustments to reflect better understanding of the impacts of policies finalized in previous rules as well as the use of updated data sources available at the time of publication of this proposed rule.

iii. 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, groups, or virtual 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 2020 MIPS performance period, the quality data submitted by MIPS APM participants reporting through the CMS Web Interface on behalf of their participant MIPS eligible clinicians will fulfill any MIPS submission requirements for the quality performance category. For other MIPS APMs, the quality data submitted by APM Entities on behalf of their participant MIPS eligible clinicians will fulfill any MIPS submission requirements for the quality performance category if that data is available to be scored. However, as proposed in section III.K.3.c.(5)(c)(i)(A), beginning in the 2020 MIPS performance period, MIPS eligible clinicians participating in MIPS APMs whose APM quality data is not available for MIPS may elect to report MIPS quality measures at either the APM entity, individual, or TIN level in a manner similar to our established policy for the Promoting Interoperability performance category under the APM scoring standard for purposes of the MIPS

quality performance category. If we determine there are not sufficient measures applicable and available, we will assign performance category weights as specified in § 414.1370(h)(5).

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.

[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**
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. If the ACO does not submit quality data, MIPS eligible clinicians participating in MIPS APMs may elect to report individually or at the TIN level.[e6] [Submissions by the ACO are not included in burden estimates 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].[7]	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].[8]	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.[9] [The burden 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.]	Advanced APM Entities will make election for participating MIPS eligible clinicians.

[6] Both group TIN and individual clinician quality data will be accepted. If both group TIN and individual scores are available for the same APM Entity, CMS will use the higher score for each TIN/NPI. We would then use the highest individual or TIN level score attributable to each MIPS eligible clinician in an APM Entity in order to determine the APM Entity score based on the average of the highest scores for each MIPS eligible clinician in the APM Entity.

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

[9] 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.

	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**
Eligible Clinicians participating in Other MIPS APMs	APM Entities submit to MIPS on behalf of their participating MIPS eligible clinicians; however if the quality data is not available to MIPS in time for scoring, MIPS eligible clinicians participating in MIPS APMs may elect to report individually or at the TIN-level.[6] [Submissions mady by APM Entities to MIPS on behalf of their participating MIPS eligible clinicians 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 PRA.]	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.]	APM Entities will make election for participating eligible clinicians.

* 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 and proposed in the CY 2020 PFS proposed rule create some additional data

collection requirements not listed in Table 2. These additional data collections 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

iv. 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. Data on the CAHPS for MIPS survey, which counts as one quality performance category measure, or can be used for completion of an improvement activity, can be submitted via CMS-approved survey vendors. Entities seeking approval to submit data on behalf of clinicians as a qualified registry, QCDR, or survey vendor must complete a self-nomination process annually. The processes for self-nomination for entities seeking approval as qualified registries and QCDRs are similar with the exception that QCDRs have the option to submit QCDR measures for the quality performance category. Therefore, differences between QCDRs and qualified registry self-nomination are associated with the preparation of QCDR measures for approval. The burden associated with qualified registry self-nomination and QCDR self-nomination and measure submission 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 for approval to do so (82 FR 53815).

In the CY 2018 Quality Payment Program final rule, previously approved qualified registries in good standing (i.e., that are not on probation or disqualified) may attest that certain aspects of their previous year's approved self-nomination have not changed and will be used for the applicable performance period (82 FR 53815). In the same rule, we stated that 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 (82 FR 53815). The self-nomination period is from July 1 to September 1 of the calendar year prior to the applicable performance period beginning with the 2020 MIPS performance period (83 FR 59906).

The CY 2017 Quality Payment Program final rule provided the definition of a qualified registry to be a medical registry, a maintenance of certification program operated by a specialty body of the American Board of Medical Specialties or other data intermediary that, with respect to a particular performance period, has self-nominated and successfully completed a vetting process (as specified by CMS) to demonstrate its compliance with the MIPS qualification criteria specified by CMS for that performance period (81 FR 77382).

In the CY 2020 PFS proposed rule, we have adjusted the number of respondents self-nominating applicants from 150 to 290 based on more recent data and the assumption that any entity which self-nominated for approval as a QCDR in previous years and that no longer qualifies as a result of policies finalized in the CY 2019 PFS final rule, effective beginning with the 2020 MIPS performance period could elect to self-nominate for approval as a qualified registry. The policies revised both the definition of a QCDR (83 FR 59895) and minimum participation requirements for entities seeking approval as a QCDR (83 FR 59897). Entities which no longer meet the criteria for approval as QCDRs may seek other options such as collaborating with another entity to meet the new requirements or to end their participation in the Quality Payment Program, however, we believe the assumption that these entities will instead elect to self-nominate as a qualified registry is both appropriate and conservative. We were unable to change our estimates in the CY 2019 PFS final rule to reflect these policies because we had neither the data to support a change nor any notifications of intent by previously approved QCDRs indicating they would no longer self-nominate as a QCDR (83 FR 59999). As a result, we have made the necessary adjustments to our respondents estimates in the CY 2020 PFS proposed rule. As previously stated, this increase is comprised of both an adjustment to due updated data (+50 self-nominations) and a revision due to policies promulgated in the CY 2019 PFS final rule (+90 self-nominations).

For the 2019 MIPS performance periods we received 198 applications for nomination to be a qualified registry, 135 of which were approved to submit data, a reduction of 6 from the currently approved estimate of 141 (83 FR 59997 through 59998). Based on the number of self-nominations received for the 2019 MIPS performance period, we estimate 200 entities will self-nominate as a qualified registry for the 2020 MIPS performance period, not considering nominations from entities which previously qualified as QCDRs. Based on our analysis of the QCDRs approved for the CY 2019 performance period, 63 of the 127 approved QCDRs (49.6 percent) would not meet the criteria for approval for the CY 2020 performance period. For the 2019 MIPS performance period, 181 entities self-nominated for approval as QCDRs, therefore we assume that 90 (49.6 percent) of these entities will self-nominate for approval as qualified registries for the 2020 MIPS performance period. In total, we estimate 290 nomination applications (200 + 90) will be received from entities seeking approval to report MIPS data as qualified registries, an increase of 140 from the currently approved estimate of 150 (83 FR 59997 through 59998). Assuming updated data is available, we will update our estimates in the final rule to reflect the actual number of nomination applications received for the 2020 MIPS performance period.

In section III.K.3.g.(4)(a)(i) of the CY 2020 PFS proposed rule, we are proposing to require qualified registries to support the reporting of improvement activities and Promoting Interoperability measures in addition to the quality performance category. Currently, qualified registries are only required to support the quality performance category while supporting improvement activities and Promoting Interoperability performance categories are optional. Qualified registries will also be required to provide enhanced performance feedback and quality improvement services beginning with the 2021 MIPS performance period. Due to a lack of information regarding how this might impact the number of entities electing to self-nominate as qualified registries, we are not making any adjustments to our respondent estimates as a result of this proposal. We also anticipate this proposal will have no impact on the time required to complete either the simplified or full self-nomination process.

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 a web-based tool.

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). 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 rate of $90.02/hr. Consistent with the CY 2019 PFS final rule (83 FR 59998), we estimate 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. When considering this rule's adjusted number of nomination applications (290) we estimate that the annual burden will range from 532.5 hours ([135 simplified self-nominations x 0.5 hr] + [155 full self-nominations x 3 hr]) to 870 hours (290 qualified registries x 3 hr) at a cost ranging from $47,936 (532.5 hr x $90.02/hr) to $78,317 (870 hr x $90.02/hr), respectively (see Table 3).

As finalized in the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364) and as further revised in the CY 2019 PFS final rule at (83 FR 60088), qualified registries may submit data for any of the three MIPS performance categories quality (except for data on the CAHPS for MIPS survey); improvement activities; and Promoting Interoperability. In section III.K.3.g.(4)(a)(i) of the CY 2020 PFS proposed rule, beginning with the 2021 performance period and for future years, we propose to require that qualified registries support the reporting of improvement activities and Promoting Interoperability measures in addition to the quality performance category. As finalized in the CY 2017 Quality Payment Program final rule, qualified registries are required to provide feedback on all of the MIPS performance categories at least 4 times a year (81 FR 77367 through 77386). In section III.K.3.g.(4)(a)(ii), we propose, beginning with the 2023 MIPS payment period, to require qualified registries to provide the following as a part of the performance feedback given at least 4 times a year: feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a

given measure within the qualified registry. Further, qualified registries will be required to attest during the self-nomination process that they can provide performance feedback at least 4 times a year, and if not, provide sufficient rationale as to why they do not believe they would be able to meet this requirement. Because we are not requiring qualified registries to provide performance feedback to their clinicians and groups at a greater frequency than what has previously been required combined with qualified registries only being required to provide feedback using data they are already collecting, we do not believe the proposal creates enough additional burden for qualified registries to elect to discontinue participation in the Quality Payment Program. Therefore, we are not adjusting our estimates for the number of qualified registries that will self-nominate in the 2021 performance period or future years as a result of this proposal; if reliable information becomes available indicating this assumption is incorrect, we will adjust our assumptions and respondent estimates at that time. As part of the current self-nomination process, qualified registries are already required to attest to the MIPS quality measures, performance categories, improvement activities, and/or Promoting Interoperability measures and objectives supported. In section III.K.3.g.(4)(a)(i) of the CY 2020 PFS proposed rule, beginning with the 2021 performance period, we are proposing to require qualified registries to support all three performance categories: quality, improvement activities, and Promoting Interoperability with the proviso that based on the proposed amendment to § 414.1400(a)(2)(iii) the requirement to support submission of Promoting Interoperability data would be inapplicable to the third party intermediary if the clinician, group or virtual group is exempt from this reporting requirement. As part of this proposal, we would require qualified registries to attest to the ability to submit data for all three of these performance categories at time of self-nomination. Because qualified registries will only be required to provide performance feedback to clinicians and not to CMS, and because qualified registries are already required to attest to the performance categories they support, we anticipate minimal changes to the self-nomination process as a result of these proposals and assume there will be minimal impact on the time required to complete either the simplified or full self-nomination process.

Qualified registries must comply with requirements on the submission of MIPS data to CMS. The burden associated with 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. 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. Therefore, we believe the estimates discussed earlier and shown in Table 3 represent the upper bound for qualified registry burden, with the potential for less additional MIPS burden if the qualified registry already provides similar data submission services.

Based on these assumptions, we provide an estimate of the total annual burden associated with a qualified registry self-nominating to be considered for approval.

Compared to the currently approved minimum estimates of 97.5 hours and $8,777 and the maximum estimates of 450 hours and $40,509, the increase in the number of respondents would adjust our total burden estimates by 435 hours and $39,159 [(-6 registries x 0.5 hr x $90.02/hr) +

(146 registries x 3 hr x $90.02/hr)] and 420 hours and $37,808 (140 registries x 3 hr x $90.02/hr). While we are proposing to adjust our total burden estimates based on more current data, the burden per response would remain unchanged.

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)	135	0
# of Qualified Registry Full Self-Nomination Applications submitted (b)	155	290
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)	**532.5**	**870**
Cost Per Simplified Process Per Registry (@ computer systems analyst's labor rate of $90.02/hr.) (f)	$45.01	$45.01
Cost Per Full Process Per Registry (@ computer systems analyst's labor rate of $90.02/hr.) (g)	$270.06	$270.06
Total Annual Cost for Qualified Registries (h) = (a)*(f)+(b)*(g)	**$47,936**	**$78,317**

2. Burden for QCDR Self-Nomination[10]

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 for approval to do so.

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 current self-nomination period, from September 1 to November 1 (82 FR 53808). The self-nomination period is from July 1 to September 1 of the calendar year prior to the applicable performance period beginning in the 2020 MIPS performance period (83 FR 59898).

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 QPP Self-Nomination Form is submitted electronically using a web-based tool. For the 2019 MIPS performance period, 126 QCDRs were approved to submit MIPS data.

For the 2019 MIPS performance period, we received 181 self-nomination applications from entities seeking approval as QCDRs, 127 of which were approved to submit data. Based on our analysis of the QCDRs approved for the CY 2019 performance period, 63 of the 127 approved

[10] 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.

QCDRs (49.6 percent) would not meet the criteria for approval for the CY 2020 performance period. For the 2019 MIPS performance period, 181 entities self-nominated for approval as QCDRs, therefore we assume that 90 (49.6 percent) of these entities will not self-nominate for approval as QCDRs for the 2020 MIPS performance period but will instead self-nominate to be qualified registries. Entities which no longer meet criteria for approval as QCDRs may seek other options as well, including collaborating with another entity to meet the new requirements or to end their participation in the Quality Payment Program; however, we believe the assumption that these entities will instead elect self-nomination as a qualified registry is both appropriate and conservative. We estimate the remaining 91 entities will submit nomination applications for approval to report MIPS data as QCDRs for the MIPS 2020 performance period, a decrease of 109 from the currently approved estimate of 200. This decrease of 109 is a result of both an adjustment due to use of more recent data accounts (decrease of 19 self-nominations) and a change due to previously finalized policies regarding the definition of a QCDR (83 FR 59895) and minimum participation requirements (83 FR 59897) (decrease of 90 self-nominations). We were unable to change our estimates in the CY 2019 PFS final rule to reflect these policies because we had neither the data to support a change nor any notifications of intent by previously approved QCDRs indicating they would no longer self-nominate as a QCDR (83 FR 59999). As a result, we are making the necessary adjustments to our respondent estimates in this proposed rule. We further estimate that the 64 QCDRs approved to submit data in the 2019 MIPS performance period that would also qualify as QCDRs for the 2020 MIPS performance period will use the simplified self-nomination process. Assuming updated data is available, we will update our estimates in the final rule to reflect the actual number of nomination applications received for the 2020 MIPS performance period.

Based on previously finalized policies in the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364) and as further revised in the CY 2019 PFS final rule (83 FR 60088), the current policy is that all third party intermediaries may submit data for any of the three MIPS performance categories quality (except for data on the CAHPS for MIPS survey); improvement activities; and Promoting Interoperability. In section III.K.3.g.(3)(a)(i) of the CY 2020 PFS proposed rule, we are proposing, beginning with the 2021 performance period and future years, to require that QCDRs support three performance categories: quality, improvement activities, and Promoting Interoperability. We are also proposing in section III.K.3.g.(3)(a)(ii), beginning with the 2023 MIPS payment year and future years, QCDRs would be required to provide services to clinicians and groups to foster improvement in the quality of care provided to patients, by providing educational services in quality improvement and leading quality improvement initiatives and to describe the quality improvement services they intend to support in their self-nomination for CMS review and approval. As finalized in the CY 2018 Quality Payment Program final rule, QCDRs are required to provide feedback on all of the MIPS performance categories that the QCDR reports at least 4 times a year (82 FR 53812). In section III.K.3.g.(3)(a)(iii) we propose, beginning with the 2023 MIPS payment year, to require that QCDRs provide the following as a part of the performance feedback given at least 4 times a year: feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure (MIPS quality measure and/or QCDR measure) within the QCDR. We also understand that QCDRs can only provide feedback on data they have collected on their clinicians and groups, and realize the comparison would be limited to that data and not reflect the larger sample of those that have submitted on the measure for MIPS, which the QCDR

does not have access to. Further, we are also proposing, beginning with the 2023 MIPS payment year, to require QCDRs to attest during the self-nomination process that they can provide performance feedback at least 4 times a year, and if not, provide sufficient rationale as to why they do not believe they would be able to meet this requirement. We do not believe these proposals create enough additional burden for QCDRs to elect to discontinue participation in the Quality Payment Program for multiple reasons: we are not requiring QCDRs to provide performance feedback to their clinicians and groups at a greater frequency than what has previously been required, QCDRs will only being required to provide feedback using data they are already collecting, and we are giving QCDRs significant flexibility to provide broad quality improvement services that are tailorable to the specific QCDR and the clinicians they support. Therefore, we are not adjusting our estimates for the number of QCDRs that will self-nominate in the 2021 performance period or future years as a result of this proposal; if reliable information becomes available indicating this assumption is incorrect, we will adjust our assumptions and respondent estimates at that time. As part of the self-nomination process, QCDRs are already required to attest to the MIPS quality measures, performance categories, improvement activities, and Promoting Interoperability measures and objectives supportedand will not be required to provide performance feedback to CMS, therefore, we anticipate no additional steps being added to the self-nomination process as a result of these proposals and assume there will be no impact on the time required to complete either the simplified or full self-nomination process. With regard to the proposal to require QCDRs to describe the quality improvement services they will provide as part of their self-nomination, we estimate this will require approximately 15 minutes to complete.

We estimate that the self-nomination process for QCDRs to submit on behalf of MIPS eligible clinicians or groups for MIPS will involve approximately 3.25 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.

As promulgated in the CY 2017 and CY 2018 Quality Payment Plan final rules (81 FR 77366 through 77374 and 82 FR 53812 through 53813), QCDRs calculate their measure results and also 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.

As discussed in section III.K.3.g.(3)(c)(i)(B)(cc) of the CY 2020 PFS proposed rule, we are proposing that in order for a QCDR measure to be considered for use in the program beginning

with the 2021 performance period and future years, all QCDR measures submitted for self-nomination must be fully developed with completed testing results at the clinician level, as defined by the CMS Blueprint for the CMS Measures Management System, as used in the testing of MIPS quality measures prior to the submission of those measures to the Call for Measures. Beginning with the 2021 performance period and future years, we are proposing in section III.K.3.g.(3)(c)(i)(B)(dd) to also require QCDRs to collect data on the potential QCDR measure, appropriate to the measure type, as defined in the CMS Blueprint for the CMS Measures Management System, prior to self-nomination. We estimate the time necessary to submit measure testing data as part of the self-nomination process will average approximately 0.5 hours per measure, understanding that this estimate may be either high or low depending on the type of measure and the quantity of data being submitted.

In section III.K.3.g.(3)(c)(i)(A)(bb) of the CY 2020 PFS proposed rule, we are proposing to state that CMS may consider the extent to which a QCDR measure is available to MIPS eligible clinicians reporting through QCDRs other than the QCDR measure owner for purposes of MIPS. If CMS determines that a QCDR measure is not available to MIPS eligible clinicians, groups, and virtual groups reporting through other QCDRs, CMS may not approve the measure. Because the choice to license a QCDR measure is an elective business decision made by individual QCDRs and we lack insight into both the specific terms and frequency of agreements made between entities, we are not accounting for QCDR measure licensing costs as part of our burden estimate. However, if information regarding the number of licensing agreements and the approximate cost per agreement becomes available, we may adjust our assumptions and burden estimates at that time.

In section III.K.3.g.(3)(c)(i)(B)(ee) of the CY 2020 PFS proposed rule, we propose, beginning with the 2020 performance period, that after the self-nomination period closes each year, we will review newly self-nominated and previously approved QCDR measures based on considerations as described in the CY 2019 PFS final rule (83 FR 59900 through 59902). In instances in which multiple, similar QCDR measures exist that warrant approval, we may provisionally approve the individual QCDR measures for 1 year with the condition that QCDRs address certain areas of duplication with other approved QCDR measures in order to be considered for the program in subsequent years. The QCDR could do so by harmonizing its measure with, or significantly differentiating its measure from, other similar QCDR measures. QCDR measure harmonization may require two or more QCDRs to work collaboratively to develop one cohesive QCDR measure that is representative of their similar yet, individual measures. We are unable to account for measure harmonization costs as part of our burden estimate, as the process and outcomes of measure harmonization will likely vary substantially depending on a number of factors, including: extent of duplication with other measures, number of QCDRs involved in harmonizing toward a single measure, and number of measures being harmonized among the same QCDRs. We intend to identify only those QCDR measures which are duplicative to such an extent as to assume harmonization will not be overly burdensome, however, because the harmonization process will occur between QCDRs without our involvement, we are unable to predict or quantify the associated effort.

As discussed in section III.K.3.g.(3)(c)(i)(B)(bb) of the CY 2020 PFS proposed rule, beginning with the 2021 performance period and future years, we are proposing that QCDRs must identify a linkage between their QCDR measures to the following, at the time of self-nomination: (a) cost

measures (as found in section III.K.3.c.(2) of this proposed rule), (b) Improvement Activities (as found in Appendix 2: Improvement Activities Tables), or (c) CMS developed MIPS Value Pathways (as described in section III.K.3.a. of the CY 2020 PFS proposed rule). We estimate that a QCDR will spend an additional 1 hour performing these activities per measure, on average.

We are also proposing to formalize factors we would take into consideration for approving and rejecting QCDR measures for the MIPS program beginning with the 2020 performance period and future years. With regard to approving QCDR measures, we are proposing the following: (a) two-year QCDR measure approval process, and (b) participation plan for existing QCDR measures that have failed to reach benchmarking thresholds. As discussed in section III.K.3.g. (3)(c)(ii)(B) of the CY 2020 PFS proposed rule, we are proposing to implement, beginning with the 2021 performance period, 2-year QCDR measure approvals (at our discretion) for QCDR measures that attain approval status by meeting the QCDR measure considerations and requirements described in section III.K.3.g.(3)(c). The two year approvals would be subject to the following conditions whereby the multi-year approval will no longer apply if the QCDR measure is identified as: topped out; duplicative of a new, more robust measure; reflects an outdated clinical guideline; requires measure harmonization, or if the QCDR self-nominating the measure is no longer in good standing. We believe this could result in reduced burden for QCDRs as they would not necessarily be required to submit every measure for approval annually. However, because we are unable to predict which previously approved QCDR measures will be removed or retained in future years, we are likewise unable to predict the impact on future burden. If this policy is finalized, the number of QCDR measures submitted in the 2021 performance period will reflect the impact of this policy; at that time we will update our assumptions and burden estimates accordingly.

We estimate that on average, each QCDR will submit information for 11.5 QCDR measures, for a total burden of 11.5 hours per QCDR (1 hr per measure x 11.5 measures). The estimated average of 11.5 measures per QCDR is based on an analysis of the QCDR measures submitted for consideration and QCDR measures approved for the 2019 MIPS performance period, as well as the measures for QCDRs approved for the CY 2019 performance period that would not meet criteria for approval for the CY 2020 performance period. For the 2019 MIPS performance period, 1,123 QCDR measures were submitted for consideration and 762 were approved; an approval rate of 68 percent. Of these approved measures, 264 are for the 63 QCDRs which would not meet criteria for approval for the 2020 MIPS performance period. Averaging the remaining 498 approved QCDR measures by the 64 QCDRs that would meet the criteria for approval for the 2020 MIPS performance period results in approximately 7.8 approved measures per QCDR (498 approved measures / 64 QCDRs). Assuming an identical 68 percent QCDR measure approval rate for measures submitted for consideration for the 2020 MIPS performance period, this results in approximately 11.5 measures submitted for consideration for each QCDR (7.8 approved measures / 0.68 approval rate). We believe the proposals to change requirements for QCDR measure submission and to require QCDRs to harmonize measures we identify as duplicative discussed earlier in this section will result in a reduction in the number of QCDR measures submitted for approval in future years. However, we are unable to quantify the impact these proposed changes will have on the number of measures QCDRs will submit for approval. As information becomes available in future years, we will revisit our assumptions to better reflect the impact of these proposals on QCDRs and the quantity of measures being submitted for

consideration annually. When combined with our previously stated assumption regarding our inability to predict which QCDR measures will maintain approval in future years, we believe the estimate of 11.5 measures per QCDR to be both conservative and appropriate as well as an overall decrease of 76 QCDR measures compared to the 1,123 QCDR measures submitted for consideration in the CY2019 performance period (1,123 QCDR measures – [91 QCDRs x 11.5 measures per QCDR]).

Beginning with the 2021 performance period, we are proposing in section III.K.3.g.(3)(c)(iii) of the CY 2020 PFS proposed rule that in instances where an existing QCDR measure has been in MIPS for 2 years, and has failed to reach benchmarking thresholds due to low adoption, where a QCDR believes the low-reported QCDR measure is still important and relevant to a specialist's practice, that the QCDR may develop and submit to a QCDR measure participation plan, to be submitted as part of their self-nomination. Because we are unable to predict the frequency with which existing QCDR measures will meet the proposed criteria for allowing QCDRs to submit a measure participation plan or the likelihood of QCDRs electing to submit a plan, we are unable to estimate the total burden associated with this proposal. However, we anticipate the time involved in developing a measure participation plan is likely to average between 1 and 2 hours, depending on the QCDR and the level of detail they choose to include. In future performance periods we may reassess availability of the number of QCDR measure participation plans submitted by QCDRs and estimate the associated burden, if possible. In aggregate, we estimate a QCDR will require 2.5 hours per QCDR measure, an increase of 1.5 hours from the currently approved estimate of 1 hour (83 FR 59999). As discussed earlier in this section, we estimate each QCDR will submit 11.5 QCDR measures for approval, on average. Therefore, we estimate each QCDR will require 28.75 hours (11.5 measures x 2.5 hr per measure) to submit QCDR measures for approval, independent of the selection of the simplified or full self-nomination process.

In the CY 2019 PFS final rule, the burden associated with self-nomination of a QCDR was estimated to range from a minimum of 9.5 hours (0.5 hours to submit information for simplified self-nomination process and 9 hours for submission of QCDR measures) to a maximum of 12 hours (3 hours for the full self-nomination process and 9 hours for the submission of QCDR measures) (83 FR 59999). For this rule, we propose to increase the burden associated with self-nomination to a minimum of 29.25 hours (0.5 hours to submit information for the simplified self-nomination process and 28.75 hours for the submission of QCDR measures) to a maximum of 32 hours (3.25 hours to submit information for the full self-nomination process and 28.75 hours for the submission of QCDR measures) to account for our revised estimate of the average number of QCDR measures submitted for consideration per QCDR as well as the revised estimate of burden per QCDR measure.

We assume 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 rate of $90.02/hr. Considering that the time per QCDR associated with the self-nomination process ranges from a minimum of 29.25 hours to a maximum of 32 hours, we estimate that the annual burden will range from 2,736 hours ([64 QCDRs x 29.25 hr] + [27 QCDRs x 32 hr]) to 2,912 hours (91 QCDRs x 32 hr) at a cost ranging from $246,295 (2,736 hr x $90.02/hr) and $262,138 (2,912 hr x $90.02/hr), respectively (see Table 4).

Independent of the change to our per response time estimate, the decrease in the number of respondents (from 200 to 91) results in an adjustment of between -1,093 hours [(-86 QCDRs x 9.5 hr) + (-23 QCDRs x 12 hr)] at a cost of -$98,392 (-1,093 hr x $90.02) and -1,308 hours (-109 QCDRs x 12 hr) at a cost of -$117,746 (-1,308 hr x $90.02/hr). Accounting for the change in the number of QCDRs, the change in time per QCDR to self-nominate results in an adjustment of 1,820 hours (91 QCDRs x 20 hr) at a cost of $163,386 (1,820 hr x $90.02/hr). When these two adjustments are combined, the net impact ranges between 727 hours (-1,093 hr + 1,820 hr) hours at a cost of $65,444 (-$98,392 + $163,386) and 512 hours (-1,308 hr + 1,820 hr) hours at a cost of $46,090 (-$117,746 + $163,836).

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. 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. As stated in section III.K.3.g.(3)(a)(i) of the CY 2020 PFS proposed rule, based on our review of existing 2019 QCDRs through the 2019 QCDR Qualified Posting, approximately 92 QCDRs, or about 72 percent of the QCDRs currently participating in the program are supporting these three performance categories. In addition, through our review of previous qualified postings for the 2018 and 2017 MIPS performance periods, we have observed that in 2018, 73 percent (approximately 110 QCDRs) and in 2017, 73 percent (approximately 83 QCDRs) have supported all three of the quality, Promoting Interoperability, and improvement activity performance categories. Given this, we believe it is reasonable that all QCDRs have the capacity to support the improvement activities and Promoting Interoperability performance categories and are not making any further changes to our burden estimates. Therefore, we believe the 2,912 hour estimate noted in this section represents the upper bound of QCDR burden, with the potential for less additional MIPS burden if the QCDR already provides similar data submission services.

Based on the assumptions previously discussed, we provide an estimate of the total annual burden associated with a QCDR self-nominating to be considered for approval.

TABLE 4: Estimated Burden for QCDR Self-Nomination

Burden and Respondent Descriptions	**Minimum Burden**	**Maximum Burden**
# of QCDR Simplified Self-Nomination Applications submitted (a)	64	0
# of QCDR Full Self-Nomination Applications submitted (b)	27	91
Total Annual Hours Per QCDR for Simplified Process (c)	29.25	19.25
Total Annual Hours Per QCDR for Full Process (d)	32	32
Total Annual Hours for QCDRs (e) = (a)*(c) + (b)*(d)	**2,736**	**2,912**
Cost Per Simplified Process Per QCDR (@ computer systems analyst's labor rate of $90.02/hr.) (f)	$2,633.09	$2,633.09
Cost Per Full Process Per QCDR (@ computer systems analyst's labor rate of $90.02/hr.) (g)	$2,880.64	$2,880.64
Total Annual Cost for QCDRs (h) = (a)*(f)+(b)*(g)	**$246,295**	**$262,138**

v. Burden Estimate for the Quality Performance Category

Under our current policies, two groups of clinicians will submit quality data under MIPS: (1) those who submit as MIPS eligible clinicians; and (2) other eligible clinicians who opt-in to submit data voluntarily but will not be subject to MIPS payment adjustments.

To determine which QPs should be excluded from MIPS, we used the QP List for the 2019 predictive file that contains current participation in Advanced APMs as of January 15, 2019 that could be connected into our respondent data and are the best estimate of future expected QPs. From this data, we calculated the QP determinations as described in the Qualifying APM Participant definition at § 414.1305 for the 2020 QP performance period. We assumed that all partial QPs would participate in MIPS data collections. Due to data limitations, we could not identify specific clinicians who may become QPs in the 2020 Medicare QP Performance Period (and therefore would no longer need to submit data to MIPS); hence, our model may under estimate or overestimate the number of respondents.

Using participation data from the 2017 MIPS performance period combined with the estimate of QPs for the 2020 performance period, we estimate a total of 833,243 clinicians will submit quality data as individuals or groups in the 2020 MIPS performance period, a decrease of 131,003 clinicians when compared to our estimate of 964,246 clinicians in the CY 2019 PFS final rule (83 FR 60002). Respondent data from the 2018 MIPS performance period was unavailable at the time of publication of the CY 2020 PFS proposed rule. Assuming that updated respondent data becomes available before the publication of the final rule, we will revise our burden estimates in that rule.

In the CY 2017 Quality Payment Program final rule, we assumed 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 to ensure that we fully accounted for any burden that may have resulted from our policies (81 FR 77501 through 77504); we continued using this assumption in both the CY 2018 Quality Payment Program and CY 2019 PFS final rules. 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 (83 FR 59752). However, in the CY 2019 PFS final rule, we elected to 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 would continue to do so for MIPS in order to avoid overstating the impact of the change as we lacked the data to accurately estimate both the number of clinicians who would be impacted by the finalized policies and the potential behavioral response of those clinicians who would be required to switch to another collection type (83 FR 60001). For the CY 2020 PFS proposed rule, beginning with the 2020 MIPS performance period, we assume only clinicians in small practices who submitted quality data via Medicare Part B claims in the 2017 MIPS performance period will continue to do so for the 2020 MIPS performance period. Further, we assume that clinicians in other practices (not small practices) who meet at least one of the following criteria will not need to find an alternate collection type for submitting quality performance category data for the Quality Payment Program for the 2020 MIPS performance period: (1) facility-based; (2) submitted quality data via Medicare Part B claims and at least one

other collection type; or (3) were previously scored as part of a group. Finally, we assume clinicians in other practices (not small practices) who meet all of the following criteria will submit via the MIPS CQM collection type for the 2020 MIPS performance period because the Medicare Part B claims collection type will no longer be available as an option for collecting and reporting quality data: (1) scored as individuals; (2) not facility-based; and (3) submitted quality data only via the Medicare Part B claims collection type in the 2017 MIPS performance period. Because we do not have data to accurately predict what collection type each affected clinician would use to collect and report quality data, we are assuming these affected clinicians will select the MIPS CQM collection type because compared to Medicare Part B claims, we believe this is the next most accessible and least burdensome alternative. Our assumptions result in a 121,858 decrease in the estimated number of clinicians who will submit quality data via Medicare Part B claims and a 15,556 increase in the number of clinicians who will submit via the QCDR/MIPS CQM collection type, as shown inTable 5.

We assume that 100 percent of APM Entities in MIPS APMs will submit quality data to CMS as required under their models. Consistent with assumptions used in the CY 2019 PFS final rule (83 FR 60000 through 60001), we include all quality data voluntarily submitted by MIPS APM participants made at the individual or TIN-level in our respondent estimates. Therefore, we are not making any adjustments to our respondent estimates as a result of the proposal discussed in section III.K.3.c.(5)(c)(i)(A) of the CY 2020 PFS proposed rule, which allows MIPS eligible clinicians participating in MIPS APMs to elect to report MIPS quality measures at either the individual or TIN-level under the APM scoring standard beginning in the 2020 MIPS performance period. To estimate who will be a MIPS APM participant in the 2020 MIPS performance period, we used the latest 2019 predictive file that contains current participation in MIPS APMs as of January 15, 2019, using all available data. This file was selected to better reflect the expected increase in the number of MIPS APMs in future years compared to previous APM eligibility files. If a MIPS eligible clinician is determined to not be scored as a MIPS APM, then their reporting assumption is based on their reporting for the CY 2017 MIPS performance period. For clinicians who participated in an APM in 2017, were not in an APM in 2019, and did not report MIPS quality data in 2017, we assume they will elect to report to MIPS via the MIPS CQM collection type, similar to our previously stated assumption regarding clinicians who are required to use an alternate reporting option. 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 APMs. The burden is excluded as sections 1899(e) and 1115A(d)(3) of the Act (42 U.S.C. 1395jjj(e) and 1315a(d)(3), respectively) state that 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. 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 2020 MIPS performance period based on data from the 2017 MIPS performance period.

For the 2020 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 estimate the burden for collecting data via collection type: claims, QCDR and MIPS CQMs, eCQMs, and the CMS Web Interface. We believe that, while estimating burden by submission type may be better aligned with the way clinicians participate with the Quality Payment Program, it is more important to reduce confusion and enable greater transparency by maintain consistency with previous rulemaking.

Table 5 shows that in the 2020 MIPS performance period, an estimated 109,951 clinicians will submit data as individuals for the Medicare Part B claims collection type; 359,621 clinicians will submit data as individuals or as part of groups for the MIPS CQM or QCDR collection types; 247,329 clinicians will submit data as individuals or as part of groups via eCQM collection types; and 116,342 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 2020 MIPS performance period (excludes QPs) (a)	109,951	359,621	247,329	116,342	833,243
Number of clinicians to collect data by collection type (as individual clinicians or groups) in 2019 MIPS performance period (excludes QPs) (b)	257,260	324,693	243,062	139,231	964,246
Difference between 2020 MIPS performance period (CY 2020 Proposed Rule) and 2019 MIPS performance period (CY 2019 Final Rule) (c)=(a)-(b)	-147,309	34,928	4,267	-22,889	-131,003

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, with the exception of

clinicians not in small practices who previously submitted quality data via Medicare Part B claims, 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 2017 MIPS performance period.

Table 6 uses methods similar to those described for Table 5 to estimate the number of clinicians that will submit data as individual clinicians via each collection type in the 2020 MIPS performance period. We estimate that approximately 109,951 clinicians will submit data as individuals using the Medicare Part B claims collection type; approximately 106,039 clinicians will submit data as individuals using MIPS CQMs or QCDR collection types; and approximately 47,455 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 2020 MIPS Performance Period (excludes QPs) (a)	109,951	106,039	47,455	0	263,445
Number of Clinicians to submit data as individuals in 2019 MIPS Performance Period (excludes QPs) (b)	257,260	71,439	47,557	0	376,256
Difference between 2020 MIPS Performance Period (CY 2020 Proposed Rule) and 2019 MIPS performance period (CY 2019 Final Rule) (c)=(a)-(b)	-147,309	+34,600	-102	0	-112,811

Consistent with the policy finalized 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 and thus, the same clinician may be counted as a respondent for more than one collection type. Therefore, 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 2020 MIPS performance period and reflects our assumption that the formation of virtual groups will reduce burden. With the previously discussed exceptions regarding groups who experienced a change in APM participation status between the 2017 and 2019 MIPS performance periods, 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 2020 MIPS performance period. First, we estimated the number of groups or virtual groups that will collect data via each collection type during the 2020 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 10,552 groups and virtual groups will submit data for the QCDR or MIPS CQM collection types on behalf of 253,582 clinicians; 4,332 groups and virtual groups will submit for eCQM collection types on behalf of 199,874 eligible clinicians; and 104 groups will submit data via the CMS Web Interface on behalf of 116,342 clinicians.

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 2020 MIPS performance period (excludes QPs) (a)	0	10,584	4,364	104	15,052
Subtract out: Number of groups to collect data by collection type on behalf of clinicians in 2020 MIPS performance period that will submit as virtual groups (b)	0	40	40	0	80
Add in: Number of virtual groups to collect data by collection type on behalf of clinicians in 2020 MIPS performance period (c)	0	8	8	0	16

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 2020 MIPS performance period (d)=(a)-(b)+(c)	0	10,552	4,332	104	14,988
Number of groups to collect data by collection type on behalf of clinicians in 2019 MIPS performance period (e)	0	10,542	4,304	286	15,132
Difference between 2020 MIPS performance period (CY 2020 Proposed Rule) and 2019 MIPS performance period (CY 2019 Final Rule) (f)=(d)-(e)	0	10	28	-182	-144

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 2020 MIPS performance period, the total number of quality measures will be 206. These measures are stratified by collection type in Table 8, as well as counts of new, removed, and substantively changed measures.

TABLE 8: Summary of Quality Measures for the 2020 MIPS Performance Period

Collection Type	# Measures Proposed as New	# Measures Proposed for Removal	# Measures Proposed with a Substantive Change*	# Measures Remaining for CY 2020
Medicare Part B Claims Specifications	0	17	22	47
MIPS CQMs Specifications	3	52	77	184
eCQM Specifications	1	6	33	45
Survey - CSV	0	0	0	1
CMS Web Interface Measure	1	1	9	10

Specifications				
Administrative Claims	0	0	0	1
Total**	4	55	95	206

* This column includes all measures that have a requested substantive change from the measure stewards. The total of 95 substantive changes reflects both measures that will continue and a subset of measures that have been proposed for removal for PY2020. There are 73 substantive changes that are proposed in Appendix 1 for measures not being proposed for removal.

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

For the 2020 MIPS performance period, there is a net reduction of 51 quality measures across all collection types compared to the 257 measures finalized for the 2019 MIPS performance period (83 FR 60003). We do not anticipate that removing these measures will increase or decrease the reporting burden on clinicians and groups. Likewise, we do not anticipate a change in reporting burden as a result of the one proposed administrative claims measure (The All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions measure) which is being proposed for the 2021 MIPS performance period as discussed in section III.K.3.c.(1)(d)(ii) of the CY 2020 PFS proposed rule.

As discussed in section III.K.3.c.(1)(c)(ii) of the CY 2020 PFS proposed rule, we are proposing to adopt a higher data completeness threshold (the percentage of eligible patients the clinician must check to see whether the measure applies to) for the 2020 MIPS performance period, such that MIPS eligible clinicians and groups submitting quality measure data on QCDR measures, MIPS CQMs, and eCQMs must submit data on at least 70 percent of the MIPS eligible clinician or group's patients that meet the denominator criteria, regardless of payer for the 2020 MIPS performance period. We believe this proposal may increase administrative burden for some clinicians as it affects the amount of data they have to collect, but will have no impact on regulatory burden as it affects neither the number of quality measures they are required to report nor the amount of data they must report for each quality measure once results have been aggregated.

1. Burden for Quality Payment Program Identity Management Application Process

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 our assumption that the number of eligible clinicians, groups, or third-parties that will register for new accounts will not change substantially from the 2019 MIPS performance period, our estimate of 3,741 new TINs remains unchanged. As shown in Table 9 it would take 1 hour at $90.02/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 $336,765 (3,741 hr x $90.02/hr) or $90.02 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)	$90.02
Total Annual Cost for completing the Identity Management Application Process (e) = (a)*(d)	$336,765

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 109,951 individual clinicians will collect and submit quality data via the Medicare Part B claims collection type. This rule proposes to adjust the number of Medicare Part B claims respondents from 257,260 to 109,951 (a decrease of 147,309) based on more recent data and our updated methodology of accounting only for clinicians in small practices who submitted such claims data in the 2017 MIPS performance period rather than all clinicians who submitted quality data codes to us for 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. This proposed rule's provisions do not necessitate the revision of either form

As shown in Table 10, consistent with our currently approved per respondent burden estimates, we estimate that the burden of quality data submission using Medicare Part B claims will range from 0.15 hours at a cost of $13.50 (0.15 hr x $90.02/hr) to 7.2 hours at a cost of $648.14 (7.2 hr x $90.02/hr). per respondent. 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 $109.36/hr for a practice administrator, 1 hour at $202.86/hr for a clinician, 1 hour at $45.24/hr for an LPN/medical assistant, 1 hour at $90.02/hr for a computer systems analyst, and 1 hour at $38.00/hr for a billing clerk. We are not proposing revisions to our currently approved per response burden estimates.

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 Medicare Part B 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 time ranges from 786,150 hours (7.15 hr x 109,951 clinicians) to 1,561,304 hours (14.2 hr x 109,951 clinicians). The estimated annual cost (per clinician) ranges from $717.70 [(0.15 hr x $90.02/hr) + (3 hr x $109.36/hr) + (1 hr x $90.02/hr) + (1 hr x $45.24/hr) + (1 hr x $38.00/hr + (1 hr x $202.86/hr)] to a maximum of $1,352.34 [(7.2 hr x $90.02/hr) + (3 hr x $109.36/hr) + (1 hr x $90.02/hr) + (1 hr x $45.24/hr) + (1 hr x $38.00/hr + (1 hr x $202.86/hr)]. The total annual cost ranges from a minimum of $78,912,163 (109,951 clinicians x $717.70) to a maximum of $148,691,575 (109,951 clinicians x $1,352.34).

Table 10 summarizes the range of total annual burden associated with clinicians submitting quality data via Medicare Part B claims.

Using the unchanged currently approved per respondent burden estimates which range from $717.70 to $1,352.34, the decrease in number of respondents from 257,260 to 109,951 results in a total adjustment of between -1,053,259 hours (-147,309 respondents x 7.15 hr/respondent) at a cost of -$105,724,111 (-147,309 respondents x $717.70/respondent) and -2,091,788 hours (-147,309 respondents x 14.2 hr/respondent) at a cost of -$199,212,442 (-147,309 respondents x $1,352.34/respondent).

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)	109,951	109,951	109,951
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
# 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)	**786,150**	**885,106**	**1,561,304**
Cost to Submit Quality Data (@ computer systems analyst's labor rate of $90.02/hr) (j)	$13.50	$94.52	$648.14
Cost to Review Measure Specifications (@ practice administrator's labor rate of $109.36/hr) (k)	$328.08	$328.08	$328.08
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $90.02/hr) (l)	$90.02	$90.02	$90.02
Cost to Review Measure Specifications (@ LPN's labor rate of $45.24/hr) (m)	$45.24	$45.24	$45.24
Cost to Review Measure Specifications (@ billing clerk's labor rate of $38.00/hr) (n)	$38.00	$38.00	$38.00
Cost to Review Measure Specifications (@ physician's labor rate of $202.86/hr) (o)	$202.86	$202.86	$202.86
Total Annual Cost Per Clinician (p) = (j)+(k)+(l)+(m)+(n)+(o)	$717.70	$798.72	$1,352.34
Total Annual Cost (q) = (a)*(p)	**$78,912,163**	**$87,820,173**	**$148,691,575**

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 359,621 clinicians will submit quality data as individuals or groups using MIPS CQM or QCDR collection types. Of these, we expect 106,039 clinicians, as shown in Table 6, will submit as individuals and 10,552 groups and virtual groups, as shown in Table 7, are expected to submit on behalf of the remaining 253,582 clinicians. As previously stated, we assume clinicians in other practices (not small practices) who meet all of the following criteria will submit via the MIPS CQM collection type for the 2020 MIPS performance period because the Medicare Part B claims collection type will no longer be available as an option for collecting and reporting quality data: (1) scored as individuals, (2) not facility based, and (3) submitted quality data only via the Medicare Part B claims collection type in the 2017 MIPS performance period. As a result of this assumption and our use of more recent data, this rule proposes to adjust the number of QCDR and MIPS CQM respondents from 81,981 to 116,591 (an increase of 34,610). 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 collection 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 $872.37 per individual clinician or group. This consists of 3 hours at $90.02/hr for a computer systems analyst (or their equivalent) to submit quality data along with 2 hours at $109.36/hr for a practice administrator, 1 hour at $90.02/hr for a computer systems analyst, 1 hour at $45.24/hr for a LPN/medical assistant, 1 hour at $38.00/hr for a billing clerk, and 1 hour at $202.86/hr for a clinician to review measure specifications. Additionally, clinicians and groups who do not submit data directly 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 $7.50 (0.083 hr x $90.02/hr for a computer systems analyst).

In aggregate, we estimate an annual burden of 1,058,996 hours (9.083 hr/response x 116,591 groups plus clinicians submitting as individuals) at a cost of $101,710,684 (116,591 responses x $872.37/response). The increase in number of respondents from 81,981 to 116,591 results in a total adjustment of 314,363 hours (34,610 respondents x 9.083 hr/respondent) at a cost of $30,192,783 (34,610 respondents x $872.37/respondent). Based on these assumptions, we have estimated in Table 11 the burden for these submissions.

Using the unchanged currently approved per respondent burden estimate, the increase in number of respondents from 81,981 to 116,591 results in a total difference of 314,363 hours (34,610 respondents x 9.083 hr/respondent) at a cost of $30,192,783 (34,610 respondents x $872.37/respondent).

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)	106,039
# of groups submitting via QCDR or MIPS CQM on behalf of individual clinicians (b)	10,552
# of Respondents (groups and clinicians submitting as individuals) (c)=(a)+(b)	116,591
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)	1,058,996
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of $90.02/hr) (m) Cost to Review Measure Specifications (@ practice administrator's labor rate of $109.36/hr) (n)	$270.06 $218.72
Cost Computer System's Analyst Review Measure Specifications (@ computer systems analyst's labor rate of $90.02/hr) (o)	$90.02
Cost LPN Review Measure Specifications (@ LPN's labor rate of $45.24/hr) (p)	$45.24
Cost Billing Clerk Review Measure Specifications (@ clerk's labor rate of $38.00/hr) (q)	$38.00
Cost Clinician Review Measure Specifications (@ physician's labor rate of $202.86/hr) (r)	$202.86
Cost for Respondent to Authorize Qualified Registry/QCDR to Report on Respondent's Behalf (@ computer systems analyst's labor rate of $90.02/hr) (s)	$7.50
Total Annual Cost Per Respondent (t) = (m)+(n)+(o)+(p)+(q)+(r)+(s)	$872.37
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of $90.02/hr) (m)	$270.06
Total Annual Cost (u) = (c)*(t)	$101,710,684

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 247,329 clinicians will elect to use the eCQM collection type; 47,455 clinicians are expected to submit eCQMs as individuals; and 4,332 groups and virtual groups are expected to submit eCQMs on behalf of the remaining 199,874 clinicians. This rule proposes to adjust the number of eCQM respondents from 51,861 to 51,787 (a decrease of 74) based on more recent data. 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.

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 third-party intermediary to derive data from their CEHRT and submit it 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 estimate that it will take no more than 2 hours at $90.02/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 $109.36/hr for a practice administrator, 1 hour at $202.86/hr for a clinician, 1 hour at $90.02/hr for a computer systems analyst, 1 hour at $45.24/hr for a LPN/medical assistant, and 1 hour at $38.00/hr for a billing clerk.

In aggregate we estimate an annual burden of 414,296 hours (8 hr x 51,787 groups and clinicians submitting as individuals) at a cost of $40,128,711 (51,787 responses x $774.88/response). Based on these assumptions, we have estimated in Table 12 the burden for these submissions.

Using the unchanged currently approved per respondent burden estimate, the decrease in number of respondents from 51,861 to 51,787 results in a total difference of -592 hours (-74 respondents x 8 hr/respondent) at a cost of -$57,341 (-74 respondents x $774.88/respondent).

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)	47,455
# of Groups submitting via EHR on behalf of individual clinicians (b)	4,332
# of Respondents (groups and clinicians submitting as individuals) (c)=(a)+(b)	51,787
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)	**414,296**
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of $90.02/hr) (l)	$180.04
Cost to Review Measure Specifications (@ practice administrator's labor rate of $109.36/hr) (m)	$218.72
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $90.02/hr) (n)	$90.02
Cost to Review Measure Specifications (@ LPN's labor rate of $45.24/hr) (o)	$45.24
Cost to Review Measure Specifications (@ clerk's labor rate of $38.00/hr) (p)	$38.00
Cost to D21Review Measure Specifications (@ physician's labor rate of $202.86/hr) (q)	$202.86
Total Cost Per Respondent (r)=(l)+(m)+(n)+(o)+(p)+(q)	$774.88
Total Annual Cost (s) = (c)*(r)	**$40,128,711**

5. Burden for Quality Data Submission by CMS Web Interface

We assume that 104 groups will submit quality data via the CMS Web Interface based on the number of groups who completed 100 percent of reporting quality data via the Web Interface in the 2018 MIPS performance period. This is a decrease of 182 groups from the currently approved number provided in the CY 2019 PFS final rule (83 FR 60007) due to receipt of more current data. We estimate that 116,342 clinicians will submit as part of groups 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. 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 6,414 hours (104 groups x 61.67 hr) at a cost of $577,359 (6,414 hr x $90.02/hr). The decrease in number of respondents results in a total adjustment of -11,224 hours (-182 respondents x 61.67 hr) at -$1,010,379 (-11,224 hr x $90.02/hr).

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)	104
Total Annual Hours Per Group to Submit (b)	61.67
Total Annual Hours (c) = (a)*(b)	**6,413**
Cost Per Group to Report (@ computer systems analyst's labor rate of $90.02/hr.) (d)	$5,551.53
Total Annual Cost (e) = (a)*(d)	**$577,359**

6. Burden for Group Registration for CMS Web Interface

Groups interested in participating in MIPS using the CMS Web Interface for the first time must complete an on-line registration process. After first time registration, groups will only need to opt out if they are not going to continue to submit via the CMS Web Interface. In Table 14, we estimate that the registration process for groups under MIPS involves approximately 0.25 hours at $90.02/hr for a computer systems analyst (or their equivalent) to register the group.

In the CY 2020 PFS proposed rule, we have adjusted the number of respondents based on more recent data. We assume that approximately 51 groups will elect to use the CMS Web Interface for the first time during the 2020 MIPS performance period based on the number of new registrations received during the CY 2018 registration period; a decrease of 16 compared to the number of groups currently approved by OMB under control number 0938-1314 (CMS-10621) (83 FR 60009). The registration period for the 2019 MIPS performance period ends on June 30, 2019; assuming updated information is available, we will update our respondent estimates in the final rule. As shown in Table 14, we estimate a burden of 12.75 hours (51 new registrations x 0.25 hr/registration) at a cost of $1,148 (12.75 hr x $90.02/hr). The decrease 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 4 hours at a cost of $360 (-16 groups x 0.25 hr x $90.02/hr).

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)	51
Annual Hours Per Group (b)	0.25
Total Annual Hours (c) = (a)*(b)	**12.75**
Labor Rate to Register for CMS Web Interface @ computer systems analyst's labor rate) (d)	$90.02/hr
Total Annual Cost for CMS Web Interface Group Registration (e) = (a)*(d)	**$1,148**

vi. Burden Estimate for the Nomination of Quality Measures

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, a 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 discussed in section III.K.3.c.(1)(d)(i) of the CY 2020 PFS proposed rule, we are proposing that beginning with the 2020 Call for Measures process, MIPS quality measure stewards would be required to link their MIPS quality measures to existing and related cost measures and improvement activities, as applicable and feasible. MIPS quality measure stewards would also be required to provide a rationale as to how they believe their measure correlates to other performance category measures and activities. We believe this would require approximately 0.6 hours at $109.36/hr for a practice administrator and 0.4 hours at $202.86 for a clinician to research existing measures or activities and provide a rationale for the linkage to the new measure. We also estimate it would require 0.3 hours at $109.36/hr for a practice administrator to make a strategic decision to nominate and submit a measure and 0.2 hours at $202.86/hr for clinician review time. We recognize there is additional burden on respondents

associated with development of a new quality measure beyond the 1.5 hour estimate (0.6 hr + 0.4 hr + 0.3 hr + 0.2 hr) which only accounts for the time required for recordkeeping, reporting, and third-party disclosures associated with the policy; but we believe this estimate to be reasonable to nominate and submit a measure. The 1.5 hour estimate also 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. Representing an average across all respondents based on our review of the nomination process, the information required to complete the nomination form, and the criteria required to nominate the measure, we believe the total estimate of 1.5 hours per measure to be reasonable and appropriate.

As shown in Table 15, we estimate that 26 submissions will be received during the 2019 Call for Quality Measures based on the number of submissions received during the 2018 Call for Quality Measures process; a decrease of 114 compared to the number of submissions currently approved by OMB (140 submissions). The 2019 Call for Quality Measures process ends on June 3, 2019; assuming updated information is available, we will update our estimate in the final rule. 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.

Consistent with the CY 2017 Quality Payment Program final rule, we also estimate it will take 4 hours at $202.86/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.

As shown in Table 15, in aggregate we estimate an annual burden of 143 hours (26 submissions x 5.5 hr/submission) at a cost of $26,821 {26 submissions x [(0.9 hr x $109.36/hr) + (4.6 hr x $202.86/hr)}.

Independent of the decrease in the number of new quality measures submitted for consideration, the increase in burden per nominated measure results in a difference of 140 hours at a cost of $20,546 {140 submissions x [(0.6 hr x $109.36/hr) + (0.4 hr x $202.86/hr)]}. The decrease in the number of new quality measures submitted results in an adjustment of -627 hours at -$117,600 (-114 submissions x [(0.9 hr x $109.36/hr) + (4.6 hr x $202.86/hr)]). In aggregate, the combine impact of these changes is -487 hours (140 – 627) at a cost of -$97,054 ($20,546 - $117,600).

TABLE 15: Burden Estimates for Call for Quality Measures

Burden and Respondent Descriptions	**Burden estimate**
# of Organizations Nominating New Quality Measures (a)	26
# of Hours Per Practice Administrator to Identify and Propose Measure (b)	0.90
# of Hours Per Clinician to Identify Measure (c)	0.60
# of Hours Per Clinician to Complete Peer Review Article Form (d)	4.00
Annual Hours Per Response (e)= (b) + (c) + (d)	5.50
Total Annual Hours (f) = (a)*(e)	**143**
Cost to Identify and Submit Measure (@ practice administrator's labor rate of $109.36/hr.) (g)	$98.42

Burden and Respondent Descriptions	Burden estimate
Cost to Identify Quality Measure and Complete Peer Review Article Form (@ physician's labor rate of $202.86/hr.) (h)	$933.16
Total Annual Cost Per Respondent (i)=(g)+(h)	$1,031.58
Total Annual Cost (j)=(a)*(i)	**$26,821**

vii. Burden Estimate for the Promoting Interoperability Performance Category

For the 2020 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 individuals and groups 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. In the 2019 and prior MIPS performance periods, individuals and groups submitting data for the quality performance category via a qualified registry or QCDR that did not also support reporting of data for the Promoting Interoperability or improvement activity performance categories would be required to submit data for these performance categories using an alternate submission type. The proposals discussed in sections III.K.3.g.(3)(a)(i) and III.K.3.g.(4)(a)(i) of the CY 2020 PFS proposed rule requiring qualified registries and QCDRs to support the reporting of quality, improvement activities, and Promoting Interoperability performance categories would alleviate this issue. 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, respectively). The Hardship Exception Application form is included as Appendix R. In addition, in the CY 2018 Quality Payment Program final rule, we established that 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). The Extreme and Uncontrollable Circumstances Application form is included as Appendix S. As discussed in section III.K.3.d.(2)(b)(ii)(A) of

the CY 2020 PFS proposed rule, we are proposing, beginning with the 2018 MIPS performance period and 2020 MIPS payment year, to attempt to provide reweighting of the performance categories, if technically and operationally feasible, for a MIPS eligible clinician who we determine has been affected by data issues outside of their control when we learn about the relevant data issue prior to the beginning of the associated payment year, otherwise we would provide a score of zero for relevant performance category. Because this is a new policy and we believe these occurrences are rare based on our experience, we are unable to estimate the number of clinicians, groups, or third party intermediaries that may contact us regarding a potential data issue. Similarly, the extent and source of documentation provided to us for each event may vary considerably. Therefore, we are not proposing any changes to our currently approved burden estimates as a result of this proposal. 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. 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. Data on the number of reweighting applications submitted for the 2018 MIPS performance period is unavailable for this proposed rule. Assuming updated information is available for the final rule, we will assess the utility of using this information to estimate burden for future performance periods and will make a determination at that time as to the most appropriate data to use in estimating future burden.

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 6,025 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. Of that amount we estimate that 3,365 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 2,660 respondents will submit a request for reweighting the Promoting Interoperability performance category to zero percent as a small practice experiencing a significant hardship.

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 would take 0.25 hours at $90.02/hr for a computer system analyst to complete and submit the application. As shown in Table 16, we estimate an annual burden of

1,506.25 hours (6,025 applications x 0.25 hr/application) at a cost of $135,593 (1,506.25 hr x $90.02/hr).

Using our unchanged currently approved per respondent burden estimate, the decreased number of respondents results in a total adjustment of -4 hours (-16 respondents x 0.25 hr/respondent) and -$360 (-16 respondents x $22.50/respondent).

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)	3,365
# of Eligible Clinicians and Groups Applying Due to Significant Hardship for Small Practice (b)	2,660
Total Respondents Due to Hardships, Other Exceptions and Hardships for Small Practices (c)	6,025
Hours Per Applicant per application submission (d)	0.25
Total Annual Hours (e)=(a)*(c)	**1,506.25**
Labor Rate for a computer systems analyst (f)	$90.02/hr
Total Annual Cost (g)=(a)*(f)	**$135,593**

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) and CY 2019 PFS final rule (83 FR 59822-59823), we established that eligible clinicians in MIPS APMs (including the Shared Savings Program) may report for the Promoting Interoperability performance category as an APM Entity group, individuals, or a group.

As shown in Table 17, based on data from the 2017 MIPS performance period, we estimate that a total of 93,863 respondents consisting of 81,358 individual MIPS eligible clinicians and 12,505 groups and virtual 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.

Because our respondent estimates are based on the number of actual submissions received for the Promoting Interoperability performance category, it is not necessary to account for policies adopted in the CY 2017 Quality Payment Program final rule regarding reweighting, which state that if a clinician submits Promoting Interoperability data, they will be scored and the performance category will not be reweighted (81 FR 77238-77245). This approach is identical to the approach we used in the CY 2019 PFS final rule (83 FR 60013 through 60014), however we failed to state the distinction in that final rule that we no longer need to make modifications to our estimates due to the use of actual MIPS submission data. As established in the CY 2017 and CY 2018 Quality Payment Program final rules and the CY 2019 PFS 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, certified registered nurse anesthetists, physical therapists; occupational therapists; qualified speech-language pathologists or qualified audiologist; clinical psychologists; and registered dieticians or nutrition professionals (81 FR 77238 through 77245, 82 FR 53680 through 53687, and 83 FR 59819 through 59820, respectively). For the same reasons discussed above regarding our use of data reflecting the actual number of Promoting Interoperability data submissions received, these estimates already account for the reweighting policies 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 (81 FR 77240 through 77243 and 82 FR 53680 through 53686).

In section III.K.3.c.(4)(f)(iii), we propose to revise the definition of a hospital-based MIPS eligible clinician to include groups and virtual groups. We propose that, beginning with the 2022 MIPS payment year, a hospital-based MIPS eligible clinician means an individual MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in an inpatient hospital, on-campus outpatient hospital, off campus outpatient hospital, or emergency room setting based on claims for the MIPS determination period, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, meet the definition of a hospital-based individual MIPS eligible clinician during the MIPS determination period. We also propose to specify that for the Promoting Interoperability performance category to be reweighted for a MIPS eligible clinician who elects to participate in MIPS as part of a group or virtual group, all of the MIPS eligible clinicians in the group or virtual group must qualify for reweighting, or the group or virtual group must meet the proposed revised definition of a hospital-based MIPS eligible clinician or the definition of a non-patient facing MIPS eligible clinician. We believe these proposals could result in a decrease in the number of data submissions for the Promoting Interoperability performance category, but we do not currently have the data necessary to determine how many groups would elect to forego submission. As additional information becomes available in future years, we will revisit the impact of this policy and adjust our burden estimates accordingly.

As discussed in section III.K.3.c.(4)(d)(i)(B) of the CY 2020 PFS proposed rule, we propose to allow clinicians to satisfy the optional bonus Query of PDMP measure by submitting a "yes/no" attestation, rather than reporting a numerator and denominator. In the CY 2019 PFS final rule, we updated our burden assumptions from 3 hours to 2.67 hours to reflect the change from 5 base measures, 9 performance measures, and 4 bonus measures to the reporting of 4 base measures (83 FR 60013 through 60014). Due to a lack of data regarding the number of health care providers who would submit data for bonus Promoting Interoperability measures, we have consistently been unable to estimate burden related to the reporting of bonus measures and are therefore unable to account for any change in burden due to the proposed change to a "yes/no" attestation for the Query of PDMP measure. If we have better data in the future, we may reassess our burden assumptions and whether we can reasonably quantify the burden associated with the reporting of bonus measures.

We assume that MIPS eligible clinicians scored under the APM scoring standard, as described in section III.K.3.c.(5) of the CY 2020 PFS proposed rule, would continue to submit Promoting

Interoperability data the same as in 2017. Each MIPS eligible clinician in an APM Entity reports data for the Promoting Interoperability performance category through either their group TIN or individual reporting. In the CY 2019 PFS final rule, we established that MIPS eligible clinicians who participate in the Shared Savings Program are no longer limited to reporting for the Promoting Interoperability performance category through their ACO participant TIN (83 FR 59822-59823). Burden estimates for this proposed rule assume group TIN-level reporting as we believe this is the most reasonable assumption for the Shared Savings Program, which requires that ACOs include full TINs as ACO participants. As we receive updated information which reflects the actual number of Promoting Interoperability data submissions submitted by Shared Savings Program ACO participants, we will update our burden estimates accordingly.

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)	81,358
Number of groups to submit Promoting Interoperability(b)	12,569
Subtract: Number of groups to submit Promoting Interoperability on behalf of clinicians in 2020 MIPS performance period that will submit as virtual groups (c)	80
Add in: Number of virtual groups to submit Promoting Interoperability on behalf of clinicians in 2020 MIPS performance period (d)	16
Number of groups to submit Promoting Interoperability on behalf of clinicians in 2020 MIPS performance period (e)=(b)-(c)+(d)	12,505
Total Respondents in 2020 MIPS performance period (CY 2020 Proposed Rule) (f) = (a) + (e)	93,863
*Total Respondents in 2019 MIPS performance period (CY 2019 Final Rule) (g)	93,869
Difference between CY 2020 Proposed Rule and CY 2019 Final Rule (h) = (f) – (g)	-6

We estimate the time required for an individual or group to submit Promoting Interoperability data to be 2.67 hours. As previously discussed, beginning with the 2021 performance period and for future years, we propose to require that QCDRs and qualified registries support three performance categories: quality, improvement activities, and Promoting Interoperability. Based on our review of 2019 qualified registries and QCDRs, we have determined that 70 percent and 72 percent of these vendors, respectively, already support reporting for these performance categories. For clinicians who currently utilize qualified registries or QCDRs that have not previously offered the ability to report Promoting Interoperability or improvement activity data, we believe this would result in a reduction of burden as it would simplify MIPS reporting. In order to estimate the impact on reporting burden, we would need to correlate the specific individual clinicians and groups who submitted quality performance category data via the MIPS CQM/QCDR collection type that are required to report data for both the quality and Promoting Interoperability performance categories with the specific qualified registries or QCDRs that are affected by this proposal. Currently, we do not have the necessary information to perform this correlation and are therefore unable to estimate the resulting impact on burden. If data becomes

available in the future which enables us to perform this analysis, we will update our burden estimates at that time.

As shown in Table 18, the total burden estimate for submission of data on the specified Promoting Interoperability objectives and measures is estimated to be 250,301 hours (93,853 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 $22,532,126 (250,301 hr x $90.02/hr).

Using our unchanged currently approved per respondent burden estimate, the decrease in number of respondents results in a total adjustment of -16 hours (-6 respondents x 2.67 hr/respondent) at a cost of -$1,440 (-16 hr x $90.02/hr).

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)	81,358
Number of groups to submit Promoting Interoperability (b)	12,505
Total (c) = (a) + (b)	93,863
Total Annual Hours Per Respondent (b)	2.67
Total Annual Hours (c) = (a)*(b)	**250,301**
Labor rate for a computer systems analyst to submit Promoting Interoperability data/hr.) (d)	$90.02hr
Total Annual Cost (e) = (a)*(d)	**$22,532,126**

viii. 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 the Call for Promoting Interoperability Performance Category Measures Submission Form that includes the measure description, measure type (if applicable), reporting requirement, and CEHRT functionality used (if applicable). This rule does not propose any changes to that form.

We estimate 28 proposals will be submitted for new Promoting Interoperability measures, based on the number of proposals submitted during the CY 2018 nomination period. This is a decrease of 19 from the estimate currently approved by OMB (47 proposals) under the aforementioned control number. The 2019 Call for Promoting Interoperability Measures process ends on July 1, 2019; assuming updated information is available, we will update our estimate in the final rule. We estimate it will take 0.5 hours per organization to submit an activity to us, consisting of 0.3 hours at $109.36/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 $202.86/hr for a clinician to review the nomination. As shown in Table 19, we estimate an annual burden of 14 hours (28 proposals x 0.5 hr/response) at a cost of $2,055 (28 x [(0.3 h x $109.36/hr) + (0.2 hr x $202.86/hr)].

Using our unchanged currently approved per respondent burden estimate, the decrease in the number of respondents results in an adjustment of -9.5 hours at a cost of -$1,394 (-19 respondents x 0.5 hr x $73.38 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)	28
# 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)	**14**
Cost to Identify and Submit Measure (@ practice administrator's labor rate of $109.36/hr.) (f)	$32.21
Cost to Identify Improvement Measure (@ physician's labor rate of $202.86/hr.) (g)	$41.29
Total Annual Cost Per Respondent (h)=(f)+(g)	$73.50
Total Annual Cost (i)=(a)*(h)	**$2,058**

ix. 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). As discussed in section III.K.3.c.(3)(d)(iii) of the CY 2020 PFS proposed rule, we are proposing, beginning with the 2020 MIPS performance period and for future years, to increase the minimum number of clinicians in a group or virtual group who are required to perform an improvement activity from at least one clinician to at least 50 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable; and these NPIs must perform the same activity for the same continuous 90 days in the performance period. Because eligible clinicians are able to attest to improvement activity measures at the group level, there is no impact on reporting burden as a result of this proposal.

As previously discussed, beginning with the 2021 performance period and for future years, we are proposing to require QCDRs and qualified registries to support three performance categories: quality, improvement activities, and Promoting Interoperability; our discussion of burden for submitting Promoting Interoperability data in noted our inability to account for the reduction in burden associated with the proposal. Consistent with our decision not to change our per respondent burden estimate to submit Promoting Interoperability data, we are not changing our per respondent burden estimate to submit improvement activity data as a result of this proposal.

Furthermore, as discussed in section III.K.3.c.(3)(e)(i) of the CY 2020 PFS proposed rule, we are proposing to establish removal factors to consider when proposing to remove improvement activities from the Inventory. However, we do not believe this would affect reporting burden, because respondents would still be required submit the same number of improvement activities and this proposal would not require respondents to submit any additional information. We are also proposing for the CY 2020 performance period and future years to: add 2 new improvement activities, modify 7 existing improvement activities, and remove 15 existing improvement activities. Because MIPS eligible clinicians are still required to submit the same number of activities, we do not expect these proposals to affect our currently approved 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.

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 described 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, based on our assessment, the MIPS APM does not receive the maximum improvement activities performance category score, then the APM Entity can submit additional improvement activities. 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. In the 2019 and prior MIPS performance periods, individuals and groups submitting data for the quality performance category through a MIPS CQM or QCDR that did not also support reporting of data for the Promoting Interoperability or improvement activity performance categories would be required to submit data for these performance categories using an alternate submission type, the proposals discussed in sections III.K.3.g.(3)(a)(i) and III.K.3.g.(4)(a)(i) of the CY 2020 PFS proposed rule requiring qualified registries and QCDRs to support the reporting of quality, improvement activities, and Promoting Interoperability performance categories would help to alleviate this issue. 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 102,754 clinicians will submit improvement activities as individuals during the 2020 MIPS performance period and 15,761 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. In addition, as previously discussed regarding our estimate of clinicians and groups submitting data for the quality and Promoting Interoperability performance categories, we have updated our estimates for the number of clinicians and groups that will submit improvement activities data based on projections of the number of eligible clinicians that were not QPs or members of an APM in the 2017 MIPS performance period but will be in the 2019 MIPS performance period, and would therefore not be required to submit improvement activities data.

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 Entity level. We also assume that the MIPS APM models for the 2020 MIPS performance period will qualify for the maximum improvement activities performance category score and, as such, APM Entities will not 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 2020 MIPS performance period (a)	102,754
# of Groups to submit improvement activities on behalf of clinicians during the 2020 MIPS performance period (b)	15,825
Subtract: # of groups to submit improvement activities on behalf of clinicians in 2020 MIPS performance period that will submit as virtual groups (c)	80
Add in: # of Virtual Groups to submit improvement activities on behalf of clinicians during the 2020 MIPS performance period (d)	16
# of Groups and Virtual Groups to submit improvement activities on behalf of clinicians during the 2020 MIPS performance period (e)	15,761
Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the 2020 MIPS performance period (CY 2020 Proposed Rule) (f) = (a) + (b) + (e)	118,515
Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the 2019 MIPS performance period (CY 2019 Final Rule) (g)	136,004
Difference between CY 2020 Proposed Rule and CY 2019 Final Rule (h)=(g)-(f)	-17,489

Consistent with the CY 2019 PFS final rule, we estimate that the per response time required per individual or group is 5 minutes at $90.02/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 (83 FR 60016).

As shown in Table 21, we estimate an annual burden of 9,876 hours (118,515 responses x 5 minutes/60) at a cost of $889,060 (9,876.25 hr x $90.02/hr). The decrease in the number of respondents results in an adjustment of -1,457 hours (-17,489 responses x 5 minutes/60) at a cost of -$131,197 (-1,457 hr $90.02/hr).

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)	118,515
Total Annual Hours Per Respondent (b)	5 minutes
Total Annual Hours (c)	**9,876.25**
Labor rate for a computer systems analyst to submit improvement activities (d)	$90.02/hr
Total Annual Cost (e) = (a)*(d)	**$889,060**

x. Burden Estimate for the Nomination of Improvement Activities

In the CY 2018 Quality Payment Program final rule, for the 2018 and future MIPS performance periods, stakeholders were provided an opportunity 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 February 1, 2018 through March 1, 2018, during which we received 128 nominations of 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 improvement activity nominations received in the CY 2018 Annual Call for Activities, we estimate that we will receive 128 nominations for the 2020 Annual Call for Activities, which is an increase of 3 from the 125 nominations currently approved by OMB. The 2019 Annual Call for Activities ends on July 1, 2019; assuming updated information is available, we will update our estimate in the final rule.

We estimate 1.2 hours at $109.36/hr for a practice administrator or equivalent to make a strategic decision to nominate and submit that activity and 0.8 hours at $202.86/hr for a clinician's review. As shown in Table D-A 36, we estimate an annual burden of 256 hours (128 nominations x 2 hr/nomination) at a cost of $37,571 (128 x [(1.2 hr x $109.36/hr) + (0.8 hr x $202.86/hr)]).

Using our unchanged currently approved per respondent burden estimate, the increase in the number of nominations results in an adjustment of 6 hours at a cost of $881 {3 activities x [(1.2 hr x $109.36/hr) + (0.8 hr x $202.86/hr)]}.

TABLE 22: Burden Estimates for Nomination of Improvement Activities

Burden and Respondent Descriptions	**Burden estimate**
# of Organizations Nominating New Improvement Activities (a)	128
# 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)	**256**
Cost to Identify and Submit Activity (@ practice administrator's labor rate of $109.36/hr.) (f)	$131.23
Cost to Identify Improvement Activity (@ physician's labor rate of $202.86/hr.) (g)	$162.29
Total Annual Cost Per Respondent (h)=(f)+(g)	$293.52
Total Annual Cost (i)=(a)*(h)	**$37,571**

xi. 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; CMS-1500 and CMS-1490S) 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, including for the 10 episode-based measures we are proposing to include in the cost performance category as discussed in section III.K.3.c.(2)(b)(iii) of the CY 2020 PFS proposed rule. Moreover, the provisions of this proposed rule do not result in the need to add or revise or delete any claims data fields. Therefore, we are not proposing any new or revised collection of information requirements or burden for MIPS eligible clinicians resulting from the cost performance category.

xii. Burden Estimate for Partial QP Elections

APM Entities may face a data submission burden under MIPS if they attain Partial QP status and elect to participate in MIPS. 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.

In section III.K.4.d.(2)(b) of the CY 2020 PFS proposal rule, we propose that, beginning for eligible clinicians who become Partial QPs in the 2020 MIPS performance period, Partial QP status will only apply to the TIN/NPI combination through which Partial QP status is attained. Any Partial QP election will only apply to TIN/NPI combination through which Partial QP status is attained so that an eligible clinician who is a Partial QP for only one TIN/NPI combination may still report under MIPS for other TIN/NPI combinations. This proposal will potentially increase the total number of Partial QP elections to participate in MIPS if clinicians achieve Partial QP status under multiple TIN/NPI combinations.

As shown in Table 23, based on our predictive QP analysis for the 2020 QP performance period, which accounts for the increase in QP and Partial QP thresholds, we estimate that 12 APM Entities and 2,010 eligible clinicians will make the election to participate as a Partial QP in MIPS representing approximately 15,500 Partial QPs, an increase of 1,941 from the 81 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 505.5 hours (2,022 respondents x .25 hr/election) at a cost of $45,080 (505.5 hours x $90.02/hr).

Using our unchanged currently approved per respondent burden estimate, the increase in the number of Partial QP elections results in an adjustment of 485.25 (1,941 elections x 0.25hr) at a cost of $43,682 (485.25 hr x $90.02/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)	2,022
Total Hours Per Respondent to Elect to Participate as Partial QP (b)	0.25
Total Annual Hours (c) = (a)*(b)	**505.5**
Labor rate for computer systems analyst (d)	$90.02/hr
Total Annual Cost (d) = (c)*(d)	**$45,505**

xiii. Burden Estimate for Other-Payer Advanced APM Determinations

1. Payer-Initiated Process

Beginning in Quality Payment Program Year 3, the All-Payer Combination Option became 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. In addition, we will need to collect data from APM entities and Eligible Clinicians regarding their participation (as measured in payments or patients) in Other Payer Advanced APMs, as well as their total participation with all payers. 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 CY 2018 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 is available at https://qpp.cms.gov/.

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 finalized our proposal 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, or through the Medicaid or Medicare Health Plan payment arrangement submission processes.

As shown in Table 24, based on the actual number of requests received in the 2018 QP performance period, we estimate that in CY 2020 for the 2021 QP performance period 110 payer-initiated requests for Other Payer Advanced APM determinations will be submitted (10 Medicaid payers, 50 Medicare Advantage Organizations, and 50 remaining other payers), a decrease of 105 from the 215 total requests currently approved by OMB under the aforementioned control number. We estimate it will take 10 hours at $90.02/hr for a computer system analyst per arrangement submission. In aggregate, we estimate an annual burden of 1,100 hours (110 submissions x 10 hr/submission) at a cost of $99,022 (1,100 hr x $90.02/hr).

Using our unchanged currently approved per respondent burden estimate, the decrease in the number of payer-initiated requests from 215 to 110 results in an adjustment of -1,050 hours (-105 requests x 10 hr) at a cost of -$94,521 (-1,050 hr x $90.02/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)	110
Total Annual Hours Per other payer payment arrangement (b)	10
Total Annual Hours (c) = (a)*(b)	**1,100**
Labor rate for a computer systems analyst (d)	$90.02/hr
Total Annual Cost for Other Payer Advanced APM determinations (e) = (a)*(d)	**$99,022**

2. Eligible Clinician-Initiated Process

Beginning in Quality Payment Program Year 3, the All-Payer Combination Option became 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. In addition, we will need to collect data from APM entities and Eligible Clinicians regarding their participation (as measured in payments or patients) in Other Payer Advanced APMs, as well as their total participation with all payers.

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. 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.

We estimate it would take 10 hours at $90.02/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 $135,030 (1,500 hr x $90.02/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)	$90.02/hr
Estimated Total Annual Cost for Other Payer Advanced APM determinations (e) = (a)*(d)	**$135,030**

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

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 also 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 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 (the same) APM Entity (83 FR 59936). 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 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.

As shown in Table 26, we assume that 20 APM Entities, 448 TINs, and 83 eligible clinicians will submit data for QP determinations under the All-Payer Combination Option in 2019, and increase of 242 from the 309 total submissions currently approved by OMB under the aforementioned control number. We estimate it will take the APM Entity representative, TIN representative, or eligible clinician 5 hours at $109.36/hr for a practice administrator to complete this submission. In aggregate, we estimate an annual burden of 2,755 hours (551 respondents x 5 hr) at a cost of $301,287 (2,755 hr x $109.36/hr).

Using our unchanged currently approved per respondent burden estimate, the increase in the number of data submissions from 309 to 551 results in an adjustment of 1,210 hours (242 requests x 5 hr) at a cost of $132,326 (1,210 hr x $109.36/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)	20
# of TINs submitting data for All-Payer QP Determinations (b)	448
# of eligible submitting data for All-Payer QP Determinations (c)	83
Hours Per respondent QP Determinations (d)	5
Total Hours (g) = [(a)*(d)]+[(b)*(d)]+[(c)*(d)]	**2,755**
Labor rate for a Practice Administrator ($109.36/hr) (h)	$109.36/hr
Total Annual Cost for Submission of Data for All-Payer QP Determinations (i) = (g)*(h)	**$301,287**

xiv. 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 11,516 (0.10 x 115,163 voluntary MIPS participants) clinicians and groups, a decrease of 101 from the currently approved estimate of 11,617. This decrease is due to the availability of updated estimates of QPs and APM participation for the 2020 performance period. Voluntary MIPS participants are clinicians that are not QPs and are expected to be excluded from MIPS after applying the eligibility requirements set out in the CY 2019 PFS final rule but have elected to submit data to MIPS. As discussed in the Regulatory Impact Analysis section of the CY 2019 PFS final rule, we estimate that 33 percent of clinicians that exceed one (1) of the low-volume criteria, but not all three (3), will elect to opt-in to MIPS, become MIPS eligible, and no longer be considered a voluntary reporter (83 FR 60050).

In section III.K.3.h.(6) of the CY 2020 PFS proposed rule, we propose to publicly report (1) an indicator if a MIPS eligible clinician is scored using facility-based measurement beginning with Year 3 (2019 performance information available for public reporting in late 2020) and (2) aggregate MIPS data beginning with Year 2 (2018 performance information available for public reporting in late 2019). We believe it is possible that the percentage of voluntary participants

electing not to participate in public reporting may change as a result of this proposals, we lack the ability to predict the behavior of clinicians' response to this proposal. Table 27 shows that for these voluntary participants, we estimate it will take 0.25 hours at $90.02/hr for a computer system analyst to submit a request to opt-out. In aggregate, we estimate an annual burden of 2,879 hours (11,516 requests x 0.25 hr/request) at a cost of $259,168 (2,879 hr x $90.02/hr).

Using our unchanged currently approved per respondent burden estimate, the decrease in the number of opt outs by voluntary participants from 11,617 to 11,516 results in an adjustment of 25.25 hours (101 requests x 0.25 hr) at a cost of -$2,273 (25.25 hr x $90.02/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)	11,516
Total Annual Hours Per Opt-out Requester (b)	0.25
Total Annual Hours for Opt-out Requester (c) = (a)*(b)	**2,879**
Labor rate for a computer systems analyst (d)	$90.02/hr
Total Annual Cost for Opt-out Requests (e) = (a)*(d)	**$259,168**

Burden Summary

TABLE 28: 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	290	3	870	90.02	78,317
§414.1400	QCDR self-nomination	4	91	32	2,912	90.02	262,138
§414.1325 and 414.1335	QPP Identity Management Application Process	9	3,741	1	3,741	90.02	337,765
§414.1325 and 414.1335	(Quality Performance Category) Claims Collection Type	10	109,951	14.2	1,561,304	Varies (see table 10)	148,691,575
§414.1325 and 414.1335	(Quality Performance Category) QCDR/MIPS CQM Collection Type	11	116,591	9.083	1,058,996	Varies (see table 11)	101,710,684

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 ($/hr)	Total Cost ($)*
§414.1325 and 414.1335	(Quality Performance Category) eCQM Collection Type	12	51,787	8.0	414,296	Varies (see table 12)	40,128,711
§414.1325 and 414.1335	(Quality Performance Category) CMS Web Interface Submission Type	13	104	61.7	6,413	90.02	577,359
§414.1325 and 414.1335	(Quality Performance Category) Group Registration for CMS Web Interface	14	51	0.25	12.75	90.02	1,148
	(Quality Performance Category) Call for Quality Measures	15	26	5.5	143	Varies (see table 15)	26,821
§414.1375 and 414.1380	(PI Performance Category) Reweighting Applications for Promoting Interoperability and Other Performance Categories	16	6,025	0.25	1,506	90.02	135,593
§414.1375	(PI Performance Category) Data Submission	18	93,863	2.67	250,301	90.02	22,532,126
	(PI Performance Category) Call for Promoting Interoperability Measures	19	28	0.5	14	Varies (see table 19)	2,055
§414.1360	(Improvement Activities Performance Category) Data Submission	21	118,515	0.083	9,876	90.02	889,060

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 ($/hr)	Total Cost ($)*
§414.1360	(Improvement Activities Performance Category) Nomination of Improvement Activities	22	128	2.0	256	Varies (see table 22)	37,571
§414.1430	Partial Qualifying APM Participant (QP) Election	23	2,022	0.25	506	90.02	45,505
§414.1440	Other Payer Advanced APM Identification: Payer Initiated Process	24	110	10	1,100	90.02	99,022
§414.1445	Other Payer Advanced APM Identification: Clinician Initiated Process	25	150	10	1,500	90.02	135,030
§414.1440	Submission of Data for All-Payer QP Determinations under the All-Payer Combination Option	26	551	5	2,755	109.36	301,287
§414.1395	(Physician Compare) Opt Out for Voluntary Participants	27	11,516	0.25	2,879	90.02	259,168
TOTAL			**515,540**	**Varies**	**3,319,382**	**Varies**	**316,249,934**

Information Collection Instruments/Instructions

Appendix A (See Table 3): 2020 Qualified Registry Fact Sheet (Revised)

Appendix B: Crosswalk - 2020 Qualified Registry Fact Sheet

Appendix C (See Table 4): 2020 Qualified Clinical Data Registry (QCDR) Fact Sheet (Revised)

Appendix D: Crosswalk - 2020 Qualified Clinical Data Registry (QCDR) Fact Sheet

Appendix E (Table 4): 2020 Qualified Clinical Data Registry (QCDR) Measure Submission Template (New)

Appendix F (See Table 14): 2019 Registration Guide for the CMS Web Interface and CAHPS for MIPS Survey (Revised)

Appendix G: Crosswalk - 2019 Registration Guide for the CMS Web Interface and CAHPS for MIPS Survey

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

Appendix I (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) (Revised)

Appendix J: Crosswalk - Submission Form for Eligible Clinician and APM Entity Requests for Other Payer Advanced Alternative Payment Model Determinations (Eligible Clinician Initiated Submission Form)

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

Appendix L: Crosswalk - Submission Form for Requests for Qualifying Alternative Payment Model Participant (QP) Determinations under the All-Payer Combination Option

Appendix M (See Table 15): Measures under Consideration 2019, Data Template for Candidate Measures (Revised)

Appendix N: Crosswalk - Measures under Consideration 2019, Data Template for Candidate Measures

Appendix O (See Table 19): Promoting Interoperability Performance Category, 2019 Call for Measures Submission Form (No Changes)

Appendix P (See Table 22): Improvement Activities Performance Category, 2019 Call for Activities Submission Form (English) (No Changes)

Appendix Q (See Table 15): Peer Reviewed Journal Article Requirement Template (No Changes)

Appendix R (See Table 16): Hardship Exception Application Form (New)

Appendix S (See Table 16): Extreme and Uncontrollable Circumstances Application Form (New)

13. Capital Costs

We believe that third parties who submit data on behalf of clinicians could incur additional costs as a result of policies finalized in the CY 2020 PFS proposed rule. In sections III.K.3.g.(3)(a)(i) and III.K.3.g.(4)(a)(i) of the CY 2020 PFS proposed rule, beginning with the 2021 performance period, we are proposing to require qualified registries and QCDRs to support all three performance categories: quality, improvement activities, and Promoting Interoperability. Currently, qualified registries and QCDRs are only required to support the quality performance category while supporting improvement activities and Promoting Interoperability performance categories is optional. In section III.K.3.g.(1) of the CY 2020 PFS proposed rule, we further state that we anticipate using the QCDR and qualified registry self-nomination vetting process to assess which of these entities will be subject to the proposed requirement to support reporting the Promoting Interoperability performance category and which entities would be subject to an exception based on which clinician types they serve and whether those clinician types are eligible for reweighting of the Promoting Interoperability performance category as discussed in section III.K.3.c.(4) of the CY 2020 PFS proposed rule. Based on our review of qualified registries and QCDRs approved to submit data for the 2019 MIPS performance period, 70 percent of qualified registries and 72 percent of QCDRs already offer support for the quality, improvement activities, and Promoting Interoperability performance categories. We believe this proposal could result in the remaining qualified registries and QCDRs incurring additional costs to upgrade information technology systems in order to make this ability available to clinicians, with less cost incurred by entities who would be subject to an exception for the Promoting Interoperability performance category. However, given that each of these entities and their information technology systems are unique, and there is no method of determining which entities may have already begun the process of developing this ability, we are unable to determine the impact of transitioning from allowing this ability as an option to requiring it. Also, given that the majority of these entities have already begun offering the ability to submit data on behalf of the improvement activities and Promoting Interoperability performance categories, we assume they have done so because they believe the benefits outweigh the costs and is therefore, in their best financial interests to do so. We are also proposing in section III.K.3.g.(3)(a)(ii) of the CY 2020 PFS proposed rule, beginning with the 2021 performance period, to require qualified registries and QCDRs to provide the following as part of the performance feedback given at least 4 times a year: feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure (MIPS quality measure and/or QCDR measure) within the qualified registry or QCDR. We understand that QCDRs can only provide feedback on data they have collected on their clinicians and groups, and realize the comparison would be limited to that data and not reflect the larger sample of those that have submitted on the measure for MIPS, which the QCDR does not have access to. As finalized in the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77367 through 77386 and 82 FR 53812), qualified registries and QCDRs are required to provide feedback on all of the MIPS performance categories that the

qualified registry or QCDR reports at least 4 times a year. Given that we are not proposing a significant change but are instead proposing to modify and strengthen the existing policy, we do not anticipate a significant increase in cost or effort for Third Party Intermediaries to comply with this proposal. In alignment with our proposal above, we are also proposing to require QCDRs to provide services to clinicians and groups to foster improvement in the quality of care provided to patients, by providing educational services in quality improvement and leading quality improvement initiatives. Similar to the requirement to support submission of Promoting Interoperability and improvement activity data, we believe this proposal could result in QCDRs incurring additional costs. We are unable to create a baseline of current service offerings for each QCDR, which would be needed in order to determine the incremental costs associated with providing any additional services required by this proposal. We believe that by offering these services, additional MIPS eligible clinicians may be encouraged to utilize these entities, thereby increasing membership and potentially offsetting some of the costs the QCDR would have to incur.

In section III.K.3.g.(3)(c)(i)(B)(cc) of the CY 2020 PFS proposed rule, we are proposing that in order for a QCDR measure to be considered for use in the program beginning with the 2021 performance period and future years, all QCDR measures submitted for self-nomination must be fully developed with completed testing results at the clinician level, as defined by the CMS Blueprint for the CMS Measures Management System, as used in the testing of MIPS quality measures prior to the submission of those measures to the Call for Measures. Beginning with the 2021 performance period and future years, we are proposing in section III.K.3.g.(3)(c)(i)(B)(dd) to also require QCDRs to collect data on the potential QCDR measure, appropriate to the measure type, as defined in the CMS Blueprint for the CMS Measures Management System, prior to self-nomination. The testing process for quality measures is dependent on the measure type (for example, a measure that is specified as an eCQM measure has additional steps it must undergo when compared to other measure types). The National Quality Forum (NQF) has developed guides for measure testing criteria and standards which further illustrate these differences based on measure type . Additionally, the costs associated with testing vary based on the complexity of the measure and the developing organization. The Journal of the American Medical Association states that the costs associated with quality measures are generally unknown or unreported[11]. While we understand the proposed policy will result in additional costs for QCDRs to develop measures, given the uncertainty regarding the number and types of measures that will be proposed in future performance periods coupled with the lack of available cost data on measure development and testing, we are unable to determine the financial impact of this proposal on QCDRs beyond the likelihood of it being more than trivial. Likewise, we understand that some QCDRs already perform measure testing prior to submission for approval

[11] Schuster, Onorato, and Meltzer. "Measuring the Cost of Quality Measurement: A Missing Link in Quality Strategy", Journal of the American Medical Association. 2017; 318(13):1219-1220. https://jamanetwork.com/journals/jama/fullarticle/2653111?resultClick=1

while others do not. This variability makes it difficult to estimate the incremental impact of this regulation.

In section III.K.3.g.(3)(c)(i)(A)(bb) of the CY 2020 PFS proposed rule, we are proposing to state that CMS may consider the extent to which a QCDR measure is available to MIPS eligible clinicians reporting through QCDRs other than the QCDR measure owner for purposes of MIPS. If CMS determines that a QCDR measure is not available to MIPS eligible clinicians, groups, and virtual groups reporting through other QCDRs, CMS may not approve the measure. Because the choice to license a QCDR measure is an elective business decision made by individual QCDRs and we have little insight into both the specific terms and frequency of agreements made between entities, we are unable to account for the financial impact of licensing QCDR measures for each QCDR. In aggregate across all QCDRs, the financial impact would be zero as fees paid by one QCDR will be collected by another QCDR.

In section III.K.3.g.(3)(c)(i)(B)(ee) of the CY 2020 PFS proposed rule, we propose, beginning with the 2020 performance period, that after the self-nomination period closes each year, we will review newly self-nominated and previously approved QCDR measures based on considerations as described in the CY 2019 PFS final rule (83 FR 59900 through 59902). In instances in which multiple, similar QCDR measures exist that warrant approval, we may provisionally approve the individual QCDR measures for 1 year with the condition that QCDRs address certain areas of duplication with other approved QCDR measures in order to be considered for the program in subsequent years. The QCDR could do so by harmonizing its measure with, or significantly differentiating its measure from, other similar QCDR measures. QCDR measure harmonization may require two or more QCDRs to work collaboratively to develop one cohesive QCDR measure that is representative of their similar yet, individual measures. We are unable to account for the financial impact of measure harmonization, as the process and outcomes will likely vary substantially depending on a number of factors, including: extent of duplication with other measures, number of QCDRs involved in harmonizing toward a single measure, and number of measures being harmonized among the same QCDRs. We intend to identify only those QCDR measures which are duplicative to such an extent as to assume harmonization will not be overly burdensome, however, because the harmonization process will occur between QCDRs without our involvement, we are unable to predict or quantify the associated effort.

In section III.K.3.c.(3)(d)(iii) of the CY 2020 PFS proposed rule, we are proposing, beginning with the 2020 MIPS performance period and for future years, to increase the minimum number of clinicians in a group or virtual group who are required to perform an improvement activity from at least one clinician to at least 50 percent of the NPIs billingunder the group's TIN or virtual group's TINs, as applicable; and these NPIs must perform the same activity for the same continuous 90 days in the performance period. Given groups' familiarity with the improvement activities in the Improvement Activities Inventory, we assume that a group would find applicable and meaningful activities to complete that are not specific to practice size, specialty, or practice setting and would apply to at least 50 percent of individual MIPS eligible clinicians in the group.

Therefore, an increase in the minimum threshold for a group to receive credit for the improvement activities performance category should not present additional complexity or burden. We also anticipate that the vast majority of clinicians performing improvement activities, to comply with existing MIPS policies, would continue to perform the same activities under the policies established in this proposed rule because previously finalized improvement activities continue to apply for the current and future years unless otherwise modified per rule-making (82 FR 54175). Most of the improvement activities in Improvement Activities Inventory remain unchanged for the 2020 MIPS performance period and most clinicians are likely to have selected improvement activities that were unaffected by the changes. Of the activities that were removed, modified, or added, many were duplicative which means many clinicians or groups would be able to continue the activity, but it would be reported under a different activity in the Improvement Activities Inventory.

We refer readers to Table H in the Appendix of the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77199), Tables F and G in the Appendix of the CY 2018 Quality Payment Program final rule (82 FR 54175 through 54229), and Tables A and B in the Appendix 2 of the CY 2019 PFS final rule (83 FR 60286 through 60303) for our previously finalized 118 improvement activities established in the Improvement Activities Inventory. In the CY 2020 PFS proposed rule, for the 2020 MIPS performance period and future years, we are proposing to: (1) add 2 new improvement activities; (2) modify 7 existing improvement activities; and (3) remove fourteen improvement activities from the Inventory.

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 revisedAppendices A (2020 Qualified Registry Fact Sheet), C (2020 QCDR Fact Sheet), F (2019 Registration Guide for CMS Web Interface and CAHPS for MIPS Survey), I (Eligible Clinician Initiated Submission Form), K (Requests form for QP Determinations under the All-Payer Combination Option), and M (2019 Measures Under Consideration Data Template) which are included in this PRA submittal to reflect changes due to proposed requirements and revised terminology as well as to provide additional clarity. Crosswalks have been provided in Appendices B, D, G, J, L, and N which clearly describe all changes from previous submittals. Also included in this PRA are three new Appendices: C (2020 QCDR Measure Submission Template), L (Hardship Exception Application Form), and M (Extreme and Uncontrollable Circumstances Application Form). These three appendices were erroneously omitted from our previously approved PRA submission and are included here for completeness. Appendices that are updated prior to publishing of the CY 2020 PFS final rule will be provided

at that time. We have updated our burden estimate for the Call for Quality Measures data collection to reflect the proposed requirement for organizations that nominate quality measures or improvement activities to link them with existing and related quality measures, cost measures, or improvement activities, as applicable and feasible; and to provide a rationale as to how they believe their measure/activity correlates to other performance category measures and activities. We have also updated our burden estimate for the QCDR self-nomination data collection to reflect the proposed requirements for QCDRs to identify a linkage between their QCDR measures to cost measures, improvement activities, or MIPS Value Pathways, to submit measure testing data for each QCDR measure submitted, and to describe the quality improvement services they intend to support as part of the self-nomination process. Appendix C (2020 QCDR Fact Sheet), Appendix E (2020 QCDR Measure Submission Template), and Appendix M (2019 MUC Template) have not been updated to reflect these proposed requirements. If these proposals are finalized, we will provide updated forms with the CY 2020 PFS final rule that reflect these additional requirements.

Table 29 includes our CY 2020 PFS proposed rule burden estimates for the Quality Payment Program. The total estimated burden is 3,319,382 hours at a cost of $316,249,934 (see Tables 29 and 30).

In order to understand the burden implications of the policies finalized in CY 2020 PFS proposed rule, we have also estimated a baseline burden of continuing the policies and information collections set forth in the CY 2019 PFS final rule into the 2020 MIPS performance period. As shown in Table 30, our estimated baseline burden estimates reflect the availability of more accurate data to account for all potential respondents and submissions across all the performance categories, more accurately reflect the exclusion of QPs from all MIPS performance categories, and better estimate the number of third-parties likely to self-nominate as qualified registries and QCDRs as well as the number of measures submitted per QCDR. The baseline burden estimates employ the improved data and revised assumptions also used for our year CY 2020 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 3,317,764 hours at a cost of $316,102,761. This baseline burden estimate is lower than the burden approved for information collection related to the CY 2019 PFS final rule due to updated data and assumptions.

As shown in Table 29, this Supporting Statement A reflects a total of 515,540 responses with an associated hours burden of 3,319,382; this is an increase of 1,619 hours. As shown in Table 29, we estimate a total burden of approximately $316,102,761 million; an increase of $147,173. The increase in burden for the 2020 MIPS performance period is reflective of the proposals to require QCDRs to submit measure testing data at the time of self-nomination, to require QCDRs to

describe the quality improvement services they intend to support as part of the self-nomination process, and to require proposed quality measures and QCDR measures to be linked to existing cost measures, improvement activities, and MIPS Value Pathways, if possible.

TABLE 29: Annual Recordkeeping and Submission Requirements

Requirement	Currently Approved Responses	Proposed Responses	Change in Responses	Currently Approved Total Burden Hours	Proposed Total Burden Hours	Change in Total Burden Hours
§414.1400 Registry self-nomination	150	290	140	450	870	420
§414.1400 QCDR self-nomination	200	91	-109	2,400	2,912	512
§414.1325 and 414.1335 CMS Quality Payment Program Identity Management Application Process	3,741	3,741	0	3,741	3,741	0
§414.1325 and 414.1335 (Quality Performance Category) Claims Collection Type	257,260	109,951	-147,309	3,653,092	1,561,304	-2,091,788
§414.1325 and 414.1335 (Quality Performance Category) QCDR/MIPS CQM Collection Type	81,981	116,591	34,610	744,633	1,058,996	314,363
§414.1325 and 414.1335 (Quality Performance Category) eCQM Collection Type	51,861	51,787	-74	414,888	414,296	-592
§414.1325 and 414.1335 (Quality Performance Category) CMS Web Interface	286	104	-182	17,636.7	6,413.3	-11,223
§414.1325 and 414.1335 (Quality Performance Category) Registration and Enrollment for CMS Web Interface	67	51	-16	16.75	12.75	-4
(Quality Performance Category) Call for Quality Measures	140	26	-114	630	143	-487
§414.1375 and 414.1380 (PI Performance Category) Reweighting Applications for Promoting Interoperability and Other Performance Categories	6,041	6,025	-16	1,510	1,506	-4
§414.1375 (PI Performance Category) Data Submission	93,869	93,863	-6	250,317	250,301	-16
(PI Performance Category) Call for Promoting Interoperability Measures	47	28	-19	23.5	14	-9.5
§414.1360 (Improvement Activities Performance Category) Data Submission	136,004	118,515	-17,489	11,334	9,876	-1,457
§414.1360 (Improvement Activities Performance Category) Nomination of Improvement Activities	125	128	3	250	384	134

Requirement	Currently Approved Responses	Proposed Responses	Change in Responses	Currently Approved Total Burden Hours	Proposed Total Burden Hours	Change in Total Burden Hours
§414.1430 Partial Qualifying APM Participant (QP) Election	81	2,022	1,941	20.25	505.5	485.25
§414.1440 Other Payer Advanced APM Identification: Payer Initiated Process	215	110	-105	2,150	1,100	-1,050
§414.1445 Other Payer Advanced APM Identification: Eligible Clinician Initiated Process	150	150	0	1,500	1,500	0
§414.1440 Submission of Data for All-Payer QP Determinations under the All-Payer Combination Option	309	551	242	1,545	2,755	1,210
§414.1395 (Physician Compare) Opt Out for Voluntary Participants	11,617	11,516	-101	2,904.25	2,879	-25.25
TOTAL	**644,144**	**515,540**	**-128,604**	**5,109,042**	**3,319,382**	**-1,789,660**

Table 30 summarizes the ICRs for the Quality Payment Program for which we have proposed 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 30: 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)	290	3	870	90.02	78,317	0	37,808
§414.1400 (QCDR self-nomination)	91	325	2,912	90.02	262,138	143,357	-97,267
§414.1325 and 414.1335 (QPP Identity Management Application Process)	3,741	1	3,741	90.02	336,765	0	0

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 ($)*	Total Cost Adjustments due to change in assumptions ($)*
§414.1325 and 414.1335 [(Quality Performance Category) Claims Collection Type]	109,951	14.2	1,561,304	Varies (see table 10)	148,691,575	0	-199,212,442
§414.1325 and 414.1335 [(Quality Performance Category) QCDR/MIPS CQM Collection Type]	116,591	9.083	1,058,996	Varies (see table 11)	101,710,684	0	30,192,783
§414.1325 and 414.1335 [(Quality Performance Category) eCQM Collection Type]	51,787	8.0	414,296	Varies (see table 12)	40,128,711	0	-57,341
§414.1325 and 414.1335 [(Quality Performance Category) CMS Web Interface Submission Type]	104	61.7	6,414	90.02	577,359	0	-1,010,379
§414.1325 and 414.1335 [(Quality Performance Category) Registration and Enrollment for CMS Web Interface]	51	0.25	12.75	90.02	1,148	0	-360
[(Quality Performance Category) Call for Quality Measures]	26	5.5	143	Varies (see table 15)	26,821	3,816	-100,869

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 ($)*	Total Cost Adjustments due to change in assumptions ($)*
§414.1375 and 414.1380[(PI Performance Category) Reweighting Applications for Promoting Interoperability and Other Performance Categories	6,025	0.25	1,506.25	90.02	135,593	0	-360
§414.1375 [(PI Performance Category) Data Submission]	93,863	2.67	250,301	90.02	22,532,126	0	-1,440
[(PI Performance Category) Call for Promoting Interoperability Measures]	28	0.5	14	Varies (see table 19)	2,055	0	-1,394
§414.1360 [(Improvement Activities Performance Category) Data Submission]	118,515	0.083	9,876	90.02	889,060	0	-131,197
§414.1360 [(Improvement Activities Performance Category) Nomination of Improvement Activities]	128	2.0	256	Varies (see table 22)	37,571	0	881
§414.1430 [Partial Qualifying APM Participant (QP) Election]	2,022	0.25	505.5	90.02	45,505	0	43,682
§414.1440 [Other Payer Advanced APM Identification: Payer Initiated Process]	110	10	1,100	90.02	99,022	0	-94,521

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 ($)*	Total Cost Adjustments due to change in assumptions ($)*
§414.1445 [Other Payer Advanced APM Identification: Clinician Initiated Process]	150	10	1,500	90.02	135,030	0	0
§414.1440 [Submission of Data for All-Payer QP Determinations under the All-Payer Combination Option]	551	5	2,755	109.36	301,287	0	132,326
§414.1395 [(Physician Compare) Opt Out for Voluntary Participants]	11,516	0.25	2,879	90.02	259,168	0	-2,273
TOTAL	**515,540**	**Varies**	**3,319,382**	**Varies**	**316,249,934**	**147,173**	**-170,302,364**

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

Table 31 provides the reasons for changes in the estimated burden for information collections in the CY 2020 PFS proposed 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 3 policies that reflect updated data and methods.

TABLE 31: Reasons for Change in Burden Compared to the Currently Approved CY 2019 Information Collection Burdens

Table in Collection of Information	**Changes in burden due to proposed Year 4 policies**	**Changes to "baseline" of burden continued Year 3 policy (*italics are changes in number of respondents' due to updated data)***
Table 3: Qualified Registry Self-Nomination	None.	Increase in number of respondents due to availability of data indicating number of existing QCDRs which would not meet previously finalized QCDR requirements effective beginning in 2020 performance period.
Table 4: QCDR Self-Nomination	*Increase of 11.5 hours (1 hour per proposed measure) per QCDR self-nomination due to proposed policy to require QCDRs to provide a linkage between proposed QCDR measures and related cost measures, improvement activities, and MIPS Value Pathways.* *Increase of 5.75 hours (0.5 hour per proposed measure) per QCDR nomination due to proposed policy to require QCDRs to provide measure testing data at the time of self-nomination.* *Increase of 0.25 hour per QCDR to describe the quality improvements services they intend to support as part of their self-nomination.*	Decrease in number of respondents due to availability of data indicating number of existing QCDRs which would not meet previously finalized QCDR requirements effective beginning in 2020 performance period. Increase in burden per respondent due to revised estimate of average number of measures per QCDR for which information is submitted.
Table 9: Quality Payment Program Identity Management Application Process	None	None
Table 10: Quality Performance Category Claims Collection Type	None.	Decrease in number of respondents due to use of updated data incorporating limitation on submission of quality data via Medicare Part B claims to small practices. Decrease in number of respondents due to updated estimates for the number of clinicians projected to be QPs or participating in APMs during the 2020 MIPS performance period.

Table in Collection of Information	**Changes in burden due to proposed Year 4 policies**	**Changes to "baseline" of burden continued Year 3 policy (*italics are changes in number of respondents' due to updated data)***
Table 11: Quality Performance Category QCDR/MIPS CQM Collection Type	None.	Increase in number of respondents due to use of updated data incorporating limitation on submission of quality data via Medicare Part B claims to small practices. and our assumption that affected clinicians will submit via the MIPS CQM collection type. Net decrease in total number of respondents (number of individual submitters decreased while the number of group submitters increased) due to updated estimates for the number of clinicians projected to be QPs or participating in APMs during the 2020 MIPS performance period.
Table 12: Quality Performance Category eCQM Collection Type	None.	Net decrease in total number of respondents (number of individual submitters decreased while the number of group submitters increased) due to updated estimates for the number of clinicians projected to be QPs or participating in APMs during the 2020 MIPS performance period.
Table 13: Quality Performance Category CMS Web Interface	None.	Decrease in number of respondents due to updated data from the 2018 MIPS performance period.
Table 14: Registration for CMS Web Interface	None.	Decrease in number of respondents due to updated data from the 2018 registration period.
Table 15: Call for Quality Measures	*Increase of 1 hour per measure due to proposed requirement to link nominated measures to existing cost measures or improvement activities.*	Decrease in number of measures submitted due to updated data.
Table 16: Reweighting Applications for Promoting Interoperability and Other Performance Categories	None.	Decrease in number of applications submitted due to updated data.
Table 18: Promoting Interoperability Performance Category Data Submission	None.	Increase in number of respondents due to updated estimates for the number of clinicians projected to be QPs or participating in APMs during the 2020 MIPS performance period.
Table 19: Call for Promoting Interoperability Measures	None.	Decrease in number of measures submitted due to updated data.
Table 21: Improvement Activities Submission	None.	Decrease in number of respondents due to updated estimates for the number of clinicians projected to be QPs or participating in APMs during the 2020 MIPS performance period.

Table in Collection of Information	**Changes in burden due to proposed Year 4 policies**	**Changes to "baseline" of burden continued Year 3 policy (*italics are changes in number of respondents' due to updated data)***
Table 22: Nomination of Improvement Activities	Increase of 1 hour per activity due to proposed requirement to link nominated improvement activities to existing quality or cost measures.	Increase in number of activities nominated due to updated data.
Table 23: Partial QP Election	None.	Increase in number of respondents due to updated projections for the 2020 MIPS performance period.
Table 24: Other Payer Advanced APM Identification: Other Payer Initiated Process	None.	Increase in number of respondents due to updated projections for the 2020 MIPS performance period.
Table 25: Other Payer Advanced APM Identification: Eligible Clinician Initiated Process	None.	None.
Table 26: Submission of Data for All-Payer QP Determinations under the All-Payer Combination Option	None.	Increase in number of respondents due to updated projections for the 2020 MIPS performance period.
Table 27: Voluntary Participants to Elect to Opt Out of Performance Data Display on Physician Compare	None.	Decrease in the number of respondents due to updated projections for the number of voluntary participants in the 2020 MIPS performance period.

Table 32 summarizes the annual burden estimates for proposed requirements for all ICRs being submitted for OMB approval under control number 0938-1314 (CMS-10621).

TABLE 32: 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)	379,749	(128,604)	varies	(1,789,661)	varies	(170,155,191)

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

** Previously, we were 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 we had not developed a unified way to identify unique respondents. This number represents the total number of unique respondents as estimated in the CY 2020 PFS proposed rule.

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, improvement activities and Promoting Interoperability data; MIPS performance category and final scores; and payment adjustment factors. 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 a website owned and maintained by CMS for the purpose of promoting more informed health care choices 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 2017 measures were made available for preview from March 28, 2019 through April 27, 2019 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.