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

A Background

The Merit-based Incentive Payment System (MIPS) is a program for certain eligible clinicians that makes Medicare payment adjustments based on performance on quality, cost and other measures and activities. 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, 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. In the CY 2021 proposed rule, we are proposing for clinicians in APM Entities, the APM Performance Pathway for both ACO and non ACOs to submit quality data. Due to data limitations and our inability to determine who would use the APM Performance Pathway versus the traditional MIPS submission mechanism for the 2021 MIPS performance period, we assume ACO APM Entities will submit data through the APM Performance Pathway and non-ACO APM Entities would participate through traditional MIPS,

[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).

thereby submitting as an individual or group rather than as an entity. We are also proposing to sunset the CMS Web Interface measures as a quality performance category collection type/submission type starting with the 2021 performance period. If this proposal is finalized, it will result in groups of 25 or more clinicians that previously submitted quality performance data via the CMS Web Interface being required to use an alternate collection type, which will have to be either the MIPS CQM and QCDR or eCQM collection type.

For the Promoting Interoperability performance category, in the CY 2021 proposed rule we are proposing that, beginning with the 2022 MIPS payment year (2020 performance year), APM Entities may submit an extreme and uncontrollable circumstances exception application for all four performance categories and applicable to all MIPS eligible clinicians in the APM Entity group. We are also proposing the new Health Information Exchange (HIE) Bi-Directional Exchange measure for which clinicians may submit a "yes/no" response.

For the improvement activities performance category, we are not proposing any new requirements which we anticipate will impact burden.

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, quality measures, and MIPS Value Pathways (MVPs) 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 2021 PFS proposed rule as a revision to our currently approved (or active) information requests submitted under this package's control number (OMB 0938-1314, CMS-10621). CMS has already received approval for collection of information associated with the CAHPS for MIPS survey under OMB control number 0938-1222 (CMS-10450). CMS has already received approval for collection of information associated with the virtual group election process under OMB control number 0938-1343 (CMS-10652).

The proposed changes in this 2020 collection of information request is associated with our August 17, 2020 (85 FR 50074) proposed rule (CMS-1734-P, RIN 0938-AU10).

Where updated data and assumptions were available at time of publication of the CY 2021 proposed rule, we have made adjustments to applicable ICRs. We are removing two of our currently approved ICRs [(1) quality performance category data submission by CMS Web Interface collection type and (2) group registration for the CMS Web Interface] as a result of the proposal to sunset the CMS Web Interface. Four ICRs [(1) quality performance category data submission by QCDR and MIPS CQM collection type, (2) quality performance category data

submission by eCQM collection type, (3) nomination of improvement activities, and (4) reweighting applications for Promoting Interoperability and other performance categories] reflect changes in burden due to proposed policies in the CY 2021 proposed rule. We estimate the proposed policies will result in a decrease in burden of -5,588 hours and -$490,680. In total, we estimate an increase in burden of 66,876 hours and $6,604,565 due to updated data and assumptions as well as proposed policies. The proposal to sunset the CMS Web Interface measures as a collection type/submission type starting with the 2021 performance period will increase the number of respondents for both the MIPS CQM and QCDR and eCQM collection types for the quality performance category by 50 and 61 respondents, respectively, as we assume respondents who previously submitted via the CMS Web Interface collection type will alternatively utilize one of these collection types to submit quality data. The proposal to require nominated improvement activities to be linked to existing and related quality and cost measures, as applicable and feasible will increase the time by 1 hour per improvement activity nominated. Finally, the proposal to allow APM Entities the ability to submit an extreme and uncontrollable circumstances exception application will increase our estimated number of respondents by 7 APM Entities. The remaining changes to our currently approved burden estimates are adjustments due to the use of updated data sources available at the time of publication of the proposed rule.

We have also proposed to add two new ICRs: the Open Authorization (OAuth) Credentialing and Token Request Process and the Nomination of MVPs. The OAuth Credentialing and Token Request Process ICR reflects the burden associated with a process for all submitter types to request approval to submit data via direct upload to CMS. The Nomination of MVPs reflects the burden associated with a new process available for all stakeholders to nominate MVPs for inclusion in the Quality Payment Program. We are submitting the new stakeholder submissions of MVP candidates instruction and template form for approval.

1. Data Collection for MIPS

    a. Quality Performance Category

The processes for reporting quality performance category data will be generally the same for the 2021 MIPS performance period as they were in the 2020 MIPS performance period. 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.

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(q)(5)(F) of the Act, as amended by section 4002(b)(1)(B) of the 21st Century Cures Act, as our authority for these exemptions.

b. 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.

For the 2021 MIPS performance period, we are proposing a scoring methodology in the CY 2021 PFS proposed rule, which reflects our decisions to include the proposed name change to the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure and the continuation of the optional Query of PDMP measure for CY 2021. Under this scoring methodology, MIPS eligible clinicians are 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 and the optional Query of PDMP, which require "yes/no" responses. In addition, we are proposing the new Health Information Exchange (HIE) Bi-Directional Exchange measure in the CY 2021 PFS proposed rule which will also require a "yes/no" response. Each measure would contribute to the MIPS eligible clinician's total Promoting Interoperability performance category score.

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, quality, cost, and/or improvement activities performance categories under specific circumstances (81 FR 77240 through 77243, 82 FR 53680 through 53686, and 82 FR 53783 through 53785). In the CY 2021 PFS proposed rule, we are proposing that, beginning with the 2022 MIPS payment year (2020 performance year), APM Entities may submit an extreme and uncontrollable circumstances exception application for all four performance categories and applicable to all MIPS eligible clinicians in the APM Entity group. Due to data limitations and our inability to determine who would use the APM Performance Pathway versus the traditional MIPS submission mechanism for the 2021 MIPS performance period, we assume ACO APM Entities will submit data through the APM Performance Pathway and non-ACO APM Entities would participate through traditional MIPS, thereby submitting as an individual or group rather than as an entity. Therefore, we limited our analysis to ACOs that were eligible for an exception due to extreme and uncontrollable circumstances during the 2019 MIPS performance period and elected not to report quality data. Based on this data, we estimate 7 APM Entities will submit an extreme and uncontrollable circumstances exception application for the 2021 MIPS performance period. We rely on section 1848(q)(5)(F) and section 1848(o)(2)(D) of the Act, as amended by section 4002(b)(1)(B) of the 21st Century Cures Act, as our authority for these exemptions.

c. Improvement Activities Performance Category

Under MIPS, clinical practice improvement activities are referred to as improvement activities. 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. We are not proposing any changes to the scoring methodology for the 2021 MIPS performance period.

d. Cost Performance Category

Under MIPS, we refer to the resource use performance category as "cost." The cost performance category measures are derived from the Medicare Parts A and B claims submission process. Cost performance category measures do not result in any submission burden because individual MIPS eligible clinicians are not asked to provide any documentation beyond the claims submission process.

e. Additional Data Collection

Under MIPS, there are information collections beyond performance category data submission. Other data submitted on behalf of MIPS eligible clinicians include virtual group elections, CAHPS for MIPS registrations, and reweighting applications.

The policies finalized in Quality Payment Program and PFS final rules from CY 2017 through CY 2020 and proposed in the CY 2021 PFS proposed rule and proposed create some additional data collection requirements not listed in Table 2. The additional data collections consist of:

- Self-nomination and ther requirements for new and returning QCDRs
- Self-nomination and other requirements for new and returning qualified registries
- Open Authorization Credentialing and Token Request Process
- 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
- Nomination of MVPs
- 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 2021 QP Performance Period, we define Partial QPs to be eligible clinicians in Advanced APMs who collectively have at least 50 percent, but less than 75 percent, of their payments for Part B covered professional services through an APM Entity, or furnish Part B covered professional services to at least 35 percent, but less than 50 percent, of their Medicare beneficiaries through

an APM Entity. If an Advanced APM Entity is notified that they attain Partial QP status, 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 and would receive a MIPS payment adjustment. If an eligible clinician does not attain either QP or Partial QP status, and does not meet any another exemption category, the eligible clinician would be subject to MIPS, would report to MIPS, and would receive the corresponding MIPS payment adjustment.

As detailed in CMS 5522-FC, 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. This Option allows for eligible clinicians to achieve QP status through their participation in both Advanced APMs and 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, we provided in the CY 2018 Quality Payment Program final rule 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 also request that we determine whether other payer arrangements are Other Payer Advanced APMs (82 FR 53867). In the CY 2019 PFS final rule, we finalized to eliminate the Payer Initiated Process that is specifically for CMS Multi-Payer Models.

As finalized in the CY 2018 Quality Payment Program, APM Entities and eligible clinicians participating in other payer arrangements 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). As finalized in the CY 2018 Quality Payment Program final rule, 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) via the eligible clinician-initiated determination process for Other Payer Advanced APMs.

We finalized in the CY 2017 Quality Payment Program final rule that 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). 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 cannot assess the eligible clinicians under the All-Payer Combination Option.

As explained in the CY 2018 Quality Payment Program final rule, in order for us to make QP determinations under the All-Payer Combination Option using either the payment amount or patient count method, we 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). In the same rule, we finalized that APM Entities or eligible clinicians must submit all of the required information about the Other Payer Advanced APMs in which they participate, including those for which there is a pending request for an Other Payer Advanced APM determination, as well as the payment amount and patient count information sufficient by 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 is available to all TINs participating in Full TIN APMs, such as the Medicare Shared Savings Program. To make QP determinations under the All-Payer Combination Option at the TIN level 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.

B Justification

1. Need and Legal Basis

Our authority for collecting this information is provided by Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10, April 16, 2015) which further amended section 1848 and 1833 of the Act, respectively.

Section 1848(q) of the Act requires the establishment of the MIPS beginning with payments for items and services furnished on or after January 1, 2019, under which the Secretary is required to: (1) develop a methodology for assessing the total performance of each MIPS eligible clinician according to performance standards for a performance period; (2) using the methodology, provide a final score for each MIPS eligible clinician for each performance period; and (3) use the final score of the MIPS eligible clinician for a performance period to determine and apply a MIPS adjustment factor (and, as applicable, an additional MIPS adjustment factor for exceptional performance) to the MIPS eligible clinician for a performance period. Under section 1848(q)(2)(A) of the Act, a MIPS eligible clinician's final score is determined using four performance categories: (1) quality; (2) cost; (3) improvement activities, and (4) Promoting Interoperability. Section 1833(z) of the Act establishes incentive payments for clinicians who are qualifying participants in advanced APMs.

2. Information Users

CMS will use data reported by MIPS eligible clinicians 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. Information provided by third party intermediaries may also be used for administrative purposes such as determining third party intermediaries and QCDR measures appropriate for the MIPS program. Information provided by clinicians, professional societies, and other respondents will be used to consider quality and Promoting Interoperability measures, improvement activities, and MVPs for inclusion in the MIPS program. Information provided by payers, APM Entities, and eligible clinicians will be used to determine 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. Clinicians and beneficiaries can view MIPS performance period data and final scores on Physician Compare. 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.

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. Lastly, CMS will make available a Public Use File in August 2020 or later which presents a comprehensive data set on performance of all clinicians across all categories, measures, and activities for MIPS.

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 external to MIPS.

With respect to participating in MIPS for MIPS APMs, CMS has set forth requirements that encourage limiting duplication of effort, but in the interest of providing flexibility in reporting, we cannot ensure that duplication does not occur. 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 2021 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. For clinicians in APM Entities, the APM Performance Pathway is available for both ACOs and non ACOs to submit quality data. We assume ACO APM Entities will submit data through the APM Performance Pathway and non-ACO APM Entities would participate through traditional MIPS, thereby submitting as an individual or group rather than as an entity.

5. Small Businesses

Because the vast majority of Medicare clinicians that receive Medicare payment under the PFS (approximately 95 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 2021 PFS proposed rule's Regulatory Impact Analysis estimates that approximately 931,050 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 80,454 clinicians in eligible specialties will be excluded from MIPS data submission requirements because they do not have sufficient charges, services or beneficiaries under the PFS and thus do not meet opt-in volume criteria. Further, we exclude an additional 220,305 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 of the CY 2021 PFS proposed rule, we explain that we assume 931,050 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 20,059 clinicians or 33 percent of clinicians who exceed at least one but not all low-volume threshold and submitted data in the 2018 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.

[3] For further detail on MIPS exclusions, see Supporting Statement B and the Regulatory Impact Analysis Section of the CY 2021 PFS proposed rule.

Additionally, we estimate that for the 2021 QP Performance Period between 196,000 and 252,000 eligible clinicians will become QPs, therefore be excluded from MIPS, and qualify for the lump sum APM incentive payment in Payment Year 2023 based on 5 percent of their Part B paid amounts for covered professional services in the preceding year.

6. Less Frequent Collection

Data on the quality, Promoting Interoperability, and improvement activities performance categories are collected from individual MIPS eligible clinicians or groups annually. If this information was collected less frequently, 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. We require additional data collections to be performed annually in order to allow us to determine which clinicians are required to report MIPS data.

Third party intermediaries are required to self-nominate annually. If qualified registries and QCDRs are not required to submit a self-nomination statement on an annual basis, 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.

7. Special Circumstances

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

- Report information to the agency more often than quarterly;
- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than 3 years;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study;
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register/Outside Consultation

Serving as the 60-day notice, the proposed rule (CMS-1734-P, RIN 0938-AU10) filed for public inspection on August 4, 2020, and published in the Federal Register on August 17 (85 FR 50074). Public comments are due on/by October 5, 2020.

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.

More detail on how the payments are calculated can be found in 42 CFR §414.1405 and §414.1450.

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. Otherwise, there are no sensitive questions associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Burden Estimates

a. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2019 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.

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, Medical and health services manager, 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]

We previously used the BLS wage rate for "Physicians and Surgeons" (occupation code 29-1060) to estimate the burden for Physicians. In BLS' most recent set of occupational wage rates, they have discontinued this occupation in their wage data. As a result, in order to estimate the burden for Physicians, we are using a rate of $212.78/hr which is the average of the mean wage rates for Anesthesiologists; Family Medicine Physicians; General Internal Medicine Physicians; Obstetricians and Gynecologists; Pediatricians, General; Physicians, All Other; and Ophthalmologists, Except Pediatric; Psychiatrists; and Surgeons, Except Ophthalmologists [($251.66 + $205.06/hr + $193.70/hr + $224.62/hr + $177.32/hr + $195.62/hr + $211.96 + $242.34/hr) ÷ 8].

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)
Anesthesiologists	29-1211	125.83	125.83	251.66
Billing and Posting Clerks	43-3021	19.53	19.53	39.06
Computer Systems Analysts	15-1211	46.23	46.23	92.46
Family Medicine Physicians	29-1215	102.53	102.53	205.06
General Internal Medicine Physicians	29-1216	96.85	96.85	193.70
Health Diagnosing and Treating Practitioners	29-1000	49.26	49.26	98.52
Licensed Practical Nurse (LPN)	29-2061	23.32	23.32	46.64
Medical and Health Services Managers	11-9111	55.37	55.37	110.74
Obstetricians and Gynecologists	29-1218	112.31	112.31	224.62
Pediatricians, General	29-1221	88.66	88.66	177.32
Physicians, All Other; and Ophthalmologists, Except Pediatric	29-1228	97.81	97.81	195.62
Psychiatrists	29-1223	105.98	105.98	211.96
Surgeons, Except Ophthalmologists	29-1248	121.17	121.17	242.34

b. 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

[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.

Advanced APM participant. As shown in the first row of Table 2, MIPS eligible clinicians and other clinicians voluntarily submitting data will submit data either as individuals, groups, APM Entities or virtual groups for the quality, Promoting Interoperability, and improvement activities performance categories. Note that virtual groups are subject to the same data submission requirements as groups, and therefore, we will refer only to groups for the remainder of this section unless otherwise noted. 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. As discussed in the CY 2021 PFS proposed rule, for clinicians in APM Entities, the APM Performance Pathway is available for both ACO and non ACOs to submit quality data. Due to data limitations and our inability to determine who would use the APM Performance Pathway versus the traditional MIPS submission mechanism for the 2021 MIPS performance period, we assume ACO APM Entities will submit data through the APM Performance Pathway and non-ACO APM Entities would participate through traditional MIPS, thereby submitting as an individual or group rather than as an entity.

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 described 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 APM have qualified for the maximum improvement activities score. Therefore, we assume that no additional submission will be needed.

Eligible clinicians who attain Partial QP status 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).

TABLE 2: Clinicians and Organizations Submitting MIPS Data on Behalf of Clinicians by Type of Data*

Clinicians and Organizations	Quality Performance Category Data	PI Performance Category Data	Improvement Activities Performance Category Data	Other Data Submitted on Behalf of MIPS Eligible Clinicians
MIPS Eligible Clinicians and Other Eligible Clinicians Voluntarily Submitting MIPS Data, Participating in Shared Savings Program, and other MIPS APMs that use the APM Performance Pathway for model measures	As virtual group, group, individual clinicians, or APM Entity.[a]	As virtual group, group, individual clinicians, or APM Entity. Certain MIPS eligible clinicians are automatically eligible for a zero percent weighting for the Promoting Interoperability performance category (please refer to the CY 2020 PFS final rule for a summary of the finalized criteria (84 FR 63111)). Clinicians who submit an application and are approved for significant hardship or other exceptions are also eligible for a zero percent weighting. 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 for this proposed rule assume group TIN-level reporting].[b]	As virtual group, group, or individual clinicians. MIPS APMs do not submit information. 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.[c]	Groups electing to use a CMS-approved survey vendor to administer CAHPS must register. MIPS APMs electing the APM Performance Pathway. APM Entities will make Partial QP election for participating eligible clinicians. Virtual groups must register via email.[d]

* 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.

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

[b] 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.

[c] The burden estimates assume 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 participating in MIPS APMs receive an improvement activities performance category score of at least 50 percent (42 CFR 414.1380) and do not need to submit improvement activities data unless the CMS-assigned improvement activities scores are below the maximum improvement activities score.

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

The policies finalized in the CY 2017 and CY 2018 Quality Payment Program final rules and CY 2019 and CY 2020 PFS final rules and proposed in the CY 2021 PFS proposed rule create some additional data collection requirements not listed in Table 2. These additional data collections consist of:

- Self-nomination of new and returning QCDRs
- Self-nomination of new and returning qualified registries
- Open Authorization Credentialing and Token Request Process
- 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
- Nomination of MVPs
- 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

c. 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. 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 nominate QCDR measures for approval for the reporting of quality performance category data. 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:

i. Burden for Qualified Registry Self-Nomination and other Requirements

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).

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. 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. The self-nomination period is from July 1 to September 1 of the calendar year prior to the applicable performance period.

In section IV.A.3.g.(3)(a) of the CY 2021 PFS proposed rule, we are proposing to codify that beginning with the 2023 payment year as a condition of approval each qualified registry must conduct an annual data validation audit that conforms to the requirements in § 414.1400(b)(2)(iv), including specific obligations discussed in detail in those sections and if one or more deficiencies or data errors are identified the qualified registry must also conduct targeted audits that conform to the § 414.1400(b)(2)(v) including specific obligations discussed in detail in those sections. In particular, we propose to codify at § 414.1400(c)(2)(iii)(G), that in a form and manner and by a deadline specified by CMS, the qualified registry must report data validation results, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by any deficiency or data error, and how and when each deficiency or data error type was corrected. In addition, we propose to codify at § 414.1400(c)(2)(iv)(D), in a form and manner and by a deadline specified by CMS, the qualified registry must report the results of each targeted audit, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by each deficiency or data error, and how and when each error type was corrected. We are not revising our burden estimates as a result of the proposal to codify that qualified registries must conduct particular data validation audits and report data validation results because we believe the burdens of the proposed data validation requirements are not greater than existing expectations for which we have already accounted for the associated burden as stated in the CY 2017 Quality Payment Program final rule (81 FR 77383 through 77384) and the CY 2019 PFS final rule (83 FR 59998 through 59999) and previously submitted to OMB for approval under control number 0938-1314 (CMS-10621). With regard to the proposal to require qualified registries conduct targeted audits if one or more data errors are identified during data validation audits, we are unable to estimate the number of targeted audits which may occur or the time and costs associated with submitting results which could vary substantially depending on the nature of the data error and the amount of data to be audited. We are seeking comment on the burdens associated with the proposed requirements for data validation audits and targeted audits,

including expected frequency of targeted audits and the anticipated scope of effort related to submitting results to assist in estimating the burden associated with this proposal and may update our burden estimates in the CY 2021 PFS final rule.

We are neither proposing changes to the currently approved number of 135 qualified registries which will self-nominate during the 2021 MIPS performance period nor the burden per respondent ranging from 0.5 hours for the simplified self-nomination form to 3 hours for the full self-nomination form. The burden associated with the qualified registry self-nomination process varies depending on the number of existing qualified registries that 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 QPP Self-Nomination Form is submitted electronically using a web-based tool. We will be submitting a revised version of the form for approval under OMB control number 0938-1314 (CMS-10621). 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).

We assume that the staff involved in the qualified registry self-nomination process will continue to be computer systems analysts or their equivalent, who have an average labor rate of $92.46/hr. Because our estimate of the time per qualified registry associated with the self-nomination process ranges from a minimum of 0.5 hours to a maximum of 3 hours, we estimate that the annual burden for self-nomination will range from 76.5 hours (153 qualified registries x 0.5 hr) to 459 hours (153 qualified registries x 3 hr) at a cost ranging from $7,073 (76.5 hr x $92.46/hr) and $42,439 (459 hr x $92.46/hr), respectively (see Table 3A).

In section VI.A.3.g.(4) of the CY 2021 PFS proposed rule, we are proposing to modify the existing requirement for third party intermediaries to submit to CMS by a date specified by the agency a Corrective Action Plan (CAP) to address identified deficiencies or data issues, including the actions it will take to prevent the deficiencies or data issues from recurring. While the requirement for third party intermediaries to submit a CAP was finalized in our CY 2017 Quality Payment Program final rule (81 FR 77389), we did not specify the information that must be included in the CAP and neglected to identify the burden associated with the required information. We are correcting that oversight in the proposed rule. We are further proposing that, unless different or additional information is specified by CMS, the CAP submitted by the third party intermediary must address four issues: (1) the issues that contributed to the non-compliance; (2) the impact to individual clinicians, groups, or virtual groups, regardless of whether they are participating in the program because they are MIPS eligible, voluntary participating, or opting in to participating in the MIPS program; (3) the corrective actions to be implemented by the third party intermediary to ensure that the non-compliance has been resolved will not recur in the future and (4) the detailed timeline for achieving compliance with the applicable requirements. Specifically, we are proposing to require that each third party intermediary be required to articulate the issues that contributed to the non-compliance; what factors caused it to fail in its obligation to meet program requirements; and to disclose to CMS the impact to individual clinicians, groups, or virtual groups, regardless of whether they are participating in the program because they are MIPS eligible, voluntary participating, or opting in

to participating in the MIPS program. The third party intermediary must address the corrective actions to be implemented to ensure that the non-compliance has been resolved and will not recur in the future and must include the detailed timeline for achieving compliance with the applicable requirements.

We have historically received a total of 34 CAPs over the 3 year period of CY 2017-2019 (an average of 11.3 per year). As third party intermediaries become increasingly effective at identifying data issues and discrepancies prior to submitting data to CMS and accounting for the estimated decrease in number of QCDRs and qualified registries self-nominating in the 2020 MIPS performance period compared to the 2019 MIPS performance period (from 350 to 229), we anticipate the annual number of CAPs received to decrease to fewer than 10 per year (83 FR 59997 through 60000 and 84 FR 63114 through 63121). The effort involved in developing a CAP including the detail specified in this proposed rule and submitting it to CMS is likely to be no more than 3 hours for a computer systems analyst at a rate of $92.46/hr. In aggregate we estimate an annual burden of no more than 30 hours (3 hr x 10 CAPs) at a cost of $2,774 (30 hr x $92.46/hr) for third party intermediaries to develop and submit a CAP. Because we are unable to predict how many of the estimated 10 third party intermediaries submitting CAPs will be qualified registries, QCDRs, survey vendors, or Health IT vendors; for simplicity we are adding the burden to the currently approved burden for qualified registries for a minimum total of 106.5 hours (76.5 hr + 30 hr) at a cost of $9,866 ($7,073 + $2,774) and maximum of 489 hours (459 hr + 30 hr) at a cost of $45,213 ($42,439 + $2,774).

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 3A 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.

TABLE 3A: Estimated Burden for Qualified Registry Self-Nomination

Burden and Respondent Descriptions	**Minimum Burden**	**Maximum Burden**
# of Qualified Registry Simplified Self-Nomination Applications submitted (a)	153	0
# of Qualified Registry Full Self-Nomination Applications submitted (b)	0	153
Total Applications	**153**	**153**
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 Self-Nomination (e) = (a)*(c)+(b)*(d)	**76.5**	**459**
# of Corrective Action Plans submitted (f)	10	10

Burden and Respondent Descriptions	Minimum Burden	Maximum Burden
Hours per Corrective Action Plan (g)	3	3
Total Annual Hours (h) = (e)+(f)*(g)	**106.5**	**489**
Computer systems analyst's labor rate of $92.46/hr (i)	**$92.46/hr**	**$92.46/hr**
Total Annual Cost (j) = (h)*(i)	**$9,866**	**$45,213**

ii. Burden for QCDR Self-Nomination and Other Requirements[5]

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.

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. 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. The self-nomination period is from July 1 to September 1 of the calendar year prior to the applicable performance period (83 FR 59898).

In section VI.A.3.g.(2)(a) of the CY 2021 PFS proposed rule, we are proposing identical requirements related to annual data validation audits and targeted audits for QCDRs as previously discussed for qualified registries. We are not revising our burden estimates as a result of the proposal to codify that QCDRs must conduct particular data validation audits and report data validation results because we believe the burdens of the proposed data validation requirements are not greater than existing expectations for which we have already accounted the associated burden as stated in the CY 2017 Quality Payment Program final rule (81 FR 77383 through 77384) and the CY 2019 PFS final rule (83 FR 59998 through 59999) and previously submitted to OMB for approval under control number 0938-1314 (CMS-10621). With regard to the proposal to require QCDRs to conduct targeted audits if one or more data errors are identified during data validation audits, we are unable to estimate the number of targeted audits which may occur or the time and costs associated with submitting results which could vary substantially depending on the nature of the data error and the amount of data to be audited. We are seeking comment on the burdens associated with the proposed requirements for data validation audits and targeted audits, including expected frequency of targeted audits and the anticipated scope of effort related to submitting results to assist in estimating the burden associated with this proposal and may update our burden estimates in the CY 2021 PFS final rule.

We are neither proposing changes to the currently approved number of 76 QCDRs which will self-nominate during the 2021 MIPS performance period nor the burden per respondent ranging from 5.5 hours for the simplified self-nomination form to 8 hours for the full self-nomination form. 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

[5] 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.

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.

We estimate that the self-nomination process for QCDRs to submit on behalf of MIPS eligible clinicians or groups for MIPS will involve approximately 3 hours per QCDR to submit information required at the time of self-nomination as described in the CY 2017 Quality Payment Program final rule including basic information about the QCDR, describing the process it will use for completion of a randomized audit of a subset of data prior to submission, providing a data validation plan, and providing results of the executed data validation plan by May 31 of the year following the performance period (81 FR 77383 through 77384). However, for the simplified self-nomination process, we estimate 0.5 hours per QCDR to submit this information.

QCDRs must 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. QCDRs are also required to link their QCDR measures as feasible to at least one of the following, at the time of self-nomination: (a) cost measures, (b) improvement activities, or (c) MIPS Value Pathways. We estimate that a QCDR will spend an additional 1 hour performing these activities per measure, on average.

In aggregate, we estimate a QCDR will require 2.5 hours per QCDR measure and will submit 2 QCDR measures for approval, on average. Therefore, we estimate each QCDR will require 5 hours (2 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. 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 $92.46/hr. Because our estimate of the time per QCDR associated with the self-nomination process ranges from a minimum of 5.5 hours to a maximum of 8 hours, we estimate that the annual burden will range from 418 hours (76 QCDRs x 5.5 hr) to 608 hours (76 QCDRs x 8 hr) at a cost ranging from $38,648 (418 hr x $92.46/hr) and $56,216 (608 hr x $92.46/hr), respectively (see Table 4A).

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. Therefore, we believe the 608 hour estimate 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 4A: Estimated Burden for QCDR Self-Nomination

Burden and Respondent Descriptions	**Minimum Burden**	**Maximum Burden**
# of QCDR Simplified Self-Nomination Applications submitted (a)	76	0
# of QCDR Full Self-Nomination Applications submitted (b)	0	76
Total Applications	**76**	**76**
Total Annual Hours Per QCDR for Simplified Process (c)	5.5	5.5
Total Annual Hours Per QCDR for Full Process (d)	8	8
Total Annual Hours (e) = (a)*(c)+(b)*(d)	**418**	**608**
Computer systems analyst's labor rate of $92.46/hr (f)	**$92.46/hr**	**$92.46/hr**
Total Annual Cost (g) = (e)*(f)	**$38,648**	**$56,216**

d. Burden Estimate for the Open Authorization (OAuth) Credentialing and Token Request Process

The following burden estimates are associated with the first year of data collection for the OAuth Credentialing and Token Request Process. This process is available to all submitter types to be approved to submit data via the direct submission type. However, we assume the only parties that will elect to undergo the process will be health IT vendors or other third party intermediaries, as we believe these are the most likely parties to be developing applications. The burden associated with this ICR belongs only to the application developer; QPP participants will not be required to do anything additional to submit their data. For third party intermediaries, OAuth Credentialing will allow QPP participants to use their own QPP credentials to login through the third party intermediary's application to submit their data and view performance feedback from QPP.

Individual clinicians or groups may submit their quality measures using the direct submission type via the MIPS CQM and QCDR or eCQM collection types as well as their Promoting Interoperability measures and improvement activities through the same direct submission type. Entities that receive approval for their applications through this process will be able to provide QPP participants a more comprehensive and less administratively burdensome experience using the direct submission type. Entities that receive approval for their applications through this process will be able to provide QPP participants a more comprehensive and less administratively burdensome experience using the direct submission type.

Beginning in the 2021 MIPS performance period, CMS will offer the Open Authorization Credentialing and Token Request Process. This process utilizes an API to allow users to transmit data through a computer-to-computer interaction. As such, it is an alternate means of operationalizing the previously established direct submission type. The process first requires software developers to apply for production OAuth credentials to the submissions API by registering their application so that it can interact with the system providing OAuth capabilities. Next, the developer must request a meeting with the Quality Payment Program development

team. During this meeting, the requesting organization will demonstrate their application's use of OAuth to successfully submit data in the Submissions API test environment. The requesting organization will also provide documentation about their terms of service, privacy policy, and related information for review by the Quality Payment Program team. If further clarification is required about any of the documentation or application, the Quality Payment Program team will follow up with the requesting organization. Once approved, the Quality Payment Program development team will issue production OAuth credentials to the requesting organization's point of contact. Detailed instructions for the authentication process and application for organizations to request OAuth credentials are available at https://cmsgov.github.io/qpp-submissions-docs/. We estimate it would take approximately 1 hour at $92.46/hr for a computer systems analyst (or their equivalent) to provide documentation and any follow-up communication via email.

We estimate that for during the 2021 MIPS performance period, 15 submitter types, consisting of third party intermediaries will complete this process to be approved for the CY 2022 submission period. We expect health IT vendors to adopt this method initially, with limited further adoption by QCDRs and Qualified Registries in future years. As shown in Table 5A, we estimate it would take 1 hour at $92.46/hr for a computer systems analyst (or their equivalent) to complete the process. We estimate an annual burden of 15 hours (15 vendors x 1 hr) at a cost of $1,387 (15 hr x $92.46/hr) or $92.46 per organization ($1,387/15 vendors).

TABLE 5A: Estimated Burden for the OAuth Credentialing and Token Request Process

Burden and Respondent Descriptions	**Burden Estimate**
# of Organizations (a)	15
Total Annual Hours Per Organization to Submit (b)	1
Total Annual Hours (c) = (a)*(b)	**15**
Cost Per Organization (@ computer systems analyst's labor rate of $92.46/hr.) (d)	$92.46/hr
Total Annual Cost (e) = (a)*(d)	**$1,387**

e. Burden Estimate for the Quality Performance Category

Under our current policies, two groups of clinicians must submit quality data under MIPS: those who submit as MIPS eligible clinicians and those who opt to submit data voluntarily but are not subject to MIPS payment adjustments. Clinicians are ineligible for MIPS payment adjustments if they are newly enrolled to Medicare; are QPs; are partial QPs who elect to not participate in MIPS; are not one of the clinician types included in the definition for MIPS eligible clinician; or do not exceed the low-volume threshold as an individual or as a group.

To determine which QPs should be excluded from MIPS, we used the QP List for the 2019 third snapshot that contains participation in Advanced APMs as of August 31, 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 (QP) definition at § 414.1305 for the 2021 QP Performance Period. We assumed that all Partial QPs will participate in MIPS data collections. Due to data limitations, we could not identify specific clinicians who have not yet enrolled in APMs, but who may become QPs in the future 2021 QP Performance Period (and therefore will no longer need to submit data to MIPS); hence, our model may underestimate or overestimate the number of respondents.

In the CY 2021 PFS proposed rule, we are proposing to sunset the CMS Web Interface measures as a collection type/submission type starting with the 2021 performance period. If this proposal is finalized, it will result in groups of 25 or more clinicians that previously submitted quality performance data via the CMS Web Interface being required to use an alternate collection type, which will have to be either the MIPS CQM and QCDR or eCQM collection type. From 2017 to 2019, the number of groups eligible to report quality measures via the CMS Web Interface (groups registered to utilize the CMS Web Interface) decreased by approximately 45 percent. Similarly, the number of groups utilizing the CMS Web Interface as a collection type decreased by approximately 40 percent from 2017 to 2019. We believe this is evidence that groups are being increasing disinclined to utilize the CMS Web Interface as their preferred option. While we know that 111 groups submitted quality performance data via the CMS Web Interface in the 2019 MIPS performance period, we are not able to ascertain what alternative collection type(s) the groups would elect. In order to estimate the number of groups that will select each of these collection types, we first clustered the number of groups which submitted data via the CMS Web Interface collection type during the 2018 MIPS performance period by practice size (between 25 and 49 clinicians, between 50 and 99 clinicians, etc.). Then, for each cluster, we allocated these groups to each of the MIPS CQM and QCDR and eCQM collection types based on the percent of TINs that submitted MIPS data via these two collection types. For example, of the 1,335 TINs with a practice size of 25 to 49 clinicians which submitted data for the 2018 MIPS performance period, 974 (73 percent) submitted data via the MIPS CQM and QCDR collection type and 361 (27 percent) submitted data via the eCQM collection type. We applied these percentages to the 11 TINs with a practice size of 25 to 49 clinicians which submitted data via the CMS Web Interface collection type for the 2018 MIPS performance period to estimate that 8 (11 TINs x 0.73) would elect to submit data via the MIPS CQM and QCDR collection type and the remaining 3 (11 TINs x 0.27) would elect to submit data via the eCQM collection type. In total, we estimate that 50 of the 111 groups that submitted data via the CMS Web Interface collection type for the 2018 MIPS performance period will now submit quality data via the MIPS CQM and QCDR collection type and 61 groups will now submit quality data via the eCQM collection type. Note that the 111 groups is an increase of 7 from our currently approved estimate of 104 groups due to updated data (84 FR 63123) (111 groups – 104 groups). We also performed this analysis to determine the number of clinicians that would be affected and would need to submit quality data via an alternate collection type. In total, of the estimated 39,318 individual clinicians affected by this proposal, we estimate that 11,448 would submit quality data as part of a group via the MIPS CQM and QCDR collection type and 27,870 would submit quality data as part of a group via the eCQM collection type. These respondent estimates are reflected in Tables 6A and 8A and the associated changes in burden are reflected in Tables 11A and 12A.

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). In the CY 2020 PFS final rule, we provided a set of assumptions and an approach to account for the clinicians not in small practices for whom the Medicare Part B claims collection type will no longer be available as an option for collecting and reporting quality data (84 FR 63121 through 63122). As in the CY 2020 PFS final rule, we are using 2018 MIPS performance period data to estimate the number of respondents, so we use the same methodology. Our assumptions result in a 101,390 decrease (from 195,977 to 94,587 in the estimated number of clinicians who will

submit quality data via Medicare Part B claims and a 12,496 increase (from 92,340 to 104,836) in the number of clinicians who will submit via the MIPS CQM and QCDR collection type.

We assume that 100 percent of ACO APM Entities will submit quality data to CMS as required under their models. While we do not believe there is additional reporting for ACO APM entities, consistent with assumptions used in the CY 2019 and CY 2020 PFS final rules (83 FR 60000 through 60001 and 84 FR 63122), we include all quality data voluntarily submitted by MIPS APM participants made at the individual or TIN-level in our respondent estimates. As stated in section VI.4.a.(4) of this proposed rule, we assume non-ACO APM Entities will participate through traditional MIPS and submit as an individual or group rather than as an entity. To estimate who will be a MIPS APM participant in the 2021 MIPS performance period, we used the latest QP List for the third snapshot data of the 2019 QP performance period and supplemented with clinicians who are in an APM in 2018 but not in the 2019 snapshot. 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 2018 MIPS performance period.

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 6A, 7A, and 8A 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 6 provides our estimated counts of clinicians that will submit quality performance category data as MIPS individual clinicians or groups in the 2021 MIPS performance period based on data from the 2018 MIPS performance period.

For the 2021 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, and eCQMs. 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 6 shows that in the 2020 MIPS performance period, an estimated 94,587 clinicians will submit data as individuals for the Medicare Part B claims collection type; 410,518 clinicians will submit data as individuals or as part of groups for the MIPS CQM or QCDR collection types; and 286,956 clinicians will submit data as individuals or as part of groups via eCQM collection type.

Table 6 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 6: Estimated Number of Clinicians Submitting Quality Performance Category Data by Collection Type

Data Description	Claims	QCDR/MIPS CQM	eCQM	CMS Web Interface	Total
2021 MIPS performance period (excludes QPs) (a)	94,587	410,518	286,956	0	792,061
*2020 MIPS performance period (excludes QPs) (b)	94,846	391,430	247,856	46,473	780,605
Difference (c)=(a)-(b)	-259	+19,088	+39,100	-46,473	+11,456

*Currently Approved

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 2018 MIPS performance period.

Table 7 uses methods similar to those described to estimate the number of clinicians that will submit data as individual clinicians via each collection type in the 2021 MIPS performance period. We estimate that approximately 94,587 clinicians will submit data as individuals using the Medicare Part B claims collection type; approximately 104,836 clinicians will submit data as individuals using MIPS CQM and QCDR collection type; and approximately 41,477 clinicians will submit data as individuals using eCQMs collection type.

TABLE 7: 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
2021 MIPS Performance Period (excludes QPs) (a)	94,587	104,836	41,477	0	240,900
* 2020 MIPS Performance Period (excludes QPs) (b)	94,846	100,269	38,935	0	234,050
Difference (c)=(a)-(b)	-259	+4,567	+2,542	0	+6,850

*Currently Approved

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 7 are not mutually exclusive.

Table 8 provides our estimated counts of groups or virtual groups that will submit quality data on behalf of clinicians for each collection type in the 2021 MIPS performance period. We assume that groups that submitted quality data as groups in the 2018 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 2021 MIPS performance period. Specifically, we estimate that 11,071 groups and virtual groups will submit data for the MIPS CQM and QCDR collection type on behalf of 305,682 clinicians; and 4,474 groups and virtual groups will submit for eCQM collection types on behalf of 245,479 eligible clinicians. In the CY 2021 PFS proposed rule, we are proposing the APM Performance Pathway for clinicians in APM Entities. The APM Performance Pathway is available for both ACO and non ACOs. However, due to data limitations and our inability to determine who would use the APM Performance Pathway versus the traditional MIPS submission mechanism, we assume non-ACO APM Entities would participate through traditional MIPS and base our estimates on submissions received in the 2018 MIPS performance period.

TABLE 8: 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
2021 MIPS performance period (excludes QPs) (a)	0	11,071	4,474	0	15,545
*2020 MIPS performance period (b)	0	10,949	4,398	104	15,451
Difference (c)=(a)-(b)	0	+122	+76	-104	+94

*Currently Approved

The burden associated with the 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' workflows. 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.

i 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 CMSHealthcare Quality Information System (HCQIS) Access Roles and Profile (HARP) system 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 9A it would take 1 hour at $92.46/hr for a computer systems analyst (or their equivalent) to obtain an account for the HARP system. In aggregate we estimate an annual burden of 3,741 hours (3,741 registrations x 1 hr/registration) at a cost of $345,893 (3,741 hr x $92.46/hr) or $92.46 per registration.

TABLE 9A: 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 $92.46/hr.) (d)	$92.46
Total Annual Cost for completing the Identity Management Application Process (e) = (a)*(d)	$345,893

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

As noted in Table 7, based on 2018 MIPS performance period data, we assume that 94,587 individual clinicians will collect and submit quality data via the Medicare Part B claims collection type, a decrease of 259 from the currently approved estimate of 94,846 based on more recent data and our methodology of accounting only for clinicians in small practices who submitted such claims data in the 2018 MIPS performance period rather than all clinicians who submitted quality data codes to us for the Medicare Part B claims collection type.

As shown in Table 10A, consistent with our currently approved per response time figures, we estimate that the burden of quality data submission using Medicare Part B claims will range from 0.15 hours (9 minutes) at a cost of $13.87 (0.15 hr x $92.46/hr) to 7.2 hours at a cost of $665.71 (7.2 hr x $92.46/hr). The burden will involve becoming familiar with MIPS quality measure specifications. We believe that the start-up cost for a clinician's practice to review measure specifications is 7 hours, consisting of 3 hours at $110.74/hr for a medical and health services manager, 1 hour at $212.78/hr for a physician, 1 hour at $46.64/hr for an LPN, 1 hour at $92.46/hr for a computer systems analyst, and 1 hour at $39.06/hr for a billing and posting clerk. We are not revising our currently approved per response time 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 676,297 hours (7.15 hr x 94,587 clinicians) to 1,343,135 hours (14.2 hr x 94,587 clinicians). The estimated annual cost (per clinician) ranges from $737.03 [(0.15 hr x $92.46/hr) + (3 hr x $110.74/hr) + (1 hr x $92.46/hr) + (1 hr x $46.64/hr) + (1 hr x $39.06/hr) + (1 hr x $212.78/hr)] to a maximum of $1,388.87 [(7.2 hr x $92.46/hr) + (3 hr x $110.74/hr) + (1 hr x $92.46/hr) + (1 hr x $46.64/hr) + (1 hr x $39.06/hr) + (1 hr x $212.78/hr)]. The total annual cost ranges from a minimum of $69,713,362 (94,587 clinicians x $737.03) to a maximum of $131,369,236 (94,587 clinicians x $1,388.87).

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

TABLE 10A: 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)	94,587	94,587	94,587
Hours Per Clinician to Submit Quality Data (b)	0.15	1.05	7.2
# of Hours Medical and health services manager 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)	**676,297**	**761,425**	**1,343,135**
Cost to Submit Quality Data (@ computer systems analyst's labor rate of $92.46/hr @ varying times) (j)	$13.87	$97.08	$665.71
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $110.74/hr @ 3 hr) (k)	$332.22	$332.22	$332.22
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $92.46/hr @ 1 hr) (l)	$92.46	$92.46	$92.46
Cost to Review Measure Specifications (@ LPN's labor rate of $46.64/hr @1 hr) (m)	$46.64	$46.64	$46.64

Burden and Respondent Descriptions	Minimum Burden	Median Burden	Maximum Burden Estimate
Cost to Review Measure Specifications (@ billing clerk's labor rate of $39.06/hr @ 1 hr) (n)	$39.06	$39.06	$39.06
Cost to Review Measure Specifications (@ physician's labor rate of $212.78/hr @ 1 hr) (o)	$212.78	$212.78	$212.78
Total Annual Cost Per Clinician (p) = (j)+(k)+(l)+(m)+(n)+(o)	$737.03	$820.24	$1,388.87
Total Annual Cost (q) = (a)*(p)	**$69,713,362**	**$77,584,325**	**$131,369,236**

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

In the CY 2021 PFS proposed rule, we are proposing to sunset the CMS Web Interface measures as a collection type and submission type starting with the 2021 performance period. Using the methodology previously described, we estimate 50 groups which previously submitted quality data via the CMS Web Interface collection type will now submit quality data via the MIPS CQM and QCDR collection type.

As noted in Tables 6A, 7A, and 8A, and based on 2018 MIPS performance period data, we assume that 410,518 clinicians will submit quality data as individuals or groups using MIPS CQM or QCDR collection types; 104,836 clinicians will submit as individuals and the remaining 305,682 clinicians will submit as members of 11,071 groups and virtual groups. 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 quality measure specifications 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 $891.13. This consists of 3 hours at $92.46/hr for a computer systems analyst (or their equivalent) to submit quality data along with 2 hours at $110.74/hr for a medical and health services manager, 1 hour at $92.46/hr for a computer systems analyst, 1 hour at $46.64/hr for a LPN, 1 hour at $39.06/hr for a billing clerk, and 1 hour at $212.78/hr for a physician 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) at $92.46/hr for a computer systems analyst at a cost of $7.70 (0.083 hr x

$92.46/hr). Overall we estimate a cost of $897.47/response [(3 hr x $92.46/hr) + (2 hr x $110.74/hr) + (1 hr x $212.78/hr) + (1 hr x $92.46/hr) + (1 hr x $46.64/hr) + (1 hr x $39.06/hr) + (0.083 hr x $92.46/hr)].

In aggregate, we estimate an annual burden of 1,052,783 hours [9.083 hr/response x (104,836 clinicians submitting as individuals + 11,071 groups submitting via QCDR or MIPS CQM on behalf of individual clinicians or 115,907 responses)] at a cost of $ 104,023,540 (115,907 responses x $897.47/response). Based on these assumptions, we have estimated in Table 11A the burden for these submissions.

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

Burden and Respondent Descriptions	**Burden Estimate**
# of clinicians submitting as individuals (a)	104,836
# of groups submitting via QCDR or MIPS CQM on behalf of individual clinicians (b)	11,071
# of Respondents (groups and clinicians submitting as individuals) (c)=(a)+(b)	115,907
Hours Per Respondent to Report Quality Data (d)	3
# of Hours Medical and health services manager 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)	**1,052,783**
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of $92.46/hr) (m)	$277.38
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $110.74/hr) (n)	$221.48
Cost Computer System's Analyst Review Measure Specifications (@ computer systems analyst's labor rate of $92.46/hr) (o)	$92.46
Cost LPN Review Measure Specifications (@ LPN's labor rate of $46.64/hr) (p)	$46.64
Cost Billing Clerk Review Measure Specifications (@ clerk's labor rate of $39.06/hr) (q)	$39.06
Cost Physician Review Measure Specifications (@ physician's labor rate of $212.78/hr) (r)	$212.78

Burden and Respondent Descriptions	Burden Estimate
Cost for Respondent to Authorize Qualified Registry/QCDR to Report on Respondent's Behalf (@ computer systems analyst's labor rate of $92.46/hr) (s)	$7.70
Total Annual Cost Per Respondent (t) = (m)+(n)+(o)+(p)+(q)+(r)+(s)	$897.47
Total Annual Cost (u) = (c)*(t)	**$104,023,540**

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

In the CY 2021 PFS proposed rule, we are proposing to sunset the CMS Web Interface measures as a collection type and submission type starting with the 2021 performance period. Using the methodology previously described, we estimate 61 groups which previously submitted quality data via the CMS Web Interface collection type will now submit quality data via the eCQM collection type.

As noted in Tables 6A, 7A, and 8A, based on 2018 MIPS performance period data, we assume that 286,956 clinicians will elect to use the eCQM collection type; 41,477 clinicians are expected to submit eCQMs as individuals; and 4,474 groups and virtual groups are expected to submit eCQMs on behalf of the remaining 245,479 clinicians. We expect the burden to be the same for each respondent using the eCQM collection type, whether the clinician is participating in MIPS as an individual or group.

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 a QCDR/qualified registry 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 QCDR/qualified registry.

We estimate that it will take no more than 2 hours at $92.46/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 $110.74/hr for a medical and health services manager, 1 hour at $212.78/hr for a physician, 1 hour at $92.46/hr for a computer systems analyst, 1 hour at $46.64/hr for an LPN, and 1 hour at $39.06/hr for a billing clerk. As shown in Table 12A, we estimate a cost of $797.34/response [(2 hr x $92.46/hr) + (2 hr x $110.74/hr) + (1 hr x $212.78/hr) + (1 hr x $92.46/hr) + (1 hr x $46.64/hr) + (1 hr x $39.06/hr)].

TABLE 12A: 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)	41,477
# of Groups submitting via EHR on behalf of individual clinicians (b)	4,474
# of Respondents (groups and clinicians submitting as individuals) (c)=(a)+(b)	45,951
Hours Per Respondent to Submit MIPS Quality Data File to CMS (d)	2
# of Hours Medical and health services manager 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)	**367,608**
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of $92.46/hr) (l)	$184.92
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $110.74/hr) (m)	$221.48
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $92.46/hr) (n)	$92.46
Cost to Review Measure Specifications (@ LPN's labor rate of $46.64/hr) (o)	$46.64
Cost to Review Measure Specifications (@ clerk's labor rate of $39.06/hr) (p)	$39.06
Cost to D21Review Measure Specifications (@ physician's labor rate of $212.78/hr) (q)	$212.78
Total Cost Per Respondent (r)=(l)+(m)+(n)+(o)+(p)+(q)	$797.34
Total Annual Cost (s) = (c)*(r)	**$36,638,570**

f. 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. As 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 an 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. MIPS quality measures are also required to be linked to existing and related cost measures and improvement activities, as applicable and feasible, with a rationale as to how the measure correlates to other performance category measures and activities. In addition, proposed measures must be accompanied by a completed Peer Review Journal Article form. We recognize there is additional burden on respondents associated with development of a new quality measure beyond the 1.5 hour estimate 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 13A, we are not making any changes to our currently approved estimate of 28 quality measure submissions. In keeping with the focus on clinicians as the primary source for recommending new quality measures, we are using medical and health services managers and clinician time for our burden estimates and assume that of the 1.5 hours per measure, medical and health services managers will account for 0.9 hours and physicians will account for the remaining 0.6 hours.

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 13A, in aggregate we estimate an annual burden of 154 hours (28 submissions x 5.5 hr/submission) at a cost of $30,197 {28 submissions x [(0.9 hr x $110.74/hr) + (4.6 hr x $212.78/hr)}.

TABLE 13A: Burden Estimates for Call for Quality Measures

Burden and Respondent Descriptions	**Burden estimate**
# of Organizations Nominating New Quality Measures (a)	28
# of Hours Per Medical and health services manager 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)	**154**
Cost to Identify and Submit Measure (@ medical and health services manager's labor rate of	$99.66

Burden and Respondent Descriptions	Burden estimate
$110.74/hr.) (g)	
Cost to Identify Quality Measure and Complete Peer Review Article Form (@ physician's labor rate of $212.78/hr.) (h)	$978.79
Total Annual Cost Per Respondent (i)=(g)+(h)	$1,078.45
Total Annual Cost (j)=(a)*(i)	**$30,197**

g. Burden Estimate for the Promoting Interoperability Performance Category

For the 2021 MIPS performance period, clinicians and groups can submit Promoting Interoperability 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 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. 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.

i. 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, quality, cost, and/or improvement activities performance categories under specific circumstances (81 FR 77240 through 77243, 82 FR 53680 through 53686, and 82 FR 53783 through 53785). Respondents who apply for a reweighting for the quality, cost, and/or improvement activities 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.

Table 16A 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 by December 31, 2019 for the 2019 MIPS performance period, we assume 51,098 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 and an additional 994 respondents will submit a request to reweight one or more of the quality, cost, Promoting Interoperability, or improvement activity performance categories due to an extreme or uncontrollable circumstance, for a total of 52,092 reweighting applications

submitted. Similar to the data used to estimate the number of respondents in the CY 2020 PFS final rule, our respondent estimate includes a significant number of applications submitted as a result of a data issue CMS was made aware of and is specific to a single third-party intermediary. While we do not anticipate similar data issues to occur in each performance period, we do believe future similar incidents may occur and are electing to use this data without adjustment to reflect this belief. Our respondent estimate is also based on data that does not include applications submitted during the extended period ending April 30, 2020 due to the 2019 Novel Coronavirus (COVID-19) pandemic, as we do not believe it would be an accurate basis for future estimates of application submissions. Of our total respondent estimate of 52,092, we estimate that 35,986 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 16,106 respondents will submit a request for reweighting the Promoting Interoperability performance category to zero percent as a small practice experiencing a significant hardship.

We are proposing in the CY 2021 PFS proposed rule that, beginning with the 2022 MIPS payment year (2020 performance year), APM Entities may submit an extreme and uncontrollable circumstances exception application for all four performance categories and applicable to all MIPS eligible clinicians in the APM Entity group. As previously discussed, due to data limitations and our inability to determine who would use the APM Performance Pathway versus the traditional MIPS submission mechanism for the 2021 MIPS performance period, we assume ACO APM Entities will submit data through the APM Performance Pathway and non-ACO APM Entities would participate through traditional MIPS, thereby submitting as an individual or group rather than as an entity. Therefore, we limited our analysis to ACOs that were eligible for an exception due to extreme and uncontrollable circumstances during the 2019 MIPS performance period and elected not to report quality data. Based on this data, we estimate 7 APM Entities will submit an extreme and uncontrollable circumstances exception application for the 2021 MIPS performance period. Combined with our aforementioned estimate of 52,092 eligible clinicians and groups, the total estimated number of respondents for the 2021 MIPS performance period is 52,099.

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 continue to estimate it will take 0.25 hours at $92.46/hr for a computer system analyst to complete and submit the application. As shown in Table 14A, we estimate an annual burden of 13,025 hours (52,099 applications x 0.25 hr/application) and $1,204,268 (13,025 hr x $92.46/hr).

TABLE 14A: 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)	35,986
# of Eligible Clinicians and Groups Applying Due to Significant Hardship for Small Practice (b)	16,106
# APM Entities requesting Extreme and Uncontrollable Circumstances exception	7
Total Respondents Due to Hardships, Other Exceptions and Hardships for Small Practices (c)	52,099
Hours Per Applicant per application submission (d)	0.25
Total Annual Hours (e)=(a)*(c)	**13,025**
Labor Rate for a computer systems analyst (f)	$92.46/hr
Total Annual Cost (g)=(a)*(f)	**$1,204,268**

ii. 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 15, based on data from the 2018 MIPS performance period, we estimate that a total of 77,499 respondents consisting of 62,746 individual MIPS eligible clinicians and 14,753 groups and virtual groups will submit Promoting Interoperability data.

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. These estimates account for previously finalized reweighting policies including exceptions for MIPS eligible clinicians who have experienced a significant hardship (including clinicians who are in small practices) and decertification of an EHR.

We assume that MIPS eligible clinicians previously scored under the APM scoring standard, as described in the CY 2020 PFS final rule, will continue to submit Promoting Interoperability data (84 FR 63006) in a similar way through the APM Performance Pathway. As a result, we do not anticipate any change in burden. Each MIPS eligible clinician in an APM Entity reports data for the Promoting Interoperability performance category through either their group TIN or individual reporting. Sections 1899 and 1115A of the Act (42 U.S.C. 1395jjj and 42 U.S.C. 1315a, respectively) state that the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models are not subject to the PRA. However, 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 through 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 15: 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)	62,746
Number of groups to submit Promoting Interoperability (b)	14,753
Total Respondents in 2021 MIPS performance period (CY 2021 Proposed Rule) (c) = (a) + (b)	77,499
Total Respondents in 2020 MIPS performance period (CY 2020 Final Rule) (d)	74,281
Difference (e) = (c) – (d)	+3,218

We estimate the time required for an individual or group to submit Promoting Interoperability data to be 2.67 hours. As shown in Table 16A, the total burden estimate for submitting data on the specified Promoting Interoperability objectives and measures is estimated to be 206,664 hours (77,499 respondents x 2.67 incremental hours for a computer analyst's time above and beyond the physician, medical and health services manager, and computer system's analyst time required to submit quality data) and $19,108,153 (206,664 hr x $92.46/hr)).

TABLE 16A: Estimated Burden for Promoting Interoperability Performance Category Data Submission

Burden and Respondent Descriptions	**Burden Estimate**
Number of individual clinicians to submit Promoting Interoperability (a)	62,746
Number of groups to submit Promoting Interoperability (b)	14,753
Total (c) = (a) + (b)	77,499
Total Annual Hours Per Respondent (b)	2.67
Total Annual Hours (c) = (a)*(b)	**206,644**
Labor rate for a computer systems analyst to submit Promoting Interoperability data/hr.) (d)	$92.46hr
Total Annual Cost (e) = (a)*(d)	**$19,108,153**

h. Burden Estimate for the Nomination of Promoting Interoperability Measures

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). We are not proposing any changes to that form.

Unchanged from our currently approved estimate, we estimate 10 proposals will be submitted for new Promoting Interoperability measures, based on the number of proposals submitted during the CY 2019 nomination period. We estimate it will take 0.5 hours per organization to submit an activity to us, consisting of 0.3 hours at $110.74/hr for a medical and health services manager to

make a strategic decision to nominate that activity and submit an activity to us via email and 0.2 hours at $212.78/hr for a clinician to review the nomination. As shown in Table 17A, we estimate an annual burden of 5 hours (10 proposals x 0.5 hr/response) at a cost of $758 (10 x [(0.3 h x $110.74/hr) + (0.2 hr x $212.78/hr)].

TABLE 17A: Estimated Burden for Call for Promoting Interoperability Measures

Burden and Respondent Descriptions	**Burden estimate**
# of Organizations Nominating New Promoting Interoperability Measures (a)	10
# of Hours Per Medical and health services manager 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)	**5**
Cost to Identify and Submit Measure (@ medical and health services manager's labor rate of $110.74/hr.) (f)	$33.22
Cost to Identify Improvement Measure (@ physician's labor rate of $212.78/hr.) (g)	$42.56
Total Annual Cost Per Respondent (h)=(f)+(g)	$75.78
Total Annual Cost (i)=(a)*(h)	**$758**

i. Burden Estimate for the Submission of Improvement Activities Data

In order to determine MIPS APM scores, we assign Improvement Activities scores to APM participants in the APP based on the requirements of participation in APMs. To develop the Improvement Activities score for MIPS APMs, we would compare requirements of the APM with the list of Improvement Activities measures for the applicable year, and score those measures as they would otherwise be scored according to § 414.1355. In the event a MIPS APM participant does not actually perform an activity for which Improvement Activities credit would otherwise be assigned under this proposal, the MIPS APM participant would not receive credit for the associated Improvement Activity. In the event that the assigned score does not represent the maximum improvement activities score, we propose that MIPS eligible clinicians reporting through the APP would have the opportunity to report additional improvement activities that then would be applied towards their scores. Our burden estimates assume there will be no improvement activities burden for MIPS APM participants electing the APP. We will assign the improvement activities performance category score at the APM Entity level.

A variety of organizations and in some cases, individual clinicians, will submit improvement activity performance category data. As finalized in the CY 2017 Quality Payment Program final rule (81 FR 77264), APM Entities only need to report improvement activities data if the CMS-assigned improvement activities score is below the maximum improvement activities score. Similar to our assumption in the CY 2018 Quality Payment Program final rule, our burden estimates assume that the MIPS APM models for the 2021 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. (82 FR 53921 through 53922).

As represented in Table 18, based on 2018 MIPS performance period data, we estimate that a total of 102,474 respondents consisting of 85,760 individual clinicians and 16,714 groups will

submit improvement activities during the 2021 MIPS performance period. In addition, 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 ACO in the 2018 MIPS performance period but will be in the 2021 MIPS performance period, and will therefore not be required to submit improvement activities data.

TABLE 18: 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 2021 MIPS performance period (a)	85,760
# of Groups to submit improvement activities on behalf of clinicians during the 2021 MIPS performance period (b)	16,714
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 2021 Proposed Rule) (c) = (a) + (b)	102,474
*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 2020 Final Rule) (d)	103,813
Difference (e)=(c)-(d)	**-1,339**

Consistent with our currently approved estimate, we estimate that the per response time required per individual or group is 5 minutes at $92.46/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 19A, we estimate an annual burden of 8,540 hours (103,813 responses x 5 minutes/60) at a cost of $789,562 (8,540 hr x $92.46/hr).

TABLE 19A: Estimated Burden for Improvement Activities Submission

Burden and Respondent Descriptions	**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)	102,474
Total Annual Hours Per Respondent (b)	5 minutes
Total Annual Hours (c)	**8,540**
Labor rate for a computer systems analyst to submit improvement activities (d)	$92.46/hr
Total Annual Cost (e) = (c)*(d)	**$789,562**

j. Burden Estimate for the Nomination of Improvement Activities

Stakeholders are provided an opportunity to propose new activities formally via the Annual Call for Activities nomination form posted on the CMS website. The 2019 Annual Call for Activities lasted from February 1, 2019 through July 1, 2019, during which we received 31 nominations of new or modified activities which will be evaluated for the Improvement Activities Under

Consideration (IAUC) list for possible inclusion in the CY 2020 Improvement Activities Inventory; we continue to use this currently approved estimate.

In the CY 2021 PFS proposed rule, we are proposing to require nominated improvement activities to be linked to existing and related quality and cost measures, as applicable and feasible. Similar to the burden assumptions finalized in the CY 2020 PFS final rule for the nomination of quality measures, we believe this will require approximately 0.6 hours at $110.74/hr for a medical and health services manager and 0.4 hours at $212.78/hr for a physician to research existing measures and provide a rationale for the linkage (84 FR 63132). We previously estimated it would require 1.2 hours for a medical and health services manager or equivalent and 0.8 hours for a physician to nominate an improvement activity (84 FR 63141). Combined with our currently approved burden estimate, we now estimate 1.8 hours at $110.74/hr for a medical and health services manager or equivalent and 1.2 hours at $212.78/hr for a physician to nominate an improvement activity.

We estimate an annual information collection burden of 93 hours (31 nominations x 3 hr/nomination) at a cost of $14,095 (31 x [(1.8 hr x $110.74/hr) + (1.2 hr x $212.78/hr)]).

TABLE 20A: Burden Estimates for Nomination of Improvement Activities

Burden and Respondent Descriptions	**Burden estimate**
# of Organizations Nominating New Improvement Activities (a)	31
# of Hours Per Medical and health services manager to Identify and Propose Activity (b)	1.8
# of Hours Per Clinician to Identify Activity (c)	1.2
Annual Hours Per Respondent (d)= (b) + (c)	3
Total Annual Hours (e) = (a)*(d)	**93**
Cost to Identify and Submit Activity (@ medical and health services manager's labor rate of $110.74/hr.) (f)	$199.33
Cost to Identify Improvement Activity (@ physician's labor rate of $212.78/hr.) (g)	$255.34
Total Annual Cost Per Respondent (h)=(f)+(g)	$454.67
Total Annual Cost (i)=(a)*(h)	**$14,095**

k. Nomination of MVPs

The following reflects the burden associated with the first year of data collection associated with a new process available for all clinicians/third party intermediaries to nominate MVPs for inclusion in the Quality Payment Program.

Beginning with the 2022 performance period, we are proposing at that stakeholders should formally submit their MVP candidates utilizing a standardized template, which will be published in the QPP resource library four our consideration for future implementation. Stakeholders should submit all information including a description of how their MVP abides by the MVP development criteria as described in the CY 2021 PFS proposed rule, and provide rationales as to why specific measures and activities were chosen to construct the MVP. As MVP candidates are received, they will be reviewed, vetted, and evaluated by CMS and our contractors to determine if the MVP is feasible and ready for inclusion in the upcoming performance period. For the 2021 MIPS performance period, we assume 25 MVP nominations will be received and the estimated

time required to submit all required information is 12 hours per nomination. We seek comment on our estimate of the time required to nominate an MVP.

Similar to the call for quality measures, nomination of Promoting Interoperability measures, and the nomination of improvement activities, we assume MVP nomination will be performed by both practice administration staff or their equivalents and clinicians. We estimate 7.2 hours at $110.74/hr for a medical and health services manager or equivalent and 4.8 hours at $212.78/hr for a physician to nominate an MVP. As shown in Table 21A, we estimate an annual burden of 300 hours (25 nominations x 12 hr/nomination) at a cost of $45,467 (25 x [(7.2 hr x $110.74/hr) + (4.8 hr x $212.78/hr)]).

TABLE 21A: Estimated Burden for Nomination of MVPs

Burden and Respondent Descriptions	**Burden Estimate**
# of Nominations of New Improvement Activities (a)	25
# of Hours Per Medical and Health Services Manager (b)	7.2
# of Hours Per Physician (c)	4.8
Annual Hours Per Respondent (d)= (b) + (c)	12
Total Annual Hours (e) = (a)*(d)	**300**
Cost to Nominate an MVP (@ medical and health services manager's labor rate of $110.74/hr) (f)	$797.33
Cost to Nominate an MVP (@ physician's labor rate of $212.78/hr) (g)	$1,021.34
Total Annual Cost Per Respondent (h)=(f)+(g)	$1,818.67
Total Annual Cost (i)=(a)*(h)	**$45,467**

l. 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 finalized to include in the cost performance category as discussed in section III.K.3.c.(2)(b)(iii) of the CY 2020 PFS final rule. Moreover, the provisions of this final rule do not result in the need to add or revise or delete any claims data fields. Therefore, we did not finalize any new or revised collection of information requirements or burden for MIPS eligible clinicians resulting from the cost performance category.

m. 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.

As shown in Table 22A, based on our predictive QP analysis for the 2021 QP performance period, which accounts for historical response rates in performance year 2019, we estimate that

100 APM Entities and 200 eligible clinicians (representing approximately 2,500 Partial QPs) will make the election to participate as a Partial QP in MIPS, a total of 300 elections which is a decrease of 1,722 from the 2,022 elections that are currently approved by OMB under the aforementioned control number. We continue to 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 75 hours (300 respondents x 0.25 hr/election) and $6,935 (75 hr x $92.46/hr).

TABLE 22A: Estimated Burden for Partial QP Election

Burden and Respondent Descriptions	**Burden Estimate**
# of respondents making Partial QP election (12 APM Entities, 2,010 eligible clinicians) (a)	300
Total Hours Per Respondent to Elect to Participate as Partial QP (b)	0.25
Total Annual Hours (c) = (a)*(b)	**75**
Labor rate for computer systems analyst (d)	$92.46/hr
Total Annual Cost (e) = (c)*(d)	**$6,935**

n. Burden Estimate for Other-Payer Advanced APM Determinations

i. Payer-Initiated Process

As previously discussed in the "Data Collection related to Advanced APMs" section, the All-Payer Combination Option is an available pathway to QP status for eligible clinicians participating sufficiently in Advanced APMs and Other Payer Advanced APMs. 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/.

As shown in Table 23A, based on the actual number of requests received in the 2019 QP performance period, we estimate that in CY 2021 for the 2022 QP performance period 80 payer-initiated requests for Other Payer Advanced APM determinations will be submitted (10 Medicaid payers, 50 Medicare Advantage Organizations, and 20 remaining other payers), a decrease of 30 from the 110 total requests currently approved by OMB under the aforementioned control number. We continue to estimate it will take 10 hours for a computer system analyst per arrangement submission. We estimate an annual burden of 800 hours (80 submissions x 10 hr/submission) and $73,968 (800 hr x $92.46/hr).

TABLE 23A: Estimated Burden for Other Payer Advanced APM Identification Determinations: Payer-Initiated Process

Burden and Respondent Descriptions	**Burden Estimate**
# of other payer payment arrangements (10 Medicaid, 50 Medicare Advantage Organizations, 20 remaining other payers) (a)	80
Total Annual Hours Per other payer payment arrangement (b)	10
Total Annual Hours (c) = (a)*(b)	**800**
Labor rate for a computer systems analyst (d)	$92.46/hr
Total Annual Cost (e) = (c)*(d)	**$73,968**

ii. Eligible Clinician Initiated Process

Under the Eligible Clinician Initiated Process, APM Entities and eligible clinicians participating in other payer arrangements have an opportunity to request that we determine for the year whether those other payer arrangements are Other Payer Advanced APMs. 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/.

We are not making any changes to our currently approved estimates. As shown in Table 24A, 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 $92.46/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 $138,690 (1,500 hr x $92.46/hr).

TABLE 24A: Estimated Burden for Other Payer Advanced APM Determinations: Eligible Clinician Initiated Process

Burden and Respondent Descriptions	**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)	$92.46/hr
Estimated Total Annual Cost (e) = (c)*(d)	**$138,690**

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

As previously discussed in the "Data Collection related to Advanced APMs" section, APM Entities or individual eligible clinicians must submit 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. 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.

We are not making any changes to our currently approved estimates. As shown in Table 25A, 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 2021. We estimate it will take the APM Entity representative, TIN representative, or eligible clinician 5 hours at $110.74/hr for a medical and health services manager to complete this submission. In aggregate, we estimate an annual burden of 2,755 hours (551 respondents x 5 hr) at a cost of $305,089 (2,755 hr x $110.74/hr).

TABLE 25A: 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 Medical and health services manager ($110.74/hr) (h)	$110.74/hr
Total Annual Cost (i) = (g)*(h)	**$305,089**

o. 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 9,904 (0.10 x 99,042 voluntary MIPS participants) clinicians and groups, a decrease of 138 from the currently approved estimate of 10,042. 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 RIA 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).

Table 26A shows that for these voluntary participants, we estimate it will take 0.25 hours at $92.46/hr for a computer system analyst to submit a request to opt-out. In aggregate, we estimate an annual burden of 2,476 hours (9,904 requests x 0.25 hr/request) at a cost of $228,931 (2,476 hr x $92.46/hr).

TABLE 26A: 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)	9,904
Total Annual Hours Per Opt-out Requester (b)	0.25
Total Annual Hours (c) = (a)*(b)	**2,476**
Labor rate for a computer systems analyst (d)	$92.46/hr
Total Annual Cost (e) = (c)*(d)	**$228,931**

TABLE 27: Burden Summary

Regulation Section(s) Under Title 42 of the CFR	Table No.	No. Respondents	Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)*
§414.1400 (Registry self-nomination)	3A	153	163	3	489	92.46	45,213

Regulation Section(s) Under Title 42 of the CFR	Table No.	No. Respondents	Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)*
§414.1400 (QCDR self-nomination)	4A	76	76	8	608	92.46	56,216
Open Authorization Credentialing and Token Request Process	5A	15	15	1	15	92.46	1,387
§414.1325 and 414.1335 (QPP Identity Management Application Process)	9A	3,741	3,741	1	3,741	92.46	345,893
§414.1325 and 414.1335 [(Quality Performance Category) Claims Collection Type]	10A	94,587	94,587	14.2	1,343,135	Varies (see table 10)	131,369,236
§414.1325 and 414.1335 [(Quality Performance Category) QCDR/MIPS CQM Collection Type]	11A	115,907	115,907	9.083	1,052,783	Varies (see table 11)	104,023,540
§414.1325 and 414.1335 [(Quality Performance Category) eCQM Collection Type]	12A	45,951	45,951	8.0	367,608	Varies (see table 12)	36,638,570
[(Quality Performance Category) Call for Quality Measures]	13A	28	28	5.5	154	Varies (see table 13)	30,197

Regulation Section(s) Under Title 42 of the CFR	Table No.	No. Respondents	Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)*
§414.1375 and 414.1380[(PI Performance Category) Reweighting Applications for Promoting Interoperability and Other Performance Categories	14A	52,099	52,099	0.25	13,025	92.46	1,204,268
§414.1375 [(PI Performance Category) Data Submission]	16A	77,499	77,499	2.67	206,664	92.46	19,108,153
[(PI Performance Category) Call for Promoting Interoperability Measures]	17A	10	10	0.5	5	Varies (see table 17)	758
§414.1360 [(Improvement Activities Performance Category) Data Submission]	19A	102,474	102,474	0.083	8,540	92.46	789,562
§414.1360 [(Improvement Activities Performance Category) Nomination of Improvement Activities]	20A	31	31	3.0	93	Varies (see table 20)	14,095
Nomination of MVPs	21A	25	25	12	300	Varies (see table 21)	45,467
§414.1430 [Partial Qualifying APM Participant (QP) Election]	22A	300	300	0.25	75	92.46	6,935
§414.1440 [Other Payer Advanced APM Identification: Payer Initiated Process]	23A	80	80	10	800	92.46	73,968

Regulation Section(s) Under Title 42 of the CFR	Table No.	No. Respondents	Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)*
§414.1445 [Other Payer Advanced APM Identification: Clinician Initiated Process]	24A	150	150	10	1,500	92.46	138,690
§414.1440 [Submission of Data for All-Payer QP Determinations under the All-Payer Combination Option]	25A	551	551	5	2,755	110.74	305,089
§414.1395 [(Physician Compare) Opt Out for Voluntary Participants]	26A	9,904	9,904	0.25	2,476	92.46	228,931
TOTAL		**347,331****	**503,591**	**Varies**	**3,004,766**	**Varies**	**294,426,167**

*With respect to the PRA, the CY 2021 PFS proposed rule does not impose any non-labor costs.
** Total number of unique respondents to quality, Promoting Interoperability, and improvement activity performance categories is calculated to be 345,802. With the exception of extreme and uncontrollable exception applications, we assume remaining number of applications for reweighting are included in this total. We also assume that all voluntary participants that opt out of Physician Compare are included in this total.

Information Collection Instruments/Instructions

Appendix A1 (See Table 3A): 2020 Qualified Registry Fact Sheet (Revised)

Appendix A2 (See Table 3A): Crosswalk - 2020 Qualified Registry Fact Sheet

Appendix B1 (See Table 4A): 2020 Qualified Clinical Data Registry (QCDR) Fact Sheet (Revised)

Appendix B2 (See Table 4A): Crosswalk - 2020 Qualified Clinical Data Registry (QCDR) Fact Sheet

Appendix C1 (Table 4A): 2020 Qualified Clinical Data Registry (QCDR) Measure Submission Template (Revised)

Appendix C2 (Table 4A): Crosswalk - 2020 Qualified Clinical Data Registry (QCDR) Measure Submission Template

Appendix D1 (See Table 23A): Submission Form for Other Payer Requests for Other Payer Advanced Alternative Payment Model Determinations (Payer Initiated Submission Form) (Revised)

Appendix D2 (See Table 23A): Crosswalk - Submission Form for Other Payer Requests for Other Payer Advanced Alternative Payment Model Determinations (Payer Initiated Submission Form)

Appendix E1 (See Table 24A): Submission Form for Eligible Clinician and APM Entity Requests for Other Payer Advanced Alternative Payment Model Determinations (Eligible Clinician Initiated Submission Form) (Revised)

Appendix E2 (See Table 24A): Crosswalk - Submission Form for Eligible Clinician and APM Entity Requests for Other Payer Advanced Alternative Payment Model Determinations (Eligible Clinician Initiated Submission Form)

Appendix F1 (See Table 25A): Submission Form for Requests for Qualifying Alternative Payment Model Participant (QP) Determinations under the All-Payer Combination Option (Revised)

Appendix F2 (See Table 25A): Crosswalk - Submission Form for Requests for Qualifying Alternative Payment Model Participant (QP) Determinations under the All-Payer Combination Option

Appendix G1 (See Table 13A): Measures under Consideration 2020, Data Template for Candidate Measures (Revised)

Appendix G2 (See Table 13A): Crosswalk - Measures under Consideration 2020, Data Template for Candidate Measures

Appendix H1 (See Table 13A): Peer Reviewed Journal Article Requirement Template (Revised)

Appendix H2 (See Table 13A): Crosswalk - Peer Reviewed Journal Article Requirement Template

Appendix I (See Table 17A): Promoting Interoperability Performance Category, 2020 Call for Measures Submission Form (No Changes)

Appendix J (See Table 20A): Improvement Activities Performance Category, 2020 Call for Activities Submission Form (No Changes)

Appendix K1 (See Table 14A): Hardship Exception Application Form (Revised)

Appendix K2 (See Table 14A): Crosswalk - Hardship Exception Application Form

Appendix L1 (See Table 14A): Extreme and Uncontrollable Circumstances Application Form (Revised)

Appendix L2 (See Table 14A): Crosswalk - Extreme and Uncontrollable Circumstances Application Form

Appendix M (See Table 21A): MVP Candidates: Instructions and Template (New)

13. Capital Costs

We are proposing to sunset the CMS Web Interface measures as a collection type for groups and virtual groups with 25 or more eligible clinicians starting with the 2021 performance period. We recognize that the sunset of the CMS Web Interface for groups and virtual groups may be burdensome to current groups and virtual groups submitting quality data on CMS Web Interface measures. Such groups and virtual groups would need to select a different collection type/submission type and redesign their systems to be able to interact with the new collection type/submission type. Given that the Medicare Part B claims collection type is limited to small practices, the alternatives for these groups and virtual groups would be either the MIPS CQM, QCDR or eCQM collection types. Given the size of the affected groups and virtual groups, we believe the majority are likely to already be using a QCDR, qualified registry, or EHR as part of their practice workflow. Of the 2,932 TINs comprised of 25 or more clinicians who submitted MIPS data via a collection type other than the CMS Web Interface, 62 percent reported via the MIP CQM and QCDR collection type and 38 percent reported via the eCQM collection type. For groups converting from Web Interface, there will be some non-recurring costs associated with modifying clinical and MIPS data reporting workflows to utilize an alternate collection type. For any remaining groups and virtual groups there will also be registry fees paid to a QCDR or qualified registry or the financial expense of purchasing/licensing and deploying an EHR system. Because we are unable to assess either the existing workflows of each individual group and virtual group or the decisions each group and virtual group will make in response to this proposal, we cannot quantify the resulting economic impact. While there may be an initial increase in burden for current groups and virtual groups utilizing the CMS Web Interface measures having to transition to the utilization of a different collection type/submission type, we recognize that we would also be reducing reporting requirements. Groups and virtual groups would no longer have to completely report on all pre-determined CMS Web Interface measures and would be able to select their own measures (at least 6) to report.

Groups and virtual groups account for less than 20 percent of organizations utilizing the CMS Web Interface measures while ACOs participating in the Medicare Shared Savings Program and Next Generation ACO Model account for more than 80 percent. In assessing the utilization of the CMS Web Interface by groups and virtual groups, there has been a substantial decrease in participation each year since the inception of MIPS in the 2017 performance period. From 2017 to 2019, the number of groups eligible to report quality measures via the CMS Web Interface (groups registered to utilize the CMS Web Interface) decreased by approximately 45 percent. Similarly, the number of groups utilizing the CMS Web Interface as a collection type decreased by approximately 40 percent from 2017 to 2019.

We are also proposing in the CY 2021 PFS proposed rule to require all third party intermediaries to attend monthly training and support sessions. With regard to survey vendors, we previously finalized the CMS-approved survey vendor approval criteria in the CY 2018 PFS final rule (83 FR 59907 through 59908) which established the requirement that the entity has successfully completed, and has required its subcontractors to successfully complete, vendor training(s) administered by CMS or its contractors. Therefore, we assume no additional impact for survey vendors as a result of this proposal. We do not have data on the number of health IT vendors that missed training and support sessions, but the most recent data cites 684 health IT developers through program year 2016 of the Medicare EHR Incentive Program. In CY 2019, 16 total

training and support sessions were missed by 14 QCDRs and 33 total sessions were missed by 27 qualified registries. Based on historical frequency and duration, we expect future training and support sessions to continue occurring monthly for approximately 2 hours each. For QCDRs and qualified registries, we estimate an impact of 98 hours [(16 sessions by QCDRs + 33 sessions by qualified registries) x 2 hours]. We lack insight into the exact occupation of session attendees, but for estimating purposes we assume a Physician labor rate of $212.78/hr and estimate a total burden of $20,852 ($212.78/hr x 98 hours).

We are also proposing to require QCDRs and qualified registries to conduct an annual data validation audit and if one or more deficiencies or data errors are identified also conduct targeted audits. We do not anticipate a significant impact to QCDRs and qualified registries as a result of this proposal. First, the proposed data validation requirements are similar to existing expectations which we have already accounted for in the CY 2017 Quality Payment Program final rule (81 FR 77383 through 77384) and the CY 2019 PFS final rule (83 FR 59998 through 59999). Second, we believe that the proposed requirements for conduct of the data validation audits are aligned with methods and procedures which stakeholders currently utilize. Regarding the proposed requirement for QCDRs and qualified registries to conduct targeted audits if one or more data errors are identified during data validation audits, we are unable to estimate the number of audits which may occur or the time and costs associated with their conduct which could vary substantially depending on the nature of the data error and the amount of data to be audited. We are seeking comment in the CY 2021 PFS proposed rule on the expected frequency of targeted audits and the anticipated scope of effort. Assuming additional data is available, we will revisit discussion of this proposal and attempt to estimate associated capital costs at that time.

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.

In the CY 2021 PFS proposed rule, we are proposing, beginning with the CY 2021 performance period and future years, to consider agency-nominated improvement activities. We are unable to estimate the number of improvement activity nominations we will receive, but similar to the per respondent estimate we have provided for the nomination of improvement activities from the public, we assume it will require 3 hours at $55.75/hr for a GS-13 Step 5 to nominate an improvement activity for a total cost of $167.25 (3 hrs x $55.75/hr) per activity.

15. Program and Burden Changes

We have revised Appendices A1 (2020 Qualified Registry Fact Sheet), B1 (2020 QCDR Fact Sheet), C1 (2020 QCDR Measure Submission Template), D1 (Payer Initiated Submission Form), E1 (Eligible Clinician Initiated Submission Form), F1 (Requests form for QP Determinations under the All-Payer Combination Option), G1 (2020 Measures Under Consideration Data Template), H1 (Peer Reviewed Journal Article Requirement Template), K1 (Hardship Exception Application Form), and L1 (Extreme and Uncontrollable Circumstances Application Form) which are included in this PRA submittal to reflect changes due to finalized requirements and

revised terminology as well as to provide additional clarity. Crosswalks have been provided in Appendices A2, B2, C2, D2, E2, F2, G2, H2, K2, and L2 which clearly describe all changes from previous submittals. Also included in this PRA is one new appendix: M (MVP Candidates: Instructions and Template). The burden associated with completing this form has also been included in this PRA.

TABLE 28: Annual Change in Burden

Burden Type	Total Requested (A)	Change Due to New Statute (B)	Change Deu to Program Discretion (C)	Change Due to Program Adjustment (D)	Total Currently Approved (E)
Total Responses	503,591	-37	+25	+28,420	475,198
Total Time (hr)	3,004,766	-5,588	+45	+72,434	2,937,890
Total Cost ($)	292,426,167	-490,680	+4,161	+7,091,084	287,821,602

The decrease of 37 responses with a total burden of -$5,588 at a cost of -$490,680 due to new statute (Column B) is due to the proposal to sunset the CMS Web Interface offset by increases due to the proposal to allow APM Entities to submit an extreme and uncontrollable circumstances exception application and the new information collection for nomination of MVPs. The increase of 25 responses with a total burden of 45 hours at a cost of $4,161 due to program discretion (Column C) is related to the new information collection related to the Open Authorization Credentialing and Token Rrequest Process and the proposal to modify the requirement for third party intermediaries to submit a CAP. The latter requirement was finalized in our CY 2017 Quality Payment Program final rule (81 FR 77389), however we did not specify the information that must be included in the CAP and neglected to identify the burden associated with the required information at that time. The remaining changes due to program adjustment (Column D) are entirely due to availability of updated data.

Table series ”B” below identifies the changes in burden for each information collection requirement set out above in the “A” series of tables under section 12 of the Supporting Statement.

TABLE 3B: Burden Reconciliation for Qualified Registry Self-Nomination and Other Requirements

Burden Category	Total Annual Respondents	Response Frequency (per year)	Total Annual Responses	Time Per Response (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)
Currently Approved	153	1	153	3	459	92.46	42,439
Proposed	153	Varies	163	3	489	92.46	45,213
Adjustment	No change	See detail	+10	No change	+30	No change	+2,774

TABLE 4B: Burden Reconciliation for QCDR Self-Nomination and other Requirements

Burden Category	Total Annual Respondents	Response Frequency (per year)	Total Annual Responses	Time Per Response (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)
Currently Approved	76	1	76	8	608	92.46	56,216
Proposed	76	1	76	8	608	92.46	56,216
Adjustment	No change	No change	No change	No change	No change	No change	No change

TABLE 5B: Burden Reconciliation for Open Authorization Credentialing and Token Request Process

Burden Category	Total Annual Respondents	Response Frequency (per year)	Total Annual Responses	Time Per Response (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)
Currently Approved	0	0	0	0	0	0	0
Proposed	15	1	15	1	15	92.46	1,387
Adjustment	+15	+1	+15	+1	+15	+92.46	+1,387

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

Burden Category	Total Annual Respondents	Response Frequency (per year)	Total Annual Responses	Time Per Response (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)
Currently Approved	3,741	1	3,741	1	3,741	92.46	345,893
Proposed	3,741	1	3,741	1	3,741	92.46	345,893
Adjustment	No change	No change	No change	No change	No change	No change	No change

TABLE 10B: Burden Reconciliation for Quality Performance Category Claims Collection Type

Burden Category	Total Annual Respondents	Response Frequency (per year)	Total Annual Responses	Time Per Response (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)
Currently Approved	94,846	1	94,846	14.2	1,346,813	Varies	131,728,954
Proposed	94,587	1	94,587	14.2	1,343,135	Varies	131,369,236
Adjustment	-259	No change	-259	No change	-3,678	No change	-359,718

TABLE 11B: Burden Reconciliation for Quality Performance Category QCDR/MIPS CQM Collection Type

Burden Category	Total Annual Respondents	Response Frequency (per year)	Total Annual Responses	Time Per Response (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)
Currently Approved	111,218	1	111,218	9.083	1,010,193	Varies	99,815,283
Proposed	115,907	1	115,907	9.083	1,052,783	Varies	104,023,540
Adjustment	+4,689	No change	+4,689	No change	+42,590	No change	+4,208,256

TABLE 12B: Burden Reconciliation for Quality Performance Category eCQM Collection Type

Burden Category	Total Annual Respondents	Response Frequency (per year)	Total Annual Responses	Time Per Response (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)
Currently Approved	43,333	1	43,333	8	346,664	Varies	34,551,134
Proposed	45,951	1	45,951	8	367,608	Varies	36,638,570
Adjustment	+2,618	No change	+2,618	No change	+20,944	No change	+2,087,436

TABLE 13B: Burden Reconciliation for Call for Quality Measures

Burden Category	Total Annual Respondents	Response Frequency (per year)	Total Annual Responses	Time Per Response (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)
Currently Approved	28	1	28	5.5	154	Varies	30,197
Proposed	28	1	28	5.5	154	Varies	30,197
Adjustment	No change	No change	No change	No change	No change	No change	No change

TABLE 14B: Burden Reconciliation for Reweighting Applications for Promoting Interoperability and Other Performance Categories

Burden Category	Total Annual Respondents	Response Frequency (per year)	Total Annual Responses	Time Per Response (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)
Currently Approved	30,620	1	30,620	0.25	7,655	92.46	707,781
Proposed	52,099	1	52,099	0.25	13,025	92.46	1,204,268
Adjustment	+21,479	No change	+21,479	No change	+5,370	No change	+496,487

TABLE 16B: Burden Reconciliation for Promoting Interoperability Performance Category Data Submission

Burden Category	Total Annual Respondents	Response Frequency (per year)	Total Annual Responses	Time Per Response (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)
Currently Approved	74,281	1	74,281	2.67	198,083	92.46	18,314,723
Proposed	77,499	1	77,499	2.67	206,664	92.46	19,108,153
Adjustment	+3,218	No change	+3,218	No change	+8,581	No change	+793,430

TABLE 17B: Burden Reconciliation for Call for Promoting Interoperability Measures

Burden Category	Total Annual Respondents	Response Frequency (per year)	Total Annual Responses	Time Per Response (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)
Currently Approved	10	1	10	0.5	5	Varies	758
Proposed	10	1	10	0.5	5	Varies	758
Adjustment	No change	No change	No change	No change	No change	No change	No change

TABLE 19B: Burden Reconciliation for Improvement Activities Submission

Burden Category	Total Annual Respondents	Response Frequency (per year)	Total Annual Responses	Time Per Response (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)
Currently Approved	103,813	1	103,813	0.083	8,651	92.46	799,879
Proposed	102,474	1	102,474	0.083	8,539.5	92.46	789,562
Adjustment	-1,339	No change	-1,339	No change	-111.5	No change	-10,317

TABLE 20B: Burden Reconciliation for Nomination of Improvement Activities

Burden Category	Total Annual Respondents	Response Frequency (per year)	Total Annual Responses	Time Per Response (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)
Currently Approved	31	1	31	2	62	Varies	9,396
Proposed	31	1	31	3	93	Varies	14,095
Adjustment	No Change	No Change	No change	+1	+31	No change	+4,698

TABLE 21B: Burden Reconciliation for Nomination of MVPs

Burden Category	Total Annual Respondents	Response Frequency (per year)	Total Annual Responses	Time Per Response (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)
Currently Approved	0	0	0	0	0	0	0
Proposed	25	1	25	12	300	Varies	45,467
Adjustment	+25	+1	+25	+12	+300	Varies	+45,467

TABLE 22B: Burden Reconciliation for Partial QP Election

Burden Category	Total Annual Respondents	Response Frequency (per year)	Total Annual Responses	Time Per Response (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)
Currently Approved	2,022	1	2,022	0.25	505.5	92.46	46,739
Proposed	300	1	300	0.25	75	92.46	6,935
Adjustment	-1,722	No change	-1,722	No change	-430.5	No change	-39,804

TABLE 23B: Burden Reconciliation for Other Payer Advanced APM Identification: Other Payer Initiated Process

Burden Category	Total Annual Respondents	Response Frequency (per year)	Total Annual Responses	Time Per Response (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)
Currently Approved	110	1	110	10	1,100	92.46	101,706
Proposed	80	1	80	10	800	92.46	73,968
Adjustment	-30	No change	-30	No change	-300	No change	-27,738

TABLE 24B: Burden Reconciliation for Other Payer Advanced APM Identification: Eligible Clinician Initiated Process

Burden Category	Total Annual Respondents	Response Frequency (per year)	Total Annual Responses	Time Per Response (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)
Currently Approved	150	1	150	10	1,500	92.46	138,690
Proposed	150	1	150	10	1,500	92.46	138,690
Adjustment	No change	No change	No change	No change	No change	No change	No change

TABLE 25B: Burden Reconciliation for Submission of Data for All-Payer QP Determinations under the All-Payer Combination Option

Burden Category	Total Annual Respondents	Response Frequency (per year)	Total Annual Responses	Time Per Response (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)
Currently Approved	551	1	551	5	2,755	110.74	305,089
Proposed	551	1	551	5	2,755	110.74	305,089
Adjustment	No change	No change	No change	No change	No change	No change	No change

TABLE 26B: Burden Reconciliation for Voluntary Participants to Elect to Opt Out of Performance Data Display on Physician Compare

Burden Category	Total Annual Respondents	Response Frequency (per year)	Total Annual Responses	Time Per Response (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)
Currently Approved	10,042	1	10,042	0.25	2,510.5	92.46	232,121
Proposed	9,904	1	9,904	0.25	2,476	92.46	228,931
Adjustment	-138	No change	-138	No change	-34.5	No change	-3,190

Table 30 provides the reasons for changes in the estimated burden for information collections in the CY 2021 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 4 policies that reflect updated data and methods.

TABLE 30: 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 5 policies	Changes to "baseline" of burden continued Year 4 policy (*italics are changes in number of respondents' due to updated data)*
Table 3: Qualified Registry Self-Nomination and Other Requirements	Increase in number of responses (+10) and burden (+ 3 hrs per response) due to proposal to require Corrective Action Plans when necessary.	None.
Table 4: QCDR Self-Nomination and Other Requirements	None.	None.

Table in Collection of Information	**Changes in burden due to proposed Year 5 policies**	**Changes to "baseline" of burden continued Year 4 policy (*italics are changes in number of respondents' due to updated data)***
Table 5: Open Authorization Credentialing and Token Request Process	New information collection request.	Not applicable.
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 from the 2018 MIPS performance period and updated QP projections for the 2021 MIPS performance period.
Table 11: Quality Performance Category QCDR/MIPS CQM Collection Type	Increase in number of respondents (+7) due to proposal to sunset the CMS Web Interface measures as a collection type/submission type.	Increase in number of respondents due to increased number of data submissions received by APM participants and updated QP projections for the 2021 MIPS performance period reflecting updated QP threshold. This is offset by decrease in number of non-APM respondents in updated 2018 MIPS performance period data.
Table 12: Quality Performance Category eCQM Collection Type	Increase in number of respondents due to proposal to sunset the CMS Web Interface measures as a collection type/submission type.	Increase in number of respondents due to increased number of data submissions received by APM participants and updated QP projections for the 2021 MIPS performance period reflecting updated QP threshold. This is offset by decrease in number of non-APM respondents in updated 2018 MIPS performance period data.
Table 13: Call for Quality Measures	None	None
Table 14: Reweighting Applications for Promoting Interoperability and Other Performance Categories	Increase in number of respondents due to proposal to allow APM Entities to submit an extreme and uncontrollable circumstances exception application.	Increase in number of applications submitted due to updated data from the 2019 MIPS performance period.
Table 16: Promoting Interoperability Performance Category Data Submission	None.	Increase in number of non-APM individual respondents and number of data submissions received by APM participants offset by decrease in number of non-APM group submissions due to use of updated data from the 2018 MIPS performance period.
Table 17: Call for Promoting Interoperability Measures	None.	None.
Table 19: Improvement Activities Submission	None.	Decrease in number of respondents due to use of updated data from the 2018 MIPS performance period.

Table in Collection of Information	Changes in burden due to proposed Year 5 policies	Changes to "baseline" of burden continued Year 4 policy (*italics are changes in number of respondents' due to updated data)*
Table 20: Nomination of Improvement Activities	Increase in per response burden (+1 hour) due to proposal to require nominated improvement activities to be linked to existing and related quality and cost measures, as applicable and feasible.	None.
Table 21: Nomination of MVPs	New information collection request.	Not applicable.
Table 22: Partial QP Election	None	Decrease in number of respondents due to updated projections for the 2021 MIPS performance period.
Table 23: Other Payer Advanced APM Identification: Other Payer Initiated Process	None.	Decrease in number of respondents due to updated projections for the 2021 MIPS performance period.
Table 24: Other Payer Advanced APM Identification: Eligible Clinician Initiated Process	None.	None.
Table 25: Submission of Data for All-Payer QP Determinations under the All-Payer Combination Option	None.	None.
Table 26: Voluntary Participants to Elect to Opt Out of Performance Data Display on Physician Compare	None.	Decrease in the number of respondents due to use of updated data from the 2018 MIPS performance period.

The following table summarizes our porposed burden changes.

TABLE 31: Annual Requirements and Burden

Regulation Section(s) Under Title 42 of the CFR	No. Respondents	Total No. Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)*
Quality Payment Program (See Subtotal Under Table 89)	346,317	28,393	varies	66,876	varies	6,604,565

* With respect to the PRA, the CY 2021 PFS proposed rule does not impose any non-labor costs.

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 is displayed on all web-based data collection forms.

18. Certification Statement

There are no exceptions to the certification statement.