

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

A. Background

The Merit-based Incentive Payment System (MIPS) is a program for certain eligible clinicians that makes Medicare payment adjustments based on performance on quality, cost and other measures and activities, and that consolidates components of three precursor programs—the Physician Quality Reporting system (PQRS), the Value Modifier (VM), and the Medicare Electronic Health Record (EHR) Incentive Program for eligible professionals. 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 by designating one representative of the participating APM Entity to opt in to MIPS. For the 2019 MIPS performance period, we also finalized an Other Payer Advanced APM option that will allow for additional APMs to apply for consideration as an Advanced APM. To provide eligible clinicians with advanced notice prior to the 2019 QP performance period, a payer-initiated process to determine Other Payer Advanced APMs and a Medicaid specific eligible clinician-initiated process to determine Other Payer Advanced APMs will begin in CY 2018.

The implementation of MIPS requires the collection of quality, advancing care information, and improvement activities performance category data.¹ For the quality performance category, MIPS eligible clinicians will have the option to submit data using various mechanisms, including Medicare claims, CMS Web Interface, qualified registries, Qualified Clinical Data Registries (QCDRs), EHRs, and CMS-approved survey vendors.² For the improvement activities and advancing care information, clinicians can submit data via CMS Web Interface, qualified registries, Qualified Clinical Data Registries (QCDRs), EHRs, or attestation. (82 FR 53619

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).

through 53620). However, starting with the CY 2017 performance period, we are making available the new CMS Application Programming Interface (API) that may be used to help streamline the process of submitting measures via third party submission mechanisms which include EHR, registry and QCDRs. We are also allowing use of the new CMS API for submission via the CMS Web Interface. We expect a reduction in time for data submission in CY 2018 as a result of allowing use of the new CMS API for these submission mechanisms.

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

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

In addition, this Quality Payment Program information collection request includes two information collections relating to Advanced APMs. These collection requests include an application for Other Payer Advanced APM determinations that are initiated by Medicaid eligible clinicians participating in Medicaid payment arrangements and an application for Other Payer Advanced APM determinations by Medicaid payers, Medicare Advantage Organizations, and other payers in CMS Multi-Payer models..

We are requesting approval of 16 information collections associated with the CY 2018 Quality Payment Program final rule with comment period (not including the separate requests for virtual group election and Consumer Assessment of Healthcare Providers and Systems (CAHPS)-related data collection) as a revision to currently approved information requests submitted under OMB control number 0938-1314. CMS is requesting approval to collect a revised CAHPS for MIPS survey (version 2.0) via CMS-approved survey vendors in the revised CAHPS for MIPS Paperwork Reduction Act (PRA) package (0938-1222). CMS has already received approval for collection of information associated with the virtual group election process via a separate virtual group PRA package under OMB control number 0938-1343 which expires 9/30/2020.

1. Data Collection for MIPS

a. Quality Performance Category

Most of the quality measures finalized for the CY 2018 MIPS performance period are the same as the CY 2017 MIPS quality measures therefore we anticipate clinicians will be more familiar with the measures and submission processes in this second year. Under MIPS, the quality performance category performance requirements are as follows: the MIPS eligible clinician or group will report at least 6 measures including at least 1 outcome measure if available; if an applicable outcome measure is not available, then the MIPS eligible clinician or group will report a high priority measure (appropriate use, patient safety, efficiency, patient experience, and care coordination measures) in lieu of an outcome measure. If fewer than 6 measures apply to the individual MIPS eligible clinician, group, or virtual group, then the MIPS eligible clinician, group, or virtual group will be required to report on each measure that is applicable. MIPS eligible clinicians, groups, and virtual groups can meet this criterion by selecting measures either individually or from a specialty-specific measure set. The quality measures as finalized in the CY 2017 Quality Payment Program final rule are at <https://qpp.cms.gov/measures/quality>. The changes to the quality performance category measures are listed in Appendix Tables Group A, Group B, C.1, C.2, D and E of the final rule with comment period.

b. Advancing Care Information Performance Category

Under MIPS, the use of CEHRT is referred to as “advancing care information.” In accordance with sections 1848(o)(2) of the Act, a MIPS eligible clinician must submit, using CEHRT, information on the measures selected by the Secretary to demonstrate they are meaningful users of CEHRT for a performance period, as defined in section 1848(o)(2) of the Act. Table 7 and 8 of the final rule with comment period (section II.C.6.f.(6) provides a list of advancing care information performance category objectives and measures.

Under the MIPS, each MIPS eligible clinician will be required to submit the required measures listed in Table 7 or Table 8 of the 2018 Quality Payment Program final rule with comment period to achieve a 50 percent base score, with the option to submit additional measures to receive a higher score. The number of base measures and optional additional measures depends on whether the eligible clinician elects to use the Advancing Care Information Measures or the 2018 Advancing Care Information Transition Objective and Measure set. MIPS eligible clinicians and groups can submit advancing care information data via qualified registry, QCDR, EHR, CMS Web Interface, or attestation data submission mechanisms for the 2018 MIPS performance period.

As described in the final rule with comment period (section II.C.6.f.(7)), we allow MIPS

eligible clinicians to apply for an exception due to a significant hardship or as a result of a decertified EHR and subsequently have their advancing care information performance category reweighted to zero. MIPS eligible clinicians with significant hardships include those who lack sufficient internet connectivity, face extreme and uncontrollable circumstances, lack control over the availability of CEHRT, or do not have face-to-face interactions with patients. We are also finalizing a new hardship exception for small practices with 15 or fewer clinicians.

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

c. Improvement Activities Performance Category

Under MIPS, clinical practice improvement activities are referred to as improvement activities. MACRA defines an improvement activity as “an activity that relevant eligible professional organizations and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes.” We are encouraging, but not requiring, a minimum number of improvement activities, conducted at the group or the individual level. MIPS eligible clinicians and groups can submit data via qualified registry, QCDR, EHR, CMS Web Interface, or attestation submission mechanisms.

If MIPS eligible clinicians submit using the attestation submission mechanism, they only need to designate a “yes” to improvement activities performed during the performance period that are selected from the new improvement activities in Appendix Tables F and G in CY 2018 Quality Payment Program final rule with comment period and <https://qpp.cms.gov/measures/ia>, which is the Improvement Activities Inventory that we finalized in the CY 2017 Quality Payment Program final rule.

We created an inventory of improvement activities that includes a broad list of activities that may be used by multiple practice types to demonstrate improvement activities. The new improvement activities are included in Appendix Tables F and G in the CY 2018 Quality Payment Program final rule with comment period and at <https://qpp.cms.gov/measures/ia>, which is the Improvement Activities Inventory that we finalized in the CY 2017 Quality Payment Program final rule.

d. Cost Performance Category

Under MIPS, we refer to the resource use performance category as “cost.” The cost performance category measures are derived from the Medicare Parts A and B claims submission

process. Cost performance category measures do not result in any submission burden because individual MIPS eligible clinicians are not asked to provide any documentation beyond the claims submission process.

e. Additional Data Collection

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

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

- Self-nomination of new and returning QCDRs and registries
- Application for advancing care information reweighting
- Call for quality measures
- Call for new improvement activities
- Call for advancing care information measures (new form)
- Opt out of performance data display on Physician Compare for voluntary reporters under MIPS.

In addition, we have finalized in the CY 2018 Quality Payment Program in section II.C.7.b.(3)(c) final rule with comment period, use of a reweighting application for the quality, cost and improvement activities performance categories, for hardship exceptions such as a natural disaster. Historically, we have received fewer than 10 significant hardship applications due to natural disasters and therefore have not included a separate burden estimate for a reweighting application for quality, cost and improvement activities performance categories.

2. Data Collection related to Advanced APMs

This information request includes three information collections related to Advanced APMs. These three 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: Medicaid specific Eligible Clinician Initiated Process

Advanced APM Entities will face a submission burden under MIPS related to Partial QP elections. Partial QPs will have the option to elect whether to report under MIPS, which determines whether they will be subject to MIPS scoring and payment adjustments. In the 2018 MIPS performance period, we define Partial QPs to be Advanced APM participants that have at least 20 percent, but less than 25 percent, of their Medicare Part B payments for covered professional services through an Advanced APM Entity, or at least 10 percent, but less than 20 percent, of their Medicare patients served through an Advanced APM Entity. If an Advanced APM Entity is notified that they meet the Partial QP threshold, a representative from the APM Entity will log into the MIPS portal to indicate whether all eligible clinicians participating in the APM Entity meeting the Partial QP threshold wish to participate in MIPS.

We finalized in the CY 2018 Quality Payment Program final rule with comment period a new Payer Initiated process for determining payment arrangements that qualify as Other Payer Advanced APMs. We anticipate Payer Initiated Other Payer Advanced APM determination requests for approximately 50 payment arrangements in Medicaid, 150 payment arrangements offered through Medicare Health Plans and 100 payment arrangements from other payers participating in CMS Multi-Payer models (82 FR 53851 through 53856.) This Payer Initiated process to determine Other Payer Advanced APMs will begin in CY 2018, and determinations would be applicable for the Quality Payment Program Year 3.

We also finalized a Medicaid specific Clinician Initiated process for determining payment arrangements that qualify as Other Payer Advanced APMs (82 FR 53860 through 53862). Specifically, we finalized that APM Entities and eligible clinicians may request determinations for any Medicaid payment arrangements in which they are participating at an earlier point (relative to the general Clinician Initiated process), prior to the start of the 2019 performance period (82 FR 53862 through 53864.) This would allow all clinicians in a given state or county to know before the beginning of the performance period whether their Title XIX payments and patients would be excluded from the all-payer calculations that are used for QP determinations for the year under the All-Payer Combination Option. This Medicaid specific Clinician Initiated determination process of Other Payer Advanced APMs will also begin in CY 2018, and determinations would be applicable for the Quality Payment Program Year 3.

B. Justification

1. Need and Legal Basis

Authority for collection of this information is provided under sections 1848(q), 1848(k), 1848(m), 1848(o), 1848(p), and 1833(z) of the Act.

Section 1848(q) of the Act requires the establishment of the MIPS beginning with

payments for items and services furnished on or after January 1, 2019, under which the Secretary is required to: (1) develop a methodology for assessing the total performance of each MIPS eligible clinician according to performance standards for a performance period; (2) using the methodology, provide a final score for each MIPS eligible clinician for each performance period; and (3) use the final score of the MIPS eligible clinician for a performance period to determine and apply a MIPS adjustment factor (and, as applicable, an additional MIPS adjustment factor 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) advancing care information.

2. Information Users

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

We also use this information to provide performance feedback to MIPS eligible clinicians and eligible entities. Some of the information collected will be made available to the public on the Physician Compare website or on data.medicare.gov. The data also may be used by CMS authorized entities participating in health care transparency projects. We anticipate that the data will also be used to produce annual statistical reports that will describe the participation experience of MIPS eligible clinicians and subgroups of MIPS eligible clinicians. We anticipate that the MIPS annual statistical reports will be modeled after two existing annual reports, the PQRS Experience Report and the Value Modifier Report. The 2015 PQRS Experience Report for example includes data on types of data submission problems or other data issues experienced and can be found at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2015_PQRS_Experience_Report.pdf. Relevant data will be provided to federal and state agencies, Quality Improvement Networks, Quality Improvement Organizations (QIOs), the Small, Underserved, and Rural Support (SURS) technical assistance contractors, and the Practice Transformation Networks (PTNs) under the Transforming Clinical Practice Initiative (TCPI) and parties assisting consumers, for use in administering or conducting federally-funded health benefit programs, payment and claims processes, quality improvement outreach and reviews, and transparency projects. In addition, this data may be used by the Department of Justice, a court, or adjudicatory body, another federal agency investigating fraud, waste, and abuse, appropriate agencies in the case of a system breach, or the U.S. Department of

Homeland Security in the event of a cybersecurity incident.

3. Use of Information Technology

All the information collection described in this form is to be conducted electronically.

4. Duplication of Efforts

The information to be collected is not duplicative of similar information collected by the CMS. The final data collection and associated burden for the CY 2017 Quality Payment Program will occur in 2018 with respect to the 2017 performance period. The data submission requirements for the CY 2018 Quality Payment Program will begin in performance period 2018, which will affect data submission burden that will occur in 2019.

With respect to participating in MIPS for MIPS APMs, CMS has set forth requirements that limit duplication of effort. Quality measures submitted by MIPS APM Entities to fulfill the requirements of their MIPS APMs will also be used to fulfill their data submission requirements under MIPS. In addition, as discussed in later sections, many APM Entities will not need to submit improvement activities because participants receive improvement activity credit based on the requirements of the model. For CY 2018 MIPS performance period, expect virtually all MIPS APMs to qualify for the maximum improvement activity performance category score.

5. Small Businesses

Because the vast majority of Medicare providers (well over 90 percent) are small entities within the definition in the Regulatory Flexibility Act (RFA), HHS's normal practice is to assume that all affected clinicians are "small" under the RFA. In this case, most Medicare and Medicaid eligible clinicians are either non-profit entities or meet the Small Business Administration's size standard for small business. The CY 2018 Quality Payment Program final rule with comment's Regulatory Impact Analysis estimates that approximately 622,000 clinicians in MIPS eligible specialties 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 383,514 clinicians in eligible specialties will be excluded from MIPS data submission requirements because they meet the low-volume threshold of less than or equal to \$90,000 in Medicare allowable charges or less than or equal to 200 Medicare patients. Further, we exclude newly enrolled Medicare professionals to reduce data submission burden to those professionals, and estimate that 85,268 would be excluded. Clinicians who meet the low-volume threshold, who are not in MIPS eligible specialties, or who are newly enrolled Medicare clinicians may opt to

³ For further detail on MIPS exclusions, see Supporting Statement B and the Regulatory Impact Analysis Section of the CY 18 Quality Payment Program final rule with comment period (82 FR 53926 through 53950).

submit MIPS data.⁴ Medicare professionals voluntarily participating in MIPS would receive feedback on their performance, but would not be subject to payment adjustments.

In section IV of the CY 2018 Quality Payment Program final rule with comment period (82 FR 53900 through 53926), we explain that we assume 604,006 MIPS eligible clinicians will submit quality data as individual clinicians, or as part of groups or Shared Savings Program ACOs. We also estimate that 288,986 clinicians or 35 percent of the clinicians not subject to a MIPS payment adjustment in CY 2018 will voluntarily submit quality data as individual clinicians, or as part of groups or Shared Savings Program ACOs. Due to limitations of historical Medicare EHR Incentive Program data, we base our estimates of the numbers of clinicians submitting advancing care information data on 2016 PQRS data. We assume that eligible clinicians who submit quality data will also submit data on improvement activities. We also assume that MIPS eligible clinicians that use the attestation submission mechanism for improvement activities will experience minimum burden because they are only required to designate a “yes” next to the improvement activities that they are performing for the CY 2018 performance period. Further detail on those estimates is provided below.

Additionally, we estimate that between 185,000 and 250,000 eligible clinicians will participate in the Quality Payment Program through the Advanced APM Path.

6. Less Frequent Collection

If data on the quality, advancing care information, and improvement activities performance categories are not collected from individual MIPS eligible clinicians or groups annually, we will have no mechanism to: (1) determine whether a MIPS eligible clinician or group meets the performance criteria for a payment adjustment under MIPS, (2) calculate for payment adjustments to MIPS eligible clinicians or groups, and (3) publicly post clinician performance information on the Physician Compare website.

If qualified registries and QCDRs are not required to submit a self-nomination statement, we will have no mechanism to determine which registries and QCDRs will participate in submitting quality measures, improvement activities, or advancing care information measures, objectives and activities. As such, we would not be able to post the annual list of qualified registries which MIPS eligible clinicians use to select qualified registries and QCDRs to use to report quality measures, improvement activities, or advancing care information measures, objectives, and activities to CMS.

7. Special Circumstances

⁴ For further detail on MIPS exclusions, see Supporting Statement B and the Regulatory Impact Analysis Section of the CY 17 Quality Payment Program final rule.

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

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

8. Federal Register/Outside Consultation

The CY 18 Quality Payment Program proposed rule which served as the 60-day Federal Register notice was published on June 20, 2017 (82 FR 30010 through 30500, RIN 0938-AS69, CMS-5517-P). The CY 18 Quality Payment Program final rule served as the 30-day Federal Register notice which published on November 16, 2017 (82 FR 53568). In the proposed rule, we estimated a total of 9,361,065 hours with a total cost of \$856,214,758 for the information collections submitted for approval as a revision of OMB control number 0938-1314. In the final rule with comment period, we have revised our estimate to 7,559,375 hours with a total cost of \$693,172,985. This is a decrease in burden of 1,801,690 hours and a decrease of \$163 million in the labor cost. The change in estimate is due to delaying facility-based measurement which was estimated at 18,207 hours at a total cost of \$657,637; reduction in participation counts due to updated data from PQRS from 2015 to 2016 which changed the number of participants included in all data submission mechanisms; a reduction in hours by 1 for the EHR quality data submission mechanism due to removing the requirement to submit test data for EHR data submission; the inclusion of burden estimates for call for quality measures and call for advancing care information measures; and the inclusion of a burden estimate for the Medicare-specific eligible clinician initiated process for Advanced APM determination.

9. Payments/Gifts to Respondents

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

10. Confidentiality

Consistent with federal government and CMS policies, CMS will protect the confidentiality of the requested proprietary information. Specifically, any confidential information (as such terms are interpreted under the Freedom of Information Act and the Privacy Act of 1974), and will be protected from release by CMS to the extent allowable by law and consistent with 5 U.S.C. § 552a(b).

11. Sensitive Questions

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

12. Burden Estimates (Total Hours & Wages)

12.1 *Wage Estimates*

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

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative, and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method. We have selected the occupations in the table below based on a study (Casalino et al, 2016) that collected data on the staff in physician's offices involved in the quality data submission process.⁵

⁵Lawrence 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.

TABLE 1: Adjusted Hourly Wages Used in Burden Estimates

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

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

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

Because of the wide range of information collection requirements under MIPS, Table 2 presents a framework for understanding how the organizations permitted or required to submit data on behalf of clinicians varies across the types of data, and whether the clinician is a MIPS eligible clinician, MIPS APM participant, or an Advanced APM participant. As shown in the first row of Table 2, MIPS eligible clinicians that are not in MIPS APMs and other clinicians voluntarily submitting data will submit data either as individuals, groups, or virtual groups, as applicable, to the quality, advancing care information, and improvement activities performance categories.

For MIPS APMs, the organizations submitting data on behalf of participating MIPS eligible clinicians will vary across categories of data, and in some instances across APMs. For the 2018 MIPS performance period, the quality data submitted by Shared Savings Program ACOs, Next Generation ACOs, and other MIPS APM Entities on behalf of their participant MIPS eligible clinicians will fulfill any MIPS submission requirements for the quality performance category. For the advancing care information performance category, billing TINs will submit data on behalf of participants who are MIPS eligible clinicians. For the improvement activities performance category, we will assume no reporting burden for MIPS APM participants. In the CY 2017 Quality Payment Program final rule, we describe how we

determine MIPS APM scores (81 FR 77185). We compare the requirements of the specific MIPS APM with the list of activities in the Improvement Activities Inventory and score those activities in the same manner that they are otherwise scored for MIPS eligible clinicians. If, by our assessment, the MIPS APM does not receive the maximum improvement activities performance category score then the APM Entity can submit additional improvement activities. We assume that MIPS APMs available for the CY 2018 MIPS performance period will receive the maximum improvement activities performance category score and, therefore, will not require the APM Entity to submit additional improvement activities. Advanced APM participants who are determined to be Partial QPs may incur additional burden if they elect to participate in MIPS.

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

| Category of Clinician | Data Submitted for Quality Performance Category | Data Submitted for Advancing Care Information Performance Category | Data Submitted for Improvement Activities Performance Category | Other Data Submitted on Behalf of MIPS Eligible Clinician |
|---|--|--|--|--|
| MIPS Eligible Clinicians (not in MIPS APMs) and Other Clinicians Voluntarily Submitting Data⁶ | As group, virtual groups, or individual clinicians | As group, virtual groups, or individuals. Clinicians who practice primarily in a hospital, ambulatory surgical center based clinicians, non-patient facing clinicians, PAs, NPs, CNSs and CRNAs are automatically eligible for a zero percent weighting for the advancing care information performance category. Clinicians approved for significant hardship exceptions are also eligible for a zero percent weighting. | As group, virtual groups, or individual clinicians | Groups electing to use a CMS-approved survey vendor to administer CAHPS must register. Groups electing to submit via CMS Web Interface for the first time must register. Virtual groups must register via email. |

⁶ Virtual group participation is limited to MIPS eligible clinicians, specifically, solo practitioners and groups consisting of 10 eligible clinicians or fewer.

| Category of Clinician | Data Submitted for Quality Performance Category | Data Submitted for Advancing Care Information Performance Category | Data Submitted for Improvement Activities Performance Category | Other Data Submitted on Behalf of MIPS Eligible Clinician |
|--|---|---|--|--|
| Eligible Clinicians participating in the Shared Savings Program or Next Generation ACO Model (both MIPS APMs) | ACOs submit to the CMS Web Interface and CAHPS for ACOs on behalf of their participating MIPS eligible clinicians. [Not included in burden estimate because quality data submission to fulfill requirements of the Shared Savings Program and Next Generation ACO models are not subject to the PRA.] ⁷ | Each group TIN in the APM Entity reports advancing care information to MIPS. ⁸ | CMS will assign the improvement activities performance category score to each APM Entity group based on the activities involved in participation in the Shared Savings Program. ⁹ [The burden estimates assume no improvement activity reporting burden for APM participants because we assume the MIPS APM model provides a maximum improvement activity performance category score.] | Advanced APM Entities will make election for participating MIPS eligible clinicians. |

⁷Sections and 3021 and 3022 of the Affordable Care Act state the Shared Savings Program and testing, evaluation, and expansion of Innovation Center models are not subject to the PRA (42 U.S.C. §1395jjj and 42 U.S.C. §1315a(d) (3), respectively)

⁸For MIPS APMs other than the Shared Savings Program, both group TIN and individual clinician advancing care information data will be accepted. If both group TIN and individual scores are submitted for the same MIPS APM Entity, CMS would take the higher score for each TIN/NPI. The TIN/NPI scores are then aggregated for the APM Entity score.

⁹ APM Entities participating in MIPS APMs do not need to submit improvement activities data unless the CMS-assigned improvement activities scores is below the maximum improvement activities score.

| Category of Clinician | Data Submitted for Quality Performance Category | Data Submitted for Advancing Care Information Performance Category | Data Submitted for Improvement Activities Performance Category | Other Data Submitted on Behalf of MIPS Eligible Clinician |
|---|--|--|---|---|
| Eligible Clinicians participating in Other MIPS APMs | MIPS APM Entities submit to MIPS on behalf of their participating MIPS eligible clinicians [Not included in burden estimate because quality data submission to fulfill requirements of Innovation Center models are not subject to the PRA]. | Each MIPS eligible clinician in the APM Entity reports advancing care information to MIPS through either group TIN or individual reporting. [The burden estimates assume group TIN-level reporting]. | CMS will assign the same improvement activities performance category score to each APM Entity based on the activities involved in participation in the MIPS APM. [The burden estimates assume no improvement activities performance category reporting burden for APM participants because we assume the MIPS APM model provides a maximum improvement activity score]. | Advanced APM Entities will make election for participating eligible clinicians. |

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

The MIPS finalized policies create some additional data collection requirements not listed in Table 2 because they are not associated with submitting MIPS data on behalf of clinicians. These additional data collection requirements, some of which were previously approved by OMB under control numbers 0938-1314 and 0938-1222 are as follows:

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

12.3 *Burden for Third Party Reporting*

Under MIPS, quality, advancing care information, and improvement activities performance categories’ data may be submitted via relevant third-party intermediaries, such as

qualified registries, QCDRs and health IT vendors. The CAHPS for MIPS survey data, which counts as one quality performance category measure, can be submitted via CMS-approved survey vendors. The burdens associated with qualified registry and QCDR self-nomination and the CAHPS for MIPS survey vendor applications are discussed below.

12.4 *Burden for Qualified Registry and QCDR Self-Nomination*¹⁰

For the 2017 MIPS performance period, 120 qualified registries and 113 QCDRs were qualified to report quality measures data, an increase from 114 qualified registries and 69 QCDRs in CY 2016.¹¹ For purposes of the 2018 MIPS performance period, we estimate the same number of qualified registries and QCDRs, for a total of 233. Qualified registries or QCDRs interested in submitting quality measure results and numerator and denominator data on quality measures, improvement activities, or advancing care information measures to use on their participants' behalf will need to complete a self-nomination process.

We estimate that the self-nomination process for qualified registries or QCDRs to submit on behalf of MIPS eligible clinicians or groups for MIPS will involve approximately 1 hour per qualified registry or QCDR to complete the online self-nomination process. The self-nomination form is submitted electronically using a web-based tool. We finalized our proposal to eliminate the option of submitting the self-nomination form via email that was available in the transition year.

In addition to completing a self-nomination statement, qualified registries and QCDRs may need to meet with CMS staff if they have additional questions about the process, primarily if this is a new QCDR or qualified registry that is self-nominating. In addition, QCDRs calculate their measure results. QCDRs must possess benchmarking capability (for QCDR measures) that compares 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, 2016 data for the 2018 MIPS performance period) before the start of the performance period. In addition, the QCDR must provide to us, if available, the entire distribution of the measure's performance broken down by deciles. As an alternative to supplying this information to us, the QCDR may post this information on their website prior to the start of the performance period, to the extent permitted by applicable privacy laws. The time it takes to perform these functions may vary depending on the sophistication of the entity, with newer QCDRs and qualified registries potentially requiring more time to prepare

¹⁰We 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.

¹¹The full list of qualified registries for 2017 is available at https://qpp.cms.gov/docs/QPP_MIPS_2017_Qualified_Registries.pdf and the full list of QCDRs is available at https://qpp.cms.gov/docs/QPP_2017_CMS_Approved_QCDRs.pdf.

for supporting MIPS eligible clinicians and returning QCDRs and qualified registry requiring more minimal time. Considering both new and returning QCDRs and qualified registries, we estimate that a qualified registry or QCDR will spend an additional 9 hours performing various other functions related to being a MIPS qualified registry or QCDR.

As shown in Table 3, we estimate that the staff involved in the qualified registry or QCDR self-nomination process will mainly be computer systems analysts or their equivalent, who have an average labor cost of \$88.10/hour. Therefore, assuming the total burden hours per qualified registry or QCDR associated with the self-nomination process is 10 hours, the annual burden hours is 2,330 ((113 QCDRs + 120 qualified registries) X 10 hours). We estimate that the total cost to a qualified registry or QCDR associated with the self-nomination process will be approximately \$881.00 (\$88.10 per hour X 10 hours per qualified registry). We also estimate that 233 qualified registries or QCDRs will go through the self-nomination process leading to a total burden of \$205,273 (\$881.00 X 233).

Qualified registries and QCDRs must comply with requirements on the submission of MIPS data to CMS. The burden associated with the qualified registry and QCDR submission requirements will be the time and effort associated with calculating quality measure results from the data submitted to the qualified registry or QCDR by its participants and submitting these results, the numerator and denominator data on quality measures, the advancing care information performance category data, and improvement activities data to us on behalf of their participants. We expect that the time needed for a qualified registry to accomplish these tasks will vary along with the number of MIPS eligible clinicians submitting data to the qualified registry or QCDR and the number of applicable measures. However, we believe that qualified registries and QCDRs already perform many of these activities for their participants. We believe the estimate noted in this section represents the upper bound of QCDR burden, with the potential for less additional MIPS burden if the QCDR already provides similar data submission services.

Based on the assumptions previously discussed, we provide an estimate of total annual burden hours and total annual cost burden associated with a qualified registry or QCDR self-nominating to be considered “qualified” to submit quality measures results and numerator and denominator data on MIPS eligible clinicians, as well as improvement activities (with a designation of “yes”), or advancing care information measures.

TABLE 3: Estimated Burden for QCDR and Qualified Registry Self-Nomination

| Burden Data Description | Burden Estimate |
|--|------------------------|
| Estimated # of Qualified registries or QCDRs Self-Nominating (a) | 233 |
| Estimated Total Annual Burden Hours Per Qualified Registry or QCDR (b) | 10 |
| Estimated Total Annual Burden Hours for Qualified Registries or QCDRs (c) = (a)*(b) | 2,330 |
| Estimated Cost Per Qualified Registry or QCDR (@ computer systems analyst's labor rate of \$88.10/hr.) (d) | \$881.00 |
| Estimated Total Annual Burden Cost for Qualified registries or QCDRs (e) = (a)*(d) | \$205,273 |

12.5 *Burden Estimate for the Quality Performance Category*

Two groups of clinicians will submit quality data under MIPS: those who submit as MIPS eligible clinicians and other eligible clinicians who opt to submit data voluntarily but will not be subject to MIPS payment adjustments.

Historically, the PQRS has never experienced 100 percent participation; the participation rate for 2015 was 69 percent.¹² For purposes of these analyses, we assume that a total of 892,992 clinicians who participated in the 2016 PQRS and who are not QPs in Advanced APMs in the 2017 Quality Payment Program performance period will continue to submit quality data as either MIPS eligible clinicians (604,006) or voluntary reporters (288,986) in the 2018 MIPS performance period. Based on 2016 data from the PQRS, and 2017 MIPS eligibility data and 2017 QP determination data, we estimate that a minimum of 90 percent of MIPS eligible clinicians not participating in MIPS APMs will submit quality performance category data including those participating as individual clinicians, groups, or virtual groups. Based on 2016 data from the PQRS, and 2017 MIPS eligibility data and 2017 QP determination data, we estimate that a minimum of 90 percent of MIPS eligible clinicians not participating in MIPS APMs will submit quality performance category data including those participating as individual clinicians, groups, or virtual groups.

We assume that 100 percent of MIPS APM Entities will submit quality data to CMS as required under their models. We anticipate that the professionals submitting data voluntarily will include clinicians that are ineligible for the Quality Payment Program, clinicians that do not exceed the low-volume threshold, and newly enrolled Medicare clinicians. Based on those assumptions, using 2017 MIPS eligibility data file and data from the 2016 PQRS, we estimate that an additional 288,986 clinicians, or 35 percent of clinicians excluded from or ineligible from MIPS, will submit MIPS quality data voluntarily. Because of the exclusion of QPs from

¹² https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2015_PQRS_Experience_Report.pdf.

our burden estimates, we are predicting a decline in the rate of voluntary quality data submission among clinicians excluded from or ineligible for MIPS relative to our estimated voluntary reporting rate of 44 percent in the CY 2017 Quality Payment Program final rule (81 FR77501). Historically, clinicians who are expected to be QPs in 2018 MIPS performance period were much more likely to have submitted quality data under the 2016 PQRS than other clinicians excluded from or ineligible from MIPS. Due to data limitations, our assumptions about quality performance category participation for the purposes of our burden estimates differs from our assumptions about quality performance category participation in the impact analysis.

Our burden estimates for data submission combine the burden for MIPS eligible clinicians and other clinicians submitting data voluntarily. We assume that clinicians will continue to submit quality data under the same submission mechanisms that they used under the 2016 PQRS. We also assume that the approximately 80 TINs that elect to form the approximately 16 virtual groups will continue to use the same submission mechanism as they did when reporting under the 2016 PQRS, but the submission will be at the virtual group, rather than group level. Our burden estimates for the quality performance category do not include the burden for the quality data that MIPS APM Entities submit to fulfill the requirements of their models. Sections 3021 and 3022 of the Affordable Care Act state the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models are not subject to the PRA (42 U.S.C. §1395jjj and 42 U.S.C. §1315a(d)(3), respectively).¹³ Tables 4-a, 4-b, and 4-c explain our revised estimates of the number of organizations (including groups, virtual groups, and individual MIPS eligible clinicians) submitting data on behalf of clinicians via each of the quality submission mechanisms.

Table 4-a provides our estimated counts of clinicians that will submit quality performance category data as MIPS individual clinicians, groups, or virtual groups in the 2018 MIPS performance period. The data estimates the number of clinicians to submit as an individual clinician or group via each mechanism during the 2017 MIPS performance period using 2016 PQRS data on individuals and groups submitting through various mechanisms, and excluding clinicians identified as QPs using the initial QP determination file as described in the 2017 Quality Payment Program final rule (81 FR 77444).

Based on these methods, Table 4-a shows that in the 2018 MIPS performance period, an estimated 278,039 clinicians will submit as individuals via claims submission mechanisms; 255,228 clinicians will submit as individuals, or as part of groups or virtual groups via qualified registry or QCDR submission mechanisms; 131,133 clinicians will submit as individuals, or as part of groups or virtual groups via EHR submission mechanisms; and 93,867 clinicians will submit as part of groups via the CMS Web Interface.

¹³Our estimates do not reflect the burden that MIPS APM participants of submitting advancing care information data, which is outside the requirements of their models.

Although we did not finalize multiple submission mechanisms within a performance category for the 2018 MIPS performance period, we are capturing the burden of any eligible clinician that may have historically submitted via multiple mechanisms, as we assume they would continue to submit via multiple mechanisms and that our MIPS scoring methodology would take the highest score. Hence, the estimated numbers of individual clinicians, groups, and virtual groups to submit via the various submission mechanisms are not mutually exclusive, and reflect the occurrence of individual clinicians or groups that submitted data via multiple mechanism under the 2016 PQRS.

TABLE 4-a: Estimated Number of Clinicians Submitting Quality Performance Category Data by Mechanism

| Description | Claims | QCDR/ registry | EHR | CMS Web Interface |
|---|---------|-------------------|---------|----------------------|
| Estimated number of clinicians to submit via mechanism (as individual clinicians, groups, or virtual groups) in Quality Payment Program Year 1 (excludes QPs) (a) | 278,039 | 255,228 | 131,133 | 93,867 |

Table 4-a provides estimates of the number of clinicians to submit quality measures via each mechanism, regardless of whether they decide to submit as individual clinicians or as part of groups or virtual groups. Because our burden estimates for quality data submission assume that burden is reduced when clinicians elect to submit as part of a group or virtual group, we also separately estimate the expected number of clinicians to submit as individuals or part of groups or virtual groups.

Table 4-b uses methods similar to those described for Table 4-a to estimate the number of clinicians to submit as individual clinicians via each mechanism in Quality Payment Program Year 2. We estimate that approximately 278,039 clinicians will submit as individuals via claims submission mechanisms; approximately 104,281 clinicians will submit as individuals via qualified registry or QCDR submission mechanisms; and approximately 52,709 clinicians will submit as individuals via EHR submission mechanisms. Individual clinicians cannot elect to submit via CMS Web Interface. Consistent with the policy finalized in section II.C.7.a. of the final rule with comment period to score individual clinicians on quality measures independently for each submission mechanism submitted via multiple mechanisms, our columns in Table 4-b are not mutually exclusive.

TABLE 4-b: Estimated Number of Clinicians Submitting Quality Performance Category Data as Individuals

| Description | Claims | QCDR/registry | EHR | CMS Web Interface |
|---|---------------|----------------------|------------|--------------------------|
| Estimated number of Clinicians to submit data as individuals in Quality Payment Program Year 1 (excludes QPs) (a) | 278,039 | 104,281 | 52,709 | 0 |

Table 4-c provides our estimated counts of groups or virtual groups to submit quality data on behalf of clinicians via each mechanism in the 2018 MIPS performance period and reflects our assumption that the formation of virtual groups will reduce burden. Except for groups comprised entirely of QPs, we assume that groups that submitted quality data as groups under the 2016 PQRS will continue to submit quality data either as groups or virtual groups via the same submission mechanisms as they did as a group or TIN within a virtual group for the 2018 MIPS performance period. The first step in estimating the numbers of groups or virtual groups to submit via each mechanism in the 2018 MIPS performance period was to estimate the number of groups to submit on behalf of clinicians via each mechanism in the 2017 MIPS performance period. We used 2016 PQRS data on groups submitting on behalf of clinicians via various mechanisms and excluded groups comprised entirely of QPs using the initial QP determination file as described in the 2017 Quality Payment Program final rule (81 FR 77444). The second and third steps in Table 4-c reflect our assumption that virtual groups will reduce the burden for quality data submission by reducing the number of organizations to submit quality data on behalf of clinicians. We assume that 40 groups that previously submitted on behalf of clinicians via QCDR or qualified registry submission mechanisms will elect to form 8 virtual groups that will submit via QCDR and qualified registry submission mechanisms. We assume that another 40 groups that previously submitted on behalf of clinicians via EHR submission mechanisms will elect to form another 8 virtual groups via EHR submission mechanisms. Hence, the third step in Table 4-c is to subtract out the estimated number of groups under each submission mechanism that will elect to form virtual groups, and the fourth step in Table 4-c is to add in the estimated number of virtual groups that will submit on behalf of clinicians via each submission mechanism.

Specifically, we assumed that 2,936 groups and virtual groups will submit data via QCDR/registry submission mechanisms on behalf of 150,947 clinicians; 1,509 groups and virtual groups will submit via EHR submission mechanisms on behalf of 78,424 eligible clinicians; and 296 groups will submit data via the CMS Web Interface on behalf of 93,867 clinicians. Groups cannot elect to submit via the claims submission mechanism.

TABLE 4-c: Estimated Number of Groups and Virtual Groups Submitting Quality Performance Category Data by Mechanism on Behalf of Clinicians

| Description | Claims | QCDR/registry | EHR | CMS Web Interface |
|--|--------|---------------|-------|-------------------|
| Estimated number of groups to submit via mechanism (on behalf of clinicians) in Quality Payment Program Year 1 (excludes QPs) (a) | 0 | 2,968 | 1,541 | 296 |
| Subtract out: Estimated number groups to submit via mechanism on behalf of clinicians in Quality Payment Program Year 1 that will submit as virtual groups in Quality Payment Program Year 2 (b) | 0 | 40 | 40 | 0 |
| Add in: Estimated number of virtual groups to submit via mechanism on behalf of clinicians in Quality Payment Program Year 2 (c) | 0 | 8 | 8 | 0 |
| Estimated number groups to submit via mechanism on behalf of clinicians in Quality Payment Program Year 2 (d)=(a)-(b)+(c) | 0 | 2,936 | 1,509 | 296 |

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

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

We anticipate that clinicians and groups using QCDR, qualified registry, and EHR submission mechanisms will have the same start-up costs related to reviewing measure specifications. As such, we estimate for clinicians, groups, and virtual groups using any of these three submission mechanisms a total of 6 staff hours needed to review the quality measures list, review the various submission options, select the most appropriate submission option, identify the applicable measures or specialty measure sets for which they can report the necessary information, which may include some minimal follow-up with CMS to ask questions or become more informed about the measures or submission process, review the measure specifications for

the selected measures or measures group, and incorporate submission of the selected measures or specialty measure sets into the practice work flows. Building on data in a recent article, Casalino et. al. (2016), we assume that a range of expertise is needed to review quality measure specifications: 2 hours of a practice administrator's time, 1 hour of a clinician's time, 1 hour of an LPN/medical assistant's time, 1 hour of a computer systems analyst's time, and 1 hour of a billing clerk's time.¹⁴ In the CY 2017 Quality Payment Program final rule we estimated 3 hours for a practice administrator's time for data submission. Because the new CMS API will be available for EHR, registry and QCDR, and CMS Web Interface submission mechanisms, we have reduced our estimate to 2 hours of a practice administrator's time for data submission for EHR and 2 hours using registry or QCDR. This CMS API will streamline the process of reviewing measure specifications and submitting measures for third-party submission mechanisms. We have also reduced our burden estimate for CMS Web Interface to reflect the new CMS API in a separate section below.¹⁵

For the claims submission mechanism, we estimate that the start-up cost for a MIPS eligible clinician's practice to review measure specifications is \$684.90, including 3 hours of a practice administrator's time (3 hours X \$105.16=\$315.48), 1 hour of a computer systems analyst time (1 hour X \$88.10/hour=\$88.10), 1 hour of an LPN/medical assistant's time (1 hour X \$43.12), 1 hour of a billing clerk's time (1 hour X \$36.12/hour = \$36.12) and 1 hour of a clinician's time (1 hour X \$202.08/hour=\$202.08). These start-up costs pertain to the specific quality submission methods below, and hence appear in the burden estimate tables. For the purposes of our burden estimates for the claims, qualified registry and QCDR, and EHR submission mechanisms, we also assume that, on average, each clinician, group, or virtual group will submit 6 quality measures.

Our estimated number of respondents for the QCDR/qualified registry and EHR submission mechanisms increased relative to the estimates in the CY 2017 Quality Payment Program final rule. Our estimated respondents for the claims submission mechanism has declined relative to the CY 2017 Quality Payment Program final rule in part because we have excluded QPs from our burden estimates; in the CY 2017 Quality Payment Program final rule, QPs were included in our burden estimates due to data limitations. The number of respondents for CMS Web Interface has declined relative to the estimates in the CY 2017 Quality Payment Program final rule because our estimates now exclude QPs and CMS Web Interface data submitted in 2016 by Shared Savings Program and Next Generation and Pioneer ACOs to fulfill the requirement of their models. As noted in this section of the CY 2018 Quality

¹⁴Our burden estimates are based on prorated versions of the estimates for reviewing measure specifications in Lawrence P. Casalino et al, "US Physician Practices Spend More than \$15.4 Billion Annually to Report Quality Measures," Health Affairs, 35, no. 3 (2016): 401-406. The estimates were annualized to 50 weeks per year, and then prorated to reflect that Medicare revenue is 30 percent of all revenue paid by insurers, and then adjusted to reflect that the decrease from 9 required quality measures under PQRS to 6 required measures under MIPS.

¹⁵CMS: New API Will Automate MACRA Quality Measure Data Sharing.

<http://healthitanalytics.com/news/cms-new-api-will-automate-macra-quality-measure-data-sharing>.

Payment Program final rule with comment period, information collections associated with the Shared Savings Program and the testing, evaluation, and expansion of CMS Innovation Center models are not subject to the PRA.

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

As noted in Table 4-a, based on 2016 PQRS data and 2017 MIPS eligibility data, we assume that 278,039 individual clinicians will submit quality data via claims. We anticipate the claims submission process for MIPS will be operationally similar to the way the claims submission process functioned under the PQRS. Specifically, clinicians will need to gather the required information, select the appropriate quality data codes (QDCs), and include the appropriate QDCs on the claims they submit for payment. Clinicians will collect QDCs as additional (optional) line items on the CMS-1500 claim form or the electronic equivalent HIPAA transaction 837-P, approved by OMB under control number 0938-1197.

The total estimated burden of claims-based submission will vary along with the volume of claims on which the submission is based. Based on our experience with the PQRS, we estimate that the burden for submission of quality data will range from 0.22 hours to 10.8 hours per clinician. The wide range of estimates for the time required for a clinician to submit quality measures via claims reflects the wide variation in complexity of submission across different clinician quality measures. As shown in Table 5, we also estimate that the cost of quality data submission using claims will range from \$19.38 (0.22 hours X \$88.10) to \$951.48 (10.8 hours X \$88.10). The total estimated annual cost per clinician ranges from the minimum burden estimate of \$704.28 to a maximum burden estimate of \$1,636.38. The burden will involve becoming familiar with MIPS data submission requirements. As noted in Table 5, we believe that the start-up cost for a clinician's practice to review measure specifications totals 7 hours, which includes 3 hours of a practice administrator's time (3 hours X \$105.16 = \$315.48), 1 hour of a clinician's time (1 hour X \$202.08/hour = \$202.08), 1 hour of an LPN/medical assistant's time (1 hour X \$43.12 = \$43.12), 1 hour of a computer systems analyst's time (1 hour X \$88.10 = \$88.10), and 1 hour of a billing clerk's time (1 hour X \$36.12/hour = \$36.12).

Considering both data submission and start-up costs, the total estimated burden hours per clinician ranges from a minimum of 7.22 hours (0.22 + 3 + 1 + 1 + 1 + 1) to a maximum of 17.8 hours (10.8 + 3 + 1 + 1 + 1 + 1). The total estimated annual cost per clinician ranges from the minimum estimate of \$704.28 (\$19.38 + \$315.48 + \$88.10 + \$43.12 + \$36.12 + \$202.08) to a maximum estimate of \$1,636.38 (\$951.48 + \$315.48 + \$88.10 + \$43.12 + \$36.12 + \$202.08). Therefore, total annual burden cost is estimated to range from a minimum burden estimate of \$195,817,307 (278,039 X \$704.28) to a maximum burden estimate of \$454,977,459 (278,039 X \$1,636.38).

Based on the assumptions discussed above, Table 5 summarizes the range of total

annual burden associated with clinicians using the claims submission mechanism.

TABLE 5: Burden Estimate for Quality Performance Category: Clinicians Using the Claims Submission Mechanism

| Burden Data Description | Minimum Burden | Median Burden | Maximum Burden Estimate |
|--|-----------------------|----------------------|--------------------------------|
| Estimated # of Clinicians (a) | 278,039 | 278,039 | 278,039 |
| Burden Hours Per Clinician to Submit Quality Data (b) | 0.22 | 1.58 | 10.8 |
| Estimated # of Hours Practice Administrator Review Measure Specifications (c) | 3 | 3 | 3 |
| Estimated # of Hours Computer Systems Analyst Review Measure Specifications (d) | 1 | 1 | 1 |
| Estimated # of Hours LPN Review Measure Specifications (e) | 1 | 1 | 1 |
| Estimated # of Hours Billing Clerk Review Measure Specifications (f) | 1 | 1 | 1 |
| Estimated # of Hours Clinician Review Measure Specifications (g) | 1 | 1 | 1 |
| Estimated Annual Burden hours per Clinician (h) = (b)+(c)+(d)+(e)+(f)+(g) | 7.22 | 8.58 | 17.8 |
| Estimated Total Annual Burden Hours (i) = (a)*(h) | 2,007,442 | 2,385,575 | 4,949,094 |
| Estimated Cost to Submit Quality Data (@ computer systems analyst's labor rate of \$88.10/hr.) (j) | \$19.38 | \$139.20 | \$951.48 |
| Estimated Cost to Review Measure Specifications (@ practice administrator's labor rate of \$105.16/hr.) (k) | \$315.48 | \$315.48 | \$315.48 |
| Estimated Cost to Review Measure Specifications (@ computer systems analyst's labor rate of \$88.10/hr.) (l) | \$88.10 | \$88.10 | 88.10 |
| Estimated Cost to Review Measure Specifications (@ LPN's labor rate of \$43.12/hr.) (m) | \$43.12 | \$43.12 | \$43.12 |
| Estimated Cost to Review Measure Specifications (@ billing clerk's labor rate of \$36.12/hr.) (n) | \$36.12 | \$36.12 | \$36.12 |
| Estimated Cost to Review Measure Specifications (@ physician's labor rate of \$202.08/hr.) (o) | \$202.08 | \$202.08 | \$202.08 |
| Estimated Total Annual Cost Per Clinician (p) = (j)+(k)+(l)+(m)+(n)+(o) | \$704.28 | \$824.10 | \$1,636.38 |
| Estimated Total Annual Burden Cost (q) = (a)*(p) | \$195,817,307 | \$229,131,940 | \$454,977,459 |

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

As noted in Table 4-a and based on the 2016 PQRS data and 2017 MIPS eligibility data, we assume that 255,228 clinicians will submit quality data as individuals, groups, or virtual groups via qualified registry or QCDR submissions. Of these, we expect 104,281

clinicians, as shown in Table 4-b, to submit as individuals and 2,936 groups, as shown in Table 4-c, are expected to submit on behalf of the remaining 150,947 clinicians. Given that the number of measures required is the same for clinicians, groups, and virtual groups, we expect the burden to be the same for each respondent submitting data via qualified registry or QCDR, whether the clinician is participating in MIPS as an individual, group or virtual group.

We estimate that burdens associated with QCDR submissions are similar to the burdens associated with qualified registry submissions. Therefore, we discuss the burden for both data submissions together below. For qualified registry and QCDR submissions, we estimate an additional time burden for respondents (individual clinicians, groups, and virtual groups) to become familiar with MIPS submission requirements and, in some cases, specialty measure sets and QCDR measures. Therefore, we believe that the costs for an individual clinician or group to review measure specifications and submit quality data total \$851.05. For review costs and data submission costs, this total includes 3 hours per respondent to submit quality data (3 hours X \$88.10/hour = \$264.00), 3 hours of a practice administrator’s time (2 hours X \$105.16/hour = \$210.32), 1 hour of a computer systems analyst’s time (1 hour X \$88.10/hour = \$88.10), 1 hour of an LPN/medical assistant’s time, (1 hour X \$43.12/hour = \$43.12), 1 hour of a billing clerk’s time (1 hour X \$36.12/hour = \$36.12), and 1 hour of a clinician’s time (1 hour X \$202.08). Clinicians, groups, and virtual groups will need to authorize or instruct the qualified registry or QCDR to submit quality measures’ results and numerator and denominator data on quality measures to us on their behalf. We estimate that the time and effort associated with authorizing or instructing the quality registry or QCDR to submit this data will be approximately 5 minutes (0.083 hours) per clinician or group (respondent) for a total burden cost of \$7.31, at a computer systems analyst’s labor rate (.083 hours X \$88.10/hour). Hence, as shown in Table 6, we estimate 9.083 burden hours per respondent, with annual total burden hours of 973,852 (9.083 burden hours X 107,217 respondents). The total estimated annual cost per respondent is estimated to be approximately \$851.05. Therefore, total annual burden cost is estimated to be \$91,247,028 (107,217 X \$851.05). Based on these assumptions, we have estimated the burden for these submissions.

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

| Burden Data Description | Burden Estimate |
|--|------------------------|
| # of clinicians submitting as individuals (a) | 104,281 |
| # of groups or virtual groups submitting via QCDR or registry on behalf of individual clinicians (b) | 2,936 |
| # of Respondents (groups and virtual groups plus clinicians submitting as individuals) (c)=(a)+(b) | 107,217 |

| Burden Data Description | Burden Estimate |
|---|------------------------|
| Estimated Burden Hours Per Respondent to Report Quality Data (d) | 3 |
| Estimated # of Hours Practice Administrator Review Measure Specifications (e) | 2 |
| Estimated # of Hours Computer Systems Analyst Review Measure Specifications (f) | 1 |
| Estimated # of Hours LPN Review Measure Specifications (g) | 1 |
| Estimated # of Hours Billing Clerk Review Measure Specifications (h) | 1 |
| Estimated # of Hours Clinician Review Measure Specifications (i) | 1 |
| Estimated # of Hours Per Respondent to Authorize Qualified Registry to Report on Respondent's Behalf (j) | 0.083 |
| Estimated Annual Burden Hours Per Respondent (k) = (d)+(e)+(f)+(g)+(h)+(i)+(j) | 9.083 |
| Estimated Total Annual Burden Hours (l) = (c)*(k) | 973,852 |
| Estimated Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of \$88.10/hr.) (m) | \$264.00 |
| Estimated Cost to Review Measure Specifications (@ practice administrator's labor rate of \$105.16/hr.) (n) | \$210.32 |
| Estimated Cost Computer System's Analyst Review Measure Specifications (@ computer systems analyst's labor rate of \$88.10/hr.) (o) | \$88.10 |
| Estimated Cost LPN Review Measure Specifications (@ LPN's labor rate of \$43.12/hr.) (p) | \$43.12 |
| Estimated Cost Billing Clerk Review Measure Specifications (@ clerk's labor rate of \$36.12/hr.) (q) | \$36.12 |
| Estimated Cost Clinician Review Measure Specifications (@ physician's labor rate of \$202.08/hr.) (r) | \$202.08 |
| Estimated Burden for Submission Tool Registration etc. (@ computer systems analyst's labor rate of \$88.1/hr.) (s) | \$7.31 |
| Estimated Total Annual Cost Per Respondent (t) = (m)+(n)+(o)+(p)+(q)+(r)+(s) | \$851.05 |
| Estimated Total Annual Burden Cost (u) = (c)*(t) | \$91,247,028 |

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

As noted in Tables 4-a, 4-b and 4-c, based on our analysis of 2016 PQRS data, the initial QP determination file and special status and 2017 MIPS eligibility (available via the NPI lookup on qpp.cms.gov) using a date range of September 1, 2015 – August 31, 2016 data, we assume that 131,133 clinicians will submit quality data as individuals or groups via EHR submissions; 52,709 clinicians are expected to submit as individuals; and 1,509 groups are expected to submit on behalf of 78,424 clinicians. We expect the burden to be the same for each

respondent submitting data via EHR, whether the clinician is participating in MIPS as an individual or group.

Under the EHR submission mechanism, the individual clinician or group may either submit the quality measures data directly to us from their EHR or utilize an EHR data submission vendor to submit the data to us on the clinician's or group's behalf.

To prepare for the EHR submission mechanism, the clinician or group must review the quality measures on which we will be accepting MIPS data extracted from EHRs, select the appropriate quality measures, extract the necessary clinical data from their EHR, and submit the necessary data to the CMS-designated clinical data warehouse or use a health IT vendor to submit the data on behalf of the clinician or group. We assume the burden for submission of quality measures data via EHR is similar for clinicians, groups, and virtual groups who submit their data directly to us from their CEHRT and clinicians, groups, and virtual groups who use an EHR data submission vendor to submit the data on their behalf. To submit data to us directly from their CEHRT, clinicians, groups, and virtual groups must have access to a CMS-specified identity management system which we believe takes less than 1 hour to obtain. Once a clinician or group has an account for this CMS-specified identity management system, they will need to extract the necessary clinical data from their EHR, and submit the necessary data to the CMS-designated clinical data warehouse.

We estimate that obtaining an account on a CMS-specified identity management system will require 1 hour per respondent for a cost of \$88.10 (1 hour X \$88.10/hour). For submitting the actual data file, we believe that this will take clinicians or groups no more than 2 hours per respondent for a cost of submission of \$176.20 (2 hours X \$88.10/hour). The burden will involve becoming familiar with MIPS submission. We believe that the start-up cost for a clinician or group to review measure specifications is a total of 6 hours, which includes 2 hours of a practice administrator's time (2 hours X \$105.16/hour = \$210.32), 1 hour of a clinician's time (1 hour X \$202.08/hour = \$202.08), 1 hour of a computer systems analyst's time (1 hour X \$88.10/hour = \$88.10), 1 hour of an LPN/medical assistant's time (1 hour X \$43.12/hour = \$43.12), and 1 hour of a billing clerk's time (1 hour X \$36.12/hour = \$36.12). Hence, and as shown in Table 7, we estimated 9 total burden hours per respondent with annual total burden hours of 487,962 (9 burden hours X 54,218 respondents). The total estimated annual cost per respondent is estimated to be \$844.04. Therefore, total annual burden cost is estimated to be \$45,762,161 = (54,218 respondents X \$844.04).

Based on the assumptions discussed above, we have estimated the burden for the quality data submission using EHR submission mechanism below in Table 7.

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

| Burden Data Description | Burden estimate |
|--|------------------------|
| # of clinicians submitting as individuals (a) | 52,709 |
| # of Groups and virtual groups submitting via EHR on behalf of individual clinicians (b) | 1,509 |
| # of Respondents (groups and virtual groups plus clinicians submitting as individuals) (c)=(a)+(b) | 54,218 |
| Estimated Burden Hours Per Respondent to Obtain Account in CMS-Specified Identity Management System (d) | 1 |
| Estimated Burden Hours Per Respondent to Submit MIPS Quality Data File to CMS (e) | 2 |
| Estimated # of Hours Practice Administrator Review Measure Specifications (f) | 2 |
| Estimated # of Hours Computer Systems Analyst Review Measure Specifications (g) | 1 |
| Estimated # of Hours LPN Review Measure Specifications (h) | 1 |
| Estimated # of Hours Billing Clerk Review Measure Specifications (i) | 1 |
| Estimated # of Hours Clinicians Review Measure Specifications (j) | 1 |
| Estimated Annual Burden Hours Per Respondent (k)=(d)+(e)+(f)+(g)+(h)+(i)+(j) | 9 |
| Estimated Total Annual Burden Hours (l)=(c)*(k) | 487,962 |
| Estimated Cost Per Respondent to Obtain Account in CMS-specified identity management system (@ computer systems analyst's labor rate of \$88.10/hr.) (m) | \$88.10 |
| Estimated Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of \$88.10/hr.) (n) | \$176.20 |
| Estimated Cost to Review Measure Specifications (@ practice administrator's labor rate of \$105.16/hr.) (o) | \$210.32 |
| Estimated Cost to Review Measure Specifications (@ computer systems analyst's labor rate of \$88.10/hr.) (p) | \$88.10 |
| Estimated Cost to Review Measure Specifications (@ LPN's labor rate of \$43.12/hr.) (q) | \$43.12 |
| Estimated Cost to Review Measure Specifications (@ clerk's labor rate of \$36.12/hr.) (r) | \$36.12 |
| Estimated Cost to D21Review Measure Specifications (@ physician's labor rate of \$202.08/hr.) (s) | \$202.08 |
| Estimated Total Annual Cost Per Respondent (t)=(m)+(n)+(o)+(p)+(q)+(r)+(s) | \$844.04 |
| Estimated Total Annual Burden Cost (u)=(c)*(t) | \$45,762,161 |

12.5.4 Burden for Quality Data Submission via CMS Web Interface

Based on 2016 PQRS data and as shown in Table 8, we assume that 296 groups will submit quality data via the CMS Web Interface in the 2018 MIPS performance period. We anticipate that approximately 93,867 clinicians will be represented.

The burden associated with the group submission requirements under the CMS Web Interface is the time and effort associated with submitting data on a sample of the organization’s beneficiaries that is prepopulated in the CMS Web Interface. Based on experience with PQRS GPRO Web Interface submission mechanism, we estimate that, on average, it will take each group 74 hours of a computer systems analyst’s time to submit quality measures data via the CMS Web Interface at a cost of \$88.10 per hour, for a total cost of \$6,519 (74 hours X \$88.10/hour). Our estimate of 74 hours for submission includes the time needed for each group to populate data fields in the web interface with information on approximately 248 eligible assigned Medicare beneficiaries and then submit the data (we will partially pre-populate the CMS Web Interface with claims data from their Medicare Part A and B beneficiaries). The patient data either can be manually entered or uploaded into the CMS Web Interface via a standard file format, which can be populated by CEHRT. Because the CMS API will streamline the measure submission process for many groups, we have reduced our estimate of the computer system’s analyst time needed for submission from 79 hours in the CY 2017 Quality Payment Program final rule to 74 hours. Because each group must provide data on 248 eligible assigned Medicare beneficiaries (or all eligible assigned Medicare beneficiaries if the pool of eligible assigned beneficiaries is less than 248) for each measure, we assume that entering or uploading data for one Medicare beneficiary across all the measures requires approximately 18 minutes of a computer systems analyst’s time (74 hours ÷ 248 patients for each measure).

The total annual burden hours are estimated to be 21,904 (296 groups X 74 annual hours), and the total annual burden cost is estimated to be \$1,929,624 (296 groups X \$6,519).

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

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

| Burden Data Description | Burden Estimate |
|--|------------------------|
| Estimated # of Eligible Group Practices (a) | 296 |
| Estimated Total Annual Burden Hours Per Group to Submit (b) | 74 |
| Estimated Total Annual Burden Hours (c) = (a)*(b) | 21,904 |
| Estimated Cost Per Group to Report (@ computer systems analyst’s labor rate of \$88.10/hr.) (d) | \$6,519 |
| Estimated Total Annual Cost Per Group (e) = (b)*(d) | \$6,519 |

| Burden Data Description | Burden Estimate |
|--|-----------------|
| Estimated Total Annual Burden Cost (f) = (a)*(e) | \$1,929,624 |

Table 9: Burden Summary for Quality Data Submission via the CMS Web Interface

| Burden Summary | By Eligible Clinician or Group |
|---|--------------------------------|
| Estimated # of Participating Eligible Professionals (g) | 252,808 |
| Average Burden Hours Per Eligible Professional (h) = (c) ÷ (g) | 0.09 |
| Estimated Cost Per Eligible Professional to Report Quality Data (i) = (f) ÷ (g) | \$7.63 |

12.5.5 Burden for Group Registration for CMS Web Interface

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

TABLE 10: Total Estimated Burden for Group Registration for CMS Web Interface

| Burden Data Description | Burden Estimate |
|--|-----------------|
| Estimated Number of New Groups Registering for CMS Web Interface (a) | 10 |
| Estimated Annual Burden Hours Per Group (b) | 1 |
| Estimated Total Annual Burden Hours (c) = (a)*(b) | 10 |
| Estimated Cost per Group to Register for CMS Web Interface @ computer systems analyst's labor rate of \$88.10/hr.) (d) | \$88.10 |
| Estimated Total Annual Burden Cost for CMS Web Interface Group Registration (e) = (a)*(d) | \$881 |

12.5.6 *Burden for Call for Quality Measures*

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

As we described previously 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>). There were no changes to the Call for Quality Measures process in the CY 2018 rule and so this process is not discussed in the CY 2018 rule, but they are included here because the activity will occur in 2018.

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

As shown in Table 11, we estimate that approximately 40 organizations, including clinicians, EHR developers, and vendors, will submit measures for the Call for Quality Measures process. In keeping with the focus on clinicians as the primary source for recommending new quality measures, we are using practice administrators and clinician time for our burden estimates. We estimate it will take 0.5 hours per organization to submit a measure to us, including an estimated 0.3 hours for a practice administrator’s at a rate of \$105.16/hour for a total of \$31.55 per measure and for clinician review time of 0.2 hours at a rate of \$202.08/hour for a total of \$40.42 per measure. We estimate that the total annual burden cost is \$2,879 (40 x \$71.97).

TABLE 11: Estimated Burden for Nomination of Quality Measures

| Burden Data Description | Burden estimate |
|--|------------------------|
| # of Organizations Nominating New Quality Measures (a) | 40 |
| Estimated # of Hours Per Practice Administrator to Identify and Propose Measure (b) | 0.30 |
| Estimated # of Hours Per Clinician to Review Measure (c) | 0.20 |
| Estimated Annual Burden Hours Per Respondent (d)= (b) + (c) | 0.50 |
| Estimated Total Annual Burden Hours (e) = (a)*(d) | 20 |
| Estimated Cost to Identify and Submit Measure (@ practice administrator's labor rate of \$105.16/hr.) (f) | \$31.55 |
| Estimated Cost to Review Improvement Measure (@ physician's labor rate of \$202.08/hr.) (g) | \$40.42 |
| Estimated Total Annual Cost Per Respondent (h)=(f)+(g) | \$71.97 |
| Estimated Total Annual Burden Cost (i)=(a)*(h) | \$2,879 |

12.6 *Burden for Advancing Care Information Data*

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

12.6.1 *Burden for Advancing Care Information Application*

MIPS eligible clinicians may apply to have their advancing care information performance category re-weighted to zero through the Quality Payment Program due to a significant hardship exception or exception for decertified EHR technology. MIPS eligible clinicians who are in small practices (15 or fewer clinicians) may, beginning with the 2018 MIPS performance period

and 2020 MIPS payment year, request a reweighting to zero for the advancing care information performance category due to a significant hardship.

Table 12 shows the estimated annualized burden for clinicians to apply for a reweighting to zero of their advancing care information performance category as well as an application for significant hardship by small practices. Based on 2016 data from the Medicare EHR Incentive Program and the first 2019 payment year MIPS eligibility and special status file, we assume 40,645 respondents (eligible clinicians, groups, or virtual groups) will submit a request for reweighting to zero of their advancing care information performance category due to a significant hardship exception, decertification of an EHR or significant hardship for small practices through the Quality Payment Program. We estimate that 5,812 respondents (eligible clinicians, groups, or virtual groups) will submit a request for a reweighting to zero for the advancing care information performance category due to a significant hardship exception or as a result of a decertification of an EHR, and 34,833 respondents will submit a request for a reweighting to zero for the advancing care information performance category as a small practice. Historically, we have received fewer than 10 significant hardship applications dues to natural disasters which is therefore is not reflected in our total number of estimated respondents.

The application to request a reweighting to zero for the advancing care information performance category due to significant hardship is an online form that requires identifying which type of hardship or if decertification of an EHR applies and a description of how the circumstances impair the ability to submit the advancing care information data, as well as some proof of circumstances beyond the submitter’s control. The estimate to submit this application is 0.5 hours of a computer system analyst’s time. Given that we expect 40,645 applications per year, the annual total burden hours are estimated to be 20,323 hours (40,645 respondents X 0.5 burden hours per respondent). The estimated total annual burden is \$1,790,412 (40,645 X \$44.05).

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

| Burden Data Description | Burden estimate |
|---|------------------------|
| # of Eligible Clinicians, Groups, or Virtual Groups Applying Due to Significant Hardship and Other Exceptions (a) | 5,812 |
| # of Eligible Clinicians, Groups, or Virtual Groups Applying Due to Significant Hardship as Small Practice (b) | 34,833 |
| Total respondents Due to Hardships, Other Exceptions and Hardships for Small Practices (c) | 40,645 |
| Estimated Burden Hours Per Applicant for Advancing Care Information (d) | 0.5 |
| Estimated Total Annual Burden Hours (e)=(a)*(c) | 20,323 |

| Burden Data Description | Burden estimate |
|--|------------------------|
| Estimated Cost Per Applicant for Advancing Care Information (@ computer systems analyst's labor rate of \$88.10/hr.) (f) | \$44.05 |
| Estimated Total Annual Burden Cost (g)=(a)*(f) | \$1,790,412 |

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

A variety of organizations will submit advancing care information data on behalf of clinicians. Clinicians not participating in a MIPS APM can submit as individuals or as part of a group or virtual group. Group TINs may submit advancing care information data on behalf of clinicians in MIPS APMs, or, except for participants in the Shared Savings Program, clinicians in MIPS APMs may submit advancing care information performance category data individually. Because group TINs in APM Entities will be submitting advancing care information data to fulfill the requirements of submitting to MIPS, we have included MIPS APMs in our burden estimate for the advancing care information performance category. Consistent with the list of APMs that are MIPS APMs on the Quality Payment Program website,¹⁶ we assume that 3 MIPS APMs that do not also qualify as Advanced APMs will operate in the 2018 MIPS performance period: Track 1 of the Shared Savings Program, CEC (one-sided risk arrangement), and the OCM (one-sided risk arrangement). Further, we assume that group TINs will submit advancing care information data on behalf of Partial QPs that elect to participate in MIPS.

As shown in Table 13, based on data from the 2015 and 2016 Medicare and Medicaid EHR Incentive Programs, the 2016 PQRS data, and 2017 MIPS eligibility data, we estimate that 195,022 individual MIPS eligible clinicians and 668 groups or virtual groups, representing 101,873 MIPS eligible clinicians, will submit advancing care information data. These estimates reflect that under the policies finalized in CY 2017 Quality Payment Program final rule, certain MIPS eligible clinicians will be eligible for automatic reweighting of their advancing care information performance category score to zero, including MIPS eligible clinicians that practice primarily in the hospital, physician assistants, nurse practitioners, clinician nurse specialists, certified registered nurse anesthetists, and non-patient facing clinicians. These estimates also account for the significant hardships finalized in the CY 2017 Quality Payment Program final rule and the final policies adopted in the CY 2018 Quality Payment Program final rule with comment period for significant hardship exceptions, including for MIPS eligible clinicians in small practices, as well as exceptions due to decertification of an EHR. Due to data limitations, our estimate of the number of clinicians to submit advancing care information data does not account for our policy finalized in CY 2018 Quality Payment Program final rule with comment period to rely on section 1848(o)(2)(D) of the Act, as amended by section 4002(b)(1)(B) of the

¹⁶https://qpp.cms.gov/docs/QPP_Advanced_APMs_in_2017.pdf

21st Century Cures Act, to assign a scoring weight of zero percent for the advancing care information performance category for MIPS eligible clinicians who are determined to be based in ASCs.

Further, we anticipate that the 480 Shared Savings Program ACOs will submit data at the ACO participant group TIN-level, for a total of 15,945 group TINs. We anticipate that the three APM Entities electing the one-sided track in the CEC model will submit data at the group TIN-level, for an estimated total of 100 group TINs submitting data. We anticipate that the 195 APM Entities in the OCM (one-sided risk arrangement) will submit data at the APM Entity level, for an estimated total of 6,478 group TINs. Based on the initial QP determination file, we estimate 2 APM Entities in the CPC+ model will submit at the group TIN-level, for an estimated total of 2 group TINs submitting data. Based on the initial QP determination file, we assume that 1 CPC+ APM entity will submit data because one or more of its participants is a partial QP, and that 1 CPC+ APM Entity will submit data because some of its participants qualify either as QPs or partial QPs. The total estimated number of respondents is estimated at 218,215.

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

| Description | Estimated # of Respondents | Estimated # of APM Entities |
|---|----------------------------|-----------------------------|
| Number of individual clinicians to submit advancing care information (a) | 195,022 | Not applicable |
| Number of groups or virtual groups to submit advancing care information (b) | 668 | Not applicable |
| Shared Savings Program ACO Group TINs (c) | 15,945 | 480 |
| CEC one-sided risk track participants ¹⁷ (d) | 100 | 3 |
| OCM one-sided risk arrangement Group TINs (e) | 6,478 | 195 |
| CPC+ TINs (f) | 2 | 2 |
| Total (g) = (a) + (b) + (c) + (d) + (e) + (f) | 218,215 | 680 |

12.6.3 Burden for Submission of Advancing Care Information Data

In Table 13, we estimate that up to approximately 218,215 respondents will be submitting data under the advancing care information performance category: 195,022 clinicians, 668 groups or virtual groups, 15,945 group TINs within the Shared Savings Program ACOs, 100 group TINs within the APM Entity participating in CECs in the one-sided risk track, and 6,478 group TINs

¹⁷ The 3 CEC APM Entities reflected in the burden estimate are the non-large dialysis organizations participating in the one-sided risk track.

within the OCM (one-sided risk arrangement), and 2 CPC+ group TINs. We estimate this is a significant reduction in respondents from the 2017 MIPS performance period as a result of our policy to provide significant hardship exceptions, including for MIPS eligible clinicians in small practices, as well as for situations due to decertification of an EHR, and our policy to allow eligible clinicians to participate as part of a virtual group.

In the CY 2017 Quality Payment Program final rule, our burden estimates assumed all clinicians who submitted quality data would also submit under the advancing care information performance category. For the final rule with comment period, MIPS special status eligibility data were available to model exceptions. The majority (267,065) of the difference in our estimated number of respondents is due to the availability of MIPS special status data to identify clinicians and groups that would also not need to report advancing care information data under CY 2017 policies, including hospital-based eligible clinicians, clinician types eligible for automatic reweighting of their advancing care information performance category score, non-patient facing clinicians, and clinicians facing a significant hardship. The remaining decline in respondents is due to policies established in the CY 2018 Quality Payment Program final rule with comment period, including 42,951 respondents who would be excluded under the final significant hardship exception for small practices. Due to data limitations, our estimate of the number of clinicians to submit advancing care information data does not account for our policy to rely on section 1848(o)(2)(D) of the Act, as amended by section 4002(b)(1)(B) of the 21st Century Cures Act, to assign a scoring weight of zero percent for the advancing care information performance category for MIPS eligible clinicians who are determined to be based in ambulatory surgical centers (ASCs) and who do not submit advancing care information data.

Our burden estimates in the CY 2017 Quality Payment Program final rule assumed that during the transition year, 3 hours of clinician time would be required to collect and submit advancing care information performance category data. We anticipate that the year-over-year consistency of data submission processes, measures, and activities and the further alignment of the advancing care information performance category with other performance categories will reduce the clinician time needed under this performance category in the 2018 MIPS performance period. Further, for some practices the staff mix requirements in the 2018 MIPS performance period may be driven more by transition to 2015 CEHRT. Therefore, as shown in Table 14, the total burden hours for an organization to submit data on the specified Advancing Care Information Objectives and Measures is estimated to be 3 incremental hours of a computer analyst's time above and beyond the clinician, practice manager, and computer system's analyst time required to submit quality data. The total estimated burden hours are 654,645 (218,215 respondents X 3 hours). At a computer systems analyst's hourly rate, the total burden cost is \$57,674,225 (218,215 X \$264.30/hour).

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

| Burden Data Description | Burden Estimate |
|--|------------------------|
| # of respondents submitting advancing care information data on behalf of clinicians (a) | 218,215 |
| Estimated Total Annual Burden Hours Per Respondent (b) | 3 |
| Estimated Total Annual Burden Hours (c) = (a)*(b) | 654,645 |
| Estimated Cost Per Respondent to Submit Advancing Care Information data (@ computer systems analyst’s labor rate of \$88.10/hr.) (d) | \$264.30 |
| Estimated Total Annual Burden Cost (e) = (a)*(d) | \$57,674,225 |

12.7 Burden for Call for Advancing Care Information Measures

Consistent with our requests for stakeholder input on quality measures and improvement activities, in 2018 we are also requesting potential measures for the advancing care information performance category that measure patient outcomes, emphasize patient safety, support improvement activities and the quality performance category, and build on the advanced use of certified EHR technology (CEHRT) using 2015 Edition Standards and Certification. There were no changes to the process for collecting advancing care information measures in the CY 2018 rule and so this process is not discussed in the CY 2018 rule, but they are included here because the activity will occur in 2018. Advancing care information measures may be submitted via a designated submission form that includes the measure description, measure type (if applicable), reporting requirement, CEHRT functionality used (if applicable) and scoring type (base, performance or bonus).

As shown in Table 15, we estimate that approximately 40 organizations, including clinicians, EHR developers, and vendors, will submit new advancing care information measures. We estimate it will take an estimated 0.5 hours per organization to submit an advancing care information measure for the Call for Advancing Care Information Measures process, including an estimated 0.3 hours per practice for a practice administrator’s time at a rate of \$105.16/hour for a total of \$31.55 per measure and clinician review time of 0.2 hours at a rate of \$202.08/hour for a total of \$40.42 per measure. We estimate that the total annual burden cost is \$2,879 (40 x \$71.97).

TABLE 15: Estimated Burden for Call for Advancing Care Information Measures

| Burden Data Description | Burden estimate |
|--------------------------------|------------------------|
|--------------------------------|------------------------|

| | |
|--|---------|
| # of Organizations Nominating New Advancing Care Information Measures (a) | 40 |
| Estimated # of Hours Per Practice Administrator to Identify and Propose Measure (b) | 0.30 |
| Estimated # of Hours Per Clinician to Identify Measure (c) | 0.20 |
| Estimated Annual Burden Hours Per Respondent (d)= (b) + (c) | 0.50 |
| Estimated Total Annual Burden Hours (e) = (a)*(d) | 20 |
| Estimated Cost to Identify and Submit Measure (@ practice administrator's labor rate of \$105.16/hr.) (f) | \$31.55 |
| Estimated Cost to Identify Improvement Measure (@ physician's labor rate of \$202.08/hr.) (g) | \$40.42 |
| Estimated Total Annual Cost Per Respondent (h)=(f)+(g) | \$71.97 |
| Estimated Total Annual Burden Cost (i)=(a)*(h) | \$2,879 |

12.8 *Burden for Improvement Activities Submission*

Requirements for submitting improvement activities did not exist in the legacy programs replaced by MIPS, and we do not have historical data which is directly relevant. In section II.C.6.e.(3) of this final rule with comment period, we finalize that (1) for purposes of the 2020 MIPS payment year and future years and future payment years, MIPS eligible clinicians or groups must submit data on MIPS improvement activities in one of the following manners: via qualified registries; EHR submission mechanisms; QCDR, CMS Web Interface; or attestation. For activities that are performed for at least a continuous 90 days during the performance period, MIPS eligible clinicians must submit a yes response for activities within the Improvement Activities Inventory. In sections II.C.6.e.(2)(a) and II.C.6.e.(3)(b) of this final rule with comment period, we finalized that the term “recognized” is accepted as equivalent to the term “certified” when referring to the requirements for a patient-centered medical home and would receive full credit for the improvement activities performance category. We also note that for the 2020 MIPS payment year and future years, to receive full credit as a certified or recognized patient-centered medical home or comparable specialty practice, at least 50 percent of the practice sites within the TIN must be recognized as a patient-centered medical home or comparable specialty practice. Finally, in the CY 2017 Quality Payment Program final rule, we describe how we determine MIPS APM scores (81 FR 77185). We compare the requirements of the specific MIPS APM with the list of activities in the Improvement Activities Inventory and score those activities in the same manner that they are otherwise scored for MIPS eligible clinicians. If, by our assessment, the MIPS APM does not receive the maximum improvement activities performance category score, then the APM Entity can submit additional improvement activities, although, as we noted, we anticipate that MIPS APMs in the 2018 MIPS performance period will not need to submit additional improvement activities as the models will already meet the maximum improvement

activities performance category score.

A variety of organizations and in some cases, individual clinicians, will submit improvement activity performance category data. For clinicians who are not part of APMs, we assume that clinicians submitting quality data as part of a group or virtual group through the QCDR and registry, EHR, and CMS Web Interface submission mechanisms will also submit improvement activities data. As finalized in the CY 2017 Quality Payment Program final rule (82 FR 77264), APM Entities only need to report improvement activities data if the CMS-assigned improvement activities score is below the maximum improvement activities score. Our CY 2018 Quality Payment Program final rule burden estimates assume all APM Entities will receive the maximum CMS-assigned improvement activities score.

In the CY 2018 Quality Payment Program proposed rule (82 FR 30228), we estimated 520,654 clinicians will submit improvement activities as individuals during the 2018 MIPS performance period, an estimated 3,818 groups to submit improvement activities on behalf of clinicians during the 2018 MIPS performance period, and an additional 16 virtual groups to submit improvement activities, resulting in 524,488 total respondents. However, the burden estimates have been updated from the CY 2018 Quality Payment Program proposed rule to reflect updated data sources on the number of respondents. In the final rule with comment period, we are updating our estimates to reflect an additional 923 groups for a total of 4,741 based using the more recent 2016 PQRS data and 85,625 fewer clinicians reporting as individuals for the improvement activities performance category.

As represented in Table 16, we estimate 435,029 clinicians will submit improvement activities as individuals during the 2018 MIPS performance period, an estimated 4,741 groups to submit improvement activities on behalf of clinicians during the 2018 MIPS performance period, and an additional 16 virtual groups to submit improvement activities, resulting in 439,786 total respondents. The burden estimates assume there will be no improvement activities burden for MIPS APM participants. We will assign the improvement activities performance category score at the APM level. We assume that the MIPS APM models for the 2018 MIPS performance period would qualify for the maximum improvement activities performance category score and the APM Entities would not need to submit any additional improvement activities.

TABLE 16: Estimated Numbers of Organizations Submitting Improvement Activities Performance Category Data on Behalf of Clinicians

| Description | Count |
|---|---------|
| Estimated # of clinicians to participate in improvement activities data submission as individuals during the 2018 MIPS performance period (a) | 435,029 |
| Estimated # of Groups to submit improvement activities on behalf of clinicians during the 2018 MIPS performance period (b) | 4,741 |

| | |
|--|---------|
| Estimated # of Virtual Groups to submit improvement activities on behalf of clinicians during the 2018 MIPS performance period (c) | 16 |
| Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the 2018 MIPS performance period (d) = (a) + (b) + (c) | 439,786 |

In Table 17, we estimate that approximately 439,786 respondents will be submitting data under the improvement activities performance category. Our burden estimates in the CY 2017 Quality Payment Program final rule assumed that during the transition year, 2 hours of clinician time would be required to submit data on the specified improvement activities. For the final rule with comment period, our burden estimate assumes that the total burden hours to submit data on the specified improvement activities will be 1 hour of computer system analyst time in addition to time spent on other performance categories. Our revised estimate is based on changes we made to include additional new high-weighted activities that were in response to comments from stakeholders (82 FR 30052). The addition of more high-weighted activities means that some clinicians will need to spend less time selecting activities because they may be able to select only two high-weighted activities instead of four medium-weighted activities.

Additionally, the same improvement activity may be reported across multiple performance periods so many MIPS eligible clinicians will not have any additional information to develop for the 2018 MIPS performance period. The total estimated burden hours are 439,786 (439,786 responses X 1 hour). At a computer systems analyst’s hourly rate, the total burden cost is \$38,745,147 (439,786 X \$88.10/hour). This is based on updated data from PQRS 2016.

TABLE 17: Estimated Burden for Improvement Activities Submission

| Burden Data Description | Burden Estimate |
|--|------------------------|
| Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the 2018 MIPS performance period (a) | 439,786 |
| Estimated Total Annual Burden Hours Per Respondent (b) | 1 |
| Estimated Total Annual Burden Hours (c) | 439,786 |
| Estimated Cost Per Respondent to submit improvement activities (@ computer systems analyst’s labor rate of \$88.10/hr.) (d) | \$88.10 |
| Estimated Total Annual Burden Cost (e) = (a)*(d) | \$38,745,147 |

12.9 *Burden for Nomination of Improvement Activities*

For the 2018 MIPS performance period, we finalized our proposal to allow clinicians, groups, and other relevant stakeholders to nominate new improvement activities using a nomination form provided on the Quality Payment Program website at qpp.cms.gov, and to send

their proposed new improvement activities to us via email. As shown in Table 18, based on a response to an informal call for new proposed improvement activities during the transition year, we estimate that approximately 150 organizations (clinicians, groups or other relevant stakeholders) will nominate new improvement activities. We estimate it will take an estimated 0.5 hours per organization to submit an activity to us, including an estimated 0.3 hours per practice for a practice administrator to make a strategic decision to nominate that activity and submit an activity to us via email at a rate of \$105.16/hour for a total of \$31.55 per activity and clinician review time of 0.2 hours at a rate of \$202.08/hour for a total of \$40.42 per activity. We estimate that the total annual burden cost is \$10,796 (150 x \$71.96).

TABLE 18: Estimated Burden for Nomination of Improvement Activities

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

12.10 *Burden for Cost*

The cost performance category relies on administrative claims data. The Medicare Parts A and B claims submission process is used to collect data on cost measures from MIPS eligible clinicians. MIPS eligible clinicians are not asked to provide any documentation by CD or hardcopy. Therefore, under the cost performance category, we do not anticipate any new or additional submission requirements for MIPS eligible clinicians.

12.11 *Burden for Partial QP Elections*

APM Entities may face a data submission burden under MIPS related to Partial QP elections. Advanced APM participants will be notified about their QP or Partial QP status before

the end of the performance period. For Advanced APMs the burden of Partial QP election would be incurred by a representative of the participating APM Entity. For the purposes of this burden estimate, we assume that all MIPS eligible clinicians determined to be Partial QPs will participate in MIPS.

Based on our analyses of the initial QP determination file as described in the 2017 Quality Payment Program final rule (81 FR 77444), we assume that approximately 17 APM Entities will submit data to elect to participate under MIPS with Partial QP status. For situations in which an eligible clinician is determined to be a Partial QP individually, we will use the eligible clinician’s actual reporting activity to determine whether to exclude the Partial QP from MIPS in the absence of an explicit election. Therefore, if an eligible clinician determined as an individual to be Partial QP submits information to MIPS (which does not include information automatically populated or calculated by CMS on the Partial QP’s behalf), we will consider the Partial QP to have reported and thus be participating in MIPS. Likewise, if an eligible clinician determined as an individual to be a Partial QP does not take any action to submit information to MIPS, then we will consider the Partial QP to have elected to be excluded from MIPS.

As shown in Table 19, we assume that 17 APM Entities will make the election to participate as a partial QP in MIPS. We estimate it will take the APM Entity representative 15 minutes to make this election. Using a computer systems analyst’s hourly labor cost, we estimate a total burden cost of just \$375 (17 participant X \$22.03).

TABLE 19: Estimated Burden for Partial QP Election

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

12.12 Burden for Other Payer Advanced APM Determinations: Payer-Initiated Process

Beginning in Quality Payment Program Year 3, the All-Payer Combination Option will be an available pathway to QP status for eligible clinicians participating sufficiently in Advanced APMs and Other Payer Advanced APMs. The All-Payer Combination Option allows for eligible clinicians to achieve QP status through their participation in both Advanced APMs and Other Payer Advanced APMs. In order to include an eligible clinician’s participation in Other Payer Advanced APMs in their QP threshold score, we will need to determine if certain payment arrangements with other payers meet the criteria to be Other Payer Advanced APMs. To provide

eligible clinicians with advanced notice prior to the start of the 2019 performance period, and to allow other payers to be involved prospectively in the process, we finalized in section II.D.6.a. of the final rule with comment period a payer-initiated determination process for identifying payment arrangements that qualify as Other Payer Advanced APMs. This payer-initiated determination process of Other Payer Advanced APMs will begin in CY 2018, and determinations would be applicable for the Quality Payment Program Year 3.

As shown in Table 20, we estimate that 300 other payer arrangements will be submitted (50 Medicaid payers, 150 Medicare Advantage Organizations, and 100 Multi-payers) for determination as Other Payer Advanced APMs. The estimated burden to apply is 10 hours per payment arrangement, for a total annual burden hours of 3,000 (300 X 10). We estimate a total cost per payer of \$881.00 using a computer system analyst’s rate of \$88.10/hour (10 X 81.10). The total annual burden cost for all other payers is \$264,300 (300 X \$881.00).

TABLE 20: Burden for Other Payer Advanced APM Determinations: Payer-Initiated Process

| Burden Data Description | Burden Estimate |
|--|------------------------|
| Estimated # of other payer payment arrangements (50 Medicaid, 150 Medicare Advantage Organizations, 100 Multi-payers) (a) | 300 |
| Estimated Total Annual Burden Hours Per other payer payment arrangement (b) | 10 |
| Estimated Total Annual Burden Hours (c) = (a)*(b) | 3,000 |
| Estimated Cost Per Other Payer (@ computer systems analyst’s labor rate of \$88.10/hr.) (d) | \$881.00 |
| Estimated Total Annual Burden Cost for Other Payer Advanced APM Determinations: Payer-Initiated Process (e) = (a)*(d) | \$264,300 |

12.13 Burden for Other Payer Advanced APM Determinations: Medicaid Specific Eligible Clinician Initiated Process

Beginning in Quality Payment Program Year 3, the All-Payer Combination Option will be an available pathway to QP status for eligible clinicians participating sufficiently in Advanced APMs and Other Payer Advanced APMs. The All-Payer Combination Option allows for eligible clinicians to achieve QP status through their participation in both Advanced APMs and Other Payer Advanced APMs. In order to include an eligible clinician’s participation in Other Payer Advanced APMs in their QP threshold score, we will need to determine if certain payment arrangements with other payers meet the criteria to be Other Payer Advanced APMs.

To provide eligible clinicians with advanced notice prior to the start of the 2019 performance period, and to allow other payers to be involved prospectively in the process, we finalized a Payer Initiated process to determine payment arrangements that qualify as Other Payer Advanced APMs. We also finalized that APM Entities and eligible clinicians may request

determinations for any Medicaid payment arrangements in which they are participating at an earlier point, prior to the start of the 2019 performance period. Both the Payer Initiated and Medicaid specific Clinician Initiated determination processes will begin in CY 2018, and determinations would be applicable for the Quality Payment Program Year 3.

As shown in Table 21, we estimate that 75 other payer arrangements will be submitted by APM Entities and eligible clinicians for determination as Other Payer Advanced APMs. The estimated burden to apply is 10 hours per payment arrangement, for a total annual burden hours of 750 (75 X 10). We estimate a total cost per payer of \$881.00 using a computer system analyst’s rate of \$88.10/hour (10 X 88.10). The total annual burden cost for all other payers is \$66,075 (75 X \$881.00).

TABLE 21: Burden for Other Payer Advanced APM Determinations: Medicaid Specific Clinician Initiated Process

| Burden Data Description | Burden Estimate |
|--|------------------------|
| Estimated # of other payer payment arrangements from APM Entities and eligible clinicians | 75 |
| Estimated Total Annual Burden Hours Per other payer payment arrangement (b) | 10 |
| Estimated Total Annual Burden Hours (c) = (a)*(b) | 750 |
| Estimated Cost Per Other Payer (@ computer systems analyst’s labor rate of \$88.10/hr.) (d) | \$881.00 |
| Estimated Total Annual Burden Cost for Other Payer Advanced APM determinations (e) = (a)*(d) | \$66,075 |

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

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

TABLE 22: Burden for Voluntary Participants to Elect Opt Out of Performance Data Display on Physician Compare

| Burden Data Description | Burden Estimate |
|---|------------------------|
| Estimated # of Voluntary Participants Opting Out of Physician Compare (a) | 22,400 |
| Estimated Total Annual Burden Hours Per Opt-out Requester (b) | 0.25 |

| Burden Data Description | Burden Estimate |
|---|------------------------|
| Estimated Total Annual Burden Hours for Opt-out Requester (c) = (a)*(b) | 5,600 |
| Estimated Cost Per Physician Compare Opt-out Request@ computer systems analyst's labor rate of \$88.10/hr.) (d) | \$22.03 |
| Estimated Total Annual Burden Cost for Opt-out Requester (e) = (a)*(d) | \$493,472 |

13. Capital Costs (Maintenance of Capital Costs)

The costs for implementation and complying with the advancing care information performance category requirements could potentially lead to higher operational expenses for MIPS eligible clinicians. However, we believe that the combination of payment incentives and long-term overall gains in efficiency will likely offset the initial expenditures. Additionally, because we are reweighting the advancing care information performance category scores for eligible clinicians that were exempt from the Medicare EHR Incentive Program or received hardship exemptions, additional requirements for EHR adoption would not be imposed during the CY 2018 MIPS performance period. As we have stated with respect to the Medicare EHR Incentive Program for Eligible Professionals, we believe that future retrospective studies on the costs to implement CEHRT and the return on investment (ROI) will demonstrate efficiency improvements that offset the actual costs incurred by MIPS eligible clinicians participating in MIPS and specifically in the advancing care information performance category, but we are unable to quantify those costs and benefits at this time.

Similarly, the costs for implementation and complying with the improvement activities performance category requirements could potentially lead to higher expenses for MIPS eligible clinicians. Costs per full-time equivalent MIPS eligible clinician for improvement activities will vary across practices, including for some activities or patient-centered medical home practices, in incremental costs per encounter, and in estimated costs per member per month. Costs may vary based on panel size and location of practice among other variables, and given the lack of historical data for improvement activities, we are unable to quantify those costs at this time.

14. Cost to Federal Government

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

respect to the application of the MIPS payment adjustments.

15. Program or Burden Changes

The total estimated burden associated with the information collections submitted for approval as a revision of OMB control number 0938-1314 is 7,559,375 hours with a total labor cost of \$693,172,985, shown in Table 23.

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

The baseline burden estimate is 7,716,356 hours at a cost of \$707 million. This baseline burden estimate is lower than the burden approved for information collection related to the CY 2017 Quality Payment Program final rule due to updated data and assumptions, and because it does not include the burden for CAHPS for MIPS.¹⁸ As shown in Table 24, our baseline estimate assumes decreased respondent time due to greater familiarity with the measures and data submission methods in their second year of participation. Further, our estimated baseline burden estimates reflect the recent availability of data sources to more accurately reflect the number of the organizations exempt from the advancing care information performance category in CY 2018, and the recent availability of preliminary data that identifies clinicians that will be excluded from MIPS in CY 2018 because they are QPs.

As shown in Table 23, this Supporting Statement A reflects a total of 1,161,681 responses with an associated hours burden of 7,559,375 at a total cost of approximately \$693 million. This is a reduction of 156,981 hours and \$13.8 million. The reduction in burden for the 2018 MIPS performance period is reflective of several finalized policies, including a new significant hardship exception for small practices for the advancing care information performance category. Our burden estimates also reflect our finalized proposal to allow MIPS eligible clinicians to form virtual groups, which would create efficiencies in data submission.

¹⁸ The burden estimate for the CY 2017 Quality Payment Program final rule was 10,940,417 hours for a total labor cost of \$1,349,763,999. For comparability for the burden estimate in the CY 2018 final rule with comment period, the burden estimate for the CY 2017 Quality Payment Program final rule has been updated using 2016 wages.

TABLE 23: Annual Recordkeeping and Submission Requirements

| | Respondents / responses | Hours per response | Total annual burden hours | Labor cost of submission | Total annual burden cost | Change from Baseline |
|--|--------------------------------|---------------------------|----------------------------------|---------------------------------|---------------------------------|-----------------------------|
| Information Collection | | | | | | |
| §414.1400 QCDR and Registries self-nomination | 233 | 10.0 | 2,330 | \$88.10 | \$205,273 | \$0 |
| §414.1330 and §414.1335 (Quality Performance Category) Claims Submission Mechanism | 278,039 | 17.8 | 4,949,094 | Varies (See Table 7) | \$454,977,459 | \$0 |
| §414.1330 and §414.1335 (Quality Performance Category) Qualified Registry or QCDR Submission Mechanisms | 107,217 | 9.1 | 973,852 | Varies (See Table 8) | \$91,247,028 | (\$27,233) |
| §414.1330 and §414.1335 (Quality Performance Category) EHR- Submission Mechanism | 54,218 | 9.0 | 487,962 | Varies (See Table 10) | \$45,762,161 | (\$4,806,434) |
| §414.1330 and §414.1335 (Quality Performance Category) CMS Web Interface Submission Mechanism | 296 | 74.0 | 21,904 | \$88.10 | \$1,929,624 | \$0 |
| §414.1330 and §414.1335 (Quality Performance Category) Registration and Enrollment for CMS Web Interface | 10 | 1.0 | 10 | \$88.10 | \$881 | \$0 |
| §414.1330 (Quality Performance Category) Call for Measures | 40 | 0.5 | 20 | Varies (See Table 11) | \$2,879 | \$2,879 |
| §414.1375 (Advancing Care Information Performance Category) Significant Hardships, including for small practices and decertification of EHRs | 40,645 | 0.5 | 20,323 | \$88.10 | \$1,790,412 | \$1,522,720 |
| §414.1375 (Advancing Care Information Performance Category) Data Submission | 218,215 | 3.0 | 654,645 | \$88.10 | \$57,674,225 | (\$11,351,949) |
| §414.1375 (Advancing Care Information Performance Category) Call for Measures | 40 | 0.5 | 20 | Varies (See Table 15) | \$2,879 | \$2,879 |
| §414.1360 (Improvement Activities Performance Category) Data Submission | 439,786 | 1.00 | 439,786 | \$88.10 | \$38,745,147 | (\$4,228) |
| §414.1360 (Improvement Activities Performance Category) Call for Activities | 150 | 0.5 | 75 | Varies (See Table 20) | \$10,796 | \$10,796 |

| | Respondents / responses | Hours per response | Total annual burden hours | Labor cost of submission | Total annual burden cost | Change from Baseline |
|--|--------------------------------|---------------------------|----------------------------------|---------------------------------|---------------------------------|-----------------------------|
| Information Collection | | | | | | |
| §414.1430 Partial Qualifying APM Participant (QP) Election | 17 | 0.3 | 4 | \$88.10 | \$375 | \$0 |
| §414.1440 Other Payer Advanced APM Determinations: Other Payer Initiated Process | 300 | 10.0 | 3,000 | \$88.10 | \$264,300 | \$264,300 |
| §414.1445 Other Payer Advanced APM Determinations: Medicaid-Specific Clinician Initiated Process | 75 | 10 | 750 | \$88.10 | \$66,075 | \$66,075 |
| §414.1395 (Physician Compare) Opt Out for Voluntary Participants | 22,400 | 0.3 | 5,600 | \$88.10 | \$493,472 | \$493,472 |
| Total for this PRA Package (0938-1314) | 1,161,681 | | 7,559,375 | | 693,172,985 | (\$13,826,723) |

Table 24 provides the reasons for changes in the estimated burden for information collections between the CY 2017 Quality Payment Program final rule and CY 2018 Quality Payment Program final rule with comment period. We have divided the reasons for our change in burden into those related to new policies in the CY 2018 final rule with comment period, and those related to changes in the baseline burden of continued Year 1 policies that reflect updated data and methods.

TABLE 24: Reasons for Change in Burden Compared to the Currently Approved CY 2017 Information Collection Burdens

| Table in PRA Package | Changes in burden due to finalized Year 2 policies | Changes to "baseline" of burden continued Year 1 policy (<i>italics are changes in number of respondents' due to updated data</i>) |
|---|---|---|
| TABLE 3: QCDR and Registry Self-Nomination | None | <i>Increase in the number of respondents as the number of QCDRs and qualified registries enrolling increases.</i> |
| TABLE 5: Quality Performance Category: Clinicians Using the Claims Submission Mechanism | None | Decrease in time needed due to familiarity with measures (-1 hr. clinician time). |

| Table in PRA Package | Changes in burden due to finalized Year 2 policies | Changes to "baseline" of burden continued Year 1 policy (<i>italics are changes in number of respondents' due to updated data</i>) |
|--|---|---|
| TABLE 6: Quality Performance Category: Qualified Registry/QCDR Submission | Decrease due to consolidated reporting opportunity in virtual group policy. | Decrease in time needed due to familiarity with measures (-1 hr. clinician time). |
| TABLE 7: Quality Performance Category: Clinicians (Submitting Individually or as Part of a Group) Using the EHR Submission Mechanism | Decrease due to consolidated reporting opportunity in virtual group policy. | Decrease in time needed due to familiarity with measures (-1 hr. clinician time). Decrease due to no need for submitting test data. |
| TABLE 8: Quality Data Submission via the CMS Web Interface | None | Decrease in time needed due to familiarity with measures (-1 hr. clinician time). Decrease in time needed due to new API (- computer systems' analyst time from 79 to 74 hrs.) <i>Decrease in respondents by not including Shared Savings Program and Next Generation ACOs. Assumption updated from Year 1 burden estimate to accurately reflect that quality measures submitted for the purposes of fulfilling the Shared Savings Program and Next Generation ACO requirements are not subject to the PRA.</i> |
| TABLE 10: Registration for CMS Web Interface | None | In the Year 1 Rule burden estimate, CMS Web Interface registration was folded in with CMS Web Interface data submission; assumed all groups using Web Interface would have to register. This has been updated to more accurately show that only new CMS Web Interface submitters are required to register. |
| TABLE 12: Application for Advancing Care Information Reweighting | Increase in the number of clinicians applying for the hardship exception due to the hardship exception for small practices. | Decrease in the time spent by hardship applicants, as hardship data was not available for the Year 1 model, so hardship applicants received the standard ACI burden estimate of 3 hours. <i>In the Year 2 model, hardship applicants are identified using data from the EHR incentive program and are estimated to need 1 hour to apply for the exception.</i> |

| Table in PRA Package | Changes in burden due to finalized Year 2 policies | Changes to "baseline" of burden continued Year 1 policy (<i>italics are changes in number of respondents' due to updated data</i>) |
|---|---|--|
| TABLE 14: Advancing Care Information Performance Category Data Submission | Decrease in participants due the hardship exception for small practices. Not included due to unavailable data: Decrease in participants due to the automatic exclusion for ASC. | <p><i>Decrease in the number of respondents (and decrease in eligible clinician population) due to availability of data on 2017 QPs.</i></p> <p><i>Increase in respondents due to the increase in MIPS APM participants.</i></p> <p>Decreased costs as labor mix changes from 3 hours of clinician time to 3 hours of computer system's analyst time because this category is typically submitted via same submission mechanism as quality (and quality has a mix of labor categories), and because in the second year this effort may be driven more by transition to 2015 CEHRT.</p> <p><i>Reduced number of participants in advancing care information performance category using newly available of MIPS special status data identifying hospital-based; non-patient facing clinicians; and certain clinician types.</i></p> |
| TABLE 17: Improvement Activities Submission | None | <p><i>Decrease in the eligible clinician population due to growth in QPs.</i></p> <p>Decrease in time and labor category needed from 3 hours of clinician time to 1 hour of computer system's analyst time to reflect that improvement activities data submission burden minimal due to attestation, and greater clinician familiarity with activities and submission process in second year of program and additional offering of more high-weighted activities</p> |
| TABLE 18: Nomination of Improvement Activities | Increase due to new policy for annual call for activities process for improvement activities via a form. The Year 1 Rule asked for comments on the development of a process, and during Year 1 CMS made an informal call for activities to be submitted by e-mail (not subject to PRA). | None |
| TABLE 19: Partial QP Election | None | Reduction in hours from 0.5 to 0.25 and change in labor category from clinician to computer systems analyst due to greater practice familiarity with QPP portal in Year 2. |
| TABLE 20: Prospective Determination of Other Payer Advanced APMs | Reflects new policy in Year 2 final rule with comment period. | None |

| Table in PRA Package | Changes in burden due to finalized Year 2 policies | Changes to "baseline" of burden continued Year 1 policy (<i>italics are changes in number of respondents' due to updated data</i>) |
|---|---|---|
| TABLE 21: Medicaid Specific Eligible Clinician Determination of Other Payer Advanced APMs | Reflects new policy in Year 2 final rule with comment period. | None |
| TABLE 22: Voluntary Participants to Elect to Opt Out of Performance Data Display on Physician Compare | Reflects new policy in Year 2 final rule with comment period. | None |

The forms, screenshots and/or test sites provided for the public and OMB review are still in the developmental phase. With that being the case, the final products may vary slightly due to technical issues associated with transitioning from the developmental phase to the active/live phase.

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 finalized providing performance feedback to MIPS eligible clinicians that includes MIPS quality and cost data and if technically feasible to also include improvement activities and advancing care information data. We plan to work collaboratively with stakeholders to design feedback reports, and to make feedback available through multiple mechanisms including qpp.cms.gov and third-party vendors. We also finalized our proposal to provide performance feedback to MIPS eligible clinicians who participate in MIPS APMs in 2018 and future years as technically feasible. This reflects our commitment to providing as timely information as possible to eligible clinicians to help them predict their performance in in MIPS.

We plan to publicly report MIPS information through the Physician Compare website, either on public profile pages or via the Downloadable Database housed on data.medicare.gov for the purpose of promoting more informed health care choices by for people with Medicare. The public reporting is anticipated to start in late 2019 for the 2018 MIPS performance period. We plan public reporting of some measures in a MIPS eligible clinician's MIPS data; in that for each performance period, we will post on a public website (for example, Physician Compare), in an easily understandable format, information regarding the performance of MIPS eligible clinicians or groups under the MIPS. The Physician Compare performance year 2016 measures will be available for preview at the Physician Compare website <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/physician-compare-initiative/>

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

17. Expiration Date

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

18. Certification Statement

There are no exceptions to the certification statement.