Supporting Statement – Part A
Physician Quality Reporting System
CMS-10276, OMB 0938-1059

Background

The Physician Quality Reporting System or PQRS (formerly known as the Physician Quality Reporting Initiative, or PQRI) was established by section 101(b) of Division B of the Tax Relief and Health Care Act of 2006 – Medicare Improvements and Extension Act of 2006 (MIEA-TRHCA) and is codified in sections 1848(a), (k), and (m) of the Social Security Act (the Act). Changes to the PQRS also resulted from the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA), the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), the Affordable Care Act (ACA), and the American Taxpayer Relief Act (ATRA) of 2012. The program provided incentive payments to eligible professionals and group practices who satisfactory reported data on Quality measures or satisfactory participated until 2014. In 2015, eligible professionals and group practices became subject to payment adjustments for those who did not meet the criteria to satisfactory report or satisfactory participate in PQRS. This will be equal to the applicable quality percent of the Secretary's estimate of allowed Part B charges for covered professional services furnished by the eligible professional or group practice during a specified year (for 2016 and subsequent years, the applicable quality percent is 2.0%).

In accordance with section 1848(k)(2) of the Act, an eligible professional or group practice who satisfactorily submits data on quality measures for covered professional services furnished for an applicable year can (1) qualify to receive an incentive payment and/or (2) be relieved from the application of a payment adjustment. In lieu of satisfactory reporting, eligible professionals may (1) qualify to receive an incentive payment and/or (2) be relieved from the application of a payment adjustment if the eligible professional satisfactorily participates in a qualified clinical data registry (QCDR). The criteria for satisfactory reporting (or, in lieu of satisfactory reporting, satisfactory participation in a Qualified Clinical Data Registry [QCDR]) for the 2018 PQRS payment adjustment are set forth in the CY 2016 Medicare Physician Fee Schedule (PFS) final rule. The ACA made changes to the PQRS, authorizing incentive payment adjustments until 2014 and requiring payment adjustments beginning in 2015 for eligible professionals or group practices that do not satisfactorily report data on quality measures during the applicable period for the year.

A QCDR is a CMS approved entity that has self-nominated and successfully completed a qualification process. A QCDR collects medical and/or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. The data submitted to CMS via a QCDR cover quality measures across multiple payers and are not limited to Medicare beneficiaries. It is different from a qualified registry as its purpose must be improving quality of care beyond submitting data to CMS for PQRS. QCDRs reduces the burden on eligible professionals by providing direct assistance with compiling the needed data for reporting. Only one set of data needs to be reported to fulfill Medicare quality reporting program and specialty organizations requirements.

A. Justification

1. Need and Legal Basis

PQRS is a quality reporting program to promote reporting of quality information by individual eligible professionals and PQRS group practices participating in the group practice reporting option (GPRO). Those who do not satisfactorily report data on quality measures for covered Medicare Physician Fee Schedule (MPDFS) services furnished to Medicare Part B beneficiaries will be subject to a negative payment adjustment under PQRS. The payment adjustment is always based on the performance period that has occurred two years previously (e.g., the 2016 payment adjustment was based on the 2014 PQRS reporting period or for the 2018 will be based on the 2016 PQRS reporting period).

The quality measures are indicators of the quality of care provided by physicians and are tools that help measure or quantify health care processes, outcomes, patient perceptions, and organizational structure and /or systems that are associated with the ability to provide high-quality health care that relate to one or more quality goals for health care. These goals include: effective, safe, efficient, patient-centered, equitable, and timely care. The PQRS measures address various aspects of care, such as prevention, chronic- and acute-care management, procedure-related care, resource utilization, and care coordination.

Driving quality improvement is a core function of CMS. The vision for the CMS Quality Strategy is to optimize health outcomes by leading clinical quality improvement and health system transformation. PQRS plays a crucial role to facilitate physician participation in this process committed to quality improvement.

Collection of Data

Individual eligible professionals do not need to sign up or pre-register with the PQRS program to begin participating in the PQRS. Eligible professionals wishing to report data on quality measures may do so via five reporting mechanisms: claims, qualified registry, EHR (which includes submitting quality measures data via a direct EHR product and an EHR data submission vendor's product that is certified by the Office of National Coordinator (ONC) as "Certified EHR Technology" (CEHRT)), and QCDR.

Eligible professionals in group practices interested in participating in the PQRS as a group practice through the group practice reporting option (GPRO) must register to submit as a group practice and follow the guidelines for the reporting mechanism for which they choose. Group practices participating via GPRO wishing to report data on quality measures may do so via four reporting mechanisms – the web interface, qualified registry, EHR (which includes submitting quality measures data via a direct EHR product and an EHR data submission vendor's product that is certified by ONC as CEHRT), and the CMS-certified survey vendor (in conjunction with registry, direct EHR product and an EHR data submission vendor's product that is certified by ONC as CEHRT, or GPRO Web Interface).

Note: For qualified registries and QCDRs to submit quality measure results with numerator and denominator data on individual quality measures or measures groups on behalf of eligible

professionals (and, in the case of qualified registries, and group practices), a qualified registry or QCDR will need to self-nominate to become "qualified. If a qualified registry was qualified for a prior year and successfully submitted quality measure results with numerator and denominator data on quality measures on behalf of their participants, the qualified registry would not need to become re-qualified for PQRS purposes. Qualified registries previously qualified to submit PQRS quality measures data may be disqualified for submitting grossly inaccurate data to CMS. In order to participate in PQRS the following year, registries that have been disqualified would be required to self-nominate and undergo the qualification process again in order to become re-qualified to submit PQRS quality measures data. However, a QCDR must become qualified every year in which it seeks to submit quality measure results on behalf of its eligible professionals.

Payment Adjustment

With respect to the 2018 PQRS payment adjustment, collection of this information applies to all eligible professionals and group practices. Therefore, since the reporting periods for the 2018 payment adjustment coincide in CY 2016, the collection of this information will apply to all eligible professionals and group practices.

Eligible professionals or group practices who do not satisfactorily report data on quality measures for covered professional services furnished during the applicable 2018 PQRS payment adjustment reporting period will be subject to a payment adjustment equal to 2.0 percent of the total estimated allowed charges. The criteria for satisfactory reporting of data on individual quality measures and measures groups (or, lieu of satisfactory reporting, satisfactory participation in a QCDR) for the 2018 PQRS payment adjustment are set forth in the CY 2016 PFS final rule.

2. Information Users

The data on quality measures collected from eligible professionals or group practices will be used by CMS to:

(1) Determine whether an eligible professional or group practice meets the criteria for satisfactory reporting of quality measures data (or, in lieu of satisfactory reporting, satisfactory participation in a QCDR) for the 2018 PQRS payment adjustment.

(2) To calculate and make payment adjustments to eligible professionals and group practices for the 2018 PQRS payment adjustment.

(3) Publicly post the names of eligible professionals and group practices who satisfactorily report quality measures data (or, in lieu of satisfactory reporting, satisfactory participation in a QCDR) on the CMS Physician Compare Web site (which will include a Medicare professional's profile page indicating with a green check mark the quality programs under which the eligible professional satisfactory or successfully reported including the 2015 PQRS reporters, PQRS GPRO-measures for diabetes mellitus and coronary artery disease[if technically feasible], EHR Incentive Program, PQRS Cardiovascular Prevention measures

group in support of Million Hearts and ACOs participating in the Medicare Shared Savings Program in 2016).

(4) To determine a group practice's quality score under the Physician Value-based Payment Modifier.

Since this data is publicly reported on Physician Compare, the data collected on quality measures from individual eligible professionals or group practices will also be used by the public for informed healthcare choices.

Only registry vendors and QCDRs that are interested in participating in PQRS will self-nominate to be a respective qualified registry and/or QCDR. The information collected from the self-nomination process for qualified registries and QCDRs will be used by CMS to determine whether the registry or QCDR meets the PQRS respective qualified registry or QCDR requirements and is qualified to submit quality measures results with numerator and denominator data on PQRS individual quality measures and/or measures groups on behalf of eligible professionals and/or group practices.

3. Improved Information Technology

There were over 280 measures for the 2015 PQRS reporting year, but not all measures are reportable via all mechanisms. Guidance on measure selection may be found on the measures codes section on the PQRS webpage.

Reporting via claims-based reporting mechanism: For claims-based reporting, the normal Medicare Part B claims submission process is used to collect data on quality measures from eligible professionals. Individual eligible professionals are not asked to provide any documentation by CD or hardcopy. According to the 2014 PQRS Experience Report[1] (p.18) 849,162 eligible professionals were eligible to participate in PQRS through the claims-based mechanism but only 299,169 participated.

Reporting via qualified registry-based reporting mechanism or QCDR: For qualified registry-based and QCDR-based reporting, qualified registries and QCDRs submit quality measures results with numerator and denominator data on PQRS measures or other measures to CMS on behalf of its eligible professional and group practice members electronically. The 2014 PQRS Experience Report[1] (p.18) stated that 880,584 eligible professionals were eligible to participate in PQRS through registry (88,623 participated), QCDR (3,274 participated), QRDA I (2,661 participated), and QRDA III (48,566 participated).

There is no application for qualified registries that wish to self-nominate to become a qualified PQRS qualified registry. Qualified registries are asked to submit a self-nomination letter requesting inclusion in PQRS for each program year in which the qualified registry seeks to be qualified to submit quality measures data on behalf of its participants. To self-nominate requires some burden to those entities providing the required documentation and is included in Table 3 on page 17 within this document.

Likewise, there is no application for clinical data qualified registries that wish to self-nominate to

become a PQRS QCDR. QCDRs must meet established requirements for being qualified to participate in the PQRS as a QCDR and are asked to submit a self-nomination statement requesting inclusion in PQRS for each program year in which the clinical data qualified registry seeks to be qualified to submit quality measures data on behalf of its participants. To self-nominate requires some burden to those entities providing the required documentation and is included in Table 3 on page 17 within this document.

Reporting via a direct EHR product that is CEHRT or EHR data submission vendor whose product is CEHRT: For EHR-based reporting, eligible professionals and group practices submit data on quality measures to CMS electronically through a direct EHR product or via an EHR data submission vendor's product that is CEHRT.

Reporting via GPRO Web Interface: This group practice reporting mechanism stems from a previously OMB-approved data collection web interface (see OMB Control Number 0938-1059). This web interface is an automated, electronic tool developed by CMS and refined with industry input. In prior years, this web interface was the "PAT," or Performance Assessment Tool. It was developed explicitly for specific Medicare demonstrations and has been used successfully over the past 4 years for these demonstrations. Although we moved away from use of the PAT, we note that the GPRO Web Interface that will be used is similar in terms of burden to using the PAT. According to the 2014 PQRS Experience Report[1] (p.18-19), 422,842 were eligible to report with 401,077 who participated by using the following mechanisms: registry, QRDA I, and III and some in conjunction with CAHPS. Out of those participating there were 112,467 web interface users.

Reporting via CMS-certified survey vendor: A CMS-certified survey vendor is certified by CMS for a particular program year to transmit survey measures data to CMS. Please note that discussion of this certified survey vendor option is discussed in a separate PRA package (OMB control number 0938-1222, CMS-10450). Therefore, we do not address this reporting option in this PRA package.

4. Duplication of Similar Information

To minimize duplication of similar information being reported amongst PQRS and other similar programs, CMS is proposing efforts to align PQRS reporting requirements with the requirements of other quality reporting programs, such as the EHR Incentive Program, the Value-based Payment Modifier, the Medicare Shared Savings Program, and Pioneer ACOs. For example, with respect to reporting as an individual eligible professional, CMS has put forth a number of requirements related to aligning the criteria for satisfactory reporting under PQRS with the requirements for meeting the clinical quality measure (CQM) component of achieving meaningful use under the EHR Incentive Program. Specifically, beginning in 2014, the measures available for reporting under the EHR-based reporting mechanisms under PQRS aligns with the EHR measures available for reporting under the EHR Incentive Program. Beginning in 2014, we have aligned the criteria for satisfactory reporting using the EHR-based reporting mechanisms under PQRS with the reporting criteria for meeting the CQM component of achieving meaningful use under the EHR Incentive Program. In addition, the Value-based Payment Modifier continues to use quality measures data reported in the PQRS to measure a physician's

performance in their program.

With respect to participating in PQRS using the group practice reporting option (GPRO), CMS sets forth requirements that align with the requirements for Accountable Care Organizations (ACOs) participating under the Medicare Shared Savings Program and Pioneer ACOs. Under the Medicare Shared Savings Program, group practices had statutory authority to earn a PQRS incentive through their participation in the Medicare Shared Savings Program. Similarly, group practices could have earned a PQRS incentive through their participation in a Pioneer ACO. By doing so, we were rewarding those practices that voluntarily agreed to participate and reduced their reporting burden they would otherwise have had if they had to submit duplicate clinical quality data using two different systems. CMS has also set forth requirements that would allow group practices to avoid the downward-based adjustment under the Value-based Payment Modifier.

5. Small Businesses

The collection of information will primarily affect small entities (e.g., individual eligible professionals). We have attempted to minimize the burden on eligible professionals by providing eligible professionals with multiple reporting options for submitting quality measures data.

6. Less Frequent Collection

Data collection for PQRS measures depends on the data submission mechanism for which the individual eligible professional or group practice chooses to report their data. For claims-based reporting mechanism, submission of claims data occurs throughout the year. Claims must be processed and reach the National Medicare claims system data warehouse (NCH file) by the last Friday in February, following the reporting year to be included in the analysis. Registry, QCDR, EHR, and GPRO web interface have specific time frames following the close of the reporting period for data submission, which occurs around January 1st through February or March following the reporting period.

If data on the quality measures are not collected from individual eligible professionals or group practices, CMS will have no mechanism to: (1) determine whether an eligible professional or group practice meets the criteria for satisfactory reporting of quality measures data for PQRS, or, in lieu of satisfactory reporting, whether an eligible professional satisfactorily participates in a QCDR, (2) to calculate for payment adjustments to eligible professionals or group practices, and (3) publicly post the names of eligible professionals and group practices who satisfactorily report quality measures data or satisfactorily participate in a QCDR on the CMS Web site.

If qualified registries and QCDRs are not required to submit a self-nomination statement, CMS will have no mechanism to determine which qualified registries and clinical data qualified registries will participate in submitting quality measures data. As such, CMS would not be able to post the annual list of qualified registries that eligible professionals use to select qualified registries and QCDRs to use to report quality measures data to CMS. Similarly, if group practices participating in PQRS GPRO are not required to indicate their intent to participate,

CMS will have no mechanism to determine that group practices be assessed differently (at the TIN level) than eligible professionals (who are assessed at the TIN/NPI level).

7. Special Circumstances

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

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

Our physician fee payment NPRM served as the 60-day notice which posted for public inspection on July 8, 2015, and published in the Federal Register on July 15, 2015 (80 FR 41686, RIN 0938-AS40, CMS-1631-P). We received comments related to our claims-based burden estimates and how they relate to reporting using other reporting mechanisms (i.e., the registry, EHR, and QCDR reporting mechanisms). The commented figures, however, only reflect our estimates for reporting via the claims-based reporting mechanism, and not the other PQRS reporting mechanisms. No other comments were received.

9. Payment/Gift to Respondent

The ACA made changes to the PQRS, authorizing incentive payments until 2014 and requiring payment adjustments beginning in 2015 for eligible professionals or group practices who do not satisfactorily report data on quality measures during the applicable reporting period for the year.

In 2015, eligible professionals or group practices who do not satisfactorily report data on quality measures for covered professional services furnished during the applicable PQRS payment adjustment reporting period will be subject to a payment adjustment equal to 1.5 percent in 2015 and 2.0 percent in 2016 and subsequent years of the eligible professional’s total estimated allowed charges for the respective year.

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, the Privacy Act of 1974, and other applicable Federal government rules and regulations) will be protected from release by CMS under 5 U.S.C. 552a(b).

11. Sensitive Questions

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

12. Burden Estimate (Total Hours & Wages) for the PQRS (CY 2016)

A detailed description of the measures was provided in the CY 2016 final rule, but not the full measure specifications and guide for how to report the measures. The PQRS measure and implementation guide have been finalized and posted on the PQRS webpage (and are attached to this package).

The annual burden estimate is calculated separately for (1) individual eligible professionals and group practices using the claims (for eligible professionals only), (2) qualified registry and QCDR, (3) EHR-based reporting mechanisms, and (4) group practices using the GPRO. There is also a separate annual burden estimate for qualified registry and QCDR vendors who wish to be qualified to submit quality measures data. Please note that we are grouping group practices using the qualified registry and EHR-based reporting mechanisms with the burden estimate for individual eligible professionals using the qualified registry and EHR-based reporting mechanisms because we believe the criteria for satisfactory reporting for group practices using these 2 reporting mechanisms under the GPRO are similar to the satisfactory reporting criteria for eligible professionals using these reporting mechanisms.

12.1 Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2015 National Occupational Employment and Wage Estimates for all salary estimates (www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits, and the adjusted hourly wage.

Estimated Hourly Wages

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Billing and Posting Clerks	43-3021	17.45	17.45	34.90
Computer Systems Analysts	15-1121	43.36	43.36	86.72

Except where noted, 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.

12.2 Individual Eligible Professionals: Reporting in General

According to the 2013 Reporting Experience, "more than 1.25 million eligible professionals were eligible to participate in the 2013 PQRS, Medicare Shared Savings Program, and Pioneer ACO Model."[1] In this burden estimate, we assume that 1.25 million eligible professionals, the same number of eligible professionals eligible to participate in the PQRS in 2012, will be eligible to participate in the PQRS. Since all eligible professionals are subject to the 2018 PQRS payment adjustment, we estimate that ALL 1.25 million eligible professionals will participate in the PQRS in 2016 for purposes of meeting the criteria for satisfactory reporting (or, in lieu of satisfactory reporting, satisfactory participation in a QCDR) for the 2018 PQRS payment adjustment.

Historically, the PQRS has never experienced 100% participation in reporting for the PQRS. In the 2013 PQRS and eRx Reporting Experience Report more than 1.25 million professionals were eligible to participate in the 2013 PQRS (including group practices reporting under the GPRO, Medicare Shared Savings Program, and Pioneer ACO Model). Therefore, we believe that although 1.25 million eligible professionals will be subject to the 2018 PQRS payment adjustment, not all eligible participants will actually report quality measures data for purposes of the 2018 PQRS payment adjustment. In this burden estimate, we will only provide burden estimates for the eligible professionals and group practices who attempt to submit quality measures data for purposes of the 2018 PQRS payment adjustment.

In 2013, 641,654 eligible professionals (51 percent) eligible professionals (including those who belonged to group practices that reported under the GPRO and eligible professionals within an ACO that participated in the PQRS via the GPRO) participated in the PQRS, Medicare Shared Savings Program, or Pioneer ACO Model.[2] We expect to see a steady increase in participation in reporting for the PQRS in 2016 than 2013. Eligible professionals have become more familiar with the PQRS payment adjustments since eligible professionals are currently experiencing the implementation of the first PQRS payment adjustment the 2015 PQRS payment adjustment. Therefore, we estimate that we will see a 70 percent participation rate in 2016. Therefore, we

[1] Centers for Medicare and Medicaid Services, *2012 Reporting Experience Including Trends (2007—2013): Physician Quality Reporting System and Electronic Prescribing (eRx) Incentive Program*, March 14, 2014, at xiii.
[2] Id. at XV.

estimate that 70 percent of eligible professionals (or approximately 840,000 eligible professionals) will report quality measures data for purposes of the 2018 PQRS payment adjustment.

With respect to the PQRS, the burden associated with the requirements of this voluntary reporting initiative is the time and effort associated with individual eligible professionals and group practices (1) identifying applicable quality measures for which they can report the necessary information, (2) selecting a reporting option, and (3) collecting and reporting the information on their selected measures or measures group to CMS using their selected reporting option. We assume that most eligible professionals participating in the PQRS will attempt to meet the criteria for satisfactory reporting for the 2018 PQRS payment adjustment.

We believe it is difficult to accurately quantify the burden because eligible professionals may have different processes for integrating the PQRS into their practice's work flows. Moreover, the time needed for an eligible professional to review the quality measures and other information, select measures applicable to his or her patients and the services he or she furnishes to them, and incorporate the use of quality data codes into the office work flows is expected to vary along with the number of measures that are potentially applicable to a given professional's practice. Since eligible professionals are generally required to report on at least nine measures covering at least three National Quality Strategy domains criteria for satisfactory reporting (or, in lieu of satisfactory reporting, satisfactory participation in a QCDR) for the 2018 PQRS payment adjustment, we will assume that each eligible professional reports on an average of nine measures for this burden analysis.

For eligible professionals who are participating in PQRS, we will assign **5 total hours** as the amount of time needed for an eligible professional's billing clerk to (1) review the PQRS Measures List, (2) review the various reporting options, (3) select the most appropriate reporting option, (4) identify the applicable measures or measures groups for which they can report the necessary information, (5) review the measure specifications for the selected measures or measures groups, and (6) incorporate reporting of the selected measures or measures groups into the office work flows. The measures list contains the measure title along with summary for the eligible professional to review. Assuming the eligible professional has received no training from his/her specialty society, we estimate it will take an eligible professional's billing clerk up to two hours to review this list, review the reporting options, select a reporting option and select the measures on which to report. If an eligible professional has received training, we believe this will take less time. CMS believes 3 hours is plenty of time for an eligible professional to review the measure specifications of nine measures or one measures group they select to report for purposes of participating in PQRS and to develop a mechanism for incorporating reporting of the selected measures or measures groups into the office work flows. Therefore, we believe that the start-up cost for an eligible professional to report PQRS quality measures data is 5 hours x **$34.90/hr** = $174.50. Therefore, since we estimate that 70 percent of eligible professionals will participate in 2016, or 840,000 reporting individuals, the total burden associated with reporting PQRS quality measures data is 840,000 individual eligible professionals x $174.50 = $146,580,000.

We continue to expect the ongoing costs associated with PQRS participation to decline based on an eligible professional's familiarity with and understanding of the PQRS, experience with participating in the PQRS, and increased efforts by CMS and stakeholders to disseminate useful educational resources and best practices.

We believe the burden associated with reporting the quality measures will vary depending on the reporting mechanism selected by the eligible professional. As such, we break down our burden estimates by eligible professionals and group practices participating in the GPRO according to the reporting mechanism used.

12.3 Reporting by Individual Eligible Professionals: Claims-Based Reporting Mechanism

According to the 2011 PQRS and eRx Experience Report, in 2011, 229,282 of the 320,422 eligible professionals (or 72 percent) of eligible professionals used the claims-based reporting mechanism. According to the 2012 Reporting Experience, 248,206 eligible professionals participated in the PQRS using the claims-based reporting mechanism in 2012.[3] According to the 2013 PQRS and eRx Experience Report, 641,654 eligible professionals participated as individuals or group practices through one of the PQRS reporting mechanism, a 47 percent increase from those that participated in 2012 (435,931). Through the individual claims-based reporting mechanism, 331,668 of those eligible professionals (or 52 percent) reported using this mechanism. Increased claims based reporting to **350,000** (approximately 5 percent increase over 2013). Though claims reporting was declining, we did see an increase in 2013 once the payment adjustment was applied to all participants, so we assume a slight increase in 2016.

According to the historical data cited above, while the claims-based reporting mechanism is still the most widely-used reporting mechanism, we were seeing a decline in the use of the claims-based reporting mechanism in the PQRS. There was a slight increase in 2013, which may be reflected by the use of administrative claims-based reporting mechanism by individual eligible professionals and group practices only for the 2015 PQRS payment adjustment (in CY2013).

While these eligible professionals continue to participate in the PQRS, these eligible professionals have started to shift towards the use of other reporting mechanisms – mainly the Group Practice Web Interface (whether used by a PQRS GPRO or an ACO participating in the PQRS via the Medicare Shared Savings Program), registry, or the EHR-based reporting mechanisms. For purposes of this burden estimate, based on PQRS participation using the claims-based reporting mechanism in 2012 and 2013, we will assume that approximately **350,000** eligible professionals will participate in the PQRS using the claims-based reporting mechanism.

Under the claims-based reporting option, eligible professionals must gather the required information, select the appropriate quality data codes (QDCs), and include the appropriate QDCs on the claims they submit for payment. The PQRS collects QDCs as additional (optional) line items on the CMS-1500 claim form or electronic equivalent HIPAA transaction 837-P, approved under OMB Control number 0938-0999. This rule did not change these forms. We note that the

[3] Id. at xvi. *See* Figure 4.

claims-based reporting option is only available to individual eligible professionals and is not available for group practice reporting under the GPRO.

Based on our experience with the Physician Voluntary Reporting Program (PVRP), we continue to estimate that the time needed to perform all the steps necessary to report each measure (that is, reporting the relevant quality data code(s) for nine measures) would range from **15 sec** (0.25 min) to over **12 min** for complicated cases and/or measures, with the median time being **1.75 min**. To report nine measures, we estimate that it will take approximately 2.25 min (0.25 min x 9) to 108 min (12 min x 9) to perform all of the necessary steps.

At an adjusted labor rate of $86.72/hr for a computer systems analyst, the per measure cost will range from **$0.36**[($86.72/hr / 60) x 0.25 min] to **$17.34** [($86.72/hr / 60) x 12 min], with a median cost of **$2.53** [($86.72/hr / 60) x 1.75 min]. To report nine measures we estimate that the cost will range from $3.24 ($0.36 x 9) to $156.06 ($17.34 x 9), with a median cost of $22.77 ($2.53 x 9).

The total estimated annual burden for this requirement will also vary along with the volume of claims on which quality data is reported. In previous years, when we required reporting on 80 percent of eligible cases for claims-based reporting, we found that on average, the median number of reporting instances for each of the PQRS measures was nine. Since we reduced the required reporting rate by over one-third to 50 percent, then for purposes of this burden analysis we will assume that an eligible professional or eligible professional in a group practice will need to report each selected measure for six reporting instances. The actual number of cases on which an eligible professional or group practice is required to report quality measures data will vary, however, with the eligible professional's or group practice's patient population and the types of measures on which the eligible professional or group practice chooses to report (each measure's specifications includes a required reporting frequency). For the 2018 payment adjustment, EPs will also report on one cross-cutting measure if they see at least one Medicare patient. However, we do not see any additional burden impact as they are still reporting on the same number of measures.

Based on these assumptions, we estimate that the per individual eligible professional reporting burden will range from **13.5 min** (0.25 min per measure x 9 measures x 6 cases per measure) to **648 min** (12 min per measure x 9 measures x 6 cases per measure), with a median burden of **94.5 min** (1.75 min per measure x 9 measures x 6 cases). We also estimate that the cost will range from $19.51 [13.5 min ($86.72/hr / 60)] to $936.58 [648 min ($86.72/hr / 60)], with a median cost of $136.58 [94.5 min ($86.72/hr / 60)].

Based on the assumptions discussed above and in Supporting Statement part B, Table 1 provides an estimate of the range of total annual burden hours and total annual cost burden associated with eligible professionals using the claims-based reporting mechanism.

Table 1: Summary of Burden Estimates for Eligible Professionals using the Claims-based Reporting Mechanism

	Minimum Burden Estimate	Median Burden Estimate	Maximum Burden Estimate
# of Participating Eligible Professionals (a)	350,000	350,000	350,000
# of Measures Per Eligible Professional Per Year (b)	9	9	9
# of Cases Per Measure Per Eligible Professional Per Year (c)	6	6	6
Total # of Cases Per Eligible Professional Per Year (d) = (b)*(c)	54	54	54
Hours Per Case (e)	0.00415 (15 sec or 0.25 min)	0.02917 (1.75 min)	0.19992 (12 min)
Total Hours For Measures Per Eligible Professional Per Year (f) = (d)*(e)	0.2241 (13.5 min)	1.57518 (94.5 min)	10.79568 (648 min)
Hours Per Eligible Professional to Prepare for PQRS Participation (g)	5	5	5
Total Annual Hours Per Eligible Professional (h) = (f)+(g)	5.2241	6.57518	15.79568
Total Annual Hours (i) = (a)*(h)	**1,828,435**	**2,301,313**	**5,528,488**
Cost Per Case (j)	$0.36	$2.53	$17.34
Cost of Cases Per Eligible Professional Per Year (k) = (d)*(j)	$19.51	$136.58	$936.58
Cost Per Eligible Professional to Prepare for PQRS Participation (l)	$174.50	$174.50	$174.50
Total Annual Cost Per Eligible Professional (m) = (k) + (l)	$194.01	$311.08	$1,111.08
Total Annual Cost (n) = (a)*(m)	**$67,903,500**	**$108,878,000**	**$388,878,000**

12.4 Reporting by Individual Eligible Professionals and Group Practices: Qualified Registry-based and QCDR-based Reporting Mechanisms

In 2011, approximately 50,215 (or 16 percent) of the 320,422 eligible professionals participating in PQRS used the qualified registry-based reporting mechanism. In 2012, 36,473 eligible professionals reported individual measures via the registry-based reporting mechanism and 10,478 eligible professionals reporting measures groups via the registry-based reporting mechanism.[4] According to the 2013 Reporting Experience, approximately 67,896 eligible professionals participated in the PQRS using the registry-based reporting mechanism (51,473 for individual measures and 16,423 for measures groups). Please note that we currently have no data on participation in the PQRS via a QCDR as 2014 is the first year in which an eligible professional may participate in the PQRS via a QCDR.

We believe that the rest of the eligible professionals not participating in other PQRS reporting mechanisms will use either the registry or QCDR reporting mechanisms for the following reasons:

- The PQRS measures set is moving away from use of claims-based measures and moving

[4] Id. at xvi. *See* Figure 4.

towards the use of registry-based measures

- We believe the number of QCDR vendors will increase as the QCDR reporting mechanism evolves.

Therefore, based on these assumptions, we expect to see a significant jump from 47,000 eligible professionals to approximately **212,000** eligible professionals using either the registry-based reporting mechanism or QCDR in 2016. We believe the majority of these eligible professionals will participate in the PQRS using a QCDR, as we presume QCDRs will be larger entities with more members.

There will be no additional time burden for individual eligible professionals or group practices to report data to a qualified registry since eligible professionals and group practices opting for qualified registry-based reporting or the use of a QCDR will already be reporting data to the qualified registry for other purposes (such as, for board certification purposes or internal quality improvement efforts) and the qualified registry will merely be re-packaging the data (numerator and denominator results) for use in the PQRS. Little, if any, additional data will need to be reported to the qualified registry or QCDR solely for purposes of participation in the PQRS. However, eligible professionals and group practices 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 CMS on their behalf. We estimate that the time and effort associated with this will be approximately **5 minutes** per eligible professional or eligible professional within a group practice.

Based on the assumptions discussed above and in Supporting Statement part B, Table 2 summarizes the total annual burden hours and total annual cost burden associated with eligible professionals using the qualified registry-based or QCDR-based reporting mechanism. Please note that, unlike the claims-based reporting mechanism that would require an eligible professional to report data to CMS on quality measures on multiple occasions, an eligible professional would not be required to submit this data to CMS, as the qualified registry or QCDR would perform this function on the eligible professional's behalf.

Table 2: Summary of Burden Estimates for Eligible Professionals (Participating Individually or as Part of a Group Practice) using the Qualified Registry-based and QCDR-based Reporting Mechanisms

	Burden Estimate
# of Participating Eligible Professionals (a)	212,000
Hours Per Eligible Professional to Authorize the Qualified registry or QCDR to Report on Eligible Professional's Behalf (b)	0.083
Hours Per Eligible Professional to Report PQRS Data to Qualified registry or QCDR (c)	3
Hours Per Eligible Professional to Prepare for PQRS Participation (d)	5
Total Annual Hours Per Eligible Professional (e) = (b)+(c)+(d)	8.083
Total Annual Hours (f) = (a)*(e)	**1,713,596**
Cost Per Eligible Professional to Authorize Qualified registry or QCDR to Report on Eligible Professional's Behalf (g)	$7.20
Cost Per Eligible Professional to Report PQRS Data to Qualified registry or QCDR (h)	$260.16

	Burden Estimate
Cost Per Eligible Professional to Prepare for PQRS Participation (i)	$174.50
Total Annual Cost Per Eligible Professional (j) = (g)+(h)+(i)	$441.86
Total Annual Cost (k) = (a)*(j)	**$93,674,320**

For CY 2014, 90 qualified registries and 50 QCDRs were qualified to report quality measures data to CMS for purposes of the PQRS.[5] Therefore, a total of 140 entities are currently classified as qualified registries and/or QCDRs under the PQRS. Although we believe the number of qualified registries will remain unchanged, we believe we will see a slight increase in the number of entities that become a QCDR. Specifically, we estimate that an additional 10 entities (bringing the total number of QCDRs to 60) will become QCDRs. We attribute this slight increase to entities that wish to become QCDRs but, for some reason (lack of information regarding the QCDR option, rejected during the qualification process, the inability to get its self-nomination info provided in time, etc.), were not selected to be QCDRs in 2014. Therefore, we estimate that a total of **150 entities** will become qualified registries and/or QCDRs under the PQRS.

Qualified registries or QCDRs interested in submitting quality measures results and numerator and denominator data on quality measures to CMS on their participants' behalf will need to complete a self-nomination process in order to be considered qualified to submit on behalf of eligible professionals or group practices unless the qualified registry or clinical data qualified registry was qualified to submit on behalf of eligible professionals or group practices for prior program years and did so successfully. We estimate that the self-nomination process for qualifying additional qualified registries or clinical data qualified registries to submit on behalf of eligible professionals or group practices for the PQRS will involve approximately **1 hour** per qualified registry or clinical data qualified registry to draft the letter of intent for self-nomination.

Please note that the self-nomination statement is an online form that entities will use to provide information on their business. The self-nomination statement is available at: https://jira.oncprojectracking.org/login.jsp. The form's screen shot is attached to this package.

In addition to completing a self-nomination statement, qualified registries and QCDRs will need to perform various other functions, such as develop a measures flow and meet with CMS officials when additional information is needed. In addition, QCDRs must perform other functions, such as benchmarking and calculating their measure results. We note, however, that many of these capabilities may already be performed by QCDRs for purposes other than to submit data to CMS for the PQRS. The time it takes to perform these functions may vary depending on the sophistication of the entity, but we estimate that a qualified registry or QCDR will spend an additional **9 hours** performing various other functions related to being a PQRS qualified entity.

We estimate that the staff involved in the qualified registry or QCDR self-nomination process will have an average labor cost of $86.72/hr. Therefore, assuming the total burden hours per qualified registry or QCDR associated with the self-nomination process is **10 hours**, we estimate

[5] The full list of qualified registries for 2014 is available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2014QualifiedRegistryVendors.pdf.

that the total cost to a qualified registry or QCDR associated with the self-nomination process will be approximately $867.20 ($86.72/hr x 10 hours per qualified registry).

We estimate that a total burden across the estimated 150 entities who will become qualified registries and/or QCDRs under the PQRS in 2016 is 150 entities x $867.20 = $130,080.

The burden associated with the qualified registry-based and QCDR reporting requirements of the PQRS will be the time and effort associated with the qualified registry calculating quality measures results from the data submitted to the qualified registry or QCDR by its participants and submitting the quality measures results and numerator and denominator data on quality measures to CMS on behalf of their participants. We expect that the time needed for a qualified registry or QCDR to review the quality measures and other information, calculate the measures results, and submit the measures results and numerator and denominator data on the quality measures on their participants' behalf will vary along with the number of eligible professionals reporting 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 (since many are quality improvement organizations or entities that assist practices with their internal quality improvement efforts). Therefore, there may not necessarily be a burden on a particular qualified registry or QCDR associated with calculating the measure results and submitting the measures results and numerator and denominator data on the quality measures to CMS on behalf of their participants. Whether there is any additional burden to the qualified registry or QCDR as a result of the qualified registry's or QCDR's participation in the PQRS will depend on the number of measures that the qualified registry or QCDR intends to report to CMS and how similar the qualified registry's measures are to CMS' PQRS measures.

At this point, we do not believe the requirement to report CAHPS for PQRS adds or reduces the burden to the group practices, as we consider reporting the CAHPS for PQRS survey as reporting three measures covering one domain.

Based on the assumptions discussed above, Table 3 summarizes total annual burden hours and total annual cost burden associated with a qualified registry or QCDR self-nominating in order to be considered "qualified" for the purpose of submitting quality measures results and numerator and denominator data on PQRS individual quality measures or measures groups on behalf of individual eligible professionals.

Table 3: Summary of Burden Estimates for Qualified registry or QCDR Vendors to Self-nominate

	Burden Estimate
# of Qualified registries or QCDRs Self-Nominating for the PQRS (a)	150
Total Annual Hours Per Qualified registry or QCDR (b)	10
Total Annual Hours For Qualified registries or QCDRs (c) = (a)*(b)	**1,500**
Cost Per Qualified registry or QCDR (d)	$867.20
Total Annual Cost For Qualified registries or QCDRs (e) = (a)*(d)	**$130,080**

12.5 Reporting by Individual Eligible Professionals and Group Practices: EHR-Based Reporting

Mechanism

According to the 2011 PQRS and eRx Experience Report, in 2011, 560 (or less than 1%) of the 320,422 eligible professionals participating in PQRS used the EHR-based reporting mechanism. 2012 saw a sharp increase in reporting via the EHR-based reporting mechanism. Specifically, according to the 2012 Reporting Experience, in 2012, 19,817 eligible professionals submitted quality data for the PQRS through a qualified EHR.[6] According to the 2013 PQRS and eRx Experience Report, in 2013, 23,194 (3.6 percent) eligible professionals participating in PQRS used the EHR-based reporting mechanism.

As seen in the 2013 Experience Report, the number of eligible professionals and group practices using the EHR-based reporting mechanism are steadily increasing as eligible professionals become more familiar with EHR products and more eligible professionals participate in programs encouraging use of an EHR, such as the EHR Incentive Program. In particular, we believe eligible professionals will transition from using the claims-based to the EHR-based reporting mechanisms. To account for this anticipated increase, we continue to estimate that approximately **50,000 eligible professionals**, whether participating as an individual or part of a group practice under the GPRO, would use the EHR-based reporting mechanism in CY 2016.

For EHR-based reporting, which includes EHR reporting via a direct EHR product and an EHR data submission vendor's product, the eligible professional or group practice must (1) review the quality measures on which we will be accepting PQRS data extracted from EHRs, (2) select the appropriate quality measures, (3) extract the necessary clinical data from his or her EHR, and (4) submit the necessary data to the CMS-designated clinical data warehouse.

Under this reporting mechanism the individual eligible professional or group practice may either submit the quality measures data directly to CMS from their EHR or utilize an EHR data submission vendor to submit the data to CMS on the eligible professional's or group practice's behalf. To submit data to CMS directly from their EHR, the eligible professional or eligible professional in a group practice must have access to a CMS-specified identity management system, such as Individuals Authorized Access to the CMS Computer Services (IACS), which we believe takes less than 1 hr to obtain. Once an eligible professional or eligible professional in a group practice has an account, he or she needs to extract the necessary clinical data from his or her EHR and submit the data to the CMS-designated clinical data warehouse.

With respect to submitting the actual data file for the respective reporting period, we believe that this will take an eligible professional or group practice no more than 2 hr, depending on the number of patients on which the eligible professional or group practice is submitting. We also believe that once the EHR is programmed by the vendor to allow data submission to CMS, the burden for the eligible professional or group practice to submit data on quality measures should be minimal since the information should already reside in the eligible professional's or group practice's EHR.

Group practices with 100 or more eligible professionals must report on CAHPS for PQRS (the

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\ Id. at XV.

survey is approved by OMB under control number 0938-1222, CMS-10450). Therefore, a group practice of 100 or more eligible professionals is required to report six or more measures covering two domains of their choosing. At this point, we do not believe the requirement to report CAHPS for PQRS adds or reduces the burden on group practices, as we consider reporting the CAHPS for PQRS survey as reporting three measures covering one domain.

Based on the assumptions discussed above and in Supporting Statement B, Table 4 summarizes the total annual burden associated with EHR-based reporting for individual eligible professionals or group practices. Please note that, unlike the claims-based reporting mechanism that would require an eligible professional to report data to CMS on quality measures on multiple occasions, an eligible professional would not be required to submit this data to CMS since the EHR product would perform this function on the eligible professional's behalf.

Table 4: Summary of Burden Estimates for Eligible Professionals (Participating Individually or as Part of a Group Practice) using the EHR-based Reporting Mechanism

	Burden Estimate
# of Participating Eligible Professionals (a)	50,000
Hours Per Eligible Professional to Obtain IACS Account (b)	1
Hours Per Eligible Professional to Submit Test Data File to CMS (c)	1
Hours Per Eligible Professional to Submit PQRS Data File to CMS (d)	2
Hours Per Eligible Professional to Prepare for PQRS Participation (e)	5
Total Annual Hours Per Eligible Professional (f) = (b)+(c)+(d)+(e)	9
Total Annual Hours (g) = (a)*(f)	**450,000**
Cost Per Eligible Professional to Obtain IACS Account (h)	$86.72
Cost Per Eligible Professional to Submit PQRS Data File to CMS (includes 1hr for submitting test file, which is optional) (i)	$260.16
Cost Per Eligible Professional to Prepare for PQRS Participation (j)	$174.50
Total Annual Cost Per Eligible Professional (k) = (h)+(i)+(j)	$521.38
Total Annual Cost (m) = (a)*(k)	**$26,069,000**

12.6 Reporting by Group Practices Using the GPRO Web Interface

As noted in the 2011 Experience Report, approximately 200 group practices participated in the GPRO in 2011. According to the 2012 Reporting Experience, 66 practices participated in the PQRS GPRO.[7] In addition, 144 ACOs earned participated in the PQRS GPRO through either the Medicare Shared Savings Program (112 ACOs) or Pioneer ACO Model (32 practices).[8] These group practices encompass 134,510 eligible professionals (or approximately 140,000 eligible professionals).[9] According to the 2013 PQRS and eRx Experience Report, 677 group practices self-nominated to participate via the PQRS GPRO (compared to 68 total that self-nominated in 2012), 550 moved on to become PQRS group practices, another 220 practices were approved by CMS to participate as Medicare MSSP ACOs, and 23 were eligible under the Pioneer ACO model. The number of eligible professionals (from the 2013 Experience Report) participating in one of these reporting methods include: 131,690 in PQRS group practices, 21,678 in Pioneer ACO, and 85,059 in MSSP ACO. Group practices participating in PQRS GPRO are increasing

[7] Id. at xv.
[8] Id. at xvi.
[9] Id. at 18.

each year, from roughly 200 group practices in 2011 and 2012, to 860 eligible practices in 2013 (including all GPRO, Pioneer ACO, and MSSP ACO. However, not all group practices use the Web Interface to report. We will assume, based on these numbers that **500 group practices** (accounting for approximately 228,000 eligible professional) will continue to participate in the PQRS using the GPRO Web Interface in 2016.

With respect to the process for group practices to be treated as satisfactorily submitting quality measures data under the PQRS, group practices interested in participating in the PQRS through the group practice reporting option (GPRO) must complete a self-nomination process similar to the self-nomination process required of qualified registries. Since a group practice using the GPRO web interface would not need to determine which measures to report under PQRS, we believe that the self-nomination process is handled by a group practice's administrative staff (billing and posting clerk).

We estimate that the self-nomination process will require **2 hours** for a group practice to review the PQRS GPRO and decide whether to participate as a group or individually. We also estimate an additional **2 hours** for a group practice to draft their letter of intent for self-nomination, gather the requested TIN and NPI information, and provide this requested information. It is estimated that each self-nominated entity will also spend **2 hours** undergoing the vetting process with CMS officials. We assume that the group practice staff involved in the self-nomination process (BLS occupation: billing and posting clerks) has an adjusted labor rate of $34.90/hr. By projecting **6 hours** (per group practice) for the self-nomination process, we estimate a total of **3,000 hours** (500 group practices x 6 hr) at a cost of $104,700 (3,000 hr x 34.90/hr).

The burden associated with the group practice reporting requirements under the GPRO mechanism is the time and effort for group practices to submit the quality measures data. For physician group practices, this is the time for the physician group to complete the web interface. We believe that the burden associated with using the GPRO web interface is comparable to that of using the Performance Assessment Tool (PAT). The PAT was the precursor to the current PQRS GPRO Web Interface and was used in several physician pay for performance demonstrations. The information collection components of the PAT have been reviewed by OMB and were approved under control number 0938-0941 (CMS-10136) for use in the PGP, MCMP, and EHR demonstrations. As the GPRO was only recently implemented in 2010, it is difficult to determine the time and effort associated with the group practice submitting the quality measures data. As such, we will use the same burden estimate for group practices participating in the GPRO as we use for group practices participating in the PGP, MCMP, and EHR demonstrations using the PAT. We estimate that the burden associated with a group practice completing data for PQRS under the web interface will be the same as for the group practice to complete the PAT for the PGP demonstration. In other words, we estimate that, on average, it will take each group practice **79 hours** to submit quality measures data via the GPRO web interface at a cost of $6,850.88 (79 hr x $86.72/hr). In aggregate, we estimate **39,500 hours** (500 group practices x 79 hr) and $3,425,440 (39,500 hr x $86.72/hr).

Based on the assumptions discussed above, Table 5 provides an estimate of the range of total annual burden hours and total annual cost burden associated with the group practice reporting of quality measures.

Table 5: Summary of Burden Estimates for Group Practices using the GPRO Web Interface Reporting Mechanism

	Burden Estimate
# of Eligible Group Practices (a)	500
# of Hours Per Group Practice to Self-Nominate to Participate in PQRS Under the Group Practice Reporting Option (b)	6
# of Hours Per Group Practice to Report (c)	79
Total Annual Hours Per Group Practice (d) = (b)+(c)	85
Total Annual Hours (e) = (a)*(d)	**42,500**
Cost Per Group Practice to Self-Nominate to Participate in PQRS Under the Group Practice Reporting Option (at a labor rate of $34.90/hr) (f)	$209.40
Cost Per Group Practice to Report(g)	$6,850.88
Total Annual Cost Per Group Practice (h) = (f) + (g)	$7,060.28
Total Annual Cost (i) = (a)*(h)	**$3,530,140**

Beginning in 2013, we have required group practices that use the GPRO web interface reporting mechanism to administer a CAHPS survey. The burden for implementing this survey is set out under a separate OMB control number/PRA package.

12.7 Total Estimated Burden of this Information Collection Requirement for 2016

It is difficult to accurately estimate the total annual burden hours and total annual burden costs associated with the submission of the quality measures data for the PQRS. For example, there are a number of reporting mechanisms available that eligible professionals can choose to use to report the PQRS measures. It may be more burdensome for some practices to use some reporting mechanisms to report the PQRS than others. This will vary with each practice. We have no way of determining which reporting mechanism an individual eligible professional will use in a given year, especially since EHR reporting and group practice reporting were new options for the 2010 PQRS and the QCDR option is new for the 2014 PQRS. Therefore, Table 6 provides a range of estimates for individual eligible professionals or group practices using the claims, qualified registry, or EHR-based reporting mechanisms. The lower range of the estimate assumes that eligible professionals will only participate in PQRS to avoid the PQRS payment adjustments that began in 2015. The upper range assumes that eligible professionals participate in PQRS for purposes of earning an incentive as well as avoiding the PQRS payment adjustments. This upper range represents the sum of the estimated maximum burden hours and burden cost per eligible professional from Tables 1, 2, and 4 above. We are requesting approval for the upper range of the estimates provided in Table 6.

Table 6: Burden Estimates for Eligible Professionals and/or Group Practices using the Claims, Qualified registry, and EHR-based Reporting Mechanisms

	Minimum Burden Estimate	**Maximum Burden Estimate**
Annual Hours for Claims-based Reporting (for individual eligible professionals only)	1,828,435	5,528,488
Annual Hours for Qualified registry-based or QCDR-based Reporting	1,715,096	1,715,096

Annual Hours for EHR-based Reporting	450,000	450,000
Total Annual Burden Hours for Eligible Professionals or Eligible Professionals in a Group Practice	**3,993,531**	**7,693,584**
Cost for Claims-based Reporting (for individual eligible professionals only)	$67,903,500	$388,878,000
Cost for Qualified registry-based Reporting	$91,870,200	$91,870,200
Cost for EHR-based Reporting	$25,655,000	$25,655,000
Total Annual Cost for Eligible Professionals or Eligible Professionals in a Group Practice	**$185,428,700**	**$506,403,200**

For purposes of estimating the reporting burden for group practices, table 7 provides a summary of an estimate for group practices to participate in PQRS under the group practice reporting option using the GPRO web interface (that is, Table 5).

Table 7: Burden Estimates for Group Practices using the GPRO Web Interface Reporting Mechanism

	Maximum Burden Estimate
# of Participating Group Practices	500
# of Hours Per Group Practice to Self-Nominate to Participate in PQRS and the Electronic Prescribing Incentive Program Under the Group Practice Reporting Option	6
# of Hours Per Group Practice to Report Quality Measures	79
Total Annual Hours Per Group Practice	85
Total Annual Hours for Group Practices	**42,500**
Cost Per Group Practice to Self-Nominate to Participate in PQRS for the Group Practice Reporting Option	$209.40
Cost Per Group Practice to Report Quality Measures	$6,850.88
Total Annual Cost Per Group Practice	$7,060.28
Annual Cost for Group Practices	**$3,530,140**

Table 8: Total Annual Burden Estimates for All Reporting Mechanisms

Section(s) in title 42 of the CFR	**Respondents**	**Responses (total)**	**Burden per Response**	**Total Annual Burden (hr)**	**Labor Rate for Reporting ($/hr)**	**Total Cost ($)**
414.90	350,000 (claims-based reporting)	350,000	15.79568	5,528,488	varies	388,878,000
	212,000 (qualified registry-based and QCDR-based reporting)	212,000	8.083	1,713,596	varies	93,674,320
	150 (qualified registry-	150	10	1,500	86.72	130,080

	based and QCDR-based self-nomination)					
	50,000 (EHR-based reporting)	50,000	9	450,000	varies	26,069,000
	500 (GPRO web interface)	500	85	42,500	varies	3,530,140
Total	**612,500**	**612,650**	**--**	**7,736,084**	**--**	**512,281,540**

12.8 Collection Instruments and Guidance Documents for 2016

- 2016 Implementation Guide (provides guidance to stakeholders on what they need to do to comply with the program requirements)

- Screen shots of the self-nomination form.

13. Capital Costs (Maintenance of Capital Costs)

CMS requirements do not require the acquisition of new systems or the development of new technology to participate in the PQRS. However, to the extent an eligible professional decides to participate in the PQRS through the EHR-based reporting mechanism and he or she does not already have an EHR, he or she will need to purchase one. The cost of purchasing an EHR product can range anywhere from $25,000 to $54,000 with ongoing maintenance costs averaging up to $18,000 per year. We believe, however, that it is unlikely than an eligible professional would purchase an EHR solely for the purpose of participating in the PQRS. Instead, we believe that having the option to use their EHR to participate in the PQRS is simply an added benefit for eligible professionals who already have an EHR product.

14. Cost to Federal Government

Aside from program administration and implementation costs, as, beginning in 2016 the PQRS will no longer provide incentives for satisfactory reporting (or, in lieu of satisfactory reporting, satisfactory participation in a QCDR), there will be no cost to the federal government with respect to the application of the PQRS payment adjustments.

15. Program or Burden Changes

The changes in the estimated burden in this PRA application for CY 2016 from the CY 2015 submission are due to the following:

Claims-based reporting

In the 2013 PQRS and eRx Experience Report, 641,654 eligible professionals participated as individuals or group practices through one of the PQRS reporting mechanism, a 47 percent

increase from those that participated in 2012 (435,931). Through the individual claims-based reporting mechanism, 331,668 of those eligible professionals (or 52 percent) reported using this mechanism. Increased claims based reporting to 350,000 (approximately five percent increase over 2013). Though claims reporting was declining, we did see an increase in 2013 once the payment adjustment was applied to all participants, so we assume a slight increase in 2016. While the claims-based reporting mechanism is still the most widely-used reporting mechanism, we were seeing a decline in the use of the claims-based reporting mechanism in the PQRS. There was a slight increase in 2013, which may be reflected by the use of administrative claims-based reporting mechanism by individual eligible professionals and group practices only for the 2015 PQRS payment adjustment (in CY2013).

While these eligible professionals continue to participate in the PQRS, they have started to shift towards the use of other reporting mechanisms – mainly the Group Practice Reporting Option Web Interface (whether used by a PQRS GPRO or an ACO participating in the PQRS via the Medicare Shared Savings Program or Pioneer ACO), registry, or the EHR-based reporting mechanisms, or participation in a Qualified Clinical Data Registry (QCDR). For purposes of this burden estimate, based on PQRS participation using the claims-based reporting mechanism in 2012 and 2013, we will assume that approximately **350,000 eligible professionals** (+ 100,000 from 250,000 eligible professionals) will participate in the PQRS using the claims-based reporting mechanism in 2016.

Registry and QCDR reporting

According to the 2013 Reporting Experience, approximately 67,896 eligible professionals participated in the PQRS using the registry-based reporting mechanism (51,473 for individual measures and 16,423 for measures groups). For 2014, 90 qualified registries and 50 QCDRs were qualified to report quality measures data to CMS for purposes of the PQRS. Therefore, a total of 140 entities are currently classified as qualified registries and/or QCDRs under the PQRS. Although we believe the number of qualified registries will remain the same in 2016, we believe we will see a slight increase in the number of entities that become a QCDR in 2016. We estimate that an additional 10 entities (bringing the total number of QCDRs to 60 in 2016) will become QCDRs in 2016. Therefore, we estimate that a total of 150 entities will become qualified registries and/or QCDRs under the PQRS in 2016.

We believe that the rest of the eligible professionals not participating in other PQRS reporting mechanisms will use either the registry or QCDR reporting mechanisms for the following reasons:

- The PQRS measures set is moving away from use of claims-based measures and moving towards the use of registry-based measures
- We believe the number of QCDR vendors will increase as the QCDR reporting mechanism evolves.

Therefore, based on these assumptions, we expect to see a significant jump from 47,000 eligible professionals to approximately **212,000 eligible professionals** (+ 47,000 from 210,000 eligible professionals) using either the registry-based reporting mechanism or QCDR in 2016. We

believe the majority of these eligible professionals will participate in the PQRS using a QCDR, as we presume QCDRs will be larger entities with more members.

Group Practice Reporting Option

According to the 2013 PQRS and eRx Experience Report, 677 group practices self-nominated to participate via the PQRS GPRO (compared to 68 total that self-nominated in 2012), 550 moved on to become PQRS group practices, another 220 practices were approved by CMS to participate as Medicare MSSP ACOs, and 23 were eligible under the Pioneer ACO model. The number of eligible professionals (from the 2013 Experience Report) participating in one of these reporting methods include: 131,690 in PQRS group practices, 21,678 in Pioneer ACO, and 85,059 in MSSP ACO. Group practices participating in PQRS GPRO are increasing each year, from roughly 200 group practices in 2011 and 2012, to 860 eligible practices in 2013 (including all GPRO, Pioneer ACO, and MSSP ACO. However, not all group practices use the Web Interface to report. We will assume, based on these numbers that **500 group practices** (+ 300 from 200 group practices) (accounting for approximately 228,000 eligible professional) will continue to participate in the PQRS using the GPRO Web Interface in 2016.

Information Collection Instruments and Instructions

The Implementation Guide, which provides guidance to stakeholders on what they need to do to comply with the program requirements, has been updated to reflect the changes in program policies for the 2016 reporting period. Consistent with Implementation Guide, Appendix J: Revision Notes, there are no changes to any of the information collection or reporting requirements. The updates did not change the time involved in reviewing the Implementation Guide.

We are also attaching screen shots of the self-nomination form. While we had set out such burden in previous packages, we did not include the form.

Our previously-approved package erroneously included our PQRS Measure-Applicability Validation (MAV) document. We are excluding the document from this proposed package since it is an informational document used to educate stakeholders on how CMS applies the MAV process. It does not provide any instruction/guidance to respondents.

16. Publication and Tabulation Dates

As required by the MIPPA, the names of eligible professionals and group practices who satisfactorily report data on quality measures for the 2018 PQRS payment adjustment 5 will be posted on the CMS website at www.medicare.gov following completion of the reporting periods occurring in 2016. Performance information on group practices and individual eligible professionals will also be posted on the Physician Compare website for a subset of the PQRS measures.

17. Expiration Date

The OMB control number and expiration date will be displayed on the Quality Net portal webpage.

18. Certification Statement

There are no exceptions to the certification statement.