Supporting Statement – Part A
Physician Quality Reporting System (CYs 2014 through 2016)
CMS-10276, OCN 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), and the Affordable Care Act (ACA). The program provides incentive payments and, beginning in 2015, payment adjustments to eligible professionals and group practices who satisfactorily report data on Quality measures. 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. The criteria for satisfactory reporting for the 2014 PQRS incentive and the 2016 PQRS payment adjustment are set forth in the CY 2013 Medicare Physician Fee Schedule (PFS) final rule with comment period and CY 2014 PFS final rule with comment period.

A. Justification

1. Need and Legal Basis

With respect to the 2014 PQRS incentive, collection of this information is voluntary and only applies to eligible professionals or group practices who wish to participate in PQRS. However, with respect to the 2016 PQRS payment adjustment, collection of this information applies to all eligible professionals and group practices. Therefore, since the reporting periods for the 2014 PQRS incentive and 2016 payment adjustment coincide in CY 2014, the collection of this information will apply to all eligible professionals and group practices.

Eligible professionals or group practices who satisfactorily report data on quality measures for covered professional services furnished during the applicable 2014 PQRS incentive reporting period may qualify to receive 2014 incentive payments equal to 0.5 percent of the total estimated allowed charges submitted by no later than 2 months after the end of the applicable incentive reporting period. In addition, eligible professionals or group practices may be subject to payment adjustments in 2016 equal to 2.0 percent of the total estimated allowed charges submitted by no later than 2 months after the end of the applicable payment adjustment reporting period. The criteria for satisfactory reporting of data on individual quality measures and measures groups for the 2014 PQRS incentive and the 2016 PQRS payment adjustment are set forth in the CY 2013 PFS final rule and CY 2014 PFS final rule.

In addition, for the PQRS, for 2011 through 2014, eligible professionals and group practices who satisfactorily report the 2012 quality measures may also earn an additional 0.5 percent incentive payment for both participating in a Maintenance of Certification Program and successfully completing a Maintenance of Certification Program practice assessment more frequently than is required to qualify for or maintain board certification status.

While individual eligible professionals do not need to sign up or pre-register to begin participating in the PQRS, group practices interested in participating in PQRS as a group practice using the group practice reporting option (GPRO) must indicate its desire to participate in PQRS for an applicable reporting period by submitting a self-nomination statement and be selected to participate in PQRS using the GPRO.

With respect to the 2014 PQRS incentive, eligible professionals wishing to report data on quality measures may do so via 4 reporting mechanisms: claims, registry, qualified clinical data registry, and EHR (which includes submitting quality measures data via a direct EHR product and an EHR data submission vendor's product). Group practices wishing to report data on quality measures or the CG CAHPS survey measures may do so via 4 reporting mechanisms beginning in 2014 –GPRO web interface, registry, EHR (which includes submitting quality measures data via a direct EHR product and an EHR data submission vendor's product), and the CMS-certified survey vendor.

Beginning in 2014, eligible professionals and group practices wishing to report data on quality measures via an EHR must use an EHR product that is certified by the Office of National Coordinator as "Certified EHR Technology" (CEHRT).

Note: With respect to registries and qualified clinical data registries, in order for registries and qualified clinical data registries to submit quality measures results and numerator and denominator data on individual quality measures or measures groups on behalf of eligible professionals (and, in the case of registries, group practices), a registry or clinical data registry will need to self-nominate to become a "qualified" PQRS registry or qualified clinical data registry. If a registry was qualified for a prior year and successfully submits quality measure results and numerator and denominator data on quality measures on behalf of their participants, the registry would not need to become re-qualified for PQRS purposes. However, a qualified clinical data registry must become qualified every year in which it seek to submit quality measure results on behalf of its eligible professionals.

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 for the 2014 PQRS incentive and the 2016 PQRS payment adjustment.

(2) To calculate and make incentive payments to eligible professionals and group practices for the 2014 PQRS incentive.

(3) Publicly post the names of eligible professionals and group practices who satisfactorily report quality measures data (or, for eligible professionals, in lieu of satisfactory reporting, satisfactorily participate in a qualified clinical data registry) on the CMS Physician Compare Web site.

(4) To determine a group practice's quality score under the physician value-based modifier.

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

3. Improved Information Technology

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. For registry-based and qualified clinical data registry-based reporting, registries submit quality measures results and numerator and denominator data on PQRS measures or measures to us electronically. For EHR-based reporting, eligible professionals submit data on quality measures to us electronically through a direct EHR product or via an EHR data submission vendor's product.

There is no application for registries that wish to self-nominate to become a qualified PQRS registry. Registries are asked to submit a self-nomination letter requesting inclusion in PQRS for each program year in which the registry seeks to be qualified to submit quality measures data on behalf of its participants.

Likewise, there is no application for clinical data registries that wish to self-nominate to become a PQRS qualified clinical data registry. Clinical data registries must meet established requirements for being qualified to participate in the PQRS as a qualified clinical data registry and are asked to submit a self-nomination statement requesting inclusion in PQRS for each program year in which the clinical data registry seeks to be qualified to submit quality measures data on behalf of its participants.

For group practices participating in the PQRS GPRO, although we are extending use of the registry and EHR-based reporting mechanisms to group practices using the GPRO, we believe the collection of information will primarily be done using a previously OMB-approved data collection web interface (see OMB Control Number (OCN) 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 the reporting via the GPRO is moving away from use of the PAT, we note that the web interface that will be used is similar in terms of burden to using the PAT.

4. Duplication of Similar Information

To minimize duplication of similar information within PQRS, as the reporting periods for the 2014 PQRS incentive and 2016 PQRS payment adjustment coincide, we will use the data submitted by the eligible professional or group practice for purposes of the PQRS incentive to determine whether a PQRS payment adjustment applies to an eligible professional or group practice.

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. 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, by 2014, the measures available for reporting under the EHR-based reporting mechanism under PQRS will align with the EHR measures available for reporting under the EHR Incentive Program. In addition, in 2014, CMS is aligning the criteria for satisfactory reporting using the EHR-based reporting mechanism under PQRS with the reporting criteria for meeting the CQM component of achieving meaningful use under the EHR Incentive 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 have statutory authority to earn a PQRS incentive through their participation in the Medicare Shared Savings Program. Similarly, group practices may earn a PQRS incentive through their participation in a Pioneer ACO. By doing so, we are rewarding those practices that voluntarily agreed to participate in these and reduced the 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

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 qualified clinical data registry, (2) to calculate and make PQRS incentive payments or 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 qualified clinical data registry on the CMS Web site.

If registries and clinical data registries are not required to submit a self-nomination statement, CMS will have no mechanism to determine which registries and clinical data 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 registries and qualified clinical data registries to use to report quality measures data to CMS. Similarly, if group practices are not required to submit a self-nomination statement, 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

The CY 2014 PFS proposed rule (RIN 0938-AR56) solicited public comment for this collection, as it pertains to PQRS in CY 2014, and published in the Federal Register on July 19, 2013 (78 FR 43282). No comments were received.

9. Payment/Gift To Respondent

As authorized under section 1848(m)(1)(A) of the Act, eligible professionals or group practices who satisfactorily report data on quality measures during PQRS reporting periods occurring in CYs 2013 and 2014 and submitted not later than 2 months after the end of the respective reporting period may qualify to earn an incentive payment equal to 0.5 percent of the total estimated allowed charges for all covered professional services furnished during 2014. Eligible professionals, including eligible professionals in a group practice participating in the PQRS GPRO, who satisfactorily report quality measures data during 2012, 2013, and 2014 could also qualify for an additional 0.5 percent incentive by both participating in a Maintenance of Certification Program and successfully completing a Maintenance of Certification Program practice assessment more frequently than is required to qualify for or maintain board certification status.

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

12. Burden Estimate (Total Hours & Wages)

The annual burden estimate is calculated separately for the 2014 PQRS for (1) individual eligible professionals and group practices using the claims (for eligible professionals only), (2) registry and qualified clinical data registry, (3) EHR-based reporting mechanisms, and (4) group practices using the GPRO. There is also a separate annual burden estimate for registries and qualified clinical data registries who wish to be qualified to submit quality measures data. Please note that we are grouping group practices using the registry and EHR-based reporting mechanisms with the burden estimate for individual eligible professionals using the 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.

Burden Estimates for the PQRS: (CY 2014)

Burden Estimate for PQRS Reporting by Individual Eligible Professionals: Reporting in General

It is the PQRS's goal to bring the program's participation rate to 50%. We believe that participation rates will steadily increase to meet this goal of 50% participation, primarily due to the implementation of payment adjustments that begin in 2015. We anticipate that the first sharp rise in participation rates will occur in CY 2013, as the reporting period for the 2015 payment adjustment

occurs in 2013. We anticipate an incremental rise in the PQRS's participation rates from 30% in 2013 to 40% in 2014 to 50% in 2015 primarily as the reporting requirements for the PQRS payment adjustments move to parallel the reporting requirements of 2013 and 2014 the PQRS incentives. In 2009, 2010, and 2011, we have seen that the number of professionals eligible to participate in the PQRS have been approximately 1 million. Therefore, we estimate that approximately (1 million x 30%) 300,000 eligible professionals will participate in 2013 and that this will increase to (1 million x 40%) 400,000 eligible professionals in 2014 and (50% x 1 million) 500,000 in 2015. The burden estimates provided are based on a participation rate of 40% for 2014.

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 identifying applicable quality measures for which they can report the necessary information, selecting a reporting option, 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 both the criteria for satisfactory reporting for the 2014 PQRS incentive and 2016 PQRS payment adjustment.

For individual eligible professionals, the burden associated with the requirements of this reporting initiative is the time and effort associated with eligible professionals identifying applicable quality measures for which they can report the necessary information, collecting the necessary information, and reporting the information needed to report the eligible professional's measures. 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 3 measures to earn a PQRS incentive, we will assume that each eligible professional who attempts to submit quality measures data is attempting to earn a PQRS incentive payment, in addition to being relieved from the 2016 PQRS payment adjustment, and reports on an average of 9 measures for this burden analysis.

Because we anticipate even greater participation in PQRS in 2014, as the reporting period for the 2016 PQRS payment adjustment occurs in CY 2014. For eligible professionals who are participating in PQRS for the first time, we will assign 5 hours as the amount of time needed for eligible professionals to review the PQRS Measures List, review the various reporting options, select the most appropriate reporting option, identify the applicable measures or measures groups for which they can report the necessary information, review the measure specifications for the selected measures or measures groups, and incorporate reporting of the selected measures or measures groups into the office work flows. The measures list contains the measure title and brief summary information 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 up to 2 hours to review this list, review the reporting options, and select a reporting option and measures on which to report. If an eligible professional has received training, then we believe this would take less time. CMS believes 3 hours is plenty of time for an eligible professional to review

the measure specifications of 9 measures or 1 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 group into the office work flows.

For purposes of this burden estimate, we will assume that a billing clerk will handle the administrative duties associated with participating in the PQRS. According to information published by the Bureau of Labor Statistics, available at http://www.bls.gov/oes/current/oes433021.htm, the mean hourly wage for a billing clerk is $16.00/hour. Therefore, for purposes of handling administrative duties, we estimate an average labor cost of $16.00/hour. In addition, for purposes of this burden estimate, we will assume that a computer analyst will engage in the duties associated with the reporting of quality measures. According to information published by the Bureau of Labor Statistics, available at http://www.bls.gov/oes/current/oes151121.htm, the mean hourly wage for a computer analyst is $39.06/hour, or approximately $40.00/hour. Therefore, for purposes of reporting on quality measures, we estimate an average labor cost of $40.00/hour.

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 actually reporting the quality measures will vary depending on the reporting mechanism selected by the eligible professional.

Burden Estimate for PQRS Reporting by Individual Eligible Professionals and Group Practices: 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. In last year's PRA estimates, we estimated that approximately 320,000 eligible professionals, whether participating individually or in a group practice, would participate in PQRS in CY 2014. However, we believe this estimate should be further modified to reflect a lower participation estimate in 2014 due to the following policy changes:

- We eliminated the option to report measures groups via claims for the 2014 PQRS incentive.
- We increased the number of measures that an eligible professional must report to meet the criteria for satisfactory reporting for the 2014 PQRS incentive from 3 measures to 9.
- In an effort to move away from claims-based reporting, we removed the claims-based reporting mechanism as an option for reporting certain measures.

Based on these policy changes, we estimate that approximately 230,000 eligible professionals (that is, the same number of eligible professionals who participated in the PQRS using the claims-based reporting mechanism in 2011) will participate in the PQRS using the claims-based reporting mechanism. Therefore, we estimate that approximately 58% of the eligible professionals participating in PQRS will use the claims-based reporting mechanism.

For 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 will collect QDCs as additional (optional) line items on the existing HIPAA transaction 837-P and/or CMS Form 1500 (OCN: 0938-0999). We do not anticipate any new forms and or any modifications to the existing transaction or form. We also do not anticipate changes to the 837-P or CMS Form 1500 for CY 2014.

We estimate the cost for an eligible professional to review the list of quality measures or measures groups, identify the applicable measures or measures group for which they can report the necessary information, incorporate reporting of the selected measures or measures group into the office work flows, and select a PQRS reporting option to be approximately $200 per eligible professional ($40 per hour x 5 hours).

Based on our experience with the 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 9 measures measure) would range from 15 seconds (0.25 minutes) to over 12 minutes for complicated cases and/or measures, with the median time being 1.75 minutes. To report 9 measures, we estimate that it would take approximately 2.25 minutes to 108 minutes to perform all the steps necessary to report 9 measures.

Per measure, at an average labor cost of $40/hour per practice, the cost associated with this burden will range from $0.17 in labor to about $8.00 in labor time for more complicated cases and/or measures, with the cost for the median practice being $1.67. To report 9 measures, using an average labor cost of $40/hour, we estimated that the time cost of reporting for an eligible professional via claims would range from $1.50 (2.25 minutes or 0.0375 hours x $40/hour) to $72.00 (108 minutes or 1.8 hours x $40/hour) per reported case.

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 9. 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 6 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).

Based on the assumptions discussed previously, we estimate the total annual reporting burden per individual eligible professional associated with claims-based reporting will range from 13.5 minutes (0.25 minutes per measure x 9 measures x 6 cases per measure) to 648 minutes (12 minutes per measure x 9 measures x 6 cases per measure), with the burden to the median practice being 94.5 minutes (1.75 minutes per measure x 9 measures x 6 cases). We estimate the total

annual reporting cost per eligible professional or eligible professional in a group practice associated with claims-based reporting will range from $9.18 ($0.17 per measure x 9 measures x 6 cases per measure) to $432.00 ($8.00 per measure x 9 measures x 6 cases per measure), with the cost to the median practice being $90.18 per eligible professional ($1.67 per measure x 9 measures x 6 cases per measure).

Based on the assumptions discussed above and in Part B of this supporting statement, 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
Estimated # of Participating Eligible Professionals (a)	230,000	230,000	230,000
Estimated # of Measures Per Eligible Professional Per Year (b)	9	9	9
Estimated # of Cases Per Measure Per Eligible Professional Per Year (c)	6	6	6
Total Estimated # of Cases Per Eligible Professional Per Year (d) = (b)*(c)	54	54	54
Estimated Burden Hours Per Case (e)	0.00415	0.02917	0.19992
Estimated Total Burden Hours For Measures Per Eligible Professional Per Year (f) = (d)*(e)	0.2241	1.57518	10.79568
Estimated Burden Hours Per Eligible Professional to Prepare for PQRS Participation (g)	5	5	5
Estimated Total Annual Burden Hours Per Eligible Professional (h) = (f)+(g)	5.2241	6.57518	15.79568
Estimated Total Annual Burden Hours (i) = (a)*(h)	**1,201,543**	**1,512,291.4**	**3,633,006.4**
Estimated Cost Per Case (j)	$0.17	$1.67	$8.00
Total Estimated Cost of Cases Per Eligible Professional Per Year (k) = (d)*(j)	$9.18	$90.18	$432
Estimated Cost Per Eligible Professional to Prepare for PQRS Participation (l)	$200	$200	$200

Estimated Total Annual Cost Per Eligible Professional (m) = (k) + (l)	$209.18	$290.18	$632
Estimated Total Annual Burden Cost (n) = (a)*(m)	**$48,111,400**	**$66,741,400**	**$145,360,000**

Burden Estimate for PQRS Reporting by Individual Eligible Professionals and Group Practices: Registry-Based and Qualified Clinical Data Registry-based Reporting Mechanisms

Last year, we estimated that approximately 64,000 eligible professionals and group practices would use the registry based reporting mechanism. We are modifying this estimate, based on updated data we have received on PQRS participation. In 2011, approximately 50,215 (or 16 percent) of the 320,422 eligible professionals participating in PQRS used the registry-based reporting mechanism. We believe the number of eligible professionals and group practices using a qualified registry or qualified clinical data registry would remain the same, as eligible professionals use registries for functions other than PQRS and therefore would obtain a qualified registry or qualified clinical data registry solely for PQRS reporting by CY 2014. Please note that this estimate would include participants choosing the newly qualified clinical data registry reporting mechanism. At least in its initial stage, we believe most of the vendors that would be approved to be a qualified clinical data registry would likely be the same clinical data registries that are currently qualified PQRS registries.

For registry-based and qualified clinical data registry-based reporting, there will be no additional time burden for eligible professionals or group practices to report data to a registry as eligible professionals and group practices opting for registry-based reporting or use of a qualified clinical data registry will more than likely already be reporting data to the registry for other purposes and the registry will merely be re-packaging the data for use in the PQRS. Little, if any, additional data will need to be reported to the registry or qualified clinical data registry solely for purposes of participation in the PQRS. However, eligible professionals and group practices will need to authorize or instruct the registry or qualified clinical data registry 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 Part B of this supporting statement, Table 2 provides an estimate of the total annual burden hours and total annual cost burden associated with eligible professionals using the registry-based or qualified clinical data registry-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 registry or qualified clinical data registry 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 Registry-based and Qualified Clinical Data Registry-based Reporting Mechanisms

	Burden Estimate

Estimated # of Participating Eligible Professionals (a)	50,000
Estimated Burden Hours Per Eligible Professional to Authorize the Registry or Qualified Clinical Data Registry to Report on Eligible Professional's Behalf (b)	0.083
Estimated Burden Hours Per Eligible Professional to Report PQRS Data to Registry or Qualified Clinical Data Registry (c)	3
Estimated Burden Hours Per Eligible Professional to Prepare for PQRS Participation (d)	5
Estimated Total Annual Burden Hours Per Eligible Professional (e) = (b) +(c)+(d)	8.083
Estimated Total Annual Burden Hours (f) = (a)*(e)	**404,150**
Estimated Cost Per Eligible Professional to Authorize Registry or Qualified Clinical Data Registry to Report on Eligible Professional's Behalf (g)	$3.32
Estimated Cost Per Eligible Professional to Report PQRS Data to Registry or Qualified Clinical Data Registry (h)	$120
Estimated Cost Per Eligible Professional to Prepare for PQRS Participation (i)	$200
Estimated Total Annual Cost Per Eligible Professional (j) = (g)+(h)+(i)	$323.32
Estimated Total Annual Burden Cost (k) = (a)*(j)	**$16,166,000**

Based on the number of registries that have self-nominated to become a qualified PQRS registry in prior program years, we estimate that approximately 50 registries or clinical data registries will self-nominate to be considered a qualified registry or qualified clinical data registry for the PQRS. We anticipate that as the PQRS program matures, the number of registries seeking to become a qualified registry or qualified clinical data registry will decrease over time.

Registries or qualified clinical data registries 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 in order to be considered qualified to submit on behalf of eligible professionals or group practices unless the registry or clinical data 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 registries or clinical data registries to submit on behalf of eligible professionals or group practices for the PQRS will involve approximately 1 hour per registry or clinical data registry to draft the letter of intent for self-nomination.

In addition to completing a self-nomination statement, registries and qualified clinical data registries 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, qualified clinical data registries 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 qualified clinical data registries 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 registry or qualified clinical data registry 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 registry or qualified clinical data registry self-nomination process will have an average labor cost of $40/hour. Therefore, assuming the total burden hours per registry or qualified clinical data registry associated with the self-nomination process is 10 hours, we estimate that the total cost to a registry or qualified clinical data registry associated with the self-nomination process will be approximately $400 ($40 per hour x 10 hours per registry). Therefore, assuming the total burden hours per registry or qualified clinical data registry associated with the self-nomination process is 10 hours, we estimate the total cost to a registry or qualified clinical data registry associated with the registry or qualified clinical data registry self-nomination process to be approximately $400 ($40 per hour x 10 hours per registry).

The burden associated with the registry-based and qualified clinical data registry reporting requirements of the PQRS will be the time and effort associated with the registry calculating quality measures results from the data submitted to the registry or qualified clinical data registry 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 registry or qualified clinical data registry 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 registry or qualified clinical data registry and the number of applicable measures. However, we believe that registries already perform many of these activities for their participants. Therefore, there may not necessarily be a burden on a particular registry or qualified clinical data registry 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 registry or qualified clinical data registry as a result of the registry's or qualified clinical data registry's participation in the PQRS will depend on the number of measures that the registry or qualified clinical data registry intends to report to CMS and how similar the registry's measures are to CMS' PQRS measures.

Based on the assumptions discussed above, Table 3 provides an estimate of total annual burden hours and total annual cost burden associated with a registry or clinical data registry 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 Registry or Qualified Clinical Data Registry Vendors to Report Quality Measures Data on Behalf of Eligible Professionals and/or Group Practices to CMS

	Burden Estimate
Estimated # of Registries or Qualified Clinical Data Registries Self-Nominating for the PQRS (a)	50
Estimated Total Annual Burden Hours Per Registry or Qualified Clinical	10

Data Registry (b)	
Estimated Total Annual Burden Hours For Registries or Qualified Clinical Data Registries (c) = (a)*(b)	**500**
Estimated Cost Per Registry or Qualified Clinical Data Registry (d)	$400
Estimated Total Annual Burden Cost For Registries or Qualified Clinical Data Registries (e) = (a)*(d)	**$200,000**

Burden Estimate for PQRS Reporting by Individual Eligible Professionals and Group Practices: EHR-Based Reporting Mechanism

Last year, we estimated that approximately 16,000 eligible professionals (0.04%), whether participating as an individual or part of a group practice, will use the EHR-based reporting mechanism by CY 2014. 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. We believe the number of eligible professionals and group practices using the EHR-based reporting mechanism would increase 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 and group practices would transition from using the claims-based to the EHR-based reporting mechanisms. We estimate that approximately 50,000 eligible professionals (which is the same estimate as we are providing for eligible professionals who use the qualified registry or qualified clinical data registry-based reporting mechanisms), whether participating as an individual or part of a group practice, would use the EHR-based reporting mechanism in CY 2014.

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 review the quality measures on which we will be accepting PQRS data extracted from EHRs, select the appropriate quality measures, extract the necessary clinical data from his or her EHR, and submit the necessary data to the CMS-designated clinical data warehouse.

For EHR-based reporting for the PQRS, 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 IACS, which we believe takes less than 1 hour to obtain. Once an eligible professional or eligible professional in a group practice has an account for this CMS-specified identity management system, he or she will need to extract the necessary clinical data from his or her EHR, and submit the necessary 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 hours, depending on the number of patients on which the eligible professional or group practice is submitting. We believe that once the EHR is programmed by the vendor to allow data submission to CMS, the burden to the eligible professional or group practice associated with submission of data on quality measures should be

minimal as all of the information required to report the measure should already reside in the eligible professional's or group practice's EHR.

Based on the assumptions discussed above and in Part B of this supporting statement, Table 4 provides an estimate of the total annual burden hours and total annual cost 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, as 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
Estimated # of Participating Eligible Professionals (a)	50,000
Estimated Burden Hours Per Eligible Professional to Obtain IACS Account (b)	1
Estimated Burden Hours Per Eligible Professional to Submit Test Data File to CMS (c)	1
Estimated Burden Hours Per Eligible Professional to Submit PQRS Data File to CMS (d)	2
Estimated Burden Hours Per Eligible Professional to Prepare for PQRS Participation (e)	5
Estimated Total Annual Burden Hours Per Eligible Professional (f) = (b) +(c)+(d)+(e)	9
Estimated Total Annual Burden Hours (g) = (a)*(f)	**450,000**
Estimated Cost Per Eligible Professional to Obtain IACS Account (h)	$40
Estimated Cost Per Eligible Professional to Submit PQRS Data File to CMS (i)	$80
Estimated Cost Per Eligible Professional to Prepare for PQRS Participation (j)	$200
Estimated Total Annual Burden Cost Per Eligible Professional (k) = (h)+ (i)+(j)	$320
Estimated Total Annual Burden Cost (m) = (a)*(k)	**$16,000,000**

Burden Estimate for PQRS Reporting by Group Practices Using the GPRO Web Interface

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 registries. However, 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. Therefore, we estimate that the self-nomination process for the group practices for the PQRS

involves approximately 2 hours per group practice to review the PQRS GPRO and make the decision to participate as a group rather than individually and an additional 2 hours per group practice to draft the 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 group practice self-nomination process has an average practice labor cost of $16 per hour. Therefore, assuming the total burden hours per group practice associated with the group practice self-nomination process is 6 hours, we estimate the total cost to a group practice associated with the group practice self-nomination process to be approximately $96 ($16 per hour x 6 hours per group practice). Because approximately 200 group practices participated in the GPRO in 2011, for purposes of this burden analysis, we will assume 200 group practices will self-nominate to participate in the PQRS under the GPRO using the GPRO web interface.

The burden associated with the group practice reporting requirements under the GPRO is the time and effort associated with the group practice submitting the quality measures data. For physician group practices, this would be the time associated with the physician group completing the web interface. We estimate that the time and effort associated with using the GPRO web interface will be comparable to the time and effort associated to using the PAT. As stated above, the information collection components of the PAT have been reviewed by OMB and was approved under OMB control number 0938-0941- Form 10136, with an expiration date of December 31, 2011 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. Since these changes will not have any impact on the information collection requirements associated with the PAT and we will be using the same data submission process used in the PGP demonstration, 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 $40 per hour. Therefore, the total estimated annual cost per group practice is estimated to be approximately $3,160.

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
Estimated # of Eligible Group Practices in 2013/2014 (a)	200
Estimated # of Burden Hours Per Group Practice to Self-Nominate to Participate in PQRS Under the Group Practice Reporting Option (b)	6

Estimated # of Burden Hours Per Group Practice to Report (c)	79
Estimated Total Annual Burden Hours Per Group Practice (d) = (b)+(c)	85
Estimated Total Annual Burden Hours (e) = (a)*(d)	**17,000**
Estimated Cost Per Group Practice to Self-Nominate to Participate in PQRS Under the Group Practice Reporting Option (at a labor rate of $16/hour) (f)	$96
Estimated Cost Per Group Practice to Complete the PAT (g)	$3,160
Estimated Total Annual Cost Per Group Practice (h) = (f) + (g)	$3,256
Estimated Total Annual Burden Cost (i) = (a)*(h)	**$651,200**

Please note that, beginning in 2013, we are requiring group practices that use the GPRO web interface reporting mechanism to administer a CAHPS survey. Please note that the burden estimates of implementing this survey is provided in a separate PRA package submission.

Burden Estimate for the Maintenance of Certification Program Incentive

Under the PQRS, through 2014, eligible professionals may receive an additional 0.5 percent incentive payment if, aside from meeting all other program requirements under the PQRS, eligible professionals participate in a qualified Maintenance of Certification Program more frequently than is required to qualify for maintenance of board certification status as well as complete a qualified Maintenance of Certification Program practice assessment. The burden associated with this additional 0.5 percent incentive is the time and effort associated with participating in a qualified Maintenance of Certification Program more frequently than is required to qualify for maintenance of board certification status as well as completing a qualified Maintenance of Certification Program practice assessment. This time and effort will vary depending on what each individual board determines as "more frequently." Information from an informal poll of a few American Board of Medical Specialties (ABMS) member boards indicates that the time an individual eligible professional spends to complete the practice assessment component of the Maintenance of Certification ranges from 8 to 12 hours. Therefore, we estimate that the total cost of participating in the additional incentive to an individual eligible professional is the time and effort associated with participating in a Maintenance of Certification Program more frequently than is required to qualify for maintenance of board certification status x 8-12 hours (the time needed to complete the practice assessment component of the Maintenance of Certification). We assume that all participating in the PQRS will attempt to qualify for this additional incentive.

Total Estimated Burden of this Information Collection Requirement for 2013 and 2014

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 measures and/or electronic prescribing measure 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 qualified clinical data registry 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, 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 begin 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: Summary of Burden Estimates for Eligible Professionals and/or Group Practices using the Claims, Registry, and EHR-based Reporting Mechanisms

	Minimum Burden Estimate	**Maximum Burden Estimate**
Estimated Annual Burden Hours for Claims-based Reporting (for individual eligible professionals only)	1,201,543	3,633,006.4
Estimated Annual Burden for Registry-based or Qualified Clinical Data Registry-based Reporting	404,150	404,150
Estimated Annual Burden Hours for EHR-based Reporting	450,000	450,000
Estimated Total Annual Burden Hours for Eligible Professionals or Eligible Professionals in a Group Practice	**2,055,693**	**4,487,156.4**
Estimated Cost for Claims-based Reporting (for individual eligible professionals only)	$48,111,400	$145,360,000
Estimated Cost for Registry-based Reporting	$16,166,000	$16,166,000
Estimated Cost for EHR-based Reporting	$16,000,000	$16,000,000
Estimated Total Annual Cost for Eligible Professionals or Eligible Professionals in a Group Practice	**$80,277,400**	**$177,526,000**

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 during 2013 and 2014 (that is, Table 5).

Table 7

	Maximum Burden Estimate
Estimated # of Participating Group Practices	200
Estimated # of Burden Hours Per Group Practice to Self-Nominate to Participate in PQRS and the Electronic Prescribing Incentive Program Under the Group Practice Reporting Option	6
Estimated # of Burden Hours Per Group Practice to Report Quality Measures	79
Estimated Total Annual Burden Hours Per Group Practice	85

Estimated Total Annual Burden Hours for Group Practices	**17,000**
Estimated Cost Per Group Practice to Self-Nominate to Participate in PQRS for the Group Practice Reporting Option	$96
Estimated Cost Per Group Practice to Report Quality Measures	$3,160
Estimated Total Annual Cost Per Group Practice	$3,256
Annual Burden Cost for Group Practices	**$651,200**

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

Following the reporting periods that occur in 2014 (for the 2014 PQRS incentive and 2016 PQRS payment adjustment), incentive payments will be made to eligible professionals who satisfactorily submit data on quality measures for the 2014 PQRS incentive.

According to the 2010 Reporting Experience, a total of $391,635,495 in PQRS incentives was paid by CMS for the 2010 program year, which encompassed 168,843 individual eligible professionals. In 2010, eligible professionals earned a 2.0% incentive for satisfactory reporting under the PQRS. For 2013 and 2014, eligible professionals can earn a 0.5% incentive for satisfactory reporting, a reduction of 1.5% from 2010. According to the 2011 Reporting Experience Report, over 1 million professionals were eligible to participate in the PQRS. A total of $261,733,236 in PQRS incentives was paid by CMS for the 2011 program year, which encompassed 26,515 practices that included 266,521 eligible professionals (or approximately 27% of the professionals eligible to participate). The average incentive earned for PQRS in 2011 per each individually-participating eligible professional was $1,059.

Therefore, based on 2010 and 2011 figures, we would expect that approximately $97 million (approximately ¼ of $391,635,495) in incentive payments would be distributed to eligible professionals who satisfactorily report. However, we expect that, due to the implementation of payment adjustments beginning in 2015, participation in the PQRS will rise to approximately 400,000 eligible professionals in 2014.

The average incentive distributed to each eligible professional in 2010 was $2,157. Taking into account the 1.5% incentive reduction from 2.0% in 2010 to 0.5% in 2014, we estimate that the average amount per eligible professional earning an incentive in 2014 will be $539. Therefore, we

estimate that the PQRS will distribute approximately$216 million ($539 x 400,000 eligible professionals) in incentive payments in 2014. We believe these incentive payments will help offset the cost to eligible professionals participating in the PQRS for the applicable year. Please note that, beginning in 2015, incentive payments for satisfactory reporting in the PQRS will cease and payment adjustments for not satisfactory reporting will commence.

15. Program or Burden Changes

The changes in the estimated burden in this PRA application for CY 2014 from the original submission are due to the following:

- A change in burden costs for eligible professionals participating in the claims-based reporting mechanism due to an increase in the number of measures an eligible professional is required to report to meet the criteria for satisfactory reporting for the 2014 PQRS incentive
- A change in participation estimates for eligible professionals using the registry, qualified clinical data registry, and EHR-based reporting mechanisms due to the release of data from the 2011 PQRS and eRx Experience Report (available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html?redirect=/PQRS/).

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 and who are successful electronic prescribers for 2014 will be posted on the CMS website at www.medicare.gov in 2015 following completion of the reporting periods occurring in 2014. Performance information on group practices will also be posted on the Physician Compare website.

17. Expiration Date

CMS would like approval for this information collection for a period of 3 years from the expiration of the current PQRS approval. There are no paper forms involved in this data collection activity.

18. Certification Statement

There are no exceptions to the certification statement.