

Supporting Statement - Part A
Physician Quality Reporting System (CYs 2013 through 2016)
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), 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 PQRS 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 in 2012 as part of the PQRS can (1) qualify to receive an incentive payment and/or (2) be relieved from the application of a payment adjustment. The criteria for satisfactory reporting for the 2013 and 2014 PQRS incentives and the 2015 and 2016 PQRS payment adjustments are proposed in the CY 2013 Medicare Physician Fee Schedule (PFS) proposed rule.

A. Justification

1. Need and Legal Basis

With respect to the 2013 and 2014 PQRS incentives, 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 2015 and 2016 PQRS payment adjustments, collection of this information applies to all eligible professionals and group practices. Therefore, since the proposed reporting periods for the 2013 and 2014 PQRS incentives and 2015 and 2016 payment adjustments coincide in CY 2013 and 2014 respectively, for CY 2013 and 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 a PQRS reporting period may qualify to receive 2013 and/or 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 2015 and/or 2016 equal to 1.5 percent and 2.0 percent respectively 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 2013 and 2014 PQRS incentives and the 2015 and 2016 PQRS payment are proposed in the CY 2013 PFS proposed rule.

In addition, for the PQRS, for 2011 through 2014, eligible professionals and group practices

who satisfactorily report the 2012 PQRS 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.

With respect to the 2013 and 2014 PQRS incentives, eligible professionals wishing to report PQRS quality measures may do so via 3 reporting mechanisms: claims, registry, and EHR (which includes direct EHR products and EHR data submission vendors). For the 2015 and 2016 payment adjustments, in addition to being able to report PQRS measures using the 3 reporting mechanisms previously described, eligible professionals may also report PQRS measures using the administrative claims reporting mechanism. Note: with respect to registries, in order for registries to submit PQRS quality measures results and numerator and denominator data on individual PQRS quality measures or measures groups on behalf of eligible professionals, a registry will need to self-nominate to become a “qualified” PQRS registry unless the registry was qualified for a prior year and successfully submits PQRS quality measure results and numerator and denominator data on quality measures on behalf of their participants.

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 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 2013 and 2014 PQRS incentives, group practices using the GPRO may report PQRS quality measures via 4 reporting mechanisms: claims, registry, EHR, and the GPRO web-interface. For the 2015 and 2016 payment adjustments, in addition to being able to report PQRS measures using the 4 reporting mechanisms previously described, group practices may also report PQRS measures using the administrative claims reporting mechanism.

2. Information Users

The data on PQRS 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 2013 and 2014 PQRS incentives and the 2015 and 2016 PQRS payment adjustments.
- (2) To calculate and make incentive payments to eligible professionals and group practices in for the 2013 and 2014 PQRS incentives.
- (3) Publicly post the names of eligible professionals and group practices who satisfactorily report PQRS quality measures data on the CMS Physician Compare Web site.

Only registry vendors that are interested in participating in PQRS will self-nominate to be a “qualified” registry. The information collected from registries through the registry self-nomination process will be used by CMS to determine whether the registry meets the PQRS registry

requirements and is qualified to submit quality measures results and numerator and denominator data on PQRS individual quality measures, measures groups, and the electronic prescribing measure 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 PQRS quality measures from eligible professionals. Individual eligible professionals are not asked to provide any documentation by CD or hardcopy. For registry-based reporting, registries submit PQRS 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 PQRS quality measures to us electronically through a direct EHR product or via an EHR data submission vendor 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 a specific program year. After a registry passes an initial qualification process that consists of interviews with CMS officials, the registry will be requested to successfully submit a “test” file in XML format to our data warehouse.

For group practices participating in the PQRS GPRO, although we are proposing that group practices using the GPRO would be able to use the claims, registry, and EHR-based reporting mechanisms, we believe the collection of information will primarily be done using a currently OMB-approved data collection web interface (see OMB Control Number 0938-0941- Form 10136). This web interface is an automated, electronic tool developed 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, registries and EHR direct vendors whose products were designated as qualified registries or EHR products in a prior year and group practices that were selected to participate in a group practice reporting option in a prior year, generally will not need to undergo the self-nomination process again.

In addition, section 1848(m)(3)(C)(iii) of the Act specifies that there shall be no double payments to eligible professionals in a group practice that receives a PQRS incentive payment for satisfactorily reporting under the group practice reporting option. Furthermore, in 2007, CMS’ Office of Research, Development, and Information sought and was granted, from OMB, a waiver for practices participating in the PGP and MCMP demonstrations that would allow these practices to earn a PQRS incentive through their participation in the demonstration. Accountable Care Organizations (ACOs) participating under the MSSP also have statutory authority to earn a PQRS incentive through their participation in the MSSP. By doing so, we are rewarding those practices

that voluntarily agreed to participate in the demonstration and reduced the reporting burden they would otherwise have had if they had to submit duplicate clinical quality data using two different systems. For similar reasons, we are proposing to deem practices that participate in the certain CMS programs to be participating in the PQRS using the GPRO.

For determining whether a PQRS payment adjustment applies to an eligible professional or group practice, we will use the data submitted by the eligible professional or group practice for purposes of the PQRS incentive.

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 PQRS quality measures data and data on the electronic prescribing measure.

6. Less Frequent Collection

If data on the PQRS 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, (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 PQRS quality measures data on the CMS Web site.

If registries are not required to submit a self-nomination statement, CMS will have no mechanism to determine which registries will participate in submitting PQRS quality measures data. 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 2013 PFS proposed rule soliciting public comment for this collection, as it pertains to the CY 2013 and 2014 PQRS, was published in the Federal Register on July 30, 2012 (77 FR 44722). Comments are due by September 4, 2012.

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 for covered professional services furnished during the 2013 and 2014 PQRS respective reporting periods may qualify to earn an incentive payment equal to 1.0 percent of the total estimated allowed charges submitted not later than 2 months after the end of the reporting period for all covered professional services furnished during the 2013 and 2014 PQRS respective reporting periods. Eligible professionals who satisfactorily report PQRS quality measures data during the 2012, 2013, and 2014 PQRS reporting period 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 CY 2013 and 2014 PQRS for (1) individual eligible professionals and group practices using the claims, registry, and EHR-based reporting mechanisms, (2) group practices using the GPRO, and (3) registries. Please note that we are grouping group practices using the claims, registry, and EHR-based reporting mechanisms with

the burden estimate for individual eligible professionals using the claims, registry, and EHR-based reporting mechanisms because we believe the proposed satisfactory reporting criteria for group practices using these 3 reporting mechanisms are similar to the proposed satisfactory reporting criteria for eligible professionals using these 3 reporting mechanisms. Please also note that we are not providing a burden estimate for eligible professionals and group practices using the proposed administrative claims reporting option for the 2015 and 2016 PQRS payment adjustments because any burden for eligible professionals and group practices using this reporting mechanism would be absorbed in the burden estimate for the Value-based Payment Modifier.

Burden Estimates for the PQRS: (CY 2013→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 and 2010, 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 to (1 million x 40%) 400,000 eligible professionals in 2014 to (50% x 1 million) 500,000 in 2015. The burden estimates provided are based on a participation rate of 40%.

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 PQRS 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.

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 PQRS 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 PQRS quality

measures data is attempting to earn a PQRS incentive payment and reports on an average of 3 measures for this burden analysis.

Because we anticipate even greater participation in the CYs 2013 and 2014 PQRS, as the reporting periods for the 2015 and 2016 PQRS payment adjustments occur in CYs 2013 and 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 3 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 PQRS 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 PQRS 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 PQRS 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

In 2010, approximately 200,000 of the roughly 245,000 eligible professionals (or 84%) of eligible professionals used the claims-based reporting mechanism. We believe that although the

number of eligible professionals or group practices using the claims-based reporting mechanism will increase in CYs 2013 and 2014, we anticipate that the percentage of eligible professionals or group practices using the claims-based reporting mechanism will decrease slightly as eligible professionals and group practices transition towards using the EHR-based reporting mechanism. We estimate that approximately 320,000 eligible professionals, whether participating individually or in a group practice, will participate in PQRS in CY 2014.

For the claims-based reporting option, eligible professionals and group practices 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 2012.

We estimate the cost for an eligible professional and group practices to review the list of PQRS quality measures or measures group, 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 a measure) on claims will 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. 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.

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 are proposing to reduce 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 or eligible professional in a group practice associated with claims-based reporting will range from 4.5 minutes (0.25 minutes per measure x 3 measures x 6 cases per measure) to 180 minutes (12 minutes per measure x 3 measures x 6 cases per measure),

with the burden to the median practice being 31.5 minutes (1.75 minutes per measure x 3 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 \$3.06 (\$0.17 per measure x 3 measures x 6 cases per measure) to \$144.00 (\$8.00 per measure x 3 measures x 6 cases per measure), with the cost to the median practice being \$30.06 per eligible professional (\$1.67 per measure x 3 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 claims-based reporting for eligible professionals and group practices.

Table 1

	Minimum Burden Estimate	Median Burden Estimate	Maximum Burden Estimate
Estimated # of Participating Eligible Professionals or Eligible Professionals within a Group Practice (a)	320,000	320,000	320,000
Estimated # of Measures Per Eligible Professional Per Year (b)	3	3	3
Estimated # of Cases Per Measure Per Eligible Professional Per Year (c)	9	9	9
Total Estimated # of Cases Per Eligible Professional Per Year (d) = (b)*(c)	27	27	27
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)	0.11205	0.7875	5.39784
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)	5.11205	5.7875	10.39784
Estimated Total Annual Burden Hours (i) = (a)*(h)	1,635,856	1,852,000	3,327,308.80
Estimated Cost Per Case (j)	\$0.17	\$1.67	\$8.00
Total Estimated Cost of Cases Per Eligible Professional Per Year (k) = (d)*(j)	\$4.59	\$45.09	\$216
Estimated Cost Per Eligible	\$200	\$200	\$200

Professional to Prepare for PQRS Participation (l)			
Estimated Total Annual Cost Per Eligible Professional (m) = (k) + (l)	\$204.59	\$245.09	\$416
Estimated Total Annual Burden Cost (n) = (a)*(m)	\$334,679,779.04	\$453,906,680	\$1,384,160,460.80

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

In 2010, approximately 40,000 of the roughly 245,000 eligible professionals (or 16%) of eligible professionals used the registry-based reporting mechanism. We believe the percentage of eligible professionals and group practices using the registry based reporting mechanism will remain the same, as eligible professionals use registries for functions other than PQRS and therefore would obtain a registry solely for PQRS reporting. Therefore, we estimate that approximately 64,000 eligible professionals will participate in PQRS in CY 2014.

For 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 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 solely for purposes of participation in the PQRS. However, eligible professionals and group practices will need to authorize or instruct the 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 registry-based reporting for individual eligible professionals.

Table 2

	Burden Estimate
Estimated # of Participating Eligible Professionals (a)	64,000
Estimated Burden Hours Per Eligible Professional to Authorize Registry to Report on Eligible Professional's Behalf (b)	0.083
Estimated Burden Hours Per Eligible Professional to Report PQRS Data to 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)	517,312

Estimated Cost Per Eligible Professional to Authorize Registry to Report on Eligible Professional's Behalf (g)	\$3.32
Estimated Cost Per Eligible Professional to Report PQRS Data to 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)	\$167,257,315.84

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-nominate in order to be considered qualified to submit on behalf of eligible professionals or group practices unless the 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 to submit on behalf of eligible professionals or group practices for the PQRS will involve approximately 1 hour per registry to draft the letter of intent for self-nomination. We estimate that each self-nominated entity will also spend 2 hours for the interview with CMS officials and 2 hours calculating numerators, denominators, and measure results for each measure the registry wishes to report using a CMS-provided measure flow. However, the time it takes to produce calculated numerators, denominators, and measure results using the CMS-provided measure flows could vary depending on the registry's experience and the number and type of measures for which the registry wishes to submit on behalf of eligible professionals. Additionally, part of the self-nomination process involves the completion of an XML submission by the registry, which we estimate to take approximately 5 hours, but may vary depending on the registry's experience. We estimate that the registry staff involved in the registry self-nomination process will have an average labor cost of \$40/hour. Therefore, assuming the total burden hours per registry associated with the registry self-nomination process is 10 hours, we estimate that the total cost to a registry associated with the registry self-nomination process will be approximately \$400 (\$40 per hour x 10 hours per registry).

The burden associated with the registry-based 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 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 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 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 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 as a result of the registry's participation in the PQRS will depend on the number of measures that the registry intends to report to CMS and how similar the registry's measures are to CMS' PQRS measures.

Registries interested in submitting quality measure 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 unless the registry was “qualified” to submit on behalf of eligible professionals for the 2009 PQRS and does so successfully. 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 additional registries will self-nominate to be considered a qualified registry for the PQRS. We anticipate that as the PQRS program matures, the number of registries seeking to become a qualified registry will decrease over time. We estimate that the self-nomination process for qualifying additional registries to submit on behalf of eligible professionals for the PQRS involves approximately 1 hour per registry to draft the letter of intent for self-nomination. It is estimated that each self-nominated entity will also spend 2 hours for the interview with CMS officials and 2 hours for the development of a measure flow. However, the time it takes to complete the measure flow could vary depending on the registry’s experience. Additionally, part of the self-nomination process involves the completion of an XML submission by the registry, which is estimated to take approximately 5 hours, but may vary depending on the registry’s experience. We estimate that the registry staff involved in the registry self-nomination process has an average labor cost of \$40 per hour. Therefore, assuming the total burden hours per registry associated with the registry self-nomination process is 10 hours, we estimate the total cost to a registry associated with the registry self-nomination process to be approximately \$400 (\$40 per hour x 10 hours per registry).

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 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

	Burden Estimate
Estimated # of Registries Self-Nominating for the PQRS (a)	50
Estimated Total Annual Burden Hours Per Registry (b)	10
Estimated Total Annual Burden Hours For Registries (c) = (a)*(b)	500
Estimated Cost Per Registry (d)	\$400
Estimated Total Annual Burden Cost For Registries (e) = (a)*(d)	\$20,000

As discussed above, the burden associated with the registry-based submission requirements of this voluntary reporting initiative is the time and effort associated with the registry calculating quality measure results from the data submitted to the 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. The time needed for a 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 is expected to vary along

with the number of eligible professionals reporting data to the registry and the number of applicable measures. However, we believe that registries already perform many of these activities for their participants. The number of measures that the registry intends to report to CMS and how similar the registry's measures are to CMS' PQRS measures will determine the time burden to the registry.

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

In 2010, only 14 of the roughly 245,000 eligible professionals (or >1%) of eligible professionals used the EHR-based reporting mechanism. We believe the number of eligible professionals and group practices using the EHR-based reporting mechanism will increase as eligible professionals become more familiar with EHR products. In particular, we believe eligible professionals and group practices will transition from using the claims-based to the EHR-based reporting mechanisms. We estimate 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 in CY 2014.

For EHR-based reporting, which includes EHR reporting via a direct EHR vendor and EHR data submission vendor, 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 PQRS 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.

Table 4

	Burden Estimate
Estimated # of Participating Eligible Professionals (a)	16,000
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)	144,000
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)	\$5,120,000

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.

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 must complete a self-nomination process similar to the self-nomination process required of registries. 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 group practice reporting option 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). We have reason to believe that approximately 200 TINs meet our definition of “group practice.” For purposes of this burden analysis we will assume that all TINs that meet our definition of “group practice” will self-nominate to participate in the PQRS under the group practice reporting option.

The burden associated with the group practice reporting requirements of this voluntary reporting initiative 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 are currently 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 MSSP has not yet been implemented, 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 MSSP 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 6 provides an estimate of the range of total annual burden hours and total annual cost burden associated with the group practice reporting of PQRS quality measures.

Table 6

	Burden Estimate
Estimated # of Eligible Group Practices in 2012 (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

Total Estimated Burden of this Information Collection Requirement for 2012

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 and the Electronic Prescribing Incentive Program. Since the two programs are separate, it is difficult to accurately determine whether, for a particular year, eligible professionals who participate in one program will also participate in the other program. In addition, there are a number of reporting mechanisms available that eligible professionals can choose to use to report the PQRS measures and/or electronic prescribing measure. 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, as stated previously, we have not yet obtained the results of the 2010 PQRS) and the only reporting mechanism available for the Electronic Prescribing Incentive Program in 2009 was claims-based reporting. Therefore, Table 9 provides a range of estimates for individual eligible professionals. The lower range of the estimate assumes that eligible professionals will only participate in the Electronic Prescribing Incentive Program for the claims-based reporting option and represents the estimated burden hours and burden cost per eligible professional from Table 7. The upper range assumes that eligible professionals participate in both the Electronic Prescribing Incentive Program and the PQRS during 2012 and represents the sum of the estimated maximum burden hours and burden cost per eligible professional from Tables 1, 2, 4 and 7 above. All of our estimates assume that availability of a group practice reporting option does not impact the number of individual eligible professionals who choose to participate in the PQRS and/or the Electronic Prescribing Incentive Program. These estimates also assume that the number of respondents remain the same regardless of whether an eligible professional is participating in one or both programs. We are, however, requesting approval for the upper range of the estimates provided in Table 9.

Table 9

	Minimum Burden Estimate	Maximum Burden Estimate
Estimated Annual Burden Hours for Claims-based Reporting	1,635,856	3,327,308.80
Estimated Annual Burden for Registry-based Reporting	517,312	517,312
Estimated Annual Burden Hours for EHR-based Reporting	144,000	144,000
Estimated Total Annual Burden Hours for Individual Eligible Professionals	2,297,178	3,988,620.80
Estimated Cost for Claims-based Reporting	\$334,679,779.04	\$1,384,160,460.80
Estimated Cost for Registry-based Reporting	\$167,257,315.84	\$167,257,315.84
Estimated Cost for EHR-based Reporting	\$5,120,000	\$5,120,000
Estimated Total Annual Cost for Individual Eligible Professionals	\$507,057,094.88	\$1,556,537,776.64

For purposes of estimating the reporting burden for group practices, we will assume that all groups eligible to participate in the group practice reporting option are participating as a group for both PQRS and the Electronic Prescribing Incentive Program. Table 10 provides a summary of an estimate for group practices to participate in both the Electronic Prescribing Incentive Program and the PQRS under the group practice reporting option during 2012 (that is, sum of Tables 5 and 8).

Table 10

	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 PQRS Quality Measures and the Electronic Prescribing Measure	151.9175
Estimated Burden Hours Per Group Practice to Review Electronic Prescribing Measure	2
Estimated Total Annual Burden Hours Per Group Practice	159.9175
Estimated Total Annual Burden Hours for Group Practices	31,984
Estimated Cost Per Group Practice to Self-Nominate to Participate in PQRS and/or the Electronic Prescribing Incentive Program Under the Group Practice Reporting Option	\$96
Estimated Cost Per Group Practice to Report PQRS Quality Measures and/or Electronic Prescribing Quality Measure	\$6,261
Estimated Cost Per Group Practice to Review the Electronic Prescribing Measure	\$80
Estimated Total Annual Cost Per Group Practice	\$6,341

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 or the Electronic Prescribing Incentive Program. Instead, we believe that having the option to use their EHR to participate in the PQRS or Electronic Prescribing Incentive Program is simply an added benefit for eligible professionals who already have a qualified EHR product.

14. Cost to Federal Government

In CYs 2013 and 2014, incentive payments will be made to eligible professionals who satisfactorily submit data on PQRS quality measures for the 2013 and 2014 PQRS incentives.

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. Therefore, based on 2010, we would expect that approximately \$97 million (approximately $\frac{1}{4}$ 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 300,000 eligible professionals and 400,000 eligible professionals in 2013 and 2014 respectively.

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 2013 and 2014, we estimate that the average amount per eligible professional earning an incentive in 2013 and 2014 will be \$539. Therefore, we estimate that the PQRS will distribute approximately \$162 million ($\$539 \times 300,000$ eligible professionals) and \$216 million ($\$539 \times 400,000$ eligible professionals) in incentive payments in 2013 and 2014 respectively. 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 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 CYs 2013 and 2014 from the original submission are due to the following:

An increase in the estimate of eligible professionals participating in PQRS in CYs 2013 and 2014

16. Publication and Tabulation Dates

As required by the MIPPA, the names of eligible professionals and group practices who satisfactorily report data on PQRS quality measures and who are successful electronic prescribers for 2012 will be posted on the CMS website at www.medicare.gov in 2013 following completion of the 2012. As stated in the final rule, 2012 performance information on group practices will also be posted on the Physician Compare website in 2013.

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.