Supporting Statement – Part A:
Physician Quality Reporting System (CY 2012) and the Electronic Prescribing Incentive Program (CYs 2012 through 2014)

A. Background

The Physician Quality Reporting System (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 Physician Quality Reporting System 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 Physician Quality Reporting System 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 Physician Quality Reporting System can qualify to receive an incentive payment. The criteria for satisfactory reporting for the 2012 Physician Quality Reporting System are proposed in the CY 2012 Medicare Physician Fee Schedule (PFS) proposed rule. In addition, the reporting period for the satisfactory submission of measures data for the 2015 payment adjustment is proposed in the 2012 PFS proposed rule.

In addition, the MIPPA authorized the implementation beginning in 2009, of the Electronic Prescribing (eRx) Incentive Program, a new program that offers incentives and payment adjustments to encourage the use of electronic prescribing. The eRx Incentive Program provides incentive payments for eligible professionals and group practices that are successful electronic prescribers from 2009 through 2012, whereas the program provides payment adjustments for eligible professionals and group practices who are not successful electronic prescribers from 2012 through 2014. In order to be considered a successful electronic prescriber for program year's 2012 through 2014 for purposes of either the incentive or payment adjustment, an eligible professional or group practice must successfully report the electronic prescribing measure in accordance with the criteria for determining a successful electronic prescriber for the respective incentive or payment adjustment outlined in the CY 2012 PFS final rule. The criteria that we will use to determine whether an eligible professional or a group practice is a successful electronic prescriber for purposes of the payment adjustment are in the CY 2012 PFS final rule with comment period.

B. Justification

1. Need and Legal Basis

Collection of this information is voluntary and only applies to eligible professionals or group practices who wish to participate in the Physician Quality Reporting System and/or the Electronic Prescribing Incentive Program.

Physician Quality Reporting System:

For the 2012 Physician Quality Reporting System, eligible professionals or group practices who satisfactorily report data on quality measures for covered professional services furnished during a Physician Quality Reporting System reporting period may qualify to receive an incentive payment equal to 1.0 percent of the total estimated allowed charges submitted by no later than 2 months after the end of the reporting period. The criteria for satisfactory reporting of data on individual quality measures and measures groups for the 2012 Physician Quality Reporting System are in the CY 2012 PFS final rule. For group practices who participate in the Physician Quality Reporting System under the group practice reporting option (GPRO), there are two reporting options (dependent on the size of the group practice) that the group practice can use to report Physician Quality Reporting System quality measures.

In addition, for the Physician Quality Reporting System, for 2011 through 2014, eligible professionals and group practices who satisfactorily report the 2012 Physician Quality Reporting System 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.

Eligible professionals wishing to report Physician Quality Reporting System quality measures may do so via 3 proposed reporting mechanisms: claims, registry, and EHR (which includes direct EHR products and EHR data submission vendors). In order for registries to submit Physician Quality Reporting System quality measures results and numerator and denominator data on individual Physician Quality Reporting System quality measures or measures groups on behalf of eligible professionals, a registry will need to self-nominate to become a "qualified" Physician Quality Reporting System registry unless the registry was qualified for a prior year and successfully submits Physician Quality Reporting System quality measure results and numerator and denominator data on quality measures on behalf of their participants.

In order for an eligible professional to submit clinical quality data from a direct EHR product or an EHR data submission vendor for the purpose of qualifying to earn a Physician Quality Reporting System incentive payment, the eligible professional must select a qualified EHR product. Furthermore, if selecting an EHR data submission vendor, the EHR data submission vendor must meet all qualifications requirements.

While individual eligible professionals do not need to sign up or pre-register to begin participating in the Physician Quality Reporting System, group practices interested in participating in a Physician Quality Reporting System GPRO must meet certain requirements to participate in Physician Quality Reporting System as a group and submit a self-nomination to CMS.

eRx Incentive Program:

The electronic prescribing incentive payment is separate from the Physician Quality Reporting System incentive payment. For the Electronic Prescribing Incentive Program, eligible professionals or group practices who successfully report the electronic prescribing measure

established under the Physician Quality Reporting System in accordance with section 1848(m)(3)(B)(ii) of the Act are considered to be successful electronic prescribers. Successful electronic prescribers are eligible to receive an incentive payment equal to 1.0 percent (for 2012) or 0.5 percent (for 2013) of the total estimated allowed charges submitted by no later than 2 months after the end of the respective incentive reporting period. Data on the electronic prescribing measure is reportable through claims, a qualified registry, or a qualified EHR product, which includes a qualified direct EHR product or a qualified EHR data submission vendor. In addition, eligible professionals and group practices who are not successful electronic prescribers will be subject to a payment adjustment equal to 1.5 percent (for 2013) or 2.0 percent (for 2014) of the total estimated allowed charges submitted by no later than 2 months after the end of the respective payment adjustment reporting period.

This clearance request is for the information collected from eligible professionals and group practices who wish to participate in the Physician Quality Reporting System for 2012 and/or the Electronic Prescribing Incentive Program for 2012 through 2014, registries who wish to become a "qualified" registry for the Physician Quality Reporting System and Electronic Prescribing Incentive Program, and EHR vendors, including direct EHR products and EHR data submission vendors, who wish to have their EHR product(s) designated as a "qualified" EHR product or wish to be designated as a "qualified" EHR data submission vendor.

2. <u>Information Users</u>

The data on Physician Quality Reporting System quality measures and/or the electronic prescribing measure 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 Physician Quality Reporting System for 2012 and/or the criteria for successful electronic prescribers for the Electronic Prescribing Incentive Program for 2012 through 2014.
(2) To calculate and make incentive payments to eligible professionals and group practices in for the Physician Quality Reporting System in 2013 (for the 2012 program year) and Electronic Prescribing Incentive Program in CYs 2012 and 2013 (for the 2012 and 2013 eRx incentive), respectively.
(3) Publicly post the names of eligible professionals and group practices who satisfactorily report Physician Quality Reporting System quality measures data and/or who are successful electronic prescribers on the CMS Physician Compare Web site. We plan to post 2012 performance information on group practices participating in the GPRO in 2013.
(4) Make payment adjustments for 2013 and 2014 for eligible professionals or group practices who are not successful electronic prescribers during the 2013 and 2014 respective 6-month, electronic prescribing payment adjustment reporting period (that is January 1, 2012-June 30, 2012 for the 2013 payment adjustment and January 1, 2013-June 30, 2013 for the 2014 payment adjustment).

The information collected from registries through the registry self-nomination process will be used by CMS to determine whether the registry meets the Physician Quality Reporting System

registry requirements and is qualified to submit quality measures results and numerator and denominator data on Physician Quality Reporting System individual quality measures, measures groups, and the electronic prescribing measure on behalf of eligible professionals.

The information collected from EHR direct and data submission vendors through the EHR self-nomination process will be used by CMS to determine whether the vendor's EHR product(s) meet the Physician Quality Reporting System EHR requirements and can be designated as qualified for the purpose of an eligible professional using clinical data extracted from the EHR to submit data on a subset of the Physician Quality Reporting System measures and the electronic prescribing measure.

Participation in the Physician Quality Reporting System and/or the Electronic Prescribing Incentive Program is voluntary in nature. Only eligible professionals or group practices that voluntarily respond and elect to participate in these incentive programs will submit the quality measures and/or electronic prescribing measure data. Similarly, only registries and EHR vendors that are interested in participating in the Physician Quality Reporting System and group practices interested in participating in the group practice reporting option will self-nominate.

3. Improved Information Technology

For claims-based reporting, the normal Medicare Part B claims submission process is used to collect data on Physician Quality Reporting System quality measures and/or the electronic prescribing measure from eligible professionals. Individual eligible professionals are not asked to provide any documentation by CD or hardcopy. For registry-based reporting, registries submit Physician Quality Reporting System quality measures results and numerator and denominator data on Physician Quality Reporting System measures or measures groups and the electronic prescribing measure results and numerator and denominator on the electronic prescribing measure to us electronically. For EHR-based reporting, eligible professionals submit data on Physician Quality Reporting System quality measures and the electronic prescribing measure to us electronically through an EHR or via an EHR data submission vendor.

There is no application for registries that wish to self-nominate to become a qualified Physician Quality Reporting System registry. Registries are asked to submit a self-nomination letter requesting inclusion in the Physician Quality Reporting System 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.

Similarly, there is no application for EHR direct and data submission vendors that wish to self-nominate one or more of their EHR products to become a qualified EHR product or that wish to become a qualified EHR data submission vendor. EHR vendors are asked to submit a self-nomination letter. After an EHR vendor passes an initial qualification process that consists of interviews with CMS officials, the vendor will be requested to successfully submit a "test" file to our data warehouse.

For group practices participating in the Physician Quality Reporting System group practice reporting option (GPRO), the collection of information will 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 Physician Quality Reporting System 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 Physician Quality Reporting System incentive through their participation in the demonstration. Accountable Care Organizations (ACOs) participating under the MSSP also have statutory authority to earn a Physician Quality Reporting System 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 also indicated in the CY 2012 PFS final rule with comment period that we are deeming practices that participate in the certain CMS programs to be participating in the 2012 Physician Quality Reporting System under the group practice reporting option.

Finally, for determining whether an electronic prescribing payment adjustment applies to an eligible professional or group practice, we will use the data submitted by the eligible professional for purposes of the electronic prescribing 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 Physician Quality Reporting System quality measures data and data on the electronic prescribing measure.

6. Less Frequent Collection

If data on the Physician Quality Reporting System quality measures and/or the electronic

prescribing measure is 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 the Physician Quality Reporting System and/or the criteria for successful electronic prescribers for the Electronic Prescribing Incentive Program, (2) to calculate and make incentive payments to eligible professionals or group practices for the Physician Quality Reporting System and Electronic Prescribing Incentive Program, (3) publicly post the names of eligible professionals and group practices who satisfactorily report Physician Quality Reporting System quality measures data and/or who are successful electronic prescribers on the CMS Web site, and (4) to calculate and make electronic prescribing payment adjustments.

If registries and EHR direct and data submission vendors are not required to submit a self-nomination letter, CMS will have no mechanism to determine which registries and EHR vendors participate. Similarly, if group practices are not required to submit a self-nomination letter, CMS will have no mechanism to determine which group practices wish to participate as such in the Physician Quality Reporting System or Electronic Prescribing Incentive Program.

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 2012 PFS proposed rule soliciting public comment for this collection, as it pertains to the 2012 Physician Quality Reporting System and the 2012 through 2014 Electronic Prescribing Incentive Program, was published in the Federal Register on July 19, 2011. The comment period ended on August 30, 2011. The CY 2012 PFS final rule was displayed in the Federal Register on November 1, 2011 and will be published on November 28, 2011.

9. Payment/Gift To Respondent

As authorized under section 1848(m)(1)(A) of the Act, eligible professionals or group practices (in the case of group practices participating in the Physician Quality Reporting System under the group practice reporting option) who satisfactorily report data on quality measures for covered professional services furnished during the 2012 Physician Quality Reporting System reporting period 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 2012 Physician Quality Reporting System reporting period. Eligible professionals who satisfactorily report Physician Quality Reporting System quality measures data during the 2012, 2013, and 2014 Physician Quality Reporting System 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.

As authorized under section 1848(m)(2)(A) of the Act, eligible professionals or group practices (in the case of group practices participating in the Electronic Prescribing Incentive Program under the group practice reporting option) who are successful electronic prescribers for the 2012 incentive 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 electronic prescribing reporting period. Eligible professionals who are successful electronic prescribers for 2013 incentive may qualify to earn an incentive payment equal to 0.5 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 electronic prescribing reporting period. Furthermore, eligible professionals who are not successful electronic prescribers for 2013 payment adjustment may be subject to a payment adjustment equal to 1.5 percent of the total estimated allowed charges submitted not later than 1 months after the end of the 6-month 2013 payment adjustment reporting period for all covered professional services furnished during the 2013 payment adjustment reporting period.

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 each incentive program and separately for 2012 for the Physician Quality Reporting System and for 2012 through 2014 for the eRx Incentive Program. In addition, within each program, the annual burden estimate is calculated separately for individual eligible professionals, group practices participating under the group practice reporting option, registries, and EHR direct and data submission vendors.

Burden Estimates for the 2012 Physician Quality Reporting System: (CY 2012)

Burden Estimate for Physician Quality Reporting System Reporting by Individual Eligible Professionals: Reporting in General

With respect to the Physician Quality Reporting System, the burden associated with the requirements of this voluntary reporting initiative is the time and effort associated with individual eligible professionals identifying applicable Physician Quality Reporting System 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 Physician Quality Reporting System 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 Physician Quality Reporting System 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 Physician Quality Reporting System incentive, we will assume that each eligible professional who attempts to submit Physician Quality Reporting System quality measures data is attempting to earn a Physician Quality Reporting System incentive payment and reports on an average of 3 measures for this burden analysis.

Because we anticipate even greater participation in the 2012 Physician Quality Reporting System than in previous years, including participation by eligible professionals who are participating in Physician Quality Reporting System for the first time in 2012, we will assign 5 hours as the amount of time needed for eligible professionals to review the 2012 Physician Quality Reporting System 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 Physician Quality Reporting System and to develop a mechanism for incorporating reporting of the selected measures or measures group into the office work flows.

In the proposed rule (76 FR 42922), based on information from the Physician Voluntary Reporting Program (PVRP), which was a predecessor to the Physician Quality Reporting System, we provided an estimated labor cost of $60/hour. However, in an effort to provide a more accurate labor cost estimate of participation for the 2012 Physician Quality Reporting System, we conducted an informal poll among a small sample of participants in the 2011 Physician Quality Reporting System to determine what employees within an eligible professional's practice are involved with Physician Quality Reporting System activities. The poll revealed that a billing clerk typically handles administrative details with respect to participating under the Physician Quality Reporting System (such as submitting self-nomination statements), whereas a computer analyst typically handles the reporting of Physician Quality Reporting System quality measures. Based on this information, we are changing our estimated labor costs associated with participating in the Physician Quality Reporting System. For purposes of this burden estimate, we will assume that a billing clerk will handle the administrative duties associated with participating in the 2012 Physician Quality Reporting System. 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 2012 Physician Quality Reporting System 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 2012 Physician Quality Reporting System quality measures, we estimate an average labor cost of $40.00/hour.

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

We believe the burden associated with actually reporting the Physician Quality Reporting System quality measures will vary depending on the reporting mechanism selected by the eligible professional.

Burden Estimate for Physician Quality Reporting System Reporting by Individual Eligible Professionals: 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 Physician Quality Reporting System 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 to review the list of Physician Quality Reporting System 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 2012 Physician Quality Reporting System 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 ranges 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 Physician Quality Reporting System measures was 9. Since we are reducing the required reporting rate by over one-third to 50 percent in this final rule, then for purposes of this burden analysis we will assume that an eligible professional will need to report each selected measure for 6 reporting instances. The actual number of cases on which an eligible professional is required to report quality measures data will vary, however, with the eligible professional's patient population and the types of measures on which the eligible professional 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 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 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 individual eligible professionals.

Table 1

	Minimum Burden Estimate	Median Burden Estimate	Maximum Burden Estimate
Estimated # of Participating Eligible Professionals (a)	158,579	158,579	158,579
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 Physician Quality Reporting System 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)	**810,663.78**	**917,775.96**	**1,648,879.07**
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 Professional to Prepare for Physician Quality Reporting System Participation (l)	$200	$200	$200
Estimated Total Annual Cost Per Eligible Professional (m) = (k) + (l)	$204.59	$245.09	$416
Estimated Total Annual Burden Cost (n) = (a)*(m)	**$32,443,677.61**	**$38,866,127.11**	**$65,968,864**

Burden Estimate for Physician Quality Reporting System Reporting by Individual Eligible Professionals: Registry-Based Reporting Mechanism

For registry-based reporting, there will be no additional time burden for eligible professionals to report data to a registry as eligible professionals 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 Physician Quality Reporting System. Little, if any, additional data will need to be reported to the registry solely for purposes of participation in the 2012 Physician Quality Reporting System. However, eligible professionals 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.

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 in 2012 (a)	35,000
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 Physician Quality Reporting System Data to Registry (c)	3
Estimated Burden Hours Per Eligible Professional to Prepare for 2012 Physician Quality Reporting System 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)	**282,905**
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 Physician Quality Reporting System Data to Registry (h)	$120
Estimated Cost Per Eligible Professional to Prepare for Physician Quality Reporting System Participation (i)	$200
Estimated Total Annual Cost Per Eligible Professional (j) = (g)+(h)+(i)	$323.32
Estimated Total Annual Burden Cost (k) = (a)*(j)	**$11,316,200**

Registries interested in submitting quality measures results and numerator and denominator data on quality measures to CMS on their participants' behalf in 2012 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 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 for the 2012 Physician Quality Reporting System 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 Physician Quality Reporting System 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 Physician Quality Reporting System 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' Physician Quality Reporting System 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 Physician Quality Reporting System and does so successfully. Based on the number of registries that have self-nominated to become a qualified Physician Quality Reporting System registry in prior program years, we estimate that approximately 50 additional registries will self-nominate to be considered a qualified registry for the 2012 Physician Quality Reporting System. We anticipate that as the Physician Quality Reporting System 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 2012 Physician Quality Reporting System 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 Physician Quality Reporting System individual quality measures or measures groups on behalf of individual eligible professionals.

Table 3

	Burden Estimate
Estimated # of Registries Self-Nominating for the 2010 Physician Quality Reporting System (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' Physician Quality Reporting System measures will determine the time burden to the registry.

Burden Estimate for Physician Quality Reporting System Reporting by Individual Eligible Professionals: EHR-Based Reporting Mechanism

For EHR-based reporting, which includes EHR reporting via a direct EHR vendor and EHR data submission vendor, the eligible professional must review the quality measures on which we will be accepting Physician Quality Reporting System 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. The EHR-based reporting mechanism was not available for eligible professionals in 2009. Indeed, the EHR-based reporting mechanism was introduced in the 2010 Physician Quality Reporting System. Because the participation results for 2010 are not yet available and participation via this reporting mechanism is voluntary, we believe it is difficult to estimate with any degree of accuracy how many, if any, eligible professionals will opt to participate in the Physician Quality Reporting System through the EHR mechanism in CY 2012.

For EHR-based reporting for the CY 2012 Physician Quality Reporting System, the individual eligible professional 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 professionals' behalf. To submit data to CMS directly from their EHR, the eligible professional 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 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 the requirement for an eligible professional to submit a test file, we believe that doing so will take less than 1 hour. With respect to submitting the actual 2012 data file in 2013, we believe that this will take an eligible professional no more than 2 hours, depending on the number of patients on which the eligible professional 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 associated with submission of data on Physician Quality Reporting System quality measures should be minimal as all of the information required to report the measure should already reside in the eligible professional'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.

Table 4

	Burden Estimate
Estimated # of Participating Eligible Professionals in 2012 (a)	35,000
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 Physician Quality Reporting System Data File to CMS (d)	2

Estimated Burden Hours Per Eligible Professional to Prepare for 2012 Physician Quality Reporting System 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)	**315,000**
Estimated Cost Per Eligible Professional to Obtain IACS Account (h)	$40
Estimated Cost Per Eligible Professional to Submit Test Data File to CMS (i)	$40
Estimated Cost Per Eligible Professional to Submit Physician Quality Reporting System Data File to CMS (j)	$80
Estimated Cost Per Eligible Professional to Prepare for 2012 Physician Quality Reporting System Participation (k)	$200
Estimated Total Annual Burden Cost Per Eligible Professional (l) = (h)+ (i)+(j)+(k)	$360
Estimated Total Annual Burden Cost (m) = (a)*(l)	**$12,600,600**

An EHR vendor interested in having their product(s) used by eligible professionals to submit Physician Quality Reporting System quality measures data to CMS were required to complete a self-nomination process in order for the vendor's product(s) to be considered "qualified" for 2012. It is difficult for us to accurately quantify the burden associated with the EHR self-nomination process as there is variation regarding the technical capabilities and experience among vendors. For purposes of this burden analysis, however, we estimate that the time required for an EHR vendor to complete the self-nomination process will be similar to the time required for registries to self-nominate, that is, approximately 10 hours at $40 per hour for a total of $400 per EHR vendor ($40 per hour x 10 hours per EHR vendor).

The burden associated with the EHR-based reporting requirements of this voluntary reporting initiative is the time and effort associated with the EHR vendor programming its EHR product(s) to extract the clinical data that the eligible professional needs to submit to CMS for purposes of reporting 2012 Physician Quality Reporting System quality measures. The time needed for an EHR vendor to review the quality measures and other information and program each qualified EHR product to enable eligible professionals to submit Physician Quality Reporting System quality measures data to the CMS-designated clinical data warehouse will be dependent on the EHR vendor's familiarity with Physician Quality Reporting System, the vendor's system capabilities, as well as the vendor's programming capabilities. Some vendors already have these necessary capabilities and for such vendors, we estimate the total burden hours to be 40 hours at a rate of $40 per hour for a total burden estimate of $1,600 ($40 per hour x 40 hours per vendor). However, given the variability in the capabilities of the vendors, we believe a more conservative estimate for those vendors with minimal experience would be approximately 200 hours at $60 per hour, for a total estimate of $8,000 per vendor ($40 per hour x 200 hours per EHR vendor).

Based on the assumptions discussed above and in Part B of this supporting statement, Table 5 provides an estimate of total annual burden hours and total annual cost burden associated with an

EHR vendor self-nominating in order to have one or more of their EHR products considered "qualified" for the purpose of eligible professionals being able to qualify to earn a Physician Quality Reporting System incentive by submitting clinical quality data from the EHR product.

Table 5

	Burden Estimate
Estimated # of EHR Vendors Self-Nominating for the 2010 Physician Quality Reporting System (a)	15
Estimated Total Annual Burden Hours Per Vendor (b)	200
Estimated Total Annual Burden Hours for EHR Vendors (c) = (a)*(b)	**3,000**
Estimated Cost Per Vendor (d)	$8,000
Estimated Total Annual Burden Cost for EHR Vendors (e) = (a)*(d)	**$120,000**

Burden Estimate for the Maintenance of Certification Program Incentive

Under the 2012 Physician Quality Reporting System, through 2014, eligible professionals may receive an additional 0.5 percent incentive payment if, aside from meeting all other program requirements under the Physician Quality Reporting System, eligible professionals participate in a qualified Maintenance of Certification Program for 2011 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 for 2011. 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 2012 Physician Quality Reporting System will attempt to qualify for this additional incentive.

Burden Estimate for Physician Quality Reporting System Reporting by Group Practices

With respect to the process for group practices to be treated as satisfactorily submitting quality measures data under the 2012 Physician Quality Reporting System, group practices interested in participating in the 2012 Physician Quality Reporting System through the group practice reporting option must complete a self-nomination process similar to the self-nomination process required of registries and EHR vendors. Therefore, we estimate that the self-nomination

process for the group practices for the 2012 Physician Quality Reporting System involves approximately 2 hours per group practice to review the 2012 Physician Quality Reporting System 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 Physician Quality Reporting System 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. Although the web interface is new for 2012, 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 Physician Quality Reporting System 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 Physician Quality Reporting System 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 Physician Quality Reporting System 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 Physician Quality Reporting System 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**

Burden Estimate for Electronic Prescribing Reporting by Individual Eligible Professionals

For the 2012 through 2014 Electronic Prescribing (eRx) Incentive Program, each eligible professional will need to report the electronic prescribing measure (which is the same measure used in the 2011 eRx Incentive Program), which indicates that at least 1 prescription created during an eligible encounter was generated and transmitted electronically using a qualified electronic prescribing system. For individual eligible professionals, the burden associated with the requirements of this initiative is the time and effort associated with eligible professionals reviewing the electronic prescribing measure specifications and program requirements to determine whether it applies to them, collecting the necessary information, and reporting the information needed to report the measure. We believe it is difficult to accurately quantify the burden because eligible professionals may have different processes for integrating reporting of the electronic prescribing measure into their practice's work flows.

Since the eRx Incentive Program consists of only 1 quality measure, we will assign 1 hour as the amount of time needed for eligible professionals to review the electronic prescribing measure and incorporate reporting of the measure into their office work flows and an additional hour as the amount of time needed for eligible professionals to select an appropriate reporting mechanism for the measure. At an average cost of approximately $40 per hour, we estimate the total cost to eligible professionals for reviewing the electronic prescribing measure, incorporating the reporting of the measure into the office work flows, and selecting an appropriate reporting mechanism to be approximately $80 ($40 per hour X 2 hours).

The time and cost associated with reporting the electronic prescribing measure to CMS would depend on the reporting mechanism selected by the eligible professional.

Burden Estimate for Electronic Prescribing Reporting by Individual Eligible Professionals Who use the Claims-based Reporting Mechanism

For claims-based reporting, the quality data codes will be collected as additional (optional) line items on the existing HIPAA transaction 837-P and/or CMS Form 1500. We do not anticipate any new forms or modifications to the existing transaction or form. We also do not anticipate changes to the 837-P or CMS Form 1500 for CYs 2012 through 2014. Based on our experience with the PVRP described above, we estimate that the time needed to perform all the steps necessary to report the electronic prescribing measure via claims to be 1.75 minutes per reporting instance. We also estimate the cost to perform all the steps necessary to report the electronic prescribing measure to be $1.17 per reporting instance based on an average practice labor cost of $40 per hour.

To qualify for an electronic prescribing incentive, the eligible professional needs to report the electronic prescribing measure at least 25 times during the reporting period. Based on the required number of reporting instances, or cases, we estimate the total annual burden per eligible professional who chooses to participate in the eRx Incentive Program through claims-based reporting of the electronic prescribing measure to be 163.75 minutes, or 2.73 hours [(1.75 minutes per reporting instance per measure x 1 measure x 25 cases per measure) + 2 hour]. The total estimated cost per eligible professional to report the electronic prescribing measure is $109.25 [($1.17 per reporting instance per measure x 1 measure x 25 cases per measure) + $80].

Table 7 provides a summary of the total annual burden hours and total annual burden costs per individual eligible professional associated with claims-based reporting of the electronic prescribing measure based on the above assumptions as well as the assumptions stated in Part B of this Supporting Statement.

Table 7

	Burden Estimate
Estimated # of Participating Eligible Professionals in 2012 through 2014 (a)	30,800
# of Measures Per Eligible Professional Per Year (b)	1
Estimated # of Cases For Measures Per Eligible Professional Per Year (c)	25
Total Estimated # of Cases Per Eligible Professional Per Year (d) = (b)*(c)	25
Estimated Burden Hours Per Case(e)	0.029167
Estimated Total Burden Hours Per Measure Per Eligible Professional Per Year (f) = (d)*(e)	0.729175
Estimated Burden Hours Per Eligible Professional to Review 2012 through 2014 electronic prescribing quality measure (g)	2
Estimated Total Annual Burden Hours Per Eligible Professional (h) = (f)+ (g)	2.729175
Estimated Total Annual Burden Hours (i) = (a)*(h)	**84,058**
Estimated Cost Per Case (j)	$1.17
Total Estimated Cost of Cases Per Eligible Professional Per Year (k) = (d)*(j)	$29.25
Estimated Cost Per Eligible Professional to Review 2012 through 2014 Electronic Prescribing quality measures (l)	$80

Estimated Total Annual Cost Per Eligible Professional (m) = (k) + (l)	$109.25
Annual Burden Cost (n) = (a)*(m)	**$3,364,900**

Burden Estimate for Electronic Prescribing Reporting by Individual Eligible Professionals Who Use the Registry-based Reporting Mechanism

Because registry-based reporting of the electronic prescribing to CMS was new for 2010, and we have yet to analyze eRx Incentive Program results from 2010, it is difficult to accurately estimate how many eligible professionals will opt to participate in the eRx Incentive Program through the registry-based reporting mechanism in CYs 2012 through 2014. We do not anticipate, however, any additional burden for eligible professionals to report data to a registry as eligible professionals opting for registry-based reporting would more than likely already be reporting data to the registry for other purposes (particularly eligible professionals who are already participating in Physician Quality Reporting System via the registry-based reporting mechanism). Little, if any, additional data would need to be reported to the registry for purposes of participation in the 2012 through 2014 eRx Incentive Program. However, in addition to the 2 hours estimated for the time needed by eligible professionals to review the applicability of the electronic prescribing measure, incorporate reporting of the measure in their practice work flows, and review the available reporting mechanisms to select the registry reporting option, incorporate reporting of the measure in their practice work flows, and review the available reporting mechanisms to select the registry reporting mechanism, eligible professionals will need to instruct or authorize the registry to submit quality measures results and numerator and denominator data on the electronic prescribing measure to CMS on their behalf. We estimate that the time and effort associated with this would be approximately 5 minutes for each eligible professional that wishes to authorize or instruct the registry to submit quality measures results and numerator and denominator data on the electronic prescribing measure to CMS on their behalf.

Based on our policy to consider only registries qualified to submit quality measures results and numerator and denominator data on quality measures to CMS on their participants' behalf for the 2012 through 2014Physician Quality Reporting System to be qualified to submit results and numerator and denominator data on the electronic prescribing measure for the 2012 through 2014 eRx Incentive Program respectively, there will be no need for a registry to undergo a separate self-nomination process for the Electronic Prescribing Incentive Program other than to indicate to us its desire to become a qualified registry for the eRx Incentive Program at the time that it does so for Physician Quality Reporting System. Therefore, we estimate that any additional burden associated with the registry self-nomination process would be minimal.

The burden for registries associated with the registry-based reporting requirements is the time and effort associated with the registry calculating results for the electronic prescribing measure from the data submitted to the registry by its participants and submitting the electronic prescribing measure results and numerator and denominator data on their participants' behalf. This burden is expected to vary along with the number of eligible professionals reporting data to the registry. However, we believe that registries already perform many of these activities for their participants. Since the eRx Incentive Program consists of only one measure, we believe that the burden

associated with the registry reporting the measure's results and numerator and denominator to CMS on behalf of their participants would be minimal.

Burden Estimate for Electronic Prescribing Reporting by Individual Eligible Professionals Who Use the EHR-based Reporting Mechanism

For EHR-based reporting, which includes EHR direct and data submission vendors, the eligible professional must review the electronic prescribing measure, extract the necessary clinical data from his or her EHR, and submit the necessary data to the CMS-designated clinical data warehouse. Because this manner of reporting quality data to CMS was also new for 2010, and 2010 program results have not yet been calculated, it is difficult to accurately estimate how many eligible professionals will opt to participate in the eRx Incentive Program through the EHR-based reporting mechanism in CY 2012. The time needed for an eligible professional to review the electronic prescribing measure and other information and determine whether the measure is applicable to his or her patients and the services her or she furnishes to them and to review the available reporting mechanisms to select the EHR reporting mechanism is expected to be similar for EHR-based reporting and claims-based reporting. Once the EHR is programmed by the vendor to allow data submission to CMS, the burden to the eligible professional associated with submission of data on the electronic prescribing measure should be minimal.

Based on our policy to consider only EHR products qualified for the 2012 through 2014 Physician Quality Reporting System to be qualified for the 2012 through 2014 eRx Incentive Program respectively, there will be no need for EHR vendors to undergo a separate self-nomination process for the Electronic Prescribing Incentive Program and therefore, no additional burden associated with the self-nomination process.

The burden associated with the EHR-based reporting requirements of this voluntary reporting initiative is the time and effort associated with the EHR vendor programming its EHR product(s) to extract the clinical data that the eligible professional needs to submit to CMS for purposes of reporting the 2012 through 2014 electronic prescribing measure. The time needed for an EHR vendor to review the measure and other information and program each qualified EHR product to enable eligible professionals to submit data on the measure to the CMS-designated clinical data warehouse will be dependent on the EHR vendor's familiarity with the electronic prescribing measure, the vendor's system capabilities, as well as the vendor's programming capabilities. Since only EHR products qualified for the 2012 through 2014 Physician Quality Reporting System will be qualified for the 2012 through 2014 eRx Incentive Program and the eRx Incentive Program consists of only one measure, we believe that any burden associated with the EHR vendor to program its product(s) to enable eligible professionals to submit data on the electronic prescribing measure to the CMS-designated clinical data warehouse would be minimal.

Burden Estimate for Electronic Prescribing Reporting by Group Practices

With respect to the process for group practices to be treated as successful electronic prescribers, depending on the group's size, a group practice will be required to report the electronic prescribing measure in at least 625 or 2,500 instances. Group practices have the same options as

individual eligible professionals in terms of the form and manner for reporting the electronic prescribing measure (that is, group practices have the option of reporting the measure through claims, a qualified registry, or a qualified EHR product (which includes EHR direct and data submission vendors)). The only difference between an individual eligible professional and group practice reporting of the electronic prescribing measure is the number of times that a group practice is required to report the electronic prescribing measure. Reporting of the electronic prescribing measure can continue to occur at the individual eligible professional level under the electronic prescribing group practice reporting option. In our analysis of the reported information, however, we will aggregate all of the information reported by the eligible professionals within the group practice to determine whether the group practice reported the measure a sufficient number of times.

Burden Estimate for Electronic Prescribing Reporting by Group Practices Who Use the Claims-based Reporting Mechanism

For group practices who are selected to participate in the 2012 through 2014 Electronic Prescribing Incentive Program group practice reporting option and choose to do so through claims-based reporting of the electronic prescribing measure, we estimate the total annual burden to be 74.92 hours per group practice [(1.75 minutes per measure x 1 measure x 2,500 cases per measure) + 2 hours]. The total estimated cost per group practice to report the electronic prescribing measure through claims-based reporting is estimated to be $3,005 [($1.17 per measure x 1 measure x 2,500 cases per measure) + $80].

Table 8 provides an estimate of the total annual burden hours and total annual burden costs per group practice associated with claims-based reporting of the electronic prescribing measure based on our above estimates as well as our estimates in Part B of this Supporting Statement.

Table 8

	Burden Estimate
Estimated # of Participating Group Practices (a)	56
# of Measures Per Group Practice Per Year (b)	1
Estimated # of Cases For Measures Per Group Practice Per Year (c)	2,500
Total Estimated # of Cases Per Group Practice Per Year (d) = (b)*(c)	2,500
Estimated Burden Hours Per Case (e)	0.029167
Estimated Total Burden Hours Per Measure Per Group Practice Per Year (f) = (d)*(e)	72.9175
Estimated Burden Hours Per Group Practice to Review Electronic Prescribing quality measure (g)	2
Estimated Total Annual Burden Hours Per Group Practice (h) = (f)+(g)	74.9175
Estimated Total Annual Burden Hours (i) = (a)*(h)	**14,984**
Estimated Cost Per Case (j)	$1.17

Total Estimated Cost of Cases Per Group Practice Per Year (k) = (d)*(j)	$2,925
Estimated Cost Per Group Practice to Review electronic prescribing quality measures (l)	$80
Estimated Total Annual Cost Per Group Practice (m) = (k) + (l)	$3,005
Annual Burden Cost (n) = (a)*(m)	**$168,280**

Burden Estimate for Electronic Prescribing Reporting by Group Practices Who Use the Registry-based Reporting Mechanism

For group practices that are selected to participate in the 2012 through 2014 eRx Incentive Program group practice reporting option and choose to do so through registry-based reporting of the electronic prescribing measure, we do not anticipate any additional burden to report data to a registry as group practices opting for registry-based reporting would more than likely already be reporting to the registry for other purposes, such as for the Physician Quality Reporting System. Little, if any, additional data would need to be reported to the registry for purposes of participation in the 2012 through 2014 eRx Incentive Program. However, in addition to the 2 hours estimated for the time needed by group practices to review the electronic prescribing measure to determine its applicability to the practice, incorporate reporting of the electronic prescribing measure into the practice's work flows, and review available reporting mechanisms to select group practice reporting of the measure through a qualified registry, the group practices will need to authorize or instruct the registry to submit the measure results and numerator and denominator data on the electronic prescribing measure to CMS on their behalf. We estimate that the time and effort associated with this would be approximately 5 minutes for each group practice that wishes to authorize or instruct the registry to submit quality measures results and numerator and denominator data on the electronic prescribing measure to CMS on their behalf.

Burden Estimate for Electronic Prescribing Reporting by Group Practices who Use the EHR-based Reporting Mechanism

For group practices who are selected to participate in the 2012 through 2014 eRx Incentive Program group practice reporting option and choose to do so through the EHR-based reporting mechanism, once the practice's EHR is programmed by the vendor to allow data submission to CMS, the burden to the group practice associated with submission of data on the electronic prescribing measure should be minimal.

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 Physician Quality Reporting System 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 Physician Quality Reporting System measures and/or electronic prescribing measure. It may be more burdensome for some practices to use some reporting mechanisms to report the Physician Quality Reporting System 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 Physician Quality Reporting System (and, as stated previously, we have not yet obtained the results of the 2010 Physician Quality Reporting System) 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 Physician Quality Reporting System 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 Physician Quality Reporting System 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	84,050	1,723,929
Estimated Annual Burden for Registry-based Reporting	282,905	282,905
Estimated Annual Burden Hours for EHR-based Reporting	315,000	315,000
Estimated Total Annual Burden Hours for Individual Eligible Professionals	**681,955**	**2,321,834**
Estimated Cost for Claims-based Reporting	$3,364,900	$69,333,764
Estimated Cost for Registry-based Reporting	$11,316,200	$11,316,200
Estimated Cost for EHR-based Reporting	$12,600,00	$12,600,000
Estimated Total Annual Cost for Individual Eligible Professionals	**$27,281,100**	**$93,249,964**

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 Physician Quality Reporting System 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 Physician Quality Reporting System 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 Physician Quality Reporting System and the Electronic Prescribing Incentive Program Under the Group Practice Reporting Option	6
Estimated # of Burden Hours Per Group Practice to Report Physician Quality Reporting System 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 Physician Quality Reporting System and/or the Electronic Prescribing Incentive Program Under the Group Practice Reporting Option	$96
Estimated Cost Per Group Practice to Report Physician Quality Reporting System 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
Annual Burden Cost for Group Practices	**$1,268,200**

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 Physician Quality Reporting System. However, to the extent an eligible professional decides to participate in the Physician Quality Reporting System 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 Physician Quality Reporting System or the Electronic Prescribing Incentive Program. Instead, we believe that having the option to use their EHR to participate in the Physician Quality Reporting System or Electronic Prescribing Incentive Program is simply an added benefit for eligible professionals who already have a qualified EHR product.

In addition, in order to report the electronic prescribing measure, the electronic prescribing measure requires eligible professionals to have and use a "qualified" electronic prescribing system. There are currently many commercial packages available for electronic prescribing. One study indicated that a mid-range complete electronic medical record costs $2,500 per license with an annual fee of $90 per license for quarterly updates of the drug database after setup costs while a

standalone prescribing, messaging, and problem list system costs $1,200 per physician per year after setup costs. Hardware costs and setup fees substantially add to the final cost of any software package. (Corley, S.T. (2003). "Electronic prescribing: a review of costs and benefits." Topics in Health Information Management 24(1): 29-38.). The cost to an eligible professional of obtaining and utilizing an electronic prescribing system varies not only by the commercial software package selected but also by the level at which the professional currently employs information technology in his or her practice and the level of training needed. For purposes of our analysis, we will use the average between a mid-range electronic medical record and a standalone system, or $1,850.

Based on Medicare claims data, we estimate that approximately 657,456 eligible professionals are eligible to participate in the Electronic Prescribing Incentive Program (that is, billed for one or more codes in the Electronic Prescribing measure's denominator). Approximately 87,692 of the 657,456 eligible professionals validly submitted a QDC for the Electronic Prescribing measure in 2009 indicating that they have a qualified Electronic Prescribing system. Therefore, we estimate that up to 569,764 eligible professionals may need to purchase a qualified Electronic Prescribing system prior to 2012 in order to avoid the Electronic Prescribing penalty that begins in 2012. Thus, the total capital costs associated with the Physician Quality Reporting System & Electronic Prescribing Incentive Program are estimated to be $1,054,063,400. We believe, however, that the actual cost will be significantly lower as some eligible professionals may have purchased a qualified electronic prescribing system in 2010, such as those eligible professionals also participating in the EHR Incentive Program, and some eligible professionals may not be subject to the payment adjustment for one or more reasons.

14. <u>Cost to Federal Government</u>

In CY 2012, incentive payments will be made to eligible professionals who satisfactorily submit data on Physician Quality Reporting System quality measures for the 2011 Physician Quality Reporting System as well as to eligible professionals who are successful electronic prescribers for the 2011 eRx Incentive Program. According to the results of the 2009 Physician Quality Reporting System, in 2009, 1,004,866 professionals were eligible to participate in the Physician Quality Reporting System via the claims-based reporting mechanism. In addition, nearly 37,000 professionals were eligible for participation via one the alternative submission methods. Of the approximately 1,0004,866 professionals eligible for Physician Quality Reporting System participation, 185,154 eligible professionals participated in the Physician Quality Reporting System via the claims method and 33,055 participated in Physician Quality Reporting System via registry. In 2009, $234,282,572.02 in incentive payments were made to those 119,804 eligible professionals who satisfactorily participated in Physician Quality Reporting System. The average incentive payment was $1,956 per eligible professional.

We expect that, for the 2012 Physician Quality Reporting System, the number of eligible professionals who qualify for a Physician Quality Reporting System incentive will increase as a result of the lessons learned from prior years, an increase in the use of the registry-based reporting mechanism, a more targeted provider education campaign, and the changes we made to the reporting criteria. Therefore, we estimate at least a 1% increase of eligible professionals receiving an incentive from 2009 to 2012. Therefore, we estimate that approximately <u>121,002</u> eligible

professionals will earn a Physician Quality Reporting System incentive in 2012. Regardless of the estimated increase in the number of eligible professionals earning an incentive, we expect the total incentive amount distributed to eligible professionals for satisfactory reporting in 2012 will be somewhat offset by the incentive amount decrease from 2.0% in 2009 to 0.5% in 2012. Therefore, using one-fourth of the 2009 average incentive amount for each eligible professional, we estimate that we will make $58,584,156 in incentive payments to eligible professionals who satisfactorily report in 2012.

For the eRx Incentive Program, CY 2010 was the first year in which incentive payments were paid to eligible professionals for being successful electronic prescribers in 2009. For the 2009 eRx Program, we made a total of $148,007,815.60 in incentive payments. 92,132 out of 669,691 eligible professionals attempted to participate in the eRx Incentive Program. Out of those 92,132 eligible professionals, 48,354 were eligible for the 2.0% electronic prescribing incentive. The average incentive amount for each eligible professional was $3,060.92.

Assuming a 12% increase in participation in the 2012 through 2014 eRx Incentive Program from 2009 to 100,800 eligible professionals, we estimate a 12% increase in the number of eligible professionals eligible for an incentive. Therefore, we estimate that 54,156 eligible professionals will receive a 2012 and/or 2013 incentive. Regardless of the estimated increase in the number of eligible professionals earning an incentive, we assume that the total incentive amount distributed will be somewhat offset by the incentive amount decrease from 2.0% in 2009 to 1.0% in 2012 and 0.5% in 2013. Therefore, using the 2009 average incentive amount and taking into account the applicable percentage amounts for the 2012 and 2013 incentives, we estimate that we will make $82,883,591.76 in incentive payments for 2012 and $41,441,795.88 in incentive payments for 2013.

Thus, the combined cost of incentive payments in CY 2012 for both incentive programs is estimated to be approximately $141 million.

15. Program or Burden Changes

The changes in the estimated burden in this PRA application for 2012 from the original submission are due to the following:

- An increase in the number of eligible professionals expected to participate in the Physician Quality Reporting System from 221,858 to 228,579 eligible professionals.
- An increase in the number f eligible professionals expected to participate in the eRx Incentive Program from 92, 132 to 100,800 eligible professionals, mainly due to the 2013 and 2014 payment adjustments.
- A decrease in the average practice labor rate from $55 per hour to $16/hour (for administrative duties) and/or $40/hour (for reporting duties) based on an informal review conducted by CMS on a small sample of participants in 2011 that described the types of employees involved in participating in the Physician Quality Reporting System and eRx Incentive Program.
- A decrease in the number of responses per individual eligible professional for the 2011 Physician Quality Reporting System from 27 to 18 responses per eligible professional as a result of the revised reporting criteria for claims-based reporting of Physician Quality Reporting System measures.

- The modification of the group practice reporting option the Physician Quality Reporting System and the Electronic Prescribing Incentive Program for 2012 by eliminating GPRO II.

16. Publication and Tabulation Dates

As required by the MIPPA, the names of eligible professionals and group practices who satisfactorily report data on Physician Quality Reporting System 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 Physician Quality Reporting System approval (12/31/2012). There are no paper forms involved in this data collection activity.

18. Certification Statement

There are no exceptions to the certification statement.