Supporting Statement for the Physician Quality Reporting Initiative (PQRI) and the Electronic Prescribing (eRx) Incentive Program

A. Background

The Physician Quality Reporting Initiative (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 PQRI 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).

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 2010 and 2011 as part of the PQRI can qualify to receive an incentive payment. The criteria for satisfactory reporting for the 2010 PQRI are specified in the CY 2010 Physician Fee Schedule (PFS) final rule with comment period. The proposed criteria for satisfactory reporting for the 2011 PQRI are specified in the CY 2011 PFS proposed rule.

In addition, the MIPPA authorized a new incentive program for successful electronic prescribers beginning in 2009. In order to be considered a successful electronic prescriber for 2010 or 2011, an eligible professional or group practice must successfully report the electronic prescribing measure in accordance with the criteria for determining a successful electronic prescriber specified in the CY 2010 PFS final rule with comment period and proposed in the CY 2011 PFS proposed rule with comment period. In addition, beginning in 2012, eligible professionals or group practices who are not successful electronic prescribers may be subject to a payment adjustment. The criteria that we propose to use to determine whether an eligible professional or a group practice is a successful electronic prescriber for purposes of the penalty are described in the CY 2011 PFS proposed 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 PQRI and/or the Electronic Prescribing (eRx) Incentive Program for 2010 and 2011.

For the PQRI, eligible professionals or group practices who satisfactorily report data on quality measures for covered professional services furnished during a PQRI reporting period may qualify to receive an incentive payment equal to 2.0 percent (for 2010) or 1.0 percent (for 2011) 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 2010 PQRI are described in the CY 2010 PFS final rule with comment period. The proposed criteria for satisfactory reporting of data on individual quality measures and measures groups for the 2011 PQRI are described in the CY 2011 PFS proposed rule. For the group practice reporting option, there is one reporting option that the group practice can use to report PQRI quality measures for 2010 and two reporting options proposed for 2011.

For 2011 PQRI, eligible professionals and group practices who satisfactorily report the 2011 PQRI quality measures may also earn an additional 0.5 percent incentive payment for participating

in a Maintenance of Certification Program practice assessment more frequently than is required to qualify for or maintain board certification status.

In order for registries to submit PQRI quality measures results and numerator and denominator data on individual PQRI quality measures or measures groups on behalf of eligible professionals, a registry will need to self-nominate to become a "qualified" PQRI registry unless the registry was qualified for a prior year and successfully submits PQRI 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 an EHR for the purpose of qualifying to earn a PQRI incentive payment, the eligible professional must select a qualified EHR product. EHR vendors must have self-nominated to have one or more their products designated as a "qualified" PQRI EHR product.

While individual eligible professionals do not need to sign up or pre-register to begin participating in the PQRI, group practices interested in participating in a PQRI group practice reporting option must meet certain requirements to participate in PQRI as a group and submit a self-nomination to CMS.

For the eRx Incentive Program, eligible professionals or group practices who successfully report the electronic prescribing measure established under the PQRI 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 2.0 percent (for 2010) or 1.0 percent (for 2011) of the total estimated allowed charges submitted by no later than 2 months after the end of the reporting period. Data on the electronic prescribing measure is reportable through claims, a qualified registry, or a qualified EHR product. The electronic prescribing incentive payment is separate from the PQRI incentive payment.

This clearance request is for the information collected from eligible professionals and group practices who wish to participate in the PQRI and/or the eRx Incentive Program for 2010 or 2011, registries who wish to become a "qualified" registry for the PQRI and eRx Incentive Program, and EHR vendors who wish to have their EHR product(s) designated as a "qualified" EHR product.

2. <u>Information Users</u>

The data on PQRI 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 PQRI and/or the criteria for successful electronic prescribers for the eRx Incentive Program for 2010 and 2011, (2) to calculate and make incentive payments to eligible professionals and group practices in 2011 and 2012 for the PQRI and eRx Incentive Program for 2010 and 2011, respectively, (3) publicly post the names of eligible professionals and group practices who satisfactorily report PQRI quality measures data and/or who are successful electronic prescribers on the CMS Web site, and (4) make payment adjustments in 2012 for eligible professionals or group practices who are not successful electronic prescribers in 2011.

The information collected from registries through the registry self-nomination process will be used by CMS to determine whether the registry meets the PQRI registry requirements and is qualified to submit quality measures results and numerator and denominator data on PQRI individual quality measures, measures groups, and the electronic prescribing measure on behalf of eligible professionals.

The information collected from EHR vendors through the EHR self-nomination process will

be used by CMS to determine whether the vendor's EHR product(s) meet the PQRI 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 PQRI measures and the electronic prescribing measure.

Participation in the PQRI and/or the eRx 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 PQRI 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 PQRI 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 PQRI quality measures results and numerator and denominator data on PQRI 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 PQRI quality measures and the electronic prescribing measure to us electronically through an EHR.

There is no application for registries that wish to self-nominate to become a qualified PQRI registry. Registries are asked to submit a self-nomination letter requesting inclusion in the PQRI 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 vendors that wish to self-nominate one or more of their EHR products to become a qualified EHR product. 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 some group practices participating in the PQRI group practice reporting option, the collection of information will be done using a currently OMB-approved data collection tool (see OMB Control Number 0938-0941- Form 10136). This tool is an automated, electronic tool developed and refined with industry input. Referred to as "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. Similar to its use in the Physician Group Practice (PGP) demonstration and the Medicare Care Management Performance (MCMP) demonstration, PAT is not an EHR. Rather, it is an Access form and database used to collect numerator and denominator information required to calculate specific clinical quality measures. PAT is used to facilitate collection and scoring of the clinical quality measure data which can be provided by a physician practice from either a paper chart or an EHR system. Initially, PAT will be pre-populated by our contractor based on claims data. PQRI group practice reporting option participants using the PAT will only have to supplement the claims data by providing information that is available from the practice's medical record. The tool will reduce the administrative burden in collecting and reporting information.

Practices participating in the PQRI group practice reporting option may input the data

directly into the tool using their computer or, alternatively, the tool is able to import data electronically from an EHR, patient registry, or other electronic file. Once completed, the PAT file is then returned to CMS for scoring.

4. Duplication of Similar Information

To minimize duplication of similar information, registries and EHR 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 PQRI 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 PQRI incentive through their participation in the demonstration. 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.

Finally, for determining whether an eRx payment adjustment (penalty) applies to an eligible professional or group practice, we propose to use the data submitted by the eligible professional for purposes of the eRx 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 PQRI quality measures data and data on the electronic prescribing measure.

6. Less Frequent Collection

If data on PQRI 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 PQRI and/or the criteria for successful electronic prescribers for the eRx Incentive Program, (2) to calculate and make incentive payments to eligible professionals or group practices for the PQRI and eRx Incentive Program, (3) publicly post the names of eligible professionals and group practices who satisfactorily report PQRI quality measures data and/or who are successful electronic prescribers on the CMS Web site, and (4) to calculate and make payment adjustments for the eRx penalty.

If registries and EHR 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 PQRI or eRx 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 statue 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 2010 PFS proposed rule soliciting public comment for this collection, as it pertains to the 2010 PQRI and the 2010 eRx Incentive Program, was published in the Federal Register on July 13, 2009. The comment period ended on August 31, 2009.

The CY 2010 PFS final rule with comment period soliciting public comment for this collection, as it pertains to the 2010 PQRI and the 2010 eRx Incentive Program, was published in the Federal Register on November 25, 2009. The comment period ended December 29, 2009.

The CY 2011 PFS proposed rule soliciting public comment for this collection, as it pertains to the 2011 PQRI and the 2011 eRx Incentive Program, was published in the Federal Register on July 13, 2010. The comment period ended on August 24, 2010.

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 PQRI under the group practice reporting option) who satisfactorily report data on quality measures for covered professional services furnished during the 2010 PQRI reporting period may qualify to earn an incentive payment equal to 2.0 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 2010 PQRI reporting period. Eligible professionals who satisfactorily report PQRI quality measures data during the 2011 PQRI reporting period may qualify to earn a 1.0 percent incentive payment. Eligible professionals who satisfactorily report PQRI quality measures data during the 2011 PQRI reporting period could also qualify for an additional 0.5 percent incentive by 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 eRx Incentive Program under the group practice reporting option) who are successful electronic prescribers for 2010 may qualify to earn an

incentive payment equal to 2.0 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 2010 electronic prescribing reporting period. Eligible professionals or group practices who are successful electronic prescribers for 2011 may qualify for a 1.0 percent incentive payment.

10. Confidentiality

Consistent with federal government and CMS policies, CMS will protect the confidentiality of the requested proprietary information. Specifically, any confidential information (as such terms are interpreted under the Freedom of Information Act, 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 2010 and 2011. 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 vendors.

Burden Estimates for the 2010 PQRI and eRx Incentive Program

Burden Estimate for PQRI Reporting by Individual Eligible Professionals

With respect to the PQRI, the burden associated with the requirements of this voluntary reporting initiative is the time and effort associated with individual eligible professionals (EPs) identifying applicable PQRI 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 EPs, the burden associated with the requirements of this reporting initiative is the time and effort associated with EPs identifying applicable PQRI quality measures for which they can report the necessary information, collecting the necessary information, and reporting the information needed to report the EP's measures. We believe it is difficult to accurately quantify the burden because EPs may have different processes for integrating the PQRI into their practice's work flows. Moreover, the time needed for an EP 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 EPs are generally required to report on at least 3 measures to earn a PQRI incentive, we will assume that each EP who attempts to submit PQRI quality measures data is attempting to earn a PQRI incentive payment and reports on an average of 3 measures for this burden analysis.

Because we anticipate even greater participation in the 2010 PQRI than in previous years, including participation by EPs who are participating in PQRI for the first time in 2010, we will assign 5 hours as the amount of time needed for eligible professionals to review the 2010 PQRI 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 PQRI and to develop a mechanism for incorporating reporting of the selected measures or measures group into the office work flows.

Information from the Physician Voluntary Reporting Program (PVRP) indicated an average practice labor cost of $50 per hour per practice. The PVRP was the precursor to the PQRI. It was a voluntary program started in 2006 and was the first step for the reporting of physician quality of care through certain quality indicators. To account for salary increases over time, we will use an average practice labor cost of $55 per hour in all of our estimates for the 2010 PQRI. Thus, we estimate the cost for an eligible professional to review the list of PQRI 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 2010 PQRI reporting option to be approximately $275 per eligible professional ($55 per hour x 5 hours). We continue to expect the ongoing costs associated with PQRI participation to decline based on an eligible professional's familiarity with and understanding of the PQRI, experience with participating in the PQRI, and increased efforts by CMS and stakeholders to disseminate useful educational resources and best practices.

We believe the burden associated with actually reporting the PQRI quality measures will vary depending on the reporting mechanism selected by the EP. For claims-based reporting, EPs 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 PQRI will collect QDCs 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 CY 2010.

Based on our experience with the PVRP, which required data submission on quality measures via claims, we estimate that the time needed to perform all the steps necessary to report each measure (that is, reporting the relevant QDC(s) for a measure) on claims ranges from 15 seconds (0.25 minutes) per reporting instance, or case, to over 12 minutes per case for complicated cases and/or measures, with the median time being 1.75 minutes. With an average practice labor cost of $55 per hour, the cost associated with this burden ranges from $0.23 in labor time to about $11.00 in labor time for more complicated cases and/or measures, with the cost for the median practice being $1.60. For an individual EP, the time and cost associated with claims-based submission of quality data codes will vary with the EP's patient population and the types of measures on which the EP chooses to report (each measure's specifications include a required reporting frequency), the reporting period on which the EP chooses to report, and the volume of claims on which quality data is reported. Results from the 2007 PQRI indicate that EPs reported on 1 to 3,331 eligible instances per measure. For all 2007 PQRI measures, the median number of

eligible instances reported on per measure was less than 60. On average, the median number of eligible instances reported on per measure was about 9. Therefore, for this analysis we estimate that for each measure, an EP will report QDCs on 9 cases. Therefore, assuming that an EP, on average, will report 3 measures and that an EP reports on 9 reporting instances per measure, we estimate that time associated with claims-based reporting of measures for individual EPs would range from approximately 6.75 min (0.25 min per reporting instance x 9 reporting instances per measure x 3 measures) to 324 min, or 5.4 hours (12 min per reporting instance x 9 reporting instances per measure x 3 measures), with a median time of 47.25 min (1.75 min per reporting instance x 9 reporting instances per measure x 3 measures). Depending on the factors discussed above, the actual time for QDC data submission could be considerably lower or higher than these estimates. The estimated cost for an individual EP would range from approximately $6.19 (0.25 min per reporting instance x 9 reporting instances per measure x 3 measures x $55 per hour) to $297 (12 min per reporting instance x 9 reporting instances per measure x 3 measures x $55 per hour), with a median cost $43.31 (1.75 min per reporting instance x 9 reporting instances per measure x 3 measures x $55 per hour).

For purposes of this burden analysis, it is difficult to accurately estimate how many EPs will opt to participate in the PQRI in CY 2010 since the program is a voluntary reporting program. Information from the "PQRI 2007 Reporting Experience Report," which is available on the PQRI section of the CMS Web site at http://www.cms.hhs.gov/PQRI, indicates that nearly 110,000 unique TIN/NPI combinations attempted to submit PQRI quality measures data via claims for the 2007 PQRI. Therefore, for purposes of conducting a burden analysis for the 2010 PQRI, we will assume that all EPs who attempted to participate in the 2007 PQRI will also attempt to participate in the 2010 PQRI via claims-based reporting. Furthermore, we believe that the burden for EPs who are participating in the PQRI for the first time in 2010 will be considerably higher than the burden for EPs who have participated in PQRI in prior years.

Based on the assumptions discussed above, 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 in 2010 (a)	110,000	110,000	110,000
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	0.11205	0.7875	5.39784

Eligible Professional Per Year (f) = (d)*(e)			
Estimated Burden Hours Per Eligible Professional to Prepare for 2010 PQRI 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)	**562,326**	**636,625**	**1,143,762**
Estimated Cost Per Case (j)	$0.23	$1.60	$11.00
Total Estimated Cost of Cases Per Eligible Professional Per Year (k) = (d)*(j)	$6.21	$43.20	$297.00
Estimated Cost Per Eligible Professional to Prepare for 2010 PQRI Participation (l)	$275	$275	$275
Estimated Total Annual Cost Per Eligible Professional (m) = (k) + (l)	$281.21	$318.20	$572.00
Estimated Total Annual Burden Cost (n) = (a)*(m)	**$30,933,100**	**$35,002,000**	**$62,920,000**

As for registry-based reporting, individual EPs must generally incur a cost to submit data to registries, which can range anywhere from no, or nominal, participation fees to several thousand dollars with a majority of registries charging fees ranging from $500-$1000. However, we believe that the majority of EPs who would choose the registry-based reporting mechanism would be those who are already submitting data to the registry for other purposes. Since this burden analysis should be limited to the incremental costs of reporting data to a registry specifically for PQRI, we do not consider use of this voluntary reporting method to be a capital cost. Since the majority of EPs electing to use this reporting mechanism would already be submitting data to the registry for other purposes, we also believe that the incremental time burden and costs associated with reporting for PQRI would be minimal. First, the EP would 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 would be approximately 5 minutes, or $4.58, for each EP that wishes to authorize or instruct the registry to submit quality measures results and numerator and denominator data on quality measures to CMS on their behalf. The other factor that influences the time and cost burden to EPs is the time and cost associated with reporting the PQRI information to the registry. There are essentially three ways in which registries collect the information from EPs for PQRI, via submission of claims-based information, a web portal based data entry system, or directly from an EHR. In the case of the claims-based information submission, the time it would take an EP to xerox their claims and send to the registry is estimated to be less than one minute per case, for a total burden of less than one hour labor time and a labor cost of less than $55. For the web portal based data entry system, it is estimated that on average it would take an EP no more than 3 hours, or $165, to submit the required information on the minimum number of patients required for satisfactory participation. With respect to EHR-based submission of data to registries, we estimate that it would take the EP 0 minutes to less than 1 hour, or no cost to $55, because the EP and registry would have a data agreement in place in which the registry is given access to directly data mine the EHR for purposes of gathering the appropriate information for the PQRI program. For purposes of this burden analysis, we will use the highest estimate, that is, the estimate for data submission via a web portal. Based on the preliminary participation data for the

2009 PQRI, we estimate that approximately 35,000 EPs will participate in the PQRI via registry submission in 2010.

Based on the assumptions discussed above, Table 2 provides an estimate of the total annual burden hours and total annual cost burden associated with registry-based reporting for individual EPs.

Table 2

	Burden Estimate
Estimated # of Participating Eligible Professionals in 2010 (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 PQRI Data to Registry (c)	3
Estimated Burden Hours Per Eligible Professional to Prepare for 2010 PQRI 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)	**282,917**
Estimated Cost Per Eligible Professional to Authorize Registry to Report on Eligible Professional's Behalf (g)	$4.58
Estimated Cost Per Eligible Professional to Report PQRI Data to Registry (h)	$165
Estimated Cost Per Eligible Professional to Prepare for 2010 PQRI Participation (i)	$275
Estimated Total Annual Cost Per Eligible Professional (j) = (g)+(h)+(i)	$444.58
Estimated Total Annual Burden Cost (k) = (a)*(j)	**$15,560,300**

Registries interested in submitting quality measure results and numerator and denominator data on quality measures to CMS on their participants' behalf in 2010 will need to complete a self-nomination process in order to be considered "qualified" to submit on behalf of EPs unless the registry was "qualified" to submit on behalf of EPs for the 2009 PQRI and does so successfully. Based on the number of registries that have self-nominated to become a qualified PQRI registry in prior program years, we estimate that approximately 50 additional registries will self-nominate to be considered a qualified registry for the 2010 PQRI. We anticipate that as the PQRI 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 EPs for the 2010 PQRI 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 $50 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 $500 ($50 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 PQRI individual quality measures or measures groups on behalf of individual EPs.

Table 3

	Burden Estimate
Estimated # of Registries Self-Nominating for the 2010 PQRI (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)	$500
Estimated Total Annual Burden Cost For Registries (e) = (a)*(d)	**$25,000**

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' PQRI measures will determine the time burden to the registry.

For EHR-based reporting, the EP must review the quality measures on which we will be accepting PQRI 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. Because this manner of reporting quality data to CMS will be new to PQRI for 2010 and participation via this reporting mechanism is voluntary, we believe it is difficult to estimate with any degree of accuracy how many, if any, EPs will opt to participate in the PQRI through the EHR mechanism in CY 2010. For purposes of quantifying the burden on EPs associated with EHR-based reporting, we will assume that the number of EPs who opt to participate

in EHR-based reporting is identical to the number of EPs who participate in registry-based reporting, or 35,000 EPs. The time needed for an EP 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 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 EP associated with submission of data on PQRI quality measures should be minimal. First, in order to participate in this option, an EP must have an IACS account, which takes less than 1 hour to obtain, or less than $55 in labor costs. The EP must submit a test file directly to CMS, which is estimated to take less than 1 hour, or less than $55 in labor costs. Finally, the EP would also be required to submit the actual data, which is estimated to take no more than 2 hours, or no more than $110 in labor costs, depending on the number of patients for which the EP is submitting.

Based on the assumptions discussed above, Table 4 provides an estimate of the total annual burden hours and total annual cost burden associated with EHR-based reporting for individual EPs.

Table 4

	Burden Estimate
Estimated # of Participating Eligible Professionals in 2010 (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 PQRI Data File to CMS (d)	2
Estimated Burden Hours Per Eligible Professional to Prepare for 2010 PQRI 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)	$55
Estimated Cost Per Eligible Professional to Submit Test Data File to CMS (i)	$55
Estimated Cost Per Eligible Professional to Submit PQRI Data File to CMS (j)	$110
Estimated Cost Per Eligible Professional to Prepare for 2010 PQRI Participation (k)	$275
Estimated Total Annual Burden Hours Per Eligible Professional (l) = (h)+(i)+(j)+(k)	$495
Estimated Total Annual Burden Cost (m) = (a)*(l)	**$17,325,000**

An EHR vendor interested in having their product(s) used by EPs to submit PQRI 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 2010. 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 $50 per hour for a total of $500 per EHR vendor ($50 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 EP needs to submit to CMS for purposes of reporting 2010 PQRI 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 EPs to submit PQRI quality measures data to the CMS-designated clinical data warehouse will be dependent on the EHR vendor's familiarity with PQRI, 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 $50 per hour for a total burden estimate of $2,000 ($50 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 $50 per hour, for a total estimate of $10,000 per vendor ($50 per hour x 200 hours per EHR vendor).

Based on the assumptions discussed above, 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 EPs being able to qualify to earn a PQRI incentive by submitting clinical quality data from the EHR product.

Table 5

	Burden Estimate
Estimated # of EHR Vendors Self-Nominating for the 2010 PQRI (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)	$10,000
Estimated Total Annual Burden Cost for EHR Vendors (e) = (a)*(d)	**$150,000**

Burden Estimate for PQRI Reporting by Group Practices

With respect to the process for group practices to be treated as satisfactorily submitting quality measures data under the 2010 PQRI, group practices interested in participating in the 2010 PQRI 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 2010 PQRI involves approximately 2 hours per group practice to review the 2010 PQRI 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 have an average practice labor cost of $55 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 $330 ($55 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 PQRI 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 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. The only modification that we intend to make to the PAT for use in the PQRI is to add a screen that provides group practices with information on completeness of their reporting and their quality measure results and numerator and denominator data. 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 the PAT for PQRI 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 complete the PAT at a cost of $55 per hour. Therefore, the total estimated annual cost per group practice is estimated to be approximately $4,345.

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 PQRI quality measures.

Table 6

	Burden Estimate
Estimated # of Eligible Group Practices in 2010 (a)	200
Estimated # of Burden Hours Per Group Practice to Self-Nominate to Participate in PQRI Under the Group Practice Reporting Option (b)	6
Estimated # of Burden Hours Per Group Practice to Complete the PAT (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 PQRI Under the Group Practice Reporting Option (f)	$330
Estimated Cost Per Group Practice to Complete the PAT (g)	$4,345
Estimated Total Annual Cost Per Group Practice (h) = (f) + (g)	$4,675
Estimated Total Annual Burden Cost (i) = (a)*(h)	**$935,000**

Burden Estimate for eRx Reporting by Individual Eligible Professionals

For the 2010 eRx Incentive Program, each EP will need to report the 2010 electronic prescribing measure, 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 EPs, the burden associated with the requirements of this initiative is the time and effort associated with EPs 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 EPs 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 EPs 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 EPs to select an appropriate reporting mechanism for them. At an average cost of approximately $55 per hour, we estimate the total cost to EPs 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 $110 ($55 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 EP. It is difficult to accurately estimate how many eligible professionals will opt to participate in the eRx Incentive Program in CY 2010. Information from the "PQRI 2007 Reporting Experience Report," which is available on the PQRI section of the CMS website at http://www.cms.hhhs.gov/PQRI, indicates that nearly 110,000 unique TIN/NPI combinations attempted to submit PQRI quality measures data via claims for the 2007 PQRI. Therefore, for purposes of conducting a burden analysis for the 2010 eRx Incentive Program, we will assume that as many eligible professionals who attempted to participate in the 2007 PQRI will attempt to participate in the 2010 eRx Incentive Program via claims. As such, we can estimate that nearly 110,000 unique TIN/NPI combinations will participate in the 2010 eRx Incentive Program via claims.

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 CY 2010. 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 $1.44 per reporting instance based on an average practice labor cost of $55 per hour.

To qualify for an eRx incentive, the EP 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 EP who chooses to participate in the 2010 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 EP to report the electronic prescribing measure is $146.00 [($1.44 per reporting instance per measure x 1 measure x 25 cases per measure) + $110]

Table 7 provides a summary of the total annual burden hours and total annual burden costs per individual EP associated with claims-based reporting of the electronic prescribing measure.

Table 7

	Burden Estimate
Estimated # of Participating Eligible Professionals in 2010 (a)	110,000
# 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 2010 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)	**300,209**
Estimated Cost Per Case (j)	$1.60
Total Estimated Cost of Cases Per Eligible Professional Per Year (k) = (d)*(j)	$40.00
Estimated Cost Per Eligible Professional to Review 2010 eRx quality measures (l)	$110
Estimated Total Annual Cost Per Eligible Professional (m) = (k) + (l)	$150.00
Annual Burden Cost (n) = (a)*(m)	**$16,500,000**

Because registry-based reporting of the electronic prescribing measure to CMS is new for 2010, it is difficult to accurately estimate how many EPs will opt to participate in the eRx Incentive Program through the registry-based reporting mechanism in CY 2010. We do not anticipate, however, any additional burden for EPs to report data to a registry as EPs opting for registry-based reporting would more than likely already be reporting data to the registry for other purposes

(particularly EPs who are already participating in PQRI 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 2010 eRx Incentive Program. However, in addition to the 2 hours estimated for the time needed by EPs 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, EPs 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 EP 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 2010 PQRI to be qualified to submit results and numerator and denominator data on the electronic prescribing measure for the 2010 eRx Incentive Program, there will be no need for a registry to undergo a separate self-nomination process for the eRx 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 PQRI. 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 eRx measure from the data submitted to the registry by its participants and submitting the eRx measure results and numerator and denominator data on their participants' behalf. This burden is expected to vary along with the number of EPs 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.

For EHR-based reporting, the EP 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 will be new for 2010, it is difficult to accurately estimate how many EPs will opt to participate in the ERx Incentive Program through the EHR-based reporting mechanism in CY 2010. The time needed for an EP 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 EP 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 2010 PQRI to be qualified for the 2010 eRx Incentive Program, there will be no need for EHR vendors to undergo a separate self-nomination process for the eRx 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 EP needs to submit to CMS for purposes of reporting the 2010 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 EPs 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 2010 PQRI will be qualified for the 2010 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 EPs to submit data on the electronic prescribing measure to the CMS-designated clinical data warehouse would be minimal.

Burden Estimate for eRx Reporting by Group Practices

With respect to the process for group practices to be treated as successful electronic prescribers under the 2010 eRx Incentive Program, a group practice will be required to report the electronic prescribing measure in at least 2,500 instances. Group practices have the same options as individual EPs in terms of the form and manner for reporting the electronic prescribing measure (that is, group practices have the option of reporting measure through claims, a qualified registry, or a qualified EHR product). The only difference between an individual EP 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 EP 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 EPs within the group practice to determine whether the group practice reported the measure a sufficient number of times.

For group practices who are selected to participate in the 2010 eRx 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 hour]. The total estimated cost per group practice to report the electronic prescribing measure through claims-based reporting is estimated to be $3,710 [($1.44 per measure x 1 measure x 2,500 cases per measure) + $110]. Since we are limiting participation in the eRx Incentive Program group practice reporting option to those group practices participating in the PQRI group practice reporting option, we will assume, for the purpose of this burden analysis, that the estimated number of group practices participating in the eRx Incentive Program group practice reporting option is the same as the estimated number of group practices participating in the PQRI group practice reporting option. There will not be a separate self-nomination process for group practices who wish to participate in the eRx Incentive Program group practice reporting option.

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.

Table 8

	Burden Estimate
Estimated # of Participating Group Practices in 2010 (a)	200

# 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 2010 eRx 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)	$1.44
Total Estimated Cost of Cases Per Group Practice Per Year (k) = (d)*(j)	$3,600
Estimated Cost Per Group Practice to Review 2010 electronic prescribing quality measures (l)	$110
Estimated Total Annual Cost Per Group Practice (m) = (k) + (l)	$3,710
Annual Burden Cost (n) = (a)*(m)	**$742,000**

For group practices that are selected to participate in the 2010 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 PQRI. Little, if any, additional data would need to be reported to the registry for purposes of participation in the 2010 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.

For group practices who are selected to participate in the 2010 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 eRx measure should be minimal.

Total Estimated Burden of this Information Collection Requirement for 2010

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 PQRI and the ERx

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 PQRI measures and/or electronic prescribing measure. It may be more burdensome for some practices to use some reporting mechanisms to report the PQRI 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 are new options for the 2010 PQRI and the only reporting mechanism available for the eRx 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 eRx Incentive Program 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 eRx Incentive Program and the PQRI during 2010 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 PQRI and/or the eRx 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	300,209	1,443,971
Estimated Annual Burden for Registry-based Reporting	72,917	355,834
Estimated Annual Burden Hours for EHR-based Reporting	70,000	385,000
Estimated Total Annual Burden Hours for Individual Eligible Professionals	**443,126**	**2,184,805**
Estimated Cost for Claims-based Reporting	$16,500,000	$78,868,405
Estimated Cost for Registry-based Reporting	$4,010,435	$19,570,870
Estimated Cost for EHR-based Reporting	$3,850,000	$21,175,000
Estimated Total Annual Cost for Individual Eligible Professionals	**$24,360,435**	**$119,614,275**

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 PQRI and the eRx Incentive Program. Table 10 provides a summary of an estimate for group practices to participate in both the eRx Incentive Program and the PQRI under the group practice reporting option during 2010 (that is, sum of Tables 5 and 8).

Table 10

	Maximum

	Burden Estimate
Estimated # of Participating Group Practices in 2010	200
Estimated # of Burden Hours Per Group Practice to Self-Nominate to Participate in PQRI and the eRx Incentive Program Under the Group Practice Reporting Option	6
Estimated # of Burden Hours Per Group Practice to Report PQRI Quality Measures and the eRx Measure	151.9175
Estimated Burden Hours Per Group Practice to Review 2010 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 PQRI and/or the eRx Incentive Program Under the Group Practice Reporting Option	$330
Estimated Cost Per Group Practice to Report PQRI Quality Measures and/or eRx Quality Measure	$8,359
Estimated Cost Per Group Practice to Review the eRx Measure	$110
Estimated Total Annual Cost Per Group Practice	$8,799
Annual Burden Cost for Group Practices	**$1,759,725**

Burden Estimates for the 2011 PQRI and eRx Incentive Program

Burden Estimate for PQRI Reporting by Individual Eligible Professionals

With respect to the PQRI, we will use the same assumptions used to develop our burden estimates for the 2011 PQRI. However, based on our assumption that group practice labor costs will rise about 3 percent each year, we will use an average practice labor cost of $58 per hour for our cost estimates. The burden hours associated with the 2011 PQRI is identical to the burden estimates provided for the 2010 PQRI with one exception. For individual EPs who choose to report via the claims-based reporting mechanism, we expect the time associated with reporting PQRI measures via claims to be lower in 2011 than in 2010 because we proposed to lower the reporting requirement from 80% to 50%. Since we are proposing to lower the reporting requirement by about one-third, we expect the number of reporting instances, or cases, reported on per measure by an individual EP to be lower by about one-third as well. Thus, for purposes of estimating the burden of claims-based reporting, we will assume that an individual EP will need to report each PQRI measure for an average of 6 cases per year. Tables 11 and 12 summarize the estimated burden hours and costs for individual EPs associated with participation in the 2011 PQRI.

Table 11

	Minimum Burden Estimate	Median Burden Estimate	Maximum Burden Estimate
Claims-based Reporting			
Estimated # of Participating Eligible Professionals	110,000	110,000	110,000

in 2011 (a)			
Estimated # of Measures Per Eligible Professional Per Year (b)	3	3	3
Estimated # of Cases Per Measure Per Eligible Professional Per Year (c)	6	6	6
Total Estimated # of Cases Per Eligible Professional Per Year (d) = (b)*(c)	18	18	18
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)	0.0747	0.52506	3.59856
Estimated Burden Hours Per Eligible Professional to Prepare for 2011 PQRI Participation (g)	5	5	5
Estimated Total Annual Burden Hours Per Eligible Professional (h) = (f)+(g)	5.0747	5.52506	8.59856
Estimated Total Annual Burden Hours for Claims-based Reporting (i) = (a)*(h)	**558,217**	**607,757**	**945,842**
Estimated Cost Per Case (j)	$0.24	$1.69	$11.60
Total Estimated Cost of Cases Per Eligible Professional Per Year (k) = (d)*(j)	$4.33	$30.45	$208.80
Estimated Cost Per Eligible Professional to Prepare for 2011 PQRI Participation (l)	$290	$290	$290
Estimated Total Annual Cost Per Eligible Professional (m) = (k) + (l)	$294.33	$320.45	$498.80
Estimated Total Annual Burden Cost for Claims-based Reporting (n) = (a)*(m)	**$32,376,300**	**$35,249,500**	**$62,920,000**

Table 12

Registry-based Reporting	
Estimated # of Participating Eligible Professionals in 2011 (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 PQRI Data to Registry (c)	3
Estimated Burden Hours Per Eligible Professional to Prepare for 2011 PQRI 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)	**282,917**
Estimated Cost Per Eligible Professional to Authorize Registry to Report on Eligible Professional's Behalf (g)	$4.81
Estimated Cost Per Eligible Professional to Report PQRI Data to Registry (h)	$174
Estimated Cost Per Eligible Professional to Prepare for 2011 PQRI Participation (i)	$290
Estimated Total Annual Cost Per Eligible Professional (j) = (g)+(h)+(i)	$468.81

Estimated Total Annual Burden Cost (k) = (a)*(j)	**$16,408,490**
EHR-based Reporting	
Estimated # of Participating Eligible Professionals in 2011 (k)	35,000
Estimated Burden Hours Per Eligible Professional to Obtain IACS Account (l)	1
Estimated Burden Hours Per Eligible Professional to Submit Test Data File to CMS (m)	1
Estimated Burden Hours Per Eligible Professional to Submit PQRI Data File to CMS (n)	2
Estimated Burden Hours Per Eligible Professional to Prepare for 2011 PQRI Participation (o)	5
Estimated Total Annual Burden Hours Per Eligible Professional (p) = (l)+(m)+(n)+(o)	9
Estimated Total Annual Burden Hours (q) = (k)*(p)	**315,000**
Estimated Cost Per Eligible Professional to Obtain IACS Account (r)	$58
Estimated Cost Per Eligible Professional to Submit Test Data File to CMS (s)	$58
Estimated Cost Per Eligible Professional to Submit PQRI Data File to CMS (t)	$116
Estimated Cost Per Eligible Professional to Prepare for 2010 PQRI Participation (u)	$290
Estimated Total Annual Burden Hours Per Eligible Professional (v) = (r)+(s)+(t)+(u)	$522
Estimated Total Annual Burden Cost (w) = (k)*(r)	**$18,270,000**

Registries interested in submitting quality measure results and numerator and denominator data on quality measures to CMS on their participants' behalf in 2011 will still need to complete a self-nomination process in order to be considered "qualified" to submit on behalf of EPs unless the registry was "qualified" to submit on behalf of EPs for the 2010 PQRI and does so successfully. We estimate that the burden associated with a registry going through the CMS vetting process and submitting the 2011 PQRI measures will be identical to our 2010 PQRI burden estimates. Although we are proposing some changes to the registry requirements for 2011, we do not believe these changes will impact the burden on registries. Rather than the registry calculating the measure results from an algorithm that they develop, we are proposing to require the registries to calculate the measure results from a CMS-supplied algorithm.

Table13 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 PQRI individual quality measures or measures groups on behalf of individual EPs.

Table 13

	Burden Estimate
Estimated # of Registries Self-Nominating for the 2011 PQRI (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)	$500
Estimated Total Annual Burden Cost For Registries (e) = (a)*(d)	**$25,000**

An EHR vendor interested in having their product(s) used by EPs to submit PQRI quality measures data to CMS were also required to complete a self-nomination process in order for the vendor's product(s) to be considered "qualified" for 2011. We estimate that burden and costs associated with an EHR vendor going through the CMS vetting process and programming its EHR product(s) to extract the clinical data that the EP needs to submit to CMS for purposes of reporting 2011 PQRI quality measures will be identical to our 2010 estimates.

Table 14 provides an estimate of the 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 EPs being able to qualify to earn a PQRI incentive by submitting clinical quality data from the EHR product.

Table 14

	Burden Estimate
Estimated # of EHR Vendors Self-Nominating for the 2011 PQRI (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)	$10,000
Estimated Total Annual Burden Cost for EHR Vendors (e) = (a)*(d)	**$150,000**

Burden Estimate for PQRI Reporting by Group Practices

With respect to the process for group practices to be treated as satisfactorily submitting quality measures data under the 2011 PQRI, group practices interested in participating in the 2011 PQRI 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 2011 PQRI GPRO I and GPRO II involves approximately 2 hours per group practice to review the 2011 PQRI 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 have an average practice labor cost of $58 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 $348 ($58 per hour x 6 hours per group practice). There are currently 36 practices participating in the 2010 PQRI GPRO. Therefore, we will assume that the same number

of group practices will participate in the GPRO I for the 2011 PQRI. Since we are proposing to pilot the PQRI GPRO II for 500 group practices, we will assume that 500 group practices will participate in the GPRO II for the 2011 PQRI, for a total of 536 group practices.

The burden associated with the group practice reporting requirements is the time and effort associated with the group practice submitting the quality measures data. For physician group practices participating in GPRO I, this would be the time associated with the physician group completing 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. The only modification that we intend to make to the PAT for use in the PQRI is to add a screen that provides group practices with information on completeness of their reporting and their quality measure results and numerator and denominator data. Since we are not changing the measures or data submission process for 2011, we estimate that the burden associated with a group practice completing the PAT for 2011 PQRI will be the same as for the group practice to complete the PAT for the 2010 PQRI GPRO. In other words, we estimate that, on average, it will take each group practice 79 hours to complete the PAT at a cost of $58 per hour. Therefore, the total estimated annual cost per group practice is estimated to be approximately $4,582.

Based on the assumptions discussed above, Table 15 provides an estimate of the total annual burden hours and total annual cost burden associated with the group practice reporting under GPRO I.

Table 15

	Burden Estimate
Estimated # of Participating Group Practices in 2011 (a)	36
Estimated # of Burden Hours Per Group Practice to Self-Nominate to Participate in PQRI Under the GPRO I (b)	6
Estimated # of Burden Hours Per Group Practice to Complete the PAT (c)	79
Estimated Total Annual Burden Hours Per Group Practice (d) = (b)+(c)	85
Estimated Total Annual Burden Hours (e) = (a)*(d)	**3,060**
Estimated Cost Per Group Practice to Self-Nominate to Participate in PQRI Under the GPRO I (f)	$348
Estimated Cost Per Group Practice to Complete the PAT (g)	$4,582
Estimated Total Annual Cost Per Group Practice (h) = (f) + (g)	$4,930
Estimated Total Annual Burden Cost (i) = (a)*(h)	**$177,480**

The reporting requirements under GPRO II vary with group practice size. Therefore, the burden associated with the group practice reporting requirements will also vary with group practice size. Since 2011 would be the first year of the GPRO II, we do not know what the average size of the groups that elect to participate in GPRO II will be. Therefore, for purposes of this burden analysis we will assume that all of the groups will have 26-50 NPIs. This means that the groups would have to report 2 measures groups and 4 individual measures. Since measures groups are

defined as 4 or more measures with common denominator coding, we will also assume that each measures group is equivalent to 3 individual measures in terms of the reporting burden. Therefore, our analysis will be based on an assumption that all of the GPRO II group practices would be reporting on 10 individual measures. Since the group practices with 26-50 NPIs will, overall, be required to report on nearly 3.5 times more measures than individual EPs, we will triple our estimates of the time associated with preparing for reporting the PQRI measures from 5 hours for individual EPs to 15 hours for group practices.

Similar to reporting by individual eligible professionals, the burden associated with reporting under GPRO II would vary by the reporting mechanism selected by the group. For the 2011 GPRO II, groups can report on measures either through claims-based reporting, which requires reporting on 50% of eligible patients, or registry-based reporting, which requires reporting on 80% of eligible patients. Therefore, we will use many of the same assumptions that we used to quantify the burden for individual EPs for claims-based and registry-based reporting. For claims-based reporting, we will assume that for each measure the group will be required to report the measure for 50 cases, since groups that have 26-50 NPIs will be required to report on a minimum of 50 patients for each measures group.

Since we are piloting the GPRO II in 2011 and limiting the number of group practices to 500, we will assume that there will be 500 group practices participating in the GPRO II. We, however, do not know which reporting mechanism the GPRO II group practices will choose. Therefore, we will assume that about 25%, or 125 practices, will participate in GPRO II via registry-based reporting and the remaining 375 practices will participate in GPRO II via claims-based reporting. Our estimates of the burden and cost associated with claims-based and registry-based reporting by group practices participating in GPRO II are summarized in Tables 16 and 17, respectively.

Table 16

	Minimum Burden Estimate	**Median Burden Estimate**	**Maximum Burden Estimate**
Claims-based Reporting			
Estimated # of Participating Group Practices in 2011 (a)	375	375	375
Estimated # of Measures Per Group Practice Per Year (b)	10	10	10
Estimated # of Cases Per Measure Per Group Practice Per Year (c)	50	50	50
Total Estimated # of Cases Per Group Practice Per Year (d) = (b)*(c)	500	500	500
Estimated Burden Hours Per Case (e)	0.00415	0.02917	0.19992
Estimated Total Burden Hours For Measures Per Group Practice Per Year (f) = (d)*(e)	2.075	14.585	99.96
Estimated Burden Hours Per Group Practice to Prepare for 2011 PQRI Participation (g)	15	15	15
Estimated Total Annual Burden Hours Per Eligible	17.075	29.585	114.96

Professional (h) = (f)+(g)			
Estimated Total Annual Burden Hours for Claims-based Reporting (i) = (a)*(h)	**6,403**	**11,094**	**43,110**
Estimated Cost Per Case (j)	$0.24	$1.69	$11.60
Total Estimated Cost of Cases Per Group Practice Per Year (k) = (d)*(j)	$120	$845	$5,800
Estimated Cost Per Group Practice to Prepare for 2011 PQRI Participation (l)	$870	$870	$870
Estimated Total Annual Cost Per Group Practice (m) = (k) + (l)	$990	$1,715	$6,670
Estimated Total Annual Burden Cost for Claims-based Reporting (n) = (a)*(m)	**$371,250**	**$643,125**	**$2,501,250**

Table 17

Registry-based Reporting	
Estimated # of Participating Group Practices in 2011 (a)	125
Estimated Burden Hours Per Group Practice to Authorize Registry to Report on Group Practice's Behalf (b)	0.083
Estimated Burden Hours Per Group Practice to Report PQRI Data to Registry (c)	9
Estimated Burden Hours Per Group Practice to Prepare for 2011 PQRI Participation (d)	15
Estimated Total Annual Burden Hours Per Group Practice (e) = (b)+(c)+(d)	24.083
Estimated Total Annual Burden Hours (f) = (a)*(e)	**3,010**
Estimated Cost Per Group Practice to Authorize Registry to Report on Group Practice's Behalf (g)	$4.81
Estimated Cost Per Group Practice to Report PQRI Data to Registry (h)	$522
Estimated Cost Per Group Practice to Prepare for 2011 PQRI Participation (i)	$870
Estimated Total Annual Cost Per Group Practice (j) = (g)+(h)+(i)	$1,396.81
Estimated Total Annual Burden Cost (k) = (a)*(j)	**$174,602**

2011 eRx Incentive Program

Burden Estimate for eRx Reporting by Individual Eligible Professionals

There are no changes to the reporting requirements for individual EPs for the 2011 eRx Incentive Program. Therefore, our burden estimates for individual EPs will be identical to the 2010 burden estimates for individual EPs. We believe, however, that the cost of participation in the 2011 eRx Incentive Program will be higher for individual EPs in 2011 consistent with our assumption that practice labor costs have increased from $55 per hour for 2010 to $58 per hour for 2011.

Table 18 provides a summary of the total annual burden hours and total annual burden costs per individual EP associated with claims-based reporting of the electronic prescribing measure.

Table 18

	Burden Estimate

Estimated # of Participating Eligible Professionals in 2011 (a)	110,000
# 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 2011 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)	**300,209**
Estimated Cost Per Case (j)	$1.69
Total Estimated Cost of Cases Per Eligible Professional Per Year (k) = (d)*(j)	$42.29
Estimated Cost Per Eligible Professional to Review 2011 eRx quality measures (l)	$116
Estimated Total Annual Cost Per Eligible Professional (m) = (k) + (l)	$158.29
Annual Burden Cost (n) = (a)*(m)	**$17,412,137**

Based on our policy to consider only registries and EHR products qualified for the 2011 PQRI to be qualified for the 2011 eRx Incentive Program, we continue to estimate that any additional burden associated with the registry and EHR self-nomination process would be minimal.

Burden Estimate for eRx Reporting by Group Practices

With respect to the process for group practices to be treated as successful electronic prescribers under the 2011 eRx Incentive Program, we are broadening the ability of group practices to participate as a group. Therefore, depending on a group practice's size, a group practice will be required to report the electronic prescribing measure for 75-2,500 instances. Group practices will continue to have the same options as individual EPs in terms of the form and manner for reporting the electronic prescribing measure (that is, group practices have the option of reporting measure through claims, a qualified registry, or a qualified EHR product). The only difference between an individual EP 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. Therefore, we will apply the same assumptions that we used to quantify the burden for individual EPs to report the electronic prescribing measure.

Table 19 provides an estimate of the total annual burden hours and total annual burden costs for group practices participating in GPRO I associated with claims-based reporting of the electronic prescribing measure. For GPRO II, we will assume that the average participating group consists of 26-50 NPIs as we did for the 2011 PQRI GPRO and is required to report the electronic prescribing measure for 475 instances. Table 20 provides an estimate of the total annual burden hours and total

annual burden costs for group practices associated with claims-based reporting of the electronic prescribing measure for GPRO II groups with 26-50 NPIs. As with the PQRI GPRO, we will assume that all groups participating in GPRO I will choose to report the 2011 electronic prescribing measure via claims and that about 75% of the GPRO II groups will choose to report the 2011 electronic prescribing measure via claims.

Table 19

	Burden Estimate
Estimated # of GPRO I Practices in 2011 (a)	36
# 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 2011 eRx 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)	$1.69
Total Estimated Cost of Cases Per Group Practice Per Year (k) = (d)*(j)	$4,229.22
Estimated Cost Per Group Practice to Review 2011 electronic prescribing quality measures (l)	$116
Estimated Total Annual Cost Per Group Practice (m) = (k) + (l)	$4,345.22
Annual Burden Cost (n) = (a)*(m)	**$156,428**

Table 20

	Burden Estimate
Estimated # of GPRO II Practices in 2011 (a)	375
# of Measures Per Group Practice Per Year (b)	1
Estimated # of Cases For Measures Per Group Practice Per Year (c)	475
Total Estimated # of Cases Per Group Practice Per Year (d) = (b)*(c)	475
Estimated Burden Hours Per Case (e)	0.029167
Estimated Total Burden Hours Per Measure Per Group Practice Per Year (f) = (d)*(e)	13.854325

Estimated Burden Hours Per Group Practice to Review 2011 eRx quality measure (g)	2
Estimated Total Annual Burden Hours Per Group Practice (h) = (f)+(g)	15.854328
Estimated Total Annual Burden Hours (i) = (a)*(h)	**5,945**
Estimated Cost Per Case (j)	$1.69
Total Estimated Cost of Cases Per Group Practice Per Year (k) = (d)*(j)	$802.75
Estimated Cost Per Group Practice to Review 2011 electronic prescribing quality measures (l)	$116
Estimated Total Annual Cost Per Group Practice (m) = (k) + (l)	$918.75
Annual Burden Cost (n) = (a)*(m)	**$344,531**

For the same reasons cited in our 2010 eRx GPRO analysis, we continue to anticipate no or minimal burden for GPRO I and GPRO II practices to report the electronic prescribing measure via registry or EHRs.

Total Estimated Burden of this Information Collection Requirement for 2011

As for 2010, we will continue to provide a range of estimates for individual eligible professionals. The lower range of the estimate assumes that eligible professionals will only participate in the eRx Incentive Program and represents the estimated burden hours and burden cost per eligible professional from Table 18. The upper range assumes that eligible professionals participate in both the eRx Incentive Program and the PQRI during 2011 and represents the sum of the estimated maximum burden hours and burden cost per eligible professional from Tables 11,12, and 18 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 PQRI and/or the eRx 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 21.

Table 21

	Minimum Burden Estimate	**Maximum Burden Estimate**
Estimated Annual Burden Hours for Claims-based Reporting	300,209	1,246,051
Estimated Annual Burden for Registry-based Reporting	72,917	355,834
Estimated Annual Burden Hours for EHR-based Reporting	70,000	385,000
Estimated Total Annual Burden Hours for Individual Eligible Professionals	**443,126**	**1,986,885**
Estimated Cost for Claims-based Reporting	$17,412,122	$72,270,958
Estimated Cost for Registry-based Reporting	$4,229,186	$20,638,372
Estimated Cost for EHR-based Reporting	$4,060,000	$22,330,000

Estimated Total Annual Cost for Individual Eligible Professionals	**$25,701,308**	**$115,239,330**

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 PQRI and the eRx Incentive Program. Table 22 provides a summary of an estimate for group practices to participate in both the eRx Incentive Program and the PQRI under the group practice reporting option during 2011 (that is, sum of Tables 15, 16, 19 and 20).

Table 22

	Maximum Burden Estimate
Estimated Annual Burden Hours for GPRO I	18,044
Estimated Annual Burden Hours for GPRO II – Claims-based Reporting	49,055
Estimated Annual Burden Hours for GPRO II – Registry-based Reporting	3,010
Estimated Total Annual Burden Hours for Group Practices	**70,109**
Estimated Annual Cost for GPRO I	$333,908
Estimated Annual Cost for GPRO II – Claims-based Reporting	$2,845,781
Estimated Annual Cost for GPRO II – Registry-based Reporting	$174,602
Estimated Total Annual Cost for Group Practices	**$3,354,291**

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 PQRI. However, to the extent an eligible professional decides to participate in the PQRI 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 about $10,000 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 PQRI or the eRx Incentive Program. Instead, we believe that having the option to use their EHR to participate in the PQRI or eRx 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 $2500 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 $1200 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 eRx Incentive Program (that is, billed for one or more codes in the eRx measure's denominator). Approximately 87,692 of the 657,456 eligible professionals validly submitted a QDC for the eRx measure in 2009 indicating that they have a qualified eRx system. Therefore, we estimate that up to 569,764 eligible professionals may need to purchase a qualified eRx system prior to 2012 in order to avoid the eRx penalty that begins in 2012. Thus, the total capital costs associated with the PQRI & eRx 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 eRx system in 2010 and some eligible professionals may not be subject to the penalty for one or more reasons.

14. Cost to Federal Government

In CY 2010 and CY 2011, incentive payments will be made to eligible professionals who satisfactorily submit data on PQRI quality measures for the 2009 and 2010 PQRI as well as to eligible professionals who are successful electronic prescribers for the 2009 and 2010 eRx Incentive Program. For the PQRI, we currently only have projections available through the 2008 PQRI year. For the 2008 PQRI, we estimate that nearly $95 million in incentive payments will be made. We expect that, for the 2009 and 2010 PQRI, the number of eligible professionals who qualify for a PQRI 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. For purposes of this burden analysis, we can only assume that those who attempt to participate in the 2009 or 2010 PQRI do so satisfactorily and qualify to earn an incentive payment for a full-year. Thus, based on preliminary data from the 2009 PQRI indicating that over 985,000 eligible professionals participated in the 2009 PQRI (an increase of over 20 percent from the number of eligible professionals who participated in 2008 PQRI), we estimate making over $150 million in incentive payments for the 2009 PQRI. This estimate takes into account a 20 percent increase in participation and the increase in the incentive payment amount from 1.5 percent in 2008 to 2.0 percent in 2009.

With respect to the potential incentive payment that will be made in CY 2011 for the 2010 PQRI, we assume that participation will continue to increase by 20 percent. Since the incentive payment amount remains unchanged from 2009 to 2010, we estimate making approximately $180 million in incentive payments for the 2010 PQRI.

For the eRx Incentive Program, CY 2010 would be the first year in which incentive payments would be paid to eligible professionals for being successful electronic prescribers in 2009. Preliminary data from the 2009 eRx Incentive Program suggests that we will be making about $134 million in incentive payments for the 2009 eRx Incentive Program. If we apply the same assumptions we used for PQRI with regards to participation, then the estimated cost of incentive payments made to eligible professionals in CY 2011 for the 2010 eRx Incentive Program is expected to be approximately $161 million.

Thus, the combined cost of incentive payments in CY 2010 for both incentive programs is estimated to be approximately $284 million. The combined cost of incentive payments in CY 2011 for both incentive programs is estimated to be approximately $341 million.

15. Program or Burden Changes

The changes in the estimated burden in this PRA application for 2010 from the original submission are due to the following:

- An increase in the number of eligible professionals expected to participate in the PQRI and/or eRx Incentive Programs via claims from 101,000 (which was based on preliminary participation numbers for the 2007 PQRI) to 180,000 for 2010 and 2011. This increase is based on the fact that the actual number of 2007 PQRI participants was near 110,000, preliminary data for the 2009 PQRI shows nearly 35,000 participants via registry, and our assumption that the number of eligible professionals who will participate in 2010 via EHR will be similar to the number that participate via registry.
- An increase in the average practice labor rate from $50 per hour to $55 per hour for 2010 and $58 per hour for 2011 due to general increases in labor costs since 2006, when the PVRP was in place.
- A decrease in the number of responses per individual eligible professional for the eRx Incentive Program from 60 to 25 responses per eligible professional (for 2010 & 2011) as a result of the revised reporting criteria for the electronic prescribing measure.
- A decrease in the number of responses per individual eligible professional for the 2011 PQRI from 27 to 18 responses per eligible professional as a result of the revised reporting criteria for claims-based reporting of PQRI measures.
- The addition of burden hours associated with reviewing and selecting a PQRI and eRx Incentive Program reporting option.
- The addition of burden for registries associated with the self-nomination process.
- The implementation of a new EHR-based reporting mechanism for the PQRI beginning in 2010 and the inclusion of burden for EHR vendors associated with this self-nomination process.
- The implementation of a new group practice reporting option for the PQRI and the eRx Incentive Program for 2010 and further expansion of these options for 2011.

16. Publication and Tabulation Dates

As required by the MIPPA, the names of eligible professionals and group practices who satisfactorily report data on PQRI quality measures and who are successful electronic prescribers for 2010 and 2011 will be posted on the CMS website at www.medicare.gov in 2011 and 2012 following completion of the 2010 and 2011 incentive payments.

17. Expiration Date

CMS would like approval for this information collection for a period of 3 years from the expiration of the current PQRI approval (12/31/2009). There are no paper forms involved in this data collection activity.

18. Certification Statement

There are no exceptions to the certification statement.