**Supporting Statement for the Physician Quality Reporting Initiative (PQRI)**

## 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(k) and (m) of the Social Security Act (the Act). The MIEA-TRHCA was amended December 2007 by Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) and on July 15, 2008, by the enactment of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).

In accordance with section 1848(k)(2) of the Social Security Act (the Act), an eligible professional who satisfactorily submits data on quality measures for covered professional services furnished in 2009 as part of the PQRI can qualify to receive an incentive payment. In addition, section 1848(m)(5)(F) of the Act requires us to establish alternative criteria for satisfactorily reporting PQRI quality measures data through medical registries. For the 2009 PQRI, eligible professionals may report 2009 PQRI quality measures results and numerator and denominator data on quality measures through a qualified clinical registry by authorizing or instructing the registry to submit quality measures results and numerator and denominator data on quality measures to CMS on their behalf. To be qualified to submit PQRI quality measures results and numerator data on quality measures on behalf of eligible professionals in 2009, a registry will need to self-nominate to become a "qualified" PQRI registry unless the registry was qualified for the 2008 PQRI and successfully submits 2008 PQRI quality measure results and numerator and denominator data on quality measures on behalf of their participants by March 31, 2009.

In addition, the MIPPA authorized a new incentive program for successful electronic prescribers beginning in 2009. In order to be considered successful electronic prescriber for 2009, an eligible professional must successfully report the electronic prescribing measure established under the PQRI in accordance with section 1848(m)(3)(B)(ii) of the Act.

## B. Justification

### 1. Need and Legal Basis

Collection of this information is voluntary and only applies to eligible professionals who wish to participate in the 2009 PQRI and/or the 2009 Electronic Prescribing (E-Prescribing) Incentive Program).

For the 2009 PQRI, eligible professionals who satisfactorily report data on quality measures for covered professional services furnished during the 2009 PQRI reporting period will receive an incentive payment equal to 2.0 percent of the total estimated allowed charges submitted by no later than 2 months after the end of the reporting period. There are 2 mechanisms that eligible professionals can use to report data on quality measures for the 2009 PQRI. An eligible professional can choose to report data on quality measures through claims-based reporting or

through a qualified PQRI registry. In addition, eligible professionals have the option of reporting data on individual quality measures or on measures groups. The criteria for satisfactory reporting of data on individual quality measures and measures groups for the 2009 PQRI are described in the CY 2009 Physician Fee Schedule final rule with comment period.

In order for registries to submit PQRI quality measures results and numerator data on quality measures on behalf of eligible professionals in 2009, a registry will need to self-nominate to become a "qualified" PQRI registry unless the registry was qualified for the 2008 PQRI and successfully submits 2008 PQRI quality measure results and numerator and denominator data on quality measures on behalf of their participants by March 31, 2009.

For the 2009 E-Prescribing Incentive Program, eligible professionals who successfully report the e-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 of the total estimated allowed charges submitted by no later than 2 months after the end of the reporting period. For 2009, data on the e-prescribing measure is reportable only through claims. The e-prescribing incentive payment is separate from the PQRI incentive payment.

This clearance request is for the information collected from eligible professionals who wish to participate in the 2009 PQRI and/or the 2009 E-Prescribing Incentive Program and registries who wish to become a "qualified" PQRI registry for the 2009 PQRI.

**2. <u>Information Users</u>**

The quality measures data collected from eligible professionals and/or registries who submit PQRI quality measures results and numerator and denominator data on behalf of eligible professionals in 2009 and the e-prescribing quality measure data collected from eligible professionals will be used by CMS to: (1) determine whether an eligible professional meets the criteria for satisfactory reporting of quality measures data for the 2009 PQRI and/or the criteria for successful electronic prescribers for the 2009 E-Prescribing Incentive Program, (2) to calculate and make incentive payments in 2010 to eligible professionals who meet the criteria for satisfactory reporting of quality measures data and/or eligible professionals who are successful electronic prescribers, and (3) publicly post the names of eligible professionals who satisfactorily report PQRI quality measures data and/or who are successful electronic prescribers on the CMS Web site.

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 for 2009 and is qualified to submit PQRI quality measures results and numerator and denominator data on behalf of eligible professionals.

Participation in the PQRI and/or the E-Prescribing Incentive Program is voluntary in nature. Only eligible professionals that are interested in participating in these programs will submit the quality measures data. Similarly, only registries that are interested in participating in the PQRI will self-nominate.

### 3. Improved Information Technology

For claims-based reporting, the normal Medicare Part B claims submission process is used to collect PQRI quality measure data and/or the electronic prescribing measure data from eligible professionals. Eligible professionals are not asked to provide any documentation by CD or hardcopy. For registry-based reporting for PQRI, registries submit PQRI quality measures results and numerator and denominator data to us electronically.

There is no application for registries that wish to self-nominate to become qualified PQRI registry. Registries are asked to submit a self-nomination letter requesting inclusion in the 2009 PQRI. After a registry passes an initial qualification process that consists of interviews with interested registries, the registry will be requested to successfully submit a "test" file in XML format to our data warehouse.

### 4. Duplication of Similar Information

To minimize duplication of similar information, registries who were qualified to submit PQRI quality measures results and numerator and denominator data on quality measures for the 2008, will not need to undergo the self-nomination process for the 2009 PQRI unless a registry fails to submit 2008 PQRI quality measures results and numerator and denominator data on behalf of eligible professionals by March 31, 2009.

### 5. Small Businesses

The collection of information will primarily affect small entities (e.g., 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.

### 6. Less Frequent Collection

If the PQRI quality measures data and/or the electronic prescribing quality measure data is not collected from eligible professionals and/or qualified PQRI registries CMS will have no mechanism to: (1) determine whether an eligible professional meets the criteria for satisfactory reporting of quality measures data for the 2009 PQRI and/or the criteria for successful electronic prescribers for the 2009 E-Prescribing Incentive Program, (2) to calculate and make incentive payments in 2010 to eligible professionals who meet the criteria for satisfactory reporting of quality measures data and/or eligible professionals who are successful electronic prescribers, and (3) publicly post the names of eligible professionals who satisfactorily report PQRI quality measures data and/or who are successful electronic prescribers on the CMS Web site.

If registries are not required to submit a self-nomination letter for the PQRI, CMS will have no mechanism to determine which registries wish to participate in the 2009 PQRI.

## 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 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 final rule with comment period was published November 19, 2008.

## 9. Payment/Gift To Respondent

As authorized under section 1848(m)(1)(A) of the Act, eligible professionals who satisfactorily report data on quality measures for covered professional services furnished during the 2009 PQRI reporting period may earn an incentive payment equal to 2.0 percent of the estimated total allowed charges submitted not later than 2 months after the end of the reporting period for all covered professional services furnished during the 2009 PQRI reporting period.

As authorized under section 1848(m)(2)(A) of the Act, eligible professionals who are successful electronic prescribers for 2009 may earn an incentive payment equal to 2.0 percent of the estimated total allowed charges submitted not later than 2 months after the end of the reporting period for all covered professional services furnished during the 2009 e-prescribing reporting period

## 10. Confidentiality

Consistent with federal government and CMS policies, CMS will protect the confidentiality of the requested proprietary information. Specifically, any confidential information (as such terms are interpreted under the Freedom of Information Act, the Privacy Act of 1974, and other applicable Federal government rules and regulations) will be protected from release by CMS under 5 U.S.C. § 552a(b).

## 11. Sensitive Questions

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

## 12. Burden Estimate (Total Hours & Wages)

Burden Estimate for PQRI

With respect to the PQRI, the burden associated with the requirements of this voluntary reporting initiative is the time and effort associated with eligible professionals identifying applicable PQRI quality measures for which they can report the necessary information. We have no way to accurately quantify the burden because it would vary with each eligible professional by the number of measures applicable to the eligible professional, the eligible professional's familiarity and understanding of the PQRI, and experience with participating in the PQRI. In addition, eligible professionals may employ different methods for incorporating the use of quality data codes into the office work flows. Therefore, we will assign 3 hours as the amount of time needed for eligible professionals to review the PQRI quality measures, identify the applicable measures for which they can report the necessary information, and incorporate the use of quality data codes into the office work flows. Information from the Physician Voluntary Reporting Program (PVRP) indicated an average labor cost of $50 per hour. Thus, we estimate the cost for an eligible professional to review the PQRI quality measures, identify the applicable measures for which they can report the necessary information, and incorporate the use of quality data codes into the office work flows to be approximately $150 per eligible professional ($50 per hour x 3 hours). We 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.

In addition, for claims-based reporting, eligible professionals must gather the required information, select the appropriate quality data codes, and include the appropriate quality data codes on the claims they submit for payment. The PQRI will collect quality-data codes as additional (optional) line items on the existing HIPAA transaction 837-P and/or CMS Form 1500. We do not anticipate any new forms and no modifications to the existing transaction or form. We also do not anticipate changes to the 837-P or CMS Form 1500 for CY 2009.

Because this is a voluntary program, it is impossible to estimate with any degree of accuracy how many eligible professionals will opt to participate in the PQRI in CY 2009. Preliminary results from the 2007 PQRI (the first year of PQRI reporting) indicate that of approximately 619,000 unique individual eligible professionals, approximately 101,000 unique individual eligible professionals, or 16%, attempted to submit PQRI quality measures data in 2007. Therefore, for purposes of conducting a burden analysis for the 2009 PQRI, we will assume that all eligible professionals who attempted to participate in the 2007 PQRI will also attempt to participate in the 2009 PQRI.

Moreover, the time needed for an eligible professional to review the quality measures and other information, select measures applicable to his or her patients and the services he or she furnishes to them, and incorporate the use of quality data codes into the office work flows is expected to vary along with the number of measures that are potentially applicable to a given professional's practice. Since eligible professionals are generally required to report on at least 3 measures to earn a PQRI incentive, we will assume that each eligible professional who attempts to

submit PQRI quality measures data is attempting to earn a PQRI incentive payment and that each eligible professional reports on an average of 3 measures for this burden analysis.

Based on our experience with the PVRP, we estimate that the time needed to perform all the steps necessary to report each measure (that is, reporting the relevant quality data code(s) for a measure) on claims ranges from 15 seconds (0.25 minutes) to over 12 minutes for complicated cases and/or measures, with the median time being 1.75 minutes. Information from the PVRP indicates that the cost associated with this burden ranges from $0.21 in labor time to about $10.06 in labor time for more complicated cases and/or measures, with the cost for the median practice being $0.90.

The total estimated annual burden for this requirement will also vary along with the volume of claims on which quality data is reported. Preliminary results from the 2007 PQRI indicate that eligible professionals 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 burden analysis, we estimate, for each measure on which an eligible professional reports, the eligible professional reports the quality data on 9 cases.

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.

**Table 1**

| | **Minimum Burden Estimate** | **Maximum Burden Estimate** |
|---|---|---|
| **Estimated # of Participating Eligible Professionals in 2009 (a)** | 101,000 | 101,000 |
| **Estimated # of Measures Per Eligible Professional Per Year (b)** | 3 | 3 |
| **Estimated # of Cases Per Measure Per Eligible Professional Per Year (c)** | 9 | 9 |
| **Total Estimated # of Cases Per Eligible Professional Per Year (d) = (b)*(c)** | 27 | 27 |
| **Estimated Burden Hours Per Case (e)** | 0.00415 | 0.19992 |
| **Estimated Total Burden Hours For Measures Per Eligible Professional Per Year (f) = (d)*(e)** | 0.11205 | 5.39784 |
| **Estimated Burden Hours Per Eligible Professional to Review 2009 PQRI quality measures (g)** | 3 | 3 |
| **Estimated Total Annual Burden Hours Per Eligible Professional (h) = (f)+(g)** | 3.11205 | 8.39784 |
| **Estimated Total Annual Burden Hours (i) = (a)*(h)** | **314,317** | **848,182** |
| **Estimated Cost Per Case (j)** | $0.21 | $10.06 |
| **Total Estimated Cost of Cases Per Eligible Professional Per Year (k) = (d)*(j)** | $5.67 | $271.62 |
| **Estimated Cost Per Eligible Professional to Review 2009 PQRI quality measures (l)** | $150 | $150 |
| **Estimated Total Annual Cost Per Eligible Professional (m) = (k) +** | $155.67 | $421.62 |

| | | |
|---|---|---|
| **(l)** | | |
| **Annual Burden Cost (n) = (a)*(m)** | **$15,722,670** | **$42,583,620** |

For registry-based reporting, there would be no additional burden for eligible professionals to report data to a registry as eligible professionals more than likely would already be reporting data to the registry. Little, if any, additional data would need to be reported to the registry for purposes of participation in the 2009 PQRI. However, eligible professionals 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 for each eligible professional 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. Since registry reporting of PQRI quality measures results and numerator and denominator data was first implemented in the 2008 PQRI and no information about 2008 PQRI participation is currently available, we have no information available regarding how many eligible professionals participate in the PQRI through registry-based reporting.

Registries interested in submitting quality measures results and numerator and denominator data on quality measures to CMS on their participants' behalf would need to complete a self-nomination process in order to be considered "qualified" to submit on behalf of eligible professionals.

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.

Burden Estimate for E-Prescribing

With respect to the E-Prescribing Incentive Program, it is impossible to estimate with any degree of accuracy how many eligible professionals will opt to participate in the e-prescribing incentive program in CY 2009. However, if we assume that every eligible professional who attempted to participate in the 2007 PQRI will also attempt to participate in the 2009 E-Prescribing Incentive Program, then we can estimate that approximately 101,000 unique individual eligible professionals will participate in the 2009 E-Prescribing Incentive Program.

Similar to claims-based reporting for the PQRI, we estimate the burden associated with the requirements of this new incentive program is the time and effort associated with eligible professionals determining whether the quality measure is applicable to them, gathering the required information, selecting the appropriate quality data codes, and including the appropriate quality data codes on the claims they submit for payment. Since the e-prescribing program consists of only 1 quality measure, we will assign 1 hour as the amount of time needed for eligible professionals to

review the e-prescribing measure and incorporate the use of quality data codes into the office work flows. At an average cost of approximately $50 per hour, we estimate the total cost to eligible professionals for reviewing the e-prescribing measure and incorporating the use of quality data codes into the office work flows to be approximately $50 ($50 per hour X 1 hour).

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 and no modifications to the existing transaction or form. We also do not anticipate changes to the 837-P or CMS Form 1500 for CY 2009. Based on our experience with the PVRP described above, we estimate that the time needed to perform all the steps necessary to report the e-prescribing measure to be 1.75 minutes. We also estimate the cost to perform all the steps necessary to report the e-prescribing measure to be $0.90 based on the experience with the PVRP described above.

The total estimated annual burden for this requirement will also vary along with the volume of claims on which quality data is reported. Based on preliminary results from the 2007 PQRI described above and the fact that the measure's denominator consists of only billing codes for professional services, we estimate that each eligible professional reports the quality data on 60 cases for the e-prescribing measure.

Table 2 provides an estimate of the total annual burden hours and total annual burden costs associated with claims-based reporting of the e-prescribing measure.

Table 2

| | **Burden Estimate** |
|---|---|
| **Estimated # of Participating Eligible Professionals in 2009 (a)** | 101,000 |
| **# of Measures Per Eligible Professional Per Year (b)** | 1 |
| **Estimated # of Cases For Measures Per Eligible Professional Per Year (c)** | 60 |
| **Total Estimated # of Cases Per Eligible Professional Per Year (d) = (b)*(c)** | 60 |
| **Estimated Burden Hours Per Case(e)** | 0.029167 |
| **Estimated Total Burden Hours Per Measure Per Eligible Professional Per Year (f) = (d)*(e)** | 1.750035 |
| **Estimated Burden Hours Per Eligible Professional to Review 2009 e-prescribing quality measures (g)** | 1 |
| **Estimated Total Annual Burden Hours Per Eligible Professional (h) = (f)+(g)** | 2.750035 |
| **Estimated Total Annual Burden Hours (i) = (a)*(h)** | **277,754** |
| **Estimated Cost Per Case (j)** | $0.90 |
| **Total Estimated Cost of Cases Per Eligible Professional Per Year (k) = (d)*(j)** | $54 |
| **Estimated Cost Per Eligible Professional to Review 2009 e-prescribing quality measures (l)** | $50 |
| **Estimated Total Annual Cost Per Eligible Professional (m) = (k) + (l)** | $104 |
| **Annual Burden Cost (n) = (a)*(m)** | **$10,504,000** |

Total Estimated Burden of this Information Collection Requirement

It is impossible 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 E-Prescribing Incentive Program. Since the two programs are separate initiatives and both are voluntary, we have no way of accurately determining whether, for a particular year, eligible professionals who participate in one program will also participate in the other program. Therefore, Table 3 provides a range of estimates. The lower range of the estimate assumes that eligible professionals will only participate in the E-Prescribing Incentive Program and represents the estimated burden hours and burden cost per eligible professional from Table 2 above. The upper range assumes that eligible professionals participate in both the E-Prescribing Incentive Program and the PQRI during 2009 and represents the sum of the estimated maximum burden hours and burden cost per eligible professional from Table 1 and the estimated burden hours and burden cost per eligible professional from Table 2. 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. For the purposes of obtaining OMB approval, we are, however, requesting approval for the upper range of the estimates provided in Table 3. The requested annual burden estimate of 1,125,935 hours represents our estimate of the maximum burden. However, we expect that the total burden hours would range somewhere between 277,754 to 1,125,935 as some eligible professionals will need more time to integrate quality data reporting under the PQRI and/or the E-Prescribing Incentive Program into their practice workflows than others and some eligible professionals may choose to participate in one program but not the other.

**Table 3**

| | **Minimum Burden Estimate** | **Maximum Burden Estimate** |
|---|---|---|
| **Estimated # of Participating Eligible Professionals in 2009** | 101,000 | 101,000 |
| **Estimated # of Measures Per Eligible Professional Per Year** | 1 | 4 |
| **Estimated Total Burden Hours For Measures Per Eligible Professional Per Year** | 0.11205 | 5.39784 |
| **Estimated Burden Hours Per Eligible Professional to Review 2009 Quality Measures for PQRI and/or the E-Prescribing Incentive Program** | 1 | 4 |
| **Estimated Total Annual Burden Hours Per Eligible Professional** | 2.750035 | 11.14788 |
| **Estimated Total Annual Burden Hours** | **277,754** | **1,125,935** |
| **Total Estimated Cost of Cases Per Eligible Professional Per Year** | $54 | $325.62 |
| **Estimated Cost Per Eligible Professional to Review 2009 quality measures for PQRI and/or the E-Prescribing Incentive Program** | $50 | $200 |
| **Estimated Total Annual Cost Per Eligible Professional** | $104 | $525.62 |
| **Annual Burden Cost (n) = (a)*(m)** | **$10,504,000** | **$53,087,620** |

**13. Capital Costs (Maintenance of Capital Costs)**

We do not anticipate that additional capital costs are incurred for the PQRI. CMS requirements do not require the acquisition of new systems or the development of new technology to participate in the PQRI.

In order to report the e-prescribing quality measure, however, the e-prescribing measure requires eligible professionals to have and use a "qualified" e-prescribing system. There are currently many commercial packages available for e-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 e-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.

### 14. Cost to Federal Government

The estimated cost of incentive payments made to eligible professionals in CY 2009 is $80 million. This estimated cost is based on our estimates of the number of eligible professionals who will satisfactorily submit PQRI quality measures data for the 2008 PQRI since incentive payments for the 2008 PQRI will not be made until 2009. An eligible professional who satisfactorily reports PQRI quality measures data for the 2008 PQRI is eligible to receive an incentive payment equal to 1.5 percent of the eligible professional's total estimated Part B allowed charges for services furnished during the 2008 PQRI reporting period. No incentive payments will be made to eligible professionals for the E-Prescribing Incentive Program until CY 2010.

### 15. Program or Burden Changes

This is a new information collection requirement.

### 16. Publication and Tabulation Dates

This information is not published or tabulated.

### 17. Expiration Date

This collection of information applies to 2009 only. A separate (revised) document will be developed for subsequent years.

### 18. Certification Statement

There are no exceptions to the certification statement.

## C. Collection of Information Employing Statistical Methods

There have been no statistical methods employed in this collection.