<u>Supporting Statement – Part B</u>

Collections of Information Employing Statistical Methods

1. Describe (including a numerical estimate) the potential respondent universe and any sampling or other respondent selection method to be used. Data on the number of entities (e.g., establishments, State and local government units, households, or persons) in the universe covered by the collection and in the corresponding sample are to be provided in tabular form for the universe as a whole and for each of the strata in the proposed sample. Indicate expected response rates for the collection as a whole. If the collection had been conducted previously, include the actual response rate achieved during the last collection.

For the 2009 PQRI and the 2009 E-Prescribing Incentive Program, the respondent universe consists of the number of eligible professionals who attempt to participate in the PQRI by reporting PQRI quality measures data and/or who attempt to participate in the E-Prescribing Incentive Program by reporting data for the e-prescribing quality measure. 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. We anticipate that the number of respondents for the 2009 PQRI will be similar to the number of respondents for the 2007 PQRI. However, since the PQRI and the E-Prescribing Incentive Program are two separate incentive programs, it is possible that some eligible professionals may elect to participate in only one of the incentive programs while others may elect to report on both programs.

Participation in both incentive programs is voluntary. Therefore, there is no sampling or other method used by CMS to select respondents. However, eligible professionals who report PQRI quality measures data may elect to report data on a sample of patients rather than all patients and still meet the criteria for satisfactory reporting. As described in the CY 2009 Physician Fee Schedule final rule with comment period, the criteria for satisfactory reporting of individual quality measures in the 2009 PQRI require eligible professionals to report quality data on at least 3 PQRI quality measures for at least 80 percent of the cases in which a measure is reportable. The criteria for satisfactory reporting of measures groups in the 2009 PQRI, require eligible professionals to report quality data on at least 1 measures group for either at least 80 percent of the cases in which a measures group is reportable or on at least 30 consecutive patients. Similarly, eligible professionals who elect to report the e-prescribing measure may elect to report data on a sample of patients rather than all patients and still meet the criteria to be a successful electronic prescriber. In accordance with section 1848(m)(3)(B)(ii), a successful electronic prescriber is an eligible professional who reports the e-prescribing measure on at least 50 percent of the cases in which the measure is reportable.

2. Describe the procedures for the collection of information including:

- Statistical methodology for stratification and sample selection,

- Estimation procedure,
- Degree of accuracy needed for the purpose described in the justification,
- Unusual problems requiring specialized sampling procedures, and
- Any use of periodic (less frequent than annual) data collection cycles to reduce burden.

For the 2009 PQRI, there are 2 mechanisms for reporting PQRI quality measures data: claimsbased reporting or registry-based reporting. For claims-based reporting, eligible professionals report quality data codes on their Medicare Part B claims. For registry-based reporting, registries provide CMS with quality measures results and numerator and denominator data on quality measures on behalf of eligible professionals. For the 2009 E-Prescribing Incentive Program, only the claims-based reporting mechanism is available. CMS analyzes the information submitted via claims or registries 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 PORI quality measures data and/or who are successful electronic prescribers on the CMS Web site. Attached, as an example, are draft business requirements that will be used for extracting and analyzing data for 2008 PQRI reporting rates and performance rates from data submitted through claims.

3. Describe methods to maximize response rates and to deal with issues of non-response. The accuracy and reliability of information collected must be shown to be adequate for intended uses. For collections based on sampling, a special justification must be provided for any collection that will not yield 'reliable' data that can be generalized to the universe studied.

We believe that providing eligible professionals with multiple reporting options will help to maximize response rates.

We also believe that the satisfactory reporting criteria for the 2009 PQRI and the 2009 E-Prescribing Incentive Program, which allow eligible professionals to report quality measures data on a sample of patients rather than on all patients in which a measure is reportable, will help to maximize response rates. The satisfactory reporting criteria for claims-based reporting of individual measures under the 2009 PQRI based on reporting on 80 percent applicable cases and the requirements to be a successful electronic prescriber under the 2009 E-Prescribing Incentive Program based on reporting on 50 percent of applicable cases are required by statute. We have created reporting options for registry-based reporting and for reporting measures groups that based on reporting on 80 percent of applicable cases for consistency. We also developed reporting options for reporting measures groups based on a sample of 30 consecutive patients to increase response rates. Patient sample sizes of 30 are commonly considered to be a reasonable minimum threshold for being able to reliably report health care performance measurement results. Results from our Better Quality Information for Medicare Beneficiaries (BQI) pilot project indicate that minimum patient sample sizes of between 30 through 50 patients per physician are needed to make reliable distinctions between physicians' performance. In addition, we decided to require a consecutive patient sample rather than a random sample of 30 patients so that eligible professionals would not be able to cherry-pick cases in an attempt to improve their performance results.

We expect additional experience with PQRI reporting to clarify optimal sample sizes and reporting criteria for use in future reporting periods. We will continually evaluate our policies on sampling and notify the public through future notice and comment rulemaking if we make substantive changes. As we evaluate our policies, we plan to continue a dialogue with stakeholders to discuss opportunities for program efficiency and flexibility.

4. Describe any tests of procedures or methods to be undertaken. Testing is encouraged as an effective means of refining collections of information to minimize burden and improve utility. Tests must be approved if they call for answers to identical questions from 10 or more respondents. A proposed test or set of tests may be submitted for approval separately or in combination with the main collection of information.

As stated above, we expect that additional experience with PQRI reporting will clarify optimal sample sizes and reporting criteria for use in future reporting periods. We will continually evaluate our policies based on our analysis of the PQRI data.

5. Provide the name and telephone number of individuals consulted on statistical aspects of the design and the name of the agency unit, contractor(s), grantee(s), or other person(s) who will actually collect and/or analyze the information for the agency.

Contractor who actually analyzes information collected: Iowa Foundation for Medical Care