Supporting Statement – Part B

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 2010 PQRI and the 2010 eRx Incentive Program, the respondent universe consists of the number of eligible professionals and group practices who attempt to participate in the PQRI by reporting data on PQRI quality measures and/or who attempt to participate in the E-Prescribing Incentive Program by reporting data on the electronic prescribing measure. Results from the 2007 PQRI (the first year of PQRI reporting) indicate that close to 110,000 TIN/NPI combinations attempted to submit PQRI quality measures data via claims in 2007. 2007 is the last year for which official participation numbers have been released. Preliminary numbers from the 2009 PQRI indicate that close to 35,000 TIN/NPI combinations attempted to submit PQRI quality measures data via registry in 2009. Since the first year of PQRI EHR reporting is 2010, we are assuming that the number of eligible professionals who choose to participate in the 2010 PQRI via EHR reporting will be similar to the number of eligible professionals who choose the registry-based reporting mechanism. Therefore, we are assuming that there will be a total of approximately 180,000 individual eligible professionals who choose to participate in the 2010 PQRI. In addition, we estimate that there are approximately 200 group practices eligible to participate in the 2010 PQRI and eRx Incentive Program as a group practice. If we assume that all will participate in the PQRI and eRx Incentive Program as group practices for 2010, then there would be approximately 200 group practice respondents for 2010. However, since the PQRI and the eRx 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.

Similarly, for the 2011 PQRI and 2011 eRx Incentive Program, we are assuming that there will be a total of approximately 180,000 individual eligible professional respondents. With respect to group practices, we know that only 36 group practices chose to participate in the 2010 PQRI group practice reporting option (GPRO I). Therefore, we will assume that these 36 groups will also choose to participate in the GPRO I. Since we are also piloting a second group practice reporting option (GPRO II) in 2011 among up to 500 group practices, we will also assume that an additional 500 group practices will be participating in the 2011 PQRI and 2011 eRx Incentive Program as group practices for a total of 536 group practices.

There is no sampling or other method used by CMS to select respondents. However, individual eligible professionals who report PQRI quality measures data and/or the electronic prescribing measure may elect to report data on a sample of patients rather than all patients and still meet the criteria for satisfactory reporting. For each PQRI quality measure or measures group

that an eligible professional reports, the 2010 criteria for satisfactory reporting utilize different patient sampling methods. Eligible professionals can choose to report the PQRI measures or a measures group for at least 80 percent of the cases in which a measure or a measures group is reportable. Or, eligible professionals can choose to report a measures group on 30 applicable patients. Similarly, eligible professionals who elect to report the electronic 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. For the 2010 E-Prescribing Incentive Program, we have revised the reporting criteria for the electronic prescribing measure to require individual eligible professionals to report the electronic prescribing measure for 25 instances rather than to report the measure for 50% of applicable cases. The 2011 reporting criteria are identical to the 2010 criteria except for we are reducing the sampling requirement from 80% to 50% for claims-based reporting of PQRI measures.

Similarly, group practices who report PQRI quality measures data and/or the electronic prescribing measure may elect to report data on a sample of patients rather than all patients and still meet the criteria for satisfactory reporting. Under the PQRI group practice reporting option (GPRO I for the 2011 PQRI), we will be using the same methods used in the Physician Group Practice Demonstration, which is currently approved under OMB Control Number 0930-0941. That is, Medicare fee-for-service patients are assigned to a physician practice if the practice provides the plurality of outpatient evaluation & management services to the patient during the performance year. The assigned patient population is the foundation from which to measure quality performance. Diagnostic data from all claims for each assigned beneficiary are used to determine whether that beneficiary has a particular condition such as diabetes, congestive heart failure, coronary artery disease, or a range of other chronic conditions. A beneficiary may be counted in one or more of each of those categories based on the number of conditions s/he has. The clinical measure denominator criteria, such as age, gender, hospitalization, etc. are further applied to each diagnostic sub-group of beneficiaries to determine which patients are eligible for reporting on the measure. Claims-based measures are derived from the full subpopulation of assigned beneficiaries who meet the clinical criteria for the measure. For the PQRI group practice reporting option, a sample of Medicare patients will be pulled from this subpopulation and input in the Performance Assessment Tool in rank order for practices to complete reporting on. In order to be considered a satisfactory reporter for the PQRI, group practices will need to complete the tool for 411 of the assigned patients in rank order and may only exclude patients if they cannot confirm the diagnosis or if they meet one of the exclusion criteria for the measure. For group practices participating in the E-Prescribing Incentive Program group practice reporting option, a group practice needs to report electronic prescribing measure for only 2500 instances for the group practice to be considered a successful electronic prescriber.

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 2010 and 2011 PQRI, there are 3 mechanisms for individual eligible professionals to report PQRI quality measures data: claims-based reporting, registry-based reporting, or EHR-based reporting. For claims-based reporting, eligible professionals report quality data codes on their Medicare Part B claims when they submit their Medicare Part B claims for payment. 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 EHR-based reporting, eligible professionals extract the relevant quality data from their EHR and submit it to a CMS-designated clinical quality data warehouse. These same 3 reporting mechanisms are also available to individual eligible professionals and group practices for the 2010 and 2011 eRx Prescribing Incentive Program.

To be consistent with the PGP demonstration, we will be employing the National Committee for Quality Assurance's hybrid methodology for capturing and reporting data for group practices participating in the PQRI under the GPRO for 2010 and GPRO I for 2011. This method requires the practice to identify the numerator of a measure through either administrative or medical record data. The denominator consists of either the total population of Medicare beneficiaries assigned to the practice who are eligible for the measure or a systematic sample of Medicare beneficiaries drawn from the measure's eligible population as defined above using Medicare claims data. A sample of 411 Medicare patients per measure module is pulled, rank ordered, and loaded into the PAT. The target sample size is designed to produce 95% confidence intervals of +/- 5% or less for a quality indicator rate.

CMS analyzes the information submitted by individual eligible professionals via claims, registries, EHRs and by group practices via the PAT for the 2010 PQRI and via claims, registries, and EHRs for the eRx Incentive Program to: (1) determine whether an eligible professional or group practice meets the criteria for satisfactory reporting of quality measures data for the given program year and/or the criteria for successful electronic prescribers for the eRx Incentive Program for the given program year, (2) to calculate and make incentive payments to eligible professionals and group practices 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 and group practices who satisfactorily report PQRI quality measures data and/or who are successful electronic prescribers on the CMS Web site. In addition to the above, CMS, for 2011 will also be analyzing the information submitted by individual eligible professionals via claims and registries for GPRO II.

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 in addition to being eligible for one or more incentive payments, providing

eligible professionals and group practices with multiple reporting options will help to maximize response rates. We also believe that the satisfactory reporting criteria, 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.

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.

With respect to group practices, we anticipate that all group practices participating under the PQRI and eRx Incentive Program group practice reporting option will be responsive since the group practices were required to self-nominate to participate in the PQRI and eRx Incentive Program group practice reporting option. Not only did the group practices voluntarily agree to participate in both incentive programs, but the group practices are also eligible to receive incentive payments for meeting the criteria for satisfactory reporting of PQRI quality measures and/or the criteria for a successful electronic prescriber.

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. For the group practice reporting option for the PQRI, we note that the methodology was derived from commercially available methods used to compute quality measures in the commercial and Medicare managed care environment.

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 analyzes information collected from individual eligible professionals participating in the PQRI and individual eligible professionals and group practices participating in the eRx Incentive Program: Iowa Foundation for Medical Care

For the methods employed in the PQRI group practice reporting option, which were adopted from the PGP demonstration, the National Committee for Quality Assurance and RTI International were consulted on the development of the sampling methodology. The contractor that will administer the quality reporting methodology for the PQRI group practice reporting option has yet to be determined.