**Supporting Statement – Part B:**

**Physician Quality Reporting System (CYs 2013 and 2014)**

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 PQRS (formerly the Physician Quality Reporting Initiative or PQRI), the respondent universe consists of the number of eligible professionals and group practices who attempt to participate in the PQRS by reporting data on PQRS quality measures and/or who attempt to participate in the Electronic Prescribing (eRx) Incentive Program by reporting data on the electronic prescribing measure. We will base our estimates for this respondent universe on data included in the “2009 Reporting Experience,” which includes the most recent available data related to participation in the PQRS.

 From 2007 through 2010, participation in the Physician Quality Reporting System has increased incrementally. According to the 2010 Experience Report, past participation in the Physician Quality Reporting System is as follows:

* In 2007, 98,696 out of 621,840 eligible professionals participated in the Physician Quality Reporting System (then known as the Physician Quality Reporting Initiative or PQRI). Therefore, approximately 16% of professionals eligible to participate did so in 2007.
* In 2008, 164,840 out of 977,415 eligible professionals participated in the Physician Quality Reporting System (then known as the Physician Quality Reporting Initiative or PQRI). Therefore, approximately 17% of professionals eligible to participate did so in 2008.
* In 2009, 221,858 out of 1,042,260 eligible professionals participated in the Physician Quality Reporting System (then known as the Physician Quality Reporting Initiative or PQRI). Therefore, approximately 21% of professionals eligible to participate did so in 2009.
* In 2010, 224,145 out of 1,017,664 eligible professionals participated in the Physician Quality Reporting System (then known as the Physician Quality Reporting Initiative or PQRI). Therefore, approximately 22% of professionals eligible to participate did so in 2010.

 The participation rates provided above show that participation in the Physician Quality Reporting System has slowly increased with each year. It is the Physician Quality Reporting System’s goal to bring the program’s participation rate to 50%. We believe that participation rates will steadily increase to meet this goal of 50% participation, primarily due to the implementation of payment adjustments that begin in 2015. We anticipate that the first sharp rise in participation rates will occur in CY 2013, as the reporting period for the 2015 payment adjustment occurs in 2013. We anticipate an incremental rise in the Physician Quality Reporting System’s participation rates from 30% in 2013 to 40% in 2014 to 50% in 2015 primarily as the reporting requirements for the Physician Quality Reporting System payment adjustments move to parallel the reporting requirements of 2013 and 2014 the Physician Quality Reporting System incentives. In 2009 and 2010, we have seen that the number of professionals eligible to participate in the Physician Quality Reporting System have been approximately 1 million. Therefore, we estimate that approximately (1 million x 30%) 300,000 eligible professionals will participate in 2013 to (1 million x 40%) 400,000 eligible professionals in 2014 to (50% x 1 million) 500,000 in 2015.

 There is no sampling or other method used by CMS to select respondents. However, individual eligible professionals who report PQRS 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 PQRS quality measure or measures group that an eligible professional reports, the criteria for satisfactory reporting utilize different patient sampling methods. Eligible professionals can choose to report the PQRS measures or a measures group for at least 50 percent (for claims) or 80 percent (for registry and EHR) 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. The 2013 and 2014 reporting criteria are largely similar to the 2012 criteria for satisfactory reporting aside from the proposal of reporting options for the EHR-based reporting mechanism that are intended to align with the reporting requirements for meeting the clinical quality measure (CQM) objective of meaningful use (MU) under the EHR Incentive Program.

 In addition, we estimate that there are approximately 200 group practices eligible to participate in the 2011 PQRS under GPROs I and II. If we assume that all will participate in the PQRS as group practices for CYs 2013 and 2014, then there would be approximately 200 group practice respondents for CYs 2013 and 2014. Please note that this group practice estimate only applies to group practices who use the GPRO web-interface, as we view the proposed satisfactory reporting criteria for group practices using the claims, registry, and EHR-based reporting mechanisms more akin to individual reporting.

 There is no sampling or other method used by CMS to select respondents with respect to GPRO participation. Group practices who report PQRS 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 PQRS group practice reporting option (GPRO) for group practices comprised of 100+ eligible professionals, we will be using the same methods used in the Physician Group Practice (PGP) Demonstration, which is currently approved under OMB Control Number 0930-0941. For group practices comprised of 25-99 eligible professionals participating under GPRO, we will be using the same methods used in the Medicare Care Management Performance (MCMP) demonstration. 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 PQRS GPRO, a sample of Medicare patients will be provided by group practices from this subpopulation and input in the GPRO Web Interface in rank order for practices to complete reporting on. In order to be considered a satisfactory reporter for the PQRS, group practices will need to complete the tool for 411 (for group practices comprised of 100+ eligible professionals) or 218 (for group practices comprised of 25-99 eligible professionals) 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.

**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 PQRS, there are 3 mechanisms for eligible professionals and group practices to report PQRS quality measures data for the 2013 and 2014 PQRS incentives and 2015 and 2016 PQRS payment adjustments: 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. In addition, group practices have the option to report PQRS quality measures data for the 2013 and 2014 PQRS incentives and 2015 and 2016 PQRS payment adjustments using the GPRO web-interface.

 To be consistent with the PGP demonstration, we employed the National Committee for Quality Assurance’s hybrid methodology for capturing and reporting data for group practices participating in the PQRS under the 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.

**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 reporting under the PQRS 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 the PQRS and eRx Incentive Program 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 PQRS data. For the GPRO for the PQRS, 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 PQRS and individual eligible professionals and group practices participating in the eRx Incentive Program: CSC.

 For the methods employed in the PQRS 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 Physician Quality Reporting System group practice reporting option: CSC.