

Supporting Statement – Part B:
Physician Quality Reporting System (PQRS) for 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. We will base our estimates for this respondent universe on data included in the 2010 PQRS and eRx Experience Report, which includes the most recent available data related to participation in the PQRS.

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

- In 2007, 98,696 out of 621,840 eligible professionals participated in the PQRS (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 PQRS (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 PQRS (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 PQRS (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 PQRS has slowly increased with each year. It is the PQRS'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 periods for the 2015 payment adjustment occur in 2013. We anticipate a rise in the PQRS's participation rates from 30% in 2013 to 40% in 2014 to 50% in 2015 primarily as the reporting requirements for the PQRS payment adjustments move to parallel the reporting requirements of 2013 and 2014 the PQRS incentives. In 2009 and 2010, we have seen that the number of professionals eligible to participate in the PQRS have been approximately 1 million. Accordingly, we expect that the number of professionals eligible to participate in PQRS for any given year will be 1 million.

Therefore, we estimate that number of eligible professionals participating in PQRS will rise to approximately (1 million x 30%) 300,000 eligible professionals in 2013 to (1 million x 40%) 400,000 eligible professionals in 2014. We expect to reach our goal of a 50% participation rate in 2015, when the ability to earn a PQRS incentive will cease, leaving only the ability to earn payment adjustments under PQRS.

There is no sampling or other method used by CMS to select respondents. However, individual eligible professionals who report PQRS 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. 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 for a certain percentage of applicable patients – 50 percent for claims and 80 percent for registry and EHR (for 2013 only). Eligible professionals can also choose to report a measures group on 20 applicable patients. The 2013 and 2014 reporting criteria are largely similar to the 2012 criteria for satisfactory reporting aside from the satisfactory reporting criteria using the EHR-based reporting mechanism that aligns with the reporting requirements for meeting the clinical quality measure (CQM) objective of meaningful use (MU) under the EHR Incentive Program.

In addition, eligible professionals may choose to report with their group practice, rather than reporting as individuals. In 2011, which is the latest information we have available regarding participation in the group practice reporting option (GPRO), approximately 200 group practices participated in the PQRS GPRO. If we assume that all will again participate in the PQRS as group practices via the GPRO for CYs 2013 and 2014 using the GPRO web-interface, then there would be approximately 200 group practice respondents using the GPRO web-interface for CYs 2013 and 2014. Note: This group practice estimate only applies to group practices that will use the GPRO web-interface, as we view the satisfactory reporting criteria for group practices using the registry and EHR-based reporting mechanisms as 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 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 was 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 5 reporting mechanisms for eligible professionals and group practices to report PQRS quality measures data for the 2013 and 2014 PQRS incentives and/or 2015 and 2016 PQRS payment adjustments:

1. The claims-based reporting mechanism: This reporting mechanism is only available to eligible professionals for purposes of reporting for the 2013 and 2014 PQRS incentives and 2015 and 2016 PQRS payment adjustments. 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.
2. The registry-based reporting mechanism: This reporting mechanism is available to eligible professionals and group practices using the GPRO for purposes of reporting for the 2013 and 2014 PQRS incentives and 2015 and 2016 PQRS payment adjustments. For registry-based reporting, registries provide CMS with quality measures results and numerator and denominator data on quality measures on behalf of eligible professionals.
3. The EHR-based reporting mechanism: This reporting mechanism is available to eligible professionals and, beginning in 2014, to group practices using the GPRO for purposes of reporting for the 2013 (for eligible professionals only) and 2014 PQRS incentives and 2015 (for eligible professionals only) and 2016 PQRS payment adjustments. 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.
4. The GPRO web interface: This reporting mechanism is available to group practices using the GPRO for purposes of reporting for the 2013 and 2014 PQRS incentives and 2015 and 2016 PQRS payment adjustments. For the GPRO web interface, group practices report certain measures in the GPRO measure set on an assigned sample of patients.

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. 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.

5. The administrative claims-based reporting mechanism: This reporting mechanism is only available to eligible professionals and group practices for purposes of reporting for the 2015 PQRS payment adjustment. Please note that, since CMS performs the measure calculations based on the claims eligible professionals and group practices would otherwise submit for reimbursement purposes, there is no burden associated with eligible professionals and group practices using this reporting mechanism. Therefore, use of this reporting mechanism is not included in our estimate.

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 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 (GPRO), 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 PQRS GPRO: CSC.