

**Supporting Statement – Part B:**  
**Physician Quality Reporting System (PQRS) for CY 2016**

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 2013 PQRS and eRx Experience Report, which includes the most recent available data related to participation in the PQRS.

From 2007 through 2011, 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.
- In 2011, 320,422 out of 1,101,773 eligible professionals participated in the PQRS. Therefore, approximately 29% of professionals eligible to participate did so in 2011. Of the 320,422 eligible professionals participating in PQRS in 2011, 266,521 of these eligible professionals (encompassing 26,515 practices) earned a total of \$261,733,236 in PQRS incentives.
- In 2012, 435,871 out of 1.2 million eligible professionals (36 percent) (including those who belonged to group practices that reported under the GPRO and eligible professionals within an ACO that participated in the PQRS via the GPRO) participated in the PQRS, Medicare Shared Savings Program, or Pioneer ACO Model.

According to the 2013 PQRS and eRx Experience Report more than 1.25 million eligible professionals were eligible to participate in the PQRS, Medicare Shared Savings Program, and

Pioneer ACO Model. In 2013, 641,654 out of 1.25 million eligible professionals (51 percent) (including those who belonged to group practices that reported under the GPRO and eligible professionals within an ACO) participated in PQRS, a six-fold increase from 2007.

We expect to see a steady increase in participation in reporting for the PQRS in 2016 over 2013. Eligible professionals are now more familiar with payment adjustments since eligible professionals are currently experiencing the implementation of the first PQRS payment adjustment, the 2015 PQRS payment adjustment. Therefore, we estimate that 70 percent of eligible professionals (or approximately 840,000 eligible professionals) will report quality measures data for purposes of the 2018 PQRS payment adjustment.

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 or satisfactory participation. For each PQRS quality measure or measures groups that an eligible professional reports, the criteria for satisfactory reporting or, in lieu of satisfactory reporting, satisfactory participation, utilize different patient sampling methods. Eligible professionals can choose to report individual PQRS measures for a certain percentage of applicable patients – e.g., 50 percent for claims and registry reporting. For the 2018 PQRS payment adjustment, we are adding to the 9 measures covering 3 National Quality Strategy (NQS), that if an eligible professional sees 1 Medicare patient face-to-face encounter they must report on at least 1 cross cutting MS (included in the 9 MS). Eligible professionals can also choose to report a one measures group on 20 applicable patients, a majority of patients (11 out of 20) must be Medicare Part B FFS patients.

Eligible professionals in a group practice which are comprised of two or more eligible professionals may choose to report as a group practice using the GPRO web interface in addition to the registry or EHR-based reporting mechanisms. According to the 2013 PQRS and eRx Experience Report, 131,690 eligible professionals participated in PQRS as part of practices electing to participate under the group practice reporting option (GPRO), approximately 550 group practices participated in the PQRS GPRO, and 85,059 eligible professionals within 220 ACOs participated as an MSSP ACO. Including those participating using group reporting options, the overall participation rate was 51.2 percent, and the total number participating in the PQRS increased 47 percent from 2012 (approximately 200 group practices accounting for 134,510 eligible professionals).

Group practices participating in PQRS GPRO are increasing each year, from roughly 200 group practices in 2011 and 2012, to 860 eligible practices in 2013 (including all GPRO, Pioneer ACO, and MSSP ACO). However, not all group practices use the Web Interface to report. We will assume, based on these numbers that 500 group practices (accounting for approximately 228,000 eligible professional) will continue to participate in the PQRS using the GPRO Web Interface in 2016.

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 using the GPRO web interface, we will be using the same methods used in the Physician Group Practice (PGP) Demonstration, which was 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 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 248 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 6 reporting mechanisms for eligible professionals and group practices to report PQRS quality measures data for the 2018 PQRS payment adjustment:

1. The claims-based reporting mechanism: This reporting mechanism is only available to individual eligible professionals (not eligible professionals who are participating as a group practice under the GPRO). For claims-based reporting, the normal Medicare Part B claims submission process is used to collect data on quality measures from eligible professionals. Individual eligible professionals are not asked to provide any documentation by CD or hardcopy.
2. The registry-based reporting mechanism: This reporting mechanism is available to eligible professionals and group practices using the GPRO. 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. Reporting via qualified registry-based reporting mechanism or clinical qualified data registry

(QCDR): For qualified registry-based and QCDR-based reporting, qualified registries and QCDRs submit quality measures results with numerator and denominator data on PQRS measures or other measures to CMS on behalf of its eligible professional and group practice members electronically. There is no application for qualified registries that wish to self-nominate to become a qualified PQRS qualified registry. Qualified registries are asked to submit a self-nomination letter requesting inclusion in PQRS for each program year in which the qualified registry seeks to be qualified to submit quality measures data on behalf of its participants. There is also no application for clinical data qualified registries that wish to self-nominate to become a PQRS QCDR. QCDRs must meet established requirements for being qualified to participate in the PQRS as a QCDR and are asked to submit a self-nomination statement requesting inclusion in PQRS for each program year in which the clinical data qualified registry seeks to be qualified to submit quality measures data on behalf of its participants.

4. The EHR-based reporting mechanism: This reporting mechanism is available to eligible professionals and to group practices reporting via the GPRO option. For EHR-based reporting, eligible professionals and group practices extract the relevant quality data from their EHR and submit it to a CMS-designated clinical quality data warehouse.
5. The GPRO web interface: This group practice reporting mechanism stems from a previously OMB-approved data collection web interface (see OMB Control Number (OCN) 0938-1059). This web interface is an automated, electronic tool developed by CMS and refined with industry input. In prior years, this web interface was the “PAT,” or Performance Assessment Tool. It was developed explicitly for specific Medicare demonstrations and has been used successfully over the past 4 years for these demonstrations. Although we moved away from use of the PAT, we note that the GPRO Web Interface that will be used is similar in terms of burden to using the PAT. This reporting mechanism is available to group practices comprised of 25 or more eligible professionals using the GPRO. For the GPRO web interface, group practices report certain measures in the GPRO measure set on an assigned sample of patients.
6. The CMS-certified survey vendor: Please note that discussion of this certified survey vendor option is discussed in a separate PRA package (OMB control number 0938-1222, CMS-10450#). Therefore, we do not address this reporting option in this PRA package.

**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.**

Eligible professionals or group practices who do not satisfactorily report or satisfactorily participate in PQRS in 2016 for the applicable 2018 PQRS payment adjustment reporting period will be subject to a payment adjustment equal to 2.0 percent of the total estimated allowed charges (professional covered services). We believe providing eligible professionals and group practices with multiple reporting options will help to maximize satisfactory reporting or satisfactorily

participation rates.

We expect additional experience with reporting under the PQRS for the payment adjustment 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 PQRS group practice reporting option GPRO web interface, we note that the sampling 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: CSC.

For the methods employed in the PQRS group practice reporting option (GPRO) web interface, 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 sampling methodology for the PQRS GPRO web interface: RTI.