

**Supporting Statement – Part B:
Physician Quality Reporting System (CY 2012) and the Electronic Prescribing Incentive
Program (CYs 2012 through 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.

Physician Quality Reporting System: (2012 Program Year)

For the 2012 Physician Quality Reporting System (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 Physician Quality Reporting System by reporting data on Physician Quality Reporting System 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 Physician Quality Reporting System.

Results from the 2009 Physician Quality Reporting System indicate that approximately 221,858 eligible professionals (identified at the TIN/NPI level) participated in the Physician Quality Reporting System via claims and registry in 2009. Of these 221,858 eligible professionals, 188,603 eligible professionals attempted to submit data on Physician Quality Reporting System measures via claims and 33,055 eligible professionals attempted to submit data on Physician Quality Reporting System measures via registry. As EHR-based reporting was not introduced into the program until 2010, we currently have no data on participation on EHR-based reporting. However, we are assuming that the number of eligible professionals who choose to participate in the 2012 Physician Quality Reporting System via EHR reporting will be similar to the number of eligible professionals who choose the registry-based reporting mechanism. We assume there will be at least a 1.0% increase in participation from 2009 to 2012. Therefore, we are assuming that a total of at least 228,579 eligible professionals will participate in the 2012 Physician Quality Reporting System. Of these 228,579 eligible professionals, we believe that approximately 33,385 (or approximately 35,000) eligible professionals will use the registry-based mechanism and 33,385 (the same amount) of eligible professionals will use the EHR-based reporting mechanism. We therefore estimate that 161,809 eligible professionals will participate using the claims-based reporting mechanism. We believe that eligible professionals that reporting via claims in 2009 will switch to EHR-based reporting, due to greater availability of EHRs and the various incentives CMS is providing for eligible professionals that adopt EHRs under programs such as the EHR Incentive Program.

There is no sampling or other method used by CMS to select respondents. However, individual eligible professionals who report Physician Quality Reporting System 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 Physician Quality Reporting System quality measure or measures group that an eligible professional reports, the 2012 criteria for satisfactory reporting utilize different patient sampling methods. Eligible professionals can choose to report the Physician Quality Reporting System 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 2012 reporting criteria are identical to the 2011 criteria for satisfactory reporting Physician Quality Reporting System core measure aside from requiring the reporting of measures with a performance rate of greater than 0.

In addition, we estimate that there are approximately 200 group practices eligible to participate in the 2011 Physician Quality Reporting System under GPROs I and II. If we assume that all will participate in the Physician Quality Reporting System as group practices for 2012, then there would be approximately 200 group practice respondents for 2012.

There is no sampling or other method used by CMS to select respondents with respect to GPRO participation. Group practices who report Physician Quality Reporting System 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 Physician Quality Reporting System 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 Physician Quality Reporting System 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 Physician Quality Reporting System, 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.

For group practices participating in the eRx Incentive Program group practice reporting option, a group practice needs to report electronic prescribing measure for only 2500 (for group practices comprised of 100+ eligible professionals) or 625 (for group practices comprised of 25-99 eligible professionals) instances for the group practice to be considered a successful electronic prescriber.

Electronic Prescribing (eRx) Incentive Program: (Program Years 2012—2014)

For the eRx Incentive Program, the respondent universe consists of the number of eligible professionals and group practices who attempt to participate in the 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 eRx Incentive Program.

Results from the 2009 eRx Incentive Program indicate that approximately 92,132 eligible professionals (identified at the TIN/NPI level) participated via the claims-based reporting mechanism in 2009. Since neither the registry nor EHR-based reporting mechanisms were available under the eRx Incentive Program in 2009. We assume the number of eligible professionals participating in the eRx Incentive Program will increase by at least 12% to 100,800 eligible professionals. Of these 100,800, we believe that the same number of eligible professionals using the registry and EHR-based reporting mechanisms will use these mechanisms to report the electronic prescribing measure under the eRx Incentive Program, because these eligible professionals have already adopted these respective systems. Therefore, we believe that 33,385 eligible professionals will use the registry-based reporting mechanism and another 33,385 eligible professionals will use the EHR-based reporting mechanism. Therefore, of these 100,800 eligible professionals, 34,030 will use the claims-based reporting mechanism.

There is no sampling or other method used by CMS to select respondents. However, individual 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. We retained the 2011 reporting criteria for the electronic prescribing measure to require individual eligible professionals to report the electronic prescribing measure for 25 instances (for the incentive) or 10 instances (for the payment adjustment) rather than to report the measure for 50% of applicable cases (which was the reporting criteria for 2009).

With respect to group practices, we know that approximately 6 group practices chose to participate in the 2011 Physician Quality Reporting System group practice reporting option (GPRO I). Therefore, we will assume that these 6 groups will also choose to participate in the GPRO for 2012. In 2011, we also piloted a second group practice reporting option (GPRO II) among up to 500 group practices. Approximately 50 group practices chose to participate in the 2011 GPRO II. Therefore, we will also assume that an additional 50 group practices will be participating in the 2012 Physician Quality Reporting System as group practices for a total of 56 group practices.

There is no sampling method used by CMS to select respondents for GPRO participation. For group practices participating in the eRx Incentive Program GPRO, a group practice needs to report electronic prescribing measure for only 2500 (for group practices comprised of 100+ eligible professionals) or 625 (for group practices comprised of 25-99 eligible professionals) 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 2011 Physician Quality Reporting System, there are 3 mechanisms for individual eligible professionals to report Physician Quality Reporting System 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 2011 eRx Incentive Program for purposes of the incentive and 12-month 2014 payment adjustment reporting period (January 1, 2012—December 31, 2012). However, only the claims-based reporting mechanism is available to individual eligible professionals and group practices for the 6-month, 2013 and 2014 payment adjustment reporting periods (January 1, 2012—June 30, 2012 and January 1, 2013—June 30, 2013 respectively).

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 Physician Quality Reporting System 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.

CMS analyzes the information submitted by individual eligible professionals via claims, registries, EHRs and by group practices via the PAT for the 2011 Physician Quality Reporting System 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 Physician Quality Reporting System quality measures data and/or who are successful electronic prescribers on the CMS Web site.

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 Physician Quality Reporting System and eRx Incentive Program 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 Physician Quality Reporting System and eRx Incentive Program GPRO will be responsive since the group practices were required to self-nominate to participate in the Physician Quality Reporting System 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 Physician Quality Reporting System 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 the Physician Quality Reporting System 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 Physician Quality Reporting System data. For the GPRO for the Physician Quality Reporting

System, 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 Physician Quality Reporting System and individual eligible professionals and group practices participating in the eRx Incentive Program: CSC.

For the methods employed in the Physician Quality Reporting System 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.