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.

RESPONSE:

This data collection effort is being conducted as part of data collection requirements under the Electronic Health Records Demonstration. The demonstration includes approximately 400 primary care physician practices that will be asked to submit data on clinical quality measures using the new tool. Participation in the demonstration is totally voluntary and practices may terminate their participation at any point. However, all physician practices participating in the demonstration will be required to submit the clinical quality data collected using this tool in order to earn financial incentives under the terms of the demonstration agreement. Thus the expected response rate is close to if not 100%.

In previous demonstrations (the Physician Group Practice demonstration and the Medicare Care Management Performance demonstration) in which the precursor to this current tool was used, participation was nearly 100%. The few practices that did not complete the tool did not do so for reasons unique to the practice and were not eligible to earn incentives under those demonstrations for that year. In most cases, the practice was able to report the data in subsequent years or terminated its participation.

The tool enables practices to report on 26 clinical quality measures relating to coronary artery disease, diabetes mellitus, congestive heart failure and certain preventive care services. Because the demonstration involves smaller practices, in most cases, a practice will report on all patients that qualify for a measure. However, in order to reduce the administrative burden of reporting for those larger practices that have many patients eligible for each measure, we employ a sampling methodology to randomly select patients for whom the practices will report. This enables us to ease the burden on practices while maintaining statistical reliability in the data consistent with commercially used data collection methodologies (e.g. the HEDIS guidelines established by the National Committee for Quality Assurance). For the EHR Demonstration, most practices will have less than 218 patients eligible for reporting on the measures. However, for the limited number of practices that do have a larger patient base, the maximum number of patients reported per reporting condition ((e.g. coronary artery disease or diabetes) is 218. The decision on the actual sample size was determined by professional statisticians employed by our demonstration data collection support contractor in an effort to reduce the reporting burden.

1

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.

RESPONSE:
There is no difference in the data collection methodology for those practices that report on all eligible patients vs. those that report on a sample of patients. Reporting on a less than annual basis would not meet the design requirements of the demonstration which call for an annual incentive based on reporting quality measures during the most recent demonstration year. This is consistent with other quality measure data collection efforts (e.g. PQRI, HEDIS, etc.) which are also conducted on an annual basis.

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.

RESPONSE:
All practices are required to respond in order to receive incentive payments under the demonstration. Staff from our Data Collection Support Contractor provides technical assistance to practices in order to help them respond and minimize reporting burden.

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.

RESPONSE:
The proposed data collection tool is a modification (web enabling and enhanced security) to an existing tool that has been used successfully with small and large physician practices in a

variety of settings for more than 5 years. Enhanced training and technical assistance as well as refinements to the tool are be made on an annual basis in response to feedback from practices and as deemed needed to improve functionality and ease of use.

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.

RESPONSE:
The data collection contractor for the demonstration is RTI, International. Please contact the CMS Project Officer for more information regarding the technical aspects of data collection.