Supporting Statement for the Business Proposal Forms for Quality Improvement Organizations (QIO) - PART A

A. Background

In 1982, Congress modified requirements for medical peer review in the Medicare program and passed the "Peer Review Improvement Act" of 1982. This legislation was enacted as part of the Tax Equity and Fiscal Responsibility Act of 1982 (P.L. 97-248), which authorizes the establishment of Quality Control Peer Review Organizations (PROs), currently known as Quality Improvement Organizations (QIOs). The QIO program was designed, as described in 42 CFR parts 475, 476, 478, and 480, to redirect and enhance cost-effectiveness of Medicare peer review.

Prior to the original inception of this business proposal format, QIO business (i.e., contract) proposals submitted to the Centers for Medicare and Medicaid Services (CMS) have not categorized the components of price (i.e., cost to the Government) of QIO activities in a manner that is satisfactory for contract negotiations. Beginning in the fifth round of contracts, CMS requested that QIOs submit business proposals in the current format.

As explained in the instructions for completing these business proposal forms, a substantial portion of the cost data, on some of the forms, is automatically calculated from previous entries on other forms. The cost reports will be revised to collect data in the same format as the business proposals. Of the business proposal forms included in this revised package, only CMS Form 719 BP will be used for cost reporting purposes during the 5-year contract cycle. For this purpose, the form will be designated CMS Form 719.

The revised business proposal forms will be useful in a number of important ways. The Government will be able to compare the costs reported by the QIOs on the cost reports to the proposed costs noted on the business proposal forms. Subsequent contract and modification negotiations will be based on historic cost data. The business proposal forms will be one element of the historical cost data from which we can analyze future proposed costs. In addition, the business proposal format will standardize the cost proposing and pricing process among all QIOs. With well-defined cost centers and line items, proposals can be compared among QIOs for reasonableness and appropriateness.

With this submission, CMS is requesting approval of the following forms which are described below. Copies of these forms and instructions for completion are attached to this request.

CMS Form 718 BP - Quality Improvement Organization Business Proposal Summary

This form summarizes the offeror's proposed costs for the 5-year CMS Medicare Review Contract and CMS's recommended costs.

CMS Form 719 BP - Quality Improvement Organization Business Proposal

This form provides the offeror's proposed costs by contract task or activity. The form provides a detailed breakdown of the offeror's total 5-year cost proposal for the CMS Medicare Review Contract.

CMS Form 720 BP - Fringe Benefit Proposal

This form provides the details of the fringe benefit costs proposed on CMS Form 719 BP. The form furnishes the total fringe benefit costs for the CMS Medicare Review Contract.

CMS Form 721 BP - Indirect and Other Direct Cost

This form provides the details for the indirect and other direct costs proposed on CMS Form 719 BP. The form furnishes the total indirect/other direct costs for the CMS Medicare Review Contract.

CMS Form SUM - Staffing Proposal Summary

This form summarizes the offeror's labor cost information in the various categories needed to analyze the 5-year costs that the offeror proposes for the CMS Medicare Review Contract.

CMS Form STAFFING - Personnel Loading Chart

This form consolidates the information previously provided by 4 forms for each of the four categories of personnel (Professional, Information Systems, Corporate Management, and Support Staff) for the offeror's cost information. The format provides a high level of detail as costs are entered by individual positions and tasks. This format is needed to properly analyze the 5-year labor costs that the offeror proposes for the CMS Medicare Review Contract.

CMS Form SC 1 - Subcontracts Proposal, Physician Reviewers and Physician Advisors

This form provides cost details regarding the physician reviewers/advisors that will be used for the CMS Medicare Review Contract.

CMS Form SC 2 - Subcontracts Proposal, Other Consultants and Other Subcontractors

This form provides cost details regarding subcontractors, other than physician reviewers/advisors, who will be used for the CMS Medicare Review Contract.

CMS Form QIO ODC - Other Direct Costs

This form provides further details for the other direct costs proposed on CMS Form 21 BP. The form furnishes the other direct costs separated by the various categories for the CMS Medicare Review Contract.

CMS Form Other Beneficiary Protection Supplemental - Beneficiary Protection Supplemental Information.

This form furnishes the other beneficiary protection supplemental information separated by the various categories within this theme area for the CMS Medicare Review Contract.

CMS Form Travel Detail - QIO Travel Detail

This form details travel costs for the CMS Medicare Review Contract.

B. Justification

1. Need and Legal Basis

The Social Security Act, as amended by the Tax Equity and Fiscal Responsibility Reform Act of 1982 (TEFRA, P.L. 97-248), requires that a QIO (in accordance with its contract with CMS) review services and items provided by physicians, other health care practitioners, and providers of health care services for which Medicare payment is sought. The QIO's review will determine whether:

- the services and items are or were reasonable and medically necessary and meet specific Medicare coverage requirements;
- the quality of the services meets professionally recognized standards of health care; and
- those services and items proposed to be provided on an inpatient basis in a hospital or other health care facility could, consistent with the provision of appropriate medical care, be effectively provided more economically on an outpatient basis or in an inpatient health care facility of a different type.

Furthermore, the Social Security Amendments of 1982 (P.L. 98-21) established the Prospective Payment System (PPS) for Medicare, and amended section 1886(a)(1)(f) of

the Act to specify that for those hospitals subject to PPS, QIOs must review.

- the validity of diagnostic information supplied by the provider;
- the completeness, adequacy, and quality of care provided;
- the appropriateness of admissions and discharges; and
- the appropriateness of care provided or proposed to be provided for which payment is sought on an "outlier" basis under PPS.

The Omnibus Budget Reconciliation (OBRA) of 1986 added section 1154(a)(1) of the Social Security Act, which has a provision for QIO review of ambulatory surgery procedures performed in ambulatory surgery centers (ASC) and hospital outpatient departments.

Additionally, in the Health Care Quality Improvement Initiative for the Fourth Contract Cycle, CMS began a fundamental change in the way QIOs carried out their responsibilities. QIOs now place less emphasis on dealing with individual clinical concerns and focus more attention on helping physicians and providers improve the mainstream of care. QIOs also analyze patterns of care and outcomes. QIOs share their information with physicians and providers to help them identify ways to achieve the best success rates in improved outcomes and quality of care.

2. Information Users

This data is used by CMS to negotiate QIO contracts. CMS provided detailed information in Part A of this supporting statement.

3. Use of Information Technology

All current QIOs have computer capability for data generation, and will be required to use such capability to submit data to CMS electronically. The electronic collection of this information eases the burden to CMS staff when compiling and summarizing this information.

When the QIOs fill out these forms, 90% of the process takes place electronically. A non-electronic copy of the forms is required since the signed hardcopy of these business proposal forms constitutes a contract between the QIO and CMS and requires a written signature. For this reason CMS cannot accept only electronic copy in lieu of a hardcopy.

CMS also requires an electronic copy of the forms assist CMS in its analysis of the QIO business proposals. If the QIOs only sent in electronic copies of the business proposal

forms CMS would then have to allocate significant time and resources to the printing and compilation of these forms. Additional resources would be required for mailing the document back to the QIO for signature. Therefore to reduce CMS costs and burden both a hardcopy and electronic copy of the business proposal forms is required.

4. Duplication of Efforts

These are the only forms used by CMS to collect this data. They do not duplicate any other data.

5. Small Businesses

This does not affect small businesses.

6. Less Frequent Collection

The data requested on the forms is collected once every 5 years. The frequency of collection is not applicable, since this data is required to negotiate and award contracts for the CMS Medicare Review.

7. Special Circumstances

There are no special circumstances associated with this collection. This information collection is consistent with guidelines at 5 CFR 1320.5.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on May 16, 2014 and there were no public comments received.

9. Payments/Gifts to Respondents

There are no payments or gifts associated with this information collection.

10. Confidentiality

We do not pledge confidentiality.

11. Sensitive Questions

There are no questions of a sensitive nature.

12. Burden Estimates (Hours & Wages)

The information requested is required from respondents every 5 years to negotiate, renew, or award contracts. Offerors furnish this information in response to a Request for Proposal. For purposes of burden estimates, it is estimated that there will be approximately 20 respondents every year. This projection assumes that in an average year, one-fifth of the 53 current QIOs, plus an additional 47 competitive bidders, will submit Business Proposals for the twelfth round of the QIO contracts:

11 current + 9 prospective = 20 respondents

The annualized burden for each respondent of requested information is 50 hours. This is derived as follows:

Form	Learning About the Form	Preparing One Set of the Forms	Assembling and Sending All Forms to CMS
Form 718 BP	Learning about Form 718 BP: .25 hours.	Preparing one set of Form 718 BP: 0.4 hours.	Assembling and sending all Forms 718 BP to CMS: .80 hours.
Form 719 BP	Learning about Form 719 BP: .25 hours.	Preparing one set of Form 719 BP: 3.3 hours.	Assembling and sending all Forms 719 BP to CMS: .80 hours.
Form 720 BP	Learning about Form 720 BP: .25 hours.	Preparing one set of Form 720 BP: 1.7 hours.	Assembling and sending all Forms 720 BP to CMS: .80 hours.
Form 721 BP	Learning about Form 721 BP: .25 hours.	Preparing one set of Form 721 BP: 1.7 hours.	Assembling and sending all Forms 721 BP to CMS: .80 hours.
Staffing Form	Learning about the Staffing Form: .50 hours.	Preparing one set of the Staffing Form: 12.5 hours.	Assembling and sending all Staffing Forms to CMS: 1.7 hours.
Form SC 1	Learning about Form SC 1: .25 hours.	Preparing one set of Form SC 1: 3.3 hours.	Assembling and sending all Forms SC 1 to CMS: .80 hours.

Form SC 2	Learning about	Preparing one set of	Assembling and
	Form SC 2: .50	Form SC 2: 3.3	sending all Forms
	hours.	hours.	SC 2 to CMS: .80
			hours.
Staffing Summary	Learning about the	Preparing one set of	Assembling and
Form	Staffing Summary	the Staffing	sending all Staffing
	Form: .25 hours.	Summary Form: 0.4	Summary Forms to
		hours.	CMS: .80 hours.
ODC Form	Learning about the	Preparing one set of	Assembling and
	ODC Form: .25	the ODC Form: 3.3	sending all ODC
	hours.	hours.	Forms to CMS: .80
			hours.
Travel Detail Form	Learning about the	Preparing one set of	Assembling and
	Travel Detail Form:	the Travel Detail	sending all Travel
	.25 hours.	Form: 3.3 hours.	Detail Forms to
			CMS: .80 hours.
BFCC Supplemental	Learning about the	Preparing one set of	Assembling and
Schedule Form	BFCC	the BFCC	sending all BFCC
	Supplemental	Supplemental	Supplemental
	Schedule Form: .25	Schedule Form: 3.3	Schedule Forms to
	hours.	hours.	CMS: .80 hours.
Totals:	Total hours learning	Total hours	Total hours
	about the forms:	preparing one set of	assembling and
	3.25 hours.	the forms: 36.67	sending all forms to
		hours.	CMS: 10.00 hours.

Hours estimated for one set of forms: 50.0 hours.

Total hours for preparing forms: 36.67 hours.

Plus 3.25 hours learning about the forms.

Plus 10 hours assembling and sending all forms to CMS.

Equals a total annual burden per response of 50 hours.

Times 20 respondents annually equals 1,000 total hours.

All costs are incurred by contracts with CMS, see #14 below.

13. Capital Costs

The QIOs will not have any capital costs associated with this information collection that they would not have without this requirement.

14. Cost for Federal Government

All costs incurred by the QIOs are regarded as bids and proposal costs, and treated as required by Federal Acquisition Regulations (FAR). Cost estimates will vary between QIOs or offerors. On average, the hourly rate of the person completing these forms is equivalent to a General Schedule (GS) 12 (\$36.23 per hour). Once received, the forms are reviewed by a GS-12 federal employee for approximately eight hours; yielding a labor cost of \$289.84 (utilizing the current hourly rates reported by the <u>Office of</u> <u>Personnel Management</u>).

15. Changes to Burden

Due to changes in the scope of work, the total annual burden per response was reduced from **85** to **50** hours. The previous package included spreadsheets that are no longer required; e.g. CKD spreadsheet, Disparities spreadsheet, and Patient Pathways spreadsheet.

Furthermore, we anticipate a decrease in burden when these forms are used for the 12th round contract negotiations because the QIOs will be more familiar with the forms, and will have implemented the accounting system revisions for the corresponding cost reports.

16. Publication/Tabulation Dates

There are no publication and tabulation dates associated with this collection.

17. Expiration Date

CMS does not object to displaying the OMB expiration date.