

**Supporting Statement for the Information Collection Requirements for the form CMS-R-118 (Title “Quality Improvement -- formerly Peer Review -- Organization Contracts: Solicitation of Statements of Interest from In-State Organizations, General Notice,” and Supporting Regulations in 42 CFR 475.102, 475.103, 475.104, 475.105, 475.106)**

A. Background

Title XI, Part B, of the Social Security Act (hereinafter “the Act”) sets forth requirements that an organization must meet to be eligible for a contract as a Utilization and Quality Control Peer Review Organization. 42 CFR Subpart C, “Utilization and Quality Control Quality Improvement Organizations”, implements Title XI, Part B, of the Act. Specific regulatory text implementing eligibility requirements for entities to undertake QIO contracts is found at 42 CFR 475.

Quality Improvement Organizations (QIOs) -- formerly known as Peer Review Organizations (PROs) -- review health care services funded under Title XVIII of the Act (Medicare) to determine whether those services are reasonable, medically necessary, furnished in the appropriate setting, and meet professionally recognized standards of quality. Congress created the QIO program in the early 1980s in order to redirect, simplify, and enhance the consistency, effectiveness, and programmatic efficiency of the peer review services Medicare retains in order to provide utilization and quality control oversight of the medical care for which Medicare reimburses providers and practitioners.

CMS currently maintains 53 QIO contracts with organizations that provide professional medical peer review activities for each of the 50 States, the District of Columbia, Puerto Rico, and the Virgin Islands. The Territories of American Samoa, the Northern Marianas Islands, and Guam are included in a single geographic coverage region with the State of Hawaii.

Organizations eligible to contract as QIOs are those which satisfactorily demonstrate that they are: (1) physician-sponsored organizations that are composed of a substantial number of licensed doctors of medicine or osteopathy practicing medicine or surgery in the respective review area; or (2) physician-access organizations that have available, by contractual arrangement or otherwise, the services of a sufficient number of licensed doctors of medicine or osteopathy practicing medicine or surgery in the review area to assure adequate peer review of the services provided by the various medical specialties and subspecialties.

Payor organizations in a given designated QIO review area may be considered as potential QIO contractors if no eligible nonpayor organization is available to undertake the contract.

Currently, the QIO contractors for 13 of the review areas are out-of-state organizations, which is to say organizations based, owned, or primarily controlled from outside the review areas. Those areas are: Alaska, Delaware, District of Columbia, Hawaii, Idaho, Illinois, Maine, Nevada, Pennsylvania, Rhode Island, S. Carolina, Vermont, and Wyoming.

Section 1153(i)(2) of the Act states:

“Not later than six months before the date on which a contract period ends with respect to an organization that is not an in-State organization, the Secretary shall publish in the Federal Register--

(i) the date on which such period ends; and

(ii) the period of time in which an in-State organization may submit a proposal for the contract ending on such date.

(B) If one or more qualified in-State organizations submits a proposal within the period of time specified under subparagraph (A)(ii), the Secretary shall not automatically renew the current contract on a noncompetitive basis, but shall provide for competition for the contract in the same manner as a new contract under subsection (b).”

thus, the Secretary cannot renew the contract of any QIO that is not an in-State organization without first publishing in the Federal Register a notice announcing when the contract will expire. This notice must be published no later than 6 months before the date on which the contract will expire, and must specify the period of time during which an in-state organization may submit a proposal to undertake the contract. If one (or more) qualified in-State organizations submit proposal(s) within the specified time period, CMS must award the QIO contract in question on a competitive basis, as specified in Section 1153 of the Act.

For the purpose of contracting with QIOs, Section 1153(i)(3) defines as an “in-State” organization one “that has its primary place of business in the State in which review will be conducted (or, which is owned by a parent corporation the headquarters of which is located in such State).”

The requirement to publish in the Federal Register the expiration date of contracts for QIO review areas which are currently held by organizations which do not meet the statutory criteria for “in-State” organizations applies to contracts which will expire on July 31, 2008.

We intend to implement the requirements of the Act in the most equitable manner practicable. We will, therefore, publish in the Federal Register a notice of contract expiration dates for any and all QIO contract areas where doubt exists in respect to the incumbent QIO’s ability to meet the statutory definition of an “in-State” organization at the time the notice is published. We will require each organization interested in submitting proposals to undertake a contract as an “in-State” organization to demonstrate that it meets the criteria for “in-State” organization as defined at 1153(i)(3), as well as all other eligibility requirements to undertake the Medicare QIO contract, as established by Sections 1152 and 1153 of the Act. If we receive at least one statement of interest from qualified in-State organization(s) for any QIO contract area, we will conduct a full and open competition in the acquisition of medical review services for that area. All potential sources of QIO services, including qualified in-State organizations, will have access to the Request for Proposal (RFP) in the normal course of competitive procurements.

Our current OMB clearance for the publication of the notice of contract expiration dates with solicitation of statements of interest from qualified in-State sources expires on August 31, 2007. To comply with Section 1153 of the Act, we must publish the solicitation of statements of interest from qualified in-State organizations **no later than** January 31, 2008. We wish to publish notice of contract expiration dates and the time periods during which interested, qualified organizations may submit statements of interest and proposals for these contracts substantially sooner than the January 2008 deadline, in order to give maximal notice and opportunity to all qualified and potentially interested organizations.

## B. Justification

### 1. Need and Legal Basis

The criteria that an organization must satisfy in order to be eligible for a Medicare QIO contract are specified by law, set forth in Sections 1152 and 1153 of the Social Security Act (the Act). In very basic terms, the applicant organization must demonstrate that it is either a physician-sponsored or physician-access organization. The qualifications for in-State status for an otherwise qualified QIO organization are also set forth in Section 1153(i) (3) of the Act, as described above.

We are soliciting information in the form of responses to our request for statements of interest from qualified in-State organizations who may wish to compete for the QIO contracts for their respective States. The responses should contain indication of interest and information demonstrating the interested organizations' eligibility to qualify as a QIO under the requirements of Sections 1152 and 1153 of the Act.

### 2. Information Users

The information provided is used by the Centers for Medicare & Medicaid Services to identify qualified sources for the procurement of medical review services.

### 3. Improved Information Technology

Not applicable.

### 4. Duplication and/or Similar Information

The information required is not duplicative.

### 5. Small Business

These requirements may affect small businesses, but the nature of the requirements benefits the respondents. The respondents already maintain the information requested, and it is therefore no additional burden. Therefore, there is not a significant economic impact on small businesses.

### 6. Less Frequent Collection

These information requirements are collected on an as-needed basis. It is not a recurrent process.

### 7. Special Circumstances for Information Collection

There are no special circumstances associated with this collection. These requirements are consistent with the guidelines in 5 CFR 1320.6

8. Federal Register and Outside Consultation

The 60-day Federal Register notice was published on August 10, 2007, attached.

In the development of the final regulations that include these requirements, we considered the correspondence received from hospitals, hospital associations, business groups, and national medical organizations. The comments were discussed in the preamble to the final rule.

9. Payments or Gifts

There are no payments or gifts associated with this collection.

10. Confidentiality

We do not pledge confidentiality of the data obtained in this collection.

11. Sensitive Questions

There are no questions of sensitive nature.

12. Estimate of Burden

The regulatory text implementing and further defining the requirements to qualify as to undertake a QIO contract are located at 42 CFR: 475.102 & 475.103 (Eligibility of physician-sponsored or physician-access organization); 475.104 (Requirements for demonstrating ability to perform review); and 475.105 & 475.106 (Prohibition against contracting with health care facilities and payor organizations).

The information that an organization is required to supply to demonstrate that it is eligible for a QIO contract is information that it would ordinarily maintain in its files. Consequently, these requirements impose no additional burden on the respondent.

13. Annualized Cost of Burden

There are no annualized costs associated with this collection.

14. Federal Cost Estimates

The use of this information by the Centers for Medicare & Medicaid Services makes no change to the administrative cost of the QIO program.

15. Changes in Burden

There are no changes in burden at this time.

16. Publication and Tabulation Dates

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

17. OMB Expiration Date

This collection does not lend itself to the displaying of an expiration date.

18. Certification Statement

There are no exceptions to the certification statement.

C. Collections of Information Employing Statistical Methods

There are no statistical methods employed in this information collection.