Supporting Statement for Paperwork Reduction Act Submission

DMEPOS supplier Accreditation Proposals from Independent Accreditation Organizations

A. BACKGROUND

Section 302(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires the Secretary to establish and implement quality standards for suppliers of certain items to be applied by recognized independent accreditation organizations. Suppliers of DMEPOS must comply with the quality standards (and thus be accredited) to furnish any item for which payment is made under Medicare Part B.The Office of Management and Budget (OMB) has asked CMS to implement the DMEPOS Competitive Acquisition for certain DMEPOS in the most efficient manner due to the cost savings to the Medicare Trust fund.

The requirements for accreditation organizations were first discussed §424.58 of the proposed rule that published on May 1, 2006 (71 FR 25654). The final requirements need to be effective by August 1, 2006. The notice to announce the final requirements, CMS-6040-N, is scheduled for publication on August 1, 2006.

B. JUSTIFICATION

1. *Need and Legal Basis*

Under Section 302 of the MMA, the DMEPOS providers and suppliers must be accredited and obtain a National Supplier Clearinghouse billing number in order to competitively bid. The competitive bidding process final rule will be published October 1, 2006. There are over 90,000 providers and suppliers that need to be accredited before the implementation of this program by 2009, whether they bid or not.

Section 302(a)(1) of the MMA added section 1834(a)(20) to the Act, which requires the Secretary to establish and implement quality standards for suppliers of certain items, including consumer service standards, to be applied by recognized independent accreditation organizations. Suppliers of DMEPOS must comply with the quality standards in order to furnish any item for which payment is made under Part B, and to receive and retain a provider or supplier billing number used to submit claims for reimbursement for any such item for which payment may be made under Medicare. Section 1834(a)(20)(D) of the Act requires us to apply these quality standards to suppliers.

Section 1834(a)(20)(E) of the Act explicitly authorizes the Secretary to establish the quality standards by program instruction, publish the quality standards through program instructions and select the accreditation organizations in order to ensure that suppliers and providers that wish to participate in competitive bidding will know what standards they must meet in order to be awarded a contract. The standards will be applied prospectively and will be published on our website. All suppliers and providers of DMEPOS and other items to which section

1834(a)(20) of the Act applies will be required to meet the quality standards established under that section.

Section 1847(b)(2)(A)(i) of the Act requires an entity (a DMEPOS supplier) to meet the quality standards specified by the Secretary under section 1834(a)(20) of the Act before being awarded a contract under the Medicare DMEPOS Competitive Bidding Program.

Section 1834(a)(20)(B) of the Act requires the Secretary, notwithstanding section 1865(b) of the Act, to designate and approve one or more independent accreditation organizations to apply the quality standards to suppliers of DMEPOS and other items.

2. *Purpose and users of the information*

This information is necessary to give the independent accreditation organizations the opportunity to submit a proposal to implement and operate the durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) accreditation program. DMEPOS accreditation is required for DMEPOS suppliers that wish to bill Part B. The information supplied by the Independent Accreditation Organizations will be used to evaluate the accreditation organizations ability to meet CMS' regulations.

3. *Improved Information Techniques*

None of this information is used electronically. The Accreditation Organization's can respond to our collection of information by gathering this information that they have electronically, however. The proposal will be receive in hard copy. The proposal does require an attestation that they will comply with certain requirements.

4. *Duplication and Similar Information*

There is no duplicative information collection instrument or process.

5. *Small Business*

These forms will affect small businesses. However, it is likely that the overwhelming preponderance of proposals will be large organizations that either employ or represent substantial numbers of providers. Moreover, the request for proposals collects a minimum amount of information on a one-time basis, so the impact on small business should be negligible.

6. *Less Frequent Collections*

This information is collected from each accreditation organization only once. The proposal information remains in effect for the entire period of time in which the accreditation organization acts in such capacity.

7. *Special Circumstances*

There are no special circumstances associated with this collection.

8. *Federal Register Notice/Outside Consultation*

The emergency Federal Register notice published on or about August 4, 2006. The notice went on display on July 28, 2006.

9. *Payment/Gift to Respondents*

N/A.

10. *Confidentiality*

CMS will comply with all Privacy Act, Freedom of Information laws and regulations that apply to this collection. Privileged or confidential commercial or financial information is protected from public disclosure by Federal law 5 U.S.C. 522(b)(4) and Executive Order 12600.

11. *Sensitive Questions*

There are no sensitive questions associated with this collection.

12. *Burden Estimate (hours)*

The total one time burden for the respondents is 200 hours. This is based on the following estimates regarding the hours associated with completing the documentation required:

10 respondents @ 20 hours each = 200 hours

Hours associated with and costs to the respondents are calculated based on the assumption that each accreditation organization has the policies and procedures already in place and merely have to compile them in the application.

The following is the documentation requested in the Federal Register Notice:
(1) A list of the types of DMEPOS suppliers, and a list of products and services for which the organization is requesting approval.
(2) A description of the duration of accreditation.
(3) A detailed comparison of the organization's accreditation requirements and standards with the applicable Medicare DMEPOS quality standard requirements such as a crosswalk.
(4) A detailed description of the organization's survey process including–-

- Frequency of the surveys performed.

Procedures for performing unannounced surveys.

- Copies of the organization's survey forms, guidelines and instructions to surveyors.
- Accreditation survey review process and the accreditation status decision-making

process to include process for deficiencies identified with accreditation requirements and procedures used to monitor the correction of deficiencies found during an accreditation survey.

- Procedures used to notify accredited facilities of deficiencies and the procedures used to monitor the correction of deficiencies in accredited facilities.
- Policies and procedures used when an organization has a dispute regarding survey findings or an adverse decision.
- Procedures for coordinating surveys with another accrediting organization if the organization does not accredit all products the supplier provides.

(5) Detailed information about the individuals who perform surveys for the accreditation organization including--

- The size and composition of accreditation teams for each type of provider and supplier accredited.
- The education and experience requirements surveyors must meet.
- The content and frequency of the in-service training provided to survey personnel.
- The evaluation systems used to monitor the performance of individual surveyors and survey teams.
- Policies and procedures regarding an individual's participation in the survey or accreditation decision process of any organization with which the individual is professionally or financially affiliated.

(6) A description of the organization's data management and analysis system for its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.

(7) The organization's procedures for responding to and for the investigation of complaints against accredited facilities including policies and procedures regarding coordination of these activities with appropriate licensing bodies (that is, National Supplier Clearinghouse, CMS, and ombudsmen programs).

(8) The organization's policies and procedures for the withholding or removal of accreditation status for facilities that fail to meet the accreditation organization's standards or requirements, and other actions taken by the organization in response to noncompliance with its standards and requirements. These policies and procedures must include notifying CMS of facilities that fail to meet the requirements of the accrediting organization.

(9) A description of all types and categories of accreditation offered by the organization, the duration of each type and category of accreditation, and a statement specifying the types and categories of accreditation for which approval of deeming authority is sought.

(10) A list of all currently accredited companies, the type and category of accreditation currently held by each company, and the expiration date of each company's current accreditation.

(11) A list of all accreditation surveys scheduled to be performed by the organization.

(12). A plan for considering the small business organizations related to burden and cost.

The accreditation organization must also submit the following supporting documentation-–

(1) A written presentation that demonstrates the organization's ability to furnish CMS with electronic data in ASCII comparable code.

(2) A resource analysis that demonstrates that the organization's staffing, funding, and other resources are adequate to perform the required surveys and related activities.

(3) A statement acknowledging that, as a condition for approval of deeming authority,

the organization will agree to—

- Prioritize surveys for those suppliers in the 10 Metropolitan Statistical Areas that need to bid in late 2007.
- Prioritize surveys for those suppliers in the 80 Metropolitan Statistical Areas that need to bid in early 2008.
- Take into consideration any previous accreditatioin, certification, and/or licensure findings that indicate that DMPOS quality standards are being met at the time the accreditation organization surveys the supplier.
- Use the streamline process that considers only use of the DME quality standards for compliance and the unannounced process.
- Notify CMS, in writing, of any company that has had its accreditation revoked, withdrawn, or revised, or that has had any other remedial or adverse action taken against it by the accreditation organization within 30 calendar days of any such action taken.
- Notify all accredited suppliers within 10 calendar days of CMS' withdrawal of the organization's approval of deeming authority.
- Notify CMS, in writing, at least 30 calendar days in advance of the effective date of any proposed changes in accreditation requirements.
- Submit to CMS, within 30 calendar days of a changes in CMS requirements, an acknowledgement of CMS' notification of the change, as well as a revised crosswalk reflecting the new requirements, and inform CMS about how the organization plans to alter its requirements to conform to CMS' new requirements.
- Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.
- Notify CMS, in writing, within 2 calendar days of a deficiency identified in any accreditation entity where the deficiency poses an immediate jeopardy to the entity's beneficiary's or a hazard to the general public.
- Provide, on an annual basis, summary data specified by CMS that relates to the past years accreditation and trends.
- Attest that the organization will not perform any DMEPOS accreditation surveys of Medicare participating suppliers with which it has a financial relationship with or interest.
- Conform accreditation requirements to changes in Medicare requirements.

13. *Cost to Respondents (Capital)*

There is no capital costs associated with this collection.

14. *Cost to Federal Government*

The cost to the Federal government is estimated at 320 hours. Hours associated with and costs to the Federal government are calculated based on the time spent on reviewing the proposals, decision making process, briefing for recommendations of approvals, contract preparation, administrative filing, mailing and other activities. There is no dollar amount associated with the cost of processing this ICR. The ICR will be conducting by existing

FTE’s that are working within their normal scope of assignments.

15. *Changes in Burden/Program Changes*

This is a new program.

16. *Publication/Tabulation*

N/A.

17. *Expiration Date*

The date will be published in the Federal Register Notice, not to exceed 90 days from the published date.

18. *Certification Statement*

There are no exceptions to item 19 of OMB Form 83-I.

COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

This collection does not use any statistical methods.