

Billing Code: 4120-01-U-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS-10206]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Center for Medicare and Medicaid Services

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR Part 1320(a)(2) (ii). This is necessary to ensure compliance with an initiative of the Administration. We

cannot reasonably comply with the normal clearance procedures because of an unanticipated event, as stated in 5 CFR 1320.13(a)(2)(iii).

Approval of this notice is essential in order to comply with Section 302 (a)(1) of the MMA that requires the Secretary to establish and implement quality standards for suppliers of certain items to be applied by recognized independent accreditation organizations. Suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (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 DMEPOS providers and suppliers must be accredited and obtain a National Supplier Clearinghouse billing number in order to participate in the Competitive Acquisition Program for DMEPOS. The competitive bidding process final rule will be published October 1, 2006. However, there are over 90,000 providers and suppliers that need to be accredited before the implementation of this program by 2009, regardless of whether they submit bids or do not submit bids. Emergency clearance is required, given the complexity of this new requirement and the fact that the industry cannot proceed until CMS publishes both the quality standards along with the approved requirements for independent accreditation organizations. Otherwise, the program is in jeopardy of not meeting the statutory deadline of full implementation by 2009.

1. Type of Information Collection Request: New collection; Title of Information Collection: Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier Accreditation Proposals from Independent Accrediting Bodies; Use: Under Section 302 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), the DMEPOS providers and suppliers must be accredited and obtain a

National Supplier Clearinghouse billing number in order to competitively bid. 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)(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. Independent accreditation organizations must furnish the specified information to CMS to allow themselves the opportunity to submit proposals to implement and operate the DMEPOS accreditation program. The information supplied by the Independent Accreditation Organizations will be used to evaluate the accreditation organizations ability to meet CMS' regulations.

Form Number: CMS-10206 (OMB#: 0938-NEW); Frequency: Reporting – One-time; Affected Public: Business or other for-profit and Not-for-profit institutions; Number of Respondents: 10; Total Annual Responses: 10; Total Annual Hours: 200.

CMS is requesting OMB review and approval of this collection by August 9, 2006, with a 180-day approval period. Written comments and recommendations will be considered from the public if received by the individuals designated below by August 7, 2006.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at <http://www.cms.hhs.gov/regulations/pr> or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below by August 7, 2006:

CMS, Office of Strategic Operations and Regulatory Affairs,

Division of Regulations Development – B

Attn: William N. Parham, III

Room C4-26-05

7500 Security Boulevard,

Baltimore, MD 21244-1850

and,

OMB Human Resources and Housing Branch

Attention: Carolyn Lovett

New Executive Office Building, Room 10235

Washington, D.C. 20503

Fax Number: (202) 395-6974

Date: _____

Michelle Shortt

Director, Regulations Development Group

Office of Strategic Operations and Regulatory Affairs