DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1279–N2]

Medicare Program; Public Meeting of the Program Advisory and Oversight Committee (PAOC) for Quality Standards and Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces the date, location, and registration requirements for the first public meeting of the Program Advisory and Oversight Committee (PAOC) for the competitive acquisition of certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). The October 6, 2004 meeting will provide a forum for the PAOC to consider issues related to competitive bidding for DMEPOS items and to furnish advice to the Secretary regarding these issues. Requirements for the PAOC are specified by section 302 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). The public is invited to attend this meeting to observe the committee's discussion. While non-committee members attending the meeting as interested observers will not have the opportunity to make oral comments or presentations, written comments will be accepted.

DATES: *The Meeting:* The PAOC meeting will take place on Wednesday, October 6, 2004, 9 a.m. through 5 p.m.

ADDRESSES: The PAOC meeting will be held in the Centers for Medicare & Medicaid Services (CMS) Auditorium. Our address is 7500 Security Boulevard, Baltimore, MD 21244.

FOR FURTHER INFORMATION CONTACT: Sean Dalenberg, (410) 786–0300.

SUPPLEMENTARY INFORMATION:

I. Regulatory Background

On December 8, 2003, the President signed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173). Section 302 of MMA requires the Secretary of the Department of Health and Human Services (the Secretary) to replace the current DME payment methodology for certain items with a competitive acquisition process to improve the effectiveness of Medicare's methodology for setting DME payment amounts. The new bidding process will establish payment for DME, and drugs and supplies used in conjunction with DME, but excluding inhalation drugs and class III devices under the Food, Drug and Cosmetic Act. In addition, this new bidding process will establish payment for enteral nutrition and off-the-shelf orthotics. Section 302 of MMA also mandates implementation of an accreditation program and development of quality standards for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). The statute requires the Secretary to establish the PAOC. The PAOC is responsible for providing advice on the development and implementation of these provisions.

Specifically, section 302 of the MMA states that the PAOC shall provide advice on the following:

- Implementation of the Competitive Acquisition Program.
- Establishment of financial standards for suppliers under the program that take into account the needs of small providers.
- Establishment of data collection requirements for the efficient management of the program.
- Development of proposals for efficient interaction among manufacturers, providers of services, suppliers, and individuals.
- Establishment of the quality standards.

The PAOC may also perform additional functions specified by the Secretary. As specified in section 302(b)(1) of MMA, which amends section 1847 of the Act by adding paragraph (c)(4), to specify that the provisions of the Federal Advisory Committee Act (5 U.S.C. App.) are not applicable for PAOC meetings.

On June 2, 2004, we published a notice in the **Federal Register** (69 FR 31125) entitled ''Request for Nominations for the Program Advisory Oversight Committee for the Competitive Acquisition of Durable Medical Equipment and Other Items'' requesting nominations from the public for committee members. We are currently in the process of reviewing and processing these nominations. The names of those selected as PAOC members will be posted at *http://www.cms.hhs.gov/suppliers/dmepos/compbid.* This Web site will also include the agenda for the first PAOC meeting. Future dates and locations for PAOC meetings and agendas will be made available at the above listed Web site address. The public may also register on the list serve at the Web site for future PAOC notifications.

II. Registration

PAOC Registration Procedures: Members of the public interested in attending the October 6, 2004 meeting must register in advance by either mail or e-mail as indicated below.

Each registrant must provide the following information: Name; company name and address (if applicable); telephone and fax numbers; e-mail address (if available); and any special needs requirements. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Special Accommodations: Persons attending the PAOC public meeting with hearing or visual impairments, special requirements, or a condition that requires special assistance or accommodation, must provide this information upon registering for the meeting.

A CMS staff member will confirm your registration by mail, e-mail or fax. We recommend that you retain a copy of this confirmation of pre-registration to facilitate your entry into the building.

Registration By Mail: We must receive your registration by mail no later than 5 p.m. on September 22, 2004 in order for you to obtain access to the building. Please address mailed registrations to Sean Dalenberg, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop C5–08–27, Baltimore, MD 21244.

Registration By E-mail: If you wish to register electronically, please submit your request to the following e-mail address: *sdalenberg@cms.hhs.gov.* We must receive your registration no later than 5 p.m., September 22, 2004.

For Additional Information: Please contact our recorded Hotline at 410–786–9379.

III. Submission of Comments

Written comments from the public addressing topics discussed at the meeting must be received by October 13, 2004. Please send your written comments to Sean Dalenberg, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop C5–08–27, Baltimore, MD 21244. A summary of the public meeting will be posted at *http://www.cms.hhs.gov/suppliers/dmepos/compbid* after the meeting.

IV. General Information

This PAOC public meeting will be held in a Federal government building; therefore, Federal security measures are in effect. In planning your arrival, we recommend allowing additional time to clear security. In order to gain access to the building and grounds, all attendees

must be prepared to provide a government-issued photo identification. Access may be denied to persons without proper identification. Security measures will also include inspection of vehicles, inside and out, at the entrance to the grounds. In addition, all persons entering the building must pass through a metal detector. All items brought to CMS, including personal items, computers, electronics, and cell phones are subject to physical inspection.

Authority: Section 302 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 17, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 04–19259 Filed 8–26–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0508]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Focus Groups as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Focus Groups as Used by the Food and Drug Administration'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 9, 2004 (69 FR 11019), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0497. The approval expires on February 28, 2006. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: August 20, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–19599 Filed 8–26–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Free Clinic—FTCA Deeming Application (NEW.)

Congress legislated FTCA medical malpractice protection for free clinic volunteer health professionals through Section 194 of the Health Insurance Portability and Accountability Act (HIPAA) amending Section 224 of the Public Health Service Act. Individuals eligible to participate in this program are health care practitioners volunteering at free clinics who meet specific eligibility requirements. If an individual meets all the requirements of this program they can be ''deemed'' to be a Federal employee. This deemed status is specifically to provide immunity from medical malpractice lawsuits as a result of the performance of medical, surgical, dental, or related activities within the scope of the volunteer's work at the free clinic.

The sponsoring free clinic entity must submit an application to the Health Resources and Services Administration (HRSA). This application will require information about the sponsoring free clinic's credentialing system, risk management practices, and quality assurance system in order to ensure the Government is not exposed to undue liability resulting from the medical malpractice coverage of non-qualified health care professionals. Attached to the application will be a listing of specific health care providers for whom the sponsoring free clinic is requesting deemed status.

Estimates of annualized reporting burden are as follows:

Type of form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
FTCA Deeming Application	600	1	600	2.5	1,500
Total	600	.....	600	.....	1,500