

Therefore, we find good cause to waive notice and comment procedures.

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

Dated: August 4, 2004.

Jacquelyn Y. White,

Director, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3136–N]

Medicare Program; Meeting of the Medicare Coverage Advisory Committee—September 28, 2004

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

ACTION: Notice.

SUMMARY: This notice announces a public meeting of the Medicare Coverage Advisory Committee (MCAC). The Committee provides advice and recommendations about whether scientific evidence is adequate to determine whether certain medical items and services are reasonable and necessary under the Medicare statute. This meeting concerns the use of portable multichannel home sleep testing devices as an alternative to facility-based polysomnography in the evaluation of obstructive sleep apnea. Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)).

DATES: The public meeting will be held on Tuesday, September 28, 2004 from 7:30 a.m. until 3:30 p.m. e.s.t.

Deadline for Presentations and Comments: Written comments must be received by September 10, 2004, 5 p.m., e.s.t.

Special Accommodations: Persons attending the meeting who are hearing or visually impaired, or have a condition that requires special assistance or accommodations, are asked to notify the Executive Secretary by September 3, 2004 (see **FOR FURTHER INFORMATION CONTACT**).

ADDRESSES: The meeting will be held at the Holiday Inn Inner Harbor, 301 West Lombard Street, Baltimore, MD 21201.

Presentations and Comments: Interested persons may present data, information, or views orally or in writing on issues pending before the Committee. Please submit written

comments to Janet A. Anderson, by e-mail at JAnderson@cms.hhs.gov or by mail to the Executive Secretary, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, MailStop C1–09–06, Baltimore, MD 21244.

Website: You may access up-to-date information on this meeting at <http://www.cms.hhs.gov/mcac/default.asp#meetings>.

Hotline: You may access up-to-date information on this meeting on the CMS Advisory Committee Information Hotline, 1–877–449–5659 (toll free) or in the Baltimore area (410) 786–9379.

FOR FURTHER INFORMATION CONTACT:

Janet A. Anderson, Executive Secretary, by telephone at (410) 786–2700 or by e-mail at JAnderson@cms.hhs.gov.

SUPPLEMENTARY INFORMATION: On December 14, 1998, we published a notice in the **Federal Register** (63 FR 68780) to describe the Medicare Coverage Advisory Committee (MCAC), which provides advice and recommendations to us about clinical issues. This notice announces a public meeting of the Committee.

Meeting Topic: The Committee will discuss the evidence, hear presentations and public comment, and make recommendations regarding the use of portable multichannel home sleep testing devices as an alternative to facility-based polysomnography in the evaluation of obstructive sleep apnea (OSA). Current national coverage guidelines specify that only polysomnography done in a facility-based sleep study laboratory may be used to identify patients with OSA requiring Continuous Positive Airway Pressure (CPAP) therapy. Polysomnography is the continuous and simultaneous monitoring and recording of various physiological and pathophysiological parameters of sleep. It includes sleep staging that is defined to include a 1 to 4 lead electroencephalogram (EEG), and electro-oculogram (EOG), and a submental electromyogram (EMG). Determination of respiratory effort, airflow, oxygen saturation, detection of cardiac abnormalities via electrocardiogram (ECG), body position, and limb movements are also essential features of the test. Portable monitoring devices encompass a wide range of technologies some of which are capable of obtaining the same measurement parameters as standard polysomnography. However, devices also exist that measure only subsets of this information. For example, certain devices measure cardiopulmonary variables, such as respiratory effort,

airflow, oxygen saturation, and heart rate or ECG, without the ability to determine sleep staging. Another category of devices measures only one or two variables, such as oxygen saturation and heart rate or ECG. Background information about this topic, including panel materials, is available on the Internet at <http://www.cms.hhs.gov/coverage/>.

Procedure: This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 45 minutes. The Committee may limit the number and duration of oral presentations to the time available. If you wish to make formal presentations, you must notify the Executive Secretary named in the **FOR FURTHER INFORMATION CONTACT** section and submit the following by the **Deadline for Presentations and Comments** date listed in the **DATES** section of this notice: a brief statement of the general nature of the evidence or arguments you wish to present, and the names and addresses of proposed participants. A written copy of your presentation must be provided to each Committee member before offering your public comments. Your presentation must address the questions asked by us to the Committee. If the specific questions are not addressed, your presentation will not be accepted. The questions will be available on our website at <http://www.cms.hhs.gov/mcac/default.asp#meetings>. We request that you declare at the meeting whether or not you have any financial involvement with manufacturers of any items or services being discussed (or with their competitors).

After the public and CMS presentations, the Committee will deliberate openly on the topic. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the chairperson. The Committee will also allow a 15 minute unscheduled open public session for any attendee to address issues specific to the topic. At the conclusion of the day, the members will vote and the Committee will make its recommendation.

Authority: 5 U.S.C. App. 2, section 10(a).

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

Dated: July 27, 2004.

Sean R. Tunis,

Director, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services.

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