DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Medicare Program; Meeting of the Medicare Evidence Development & Coverage Advisory Committee—(MedCAC)

September 12, 2007.

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

ACTION: Notice.

SUMMARY: This notice announces a public meeting of the Medicare Evidence Development and Coverage Advisory Committee (MedCAC) (Committee). Among other things, 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 will consider the evidence on the diagnostic criteria for obstructive sleep apnea (OSA) in Medicare beneficiaries who may be candidates for continuous positive airway pressure (CPAP) therapy and alternatives to facility-based polysomnography (PSG) in the diagnosis of OSA, including home sleep testing devices and clinical diagnosis without the use of sleep testing.

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 Wednesday, September 12, 2007 from 7:30 a.m. until 4:30 p.m., daylight savings time (d.s.t).

Deadline for Presentations and Comments: Send written comments and presentations to the address specified in the **ADDRESSES** section by 5 p.m., d.s.t. on August 13, 2007. Please note that the presentation you submit will be final, as no further changes to the presentation will be accepted after submission.

Deadline for Meeting Registration: For security reasons, individuals wishing to attend this meeting must register by 5 p.m., d.s.t. on September 5, 2007.

Deadline for Submitting Request for 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 as specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

ADDRESSES: *Meeting Location:* The meeting will be held in the main auditorium of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244.

Registration: Register by contacting Maria Ellis 410–786–0309; *Maria.Ellis@cms.hhs.gov*; Centers for Medicare & Medicaid Services, OCSQ-Coverage and Analysis Group, C1–09–06, 7500 Security Boulevard, Baltimore, MD 21244.

Presentation and Comment Submission: Submit presentation and comments to Michelle Atkinson, Centers for Medicare & Medicaid Services, OCSQ-Coverage and Analysis Group, C1–09–06, 7500 Security Boulevard, Baltimore, MD 21244.

Web site: You may access up-to-date information on this meeting at *http://www.cms.hhs.gov/FACA/02_MCAC.asp#TopOfPage*.

Submission of 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 and presentations to the Executive Secretary at the address specified in the **ADDRESSES** section of this notice.

FOR FURTHER INFORMATION CONTACT: Michelle Atkinson, Executive Secretary for MedCAC, (410–786–2881; *Michelle.Atkinson@cms.hhs.gov*).

SUPPLEMENTARY INFORMATION:

I. Meeting Topic

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 CMS about clinical issues. The MCAC was subsequently rechartered as the Medicare Evidence Development and Coverage Advisory Committee (MedCAC).

This notice announces the September 12, 2007 public meeting of the Committee.

This meeting will inform CMS in its reconsideration of the Medicare National Coverage Determination (NCD) on continuous positive airway pressure (CPAP) therapy for OSA. We received a complete formal written request from the American Academy of Otolaryngology-Head and Neck Surgery to modify the NCD to include the use of portable multichannel home sleep testing devices as an alternative to facility-based polysomnography (PSG) in the evaluation of OSA. In addition, we received an incomplete request from a Medicare beneficiary, numerous informal requests from stakeholders, and interest from Medicare contractors concerning the criteria for determining the apnea-hypopnea index (AHI) in sleep testing. We are also aware of recently published research suggesting a benefit for the use of CPAP without prior sleep testing in selected populations (trial of CPAP).

During this meeting, the Committee will consider evidence and hear presentations and public comments on the use of home sleep testing devices or clinical diagnosis as an alternative to facility-based PSG in the diagnosis or both of obstructive sleep apnea (OSA); the criteria for determining the AHI; the use of clinical signs, symptoms or patient questionnaire results to establish a diagnosis of OSA; and the generalizability of the evidence to the Medicare beneficiary population.

Background information about this topic, including panel materials, is available on the Internet at *http://www.cms.hhs.gov/coverage/*.

II. Meeting Procedures

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 as specified in **FOR FURTHER INFORMATION CONTACT** section of the notice and submit the following to the address specified in the **ADDRESSES** section of this notice by the date specified in the **DATES** section of this notice: (1) A brief statement of the general nature of the evidence or arguments you wish to present; (2) the names and addresses of proposed participants; and (3) a written copy of your presentation. Your presentation should consider the questions we have posed to the Committee and focus on the issues specific to the topic. The questions will be available on the following Web site: *http://www.cms.hhs.gov/FACA/02_MCAC.asp#TopOfPage.* We require that you declare at the meeting whether 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.

III. Registration Instructions

The Coverage and Analysis Group is coordinating meeting registration. While there is no registration fee, individuals must register to attend. Register by contacting Maria Ellis at the address specified in the **ADDRESSES** section of this notice. Please provide your name, address, organization, telephone and fax numbers, and e-mail address.

You will receive a registration confirmation with instructions for your arrival at the CMS complex. You will be notified if the seating capacity has been reached.

This meeting is located on Federal property; therefore, for security reasons, any individuals wishing to attend this meeting must register by 5 p.m. d.s.t. on September 5, 2007.

IV. Security, Building, and Parking Guidelines

This meeting will be held in a Federal government building; therefore, Federal security measures are applicable. In planning your arrival time, we recommend allowing additional time to clear security.

In order to gain access to the building and grounds, individuals must present photographic identification to the Federal Protective Service or Guard Service personnel before being allowed entrance.

Security measures also include inspection of vehicles, inside and out, at the entrance to the grounds. In addition, all individuals entering the building must pass through a metal detector. All items brought to CMS, whether personal or for the purpose of demonstration or to support a demonstration, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for demonstration or to support a demonstration.

Parking permits and instructions will be issued upon arrival.

Note: Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 30 to 45 minutes prior to the convening of the meeting.

All visitors must be escorted in areas other than the lower and first floor levels in the Central Building.

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: June 11, 2007.

Barry M. Straube,

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

[FR Doc. E7–12046 Filed 6–21–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2000D–0084]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Special Protocol Assessment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 23, 2007.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974. All comments should be identified with the OMB control number 0910–0470. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on Special Protocol Assessment (OMB Control Number 0910–0470)—Extension

In the **Federal Register** of July 31, 2006 (71 FR 43199), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Notification for Carcinogenicity Protocols	21	2.19	46	8	368
Requests for Special Protocol Assessment	151	2.48	374	15	5,610
Total					5,978

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.