

Persons wishing to attend this meeting, which is located on Federal property, must e-mail the Panel DFO to register in advance no later than 5 p.m. (e.d.t.), Wednesday, August 9, 2006. A confirmation will be sent to the requester(s) via return e-mail.

The following information must be e-mailed or telephoned to the DFO by the date and time above:

- Name(s) of attendee(s),
- Title(s),
- Organization,
- E-mail address(es), and
- Telephone number(s).

VIII. Security, Building, and Parking Guidelines

Persons attending the meeting must present photographic identification to the Federal Protective Service or Guard Service personnel before they will be allowed to enter the building.

Security measures will 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 such as desktops, cell phones, palm pilots, etc., are subject to physical inspection.

Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. (Note: Presenters must also be registered for attendance at the meeting.) The public may enter the building 30–45 minutes before the meeting convenes each day. (The meeting on Wednesday, August 23, 2006, convenes at 1 p.m.)

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

Parking permits and instructions are issued upon arrival by the guards at the main entrance.

IX. Special Accommodations

Individuals requiring sign-language interpretation or other special accommodations must send a request for these services to the DFO by 5 p.m. (e.d.t.), Wednesday, August 9, 2006.

Authority: Section 1833(t)(9) of the Act (42 U.S.C. 13951(t)). The Panel is governed by the provisions of Public Law 92–463, as amended (5 U.S.C. Appendix 2).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare-Hospital Insurance; and Program No. 93.774, Medicare-Supplementary Medical Insurance Program).

Dated: June 16, 2006.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E6–9905 Filed 6–22–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3170–N]

Medicare Program; Meeting of the Medicare Coverage Advisory Committee—August 30, 2006

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

ACTION: Notice.

SUMMARY: This notice announces a public meeting of the Medicare Coverage Advisory Committee (MCAC) (“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 discuss the following issues: (1) Glycemic control and the use of glucose monitors by which sensors automatically monitor glucose levels in body fluids; and (2) whether and how the frequency of outpatient glucose monitoring is related to glycemic control and clinical outcomes in the various Medicare populations.

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 Wednesday, August 30, 2006 from 7:30 a.m. until 4:30 p.m., e.s.t.

Deadlines: Deadline for Presentations and Comments: Send written comments and presentations to the address listed in the **ADDRESSES** section of this notice by 5 p.m., e.s.t. on July 31, 2006. [Please note that the presentation you submit will be final, as no further changes to the presentation can be accepted after submission.]

Deadline for Meeting Registration: For security reasons, individuals wishing to attend this meeting must register by 5 p.m., e.s.t. on August 24, 2006.

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 (see **FOR FURTHER INFORMATION CONTACT**) by August 24, 2006.

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

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 listed in the **ADDRESSES** section of this notice.

FOR FURTHER INFORMATION CONTACT: Michelle Atkinson, Executive Secretary for MCAC, (410–786–2881; Michelle.Atkinson@cms.hhs.gov; Centers for Medicare & Medicaid Services, OCSQ—Coverage and Analysis Group, C1–09–06, 7500 Security Boulevard, Baltimore, MD 21244).

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.

This notice announces the August 30, 2006 public meeting of the Committee. During this meeting, the Committee will discuss evidence and hear presentations and public comments concerning outpatient glycemic control (as measured by glycated hemoglobin), the frequency of glucose monitoring, and clinical outcomes in the Medicare populations. Specifically, the Committee will review the available data on the ability of glycemic control to blunt the progression of disease, reverse diabetic complications, and alter morbidity and mortality in the Medicare populations; whether the effects of glycemic control (if any) are linear and mitigated by increased hypoglycemic risk; and whether the frequency of

outpatient glucose monitoring is a determinant of glycemic control and clinical outcomes in the Medicare populations. The role of variables such as the type of diabetes, the therapeutic regimen employed, the age of hyperglycemic onset, the duration of diabetes, the duration of poor glycemic control, the level of hyperglycemia, and concomitant disease will be discussed. The impediments to glucose monitoring and use of monitoring data will be considered. In addition to evaluating the available data, the Committee will identify areas in which the current data are deficient and in which additional research is warranted.

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 (see **FOR FURTHER INFORMATION CONTACT**) and submit the following to the address listed in the **ADDRESSES** section of this notice by the date listed in the **Deadlines** 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 listed 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. e.s.t. on August 24, 2006.

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 7, 2006.

Barry M. Straube,

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

[FR Doc. E6-9480 Filed 6-22-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0226]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 015

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a publication containing modifications the agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA recognized consensus standards). This publication, entitled "Modifications to the List of Recognized Standards, Recognition List Number: 015" (Recognition List Number: 015), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit written or electronic comments concerning this document at any time. See section VII of this document for the effective date of the recognition of standards announced in this document.

ADDRESSES: Submit written requests for single copies of "Modifications to the List of Recognized Standards, Recognition List Number: 015" to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health (HFZ-220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301-443-8818. Submit written comments concerning this document, or recommendations for additional standards for recognition, to the contact person (see **FOR FURTHER INFORMATION CONTACT**). Submit electronic comments by e-mail: standards@cdrh.fda.gov. This document may also be accessed on FDA's Internet site at <http://www.fda.gov/cdrh/fedregin.html>. See section VI of this document for electronic access to the