

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3137-N]

Medicare Program; Meeting of the Medicare Coverage Advisory Committee—November 4, 2004

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

ACTION: Notice.

SUMMARY: This notice announces a public meeting of the Medicare Coverage Advisory Committee. This 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 bariatric surgery for the treatment of morbid obesity. Notice 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 Thursday, November 4, 2004 from 7:30 a.m. until 4:30 p.m. e.s.t.

Special Accommodations: For anyone attending the meeting who is hearing or visually impaired, or who requires special assistance or accommodations, please notify the Executive Secretary by October 18, 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 (and Deadline): Interested persons may present data, information, or views orally or in writing on issues pending before the Committee. Please submit written comments to Kimberly Long, by email at klong@cms.hhs.gov or by mail to the Executive Secretary, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop C1-09-06, Baltimore, MD 21244. Written comments must be received by October 4, 2004, 5 p.m., e.s.t.

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

FOR FURTHER INFORMATION CONTACT: Kimberly Long, Executive Secretary, by telephone at 410-786-5702 or by e-mail at klong@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, 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 bariatric surgery for the treatment of morbid obesity. 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 October 4, 2004, 5 p.m., e.s.t.: 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 the CMS Web site 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: August 26, 2004.

Sean R. Tunis,

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

[FR Doc. 04-21201 Filed 9-23-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3141-N]

Procedure for Producing Guidance Documents Describing Medicare's Coverage Process

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

ACTION: Notice.

SUMMARY: This notice implements part of section 731 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 by describing a method of developing, and making available to the public, guidance documents under the Medicare program. The guidance documents would explain the factors considered in making national coverage determinations of whether an item or service is reasonable and necessary.

FOR FURTHER INFORMATION CONTACT: Vadim Lubarsky, (410) 786-0840.

SUPPLEMENTARY INFORMATION:

I. Background

Section 731 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173, enacted on December 8, 2003), requires that the Secretary make available to the public the factors that are considered in making national coverage determinations of whether an item or service is reasonable and necessary. That section further specifies that the Secretary develop guidance documents to implement section 731 of the MMA in a manner similar to the development of guidance documents under section 701(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)). This notice describes the method we are adopting to develop and make public guidance documents consistent with these requirements.

II. CMS Guidance Documents

For the purposes of this notice, the term "guidance documents" means documents prepared for our staff, potential requestors of National Coverage Determinations (NCDs), and other interested parties explaining the

NCD process and other issues involved in making coverage determinations. Those documents will be specifically labeled as guidance documents and do not include other CMS reports, documents, letters, or program instructions.

Guidance documents give the public, particularly individuals or organizations that might request an NCD, detailed information on current interpretations of the statute, the NCD process, and related evaluation and decision-making factors. A more precise understanding of these factors assists product developers and others in making decisions by understanding:

- The implications of making an NCD request.
- What content is necessary in an NCD request.
- Relevant timelines and their relation to the overall NCD process.
- What types of scientific and other information are considered in the process.
- How various types of evidence are evaluated for reasonable and necessary determinations.

In general, guidance documents reduce uncertainty about key aspects of the NCD process. Guidances may be useful in certain cases to help plan investment strategies, research and development efforts, and marketing and clinical diffusion strategies.

CMS strives to achieve consistent and fair review of NCDs. Guidances are an additional tool that may be used in this effort.

III. Effect of Guidance Documents

A guidance document represents the agency's current thinking on the relevant subject. It is not intended to be a comprehensive description or analysis of all issues and factors that might affect an individual NCD. A guidance document is not binding on the Agency or the public. For example, the guidance documents will describe how we will evaluate different types of study designs in determining whether an item or service is reasonable and necessary. This does not mean the absence of a particular type of research will necessarily result in a noncoverage decision nor does submitting data from a particular type of study ensure coverage. Every effort will be made to describe in general terms the factors that are most important in making a coverage determination. Nonetheless, each NCD involves unique factors that cannot be described explicitly in the guidance documents.

IV. Development of Guidance Documents

For all guidance documents, the public will have an opportunity to comment upon issuance. Usually, guidance documents will not be considered in effect until CMS has analyzed public input received during a period for public comment. In cases of immediate need or for minor policy changes, however, guidance documents may be made effective upon issuance, prior to the public comment period. Each document will clearly denote the appropriate addresses for hard copy and electronic submission of comments. We will consider changes to the documents based on the comments as appropriate. Comments will be taken and reviewed on a continuous basis.

V. Public Notification of New Guidance Documents

We will provide notice of new guidance documents and make them available on the Internet at <http://www.cms.hhs.gov/coverage>. At regular intervals, we will update a list of all guidance documents in the **Federal Register**. Individuals who need assistance accessing the guidance documents for any reason may send an e-mail to CAGInquiries@cms.hhs.gov.

VI. Public Input

We will provide a list of possible topics for guidance documents development related to section 731 of the MMA on our Web site. We invite public input regarding these and other possible topics for new guidance documents via the public comments function available at <http://www.cms.hhs.gov/coverage>. While these suggestions will be given serious consideration, we are not required to issue every document on the list and are not precluded from issuing other guidance documents not included on the list.

We will review existing guidance documents on a regular basis. The public may submit proposals for review and revision of existing documents on the basis that they are no longer current. A statement explaining why the existing document needs updating and/or revision must accompany each request. We will review the statement and, when appropriate, develop the necessary revisions in accordance with the procedures specified in this notice.

VII. Dissemination/Availability to the Public

A list of all guidance documents will be maintained on the CMS Coverage home page. The list will include the

title of each document and issue and revision date.

VIII. List of Proposed Guidance Documents

We will update this list as we continue to develop guidance documents. The first guidance document will be the "Revised Process for Making Medicare National Coverage Determinations."

Authority: Section 731 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.
(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: May 4, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 04-21197 Filed 9-23-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Office of AIDS Research Advisory Council.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact person listed below in advance of the meeting.

Name of Committee: Office of AIDS Research Advisory Council.

Date: October 13-14, 2004.

Time: 9 a.m. to 12 p.m.

Agenda: A Report of the Director addressing OAR initiatives. The meeting will focus on research approaches to addressing HIV/AIDS as a chronic disease in the United States, including discussions about clinical complications, treatment and adherence issues, and disease management.

Place: National Institutes of Health, Building 31, 31 Center Drive, Room 6C10, Bethesda, MD 20892.

Contact Person: Jack Whitescarver, Director, Office of AIDS Research, OD, National Institutes of Health, 9000 Rockville Pike, Building 2, Room 4E14, Bethesda, MD 20892, (301) 496-0357.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when