

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.

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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