In addition, if the cost incurred by the intermediary, RHHI, carrier, or DMEPOS regional carrier to meet its contractual requirements exceeds the amount that we find to be reasonable and adequate to meet the cost that must be incurred by an efficiently and economically operated intermediary or carrier, these high costs may also be grounds for adverse action.

IX. Collection of Information Requirements

This document does not impose information collection and record keeping requirements. Consequently the Office of Management and Budget need not review it under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

X. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are unable to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **Comment Period** section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in the preamble of that document.

XI. Regulatory Impact Statement

We have examined the impacts of this notice as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354), section 1102(b) of the Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million in any one year). Since this notice only describes criteria and standards for evaluating FIs (including RHHIs), carriers, and DMEPOS regional carriers and has no significant economic impact on the program, its beneficiaries, providers or suppliers, this is not a major notice.

The RFA requires agencies to analyze options for regulatory relief of small businesses, but intermediaries, RHHIs, carriers and DMEPOS regional carriers are not small businesses.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This notice does not affect small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. In accordance with section 202, we have determined that the notice does not impose any unfunded mandates on States, local or tribal governments, or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a notice that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. We have determined that the notice does not significantly affect the rights, roles, and responsibilities of States.

We have not prepared a Regulatory Impact Analysis for this notice, in accordance with Executive Order 12866, because it will not have a significant economic impact, nor does it impose any unfunded mandates on State, local, or tribal governments or the private sector. Furthermore, we certify that the notice will not have a significant impact on a substantial number of small entities or small rural hospitals.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

Authority: Sections 1816(f), 1834(a)(12), and 1842(b) of the Social Security Act (42 U.S.C. 1395h(f), 1395m(a)(12), and 1395u(b))

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

Dated: May 27, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Editorial Note: This document was recieved at the Office of the Federal Register on November 23, 2004.

[FR Doc. 04–26278 Filed 11–24–04; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3149–N]

Medicare Program; Meeting of the Medicare Coverage Advisory Committee—January 25, 2005

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 data from and the quality of clinical evidence pertaining to the effects of lifestyle modification such as diet, exercise, stress reduction and group counseling as it relates to reversal or resolution of diseases such as coronary heart disease and diabetes. 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, January 25, 2005, from 7:30 a.m. until 4:30 p.m. e.s.t.

Deadline for Presentations and Comments: Written comments and presentations must be received by December 27, 2005, 5 p.m., e.s.t.

ADDRESSES: The meeting will be held in the auditorium at the Centers for Medicare & Medicaid Services, 7500 Security Blvd, Baltimore, MD 21244.

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 Michelle Atkinson, by e-mail at *Matkinson@cms.hhs.gov* or by mail to the Executive Secretary for MCAC, Coverage and Analysis Group, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop C1–09–06, Baltimore, MD 21244.

Web site: 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: Michelle Atkinson, Executive Secretary, by telephone at 410–786–2881 or by e-mail at *Matkinson@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 address the data from and the quality of clinical evidence pertaining to the effects of lifestyle modification such as diet, exercise, stress reduction and group counseling as it relates to reversal or resolution of diseases such as coronary heart disease and diabetes.

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. The questions will be available on our Web site at *http://www.cms.hhs.gov/mcac/default.asp#meetings*. If the specific questions are not addressed, your presentation will not be accepted. 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.

Registration Instructions

The Coverage and Analysis Group is coordinating meeting registration. While there is no registration fee, individuals must register to attend. You may register by contacting Maria Ellis at 410–786–0309, mailing address: Coverage and Analysis Group, OCSQ; Centers for Medicare & Medicaid Services; 7500 Security Blvd, Mailstop: C1–09–06; Baltimore, MD 21244, or by e-mail at *Mellis@cms.hhs.gov*. Please provide your name, address, organization, telephone and fax number, 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.

Because the meeting is located on Federal property, for security reasons, any persons wishing to attend this meeting must register by close of business on January 17, 2005. In order to gain access to the building and grounds, participants must show to the Federal Protective Service or guard service personnel, government-issued photo identification and a copy of their registration confirmation. Individuals who have not registered in advance will not be allowed to enter the building to attend the meeting.

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 January 3, 2005 (*see* **FOR FURTHER INFORMATION CONTACT**).

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: November 17, 2004.

Sean R. Tunis,

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

[FR Doc. 04–26173 Filed 11–24–04; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Industry Exchange Workshop on Food and Drug Administration Clinical Trial Requirements; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Pacific Region, in cooperation with the Society of Clinical Research Associates (SoCRA), is announcing a workshop on FDA Clinical trial statutory and regulatory requirements. Topics for discussion include: Pre-IND (investigational new drug application) meetings and FDA meeting process, medical device, drug and biological product aspects of clinical research, investigator initiated research, informed consent requirements, adverse event reporting, how FDA conducts bioresearch inspections, ethics in subject enrollment, FDA regulation of Institutional Review Boards, FDA and confidence in the conduct of clinical research, and what happens after the FDA inspection. This 2-day workshop for the clinical research community targets sponsors, monitors, clinical investigators, institutional review boards, and those who interact with them for the purpose of conducting FDA regulated clinical research. The workshop will include both industry and FDA perspectives on proper conduct of clinical trials regulated by FDA.

Date and Time: The public workshop is scheduled for Wednesday, January 12, 2005, from 8:15 a.m. to 4:15 p.m. and Thursday, January 13, 2005, from 8:15 a.m. to 4 p.m.

Location: The public workshop will be held at the Holiday Inn Fisherman's Wharf, 1300 Columbus Ave., San Francisco, CA 94133, 415–771–9000, FAX: 415–771–7006.

Contact: Marcia Madrigal, Small Business Representative, FDA, 1301 Clay St., suite 1180–N, Oakland, CA 94612–5217, FAX: 510–637–3977, e-mail: *marcia.madrigal@fda.gov*.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) and the registration fee of $485 (member) or $560 (nonmember), $460 (government employee nonmember) (includes a 1 year membership). The registration fee for FDA employees is waived. Make the registration fee payable to SoCRA, P.O. Box 101,