

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

applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign in at the security desk upon entering the building.

Information is also available on the Institute's/Center's home page: <http://www.nih.gov/od/oar/index.htm>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: September 17, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04-21447 Filed 9-23-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Initial Review Group, Subcommittee G-Education, Review of K01, K05, K07, K22, K23 and K24 Applications.

Date: October 26-27, 2004.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Suites Alexandria, 601 North Saint Asaph Street, Alexandria, VA 22314.

Contact Person: Ilda M. McKenna, Scientific Review Administrator, Research Training Review Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 8111, Bethesda, MD 20892, (301) 496-7481, mckennai@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: September 16, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04-21439 Filed 9-23-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center For Complementary & Alternative Medicine; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Complementary and Alternative Medicine Special Emphasis Panel; Db-16 Basic Science.

Date: October 18-19, 2004.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Dale L. Birkle, PhD, Scientific Review Administrator, NIH/NCCAM, 6707 Democracy Blvd., Democracy Two Building, Suite 401, Bethesda, MD 20892, (301) 451-6570, birkled@mail.nih.gov.

Name of Committee: National Center for Complementary and Alternative Medicine Special Emphasis Panel; JH-05 Clinical Science.

Date: October 25-26, 2004.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Jeanette M. Hosseini, Scientific Review Administrator, National Center for Complementary and Alternative Medicine, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, (301) 594-9096.

Name of Committee: National Center for Complementary and Alternative Medicine Special Emphasis Panel.

Date: November 3-5, 2004.

Time: 6 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Premier at Tyson's Corner, 8661 Leesburg Pike, Vienna, VA 22182.

Contact Person: Dale L. Birkle, PhD, Scientific Review Administrator, NIH/NCCAM, 6707 Democracy Blvd., Democracy Two Building, Suite 401, Bethesda, MD 20892, (301) 451-6570, birkled@mail.nih.gov.

Name of Committee: National Center for Complementary and Alternative Medicine Special Emphasis Panel; CP-18 Training.

Date: November 5, 2004.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Carol Pontzer, PhD, Scientific Review Administrator, National Center for Complementary and Alternative Medicine, 6707 Democracy Blvd., Bethesda, MD 20892.

Dated: September 10, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04-21436 Filed 9-23-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.