

information and does not set forth requirements.

II. Comments

This draft document is being distributed for comment purposes only, and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this guidance document. Written comments may be submitted at any time, however, comments should be submitted by November 15, 1999, to ensure adequate consideration in preparation of the final document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance document using the World Wide Web (WWW). For WWW access, connect to CDER at "http://www.fda.gov/cder/guidance/index.htm", or CBER at "http://www.fda.gov/cber/guidelines.htm".

Dated: August 9, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.
[FR Doc. 99-21254 Filed 8-16-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), announcement is made of the following National Advisory body scheduled to meet during the month of September 1999.

The National Advisory Committee on Rural Health will convene its thirty-third meeting at the time and place specified below:

Name: National Advisory Committee on Rural Health

Date and Time: September 13, 1999; 8:30 a.m.-5:00 p.m.; September 14, 1999; 8:30 a.m.-5:00 p.m.; September 15, 1999; 8:30-11:30 a.m.

Place: Omni Shoreham Hotel, 2500 Calvert Street, NW, Washington, DC 20008, Phone: (202) 234-7000.

Purpose: The National Advisory Committee on Rural Health provides advice and recommendations to the Secretary with respect to the delivery, research, development, and administration of health care services in rural areas.

Agenda: The plenary session on Monday morning, September 13, at 8:30 a.m., will include Office of Rural Health Policy update, legislative updates, NRHA Policy Institute overview, and presentation on the rural public health infrastructure project. After lunch, the Committee will begin formulating recommendations and review committee process and organization. Tuesday morning, September 14, will be spent exploring future committee options, topics and issues for the Committee. After lunch, a presentation on the Medicare Reform and its Implication for Rural: A Review of the Premium Support and the Administration proposal will be followed by panelist and Committee discussion. Late afternoon the Committee will continue formulating recommendations.

The final plenary session will be convened on Wednesday, at 8:30 a.m. During this session the Committee will conclude discussions on recommendations, Committee structure and future activities. The meeting will adjourn at 11:30 a.m.

Anyone requiring information regarding the subject Committee should contact Wayne W. Myers, M.D., Executive Secretary, National Advisory Committee on Rural Health, Health Resources and Services Administration, Room 9A-55, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, telephone (301) 443-0835, FAX (301) 443-2803.

Persons interested in attending any portion of the meeting should contact Sandi Lyles or Lilly Smetana, Office of Rural Health Policy, (301) 443-0835.

Agenda items are subject to change as priorities dictate.

Dated: August 11, 1999.

James J. Corrigan,

Associate Administrator for Operations and Management.

[FR Doc. 99-21256 Filed 8-16-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood 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 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 Heart, Lung, and Blood Institute Special Emphasis Panel; PA-98-052 "Mentored Patient-Oriented Research Career Development Award" also PA-98-053 "Midcareer Investigator Award in Patient-Oriented Research".

Date: September 28-29, 1999.

Time: September 28, 1999, 7 pm to 9 pm.

Agenda: To review and evaluate grant applications.

Place: Chevy Chase Holiday Inn, 5520 Wisconsin Ave., Chevy Chase, MD 20815.

Time: September 29, 1999, 8:30 am to 5 pm.

Agenda: To review and evaluate grant applications.

Place: Chevy Chase Holiday Inn, 5520 Wisconsin Ave., Chevy Chase, MD 20815.

Contact Person: Diane M. Reid, MD, Scientific Review Administrator, NIH, NHLBI, DEA, Two Rockledge Center, 6701 Rockledge Drive, Room 7182, Bethesda, MD 20892-7924, (301) 435-0277.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research, 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: August 10, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99-21219 Filed 8-16-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; 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 Institute of Nursing Research Special Emphasis Panel, Individual National Research Service Award Applications (NRSA).