

that the trials meet the qualifying criteria in order to maintain Medicare coverage of routine costs. This certification process will only affect the future status of a trial and will not be used to retroactively change the earlier deemed status."

The Panel will be developing criteria for identifying other trials that are likely to have the seven desirable characteristics of clinical trials. (From HCFA's Final National Coverage Decision posted on HCFA's website (<http://www.hcfa.gov/quality/8d2.htm>).

## 2. Purpose

AHRQ is holding this second meeting to ensure that all interested parties have adequate time to provide comments and pertinent information that would contribute to defining specific and unambiguous qualifying criteria for identifying clinical trials appropriate for Medicare coverage. We are soliciting comments about what specific qualifying criteria might be used to select trials that are likely to have the desirable characteristics of scientifically sound clinical trials identified by HCFA. The criteria should be easily verifiable, should not require a detailed and expert trial by trial review, and, where possible, be dichotomous (that is, objective yes/no responses). Some examples might be:

Is the trial approved by an investigational review board (IRB)?  
Does the trial have a written protocol?  
Has the trial been approved by a Federal agency?  
Has the trial received and external, non-Federal funding?  
Has the trial been reviewed by any external, non-Federal group?  
Does a data safety and monitoring board provide independent oversight of the trial?

AGRQ is also interested in receiving information on the availability of relevant literature (citations or copies if possible) that might assist the Panel in its formation of the qualifying criteria.

## Agenda

The meeting will begin at 9 a.m. and continue through 1 p.m. If more requests to make oral statements are received than can be accommodated at this meeting, the chair person will allocate speaking time in a manner that attempts, to the extent possible, to have a range of information, findings, and views presented orally. Those who cannot be granted speaking time because of time constraints are assured that their written comments will be considered along with other evidence during the course of further discussions and report preparation.

Dated: October 26, 2000.

**John M. Eisenberg,**

*Director.*

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**BILLING CODE 4160-90-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention (CDC)

#### The Advisory Committee to the Director, National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC); Meeting.

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub.L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting:

*Name:* Advisory Committee to the Director, NCEH.

*Times and Dates:* 9 am-5 pm (EST), November 20, 2000; 9 am-12 pm (EST), November 21, 2000.

*Place:* Swissotel, 3391 Peachtree Road, NE, Atlanta, GA 30326.

*Status:* Open to the public for observation and comment, limited only by the space available. The meeting room accommodates approximately 45 people.

*Purpose:* The Secretary, and by delegation, the Director, Centers for Disease Control and Prevention, are authorized under Section 301(42 U.S.C. 241) and Section 311(42 U.S.C. 243) of the Public Health Service Act, as amended, to (1) conduct, encourage, cooperate with, and assist other appropriate public authorities, scientific institutions, and scientists in the conduct of research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases, and other impairments; (2) assist States and their political subdivisions in the prevention of infectious diseases and other preventable conditions, and in the promotion of health and well being; and (3) train State and local personnel in health work. The purpose of this meeting is to provide advice on: (1) Environmental public health problems that potentially pose the greatest risks to human health and may not be receiving adequate attention; (2) the primary prevention of birth defects and developmental and other disabilities; (3) the prevention of secondary conditions in persons with a primary disability; and (4) the research agenda needed to improve the science base relative to human health effects and environmental exposures, and that will ultimately provide sound human health data for policy and decision-making.

*Matters to be Discussed:* Agenda items will include implications of the Child Health Bill, the National Exposure Report, the Genetics Assessment Testing Program, and on a shared vision of environmental health between

NCEH and the Agency for Toxic Substances and Disease Registry (ATSDR) at CDC.

Agenda items are tentative and subject to change as priorities dictate.

*Contact Person for more Information:*

Michael J. Sage, Designated Federal Official, CDC, 4770 Buford Highway, NE, MS F-29, Atlanta, Georgia 30341-3724; telephone 770-488-7020, fax 770-488-7024; e-mail: [mjs6@cdc.gov](mailto:mjs6@cdc.gov).

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: October 27, 2000.

**Carolyn J. Russell,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

**[Program Announcement No. ACF/ACYF-PA-HS-2001-02B]**

#### Fiscal Year 2001 Discretionary Announcement for Select Service Areas of Early Head Start; Availability of Funds and Request for Applications

**AGENCY:** Administration on Children, Youth and Families, ACF, DHHS.

**ACTION:** Correction.

**SUMMARY:** This document contains a correction to the Notice that was published in the **Federal Register** on Wednesday, September 13, 2000.

On page 55256, in the State of Alaska, in the Funding for the following counties column, delete "\$797,487" and replace with "\$914,488".

On page 55256, in the State of Arizona, in the County of Maricopa, in the Funding for the following counties column, delete "\$895,843" and replace with "\$956,190".

On page 55256, in the State of California, add "Alameda" to the County column, and next to that add "\$1,254,931" in the Funding for the following counties column, and in the Current service area column add "San Leandro, San Lorenzo, Castro Valley, Hayward, Union City, Fremont, Newark, Livermore, Pleasanton, and Dublin".

On page 55256, in the State of California, in the County of El Dorado, in the Funding for the following counties column, delete "884,818" and replace with "\$947,640".

On page 55256, in the State of California, in the County of Fresno, in the Funding to the following counties column, delete "752,322" and replace with "798,213".

On page 55256, in the State of California, in the County of Nevada, in the Funding to the following counties column, delete "\$1,077,655" and replace with "\$1,146,292".

On page 55256, in the State of California, in the County of San Mateo, in the Funding to the following counties column, delete "\$641,039" and replace with "\$1,072,738" and in the Current service area column, delete "Half Moon Bay" with replace with "Entire County".

On page 55256, in the State of Colorado, in the County of Denver, next to the Funding amount of \$1,380,779, in the Current service area column, after Montbello delete "and City Park" and replace with "City Park, Globeville, Skyland and North Capitol Hill".

On page 55257, in the State of Hawaii, in the County of Oahu, in the Funding for the following counties column, delete "\$635,745" and replace with "\$678,925" and in the County of Oahu, in the Funding for the following counties column, delete "\$453,443" and replace with "\$481,104".

On page 55257, in the State of Idaho, add "Nez Perce" to the County Column, and add "Nez Perce Reservation" in the Current service area column.

On page 55259, in the State of New York, in the County of Saratoga, in the Funding for the following counties column, delete "\$998,746" and replace with "\$927,124".

On page 55259, in the State of North Dakota, delete "Carson" from the County column, delete "\$797,487" from the Funding for the following counties column, and delete "Boundaries of Standing Rock Reservation" from the Current service area column.

On page 55259, in the State of North Dakota, in the County of Sioux, add "\$797,487" to the Funding for the following counties column and delete "Boundaries of Standing Rock Reservation" from the Current service area column and replace with "Standing Rock Sioux Reservation".

On page 55259, in the State of South Dakota, in the County of Pennington, in the Funding for the following counties column, delete "\$795,140" and replace with "\$1,155,140".

On page 55259, in the State of South Dakota, in the County column, after Meade, add the following County: "Lawrence" and in the Current service area column add "Entire County".

On page 55259, in the State of South Dakota, in the County column after

Lawrence, add the following County: "Fall River" and in the Current service area column add "Entire County".

On page 55259, in the State of South Dakota, in the County Column after "Fall River", add the following County: "Custer" and in the Current service area column add "Entire County".

On page 55259, in the State of South Dakota, in the County Column after "Custer", add the following County: "Jackson" and in the Current service area column add "Entire County".

On page 55259, in the State of South Dakota, in the County Column after "Jackson", add the following County: "Haakon" and in the Current service area column add "Entire County".

On page 55259, in the State of South Dakota, add "Corson" to the County column, and in the Current service area column add "Standing Rock Sioux Reservation" and add the following note in the Current service area column: "Note: for funding level see North Dakota, Sioux County".

On page 55260, in the State of Virginia, in the County of Buchanan, in the Funding for the following counties column, delete "\$425,640" and replace with "\$657,534".

**FOR FURTHER INFORMATION CONTACT:** The ACYF Operations Center at 1-800-351-2293 or send an email to [chs@lcnnet.com](mailto:chs@lcnnet.com). You can also contact Judith Jerald, Early Head Start, Head Start Bureau at (202) 205-8074.

Dated: October 24, 2000.

**Patricia Montoya,**

*Commission, Administration on Children, Youth and Families.*

[FR Doc. 00-27970 Filed 10-31-00; 8:45 am]

**BILLING CODE 4184-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Request for Nominations for Members on Public Advisory Committees; Pharmacy Compounding Advisory Committee

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting nominations for four members to serve on the Pharmacy Compounding Advisory Committee in the Center for Drug Evaluation and Research.

FDA has special interest in ensuring that women, minority groups, and the physically challenged are adequately represented on advisory committees

and, therefore, extends particular encouragement to nominations for appropriately qualified female, minority, or physically challenged candidates. Final selection from among each vacancy will be determined by the expertise required to meet specific agency needs and in a manner to ensure appropriate balance of membership.

**DATES:** Nominations should be received on or before December 1, 2000.

**ADDRESSES:** All nominations for membership should be sent to Jayne E. Peterson (address below).

#### FOR FURTHER INFORMATION CONTACT:

*Regarding all nominations for membership:* Jayne E. Peterson, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001.

**SUPPLEMENTARY INFORMATION:** On November 21, 1997, the President signed the Food and Drug Administration Modernization Act of 1997 (Public Law 105-115) (the Modernization Act). Section 127 of the Modernization Act added section 503A to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 353a). Section 503A of the act directs FDA to issue regulations relating to the application of Federal law to the practice of pharmacy compounding. To assist the agency in preparing these regulations, Congress directed FDA to convene and consult an advisory committee that will include representatives of the National Association of Boards of Pharmacy (NABP), the United States Pharmacopeia (USP), pharmacy, physician and consumer organizations, as well as other experts selected by the agency. The Pharmacy Compounding Advisory Committee was formed on March 10, 1998, and 15 members were appointed to the committee. The terms of four members have expired or the positions have otherwise become vacant. Accordingly, FDA is requesting nominations for four members to serve on the Pharmacy Compounding Advisory Committee.

#### Function

The function of the committee is to provide advice on scientific, technical, and medical issues concerning drug compounding by licensed practitioners and to make appropriate recommendations to the Commissioner of Food and Drugs.

#### Criteria for Members

Persons nominated for membership should have expertise in one or more of the following fields: Pharmaceutical