DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Public Meeting on Medicare Coverage of Clinical Trials

AGENCY: Agency for Healthcare Research and Quality (AHRQ), formerly AHCPR, DHHS.

ACTION: Notice of public meeting.

SUMMARY: On October 20, 2000, AHRQ held a public meeting to hear comments from the public on specific qualifying criteria for identifying clinical trials appropriate for Medicare coverage. To provide additional time for organizations and institutions interested in presenting and/or submitting their comments, AHRQ is holding a second public meeting on November 20, from 9 a.m. to 1 p.m.

In the past, Medicare has not paid for health care services provided as part of clinical trials because of their experimental nature. To carry out an executive memorandum from the President of the United States to the Secretary of Health and Human Services, received on June 7, 2000 directing Medicare to promptly provide for payment of routine patient care costs incurred by Medicare beneficiaries in connection with participation in clinical trials, the Health Care Financing Administration (HCFA) has issued a National Coverage Decision. The text of the NCD is available on the HCFA website: (*http://www.hcfa.gov/quality/8d2.htm*). In order to implement this new coverage policy for routine costs in clinical trials, HCFA must define the clinical trials for which payment of routine costs would be appropriate. Therefore, HCFA requested AHRQ to convene a multi-agency Federal Panel (the ''Panel'') to develop readily verifiable criteria by which to identify trials that meet an appropriate standard of quality. The qualifying criteria will be developed under the authority to support health care research in § 1142 of the Social Security Act (Act).

This notice announces a public meeting for the purpose of receiving oral and written comments on easily verifiable qualifying criteria for identifying clinical trials appropriate for Medicare coverage. The criteria should be objective (dichotomous yes/no answers) and should not require a detailed and technical expert assessment of each trial.

DATES: The second public meeting will take place on November 20, from 9 a.m. to 1 p.m.

ADDRESSES: The meeting will be held at the Agency for Healthcare Research and Quality Conference Center, 6010 Executive Blvd., 4th Floor, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Nilam Patel, M.P.H., Center for Practice and Technology Assessment, AHRQ, 6010 Executive Blvd., Suite 300, Rockville, MD 20852; phone: (301) 594–0236; Fax: (301) 594–4027; E-mail: *npatel@ahrq.gov.*

Arrangements for the Public Meeting: All representatives of organizations and other individuals who wish to attend, provide relevant written comments and information to AHRQ, and/or make a brief (10 minutes or less) oral statement at the meeting, must register with Nilam Patel, AHRQ, at the above address no later than three days prior to the date of the meeting. A copy of written materials should also be submitted to Ms. Patel. On the day of the meeting, presenters are requested to bring 25 copies of their written materials for distribution.

If sign language interpretation or other reasonable accommodations for a disability is needed, please contact Linda Reeves, Assistant Administrator for Equal Opportunity, AHRQ, at (301) 594–6662 no later than three days before the meeting date.

SUPPLEMENTARY INFORMATION:

1. Background

In June, 2000, the President of the United States issued an executive memorandum directing the Secretary of Health and Human Resources to ''explicitly authorize Medicare payment for routine patient care costs * * * and costs due to medical complications associated with participation in clinical trials.'' In keeping with the President's directive, HCFA has developed and added a new section in the Medicare Coverage Issues Manual that will implement national coverage of routine costs of qualified clinical trials. For the purposes of this national coverage decision, routine costs of clinical trials include all items and services that are otherwise generally available to Medicare beneficiaries (conventional care); for example, hospital services, physician services, and diagnostic tests that are not statutorily excluded from coverage. Certain costs, such as the investigational item or service, itself, items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (*e.g.,* monthly CT scans for a condition usually requiring only a single scan), and items and services customarily provided by the research sponsors free of charge for any enrollee in the trial will not be covered.

In order to implement the coverage policy, a system must be in place to help identify trials that meet an appropriate standard of quality and for which it is appropriate for Medicare to pay the associated routine costs. HCFA requested AHRQ to form a multi-agency Federal Panel to develop qualifying criteria that would indicate a high probability that a trial has the following desirable characteristics of a scientifically sound clinical trial:

(1) The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes;

(2) The trial is well-supported by available scientific and medical information or it is intended to clarify to establish the health outcomes of interventions already in common clinical use;

(3) The trial does not unjustifiably duplicate existing studies;

(4) The trial design is appropriate to answer the research question being asked in the trial;

(5) The trial is sponsored by a credible organization or conducted by an individual capable of executing the proposed trial successfully;

(6) The trial is in compliance with Federal regulations relating to the protection of human subjects; and

(7) The trial is conducted according to appropriate standards of scientific integrity.

Certain trials are presumed by AHRQ, and the other members of the Panel that it has convened, to be of sound quality and to have these desirable characteristics. Guided by the assumptions of the Panel and discussions with AHRQ, HCFA announced both long term and short term types of automatic qualification for Medicare coverage of the routine costs of clinical trials in its related NCD.

''Effective September 19, 2000, clinical trials that are deemed to be automatically qualified are:

1. Trials funded by NIH, CDC, AHRQ, HCFA, DOD, and VA;

2. Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, HCFA, DOD and VA;

3. Trials conducted under an investigational new drug application (IND) reviewed by the FDA; and

4. Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1) will be deemed automatically qualified until the qualifying criteria are developed and the certification process is in place. At that time the principal investigators of these trials must certify

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.

[FR Doc. 00–28036 Filed 10–31–00; 8:45 am]

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*.

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.

[FR Doc. 00–27986 Filed 10–31–00; 8:45 am]

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''.