

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 3, 2000, 8 a.m. to 5:30 p.m.

Location: Holiday Inn, Versailles I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Nancy T. Cherry or Denise H. Royster, Center for Biologics Evaluation and Research (HFM 71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12391. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 3, 2000, the committee will hear an update on issues relating to transmissible spongiform encephalopathy and will review safety and efficacy data pertaining to a diphtheria/tetanus/acellular pertussis vaccine manufactured by Aventis Pasteur Ltd.

Procedure: On November 3, 2000, from 8:30 a.m. to 5:30 a.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 26, 2000. Oral presentations from the public will be scheduled between approximately 1:50 p.m. and 2:20 p.m., and between approximately 3:20 p.m. and 3:50 p.m. on November 3, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 26, 2000, and submit a brief statement of the general nature of the evidence or arguments

they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On November 3, 2000, from 8 a.m. to 8:20 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information. (5 U.S.C. 552b(c)(4)). This portion will be closed to permit discussion of pending investigational new drug applications or pending product licensing applications.

FDA regrets that it was unable to publish this notice 15 days prior to the November 3, 2000, meeting of the Vaccines and Related Biological Products Advisory Committee. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Vaccines and Related Biological Products Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 17, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00-27229 Filed 10-23-00; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-3058-N]

Medicare Program; Meeting of the Executive Committee of the Medicare Coverage Advisory Committee—November 7, 2000

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces a public meeting of the Executive Committee (the Committee) of the Medicare Coverage Advisory Committee (MCAC). The Committee will hear and discuss presentations from interested parties and deliberate the scientific evidence and potential clinical utility concerning FDG Positron Emission Tomography (PET). Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)).

DATES: The Meeting will be held on November 7, 2000, from 8 a.m. until 4 p.m., EST.

Deadline for Presentations and Comments: October 31, 2000, 5 p.m., EST.

Special Accommodations: Persons attending the meeting who are hearing-impaired and require sign language interpretation, or have a condition that requires other special assistance or accommodations, are asked to notify the Executive Secretary by October 31, 2000.

ADDRESSES: The meeting will be held at the Baltimore Convention Center, One West Pratt Street, Baltimore, Maryland 21201.

Presentations and Comments: Submit formal presentations and written comments to Constance A. Conrad, Executive Secretary, Office of Clinical Standards and Quality, Health Care Financing Administration, 7500 Security Boulevard, Mail Stop S3-02-01, Baltimore, MD 21244.

Website: You may access up-to-date information on this meeting at www.hcfa.gov/quality/8b.htm.

Hotline: You may access up-to-date information on this meeting on the HCFA Advisory Committee Information Hotline, 1-877-449-5659 (toll free) or in the Baltimore area (410) 786-9379.

FOR FURTHER INFORMATION CONTACT: Constance A. Conrad, Executive Secretary, 410-786-4631.

SUPPLEMENTARY INFORMATION: On April 27, 1999, we published a notice in the **Federal Register** (64 FR 22619) to describe the Medicare Coverage Advisory Committee (MCAC), which provides advice and recommendations to HCFA regarding clinical issues.

In that notice, we announced that we would generally give at least 30 days advance notice of MCAC public meetings. We also stated that persons wishing to make presentations should submit the presentations to us at least 20 days before the meeting. We now realize that this could create a problem if we shorten the 30-day notice for the meeting. In some instances, there may be less than 20 days before the meeting, making it impossible to afford the public that amount of time to submit materials. Finally, it has also been our practice to afford the public an additional period of up to 20 days following an MCAC meeting to submit any further comments they may have. Experience has shown that there will be instances when public interest in prompt consideration of an issue outweighs the 30-day advance notice, the 20-day pre-meeting deadline for presentation materials, and the 20-day

post-meeting deadline for submission of additional comments.

This notice clarifies that we may not apply the 30-day notification, the 20-day pre-meeting presentation deadline, or the 20-day post-meeting deadline for submission of additional comments when it is in the public interest to reach an expeditious decision with respect to a coverage matter, and when we are assured that parties interested in the topic of the meeting are well aware of HCFA's consideration, and have ample time to establish and document their positions. Therefore, this notice announces the following public meeting of the MCAC, which is being convened under the terms of the exception policy detailed above. This exception policy is being exercised in the interest of reaching an expeditious decision on the scientific evidence of FDG PET.

Current Panel Members: Harold C. Sox, MD (Chairperson); Thomas V. Holohan, MD (FACP); Leslie P. Francis, JD, PhD; John H. Ferguson, MD; Robert L. Murray, PhD; Alan M. Garber, MD, PhD; Michael D. Maves, MD, MBA; Frank J. Papatheofanis, MD, PhD; Ronald M. Davis, MD; Daisy Alford-Smith, PhD; Joe W. Johnson, DC; Robert H. Brook, MD, ScD; Linda A. Bergthold, PhD; Randel E. Richner, MPH.

In addition, to augment the panel's consideration of PET coverage issues, HCFA has asked Dr. Richard Klausner, Director of the National Cancer Institute (NCI) to designate a representative to participate in the MCAC review. Dr. Ellen Feigal, Deputy Director of the Division of Cancer Treatment and Diagnosis of the NCI, will serve as the NCI representative. The Division of Cancer Treatment and Diagnosis is a national program of funding cancer research in biomedical imaging, diagnostics, radiation biology and therapy, drug discovery and development, and clinical trials.

Meeting Topic: The Committee will hear and discuss presentations from interested parties and deliberate the scientific evidence of FDG PET.

Procedure and Agenda: This meeting is open to the public. The Committee will hear oral presentations from the public and may limit the number and duration of oral presentations to the time available. If you wish to make formal presentations, you must notify the For Further Information Contact, and submit the following by the Deadline for Presentations and section of this notice: a Comments date listed in the **DATES** brief statement of the general nature of the evidence or arguments you wish to present, the names and addresses of proposed participants, and an estimate of the time required to make

the presentation. We will 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 public presentation, we will make a presentation to the Committee, after which the Committee will deliberate openly. 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 then allow an open public session for any attendee to address issues specific to the topic. Following the open session, the members will vote, and the Committee will make its recommendation.

Authority: 5 U.S.C. App. 2, section 10(a)(1) and (a)(2).

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

Dated: October 20, 2000.

Jeffrey L. Kang,

Director, Office of Clinical Standards and Quality, Health Care Financing Administration.

[FR Doc. 00-27410 Filed 10-20-00; 3:37 pm]

BILLING CODE 4120-01-U

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4497-N-09]

RIN 2577-AC08

Public Housing Assessment System (PHAS); Notice of PHAS Transition Assistance for Certain PHAs Concerning PHA Inspection of Occupied Units

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, and Office of the Director of the Real Estate Assessment Center, HUD.

ACTION: Notice.

SUMMARY: This document notifies public housing agencies (PHAs) with fiscal years ending September 30, 2000, December 31, 2000, March 31, 2001, and June 30, 2001, that they may conduct annual physical inspections of their units in accordance with HUD's Housing Quality Standards.

FOR FURTHER INFORMATION CONTACT: For further information contact the Real Estate Assessment Center (REAC), Attention: Wanda Funk, U. S. Department of Housing and Urban Development, 1280 Maryland Avenue,

SW, Suite 800, Washington DC, 20024; telephone Technical Assistance Center at (888)-245-4860 (this is a toll free number). Persons with hearing or speech impairments may access that number via TTY by calling the Federal Information Relay Service at (800) 877-8339. Additional information is available from the REAC Internet Site, <http://www.hud.gov/reac>.

SUPPLEMENTARY INFORMATION:

I. Background

On January 11, 2000 (65 FR 1712), HUD issued a final rule, as amended June 6, 2000 (65 FR 36042), that made certain amendments to the Public Housing Assessment System (PHAS) regulations. The PHAS was implemented by final regulations published on September 1, 1998. The amendments published to the PHAS regulations on January 11, 2000, followed a proposed rule published on June 22, 1999, and were prompted by both statutory and administrative changes to the PHAS.

II. Additional Transition Assistance to Certain PHAs

Following publication of the January 11, 2000, final rule, HUD was asked to provide further transition assistance to PHAs with fiscal years ending March 31, 2000, and June 30, 2000, by allowing these PHAs to inspect occupied units in accordance with HUD's Housing Quality Standards (HQS). Under sub-indicator #3 of PHAS Indicator #3, Management Operations, PHAs are assessed on the percentage of units and systems that a PHA inspects on an annual basis in order to determine short-term maintenance needs and long-term Capital Fund needs. PHAs must inspect these units in accordance with HUD's Uniform Physical Condition Standards (UPSC). In a June 6, 2000 (65 FR 36047) notice, HUD advised PHAs with fiscal years ending March 31, 2000 and June 30, 2000, of the extended transition assistance permitting these PHAs to inspect their units in accordance with HQS because HUD only recently released its physical inspection and training guidebook.

Through this notice, HUD advises that it will further extend the transition assistance provided in the June 6, 2000, notice to PHAs with fiscal years ending September 30, 2000, December 31, 2000, March 31, 2001, and June 30, 2001. All PHAs with fiscal years ending on or after September 30, 2001, must inspect units in accordance with HUD's UPSC.