

42 CFR 447.53(d) Imposition of Cost Sharing Charges Under Medicaid (BERC-509);

Form No.: HCFA-R53;

Use: The information collection requirement at 42 CFR 447.53(d) requires the States to include in their Medicaid State plan their provisions for imposition of cost sharing on the medically and categorically needy;

Respondents: State or local government;

Number of Respondents: 54;

Total Annual Responses: 54;

Total Annual Hours Requested: 2,700.

4. Type of Request: Reinstatement;

Title of Information Collection:

Medicare Current Beneficiary Survey—Community Component Supplement PR: "Sources Of Information About Medicare";

Form No.: HCFA-P-0015A;

Use: This supplement is intended to find out from a systematic sample of Medicare beneficiaries, how they obtain information about program rules and procedures when they need it. It also elicits their opinion of the adequacy of the information they found, and alternative means by which HCFA might provide this information;

Respondents: Individuals and households;

Number of Respondents: 12,000;

Total Annual Responses: 12,000;

Total Annual Hours Requested: 2,000.

5. Type of Request: Reinstatement;

Title of Information Collection:

Application for Hospital Insurance;

Form No.: HCFA-18;

Use: This form is used to establish entitlement to Hospital Insurance and Supplementary Medical Insurance for beneficiaries covered under only title XVIII of the Social Security Act;

Respondents: Business or other for profit, Federal Government, State or local government, farms, individuals and households;

Number of Respondents: 50,000;

Total Annual Responses: 50,000;

Total Annual Hours Requested: 12,500.

Additional Information or Comments: Call the Reports Clearance Office on (410) 966-5536 for copies of the clearance request packages. Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: March 7, 1995.

Kathleen B. Larson,

Director, Management Planning and Analysis Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 95-6553 Filed 3-16-95; 8:45 am]

BILLING CODE 4120-03-P

Food and Drug Administration

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1-800-741-8138 or 301-443-0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETINGS: The following advisory committee meetings are announced:

Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. April 6 and 7, 1995, 9 a.m., Holiday Inn—Gaithersburg, Whetston and Walker Rooms, Two Montgomery Village Ave., Gaithersburg, MD. A limited number of overnight accommodations have been reserved at the Holiday Inn—Gaithersburg. Attendees requiring overnight accommodations may contact the hotel at 301-948-8900 and reference the FDA Panel meeting block. Reservations will be confirmed at the group rate based on availability.

Type of meeting and contact person. Open public hearing, April 6, 1995, 9 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 4 p.m.; open public hearing, April 7, 1995, 9 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 4 p.m., Cornelia B. Rooks, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-1243, or FDA Advisory Committee Information Hotline, 1-800-741-8138, (301-443-0572 in the Washington, DC area), Clinical Chemistry and Clinical Toxicology Devices Panel, code 12514.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before March 30, 1995, 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 required to make their comments.

Open committee discussion. On April 6, 1995, the committee will discuss a premarket approval application for a fetal fibronectin enzyme immunoassay which is to be used in symptomatic women as an aid in the prediction of impending preterm delivery. On April 7, 1995, the committee will discuss a group of 510(k) applications pertaining to sweat patch collection of drugs of abuse and their measurement. The collection devices are intended for use by professionals in drug treatment programs.

Pulmonary-Allergy Drugs Advisory Committee

Date, time, and place. April 10, 1995, 8 a.m., Holiday Inn, Plaza Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Type of meeting and contact person. Open public hearing, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 5 p.m.; Leander B. Madoo, Center for Drug Evaluation and Research (HFD-9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4695, or

FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area) Pulmonary-Allergy Drugs Advisory Committee, code 12545.

General function of the committee.

The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms.

Agenda—Open public hearing.

Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before March 24, 1995, 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 required to make their comments.

Open committee discussion. The committee will discuss new drug application (NDA) 20-471, Abbott Laboratories, Leutrol (zileuton) as an anti-asthmatic drug.

Dental Drug Products Panel Plaque Subcommittee (Nonprescription Drugs) of the Medical Devices Advisory Committee

Date, time, and place. April 10, 11, and 12, 1995, 9 a.m., Parklawn Bldg., conference room G, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person.

Open public hearing, April 10, 1995, 9 a.m. to 11 a.m., unless public participation does not last that long; open committee discussion, 11 a.m. to 5 p.m.; open public hearing, April 11, 1995, 9 a.m. to 11 a.m., unless public participation does not last that long; open committee discussion, 11 a.m. to 5 p.m.; open public hearing, April 12, 1995, 9 a.m. to 11 a.m., unless public participation does not last that long; open committee discussion, 11 a.m. to 4 p.m.; Jeanne L. Rippere or Stephanie A. Mason, Center for Drug Evaluation and Research (HFD-813), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301-594-1003, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Dental Products Panel of the Medical Devices Advisory Committee, code 12518.

General function of the committee.

The committee reviews and evaluates data on the safety and effectiveness of

marketed and investigational devices and makes recommendations for their regulation.

The Dental Products Panel of the Medical Devices Advisory Committee functions at times as a nonprescription drug advisory panel. As such, the panel reviews and evaluates available data concerning the safety and effectiveness of active ingredients, and combinations thereof, of various currently marketed nonprescription drug products for human use, the adequacy of their labeling, and advises the Commissioner of Food and Drugs on the promulgation of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded.

Agenda—Open public hearing.

Interested persons may present data, information, or views, orally or in writing, on the general issues pending before the subcommittee. Those desiring to make formal presentations should notify the contact person before April 5, 1995, 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 required to make their comments.

Open committee discussion. The subcommittee will continue with its discussion begun during the December 5 and 7, 1994, meeting on developing general guidelines for determining the safety and effectiveness of antiplaque and antiplaque-related drug products. The subcommittee will also begin discussion on the safety and effectiveness of the ingredients stannous fluoride, zinc citrate, peppermint oil, and sage oil for antiplaque and antiplaque-related uses.

Ear, Nose, and Throat Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. April 20, 1995, 8 a.m., Corporate Bldg., Main Conference Room, 9200 Corporate Blvd., Rockville, MD. A limited number of overnight accommodations are available at the Holiday Inn—Gaithersburg, Two Montgomery Village Ave., Gaithersburg, MD. Attendees requiring overnight accommodations may contact the hotel at 301-948-8900 and reference the FDA Panel meeting block. Reservations will be confirmed at the group rate based on availability.

Type of meeting and contact person.

Open public hearing, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 6 p.m.; Harry R. Sauberman,

Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2080, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Ear, Nose, and Throat Devices Panel, code 12522. If anyone who is planning to attend the meeting will need any special assistance as defined under the Americans with Disabilities Act, please notify the contact person above.

General function of the committee.

The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

Agenda—Open public hearing.

Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before April 10, 1995, 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 required to make their comments.

Open committee discussion. The committee will discuss a supplement to a premarket approval application that seeks to expand the indication for use for an approved cochlear implant device to include postlinguistically hearing-impaired adults who demonstrate severe-to-profound hearing loss and who obtain some minimal benefit from conventional amplification. The discussion will include the review of clinical data obtained with the use of various speech processors.

National Mammography Quality Assurance Advisory Committee

Date, time, and place. April 24, 1995, 10 a.m., and April 25 and 26, 1995, 9 a.m., Dupont Plaza Hotel, 1500 New Hampshire Ave. NW., Washington, DC. A limited number of overnight accommodations have been reserved at the Dupont Plaza Hotel. Attendees requiring overnight accommodations may contact the hotel at 202-483-6000 and reference the FDA Committee meeting block. Reservations will be confirmed at the group rate based on availability.

Type of meeting and contact person.

Open committee discussion, April 24, 1995, 10 a.m. to 3 p.m.; open subcommittee discussions, 3 p.m. to 5 p.m.; open subcommittee discussions, April 25, 1995, 9 a.m. to 5 p.m.; open

public hearing, April 26, 1995, 9 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 3 p.m.; Charles K. Showalter, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-3332, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), National Mammography Quality Assurance Advisory Committee, code 12397.

General function of the committee. The committee advises on developing appropriate quality standards and regulations for the use of mammography facilities.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before April 18, 1995, 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 required to make their comments.

Open committee discussion. On April 24 and 26, 1995, the committee will discuss: (1) The development of three working groups (i.e., subcommittees) to consider access to mammography services, physicists availability, and cost benefit of compliance; (2) the Congressional reports and determinations mandated in the Mammography Quality Standards Act (the MQSA); (3) the work of the subcommittees; and (4) a briefing on inspections to date.

Open subcommittee discussions. On April 24 and 25, 1995, the three subcommittees will meet concurrently. The subcommittees will discuss preliminary information which is necessary to make the determinations and subsequently prepare the reports as mandated in the MQSA. Upon completion, the subcommittee reports will be reviewed by the committee prior to submission to the Secretary and Congress.

Subcommittees of the National Task Force on AIDS Drug Development

Date, time, and place. April 25, 1995, 8:30 a.m.; April 26, 1995, 10 a.m.; Salons 1, 2, and 3, Congressional Ballroom; Bethesda Marriott, 5151 Pooks Hill Rd., Bethesda, MD.

Type of meeting and contact person. Open subcommittee discussion, April

25, 1995, 8:30 a.m. to 4:30 p.m.; open public hearing, 4:30 p.m. to 5:30 p.m., unless public participation does not last that long; open subcommittee discussions, April 26, 1995, 10 a.m. to 4:30 p.m.; open public hearing, 4:30 p.m. to 5:30 p.m., unless public participation does not last that long; Jean H. McKay or Kimberley M. Miles, Office of AIDS and Special Health Issues (HF-12), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-0104, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), National Task Force on AIDS Drug Development, code 12602.

General function of the task force. The National Task Force on AIDS Drug Development shall identify any barriers and provide creative options for the rapid development and evaluation of treatments for human immunodeficiency virus (HIV) infection and its sequelae. It also advises on issues related to such barriers, and provides options for the elimination of these barriers.

Open task force discussion. The four subcommittees of the task force will meet to discuss barriers related to the identification of specific drug targets and solutions to these barriers in preparation for the next full meeting of the task force. Members of the subcommittees, Federal government, and the public will participate in these discussions.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the task force. Those desiring to make formal presentations should notify the contact person before April 19, 1995, 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 required to make their comments.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above)

beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: March 13, 1995.

Lireka P. Joseph,

Acting Deputy Commissioner for Operations.
[FR Doc. 95-6692 Filed 3-16-95; 8:45 am]

BILLING CODE 4160-01-F

National Institutes of Health

National Cancer Institute; Notice of Meetings

Pursuant to Pub. L. 92-463, notice is hereby given of the meetings of the National Cancer Institute for April and May 1995.

These meetings will be open to the public to discuss administrative details or other issues relating to committee activities as indicated in the notice and for the review of concepts being considered for funding. Attendance by the public will be limited to space available.

These meetings will be closed to the public as indicated below in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and sec. 10(d) of Pub. L. 92-463, for the review, discussion and evaluation of individual grant applications and contract proposals. These applications and proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications and proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. Carole Frank, the Committee Management Officer, National Cancer Institute, Executive Plaza North, Room 630E, 6130 Executive Blvd MSC 7405, Bethesda, Maryland 20892-7405, (301-496-5708) will provide a summary of the meetings and the roster of committee members, upon request. Other information pertaining to the meetings may be obtained from the contact person indicated below.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodation, should contact the Executive Secretary/Scientific Review Administrator listed for that particular meeting.

Committee name: Cancer Centers and Research Programs Review Committee—Subcommittee D.

Contact person: Dr. John W. Abrell, Scientific Review Administrator, National Cancer Institute, Bldg. EPN, Room 635B, 6130 Executive Blvd MSC 7405, Bethesda, MD 20892-7405. Telephone: (301) 496-9767.

Date of meeting: April 11-12, 1995.

Place of meeting: The Holiday Inn Crowne Plaza, 1750 Rockville Pike, Rockville, MD 20852.

Closed: 8 am to adjournment.

Agenda: Review, discussion and evaluation of individual grant applications.

Committee name: Biometry and Epidemiology Contract Review Committee.

Contact person: Dr. Harvey P. Stein, Scientific Review Administrator, National Cancer Institute, Bldg. EPN, Room 601C, 6130 Executive Blvd MSC 7405, Bethesda, MD 20892-7405. Telephone: (301) 496-7030.

Date of meeting: April 12-13, 1995.

Place of meeting: Conference Room G, 6130 Executive Blvd., Rockville, MD 20852.

Closed: 9 am to adjournment.

Agenda: Review, discussion and evaluation of individual contract proposals.

Committee name: Acrylonitrile Study Advisory Panel.

Contact person: Dr. Aaron Blair, Executive Secretary, National Cancer Institute, 6130 Executive Blvd., Room 418, Rockville, MD 20852. Telephone: (301) 496-9093.

Date of meeting: May 3, 1995.

Place of meeting: Conference Rooms 1 & 2, 6100 Executive Blvd., Rockville, MD 20852.

Open: 10 am to adjournment.

Agenda: Review and discussion of study progress.

(Catalog of Federal Domestic Assistance Program Numbers: 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.)

Dated: March 13, 1995.

Margery G. Grubb,

Senior Committee Management Specialist, NIH.

[FR Doc. 95-6570 Filed 3-16-95; 8:45 am]

BILLING CODE 4140-01-M

National Institute on Deafness and Other Communication Disorders; Notice of Meeting of the Ad Hoc Hearing and Hearing Impairment Subcommittee of the National Deafness and Other Communication Disorders Advisory Council

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Ad Hoc Hearing and Hearing Impairment Subcommittee of the National Deafness and Other Communication Disorders Advisory Council on April 6, 1995. The meeting will take place from 1 p.m. to 4 p.m. in Conference Room 9, Building 31C, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892, and will be conducted as a

telephone conference with the use of a speaker phone.

The meeting, which is open to the public, will be held to discuss changes in the scientific field of hearing and hearing impairment since the Research Plan was written, compare the research portfolio of the Institute with the priorities in the Research Plan to determine areas of emphasis and levels of activity, and to identify gaps and to suggest new initiatives in preparation for the updating of the hearing and hearing impairment section of the Research Plan. Attendance by the public will be limited to the space available.

Summaries of the Subcommittee's meeting and a roster of members may be obtained from Mr. Baldwin Wong, Program Analyst, National Institute on Deafness and Other Communication Disorders, Building 31, Room 3C08, National Institutes of Health, Bethesda, Maryland 20892, (301) 402-1129, upon request.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Mr. Wong in advance of the meeting.

(Catalog of Federal Domestic Assistance Program No. 93.173, Biological Research Related to Deafness and Communication Disorders)

Dated: March 13, 1995.

Margery G. Grubb,

Senior Committee Management Specialist, NIH.

[FR Doc. 95-6569 Filed 3-16-95; 8:45 am]

BILLING CODE 4140-01-M

National Institute of Dental Research; 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 National Institute of Dental Research Special Emphasis Panel (SEP) meetings.

Name of SEP: National Institute of Dental Research Special Emphasis Panel-Perio. Complications of Diabetes.

Dates: April 13, 1995.

Time: 9:00 a.m.

Place: Natcher Building, NIH, Conf. Center A.

Contact Person: Dr. Yong Shin, Scientist Review Administrator, 4500 Center Drive, Natcher Building, Room 4AN-38J, Bethesda, MD 20892, (301) 594-2372.

Purpose/Agenda: To evaluate and review grant applications and/or contract proposals.

Name of SEP: National Institute of Dental Research Special Emphasis Panel-Sensor for High Resolution (Teleconference).

Dates: April 17, 1995.