could be unduly restrictive and limit the agency's discretion when determining whether certain stages of a disease or condition are ''serious.'' Instead, § 812.36(a) applies the treatment IDE rule to ''immediately life-threatening'' diseases, and defines that as a stage of a disease in which there is a reasonable likelihood that death would occur within a matter of months or in which premature death is likely without early treatment.

This definition could be used to help define the category of device trials that could be included in a clinical trials data bank. The clinical trials data bank could contain a list of clinical trials, whether Federally or privately funded, of investigational devices for serious or life-threatening diseases, a description of the investigational device, eligibility criteria for patients, the location of clinical trials sites, and a point of contact for those wanting to enroll in the trial. In evaluating the public health need for a device trials data bank and the effects a mandatory public data bank would have on innovation and research, FDA is currently assuming the devices that would fall within the scope of the provision are those intended to treat such ''immediately life-threatening'' situations, but FDA invites public comment on this issue.

FDA is in the process of consulting with NIH on the feasibility of adding device trials to the data bank. In addition, through this notice, FDA is soliciting comments and information that will help the agency draft its report to Congress under section 113(b) of FDAMA. In particular, FDA seeks input in response to the following questions:

1. Is there a public health need for inclusion of device investigations within the scope of the data bank under 402(j) of the PHS Act?

2. If there is a public health need, what category of device trials should be made publicly available and how should this category be defined? FDA's treatment IDE regulation applies only to devices for which no comparable or satisfactory alternative exists. Should a data bank for IDE's be similarly restricted? Should the trials that become part of the data bank include feasibility/pilot trials or only studies that are intended to demonstrate reasonable assurance of safety and effectiveness?

3. Investigational device trials have historically been smaller in numbers of subjects and numbers of investigational sites than investigational drug trials. What impact, both positive and negative, would the release of information have on these device trials, the sponsors, the investigators, the investigational sites, and the patients? Will a public data bank create pressures to increase the size of device trials or number of sites in situations where such expansion may increase risk to patients?

4. IDE information is generally protected from public disclosure under FDA regulations. If public disclosure were voluntary, would disclosure by one sponsor put pressure on sponsors of similar investigations to disclose the existence of their studies against their better judgment? Is this in the interest of the public health?

5. If disclosure is mandatory, is it likely to hamper innovations and investment in research and development? Would disclosure of these investigational device trials help or hinder research by increasing patient enrollment?

6. Because sponsors can recover some of the costs of the device research and development under the investigational device regulations, should FDA be concerned that publicly available information concerning investigational device trials will result in undue financial pressure or incentives on the trial sponsors to add subjects to the trials without appropriate consideration of risk? Should FDA be concerned about the possibility that improper promotion and commercialization will occur as a result of a public data bank for IDE trials?

7. Will public disclosure of information about device trials for products to treat serious or life-threatening diseases or conditions affect reimbursement policies of third party payers?

8. What other important information or issues should the agency consider?

FDA is planning a public meeting to give interested parties a chance to present their views on the feasibility, utility, and effects of a data bank for device trials. Information regarding the date and place of this meeting is published elsewhere in this issue of the **Federal Register**.

Interested persons may, on or before August 23, 1999Dockets Management Branch (address above) written comments regarding this notice. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 14, 1999.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 99–15757 Filed 6–21–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1081–2N]

Medicare Program; Cancellation of the June 24, 1999, Meeting of the Competitive Pricing Advisory Committee and the Area Advisory Committee for the Kansas City Metropolitan Area

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

ACTION: Notice of meeting cancellation.

SUMMARY: This notice announces the cancellation of the June 24, 1999, meeting of the Competitive Pricing Advisory Committee and the Area Advisory Committee for the Kansas City metropolitan area.

FOR FURTHER INFORMATION CONTACT: Sharon Arnold, Ph.D., Executive Director, Competitive Pricing Advisory Committee, Health Care Financing Administration, 7500 Security Boulevard C4–14–17, Baltimore, MD 21244–1850, (410) 786–6451 (for information about the CPAC).

Richard P. Brummel, Deputy Regional Administrator, Health Care Financing Administration, Richard Bolling Federal Building, Room 235, 601 East 12th Street, Kansas City, MO 64106, (816) 426–5233 (for information about the Kansas City metropolitan area AAC).

SUPPLEMENTARY INFORMATION: This notice announces the cancellation of the June 24, 1999, meeting of the Competitive Pricing Advisory Committee and the Area Advisory Committee for the Kansas City metropolitan area. The meeting will be rescheduled and announced in a subsequent **Federal Register** notice. (Section 4012 of the Balanced Budget Act of 1997, Pub. L. 105–33 (42 U.S.C.1395w–23 note) and section 10(a) of Pub. L. 92–463 (5 U.S.C. App.2, section 10(a))

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 17, 1999.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 99–15986 Filed 6–18–99; 1:45 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Statement of Organization, Functions, and Delegations of Authority Office of Communications and Operations Support

Part F of the Statement of Organization, Functions, and Delegations of Authority; for the Department of Health and Human Services, Health Care Financing Administration (HCFA), **Federal Register**, Vol. 62, No. 129, pp. 36294–36295, dated Monday, July 7, 1997, is amended to reflect a reorganization in the Office of Communications and Operations Support.

The specific change will transfer the Audit Liaison Staff from the Office of Financial Management to the Office of Communications and Operations Support to ensure timely resolution of all audit findings and recommendations.

The specific amendments to part F are described below:

Section F.10.A.5., Health Care Financing Administration, is amended by the creation of a new Division of Audit Liaison in the Office of Communications and Operations Support, Operations Support Group, and adding the function of this new Division to the Office functional statement. The existing functional statement is superseded by the following revision:

Office of Communications and Operations Support (FAL)

- Serves a neutral broker coordination role, including scheduling meetings and briefings for the Administrator and coordinating communications between and among central and regional office, in order to ensure that emerging issues are identified early, all concerned components are directly and fully involved in policy development/decision making and that all points of view are presented.
- Coordinates and monitors assigned Agency initiatives which are generally tactical, short-term and cross-component in nature (e.g., legislative implementation).
- Provides operational and analytical support to the Executive Council.
- Manages speaking and meeting requests for or on behalf of the Administrator and Deputy Administrator and researches and writes speeches.
- Coordinates agency-wide communication policies to insure that messages for external audiences appropriately incorporate Agency themes.
- Coordinates the preparation of manuals and other policy instructions to insure accurate and consistent implementation of the Agency's programs.
- Manages the Agency's system for developing, clearing and tracking regulations, setting regulation priorities and corresponding work agendas; coordinates the review of regulations received for concurrence from departmental and other government agencies and develops routine and special reports on the Agency's regulatory activities.
- Manages the Agency-wide clearance system to insure appropriate involvement from Agency components and serves as a primary focal point for liaison with the Executive Secretariat in the Office of the Secretary.
- Operates the agency-wide correspondence tracking and control system and provides guidance and technical assistance on standards for content of correspondence and memoranda.
- Formulates strategies to advance overall communications goals and coordinates the design and publication process in electronic and other media for HCFA electronic information, publications and reports to ensure consistency with other information.
- Provides management and administrative support to the Office of the Attorney Advisor and staff.
- Acts as audit liaison with the General Accounting Office (GAO) and the HHS Office of Inspector General (OIG).

The function of this newly-created Division was deleted from the functional statement of the Office of Financial Management.

Dated: May 28, 1999.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 99–15806 Filed 6–21–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF THE INTERIOR

Geological Survey

Request for Public Comments on Information Collection To Be Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

A request to reinstate the collection of information listed below will be submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). Copies of the proposed collection of information and related forms may be obtained by contacting the Bureau's Clearance Officer at the phone number listed below. Comments and suggestions on the requirement should be made within 60 days directly to the Bureau Clearance Officer, U.S. Geological Survey, 807 National Center, Reston, VA 20192.

As required by OMB regulations at 5 CFR 1320.8(d)(1), the U.S. Geological Survey solicits specific public comments regarding the proposed information collection as to:

1. Whether the collection of information is necessary for the proper performance of the functions of the Bureau, including whether the information will have practical utility;

2. The accuracy of the Bureau's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

3. The utility, quality, and clarity of the information to be collected; and,

4. How to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated electronic, mechanical, or other forms of information technology.

Title: State Water Research Institute Program.

Current OMB approval number: 1028–0044.

Abstract: Respondents supply information on eligibility for Federal grants to support water-related research and provide performance reports on accomplishments achieved through use of such funds. This information allows the agency to determine compliance with the objectives and criteria of the grant program.

Bureau form number: None.

Freqiemcu: Annually.

Description of respondents: State water research institutes.

Annual Responses: 108.

Annual burden hours: 5,832.