

Doppler signal (blood flow), and visualize wall motion of the heart.

**Closed committee deliberations.** FDA staff will present to the committee trade secret and/or confidential commercial information regarding present and future FDA issues. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Each public advisory committee meeting listed above 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. The dates and times reserved for the separate portions of each committee meeting are listed above.

The open public hearing portion of the meeting(s) 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, 5600 Fishers Lane, rm. 12A-16, 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, 12420 Parklawn Dr., rm. 1-23, 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.

The Commissioner has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled

for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, deliberation to formulate advice and recommendations to the agency on matters that do not independently justify closing.

This notice is issued under section 10(a)(1) and (a)(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: January 22, 1997.  
Michael A. Friedman,  
Deputy Commissioner for Operations.  
[FR Doc. 97-2239 Filed 1-28-97; 8:45 am]  
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## **Health Care Financing Administration** **[Form # HCFA-1500]**

### **Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)**

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services (DHHS), has submitted to the Office of Management and Budget (OMB) the following request for Emergency review. We are requesting an emergency review because the collection of this information is needed prior to the expiration of the normal time limits under OMB's regulations at 5 CFR, Part 1320, in order to prevent providers from denying services to beneficiaries. The Agency cannot reasonably comply with the normal clearance procedures because public harm is likely to result if normal clearance procedures are followed. Without this information, HCFA would not be able to process claims possibly resulting in the denial of services to

Medicare Beneficiaries, due to provider non-payment.

HCFA is requesting that OMB provide a seven working day review and a 180-day approval. During this 180-day period HCFA will pursue OMB clearance of this collection as stipulated by 5 CFR 1320.5.

#### 1. Type of Information Collection

*Request:* Reinstatement without change, of a previously approved collection;

*Title of Information Collection:*

Medicare/Medicaid Health Insurance Common Claim Form and Instructions, and Supporting Regulations 42 CFR 424.32 (Basic Requirements for all Claims) and 42 CFR 414.40 (Coding and Ancillary Policies); *Form No.:* HCFA-1500; *Use:* This form and instructions are standardized for use in the Medicare/Medicaid programs to apply for reimbursement for covered services. HCFA does not require exclusive use of this form for Medicaid. 42 CFR 424.32 and 42 CFR 414.40 are regulations underlying the use of the form HCFA-1500 and the information captured on the form HCFA-1500, including the use of diagnostic and procedural coding systems; *Frequency:* On occasion;

*Affected Public:* Business or other for profit, not for profit institutions, State, local or tribal government; *Number of Respondents:* 976,239; *Total Annual Responses:* 614,967,982; *Total Annual Hours:* 52,139,385.

To request copies of the proposed paperwork collections referenced above, call the Reports Clearance Office on (410) 786-1325. Written comments and recommendations for the proposed information collections should be sent within five working 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: January 23, 1997.

Edwin J. Glatzel,

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

[FR Doc. 97-2088 Filed 1-28-97; 8:45 am]

BILLING CODE 4120-03-P

[ORD-089-N]

#### Medicare and Medicaid Programs; Small Business Innovation Research Grants for Fiscal Year 1997

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

**ACTION:** Notice.

**SUMMARY:** This notice announces the availability of HCFA funding, through grants, for small businesses under the Small Business Innovation Research (SBIR) Program. This notice contains information about the subject areas for grants that will be given priority, application requirements, review procedures, and other relevant information.

**DATES:** Grant applications must be submitted by April 29, 1997, in order to be considered under the fiscal year (FY) 1997 annual funding cycle.

**ADDRESSES:** Standard application forms and related instructions are available from and must be formally submitted to: HCFA Grants Officer, Office of Acquisition and Grants, Health Care Financing Administration, 7500 Security Boulevard, C2-21-15, Baltimore, MD 21244-1856, (410) 786-5701.

**FOR FURTHER INFORMATION CONTACT:** Carl Hackerman, (410) 786-6644. *Internet:* Chackerman@hcfa.gov.

#### SUPPLEMENTARY INFORMATION:

##### I. Small Business Innovation Research Program

The Small Business Innovation Development Act of 1982 (Public Law 97-219, enacted on July 22, 1982), as amended by the Small Business Innovation Research Program Extension (Public Law 99-443, enacted on October 6, 1986), the Small Business Administration Reauthorization and Amendment Act of 1988 (Public Law 100-590, enacted on November 3, 1988), the Small Business Research and Development Enhancement Act of 1992 (Public Law 102-564, enacted on October 28, 1992), and the Small Business Administration Reauthorization Act of 1994 (Public Law 104-403, enacted on October 2, 1994), (15 U.S.C. 638(e) through (m)), requires Federal agencies to reserve a specific amount of their extramural research and budgets for a Small Business Innovation Research (SBIR) Program. This SBIR Program is intended to—

- Stimulate technological innovation;
- Use small business to meet Federal research and demonstrations ("R & D") needs;
- Increase private sector commercialization of innovations derived from Federal R & D; and
- Foster and encourage participation by minority and disadvantaged persons in technological innovation.

The principal purpose of HCFA's SBIR Program is to provide assistance to creative applicants so that innovation

can be encouraged that will result in better health care.

#### A. SBIR Program Phases, Award Amounts, and Period of Support

The SBIR Program consists of the following three phases:

##### Phase I

The objective of this phase is to establish the technical merit and feasibility of proposed research or Research and Demonstrations efforts and to determine the quality of performance of the small business awardee organization before furnishing further Federal support in Phase II. Phase I awards will be approximately \$50,000 (for both direct and indirect costs) for a period not to exceed 12 months.

##### Phase II

The objective of this phase is to continue the research or R & D efforts initiated in Phase I and to actually create the proposed product and test it before marketing. Funding is based on the results of Phase I and technical merit of the Phase II application, including its potential for commercialization. (Only Phase I awardees are eligible to apply for Phase II funding.) Phase I awardees are eligible to apply for Phase II funding only from the Federal agency that supported their Phase I project. Phase II awards will be approximately \$100,000 to 150,000 (for both direct and indirect costs) for a period normally not to exceed 12 months.

##### Phase III

The objective of this phase, if appropriate, is for the small business concern to pursue with non-Federal funds the commercialization of the results of the research or R & D in Phases I and II.

The purpose of this notice is to invite Phase I and II grant applications from for-profit domestic small business concerns that have the expertise to develop or further develop innovative technology. This technology should be compatible with the general mission of HCFA and contribute to the health care field. HCFA is responsible for the Medicare program, Federal participation in the Medicaid program, and related health care quality assurance programs. HCFA's mission is to promote the timely delivery of appropriate quality health care to its Medicare beneficiaries and Medicaid recipients—over 70 million of the nation's aged, disabled, and poor. HCFA must also ensure that Medicare beneficiaries and Medicaid recipients are aware of the services for