

product is effective, and any study in which a single investigator makes a significant contribution to the demonstration of safety. Applicants are required to certify to the absences of certain financial interests of clinical investigators or to disclose those financial interests. If the applicant does not include certifications and/or disclosure or does not certify that it was not possible to obtain the information, the agency may refuse to file the application.

II. Discussion of Comments

The agency has received 12 comments on the draft guidance which published in the **Federal Register** of October 26, 1999 (64 FR 57640). Some commenters asked whether use of Forms FDA 3454 and 3455 is mandatory. One comment asked how much information should be submitted when incomplete financial information is known. There were numerous commenters who asked whether information could be submitted through a questionnaire instead of through internal systems. Some commenters requested clarification on what FDA meant by the definition of "sponsor of the covered study." Comments were received on whether travel expenses for investigators should be tracked as significant payments of other sorts. Several commenters asked for clarification on FDA's definition of clinical investigator and subinvestigators. A few comments discussed the need to allow exemption for large scale efficacy studies from the covered clinical study definition. There were also comments requesting clarification on what FDA means by completion of the study and 1 year following completion of the study.

III. Status of the Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). This guidance document represents the agency's current thinking on financial disclosure by clinical investigators. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

IV. Electronic Access

Persons interested in obtaining a copy of the guidance on the Internet may access the guidance at <http://internet-dev.fda.gov/oc/guidance/finsumm.html> or <http://www.fda.gov/ohrms/dockets/default.htm>.

V. Comments

Interested persons may, at any time, submit written comments to the Dockets Management Branch (address above) regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 20, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01-7564 Filed 3-27-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration [HCFA-4020-N]

Medicare Program; Renewal of the Advisory Panel for Medicare Education (APME)

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

ACTION: Notice.

SUMMARY: This notice announces the renewal of the Advisory Panel on Medicare Education (the Panel or APME). The Panel advises the Secretary of the Department of Health and Human Services (the Secretary) and the Administrator of the Health Care Financing Administration (the Administrator) concerning optimal strategies for implementing a national Medicare education program; enhancing the Federal Government's effectiveness in informing the Medicare consumer; expanding outreach to vulnerable and under-served communities; and assembling an information base of "best practices" for helping consumers to evaluate health plan options and build a community infrastructure for information, counseling, and assistance. In accordance with the Federal Advisory Committee Act, 5 U.S.C. Appendix 2, this notice announces the signing of the APME charter renewal by the Secretary on January 18, 2001. The charter will terminate on January 21, 2003, unless renewed by the Secretary.

FOR FURTHER INFORMATION CONTACT: Nancy Caliman, Partnership Development Group, Center for Beneficiary Services, HCFA, 7500 Security Boulevard, Mail Stop S2-23-

05, Baltimore, MD 21244, (410) 786-5052, or E-mail ncaliman@hcfa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On February 17, 1999, we published a notice in the **Federal Register** (64 FR 7899) announcing the establishment of the Citizens Advisory Panel on Medicare Education. The Secretary signed the charter for the Citizens Advisory Panel on Medicare Education on January 21, 1999. The name of the committee was changed to the Advisory Panel on Medicare Education via an amended charter signed by the Secretary on July 24, 2000.

The Panel, chartered under section 1114(f) of the Social Security Act (42 U.S.C. section 1314(f)), is governed by the provisions of the Federal Advisory Committee Act (FACA) (5 U.S.C. Appendix 2), that set forth standards for the formation and use of advisory committees.

The Panel consists of up to 20 members with expertise in senior citizen advocacy; outreach to minority communities; health communications; disease-related health advocacy; disability policy and access; health research; health insurers and plans; providers and clinicians; and matters of labor and retirement. There are currently 16 members on the Panel.

The Panel advises the Secretary and the Administrator concerning optimal strategies for—

- Developing and implementing a national Medicare education program that describes the options for selecting a health plan under Medicare;
- Enhancing the Federal Government's effectiveness in informing the Medicare consumer, including providing information about the appropriate use of public-private partnerships;
- Expanding outreach to vulnerable and under-served communities, including racial and ethnic minorities, in the context of a national Medicare education program; and,
- Assembling an information base of "best practices" for helping consumers to evaluate health plan options and build a community infrastructure for information, counseling and assistance.

II. Provisions of This Notice

This notice announces the signing of the APME charter renewal by the Secretary on January 18, 2001. The charter will terminate on January 21, 2003, unless renewed by appropriate action before its expiration date.

III. Copies of the Charter

You may obtain a copy of the charter for the APME by submitting a request to Nancy Caliman, Partnership Development Group, Center for Beneficiary Services, Health Care Financing Administration, 7500 Security Boulevard, Mail Stop S2-23-05, Baltimore, MD 21244, (410) 786-5052, or E-mail the request to ncaliman@hcfa.gov. A copy of the charter is also available on the Internet at <http://www.hcfa.gov/events/apme/homepage.htm>.

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh)

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

Dated: March 14, 2001.

Michael McMullan,

Acting Deputy Administrator, Health Care Financing Administration.

[FR Doc. 01-7631 Filed 3-27-01; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4653-N-02]

Notice of Proposed Information Collection for Public Comment: HUD Urban Scholars Fellowship Program

AGENCY: Office of the Assistant Secretary for Policy Development and Research, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below

will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. Public comments on the subject proposal are being solicited. An emergency paperwork number has been granted so that the program can make awards and operate in FY 2001.

DATES: *Comments Due Date:* May 29, 2001.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name or OMB control number and be sent to: Reports Liaison Officer, Office of Policy Development and Research, Department of Housing and Urban Development, 451 7th Street, SW., Room 8226, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Jane Karadbil, Office of University Partnerships, Department of Housing and Urban Development, 451 7th Street, Washington, DC 20410; telephone (202) 708-1537 (this is not a toll-free number). Copies of the proposed forms and other available documents to be submitted to OMB may be obtained from Ms. Karadbil.

SUPPLEMENTARY INFORMATION: An emergency paperwork has been granted so that the program can make awards and operate in FY 2001. The Department will submit the proposed information collection to OMB for review for a regular paperwork clearance, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected entities concerning the proposed information collection to: (1) Evaluate

whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of information to be collected; and (4) Minimize the burden of collection of information on those who are to respond; including through the use of appropriate technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of the Proposal: HUD Urban Scholars Fellowships Program.

Description of the need for the information and proposed use: The information is being collected to enable the selection of fellows in this competitive fellowship program. The information is also being used to monitor the performance of applicants to ensure that they meet program goals and requirements.

Members of the affected public: Ph.D.'s with academic appointments at institutions of higher education: 100 applicants and 10 fellows.

Estimation of the total number of hours needed to prepare the information collection including the number of respondents, frequency of response, and hours of response: Information pursuant to submitting applications will be submitted once. Information pursuant to fellows' monitoring requirements will be halfway through their fellowships and at the completion of the grant.

The following chart details the respondent burden on an annual basis:

	Number of respondents	Total annual responses	Hours per response	Total hours
Application	100	100	32	3,200
8-month Reports	10	10	8	80
Final Report	10	10	4	40
Total				3,320

Status of proposed information collection: An emergency paperwork number has been granted. This is a new paperwork request for a regular paperwork number, pending OMB approval.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: March 15, 2001.

Lawrence L. Thompson,

General Deputy Assistant Secretary for Policy Development and Research.

[FR Doc. 01-7574 Filed 3-27-01; 8:45 am]

BILLING CODE 4210-62-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4649-M-13]

Notice of Proposed Information Collection: Comment Request, Economic Development Initiative and Brownfields Economic Development Initiative Grant Programs

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.