

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Office of the Secretary**

[Document Identifier: OIG-10-ICF]

**Agency Information Collection Activities: Proposed Collection; Comment Request****AGENCY:** Office of Inspector General (OIG), HHS.**ACTION:** Notice.

**SUMMARY:** The proposed information collection requirement described below will be submitted to the Office of Management and Budget for review, as required by the Paperwork Reduction Act. The Department is soliciting public comment on the proposed application of preliminary questions under the Office of Inspector General's (OIG) advisory opinion process in accordance with section 205 of the Health Insurance Portability and Accountability Act of 1996.

**DATES:** Written comments should be received by May 20, 1997.

**ADDRESSES:** Interested persons are invited to submit comments regarding this collection of information.

Comments should refer to the document identifier code OIG-10-IFC, and should be sent to: Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue, S.W., Washington, D.C. 20201.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the project or to obtain a copy of the information collection plans and instruments, please contact the OS Reports Clearance Officer, (202) 690-6207.

**SUPPLEMENTARY INFORMATION:** The Department of Health and Human Services, Office of the Secretary periodically publishes summaries of proposed information collection projects and solicits public comments in compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995. Interested persons are invited to send comments regarding burden estimates or any aspect of the collection of information, including (1) 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) the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information

on respondents, including through the use of automated collection techniques or other forms of information technology.

*Type of information collection request:* OIG Advisory Opinion Procedures in 42

CFR Part 1008 and Preliminary Questions. Section 205 of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, requires the Department to provide advisory opinions to the public regarding several categories of subject matter, including the requestor's potential liability under sections 1128, 1128A and 1128B of the Social Security Act (the Act). The Office of Inspector General (OIG) has separately published interim final regulations in the **Federal Register** on February 19, 1997 (62 FR 7350) setting forth the procedures under which members of the public may request advisory opinions from the OIG. That discussion contains a more thorough discussion of the advisory opinion process and the role of these preliminary questions. In order to aid potential requestors and the OIG in providing opinions under this process, the OIG is providing preliminary questions that may be answered in an advisory opinion request. These preliminary questions will be voluntary and will correspond with each sanction provision about which advisory opinions will be rendered. The aggregate information burden for the information collection requirements contained in the interim final rule, in conjunction with the preliminary questions, is set forth below.

*Respondents:* The "respondents" for the collection of information described in the OIG rulemaking will be self-selected individuals and entities that choose to submit request for advisory opinions to the OIG. We anticipate that the respondents will include many types of health care providers, from sole practitioner physicians to large diversified publicly-traded corporations.

*Estimated number of respondents:* 500. Most individuals and entities that provide medical services that may be paid for by Medicare, Medicaid or Federal health care programs could potentially have questions regarding one of the subject matters about which the OIG will issue advisory opinions. In reality, we believe that the number of requestors will be a small fraction of such providers.

Over the past several years, the Office of the General Counsel, Inspector General Division has answered telephone inquiries from individuals and entities seeking *informal* guidance with respect to the Medicare and State

health care programs' anti-kickback statute and other sanction authorities. Many of the inquiries related to authorities outside the scope of the advisory opinion process, such as the self-referral provisions of section 1877 of the Act. In addition, we believe that most of the inquiries received have been of a nature that the caller or requestor would be unlikely to request a formal written advisory opinion on the subject matter. Many inquiries related to rather simple and straight-forward matters that could have been researched by private counsel at relatively minor expense. Nevertheless, the rate of these telephone inquiries form a starting point for estimating point for estimating the potential number of advisory opinion requests.

We estimate that the OIG received an average of six related telephone inquiries per day over the past several years. Using that history as a general guide and benchmark, we estimate an annual number of 500 respondents. Obviously, the actual number of requests could be larger since, for the first time, formal written opinions are available. Conversely, the number of inquiries could be less based on combination of several unquantifiable reasons, including the desire not to have one's arrangement be subject to scrutiny by the OIG (following issuance of the opinion) and the general public.

*Estimated number of responses per respondent:* One.

*Estimated total annual (hour) burden on respondents:* 5,000 hours. We believe that the burden of preparing requests for advisory opinions will vary widely depending upon the differences in the size of the entity making the request and the complexity of the advice sought. We estimate that the average burden for each submitted request for an advisory opinion will be in the range of 2 to 40 hours. We further believe that the burden for most requests will be closer to the lower end of this range, with an average burden of approximately 10 hours per respondent.

The OIG is requiring requests for advisory opinions to involve *actual or intended fact scenarios*. We anticipate that most requests will involve business arrangements into which the requesting party intends to enter. Because the facts will relate to business plans, the requesting party will have collected and analyzed all, or almost all, of the information we will need to collect to review the request. Therefore, in order to request an advisory opinion, in many instances the requestor will simply have need to compile already collected information for our examination. In some cases, the requestor may need to

expend a more significant amount of time and cost in preparing a submission related to more complex arrangements that involve a large number of parties or participants.

*Estimated annual cost burden on respondents (in addition to the hour burden):* \$1,000,000. In addition to the hour burden on respondents discussed above, some respondents may incur additional information collection costs related to the purchase of outside professional services, such as attorneys or consultants. We believe that the cost burden related to such outside assistance will vary from zero to 40 hours per request, with an average of 10 hours. At the rate of \$200 per hour, this total burden would amount to \$1,000,000.

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

Dated: March 10, 1997.

**Dennis P. Williams,**

*Deputy Assistant Secretary, Budget.*

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BILLING CODE 4150-04-P

### **Notice of a Cooperative Agreement With the National Association for Equal Opportunity in Higher Education**

The Office of Minority Health (OMH), Office of Public Health and Science, announces that it will enter into an umbrella cooperative agreement with The National Association For Equal Opportunity in Higher Education (NAFEO). This cooperative agreement will establish the broad programmatic framework within which specific projects can be funded as they are identified during the project period.

The purpose of this cooperative agreement is to assist the national association in expanding and enhancing its activities relevant to education, health promotion and disease prevention, and family and youth violence prevention with the ultimate goal of improving the health status of minorities and disadvantaged people. The OMH will provide consultation, including administrative and technical assistance as needed, for the execution and evaluation of all aspects of this cooperative agreement. The OMH will also participate and/or collaborate with the awardee in any workshops or symposia to exchange current information, opinions, and research findings.

### **Authorizing Legislation**

This cooperative agreement is authorized under Title XVII, Section 1707(d)(1) of the Public Health Service

Act, as amended by Public Law 101-527.

### **Background**

Assistance will be provided only to NAFEO. No other applications are solicited. NAFEO is the only organization capable of administering this cooperative agreement because it has:

1. A well developed infrastructure and communications network to coordinate and implement various health promotion and prevention educational programs within the Historically Black Colleges and Universities (HBCUs) communities and with local community organizations in close proximity to their campuses. It is the only organization of its kind that works exclusively with both public and private, two- and four-year, and graduate and professional black colleges and universities. Since the presidents of the black colleges and universities represent their institutions in NAFEO, it has a direct linkage that would facilitate the coordination of activities that will benefit all of these institutions.

NAFEO has extensive experience in convening general conferences and specific technical assistance workshops for black colleges and universities. This experience provides a foundation upon which to develop and promote health education related programs aimed at preventing and reducing unnecessary morbidity and mortality rates among African American populations.

2. Established itself and its members as a national association with professionals who serve as leaders and experts in planning, developing, implementing, and promoting educational and policy campaigns (locally and nationally) aimed at reducing adverse health behaviors and improving the African American community's overall educational and social well being.

3. Experience in implementing workshops to assist specific Federal agencies in involving HBCUs in an appropriate and effective manner in their programs, including:

Work with Department of Defense (DOD) to increase participation of HBCUs in DOD funded activities as prime contractors or as subcontractors, or collaborators or partners with industry, major research universities, and small and disadvantaged businesses. This included the conduct of approximately 15 Defense Technical Assistance workshops to increase the participation of HBCUs and other minority institutions in the DOD procurement process.

A series of 20 regional seminars involving the U.S. Agency for International Development (AID) officials and representatives of HBCUs to increase the involvement of HBCUs in U.S. AID development programs.

Workshops for the Air Force Office of Scientific Research (AFOSR) on solving technical problems of development and maintenance of a superior Air Force weapons systems and a safeguard for defense.

4. Developed a base of critical knowledge, skills, and abilities related to HBCU issues including health and social problems. Through the collective efforts of its members, community-based organizations, volunteers, NAFEO has demonstrated (1) the ability to work with academic institutions and health groups on mutual education, research, and health endeavors relating to the goal of health promotion and disease prevention of African Americans; (2) the leadership necessary to attract minority students into public service and health careers; and (3) the leadership needed to assist health care professionals to work more effectively with African American clients and communities.

This cooperative agreement will be awarded in FY 1997 for a 12-month budget period within a project period of 3 years. Continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds.

### **Where To Obtain Additional Information**

If you are interested in obtaining additional information regarding this project, contact Ms. Georgia Buggs, Office of Minority Health, 5515 Security Lane, Suite 1000, Rockville, Maryland 20852 or telephone (301) 443-5084.

**Clay E. Simpson, Jr.,**

*Deputy Assistant Secretary for Minority Health.*

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### **Agency for Toxic Substances and Disease Registry**

[ATSDR-118]

### **Quarterly Public Health Assessments Completed**

**AGENCY:** Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** This notice is a quarterly announcement that contains a list of sites for which ATSDR has completed