

side, with one-inch margins, and unreduced font.

The application should follow this format:

1. *Introduction*: Present the overall objectives of the cooperative agreement program. Present the general plan for management and implementation of the activities.

2. *Individual Project Proposals*: Present a detailed proposal for each separate project/activity (for multi-year projects, present details for the first year and include only a brief description of future-year activities). Each proposal should include the following sections in this order:

- a. Title
- b. Background and Need
- c. Objectives
- d. Operational Plan
- e. Budget and Justification

If requesting funds in the "Contractual" line-item, the Budget section should include the following information for each contract: (a) name of proposed contractor, (b) breakdown and justification for estimated costs, (c) description and scope of activities to be performed by contractor, (d) period of performance, and (e) method of contractor selection (e.g., sole-source or competitive solicitation).

#### F. Submission and Deadline

Submit the original and five copies of PHS-398 (OMB Number 0925-0001)(adhere to the instructions on the Errata Instruction Sheet for PHS 398). Forms are in the application kit.

On or before June 1, 2001, submit the application to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

#### G. Evaluation Criteria

The application will be evaluated against the following criteria by an independent review group appointed by CDC.

1. *Background and Need* (25 points): The extent to which the background and need are clearly presented for the program.

2. *Objectives* (30 points): The extent to which the activities proposed and their objectives are clear and consistent with the purpose and Program Requirements of this cooperative agreement announcement.

3. *Operational Plan* (45 points): The extent to which the operational plan(s) for conducting the proposed activities

- a. are clear, detailed, and appropriate to achieve the stated objectives;
- b. identify the key personnel and organizations responsible for the proposed activities;

c. identify a specific timetable for activities;

d. include a plan for evaluation of progress towards objectives; and

4. *Human Subjects* (not scored): Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects?

5. *Budget* (not scored): The extent to which the project budget includes detailed line-item justification and is appropriate for the activities proposed.

#### H. Other Requirements

##### Technical Reporting Requirements

Provide CDC with original plus two copies of

1. Progress reports (semiannual);
2. Financial Status Report, no more than 90 days after the end of the budget period; and
3. Final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

For descriptions of the following Other Requirements, see Attachment I. AR-9 Paperwork Reduction Act

Requirements  
AR-10 Smoke-Free Workplace

Requirements  
AR-11 Healthy People 2010

AR-12 Lobbying Restrictions  
AR-22 Research Integrity

#### I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301(a), 307, and 317(k)(1) and 317(k)(2) of the Public Health Service Act, [42 U.S.C. sections 241(a), 2421, and 247b(k)(1) and 247(k)(2)], as amended. The Catalog of Federal Domestic Assistance number is 93.283.

#### J. Where to Obtain Additional Information

This and other CDC announcements can be found on the CDC home page Internet address—<http://www.cdc.gov> Click on "Funding" then "Grants and Cooperative Agreements."

To obtain additional information, contact: Mattie B. Jackson, Lead Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Room 3000, 2920 Brandywine Road, Atlanta, GA 30341-4146, Telephone number 770-488-2718, Email address [mij3@cdc.gov](mailto:mij3@cdc.gov).

For program technical assistance, contact: Ann Moen, Public Health

Advisor, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E. MS G-16, Atlanta, GA 30333, Telephone 404-639-4652, Email address [amoen@cdc.gov](mailto:amoen@cdc.gov).

Dated: April 10, 2001.

**John L. Williams,**

*Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 01-9314 Filed 4-13-01; 8:45 am]

BILLING CODE 4163-18-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[Program Announcement #01048]

#### Cooperative Agreement for Early Hearing Detection and Intervention (EHDI) Tracking, Research, and Integration; Notice of Availability of Funds

##### A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2001 funds for a cooperative agreement program in Early Hearing Detection and Intervention.

This program addresses the "Healthy People 2010" focus area of Vision and Hearing.

The purpose of this cooperative agreement is to: (1) assist States in developing or enhancing a sustainable, centralized EHDI tracking and surveillance system, (2) integrate the EHDI system with other newborn screening programs, and (3) conduct applied research. Early Hearing Detection and Intervention (EHDI) is a national initiative to improve the communicative, cognitive, and social outcomes of children with hearing loss through a program of services and research.

##### B. Eligible Applicants

Assistance will be provided only to the health departments of States or their bona fide agents, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, federally recognized Indian tribal governments, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau. Only one application from each State or Territory may be submitted.

Two levels of cooperative agreements will be awarded: Level I: Eligible applicants for Level I funding are States or Territories that (1) do not have an established State centralized EHDI surveillance and tracking program, or (2) are in the beginning stages of establishing a centralized EHDI tracking and surveillance, or (3) already have a program but would like to refine their existing surveillance and tracking program to integrate it with other newborn screening and tracking programs.

Level II: Eligible applicants for Level II are those States that (1) have an existing State-wide, centralized, electronic, population-based (i.e., complete geographic coverage) surveillance and tracking program or (2) States that have a regional centralized, electronic, EHDI surveillance and tracking program that includes data on at least 85 per cent of all live births in the region from a birth population of at least 10,000 live births per year. Level II States must have integrated or be in the process of integrating the EHDI tracking and surveillance system with other newborn screening systems, such as blood spot screening and birth defects registries.

States that were awarded FY 2000 Level I funds under CDC Program Announcement 00076 and meet the Level II component criteria may request additional funds from this FY 2001 announcement for Level II activities.

**Note:** Effective January 1, 1996, Public Law 104-65 states that an organization, described in section 501(c)(4) of the Internal Revenue Code of 1986, which engages in lobbying activities shall not be eligible to receive Federal funds constituting an award, grant (cooperative agreement), contract, loan, or any other form.

### C. Availability of Funds

Approximately \$1,900,000 will be available in FY 2001 to fund up to 10 awards. It is expected that up to 7 awards will be made to Level I applicants, ranging from \$100,000 to \$150,000. It is expected that up to 3 awards will be made to Level II applicants. Level II awards are expected to range from \$250,000 to \$350,000. Awards for States with existing Level I awards requesting funds for Level II activities will range from an additional \$150,000 to \$200,000.

It is expected that awards will begin on or about August 1, 2001, and will be made for a 12-month budget period within a project period of up to four years. Funding estimates may vary and are subject to change. Continuation awards within the approved project period will be made on the basis of

satisfactory progress as evidenced by required reports and availability of funds.

### Use of Funds

Project funds may not be used to supplant other available applicant or collaborating agency funds or to supplant State funds available for screening, diagnosis, intervention, or tracking for hearing loss, or other disorders detected by newborn screening. Project funds may not be used for construction, for lease or purchase of facilities or space, or for patient care.

### D. Program Requirements

In conducting activities to achieve the purpose of this program, the Level I and Level II recipients will be responsible for activities under Section 1. (Recipient Activities). CDC will be responsible for the activities listed under Section 2. (CDC Activities).

#### 1. Recipient Activities

##### Level I

a. Establish and implement a State surveillance and data tracking system to assure minimal loss to follow-up by monitoring the status and progress of infants through the three components of the EHDI program (screening, detection, and intervention);

b. Establish methods for populating the EHDI data base (e.g., linking with the electronic birth certificate);

c. Develop strategies to collect standardized EHDI data (including the type of hearing loss and type of intervention services) from multiple sources, e.g. birthing hospitals, diagnostic centers, audiologists, physician, intervention programs;

d. Develop and enumerate reporting systems that will ensure that tracking and surveillance data collected from multiple sources will be used so that there is minimal loss to follow-up;

e. Develop mechanisms to identify and collect standardized data on infants/children with late onset or progressive hearing loss;

f. Outline an analytic plan to use State EHDI data in order to obtain outcome data such as: percent of infants screened, referred, evaluated, and enrolled in intervention programs; unexpected clusters of infants with hearing loss in particular regions at particular times; unexpected differences in measure of EHDI screening performance between participating birthing hospitals; false positive rates; loss to follow-up rates;

g. Document concerns from parents and professionals about the EHDI process;

h. Design the program so that it can be integrated with other screening and tracking programs that identify children with special health care needs such as newborn blood spot screening, birth defects registries, fetal alcohol syndrome surveillance, and Part C of the Individuals with Disabilities Education Act (IDEA);

i. Collaborate with State programs such as Maternal and Child Health, Part C, private service programs, and advocacy groups to build a coordinated EHDI infrastructure;

j. Develop an evaluation plan to monitor progress on activities and to assess the timeliness, completeness, and success of the project; and

k. Prepare and publish manuscript(s) which describe(s) the tracking system, definitions, methodology, collaborative relationships, data collection, findings, and recommendations across sites. Collaboration with other participating sites is encouraged.

##### Level II Research Activities

Level II applicants will be responsible for all Level I activities. They will also be responsible for activities that build on the integration of EHDI with other newborn screening and monitoring systems in order to design and carry out the additional Level II activities.

Level II recipients will collaborate with other Level II recipients to develop and participate in a common set of activities. Applicants are encouraged to develop collaborative relationships with universities in carrying out the Level II activities. The recipients will:

a. Share information and collaborate with other Level I and Level II recipients, and with other federal and national agencies (such as, but not limited to, Health Resources and Services Administration, National Institute on Deafness and other Communication Disorders, Directors of Speech and Hearing Programs in State Health and Welfare Agencies, Joint Committee on Infant Hearing, and advocacy groups);

b. Work with other Level II recipients to identify genetic and other causes of hearing loss. Develop a common data set from a population-based set of children with hearing loss identified from the State EHDI programs. Collect biological samples from these children;

c. Choose an additional research area such as one of the following and develop a research plan:

1. costs and effectiveness of EHDI programs,
2. benefits of early identification and intervention for children with hearing loss,

3. psychological and family issues related to hearing loss.

d. Collaborate with other Level II recipients to develop a common set of research questions, and implement a common research protocol and analytic plan; and

e. Collaborate with other Level II recipients in a pooled anonymized data set. Data analysis will be conducted at the State and federal levels.

## 2. CDC Activities

a. Provide technical assistance as needed on the design, development, and evaluation methods and approaches used for State-based EHDI tracking and surveillance;

b. Provide technical assistance as needed on the development of research questions and analytic guidance;

c. Provide technical assistance as needed for the collection and analysis of data across sites; and

d. Facilitate collaborative efforts to compile and disseminate program results through presentations and publications.

## E. Application Content

Use the information in the Program Requirements, Application Content, Evaluation Criteria, and Other Requirements sections to develop the application content. Forms are in the application kit. Applications will be evaluated on the criteria listed, so it is important to follow them in describing the program plan. The applicant should provide a detailed description of first-year activities and briefly describe future-year objectives and activities.

The application must contain the following:

**Cover Letter:** A one-page cover letter stating whether the applicant is applying for: Level I funding only, (2) Level II funding, or (3) already funded for Level I activities and is requesting additional funds for Level II Activity. If applying for Level II, applicant must explain how the applicant fulfills eligibility requirements.

**Budget and Budget Justification:** The budget should be reasonable, clearly justified, and consistent with the intended use of the agreement funds. The applicant must include a detailed first-year budget justification with future annual projections. Budgets should include costs for travel for two project staff to attend annual meetings. The applicant should provide a budget justification for each budget item. Proposed sub-contracts should identify the name of the contractor, if known; describe the services to be performed; provide an itemized budget and justification for the estimated costs of

the contract; specify the period of performance; and describe the method of selection.

**Abstract:** A one-page, single-spaced, typed abstract must be submitted with the application. The heading should include the title of the grant program, project title, organization, name and address, project director and telephone number. The abstract should clearly state for which level of activities the applicant is applying (Level I, Level II, or Research only). The abstract should briefly summarize the project for which funds are requested, the activities to be undertaken, and the applicant's organization structure.

The abstract should precede the Program Narrative.

**Table of Contents:** A table of contents that provides page numbers for each of the following sections should follow the abstract (all pages must be numbered).

**Narrative:** The narrative for Level I applicants should be no more than 25 double-spaced pages. For Level II applicants, the narrative should be no more than 35 double-spaced pages. For applicants with existing Level I awards who are requesting additional Level II funds, the narrative should be no more than 25 pages and must include an update of all activities required by Program Announcement 00076. The narrative is to be printed on one side, with one inch margins, and unreduced font (12 pitch). The narrative must contain the following sections:

- a. Understanding the Problem and Current Status
- b. Goals and Objectives
- c. Description of Program and Methodology
- d. Collaborative Efforts
- e. Evaluation Plan
- f. Staffing and Management System (One-page CV or resume for each key personnel must be included in an attachment). Plan must also provide details of the role of each key personnel.
- g. Organizational Structure and Facilities (Must include an organizational chart)
- h. Human Subjects Review

## F. Submission and Deadline

### Letter of Intent

A letter of intent (LOI) is requested to enable CDC to determine the level of interest in the announcement. The LOI should specify the Level for which the applicant is applying. Include name, address, and telephone number for key contact.

The LOI is requested on or before May 11, 2001. Submit the letter of intent to the Grants Management Specialist identified in the "Where to Obtain

Additional Information" section of this announcement.

### Application

Submit the original and two copies of PHS 5161-1 (OMB Number 0937-0189) on or before June 11, 2001 to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

**Deadline:** Applications shall be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date; or

(b) Sent on or before the deadline date and received in time for submission to the Objective Review Panel. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

**Late applications:** Applications which do not meet the criteria in (a) or (b) above are considered late applications, will not be evaluated by the review panel and will be returned to the applicant.

## G. Evaluation Criteria

Each application will be evaluated individually against the following criteria by an independent review panel appointed by CDC.

### 1. Understanding the Problem and Current Status (20 percent)

a. Extent to which the applicant has a clear, concise understanding of the requirements and purpose of the cooperative agreement;

b. Extent to which the applicant understands the challenges, barriers, and problems associated with developing and implementing an EHDI tracking and surveillance program;

c. Extent to which the applicant describes the need for funds to develop/enhance an EHDI tracking and surveillance program in their State;

d. Extent to which the applicant describes the target population and the current status of their existing EHDI program, e.g., number of birthing hospitals with and without universal hearing screening programs; number of infants born, number of infants screened, identified and referred to intervention; protocol for screening and referral, including informed consent information;

e. Extent to which applicant describes (1) Their current EHDI tracking and surveillance system (if any exists); (2) other relevant tracking, surveillance

systems, or registries in the State; and (3) linkages with other relevant systems;

f. Extent to which applicant describes diagnostic facilities and intervention services available in the State for infants/children with hearing loss; and

g. Extent to which applicant shows willingness to integrate EHDI surveillance and tracking system with other newborn screening program activities.

## 2. Goals and Objectives (10 percent)

a. Extent to which applicant clearly describes the short- and long-term goals and measurable objectives of the project;

b. Extent to which applicant's goals and objectives are realistic and are consistent with the stated goals and purpose of this announcement; and

c. The degree to which the applicant has met the CDC policy requirements regarding the inclusion of women, ethnic and racial groups in the proposed research. This includes the proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation and justification when representation is limited or absent.

## 3. Description of Program and Methodology (35 percent)

a. Extent to which applicant describes the methods they will use to address all Level I activities, such as: establishing and implementing an EHDI tracking and surveillance system; describing methods of populating the data base; standardizing data from multiple sources; developing strategies for reporting system; documenting methods for collecting data on infants/children with late onset or progressive hearing loss; designing analytic plan, documenting concerns; and preparing manuscripts;

b. Extent to which applicant describes plan for integrating EHDI data with other newborn screening systems;

c. (Level II States Only) Extent to which applicant demonstrates that their State meets the criteria to be a Level II State, i.e., has a state-wide or regional annual birth population of >10,000);

d. (Level II States Only) Extent to which applicant describes a feasible plan for designing and implementing Level II activities, including the specific plan for a study of genetic and other causes of hearing loss, and the collection of biologic samples;

e. (Level II States Only) Extent to which applicant demonstrates willingness to collaborate with other recipients to develop a research plan and carry out the research project that allows for anonymized pooling of data; and

f. (Level I and Level II) Extent to which applicant provides a time line which includes activities to be accomplished and personnel responsible to complete the project.

## 4. Collaborative Efforts (10 percent)

a. Extent to which applicant describes their methods for collaboration with multiple data sources (include written assurances) such as hospitals, diagnostic centers, and intervention service providers;

b. Extent to which collaborative relationships are documented which will facilitate linkage with other screening programs. (Letters of agreement and cooperation from collaborating programs should be included);

c. Extent to which collaborative efforts with other relevant programs are documented (such as MCH, Part C, etc.);

d. (Level II States only) Extent to which applicant is willing to work collaboratively with other agencies and Level II recipients to develop multi-site research questions and analytic guidelines; and

e. Extent to which applicant states their willingness to work collaboratively with other funded States and to modify their projects if necessary in order to allow anonymized pooled data sets of standardized data.

## 5. Evaluation Plan (10 percent)

Extent to which applicant describes an evaluation plan that will monitor progress, and assess timeliness, completeness, and success of the objectives and activities of the project.

## 6. Staffing and Management System (10 percent)

a. Extent to which key personnel have skills and experience to develop and implement an EHDI tracking and surveillance system;

b. Extent of the managerial ability to coordinate the tracking, surveillance, and research, and integration components of the project;

c. Extent to which expertise in abstracting screening, identification, and intervention records are demonstrated;

d. Extent to which expertise in epidemiologic methods, public health surveillance, data management and computer programming is demonstrated; and

e. Extent to which there is sufficient dedicated staff time to develop and implement an EHDI tracking and surveillance system and to integrate the EHDI system with other newborn screening systems (include percentage

of time each staff member will contribute to the project).

## 7. Organizational Structure and Facilities (5 percent)

Extent to which organization structure and facilities/space/equipment are adequate to carry out the activities of the program.

## 8. Human Subjects Review (Not Scored)

The extent to which the applicant complies with the Department of Health and Human Services Regulations (45 CFR Part 46) regarding the protection of human subjects.

## 9. Budget (Not Scored)

The budget will be evaluated for the extent to which it is reasonable, clearly justified, and consistent with the intended use of the cooperative agreement funds.

## H. Other Requirements

Recipients will regularly share anonymized individual State EHDI data with other award recipients.

Recipients will provide CDC with the original plus two copies of:

1. Semi-annual progress reports, no more than 30 days after the end of the report period;

2. Financial status report, no more than 90 days after the end of the budget period; and

3. Final financial report and performance report, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Addendum I in the application kit.

AR-1 Human Subjects Requirements

AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

AR-7 Executive Order 12372 Review

AR-9 Paperwork Reduction Act

AR-10 Smoke-Free Workplace Requirements

AR-11 Healthy People 2010

AR-12 Lobbying Restrictions

## I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301 and 317 of the Public Health Service Act, 42 U.S.C. sections 241 and 247b, as amended. The Catalog of Federal Domestic Assistance number is 93.283.

## J. Where To Obtain Additional Information

This and other documents may be downloaded through the CDC homepage on the Internet at <http://www.cdc.gov> (click on "Funding"). Refer to Program Announcement #01048 when you request information.

For business management technical assistance, contact: Sonia Rowell, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146, Telephone number: 770-488-2718, E-mail address: [srowell@cdc.gov](mailto:srowell@cdc.gov)

For program technical assistance, contact: June Holstrum, Ph.D., Early Hearing Detection and Intervention Program, National Center for Environmental Health, Centers for Disease Control and Prevention, 4770 Buford Highway, NE, Mailstop F-15, Atlanta, GA 30341-3717, Telephone number: 770-488-7361, E-mail address: [jholstrum@cdc.gov](mailto:jholstrum@cdc.gov)

Dated: April 10, 2001.

**John L. Williams,**

*Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 01-9315 Filed 4-13-01; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Epidemiology Research Needs Related to the Radiofrequency Energy From Wireless Phones

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public meeting.

The Food and Drug Administration (FDA) is announcing a public meeting to discuss the health effects of radio frequency (RF) emissions from wireless phones. Currently, the scientific literature relating to the health effects of low level exposure to RF does not demonstrate the existence of any health risk from wireless phones. National and international scientific experts will discuss the need for research into the incidence, distribution, and control of any adverse effects related to RF energy from wireless phones. This meeting is being convened as part of the Cooperative Research and Development Agreement (CRADA) between FDA's Center for Devices and Radiological Health and the Cellular

Telecommunications Industry Association (CTIA). This is the second meeting on this subject. FDA announced the first meeting on April 18 and 19, 2001 in the **Federal Register** of March 27, 2001.

*Date and Time:* The meeting will be held on May 2, 2001, 8:30 a.m. to 5 p.m. and on May 3, 2001, 8:30 a.m. to 5 p.m.

*Location:* The meeting will be held at the Marriott Kingsgate Conference Center, University of Cincinnati, Cincinnati, OH 45219.

*Contact:* Russell D. Owen, Center for Devices and Radiological Health, Food and Drug Administration (HFZ-114), 12709 Twinbrook Pkwy., Rockville, MD 20857, 301-443-7118, FAX 301-594-6775. Further information about the CRADA is available on the Internet at <http://www.fda.gov/cdrh/ocd/wlessphonecrada.html>.

*Agenda:* On May 2, 2001, the scientific experts will review completed and ongoing epidemiology studies and discuss scientific questions that have been raised by this research. On May 3, 2001, the scientific experts will discuss specific studies that could address these scientific questions.

*Procedure:* Interested persons may present scientific information relevant to items on the agenda. Written submissions may be made to the contact person by April 23, 2001. Oral presentations from the public will be scheduled on May 2, 2001, between 3 p.m. and 5 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 23, 2001, and submit a brief statement of the general nature of the information they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

*Transcripts:* Transcripts 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.

If you need special accommodations due to a disability, please contact Abiy B. Desta, 301-443-7192 at least 7 days in advance.

Dated: April 11, 2001.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

[FR Doc. 01-9403 Filed 4-12-01; 9:55 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[Document Identifier: HCFA-R-312]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Health Care Financing Administration, HHS.

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, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Collection Request:* Extension of a currently approved collection;

*Title of Information Collection:* Conflict of Interest and Ownership and Control Information;

*Form No.:* HCFA-R-312 (OMB# 0938-0795);

*Use:* This Conflict of Interest questionnaire is sent to all Medicare Fiscal Intermediaries (FIs) and Carriers to collect full and complete information on any entity's or individual's ownership interest (defined as a 5 percent or more) in an organization that may present a potential conflict of interest in their role as a Medicare FI or Carrier. The information gathered is used to ensure that all potential, apparent and actual conflicts of interest involving Medicare contracts are appropriately mitigated and that employees of the contractors, including officers, directors, trustees and members of their immediate families, do not utilize their positions with the contractor for their own private business interest to the detriment of the Medicare program;

*Frequency:* Annually;

*Affected Public:* Not-for-profit institutions, and Business or other for-profit;