

recruiting into or retaining participants in scientific studies.

#### *E. Dissemination of Research Results*

Externally awarded investigators are urged to make special efforts to disseminate relevant research results to the communities who participated in the studies and to the populations to which they pertain, especially racial and ethnic minority populations which may have cultural, language, and socioeconomic barriers to the easy receipt of such information.

### **VI. Evaluation**

#### *CDC Inclusion Review Committee Responsibility and Members*

A CDC Inclusion Review Committee (IRC) with representatives from the CDC Office of the Associate Director for Science, the CDC Office of the Associate Director for Minority Health, and the CDC Office of the Associate Director for Women's Health will review any questions, issues, or comments pertaining to this policy and recommend necessary changes or modifications to the Director, CDC. This committee will meet regularly to review compliance with this policy and evaluate the impact of this policy on research activities at CDC. The CDC IRC may periodically conduct random audits of research protocols to assess compliance with this policy.

Dated: March 30, 1995.

**Claire V. Broome,**

*Deputy Director, Centers for Disease Control and Prevention (CDC) and Deputy Administrator, Agency for Toxic Substances and Disease Registry (ATSDR).*

[FR Doc. 95-8718 Filed 4-7-95; 8:45 am]

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#### **[Announcement 525]**

### **Continuation of the Development of Technology for the Measurement of Lead in Blood; Notice of Availability of Funds for Fiscal Year 1995**

#### **Introduction**

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1995 funds for a grant program for the continuation of the development of new and innovative technology, or significant improvement of existing technology, for the measurement of lead in blood. CDC has supported such development efforts under a grant program since FY 1992 and under Cooperative Research and Development Agreements (CRADAs) since 1991. State, community and physician office-based childhood lead poisoning

prevention programs have a need for reasonably priced, accurate, precise, portable, rugged, and easy-to-operate instruments or analytical techniques to measure the concentration of lead in blood. Such programs screen large numbers of infants and young children and identify those with lead poisoning.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Environmental Health. (For ordering a copy of "Healthy People 2000," see the section **Where To Obtain Additional Information.**)

#### **Authority**

This program is authorized under sections 301(a) [42 U.S.C. 241(a)] and 317B(b) [42 U.S.C. 247b-3(b)] of the Public Health Service Act, as amended.

#### **Smoke-Free Workplace**

PHS strongly encourages all grant recipients to provide a smoke-free workplace and to promote the nonuse of all tobacco products, and Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

#### **Eligible Applicants**

Eligible applicants are limited to those organizations which are currently developing innovative technology for the measurement of lead in blood, funded under CDC grant Announcement 269 (included in the application package), or organizations which have a current CDC Cooperative Research and Development Agreement (CRADA) dealing with blood lead measurement technology. However, if funded, the CDC CRADA dealing with blood lead will be terminated.

**Note:** Eligible applicants are encouraged to enter into contracts, including consortia agreements, as necessary to meet the requirements of the program and strengthen the overall application.

#### **Availability of Funds**

Approximately \$800,000 is available in FY 1995 to fund up to three grants. It is expected that the average award will be \$250,000, ranging from \$100,000 to \$500,000. It is expected that the awards will begin on or about June 30, 1995, and will be made for a 12-month budget period within a project period of

up to one year. Funding estimates may vary and are subject to change.

#### **Purpose**

State and community health agencies are the principal delivery points for childhood lead screening and related medical and environmental management activities. Universal screening of children is recommended in "Preventing Lead Poisoning in Young Children—a Statement by the Centers for Disease Control," (October 1991); however, the lack of analytical systems (methods plus instrumentation) which are easy-to-operate, rugged, and suitable for field use in screening programs have made it difficult and costly for agencies to develop programs for the elimination of this totally preventable disease. This program will provide financial support for the continuation and possible completion of the development and validation of new and innovative technology leading to better blood lead measurement systems.

#### **Program Requirements**

The following are essential requirements of the Grantee:

1. Provide a principal investigator with the authority, responsibility, and research experience to carry out the objectives of the grant.
2. Provide qualified staff, laboratory and/or production facilities, equipment, and other resources necessary to carry out the objectives of the grant.
3. Conduct a scientifically sound, goal-oriented research and development program which will yield all or portions of practical analytical systems which measure one or more chemicals in complex solutions. Understand and address the difficult analytical problem presented by a blood sample matrix.
4. Publish the results of the research effort in the peer-reviewed scientific literature, or otherwise make the research findings available for objective evaluation and use.
5. Provide evidence of significant progress under the previous grant or CRADA for blood lead measurement technology consistent with the goals and objectives of the original grant or CRADA, and clearly show that successful completion could be reasonably expected within the one year project period.

#### **Evaluation Criteria**

The applications will be reviewed and evaluated according to the following criteria:

##### *1. Understanding of the Problem (30%)*

By progress under previous grant or CRADA agreement, the Applicant has

demonstrated understanding of whole blood matrix effects, interferences, and contamination issues. Applicant's prototype instrument(s) and/or experimental data address CDC criteria of accuracy, precision, compactness, ruggedness and ease of use, as described in grant Announcement 269 and/or CRADA agreement.

#### 2. *Technical Progress and Approach to Remaining Problems (30%)*

Sound technical approach, as demonstrated by analytical performance of applicant's prototype instruments or experimental data. Performance should meet CDC criteria, or show evidence of adequate performance attainable under this announcement.

#### 3. *Management Plan (20%)*

Applicant should describe a plan to finalize the development of their instrument as a manufacturable, marketable, commercial product. Key points include appropriate business resources or collaborations, market research, field testing, regulatory compliance, distribution and support, or plans to sell the technology to a third party for final production and marketing.

#### 4. *Program Personnel (10%)*

The extent to which the proposal has described (a) the qualifications and commitment of the applicant including training and experience in chemistry, biochemistry, biomedical engineering or other relevant scientific disciplines, (b) detailed allocations of time and effort of staff devoted to the project.

#### 5. *Collaboration (5%)*

While collaboration is not required, it is encouraged if necessary to accomplish the research objectives in a timely manner. If applicable, the applicant should have demonstrated the ability to collaborate with other research centers, manufacturers, or commercial interests to conduct the described research and development plan. Evidence of collaborative relationships include jointly developed plans for developing separate components of the analytical system and written commitments of support from other program-related entities that describe the collaborative activities or serious negotiation or agreements with companies experienced in the development, marketing and support of clinical instruments.

#### 6. *Publication of the Research Effort (5%)*

The purpose of this grant is to encourage the rapid development and

deployment of measurement systems for blood lead which will be useful in lead poisoning prevention screening programs. Therefore, an explanation of how the grantee plans to encourage the publication of the research findings or otherwise make the information available to the public is required.

*Research which results only in findings of academic interest with no practical application to the objectives of the grant is not acceptable.*

#### 7. *Budget Justification (Not Scored)*

The budget will be evaluated for the extent to which it is reasonable, clearly justified, and consistent with the intended use of grant funds. The adequacy of existing and proposed facilities to support program activities also will be evaluated.

#### 8. *Human Subjects Review (Not Scored)*

The applicant must clearly indicate whether or not human subjects will be involved in their research.

#### **Executive Order 12372 Review**

This program is not subject to the Executive Order 12372 review.

#### **Public Health System Reporting Requirements**

This program is not subject to the Public Health System Reporting Requirements.

#### **Catalog of Federal Domestic Assistance Number**

The Catalog of Federal Domestic Assistance number is 93.197.

#### **Other Requirements**

##### *Human Subjects*

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services Regulations, 45 CFR part 46, regarding the protection of human subjects. Assurance must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and forms provided in the application kit.

##### *Paperwork Reduction Act*

Projects that involve the collection of information from 10 or more individuals and funded by this grant will be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

#### **Application Submission and Deadline**

The original and five copies of the application form PHS 398 (OMB Number 0925-0001) must be submitted to Henry S. Cassell, III, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E-13, Atlanta, GA 30305, on or before *May 31, 1995*.

1. 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 group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

2. Late Applications: Applications which do not meet the criteria in 1.a. or 1.b. above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

#### **Where to Obtain Additional Information**

A complete program description, information on application procedures, an application package, and business management technical assistance may be obtained from Adrienne Brown, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E-13, Atlanta, GA 30305, telephone (404) 842-6630. Programmatic technical assistance may be obtained from Dayton T. Miller, Ph.D. or Robert L. Jones, Ph.D., Nutritional Biochemistry Branch, Division of Environmental Health Laboratory Sciences, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway NE., Mailstop F-18, Atlanta, GA 30341-3724, telephone (404) 488-4452.

Please refer to Announcement 525 when requesting information and submitting an application.

Potential applicants may obtain a copy of "Healthy People 2000" (Full Report, Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report, Stock No. 017-001-00473-1) referenced in the "Introduction"

through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone (202) 512-1800.

A copy of "Preventing Lead Poisoning in Young Children—a Statement by the Centers for Disease Control," (October 1991) may be obtained from the Lead Poisoning Prevention Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Mailstop F-28, Atlanta, GA 30333, telephone (404) 488-7330.

Dated: April 3, 1995.

**Joseph R. Carter,**

*Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 95-8717 Filed 4-7-95; 8:45 am]

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**CDC Advisory Committee on the Prevention of HIV Infection: Meeting**

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announced the following committee meeting.

*Name:* CDC Advisory Committee on the Prevention of HIV Infection.

*Times and Dates:* 9 a.m.-4:30 p.m., May 8, 1995; 9 a.m.-12 noon, May 9, 1995.

*Place:* Sheraton Colony Square Hotel, 188 14th Street, NE, Atlanta, Georgia 30061.

*Status:* Open to the public, limited only by the space available.

*Purpose:* This committee charged with advising the Director, CDC, regarding objectives, strategies, and priorities for HIV prevention efforts including maintaining surveillance of HIV infection and AIDS, the epidemiologic and laboratory study of HIV and AIDS, information/education and risk reduction activities designed to prevent the spread of HIV infection, and other preventive measures that become available.

*Matters to Be Discussed:* The Committee will be updated on the ongoing reorganization of CDC's HIV/AIDS prevention programs. Other discussions will center around current HIV prevention activities. Agenda items are subject to change as priorities dictate.

*Contact Person for More Information:* Connie Granoff, Committee Assistant, Office of the Associate Director for HIV/AIDS, CDC, 1600 Clifton Road, NE, Mailstop E-40, Atlanta, Georgia 30333, telephone (404) 639-2918.

**Carolyn J. Russell,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).*

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**National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Mental Health Statistics: Meeting**

Pursuant to Pub. L. 92-463, the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC), announces the following subcommittee meeting.

*Name:* NCVHS Subcommittee on Mental Health Statistics.

*Time and Date:* 9 a.m.-5 p.m., May 17, 1995.

*Place:* Room 503A-529A, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

*Status:* Open.

*Purpose:* The Subcommittee will continue to work in developing managed care minimum data sets for enrollment and encounter data.

*Contact Person for More Information:* Substantive program information as well as summaries of the meeting and a roster of committee members may be obtained from Gail F. Fisher, Ph.D., Executive Secretary, NCVHS, NCHS, CDC, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone number 301/436-7050.

**Carolyn J. Russell,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 95-8714 Filed 4-7-95; 8:45 am]

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**Health Care Financing Administration**

[MB-84-N]

RIN 0938-AG77

**Medicaid Program; Rescission of the Guidelines for Documenting Medicaid Recipient Access to Immunizations Under the Vaccines for Children (VFC) Program**

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

**ACTION:** Notice.

**SUMMARY:** This notice rescinds the guidelines that we published in the **Federal Register** on October 3, 1994, that required States to document equal access to immunizations for Medicaid children if States elected to use lower vaccine administration fees than the maximum charges that were published and applicable under the Vaccines for Children program. These guidelines are rescinded in response to public comments on the October 3, 1994 notice. States indicated that there were numerous problems regarding the collection of useable data.

**FOR FURTHER INFORMATION CONTACT:** Marge Sciulli, (410) 966-0691.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

On October 3, 1994, we published in the **Federal Register** a notice with comment period (59 FR 50235) that listed, by State, the interim regional maximum charges that providers may impose for the administration of pediatric vaccines to Federally vaccine-eligible children under the Vaccines for Children (VFC) Program. (The VFC Program, which became effective on October 1, 1994, required States to provide a program for the purchase and distribution of pediatric vaccines to registered providers.) State Medicaid agencies may establish lower Medicaid fees than the maximum charges. According to the guidelines, States were required to provide assurances of equal access to immunizations for Medicaid children to the same extent as for the general population, unless their Medicaid payment rates equaled the maximum charges.

The October 3, 1994, notice allowed States the option of using one or more of the following guidelines to document equal access to immunizations for Medicaid children:

(1) Comparison of Ratios. In order for a State to have used this guideline as an equal access assurance, the ratio of Medicaid children immunized to the number of Medicaid children would have to be equal to or greater than the ratio of children in the general population immunized to the number of children in the general population.

(2) Comparison to Private Insurance. In order for the State to have used this guideline as an equal access assurance, the Medicaid rates for the administration of pediatric vaccines would have to be set at a rate equal to or greater than the private insurance company's rates up to the established State maximum fee.

(3) Practitioner Participation. Under this guideline, the State would have compared the number of Medicaid pediatric practitioners who are Medicaid program-registered providers to the total number of pediatric practitioners providing immunizations to children. The program-registered providers must have at least one Medicaid pediatric immunization claim per month or an average of 12 such claims during the year. The State would have needed 50 percent participation to show equal access through use of this guideline.

(4) Other. States had the flexibility to devise alternative measures of equal access to immunizations. These measures were to have been evaluated by HCFA before being found acceptable.