

meeting should contact Mrs. Bonnie Campbell, Committee Management Officer, Office of Research Review, Education and Policy, AHRQ, 2101 East Jefferson Street, Suite 400, Rockville, Maryland 20852, Telephone (301) 594-1846.

Agenda items for this meeting are subject to change as priorities dictate.

This notice is being published less than 15 days prior to the November 1 meeting due to the time constraints of reviews.

Dated: October 18, 2001.

John M. Eisenberg,

Director

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 02011]

Cooperative Agreements for the Development and Improvement of Population-Based Birth Defects Surveillance Programs and the Integration of Surveillance Data With Public Health Programs; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2002 funds for a cooperative agreement program for developing and improving birth defects surveillance and integrating surveillance data with other public health programs. This program addresses the "Healthy People 2010" focus area of Maternal, Infant, and Child Health.

The purpose of the program is to support: (1) The development, implementation, expansion, and evaluation of population-based birth defects surveillance systems; (2) the development and implementation of population-based programs to prevent birth defects; and (3) the development and implementation or expansion of activities to improve the access of children with birth defects to health services and early intervention programs.

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 Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, the

Republic of Palau, and federally recognized Indian tribal governments.

Recipients funded under CDC Program Announcement 00094 (Cooperative Agreements for the Development of State-Based Birth Defect Surveillance Programs and the Use of the Surveillance Data for Public Health Programs) and Program Announcement 96043 (Centers of Excellence to Provide Surveillance, Research, Services, and Evaluation Aimed at Prevention of Birth Defects) are not eligible. See Attachment I in the Application Kit for a list of the States currently funded under these program announcements.

The eligible States are: Alabama, Alaska, Colorado, Delaware, Florida, Georgia, Hawaii, Idaho, Indiana, Kansas, Kentucky, Maine, Maryland, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Utah, Vermont, Virginia, West Virginia and Wyoming.

Applicants may apply under one of two categories:

Category 1—States/territories/tribes with no birth defects surveillance systems; or

Category 2—States/territories/tribes with newly implemented or ongoing surveillance systems.

Note: Title 2 of the United States Code, Section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, or loan.

C. Availability of Funds

Approximately \$2,400,000 is available in FY 2002 to fund approximately 4-8 awards in Category 1, and 8-10 awards in Category 2. It is expected that the awards will range from \$50,000 to \$250,000. The average award will be \$100,000 for Category 1 States and \$200,000 for Category 2 States. The awards will begin on or about March 1, 2002, and will be made for a 12-month budget period within a project period of up to three years. Funding estimates may change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

Use of Funds

These awards may be used for personnel services, equipment, travel, and other costs related to project activities. Project funds may not be used to supplant State funds available for

birth defects surveillance or prevention, health care services, patient care, construction, nor lease/purchase of facilities or space.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1. Recipient activities for States with no birth defects surveillance systems; or 2. Recipient activities for States with newly implemented or ongoing surveillance systems; and CDC will be responsible for the activities under 3. CDC activities.

1. Recipient Activities for States with no birth defects surveillance systems:

a. Develop and begin implementation of a population-based surveillance system to ascertain cases and generate timely population-based data of major birth defects occurring in the State.

b. Analyze and disseminate the surveillance data generated by the system in a timely fashion including rates and trends of major birth defects.

c. Develop and implement a plan to evaluate the surveillance methodology used.

d. Involve the appropriate partners within the State to develop a plan and begin implementation of a birth defects prevention program (i.e., Neural Tube Defects (NTD) occurrence prevention). Share results with appropriate organizations within the State and with other States.

e. Develop a plan to evaluate the prevention activities.

f. Involve the appropriate partners within the State to develop a plan and begin implementation of activities to improve the access of children with birth defects to comprehensive, community-based, family-centered care (e.g., establish linkages with other programs like Children with Special Health Care Needs).

g. Develop a plan to evaluate the identification of and/or timeliness of referral to services among eligible children or families.

2. Recipient Activities for States with newly implemented or ongoing surveillance systems:

a. Broaden methodologies and approaches which will improve, sustain, and expand the capacity of the existing population-based surveillance system to ascertain cases and generate timely population-based data of major birth defects occurring in the State.

b. Analyze and disseminate the surveillance data generated by the system in a timely fashion including rates and trends of major birth defects (e.g., publish a report on the surveillance data).

c. Evaluate the surveillance methodology used.

d. Involve the appropriate additional partners within the State to expand birth defects prevention programs (i.e., Neural Tube Defects (NTD) occurrence prevention). Share results with appropriate organizations within the State and with other States.

e. Evaluate the prevention progress.

f. Involve the appropriate partners within the State to expand activities to improve the access of children with birth defects to comprehensive, community-based, family-centered care (e.g., establish linkages with other programs like Children with Special Health Care Needs).

g. Evaluate the progress on improving access to services (e.g., identification of children and families eligible for services; evaluate the timeliness of referral to services).

3. CDC Activities:

a. Assist, if requested, in designing, developing, and evaluating methodologies and approaches used for population-based birth defects surveillance.

b. Assist, if requested, in analyzing surveillance data related to birth defects.

c. Assist, if requested, in designing plans for prevention programs and plans to improve the access of children with birth defects to health services and intervention programs.

d. Provide, if requested, a reference point for sharing regional and national data and information pertinent to the surveillance and prevention of birth defects.

E. Content

Letter of Intent (LOI)

A LOI is requested for this program. The LOI will not be used to eliminate potential applicants, but it will enable CDC to determine the level of interest and plan the review more efficiently. The narrative should be no more than two, double-spaced pages, printed on one side, with one inch margins and 12 point font. The LOI should include the following information: this program announcement number; applicant's name and address; project director's name, phone number, and email; identification of the category for which the applicant is applying (Category 1 or Category 2); a brief description of the number of state-wide births and current birth defect surveillance system; and a brief description of the planned statement of work.

Applications

Use the information in the Program Requirements, Other Requirements, and

Evaluation Criteria sections to develop the application content. Your application 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:

1. *Cover Letter*: A one page cover letter should indicate whether the applicant is applying for Category 1 or Category 2.

2. A one-page, single-spaced, typed abstract in 12 point font 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 which option the applicant is applying for: Category 1 or Category 2. The abstract should briefly summarize the program for which funds are requested, the activities to be undertaken, and the applicant's organization structure. The abstract should precede the program narrative. A table of contents that provides page numbers for each of the following sections should be included. All pages must be numbered.

3. *Narrative*: The narrative should be no more than 25 double-spaced pages printed on one side, with one inch margins, and un-reduced font (12 point). The required detailed budget and detailed budget justification are not considered to be part of the program narrative. The narrative should specifically address item 1 or 2 in the "Program Requirements" and should contain the following sections:

a. Understanding of the Public Health Impact of Birth Defects;

b. Impact on Population-Based Birth Defects Surveillance;

c. Use of Surveillance Data for Prevention Activities;

d. Use of Surveillance Data for Improving Access to Health Services and Early Intervention Programs;

e. Organizational and Program Personnel Capability; and

f. Human Subjects Review

4. *Budget and Budget Justification*—Provide a detailed budget which indicates the anticipated costs for personnel, fringe benefits, travel, supplies, contractual, consultants, equipment, indirect, and other items.

F. Submission and Deadline

Letter of Intent (LOI)

On or before November 16, 2001, submit the LOI to the officials

designated for programmatic technical assistance 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). Forms are available in the application kit and at the following Internet address: www.cdc.gov/od/pgo/forminfo.htm.

On or before December 7, 2001, submit the application 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 independent review group. (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 considered, and will be returned to the applicant.

G. Evaluation Criteria

Each application will be evaluated individually against the following criteria by an independent review group appointed by CDC as they relate to the applicant's response to either item 1 or 2 in the "Program Requirements" section.

1. Applicant's understanding of the public health impact of birth defects (5 points):

The extent to which the applicant has a clear, concise understanding of the requirements, objectives, and purpose of the cooperative agreement. The extent to which the application reflects an understanding of the public health impact of birth defects in their State and the purpose and complexities of birth defects surveillance as it relates to their State.

2. Impact on population-based birth defects surveillance (20 points):

The extent to which the applicant describes the anticipated level of impact this cooperative agreement will have on birth defects surveillance activities in the State. The current and proposed activities evaluated in this element are specific for Category 1 and Category 2.

a. Evaluation criteria for Category 1 (States with no birth defects surveillance systems):

- (1) Plans for developing population-based birth defects surveillance;
- (2) Methods of case ascertainment;
- (3) Timeliness of case ascertainment;
- (4) Level of coverage of the population;
- (5) Specific birth defects ascertained;
- (6) Plans for analyzing and reporting surveillance data to appropriate State, local, and federal health officials;
- (7) Plans for evaluating the surveillance methodology and the quality of the surveillance data; and
- (8) 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:

(a) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

(b) The proposed justification when representation is limited or absent.

(c) A statement as to whether the design of the study is adequate to measure differences when warranted.

(d) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

b. Evaluation criteria for Category 2 (States with newly implemented or ongoing birth defects surveillance systems):

- (1) Ability to improve/expand population-based birth defects surveillance;
- (2) Methods of case ascertainment;
- (3) Timeliness of case ascertainment;
- (4) Level of coverage of the population;
- (5) Specific birth defects ascertained;
- (6) Analyzing and reporting surveillance data to appropriate State, local, and federal health officials;
- (7) Evaluating the surveillance methodology and quality of the surveillance data; and
- (8) 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:

(a) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

(b) The proposed justification when representation is limited or absent.

(c) A statement as to whether the design of the study is adequate to measure differences when warranted.

(d) A statement as to whether the plans for recruitment and outreach for

study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

3. Use of the surveillance data for prevention activities (30 points):

The extent to which the applicant describes the plans for using surveillance data to develop and implement or expand existing programs to prevent birth defects. The current and proposed activities evaluated in this element are specific for Category 1 and Category 2.

a. Evaluation criteria for Category 1 (States with no birth defects surveillance systems):

(1) Ability to work with appropriate partners in the State (e.g., provide letters of support, Memorandums of Agreement/Understanding); and

(2) Plan for using the surveillance data to develop prevention programs; and/or Plan for sharing surveillance data (e.g., personal identifiers and contact information) with programs or agencies so that children or families can be enrolled in prevention programs.

b. Evaluation criteria for Category 2 (States with newly implemented or ongoing birth defects surveillance systems):

(1) Ability to work with appropriate partners in the State (e.g., provide letters of support, Memorandums of Agreement/Understanding);

(2) Use of surveillance data to expand prevention programs; and/or sharing of surveillance data (e.g., personal identifiers and contact information) with programs or agencies so that children or families are enrolled in prevention programs; and

(3) Evaluation of progress made in the prevention of birth defects.

4. Use of surveillance data for improving access to health services and early intervention programs (30 points). The extent to which the applicant describes the plans to develop and implement or expand existing activities to improve the access of children with birth defects to health services and early interventions. The current and proposed activities evaluated in this element are specific for Category 1 and Category 2.

a. Evaluation criteria for Category 1 (States with no birth defects surveillance systems):

(1) Identification of appropriate programs within the State for referral to health services (e.g., provide letters of support, Memorandums of Agreement/Understanding);

(2) Plan for linking programs or developing other approaches to increase identification of children or families eligible for health services; and

(3) Plan to evaluate the implementation process.

b. Evaluation criteria for Category 2 (States with newly implemented or ongoing birth defects surveillance systems):

(1) Ability to integrate programs within the State (e.g., provide letters of support, Memorandums of Agreement/Understanding, documentation of numbers of eligible children or families referred for and percent receiving services);

(2) Improve and expand approaches to increase identification of children or families eligible for health services; and

(3) Plan for evaluating outcomes of children who receive services.

5. Organizational and program personnel capability (15 points):

a. The extent to which the applicant has the experience, skills, and ability to develop and improve birth defects surveillance and use surveillance data to develop prevention programs and improve access to health services or early intervention programs.

b. The adequacy of the present staff and/or the capability to assemble competent staff to either implement or improve upon a birth defects surveillance system and develop programs for prevention or improving access to health services and early intervention programs. If it is necessary to hire staff to conduct program activities, provide plans for identifying and hiring qualified applicants on a timely basis. Also, provide plans for how work on program activities will be conducted prior to hiring necessary staff.

c. To the extent possible, the applicant shall identify all current and potential personnel who will work on this cooperative agreement including qualifications and specific experience as it relates to the requirements set forth in this announcement.

6. Human Subjects Review (not scored):

Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects? (Not scored; however, an application can be disapproved if the research risks are sufficiently serious and protection against risks are so inadequate as to make the entire application unacceptable.)

7. Budget justification and adequacy of facilities (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. The applicant shall describe and indicate the availability of

facilities and equipment necessary to carry out this project.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Semiannual progress reports;
2. financial status report, no more than 90 days after the end of the budget period; and
3. final financial status 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.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment II 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 Requirements
- 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(a), 311 and 371 (C) of the Public Health Service Act [42 U.S.C. 241(a), 243, and 247 (b-4)], 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."

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from:

Virginia Hall-Broadnax, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Announcement 02011, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146, Telephone: (770) 488-2761, E-mail address: vdh2@cdc.gov.

Programmatic technical assistance may be obtained from:

Larry D. Edmonds or Amanda S. Brown, National Center on Birth Defects

and Developmental Disabilities, Centers for Disease Control and Prevention, 4770 Buford Highway N.E., Atlanta, GA 30341-3724, Telephone: (770) 488-7171, E-mail address: LEdmonds@cdc.gov or ABrown2@cdc.gov.

Dated: October 18, 2001.

Rebecca B. O'Kelley,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 02018]

New York Emergency Disaster Relief Related to Asthma; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of funds for a cooperative agreement program for New York Emergency Disaster Relief Related to Asthma. The purpose of the program is to assist the New York State Department of Human Services in assessing public health threats and addressing public health issues related to asthma, as a result of the terrorist attack of September 11, 2001. This program addresses the "Healthy People 2010" focus areas of Environmental Health and Public Health Infrastructure.

B. Eligible Applicant

Eligible applicant is Health Research, Inc./New York State Department of Health. No other applications are solicited.

This project is authorized by H.R. 2888, 2001 Emergency Supplemental Appropriations Act for Recovery from and Response to Terrorist Attacks on the United States.

C. Availability of Funds

Approximately \$5,200,000 is available to fund this award. The award is expected to be made for a 12-month budget period within a 5 year project period. As long as funds are continued or directed for this applicant continuation funding will be made available for up to 5 years. Funding estimates may vary and are subject to change.

At the request of the applicant, Federal personnel, equipment, or

supplies may be provided in lieu of a portion of the financial assistance.

D. Where To Obtain Additional Information

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Sharon Robertson, Lead Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146, Telephone: (770) 488-2740, E-mail address: sqr2@cdc.gov.

For program technical assistance, contact: Liane Hostler, Air Pollution and Respiratory Health Branch, National Center for Environmental Health, Centers for Disease Control and Prevention, 1600 Clifton Road, NE (MS E-17), Atlanta, GA 30333, Telephone number: (404) 498-1009, E-mail address: lch2@cdc.gov.

Dated: October 18, 2001.

Rebecca O'Kelley,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10051]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS), 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