

(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.”

Should you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Jesse Robertson, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Announcement 01115, Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone number: (770) 488–2747, Email address: jrt4@cdc.gov.

For program technical assistance, contact: Leslie Given, MPA, Public Health Advisor, Division of Cancer Prevention and Control, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway, NE, Mailstop K–57, Atlanta, GA, Telephone: (770) 488–3099, Email address: llg5@cdc.gov.

Dated: June 7, 2001.

John L. Williams,

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 01105]

Replication and Implementation of Scientifically-Proven Asthma Interventions; 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 for Replication and Implementation of Scientifically-Proven Asthma Interventions. This program addresses the “Healthy People 2010” focus area of Respiratory Diseases.

The purpose of the program is to implement one of the following scientifically proven asthma

interventions: (1) “Open Airways” or (2) “Asthma Care Training for Kids: ACT”, to improve quality of life, decrease acute care visits, decrease hospitalizations, and increase compliance with asthma care plans and asthma medication regimens. These existing interventions have been selected because they have been validated as being safe and effective.

No research may be conducted as part of this cooperative agreement.

B. Eligible Applicants

Applications may be submitted by non-profit, public and private organizations or agencies that have affiliate/local offices in States, U.S. territories, or Indian tribes or Indian tribal organizations; local education agencies; hospitals; community-based organizations; managed care organizations; community health centers, and city or county public health agencies.

To be an eligible applicant, you must provide the following:

1. Evidence that applicant has direct access to target populations needed to implement these interventions.
2. Evidence of an established record of successful service in the community, through letters of support.
3. Evidence, through letters of support, of working relationships with other appropriate organizations within the specific community of the target populations.
4. If the applicant proposes the use of “Open Airways”, then a specific letter of support from the local chapter of American Lung Association is required.

This documentation should be placed after the face page of the application. An applicant that does not provide the above documentation will be determined non-responsive and returned without review.

Note: Title 2 of the United States Code, Chapter 26, Section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

C. Availability of Funds

Approximately \$1,000,000 is available in FY 2001 to fund approximately five to ten awards. It is expected that the average award will be \$125,000, ranging from \$100,000 to \$150,000. It is expected that the awards will begin on or about September 30, 2001, 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.

Funding Preferences

Funding preferences may include: (1) Geographic distribution, (2) racial and ethnic populations with a disproportionate asthma burden, (3) the mix between the two interventions to be implemented under this announcement, and (4) balance of organization type (i.e. Non-profit, managed care, community-based organization, etc.).

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), and CDC will be responsible for the activities listed under 2. (CDC Activities).

1. Recipient Activities

a. Implement the selected science-based asthma intervention designed to improve the quality of life of persons with moderate to severe persistent asthma by improving overall management of the disease.

b. Develop a quality assurance plan that allows confirmation that the implementation adheres to the selected intervention protocol.

c. Develop a plan to integrate the intervention into the organization's standard practice over time assuring institutionalization of the intervention. If needed, institute activities to change organizational policies and health care provider practices to ensure institutionalization.

2. CDC Activities

a. If requested, provide consultation and technical assistance regarding the implementation and evaluation of the intervention.

b. Provide liaison among grantees and potential sources of information and assistance.

c. Coordinate activities among sites, when appropriate.

d. Convene meetings among collaborators to discuss program issues, when appropriate.

E. Content

Letter of Intent (LOI)

A non-binding LOI is requested, and it should include:

1. Name and address of organization;
2. Contact person; and
3. Selected intervention.

The LOI will be used to ascertain the level of interest in this announcement and to assist in determining the size and composition of the independent review panel.

Applications

To develop the application content, use the information below in addition to the information listed in "Program Requirements," "Other Requirements," and "Evaluation Criteria" sections. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The application, excluding appendices, should be no more than 15 double-spaced pages, printed on one side, with one-inch margins, and un-reduced font. The application must be submitted unstapled and unbound.

1. Description of Applicant, Health Problem, and Population To Be Served

Describe the applicant's organization type (i.e., school district, community health center, local health department, etc.) and structure. Describe the population to be served and the asthma problem that will be addressed in this population by the intervention. Provide data to demonstrate the number of persons with moderate to severe persistent asthma who will be enrolled in the intervention over the three-year period and describe the source of that data.

2. Program Plan

a. Describe in detail the plans for implementing the intervention in the described population. Provide information on how the applicant will access the intervention protocol and the materials necessary for the intervention. Provide specific objectives for the proposed activities that are realistic, time-phased, and measurable, and reflect the three-year period of this announcement. Assume that the intervention patients are receiving appropriate medical care (based on the National Asthma Education and Prevention Program (NAEPP) Guidelines) prior to enrollment in the intervention activity. For school-based projects, describe which of the American Lung Association/Kaiser Permanente Key Elements of School-based Asthma Management are already implemented (see attachment 2, part II, for reference).

b. Describe in-kind contributions of the organization to support the intervention, the plan to integrate the intervention into its standard practice over time, and document the agency's willingness to do so. Describe policy and practice changes necessary to make institutionalization possible.

3. Evaluation of Intervention

Describe how progress toward effective implementation of the intervention will be evaluated. Describe

proposed process evaluation measures. (Note: Because the safety and effectiveness of the interventions to be implemented has been demonstrated previously, outcome evaluation will not be funded through this announcement.)

4. Management and Staffing Plan

a. Describe the qualifications, primary roles and responsibilities for each of the project staff over the three-year grant period. Include a description of intervention staff and the management plan for oversight of these staff.

b. Provide a plan to expedite filling of the staff position(s) and assure that they have been or will be approved by the applicant's personnel system.

c. Describe in detail needed training for staff and how that training will be provided.

5. Budget

This section must include a detailed first-year budget and narrative justification and future annual projections. The applicant should describe the program purpose for each budget item. For contracts contained within the application budget, applicants should name the contractor, if known; describe the services to be performed; justify the use of a third party; and provide a breakdown or a justification for the estimated costs of the contracts, the kinds of organizations or parties to be selected, the period of performance, and the method of selection. [Note: The funds for this intervention may not be used to supplant existing funds.]

F. Submission and Deadline

Letter of Intent (LOI)

On or before July 16, 2001, submit the LOI 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 0920-0428). Forms are available in the application kit and at the following Internet address: www.cdc.gov/od/pgo/forminfo.htm.

On or before August 13, 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:

1. Received on or before the deadline date; or
2. 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 which do not meet the criteria in 1. or 2. above 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.

1. Description of Applicant, Health Problem and Population To Be Served (15 points)

The extent to which the applicant describes the understanding of the population's need. Applicant's description of and access to an adequate number of the target population. Adequate description of the source of the data provided describing the target population.

2. Program Plan (35 points)

a. The extent to which the applicant describes the appropriateness of the proposed approach to implementation of the intervention. The ability to meet the objectives and the adequacy of the plan to carry out the proposed activities within the time-line provided.

b. The extent to which objectives are measurable against the stated purpose of the cooperative agreement. Applicant description of access to the information and materials necessary for the implementation of the intervention.

c. The extent that organizational support and the feasibility of the plan for institutionalization is described by the applicant.

3. Evaluation of Intervention (30 points)

The extent to which the applicant describes the feasibility and appropriateness of the plan to monitor progress toward meeting the objectives of the project. Appropriateness of proposed process measures.

4. Management and Staffing Plan (20 points)

The extent to which the applicant's overall ability to perform the proposed activities as reflected in the staff's qualifications and experience are described. The demonstration of the timely start of the intervention plan through the expedited hiring or availability of staff. Description of and access to needed training for staff.

5. Budget (Not scored)

The extent to which the budget is reasonable, adequately justified and consistent with the intended use of the cooperative agreement funds.

F. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Semi-annual progress reports;
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.

The following additional requirements may be applicable to this program. For a complete description of each, see Attachment I of the announcement.

- AR-7 Executive Order 12372 Review
- AR-8 Public Health System Reporting Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions
- AR-14 Accounting System Requirements
- AR-15 Proof of Non-Profit Status

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. section 241 and 247b], 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 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) 488-2724, Email address: Srowell@cdc.gov.

For program technical assistance, contact: Dan Burrows, Air Pollution and Respiratory Health Branch, National Center for Environmental Health, Centers for Disease Control and Prevention, 1600 Clifton Rd., NE (MS-E17), Atlanta, GA 30333, Telephone number: (404) 498-1004, Email address: DBurrows@cdc.gov.

Dated: June 7, 2001.

John L. Williams,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Nonvoting Representatives of Consumer and Industry Interests on Public Advisory Panels or Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for nonvoting consumer representatives and nonvoting industry representatives to serve on certain device panels of the Medical Devices Advisory Committee in the Center for Devices and Radiological Health

(CDRH). Nominations will be accepted for current vacancies and for those that will or may occur through July 31, 2002.

FDA has a special interest in ensuring that women, minority groups, individuals with disabilities, and small businesses are adequately represented on advisory committees and, therefore, encourages nominations for appropriately qualified candidates from these groups, as well as nominations from small businesses that manufacture medical devices subject to the regulations.

DATES: Nominations should be received by July 13, 2001, for vacancies listed in this notice.

ADDRESSES: All nominations and curricula vitae (which includes nominee's office address, telephone number, and e-mail address) for consumer representatives should be submitted in writing to Maureen A. Hess (address below). All nominations and curricula vitae (which includes nominee's office address, telephone number, and e-mail address) for industry representatives should be submitted in writing to Kathleen L. Walker (address below).

FOR FURTHER INFORMATION CONTACT:

Regarding consumer representatives:

Maureen A. Hess, Office of Consumer Affairs (HFE-50), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5006, e-mail: MHess@OC.FDA.GOV.

Regarding industry representatives:

Kathleen L. Walker, Office of Systems and Management (HFZ-17), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-1283, ext. 114, e-mail: KLW@CDRH.FDA.GOV.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for nonvoting members representing consumer and industry interests for the vacancies listed below:

Medical Devices Panels	Approximate Date Representative is Needed	
	Consumer	Industry
Anesthesiology and Respiratory Therapy Devices Panel	Dec. 1, 2001	Dec. 1, 2001
Circulatory System Devices Panel	July 1, 2002	NV ¹
Clinical Chemistry and Clinical Toxicology Devices Panel	Mar. 1, 2002	NV ¹
Dental Products Panel	NV ¹	Nov. 1, 2001
General Hospital and Personal Use Devices Panel	NV ¹	Jan. 1, 2002
Ophthalmic Devices Panel	Nov. 1, 2001	Nov. 1, 2001

¹NV = No vacancy

I. Function

The functions of the medical device panels are to: (1) Review and evaluate

data on the safety and effectiveness of marketed and investigational devices and make recommendations for their

regulation; (2) advise the Commissioner of Food and Drugs regarding recommended classification or