DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 02085]

Addressing Asthma From a Public Health Perspective: Implementation of State Asthma Plans; 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 Addressing Asthma from a Public Health Perspective. This program addresses the ''Healthy People 2010'' focus areas of Environmental Health, Respiratory Diseases and Occupational Safety and Health.

The purpose of this program is the to implement State Asthma Plans.

Measurable outcomes of the program will be in alignment with the following performance goal for the National Center for Environmental Health (NCEH): Improve state and local public health capacity to prevent and control asthma.

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, the Federated States of Micronesia, the Republic of the Marshall Islands, the Republic of Palau, and federally recognized Indian tribal governments.

If currently funded applicants under Program Announcements 99109 or 01106 Part A apply and are selected for funding under this announcement, they will lose continued funding under those Program Announcements (see Attachments I and II).

To be eligible, applicants must:

1. Submit a copy of your approved, comprehensive State Asthma Plan. Approval can be documented with a letter from the Agency's Health or Medical Director and letters from key partners or by appropriate sign-offs in the asthma plan. Plans that are pending final approval may be accepted if the draft plan is accompanied by letters from the Agency's Health or Medical Director and key partners stating their commitment to and approval of the plan, as well as a description of the plan's approval process status.

2. Have an operational surveillance system for asthma. This may be demonstrated through submission of your most comprehensive published surveillance report(s) (at least one, no more than three) that describes asthma within the jurisdiction, including, if available, a report on asthma in the Medicaid population.

These documents should be placed directly behind the face page (first page) of your application. Applications that fail to submit evidence requested above will be considered non-responsive and returned without review.

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 $1,500,000 is available in FY 2002 to fund approximately two to four awards. It is expected that the average award will be $700,000. It is expected that the awards will begin on or about September 30, 2002, and will be made for a 12-month budget period within a project period of up to five 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

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

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. Expand and continue existing surveillance efforts related to asthma occurrence, severity, management and other indicators in order to monitor the effectiveness of the intervention activities.

b. Conduct analysis and interpretation of surveillance data and disseminate this data through appropriate surveillance reports to local, state and federal partners and agencies.

c. Maintain existing statewide coalition and partnership activities to oversee implementation and evaluation of the state asthma plan. Expand partnership activities as appropriate.

d. Implement defined aspects of the completed state asthma plan. Assure institutionalization of asthma intervention activities.

e. Maintain existing asthma related activities currently underway in the health agency and expand as appropriate.

f. For all activities, develop and implement an evaluation plan which measures the effectiveness of your activities involved in each step indicated and document lessons learned.

g. Participate in CDC convened meetings and periodic conference calls for grantees to share experiences, data and materials.

2. CDC Activities

a. Participate with recipients in further development and enhancement of existing surveillance activities, including data collection methods and data analysis.

b. Collaborate with recipients on data analysis and interpretation of individual state surveillance data and release of surveillance reports.

c. Provide technical and scientific assistance and consultation on program development, implementation of asthma plan and intervention activities and operational issues.

d. Serve as a facilitator for communication between states to share expertise regarding various topics, including the expansion and development of partnerships, implementation of state plans, surveillance activities and others.

e. Facilitate working group conference calls with recipients.

f. Collaborate on the development of an appropriate evaluation plan which measures the effectiveness of recipient activities involved in each step indicated.

g. Convene meetings and periodic conference calls for grantees to share experiences, data and materials.

E. Content

Letter of Intent (LOI)

A nonbinding LOI is required for this program. The Program Announcement title and number must appear in the LOI. The narrative should be no more than two pages, single-spaced, printed on one side, with one inch margins and at least 12 point font. Your letter of intent 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 and should include the following information:

1. Name and address of organization.

2. Contact person and telephone number.

Applications

The Program Announcement title and number must appear in the application. The narrative should be no more than 30 double-spaced pages, printed on one side, with one-inch margins, and at least 12 point font.

Excluding documents requested in this announcement (e.g., asthma plan, surveillance reports, letters of support, organizational chart, CVs/resumes) attachments/appendices should be limited to 20 pages. The application and attachments/appendices must be submitted unstapled, one-sided and unbound.

The applicant should document assurance of their ability to access and utilize funds, if awarded, for the purposes of this announcement.

The applicant should document assurance of the ability of project staff to travel to Atlanta to participate in the CDC National Asthma Conference and/or grantee meetings and willingness to share innovations, information, data and materials.

Include each of the following sections:

1. Description of Problem

Describe what is known of the asthma problem in the State or jurisdiction. Include a description of populations at increased risk of poorly controlled asthma within the jurisdiction (e.g., ethnic groups, socio-economic groups, geographic areas). Attach published surveillance reports that describe asthma within the jurisdiction including, if available, reports on asthma in the Medicaid population and for the enrollees of the State Children's Health Insurance Program (SCHIP).

2. Approved Asthma Plan

Describe how the asthma plan and the plan's implementation strategy were developed. Include a list of the partners that participated in the development of the plan (if not listed in the provided plan). Also, show support for the plan as demonstrated by a letter from the Agency's Health or Medical Director and from key partners. The approved plan (or attachments to that plan) must include:

a. An assessment of the asthma burden in the state/territory/tribe using population-based data.

b. Measurable objectives that address people with asthma across the state/territory/tribe and include people with asthma of all ages, race/ethnic groups and gender.

c. A description of how the plan's implementation would reach all persons with asthma in the state regardless of age, race/ethnicity or gender.

d. Proposed strategies to meet the plan's objectives, including, but not limited to, efforts to (1) expand surveillance for asthma, (2) improve provider compliance with the National Asthma Education and Prevention Program's (NAEPP) ''Guidelines for the Diagnosis and Management of Asthma,'' (Clinical Practice Guidelines, Guidelines for the Diagnosis and Management of Asthma. National Institutes of Health (NIH), National Heart, Lung and Blood Institute. NIH Publication No. 97–4051, April 1997), (3) improve the skills of patients and families affected by asthma to manage the disease.

e. A methodology for evaluating the asthma plan's implementation and measure progress toward objectives described in ''b.'' above.

f. An assessment of existing and needed resources to implement these strategies.

3. Partnership Oversight

Describe how the partners who developed the asthma plan will continue to work together to implement and monitor the intervention activities and modify the asthma plan over time.

4. Surveillance and Evaluation

Describe the surveillance system currently in place within the health agency and its ability to support the evaluation of asthma intervention activities and a continued planning process. All asthma indicators assessed over time should be noted including, but not limited to, prevalence, mortality, hospitalization, emergency care and measures of disease management status (refer as needed to the surveillance reports that were included under Section 1. Description of the Problem). Ability to provide measurement of progress in meeting all plan objectives should be addressed. Intentions to use Behavioral Risk Factor Surveillance System (BRFSS) asthma module(s) and the frequency of use should be included; also, plans for further development of the asthma surveillance activity should be presented in detail. Surveillance of work-related/occupational asthma is encouraged and must be discussed. This section might include the applicant's definition of work-related/occupational asthma (e.g., Surveillance of Work-Related Asthma in Selected U.S. States Using Surveillance Guidelines for State Health Departments—California, Massachusetts, Michigan and New Jersey, 1993–1995—MMWR June 25, 1999/48(SS03); 1–20). Discussion might include which existing databases will be used to collect and analyze work-related/occupational asthma.

5. Implementation of the Asthma Plan

a. Identify the specific objectives of the asthma plan that are to be focused upon and the specific intervention strategies from the plan to be implemented that will use the resources provided through this announcement. Interventions that change systems and individuals to provide improved disease management or education are preferred. Provide specific, realistic, measurable and time-phased process objectives for each of the strategies and interventions to be implemented that reflect the five-year period of this announcement. Describe how both process and outcome objectives for all activities will be evaluated and documented.

b. Demonstrate the scientific basis for proposed interventions. If proposed interventions include case management programs, assure that patients enrolled are those with moderate to severe persistent asthma and are receiving care consistent with the NAEPP Guidelines for the Diagnosis and Management of Asthma. Explain how it was decided by members of the statewide partnership group that these particular objectives and strategies will be addressed.

c. Describe which objectives and strategies from the plan are currently being addressed utilizing other resources.

d. Demonstrate that the plan addresses asthma in persons of all ages, race/ethnic groups and gender, and includes key environments in which persons with asthma spend significant time (e.g., home, school, workplace). Include a discussion on work-related/occupational asthma in the plan. This discussion might include the guidelines that the applicant will use for work-related/occupational asthma (e.g., Minimum and Comprehensive State-Based Activities in Occupational Safety and Health, June 1995—DHHS (NIOSH) Publication No. 95–107).

e. Explain how the resources from this solicitation will be utilized to leverage additional resources for implementation of other components of the plan. Explain how interventions will be institutionalized and sustained without funding under this announcement.

6. Management and Staffing for Intervention Activities

a. Describe existing asthma program staff within the health department and their management structure, the current function of the asthma staff and their role in this project plan. Provide an organizational chart for the health agency that identifies the unit(s) that

will participate in the proposed activities. If plan implementation will be coordinated from an office other than within the health department, describe that office and its staff, the oversight of that office and its staff, an organizational chart and the ties of that office to the health agency.

b. Describe asthma surveillance staff and their role within the project activities. Describe all staff who will be responsible for oversight of program evaluation.

c. If intervention activities will be implemented through contracts, define the process by which these contracts will be awarded and monitored.

d. Describe staff available or to be hired for those aspects of the plan to be implemented with these resources. For each position, describe the primary roles and responsibilities over the five-year grant period.

e. Include the specific staff activities that will contribute to meeting each objective that is to be addressed. Discuss the role of the statewide partnership group in oversight of intervention activities.

f. Document assurance of ability of key project staff to travel to Atlanta to participate in the CDC National Asthma Conference and/or grantee meetings and willingness to share innovations, information, data and materials.

g. Document assurance of ability to access and utilize funds, if awarded, for the purposes of this announcement.

7. 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. The budget should include travel for key project staff to meet once per year with CDC staff and other grantees. This section should also include a listing of other funds, outside the cooperative agreement, that will be used to support this intervention.

F. Submission and Deadline

Letter of Intent (LOI)

On or before May 24, 2002, 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*

Application forms must be submitted in the following order:
Cover Letter
Table of Contents
Application
Budget Information Form
Budget Justification
Checklist
Assurances
Certifications
Disclosure Form
HIV Assurance Form (if applicable)
Human Subjects Certification (if applicable)
Indirect Cost Rate Agreement (if applicable)
Narrative

On or before 5:00 pm Eastern Time June 24, 2002, submit the application to:

Technical Information Management-PA02085, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Rd., Room 3000, Atlanta, GA 30341–4146.

Deadline: Letters of intent and applications shall be considered as meeting the deadline if they are received before 5:00 pm Eastern Time on the deadline date. Applicants sending applications by the United States Postal Service or commercial delivery services must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If an application is received after closing due to (1) carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time or (2) significant weather delays or natural disasters, CDC will upon receipt of proper documentation, consider the application as having been received by the deadline.

Applications which do not meet the above criteria will not be eligible for competition and will be destroyed. Applicants will be notified of their failure to meet the submission requirements.

G. Evaluation Criteria

Applicants are required to provide Measures of Effectiveness that will demonstrate the accomplishment of the various identified objectives of the grant or cooperative agreement. Measures of Effectiveness must relate to the performance goal (or goals) as stated in section ''A. Purpose'' of this announcement. Measures must be objective and quantitative and must measure the intended outcome. These Measures of Effectiveness shall be submitted with the application and shall be an element of evaluation.

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

1. Description of the Problem (5 points)

The extent to which the agency's commitment to addressing asthma is demonstrated by accomplishments to date in understanding the problem. The extent to which the agency has been able to identify populations at increased risk and effectively disseminate and use that information in the planning process.

2. Asthma Plan (20 points)

The extent to which a wide variety of appropriate partners were engaged to develop the asthma plan; the commitment by the Agency to the implementation of this plan as demonstrated by the inclusion of a letter of support from the Agency's Health or Medical Director; the extent to which the intervention plan is supported in the community by the inclusion of letters of support from key members of the community; and the extent to which the asthma plan is comprehensive and includes the items listed in the application section for this announcement.

3. Partnership Oversight (10 points)

The extent to which appropriate partners will be a part of the implementation and oversight of the asthma plan.

4. Surveillance and Evaluation (20 points)

The current state of the asthma surveillance system; the quality and scope of surveillance reports provided; the ability to provide a measurement of progress in meeting all plan objectives; the plan for appropriate continued development of the asthma surveillance activity; and the ability to support evaluation of implementation activities.

5. Implementation of the Asthma Plan (30 points)

Clear link between the asthma plan and the proposed implementation; the appropriateness and scientific support for the proposed implementation; the involvement of statewide partners in implementation of the plan and its monitoring over time; the use of these resources to leverage additional resources for plan implementation; the plans to institutionalize specific

interventions; specific objectives that are realistic, measurable and time phased; and clear definition of both process and outcome measures for the evaluation of implementation activities.

6. Management and Staffing for Intervention Activities (15 points)

The current functioning of asthma staff (program and surveillance) within the health agency; the description of staff to be hired or contracts to be developed; the link of staff to program objectives; and the continued role of the statewide partnership group.

7. Budget (Not scored)

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

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Semi-annual progress reports (The progress report will include a data requirement that demonstrates measures of effectiveness.) The progress reports shall include the following items:

a. A brief project description.

b. A comparison of actual accomplishments to the goals and objectives established for the period.

c. In the case that established goals and objectives may not be accomplished or are delayed; documentation of both the reason for the deviation and the anticipated corrective action or a request for deletion of the activity for the project.

d. A financial summary of obligated dollars to date as a percentage of total available dollars.

e. Other pertinent information (i.e. curriculum vitae for new key personnel).

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

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 are applicable to this program. For a complete description of each, see Attachment III of the application kit.

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 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, the necessary applications and associated forms can be found on the CDC home page Internet address—*http://www.cdc.gov* Click on ''Funding'' then ''Grants and Cooperative Agreements.''

For business management assistance, contact:

Sonia V. Rowell, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention, Program Announcement 02085, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146. *Telephone number:* (770) 488–2724. *Email address: SRowell@cdc.gov.*

For program technical assistance, contact:

Daniel J. Burrows, M.S., Public Health Advisor, Air Pollution and Respiratory Health Branch, National Center for Environmental Health, Centers for Disease Control and Prevention, Mailstop E–17, 1600 Clifton Rd., NE, Atlanta, GA 30333.

Telephone number: (404) 498–1004.

Email address: DBurrows@cdc.gov.

Dated: May 4, 2002.

Sandra R. Manning,

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

[FR Doc. 02–11564 Filed 5–8–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 02167]

''Phase I Study To Assess The Safety, Tolerability, Immunogenicity, And Shedding Of Attenuated Measles Vaccine Administered As A Single Intranasal Dose To Healthy Adults''; 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 ''Phase I Study to Assess the Safety, Tolerability, Immunogenicity, and Shedding of Attenuated Measles Vaccine Administered as a Single Intranasal Dose to Healthy Adults.'' This program addresses the ''Healthy People 2010'' focus area ''Immunization and Infectious Diseases'' and ''Medical Product Safety''.

The purpose of the program is to conduct a double blinded, randomized, placebo controlled, 2-step, single-center study of intranasal administration of attenuated measles vaccine in healthy adults to assess safety and immunogenicity of vaccine, tolerability of vaccination, and shedding of vaccine virus.

Research Objectives

Primary

1. To determine the safety and tolerability of live attenuated measles vaccine administered intranasally (IN) to healthy adults.

2. To compare the serum antibody responses elicited following IN versus subcutaneous (SC) administration of live attenuated measles vaccine, using standard methods (plaque-reduction neutralization titers and ELISAs).

Secondary

1. To measure the incidence of measles vaccine viral shedding following vaccination.

2. To explore the utility of mucosal antibody measurements in evaluating responses to measles immunization.

Background

Measles continues to be a major source of morbidity and mortality in developing countries despite the availability of an effective vaccine. Expanded immunization programs are hampered by the fact that until now there has only been a parenteral vaccine available. Inappropriate vaccination procedures can lead to injection site infections, nerve damage or transmission of blood-borne pathogens.

Mucosal immunization has proven to be an effective and non-invasive manner by which to induce a local and systemic immune response. Measles immunization via aerosol has been studied extensively and has been found to be safe and effective. Previous studies of IN measles vaccination have yielded variable results attributable to varied doses and methods of administration plus interference by concomitant upper respiratory infections, making it difficult to determine if this is an effective vaccination route. No serious adverse events have been reported. Currently, the only Food and Drug