

Dated: September 5, 2002.

Sandra R. Manning,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 03006]

Immunization and Vaccines for Children Grants; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2003 funds for a grant program for Preventive Health Services, Immunization and the Vaccines for Children (VFC) program. Both programs address the "Healthy People 2010" priority area under Immunization and Infectious Diseases.

The purpose of this grant program is to support efforts to plan, develop, and maintain a public health infrastructure, which assures an effective national immunization system. As a part of this system, the purpose of the VFC program is to increase access to vaccines for eligible children by supplying Federal government-purchased pediatric vaccines to public and private health care providers registered with the program. Eligible children include newborns through those 18 years of age who are Medicaid-eligible, not insured, American Indian/Alaska Natives, and children not insured with respect to the vaccine who are served by a Federally-Qualified Health Center or a Rural Health Clinic.

Measurable outcomes of the program will be in alignment with one or more of the following performance goals for the National Immunization Program:

1. Reduce the number of indigenous cases of vaccine-preventable diseases.
2. Ensure that two year-olds are appropriately vaccinated.
3. Improve vaccine safety surveillance.
4. Increase routine vaccination coverage levels for adolescents.
5. Increase the proportion of adults who are vaccinated annually against influenza and who have ever been vaccinated against pneumococcal diseases.

B. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 317 of the Public Health Service Act, [42 U.S.C. 247b], as amended. The Catalog of Federal Domestic Assistance number is 93.268. The VFC Program is authorized under Section 1902(a)(62), of the Social Security Act, 42 U.S.C. section 1396a(a)(62). The VFC Program was established under the authority of Section 1928(a) of the Social Security Act, 42 U.S.C. 1396s(a).

C. Eligible Applicants

Limited Competition

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, and the Republic of Palau. In consultation with States, assistance may be provided to political subdivisions of States. The Federated States of Micronesia, the Republic of Palau and the Republic of the Marshall Islands are not eligible for funding through the VFC Program. Competition is limited to these entities because they have the primary responsibility for carrying out the public health assurance functions required to achieve the desired outcomes and performance goals established by CDC.

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.

D. Funds

Availability of Funds

Section 317

Approximately \$180,000,000 in Section 317 funds is available in FY 2003 to fund 64 awards for program operations. It is expected that the average Section 317 award for program operations will be \$2.8 million, ranging from \$62,000 to \$16,000,000.

In addition, approximately \$208,000,000 in Section 317 funds is available in FY 2003 to fund 64 Section 317 awards for vaccine purchases. It is expected that the average Section 317 award for vaccine purchase will be \$3,250,000, ranging from \$6,000 to \$25,000,000.

VFC

Approximately \$65,000,000 in VFC funds is available in FY 2003 to fund 61

awards for program operations. It is expected that the average VFC award for program operations will be \$1,000,000, ranging from \$99,000 to \$7,000,000.

In addition, approximately \$704,000,000 in VFC funds is available in FY 2003 to fund 61 VFC awards for vaccine purchase. It is expected that the average VFC award for vaccine purchase will be \$11,555,000, ranging from \$298,000 to \$121,000,000.

All applicants eligible for VFC funding are expected to apply for both Section 317 and VFC funds.

It is expected that the awards will begin on or about January 1, 2003 and will be made for a 12-month budget period within a project period of up to five years. Funding estimates may change. All awards are subject to availability of funds.

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.

Direct Assistance

You may request Federal personnel and vaccines for which CDC has established purchase contracts as Direct Assistance (DA) in lieu of a portion of financial assistance. Grantees may also access Federal contracts for equipment, supplies, and services needed for immunization registry development by requesting these costs as DA.

Use of Funds

Funding requests not directly related to immunization activities are outside the scope of these grant programs and will not be funded.

Immunization grant funds are intended to supplement and may not be used to supplant state and local resources.

Grant funds awarded for vaccine may be used only for purchasing vaccines. Vaccines obtained through the VFC Program may be administered only to VFC-eligible persons in risk groups recommended by the Advisory Committee on Immunization Practices (ACIP). Vaccines and related products acquired with 317 funds [with the exception of Td/DT toxoids and hepatitis B immune globulin (HBIG)] are not to be administered to persons eligible for the VFC Program. Additional information about limitations on the use of VFC funds for program operations is provided in the CDC document entitled "VFC Operations Guide" which is available from CDC upon request. (See section J. Where to Obtain Additional Information).

Based on the availability of appropriated 317 funds, Section 317

grant funds may also be used to implement programs to ensure vaccination of adolescents and adults. Also based upon the availability of grant funds, vaccines may be purchased for adults not covered by Medicare, including hepatitis B vaccine for persons at high risk, influenza vaccine for persons 50 years of age and older, and any other vaccines recommended by the ACIP for adults.

The amount of grant funds used for shipping vaccine to providers should be within the per-dose cost standards established by CDC through on-going cost studies.

Grant funds may not be used to purchase or lease vehicles or for administrative overhead such as rent and utilities. Costs associated with purchasing or leasing vehicles will be denied except in cases where the application provides strong evidence of exceptional need directly related to the implementation of the program. Requests for funds to support administrative overhead covered by the indirect cost agreement will also be denied. Applications that include requests for funding to support administrative overhead should include a copy of the grantee's indirect cost rate agreement.

Recipient Financial Participation

Documentation of recipient financial participation is required for this program in accordance with this Program Announcement. Although CDC does not require grantees to match funding for immunization activities, CDC wishes to fully document grantee financial participation in immunization programs as recommended by the Institute of Medicine ("Calling The Shots, Immunization Finance Policies and Practices", National Academy of Sciences, 2000). Therefore, grantees should fully and comprehensively document all support by grantee and sub-grantee agencies, including in-kind support, for immunization program activities and vaccine purchases.

Funding Priority

As funding levels permit, funds will be awarded for the program activities listed in the "2002 VFC Operations Guide" and the "Immunization Program Operations Manual" (available from CDC upon request: See section J. Where to Obtain Additional Information); including screening and referral of children enrolled in the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) in areas where evidence suggests that WIC enrollees are significantly under-immunized.

Priority will be given to funding activities proven to be effective in raising immunization coverage. These activities are described in the "Community Guide to Preventive Health Services" published by CDC and available through the following Web site: www.thecommunityguide.org.

Priority will also be given to funding activities that: (1) Identify areas where immunization coverage is low relative to the over-all population; (2) identify the under-immunized individuals in these areas; and (3) implement proven strategies to ensure that these individuals are fully vaccinated.

Funding Preferences

Funding preference will be given to current recipients.

E. Program Requirements

In conducting activities to achieve the purposes of these programs, the recipient will be responsible for the following activities:

1. Program Management

a. Identify areas where immunization coverage is low and implement strategies to ensure that under-immunized individuals in these areas are identified and receive ACIP-recommended vaccines.

b. Build and participate in community-based and program-wide coalitions to promote specific activities or projects intended to assure immunization of all age groups.

c. Coordinate educational and other activities with state and local WIC programs, to assure that children participating in WIC are screened and referred for immunizations using a documented immunization history in accordance with policy of the United States Department of Agriculture.

d. Coordinate program planning and implementation with the Indian Health Service, Tribal/638 health clinics and other entities that provide medical services to Native populations to assure consistent and immediate access to all VFC vaccines by American Indian and Alaska Native populations.

2. Vaccine Management

a. Establish a cost-effective system for distributing federally-purchased vaccine to private and public health care providers.

b. Estimate 317 and VFC vaccine needs, based on ACIP recommendations, populations to be served, anticipated vaccine uptake and wastage rates, state/local vaccine supply policies and existing vaccine inventories.

c. Follow a CDC-approved purchasing plan for VFC vaccine to ensure that total annual VFC vaccine purchases do not exceed the amount needed for VFC eligible children and are consistent with the number of VFC-eligible children reported to and certified by CDC.

d. Provide vaccines to VFC enrolled providers in sufficient quantities to immunize VFC-eligible children in accordance with ACIP resolutions.

e. Update (annually) and maintain VFC program records on all participating providers.

f. Establish a system to document wasted and unaccounted for vaccines purchased with 317 and VFC funds.

g. Implement a program with immunization providers and vaccine depots to minimize and report vaccine wastage.

h. Submit claims for rebate of excise tax for vaccines that cannot be administered because of shelf-life expiration or improper storage and handling.

i. Maintain a system for detecting, responding to, and reporting suspected cases of fraud and abuse involving Federally-purchased vaccine.

3. Immunization Registries

Develop, update, and/or implement a plan to reach the Healthy People 2010 goal of enrolling at least 95 percent of children under six years of age in a fully operational registry.

4. Provider Quality Assurance

a. Work with health insurance companies, managed care organizations (MCOs) and the State Medicaid agency to ensure that local health departments are appropriately reimbursed for vaccines and vaccine administration costs that are covered benefits.

b. Work with private health care providers to reduce referrals to public clinics and remove the barriers to immunization that drain limited 317 vaccine resources in public clinics.

c. Provide educational opportunities for public and private providers concerning the standards for pediatric and adult immunization practices, reporting of suspected vaccine preventable diseases (VPDs), and provider responsibilities under the National Childhood Vaccine Injury Act (sections 2125 and 2126 of the Public Health Service Act, 42 U.S.C. sections 300aa-25 and 300aa-26); including recordkeeping, reporting and use of Vaccine Information Statements.

d. Conduct site visits to VFC provider offices to evaluate vaccine management, ensure compliance with VFC program requirements, assess immunization

practices and make recommendations for improvement.

5. Service Delivery

a. Coordinate with local public health agencies and clinics to make immunization services and ACIP-recommended vaccines available for underserved populations of all age groups in every county and major city.

b. Enroll health care providers who serve children into the VFC program in accordance with Section 1902(a)(62), of the Social Security Act and Section 1928 (42 U.S.C. 1396s) (a) of the Social Security Act.

c. Assess completeness of prenatal hepatitis B surface antigen (HbsAg) screening and appropriate vaccination of infants at high risk of perinatally-acquired hepatitis B infection.

d. Conduct and coordinate case management of infants at high risk of perinatally-acquired hepatitis B infection to ensure completion of the hepatitis B vaccination series.

e. Work with child care facilities, schools, state, and local agencies, to identify and provide appropriate vaccinations to under-immunized infants and children entering day care and school.

6. Consumer Information

a. Undertake appropriate efforts to inform, influence, and motivate the public about the importance and safety of immunizations.

b. Distribute Vaccine Information Statements (VIS) and CDC's instructions for their use to ensure proper use of VIS in accordance with the National Childhood Vaccine Injury Act (section 2126 of the Public Health Service Act, 42 U.S.C. 300aa-26).

7. Surveillance

a. Investigate and document suspected VPD cases in accordance with CDC's "Manual for Surveillance of Vaccine Preventable Diseases".

b. Submit timely case reports to CDC on cases of VPD designated as reportable by the Council of State and Territorial Epidemiologists.

c. Coordinate and monitor the Vaccine Adverse Events Surveillance System mandated by the National Childhood Vaccine Injury Act of 1986.

d. Follow up on all reports of serious adverse events (e.g., death, life-threatening illness, hospitalization and permanent disability) following immunization.

8. Population Assessment

a. Identify and monitor pockets of under-immunized children and adults by using immunization coverage

estimates (e.g., cluster surveys, immunization registries, Medicare billing data, retrospective analysis of school immunization surveys, provider coverage assessments and Behavioral Risk Factor Sample Survey).

b. Estimate immunization coverage and exemption rates among children in day care and kindergarten.

c. Use existing coverage data to monitor and analyze uptake of new and recently introduced vaccines.

F. Content

Applications

The Program Announcement title and number must appear in the application. 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 laying out the program plan. The narrative should be no more than 80 pages, double-spaced, printed on one side, with one-inch margins, and 12 point Courier font.

The application should consist of, at minimum, a description of Program Need, Objectives, Methods, Evaluation, Budget, Budget Justification, Applicant Resources, and Management Plan. All applications must clearly differentiate 317 and VFC funding streams to enable CDC and grantee financial offices to track these funds separately. CDC will provide instructions and a budget template for this purpose in a Grant Guidance document. Requests for VFC funds must be justified based on the number and proportion of the population eligible for VFC vaccines.

Direct Assistance

To request new direct-assistance assignees, include:

- a. Number of assignees requested.
- b. Description of the position and proposed duties.
- c. Ability or inability to hire locally with financial assistance.
- d. Justification for request.
- e. Organizational chart and name of intended supervisor.
- f. Opportunities for training, education, and work experiences for assignees.
- g. Description of assignee's access to computer equipment for communication with CDC (e.g., personal computer at home, personal computer at workstation, shared computer at workstation on site, shared computer at a central office).

G. Submission and Deadline

Submit the original and two copies of PHS 5161-1 (OMB Number 0920-0428).

Forms are available at the following internet address: www.cdc.gov/od/pgo/forminfo.htm.

If you do not have access to the internet, or if you have difficulty accessing the forms on-line, you may contact the CDC Procurement and Grants Office Technical Information Management Section at: 770-488-2700.

Application forms can be mailed to you.

The application must be received by 5 p.m. Eastern Time October 28, 2002. Submit the application to: Technical Information Management-PA03006, Procurement and Grants Office, Center for Disease Control and Prevention, 2920 Brandywine Rd, Room 3000, Atlanta, GA 30341-4146. Forms may not be submitted electronically.

Deadline: Applications shall be considered as meeting the deadline if they are received before 5 P.M. 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 close due to (1) carrier error, when the carrier accepted the package with a guarantee for delivery of 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 be returned to the applicant. Applicants will be notified of their failure to meet the submission requirements.

H. Evaluation Criteria

Application

Applicants are required to provide Measures of Effectiveness that will demonstrate the accomplishment of various identified objectives of the grant. Measures of Effectiveness must relate to the performance goals as stated in section "A. Purpose" of this announcement. They should be expressed as: (1) A stated percentage increase in coverage for individual vaccines or maintenance of coverage at the national goal of 90 percent, and (2) objectives related to specific programmatic areas for which a need for additional programmatic emphasis has been identified. 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. Methods (30 points)

Are the proposed activities and interventions potentially effective in directly impacting immunization coverage and disease reduction, (especially in under-immunized geographical areas and sub-populations)? Is the management plan likely to ensure that grant-funded activities will be implemented in a timely fashion?

2. Program Plan (25 points)

Does the application propose effort for required activities in all program components outlined in section "D. Program Requirements" and for populations of all ages (infants, children, adolescents and adults)?

3. Objectives (25 points)

Does the program objectives focus on specific activities that potentially impact program need?

4. Evaluation (20 points)

Are quantified performance measures that will demonstrate program effectiveness as indicated by achievement of program objectives and intended outcomes clearly stated?

5. Budget (not scored)

Are the budget and budget justification thorough in explaining the purpose for which each line item is requested, and how the amounts were derived? Are the budget items apportioned across the program components? Are the 317 and VFC funds clearly differentiated?

I. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Semiannual progress reports. The progress report will include a data element that demonstrates measures of effectiveness. The first report will cover the period January 1 to June 30, and the second report (which serves as the continuation application) will cover the period July 1 to December 30. A copy of the progress report due on July 30 must be submitted via computer-based systems and formats developed by CDC that specify required data elements related to measures of effectiveness (the original and two copies are to be mailed).

2. Ad hoc reports, *i.e.*, VPD case reports and ongoing purchase and inventory reports for all vaccines purchased with public funds, via forms, templates, and computer-based systems

developed by CDC should be submitted as information is collected or as requested by CDC.

3. Financial Status Report, with an attachment that delineates separate VFC and 317 expenditures and obligations by object class category, no more than 90 days after the end of the budget period.

4. Final financial and performance report, with an attachment that delineates separate VFC and 317 expenditures and obligations by object class category, 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 I in the application kit.

- AR-1 Human Subjects Requirements
- 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

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: <http://www.cdc.gov>.

Click on "Funding" then "Grants and Cooperative Agreements."

For general questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Rd. Room 3000, Atlanta, GA 30341-4146, Telephone: 770-488-2700.

For business management and budget assistance, contact: Peaches Brown, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146, Telephone number: (770) 488-2738, E-mail address: prb0@cdc.gov.

For program technical assistance, contact: Glen Koops, Acting Chief, Program Operations Branch, ISD, National Immunization Program, Mailstop E-52, 1600 Clifton Rd., Atlanta, GA 30333, Telephone number: (404) 639-8215, E-mail address: gak3@cdc.gov.

Dated: September 6, 2002.

Sandra R. Manning,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Alcohol Syndrome and Fetal Alcohol Effect National Task Force Meeting; Correction

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Notice; correction.

Name: National Task Force on Fetal Alcohol Syndrome and Fetal Alcohol Effect (NTFFAS/FAE): Correction.

Times and Dates: 8:30 a.m.-4:30 p.m., September 20, 2002. 8:30 a.m.-12 noon, September 21, 2002.

SUMMARY: The National Task Force on Fetal Alcohol Syndrome and Fetal Alcohol Effect published a notice in the **Federal Register** of August 8, 2002, announcing a meeting place.

Correction

In the **Federal Register** of August 8, 2002, Volume 67, Number 153, Notice, Page 51584, "Place" should read:

Place: Marriott Atlanta Marquis, 265 Peachtree Center Avenue, Atlanta, Georgia 30303, telephone 404/521-0000; fax 404/586-6299.

FOR FURTHER INFORMATION CONTACT:
Louise Floyd, 770/488-7372.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: September 5, 2002.

John Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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