

1. History and Experience (30 points)

The extent to which the proposal clearly demonstrates the applicant's solid reputation and history of serving families affected by asthma. The proposal should demonstrate that the applicant has a broad range of knowledge and expertise in the field of asthma, as well as significant years of experience in the dissemination and application of this knowledge and expertise. The proposal should also demonstrate that the applicant's membership is comprised of families affected by asthma and that this membership is national in scope.

2. Proposed Program (30 points)

The extent to which the proposal clearly demonstrates the applicant's understanding of the issues surrounding asthma and asthma education activities and addresses gaps in the current state of asthma educational materials and activities. The proposal demonstrates that the applicant has a clear understanding of the gaps and needs and has a clear plan of activities which will address these gaps. The applicant must demonstrate their educational materials are in adherence to the NAEPP guidelines and when these guidelines are updated, materials are appropriately updated.

3. Evaluation Plan (30 points)

The extent to which the applicant describes a realistic plan to accurately measure the effectiveness of their activities and which has mechanisms to insure quality improvement occurs over the life of the project.

4. Facilities, Staff, and Resources (10 points)

The extent to which the applicant can provide adequate facilities, staff and/or collaborators, and resources to accomplish the proposed goal(s) and objectives during the project period. The extent to which the applicant demonstrates staff and/or collaborator availability, expertise, previous experience, and capacity to perform the undertaking successfully.

5. Budget (not scored)

The extent to which the proposal demonstrates appropriateness and justification of the requested budget relative to the activities proposed.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Semiannual progress reports (The progress report will include a data requirement that demonstrates measures of effectiveness.) The progress report 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; 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 are 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-21 Small, Minority, Women-Owned Businesses

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 301 and 317(k)(2) of the Public Health Service Act, [42 U.S.C. 241 and 247b(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."

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Sonia Roswell, Grants Management Specialist
Acquisition Assistance Branch B,
Procurement and Grants Office

Centers for Disease Control and Prevention

Announcement 02115

2920 Brandywine Road, Room 3000
Atlanta, GA 30341-4146

Telephone number (770) 488-2724
email address srowell@cdc.gov

For program technical assistance, contact:

Sheri Disler, Public Health Advisor
National Center for Environmental Health

Centers for Disease Control and Prevention

1600 Clifton Road, NE, MS E-17
Atlanta, GA 30333

Telephone number (404) 498-1018
email address sdisler@cdc.gov

Dated: April 30, 2002.

Sandra R. Manning, CGFM,

*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 02086]

Prevention of Viral Hepatitis Among High-Risk Youth Through Integrating Prevention Services Into Existing 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 Prevention of Viral Hepatitis among High-Risk Youth Through Integrating Prevention Services into Existing Programs. This program addresses the "Healthy People 2010" focus area of Immunization and Infectious Diseases.

The purpose of the program is to evaluate the feasibility and effectiveness of integrating activities to prevent infection with Hepatitis A Virus (HAV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) into existing programs that serve high-risk adolescents populations.

High-risk adolescents are youth aged 11-19 years who engage or are at risk for engaging in behaviors shown to be associated with transmission of infection with hepatitis viruses or other blood borne virus infections such as Human Immunodeficiency Virus (HIV/AIDS), injecting or non-injecting drug

use, male homosexual activity, sexual activity with multiple partners, and behaviors leading to incarceration.

Prevention of infection with hepatitis viruses is achieved through immunization (HAV, HBV) and risk reduction intervention (HCV) to prevent injection drug use and high risk sexual practices. For adults, activities to prevent viral hepatitis have been effectively integrated into other prevention programs. However, the feasibility of providing such services for high-risk youth, and the effectiveness of these prevention services in reducing all types of viral hepatitis in this population has not been evaluated. This announcement is intended to support the formative, operational and evaluation research required to determine the most effective means of integrating viral hepatitis prevention activities into existing disease prevention and health promotion programs.

B. Eligible Applicants

Applications may be submitted by public and private non-profit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit organizations, State and local governments 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, federally recognized Indian Tribal Governments, Indian Tribes, or Indian Tribal Organizations. Faith-based Organizations are eligible to apply.

Eligible applicants are required to have a minimum of two years of experience in developing and implementing public health prevention or promotion activities in addition to having access to the at risk adolescent population to be served.

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.

A. Availability of Funds

Approximately \$150,000 is available in FY 2002 to fund one award. It is expected that the award will begin on or about September 1, 2002 and will be made for a 12 month budget period within a project period up to five years. The funding estimate 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

Preference will be given to population based programs that deliver or provide oversight for public health services to large adolescent populations (1000 to 3000 individuals served per year) in which a high proportion have risk factors for infection with hepatitis viruses. Such community-based programs should attempt to identify and follow cohorts of youth through indicators of risk and specific programs, including: demographic characteristics and health disparities which identify high-risk youth, correctional settings, residential community programs, court mandated programs, job corps, drug detoxification and rehabilitation programs, homeless and runaway shelters, HIV/AIDS prevention services, and Sexually Transmitted Disease (STD) prevention and treatment programs.

B. 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. Develop and implement protocol(s) to integrate currently recommended viral hepatitis prevention services into existing public health programs and services, as appropriate for adolescents in the particular setting(s) proposed. Viral hepatitis prevention services may include, but are not limited to:

- (1) Providing hepatitis B vaccination.
- (2) Assessing risk histories for viral hepatitis among clients.
- (3) Providing client-centered prevention counseling to patients with risks for infection.
- (4) Providing testing to appropriate risk groups for HCV infection (anti-HCV), and chronic or past hepatitis B virus (HBV) infection, hepatitis B surface antigen, (HbsAg) or anti-HBc, when appropriate.

(5) Providing hepatitis A vaccine to persons in appropriate risk groups (e.g., men having sex with men (MSM) and, illegal drug users).

(6) Providing secondary prevention services for anti-HCV positive and HBsAg-positive persons, including: (1) Counseling on how to prevent transmission to others, (2) identification of partners (sex and/or needle sharing) for counseling and referral services, if

appropriate, and (3) providing hepatitis B vaccination for at-risk (sex or needle sharing) partners and household contacts of HBsAg-positive persons.

(7) Providing, either directly or by referral, appropriate services to persons found to be HBsAg-positive or anti-HCV positive, including: (1) Alcohol and drug counseling, and (2) appropriate medical referral and assistance in accessing medical care for evaluation of chronic liver disease and possible treatment.

b. Provide staff training regarding viral hepatitis prevention and control related to implementing this program.

c. Develop and implement protocols, data collection and analytic systems to assess the feasibility, impact, and effectiveness of integrating viral hepatitis prevention services into existing programs for high-risk youth. Areas of analysis could include prevention of infections, completion of hepatitis B vaccine series, determining cost effectiveness of interventions, and defining the determinants of prevention services.

d. Conduct appropriate data analysis and interpretation.

e. Attend and participate in an annual meeting of project managers, to plan and present program activities and evaluate activities.

2. CDC Activities

a. Provide technical support for and training in the design, implementation, and evaluation of program activities, if requested. This includes training on participation in the Vaccine for Children (VFC) Program on how to acquire vaccine for eligible adolescents.

b. Assist in data management, analysis, presentation, and publication of project findings.

c. Assist in the development of a research protocol for Institutional Review Board (IRB) review by all cooperating institutions participating in the research project. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

E. Content

Letter of Intent (LOI)

An LOI is optional for this program. The narrative should be no more than five double spaced pages, printed on one side, with one inch margins, and unredacted font. Your letter of intent will be used to plan and execute the evaluation of applications, and should include the following information: (1) Name and address of institution, and (2) name, address, and telephone number of a contact person.

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 laying out your program plan. The narrative should be no more than 20 double spaced pages, printed on one side, with one inch margins, and unrounded fonts.

The narrative should consist of, at a minimum, a Plan, Objectives, Methods, and Evaluation. The Budget should contain a line item descriptive justification for personnel, travel, supplies, laboratory testing, and other services related to the project. Contracts should include the name of the person or firm to receive the contract, the method of selection, the period of performance, and a description of the contracted service requested, itemized budget with narrative justification and method of accountability. Funding levels for years two and three should be estimated. A one page executive summary and a complete index to the application and its appendices should be provided.

F. Submission and Deadline

Letter of Intent (LOI)

On or before June 1, 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 five copies of PHS-398 (OMB Number 0925-0001) (adhere to the instructions on the Errata Instruction Sheet for PHS 398). Forms are available in the application kit and at the following Internet address: www.cdc.gov/od/pgo/forminfo.htm

On or before July 1, 2002, submit the application to the Technical Information Management Section 2920 Brandywine Road, Suite 3000, Atlanta, Georgia 30341.

Deadline: Applications shall be considered as meeting the deadline if they are either:

1. Received on or before the deadline date.
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. Background and Need (10 total points)
 - a. The extent to which the applicant demonstrates a clear understanding of the subject area and of the purpose and objectives of this cooperative agreement. (5 points)
 - b. The extent to which the applicant demonstrates need based on disease burden of viral hepatitis (i.e., prevalence, incidence data) among adolescent high-risk populations, as well as prevalence of risk factors for viral hepatitis among populations accessible to the applicant programs and services. (5 points)

2. Capacity (40 total points)

The extent to which the applicant provides evidence of ability to provide all recommended and appropriate viral hepatitis prevention and control activities and services annually to 1000 to 3000 adolescents with identifiable risk factors for viral hepatitis. This should include:

- a. Description of adequate resources, including personnel and facilities (both technical and administrative), either direct or through collaboration, for conducting the project. (10 points)
- b. Description of population served by existing program(s) and access to additional populations with identifiable risk factors for viral hepatitis (heterosexuals at high risk, MSM, injection drug users (IDUs), sex partners of IDUs), that may accept viral hepatitis prevention and control activities and services provided through an integrated program. (10 points)
- c. The extent to which the applicant documents experience of proposed personnel, either direct or collaborating, in providing viral hepatitis prevention and control activities and services (e.g., training, testing, counseling, vaccination, clinical services). (10 points)
- d. Evidence of existing quality assurance mechanisms to insure appropriate counseling and other services as recommended for the proposed setting, as provided by published CDC guidelines in various settings (e.g. STD, HIV, Drug Treatment) and the extent the applicant demonstrates how the planned integration activities may improve existing prevention services. (10 points)

3. Objectives and Technical Approach (45 total points)

a. The extent to which the applicant describes objectives of the proposed project which are (1) consistent with the purpose and goals of this cooperative agreement program, (2) measurable and time-phased, and (3) consistent with published CDC guidelines on prevention and control of Hepatitis C (MMWR 1998;47[No. RR-19], Hepatitis B (MMWR 1991;40[No.RR-13] and Hepatitis A (MMWR 1999;48[No.RR-12]. (15 points)

b. The extent and quality of an operational plan proposed for implementing the program, including maximizing the use of existing resources and staff to integrate viral hepatitis prevention services, which clearly and appropriately addresses all "Recipient Activities" in the application. (10 points)

c. The extent to which the applicant clearly identifies specific assigned responsibilities of all key professional personnel. (5 points)

d. The extent to which the applicant prioritizes resources for evaluation and determination of effectiveness of integrating services through a detailed and adequate plan for evaluating progress toward achieving program process and outcome objectives. This should include methods and instruments for evaluating progress in planning, implementation, and effectiveness of interventions through measurement of outcomes related to viral hepatitis and to impact of integrating these services on other prevention services offered (e.g., HIV counseling and testing). (10 points)

e. The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed program. This includes: (1) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation. (2) The proposed justification when representation is limited or absent. (4) A statement as to whether the plans for recruitment and outreach for participants include the process of establishing partnerships with community or communities and recognition of mutual benefits. (5 points)

4. Measures of Effectiveness

The extent the applicant provide Measures of Effectiveness that will demonstrate the accomplishment of the purpose of the cooperative agreement. The measures must be objective/quantitative and must adequately

measure the intended outcome? (5 points)

5. Budget (Not Scored)

The budget will be reviewed to determine the extent to which it is reasonable, clearly justified, consistent with the intended use of funds, and allowable.

6. Human Subjects (Not Scored)

Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects?

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.
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 I of the announcement.

- AR-1 Human Subjects Requirements
- AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
- AR-3 Animal Subjects Requirements
- 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
- AR-15 Proof of Non-Profit Status
- AR-22 Research Integrity

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under Sections 301(a) and 317(k)(2) of the Public Health Service Act [42 U.S.C. Sections 241(a) and 247b(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."

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

Reneé Benyard, Grants Management Specialist, Acquisition and Assistance, Branch B, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146, Telephone number: (770)488-2722, Fax number: (770)488-2777, email address: bnb8@cdc.gov.

For program technical assistance, contact: Joanna Buffington, Program Management Official, Division of Viral Hepatitis, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mailstop G-37, Atlanta, GA 30333, Telephone number: (404)371-5460, Fax number: (404) 371-5488, e-mail address: jyb4@cdc.gov.

Dated: April 30, 2002.

Sandra R. Manning,

CGFM, Director, Procurement and Grants Office, Center for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N-0123]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food Canning Establishment Registration, Process Filing and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting and recordkeeping requirements for firms that process acidified foods and thermally processed

low-acid foods in hermetically sealed containers.

DATES: Submit written or electronic comments on the collection of information by July 5, 2002.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.