

and capacity to carry out the program objectives and specific project plan.

Budget (Reviewed But Not Scored)

The extent to which the budget and justification are consistent with program objectives and purpose.

Human Subjects (Reviewed But 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. Progress reports (annual);
2. Financial status report, not 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 Section J., "Where to Obtain Additional Information".

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-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
- AR-7 Executive Order 12372 Review
- AR-8 Public Health System Reporting Requirements
- 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 section 301(a) [42 U.S.C. 241(a)] of the Public Health Service Act, as amended. The Catalog of Federal Domestic Assistance number is 93.283.

J. Where To Obtain Additional Information

If you have questions after reviewing the contents of all the documents, business management assistance may be obtained from: Robert Hancock, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 00088, Centers for Disease Control and Prevention (CDC), Room 3000, 2920

Brandywine Road, Atlanta, GA 30341-4146, telephone (770) 488-2746, E-mail address: RNH2@cdc.gov.

This and other CDC announcements can be found on the CDC home page internet address: <http://www.cdc.gov>.

For program technical assistance, contact: Lynda Doll, Ph.D., Program Director, Prevention Research Centers Office, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Atlanta, GA 30341-3724, telephone 404-488-5395, E-mail address: LSD1@cdc.gov.

Dated: May 10, 2000.

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 00046]

Integration of Viral Hepatitis Prevention Services Into Existing Prevention Programs; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2000 funds for a cooperative agreement program for integration of viral hepatitis prevention services into existing prevention programs. CDC is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010", a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the focus areas of Immunization and Infectious Diseases. For the conference copy of "Healthy People 2010", visit the internet site <http://www.health.gov/healthypeople>.

The purpose of the program is to develop strategies and guidance for integrating recommended viral hepatitis prevention and control services for persons at high risk for infection into existing settings that provide public health services and to improve public health service delivery by integrating viral hepatitis with existing prevention services to reach persons at high risk for disease. This announcement is intended to support implementation and

evaluation of integrating currently recommended prevention activities for viral hepatitis (including hepatitis A and hepatitis B vaccination) into existing disease prevention programs, with the primary intent to improve delivery of established prevention services that may directly benefit clients served by these programs.

B. Eligible Applicants

Limited Competition

Because of the requirement that viral hepatitis services be integrated with existing state or local public health programs, assistance will be provided only to the health departments of States or their bona fide agents, including the District of Columbia and the cities of Philadelphia, New York City, San Francisco, Los Angeles, Houston, Chicago, and Baltimore, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, federally recognized Indian tribal governments, 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.

C. Availability of Funds

Approximately \$800,000 is available in FY 2000 to fund approximately four awards. It is expected that the average award will be \$200,000, ranging from \$150,000 to \$400,000. It is expected that the awards will begin on or about September 30, 2000, and will be made for a 12-month budget period within a project period of up to three 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 programs that deliver or provide oversight for public health services to populations in which a high proportion (1000 to 3000 individuals with identifiable risk factors for viral hepatitis are likely to be infected with hepatitis C virus (HCV).

Such programs include STD Clinics, HIV/AIDS counseling/testing sites, correctional settings and providers of services to injection drug users. Also to ensure geographic diversity, additional consideration will be given to the location of the program based on the region of the U.S. (Northeast, southeast, northwest, southwest, north central, and south central states). Finally, to ensure

racial and ethnic diversity of the program populations served, consideration will be given to gender and ethnicity of the populations served.

D. Program Requirements

In conducting activities to achieve the purposes 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 the particular setting(s) proposed. Viral hepatitis prevention services may include, but are not limited to:

- (1) Assessing risk histories for viral hepatitis among clients;
- (2) Providing client-centered prevention counseling to patients with risks for infection;
- (3) Providing testing to appropriate risk groups for HCV infection (anti-HCV) and chronic hepatitis B virus (HBV) infection (hepatitis B surface antigen (HBsAg), when appropriate);
- (4) Providing hepatitis B vaccine to persons in appropriate risk groups (*e.g.*, >1 sex partner in prior 6 months, history of other sexually transmitted diseases (STDs), men who have sex with men (MSM), incarcerated persons, injecting drug users);

(5) Providing hepatitis A vaccine to persons in appropriate risk groups (*e.g.*, MSM, illegal drug users);

(6) Providing primary prevention services for anti-HCV positive and HBsAg-positive persons, including: (a) Counseling on how to prevent transmission to others, (b) Identification of partners (sex and/or needle-sharing) for counseling and referral services, if appropriate, and (c) Providing hepatitis B vaccination for at-risk (sex or needle-sharing) partners and household contacts of HBsAg-positive persons; and

(7) Providing, either directly or by referral, appropriate services to persons found to be HBsAg-positive or anti-HCV positive, including:

(a) Alcohol and drug counseling, and (b) 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 a monitoring and evaluation system to assess the feasibility, impact, and effectiveness of integrating viral

hepatitis prevention services into existing prevention programs, including measurement of the cost of services and the impact of integration on existing disease 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.

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. Application Content

Letter of Intent (LOI)

In order to assist CDC in planning and executing the evaluation of applications submitted under this announcement, all parties intending to submit an application are requested to inform CDC of their intention to do so at least thirty (30) days prior to the application due date. Notification should include: (1) Name and address of institution, and (2) name, address, and telephone number of contact person. Notification should be provided by facsimile, postal mail, or E-mail, to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement".

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 (excluding appendices), printed on one side, with one inch margins, unrounded (12-point) font, unbound, and unstapled. A complete index to the application and its appendices should be provided, and a one-page executive summary included.

F. Submission and Deadline

Letter of Intent (LOI)

One original and two copies of the Letter of Intent (LOI) must be submitted on or before June 15, 2000. Submit the letter of intent to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

Application

Applications should include an original and two copies of PHS 5161-1 (OMB Number 0937-0189). Forms are in the application kit. Submit the application to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement on or before July 14, 2000.

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

(a) Received on or before the deadline date; or

(b) Sent on or before the deadline date and received prior to submission to the review panel. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

Late Applications: Applications which do not meet the criteria in (a) or (b) above are considered late applications, will not be considered, and will be returned to the applicant.

G. Evaluation Criteria

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

1. Background and Need (10 Points)

a. 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. Extent to which the applicant demonstrates need based on disease burden of viral hepatitis (*i.e.*, prevalence, incidence data) among 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 Points)

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 individuals 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 (MSM, injection drug users (IDUs), sex partners of IDUs, heterosexuals at high risk) that may accept viral hepatitis prevention and control activities and services provided through an integrated program (10 points);
- c. Extent to which 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 (50 Points)

- a. 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. Extent and quality of 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. (15 points)
- c. Extent to which the applicant clearly identifies specific assigned responsibilities of all key professional personnel. (5 points)
- d. 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; (3) A statement as to whether the plans for recruitment and outreach for participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits. (5 points)

4. 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.

- a. Submit line-item descriptive justification for personnel, travel, supplies, laboratory testing, and other services related to the project;
- b. For contracts, 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.

c. Funding levels for years two and three should be estimated.

5. 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. Progress reports (semiannual);
2. Financial status report, no more than 90 days after the end of the budget period; and
3. Final financial status and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

For descriptions of the following Other Requirements, see Attachment I in the application kit.

- AR-1—Human Subjects Requirements
- AR-2—Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
- AR-7—Executive Order 12372 Review
- AR-9—Paperwork Reduction Act Requirements
- AR-10—Smoke-Free Workplace Requirements
- AR-11—Healthy People 2010
- AR-12—Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301(a), and 317(k)(1) and 317(k)(2) of the Public Health Service Act, [42 U.S.C. sections 241(a), and 247b(k)(1) and 247(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".

To obtain additional information, contact: Gladys Gissentanna, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Room 3000, 2920 Brandywine Road, Atlanta, GA 30341-4146, Telephone number (770) 488-2753, Facsimile number (770) 488-2777, E-mail address gcg4@cdc.gov.

For program technical assistance, contact: Dr. Joanna Buffington, Centers for Disease Control and Prevention, National Center for Infectious Diseases, Division of Rickettsial Diseases, Hepatitis Branch, 1600 Clifton Road, NE, M/S G-37, Atlanta, GA 30333, Telephone: (404) 371-5460, E-mail address: eem1@cdc.gov.

Dated: May 10, 2000.

John L. Williams,

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

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