DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 03117]

Initiative To Integrate Clinical Laboratories in Public Health Laboratory Testing; Notice of Availability of Funds

Application Deadline: August 8, 2003.

A. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 317(k)(2) of the Public Health Service Act, 42 U.S.C. 247b(k)(2), as amended. The Catalog of Federal Domestic Assistance number is 93.283.

B. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2003 funds for a cooperative agreement program regarding an Initiative to Integrate Clinical Laboratories in Public Health Testing. This program addresses the ''Healthy People 2010'' focus areas of Access to Quality Health Services, and Public Health Infrastructure.

The purpose of the program is to demonstrate the potential ways in which clinical laboratories may be better prepared to conduct public health related testing and participate in the public health system. Activities must revolve around national priorities for public health testing, such as those related to antimicrobial susceptibility, hepatitis C virus, HIV/AIDS, rapid HIV testing, foodborne diseases, sexually transmitted diseases, West Nile Virus, and other diseases of public health significance. Specifically, activities should center on investigating shortcomings in the delivery of medical and public health laboratory services, creating and demonstrating new approaches to create and implement voluntary laboratory practice standards, assessing the factors that impact why voluntary standards are or are not followed by clinical laboratories, training clinical laboratorians to better understand and adhere to voluntary national guidelines for testing and, as applicable, reporting results to public health authorities in the areas listed above. To the extent possible, the investigator(s) should demonstrate the possibilities for conducting some of the above activities in regional (inter-state) settings, and possibly in collaboration with Indian Health Service (IHS) clinical laboratories.

Measurable outcomes of the program will be in alignment with one or more of the following performance goals for the Public Health Practice Program Office: Increase the number of frontline public health workers at the state, tribal and local level that are competent to respond to bioterrorism, other infectious disease outbreaks, and other public health threats and emergencies, and prepare frontline state and local health departments and laboratories to respond to current and emerging public health threats.

C. Eligible Applicants

Applications may be submitted by:

- Public nonprofit organizations
- Private nonprofit organizations
- Universities
- Research institutions
- Faith-based organizations
- State, tribal, and local governments

or their bona fide agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau)

Consideration will be given to those entities that are expected to have sufficient resources in terms of expertise in public health laboratory testing and medical microbiology to investigate and determine the influence on the delivery of public health laboratory testing. Important resources include standing advisory organizations composed of public health and private laboratorians, access to local and national subject matter experts, and demonstrated credibility in building laboratory partnerships.

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. Funding

Availability of Funds: Approximately $200,000 is available in FY 2003 to fund approximately one award. It is expected that the average award will be $200,000, ranging from $180,000 to $220,000. It is expected that the award will begin on or about September 15, 2003 and will be made for a 12-month budget period within a project period of up to three budget 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.

Recipient Financial Participation: Matching funds are not required for this program.

Funding Preferences: Funding preferences will be given to those entities that have demonstrated significant expertise in microbiology and public health testing and that have available resources that can be leveraged. Important resources include standing advisory organizations composed of public health and private laboratorians, access to local and national subject matter experts, and demonstrated credibility in building laboratory partnerships.

E. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities listed in 1. Recipient Activities, and 2. Optional Recipient Activities, and CDC will be responsible for the activities listed in 3. CDC Activities.

1. Required Recipient Activities:

(a) Collaborate with CDC, including subject matter experts, to determine specific programs (STDs, antimicrobial susceptibility testing, etc.) that could be selected as the best models for demonstrating the local and regional benefits of improved integration of clinical laboratories into the delivery of testing that has public health implications.

(b) Identify training needs and work with laboratory training experts, including the American Society for Clinical Pathology (ASCP) and the National Laboratory Training Network (NLTN), and conduct training to improve laboratory practices in areas of national priority, as mentioned in the purpose section of this announcement. To the extent possible, all training should be evaluated for its impact on knowledge and practices.

2. Optional Recipient Activities:

(a) Select ways to link clinical laboratories into the public health system using communication and promotion, which may include newsletters, e-mails, websites, teleconferences, site visits, *etc.*

(b) Determine factors that affect adherence to voluntary guidelines, such as the National Committee for Clinical Laboratory Standards (NCCLS) guidelines for antimicrobial susceptibility testing, or CDC Morbidity and Mortality Weekly Reports (MMWR) Recommendations and Reports, or locally derived laboratory practice standards.

(c) Work with local and national stakeholders to identify the need for

additional laboratory practice guidelines and then, through a consensus process, draft and implement needed guidelines.

(d) Determine the factors that influence the delivery of medical and public health laboratory testing services. This may involve providers (laboratorians) and/or users (physicians and medical staff) of these testing services.

3. CDC Activities:

(a) Provide assistance as requested, especially subject matter expertise on specific public health programs that depend upon laboratory testing.

(b) Provide, if requested, access to and technical support for the National Laboratory Database, a searchable index of clinical and public health laboratories, which provides testing capabilities and contact information.

(c) If requested, assist with survey design, validation and statistical analysis.

(d) Provide graphic art support, as requested.

(e) Make available consultation on performance of outcomes assessments, including training and any other systematic interventions.

(f) Collaborate to leverage findings through partnerships with the NLTN, Association of Public Health Laboratories, the ASCP, and others.

(g) Assist, if requested, in the development of a study protocol for review by all cooperating partnership institutions participating in the project.

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 your program plan. The narrative should be no more than 50 pages, double-spaced, printed on one side, with one inch margins, and unreduced 12-point font.

The narrative should consist of Background (including relevant activities by the recipient), Plan, Objectives, Methods, Evaluation and Budget.

The plan should address activities to be conducted over the entire three year project period. The plan for year one should be detailed, while the plan can be brief for years two through three.

G. Submission and Deadline

Application Forms: Submit the signed original and two copies of PHS 5161–1 (OMB Number 0920–0428). Forms are available at the following Internet address: *http://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 (PGO–TIM) at: 770–488–2700. Application forms can be mailed to you.

Submission Date, Time, and Address: The application must be received by 4 p.m. Eastern Time, August 8, 2003. Submit the application to: Technical Information Management—PA#03117, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341–4146.

Applications may not be submitted electronically.

A postcard will be mailed by PGO-TIM, notifying you that CDC has received your application.

Deadline: Applications shall be considered as meeting the deadline if they are received before 4 p.m. Eastern Time on the deadline date. Any applicant who sends their application 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. Any application that does not meet the above criteria will not be eligible for competition, and will be discarded. The applicant 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 the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goals stated in the purpose section of this announcement. Measures must be objective and quantitative and must measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

An independent review group appointed by CDC will evaluate each application against the following criteria:

1. Methods (30 points): The extent to which the applicant's proposal demonstrates the necessary approaches to be used in accomplishing the activities.

2. Objectives (20 points):

a. The applicant's proposal should describe program objectives that fit the activities in the application, including specific outcomes.

b. The extent to which the applicant describes objectives that are specific, measurable, and feasible, including a reasonable schedule for implementation.

3. Plan (20 points):

a. The extent to which the proposed plan demonstrates the applicant's understanding of the issues.

b. The extent to which the applicant describes a proposed plan for collaboration with CDC to accomplish the proposed activities.

c. The extent to which the proposed activities are capable of achieving the intent of this program announcement.

d. The plan should address activities to be conducted over the entire three-year project period.

5. Evaluation (20 points): The quality of the applicant's plan for evaluating the proposed program activities.

6. Background (10 points):

a. The applicant's proposal should demonstrate an understanding of the need to better integrate activities between public health laboratories and private, clinical laboratories.

b. The importance of the chosen public health problem(s) should be clearly elaborated and the relevance to CDC goals should be clarified.

7. Budget (reviewed, but not scored): The extent to which the budget is appropriate, reasonable, justified, and consistent in relation to the activities proposed.

8. Performance Goals (reviewed but not scored): The extent to which the application the performance goals listed in the purpose section of this announcement.

9. Does the application adequately address the requirements of Title 45 CFR part 46 for the protection of human subjects? Not scored; however, an application can be disapproved if the research risks are sufficiently serious and protection against risks is so inadequate as to make the entire application unacceptable.

I. Other Requirements

Technical Reporting Requirements: Provide CDC with original plus two copies of:

1. Interim progress report, no less than 90 days before the end of the budget period. The progress report will

serve as your non-competing continuation application, and must contain the following elements:

a. Current Budget Period Activities Objectives.

b. Current Budget Period Financial Progress.

c. New Budget Period Program Proposed Activity Objectives.

d. Detailed Line-Item Budget and Justification.

e. Additional Requested Information.

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.

Additional Requirements: The following additional requirements are applicable to this program. For a complete description of each, see Attachment I of the program announcement, as posted on the CDC web site.

AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2010
AR–12 Lobbying Restrictions
AR–15 Proof of Non-Profit Status

Executive Order 12372 does not apply to this program.

J. Where To Obtain Additional Information

This and other CDC announcements, the necessary applications, and associated forms can be found on the CDC web site, Internet address: *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 Road, Atlanta, GA 30341–4146, Telephone: 770–488–2700.

For business management and budget assistance, contact: Deborah Workman, Contract Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: (770) 488–2085, E-mail address: *atl7@cdc.gov.*

For program technical assistance, contact: J. Rex Astles, Ph.D., Office of Laboratory Systems Development, Division of Laboratory Systems (Mail Stop G–25), CDC Public Health Practice Program Office, 4770 Buford Hwy., NE., Atlanta, GA 30341–3717, Telephone: (770) 488–8052, E-mail address: *jastles@cdc.gov.*

Dated: July 1, 2003.

Edward Schultz,

Acting 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 04009]

Viral Hepatitis Integration and Intervention Projects; Notice of Availability of Funds

Application Deadline: October 7, 2003.

A. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 301(a) and 317(k)(1) and 317(k)(2) of the Public Health Service Act, (42 U.S.C. 241(k) and 247b(k)(1) and 247(k)(2)), as amended. The Catalog of Federal Domestic Assistance number is 93.283.

B. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2004 funds for a cooperative agreement program for Viral Hepatitis Integration and Intervention Projects. This program addresses the ''Healthy People 2010'' focus area of Immunization and Infectious Diseases.

The purpose of this program is to (1) improve the delivery of existing viral hepatitis prevention services in programs known to serve adults and adolescents at high risk for infection (*e.g.* Sexually Transmitted Disease (STD) clinics, Human Immunodeficiency Virus (HIV) counseling and testing sites, health care programs serving correctional facilities, primary health care settings, substance abuse prevention or treatment centers); (2) evaluate the effectiveness of different strategies to deliver recommended hepatitis preventive services (*e.g.* vaccination, testing and counseling, receipt of test results, and medical and other appropriate services for infected persons); (3) evaluate the impact of integration of viral hepatitis prevention services on existing prevention services (*e.g.*, STD or HIV counseling and testing); (4) to conduct research to identify, develop and evaluate specific programmatic interventions and approaches to achieve successful integration of recommended preventive services and increase levels of coverage for these services; and (5) to produce materials that convey to other public health programs the lessons learned with respect to integration of viral hepatitis prevention activities into existing public health and clinical care programs.

Recommendations for prevention and control of hepatitis A virus (HAV), hepatitis B virus (HBV), and hepatitis C virus (HCV) among adults and adolescents at high risk of infection have been published by CDC (references 1–6, Appendix II, as posted with this announcement on the CDC web site). The primary goals of these recommendations are to decrease the incidence of acute viral hepatitis infections and to decrease the risk of complications from chronic infection with HBV or HCV among populations known to be at high risk for infection. Despite effective vaccines to prevent both HAV and HBV infections, and known behavioral changes necessary to prevent infection with HCV and the serious consequences of chronic HBV or HCV infection, new infections and adverse outcomes of chronic infection continue to occur among high risk adults and adolescents.

Measurable outcomes of the program will be in alignment with one or more of the following performance goals for the National Center for Infectious Diseases (NCID): Protect Americans from Infectious Diseases; National Immunization Program (NIP): Reduce the number of indigenous cases of vaccine preventable diseases; and National Center for HIV, STD, and Tuberculosis (TB) Prevention (NCHSTP):

Increase the proportion of HIV-infected people who are linked to appropriate prevention, care, and treatment services and strengthen the capacity nationwide to monitor the epidemic, develop and implement effective HIV prevention interventions and evaluate prevention programs.

C. Eligible Applicants

Assistance will be provided only to the health departments of States or their bona fide agents and territories, 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 and political subdivisions of states (in consultation with States).