

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-1 Human Subjects Requirements.
- AR-4 HIV/AIDS Confidentiality Provisions.
- AR-12 Lobbying Restrictions.
- AR-14 Accounting System Requirements.

Executive Order 12372 does not apply to this program.

#### **J. Where To Obtain Additional Information**

This and other CDC announcements 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: Diane Flournoy, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Atlanta, GA 30341-4146, Telephone: (770) 488-2072, E-mail: [dmf6@cdc.gov](mailto:dmf6@cdc.gov).

For program technical assistance, contact: David B. Nelson, Chief of Party, Global AIDS Program, Zambia, American Embassy, Corner of Independence and United Nations Avenues, Lusaka, Zambia, Telephone:

+260-1-250955, E-mail: [nelsond@zamcdc.org.zm](mailto:nelsond@zamcdc.org.zm).

Dated: July 1, 2003.

**Sandra R. Manning,**

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

[FR Doc. 03-17170 Filed 7-7-03; 8:45 am]

**BILLING CODE 4163-18-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Disease Control and Prevention**

**[Program Announcement 03044]**

#### **Enhancement of an Integrated HIV Program for Voluntary Counseling and Testing, Clinical and Home-Based Care in Malawi; Notice of Availability of Funds**

*Application Deadline:* August 7, 2003.

##### **A. Authority and Catalog of Federal Domestic Assistance Number**

This program is authorized under section 307 of the Public Health Service Act, (42 U.S.C. 242l), as amended. The Catalog of Federal Domestic Assistance number is 93.941.

##### **B. Purpose**

The Centers for Disease Control and Prevention (CDC) announce the availability of fiscal year (FY) 2003 funds for a cooperative agreement program for the enhancement of an integrated HIV voluntary counseling and testing (VCT), clinical and home-based care program in Malawi.

The purpose of this program is to provide assistance to a Malawi-based public or private non-profit organization in the provision of an integrated HIV program that includes VCT, clinical care, and home-based care in the country of Malawi. This program will also assist in the development of plans and strategies for replicating a successful service model to extend these service capabilities to other private and public sector sites and providers.

The HIV epidemic in Malawi has matured to the point that both illness and mortality are at very high levels. Malawi has recently succeeded in garnering initial approval for a large Global Fund award to address the HIV epidemic. Three critical elements included in the Global Fund award are: (1) VCT; (2) clinical care and treatment for HIV and opportunistic infections; and (3) home-based care for HIV-infected individuals. Thoughtful, integrated, and innovative programs to address this triad of services are urgently needed to effectively address

implementation of Global Fund activities. Extension of successful integrated programs through training and replication of successful models is a critical step in increasing availability and accessibility to these HIV services for those in need.

Measurable outcomes of the program will be in alignment with one or more of the following performance goals for the National Center for HIV, STD and TB Prevention: Working with other countries, USAID, international, and U.S. Government agencies, reduce the number of new HIV infections among 15 to 24 year olds in sub-Saharan Africa from an estimated two million by 2005.

##### **C. Eligible Applicants**

Applications may be submitted by public and private non-profit organizations and by governments and their agencies with a current capacity for providing three integrated services: (1) VCT; (2) ambulatory facility-based HIV clinical care and anti-retroviral (ARV) treatment; and (3) home-based care in the country of Malawi. Organizations based outside Malawi, including organizations whose headquarters are based outside Malawi, are not eligible to apply.

##### **D. Funding**

###### *Availability of Funds*

Approximately \$175,000 is available in FY 2003 to fund one award. 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 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**

Funds may be utilized only for activities associated with HIV/AIDS. CDC funds may be used for direct costs such as salaries; necessary travel; operating costs, including supplies, fuel, utilities, etc.; and staff training costs, including registration fees and purchase and rental of training related equipment.

##### **Antiretroviral Drugs**

The purchase of antiretroviral drugs, reagents, and laboratory equipment for antiretroviral treatment projects requires pre-approval from the Global AIDS Program headquarters.

##### **Needle Exchange**

No funds appropriated under this Act shall be used to carry out any program of distributing sterile needles or

syringes for the hypodermic use of any illegal drug.

Funds may be spent for reasonable program purposes, including personnel, travel, supplies, and services. Equipment may be purchased if deemed necessary to accomplish program objectives, however, prior approval by CDC officials must be requested in writing.

All requests for funds contained in the budget shall be stated in U.S. dollars. Once an award is made, CDC will not compensate foreign grantees for currency exchange fluctuations through the issuance of supplemental awards.

The costs that are generally allowable in grants to domestic organizations are allowable to foreign institutions and international organizations, with the following exception: With the exception of the American University, Beirut, and the World Health Organization, Indirect Costs will not be paid (either directly or through sub-award) to organizations located outside the territorial limits of the United States or to international organizations regardless of their location.

The applicant may contract with other organizations under this program; however the applicant must perform a substantial portion of the activities (including program management and operations, and delivery of prevention services for which funds are required).

You must obtain an annual audit of these CDC funds (program-specific audit) by a U.S.-based audit firm with international branches and current licensure/authority in-country, and in accordance with International Accounting Standards or equivalent standard(s) approved in writing by CDC.

A fiscal Recipient Capability Assessment may be required, prior to or post award, in order to review the applicant's business management and fiscal capabilities regarding the handling of U.S. Federal funds.

#### *Recipient Financial Participation*

Matching funds are not required for this program.

#### *Funding Preferences*

Preference will be given to applicants who can demonstrate, (1) the capacity to work with in-patient facilities within an established patient referral relationship, and (2) a well-organized program for training its own staff, with a capability of extending this training to other sites by assisting and mentoring these sites to develop and extend the integrated services model.

### **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 CDC will be responsible for the activities listed in 2. CDC Activities.

#### 1. Recipient Activities

a. In collaboration with CDC, the applicant will develop plans for strengthening existing institutional capacity to enable the expansion of the organization's services, and the provision of technical assistance including training to extend services nationwide through replication of a successful model.

b. The applicant will provide necessary staff and training time for replicating the integrated HIV services model and extending it to additional sites.

c. In collaboration with CDC, develop and conduct training programs for staff and other health care providers for extending the integrated HIV testing and care model to other sites and providers.

d. Develop and implement a computerized client record system with the goal of maximizing compatibility with established client record systems in collaborating facilities, and improve coordination of patient care.

e. Provide safe water system education and support and cotrimoxazole prophylaxis to HIV-positive clients in clinical and home-based care settings, as indicated, to reduce the occurrence of opportunistic infections.

f. In collaboration with CDC, the applicant will hire or assign information management staff with the necessary technical skills and experience to implement and manage the computerization of client record data.

#### 2. CDC Activities

a. Collaborate with the grantee on designing and implementing the activities listed above, including, but not limited to the provision of technical assistance to develop program activities, laboratory services, data management and analysis, quality assurance, presentation of program results and findings, and management and tracking of finances. CDC will accomplish these activities using its own Malawi-based technical staff or by bringing in consultants from CDC or other organizations to accomplish the technical assistance activities.

b. Assist in training and capacity building to ensure successful implementation of program and activities. CDC will assist the recipient

in enhancing its laboratory services and in conducting quality assurance of its HIV testing according to national standards being set by the Malawi National Public Health Reference Laboratory.

c. CDC will assist the recipient organization in conducting assessments of the quality of the services provided and maintaining high quality services in VCT, clinical care, and home-based care. These might include laboratory, monitoring and evaluation, counseling, and site management issues including the maintenance of client confidentiality.

d. Assist the recipient in developing and implementing improved computerized client record data collection and improved data management systems. CDC/GAP/Malawi's information technology specialist and epidemiologist will assist in identifying an appropriate staff member for the organization and in providing technical assistance to computerize and manage clinical and VCT data collected by the organization. CDC will assist the organization in using the data to inform program improvements.

e. Assist the successful recipient in hiring a data management staff person to work with CDC in developing and implementing the system and to manage it long-term.

### **E. 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 40 pages, double-spaced, printed on one side, with one-inch margins, and unreduced 12-point font.

The narrative should consist of, at a minimum, a Plan, Objectives, Methods, Evaluation and Budget. The project plan should include activities to be conducted throughout the three-year project period.

### **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 7, 2003. Submit the application to: Technical Information Management-PA 03044, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341-4146.

Applications may not be submitted electronically.

#### *CDC Acknowledgement of Application Receipt*

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**

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. Ability to Carry Out the Project (40 points). The extent to which the

applicant understands and describes activities which are realistic, achievable, time-framed and appropriate to effectively plan, coordinate, and complete these activities. Applicant must show how and at what intervals the effectiveness and productivity of this program activity will be monitored and evaluated. Applicant should include a description of applicant organizational structure and use it to explain how the work will be carried out.

2. Technical and Programmatic Approach (20 points). The extent to which the applicant's proposal demonstrates understanding of the technical and organizational aspects of conducting all included HIV testing and care activities and computerization of client record data.

3. Personnel (20 points). The adequacy of personnel, including training, availability, and experience, in order to carry out the technical and organizational aspects of all proposed activities.

4. Administrative and Accounting Management Plan (20 points). (a) The adequacy of the plans to account for, prepare reports, monitor, and audit expenditures under this agreement; (b) The extent to which the application demonstrates ability to administer and manage the budget; (c) The extent to which the budget is itemized and well justified; (d) Demonstration of plans to engage an outside accounting firm to design and manage the financial system to meet CDC and the recipient's accounting requirements.

5. Budget (Not rated, but evaluated). The extent to which the budget is detailed, clear, justified, provides direct support, and is consistent with the proposed program activities.

6. Protection of Human Subjects (Not rated, but evaluated). 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-4 HIV/AIDS Confidentiality Provisions.

AR-6 Patient Care.

AR-8 Public Health System Reporting Requirements.

AR-9 Paperwork Reduction Act Requirements.

AR-12 Lobbying Restrictions.

AR-14 Accounting System Requirements.

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: Cynthia Montgomery, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Atlanta, GA 30341-4146, Telephone: 770-488-2757

For program technical assistance, contact: Margaret Davis, MD, MPH, Kang'ombe Building 8 West, Lilongwe, Malawi, Telephone Number: 265-1-775-188, Fax Number: 265-1-775-848, E-mail address: [DavisM@malcdc.co.mw](mailto:DavisM@malcdc.co.mw). Mailing Address: c/o U.S. Embassy, PO Box 30016, Lilongwe 3, Malawi.

Dated: July 1, 2003.

**Edward Schultz,**

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

[FR Doc. 03-17173 Filed 7-7-03; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[Program Announcement 03112]

#### Enhancement of Antenatal Care Services and Blood Safety for Preventing Transmission of HIV, Syphilis, and Malaria in the Republic of Tanzania; Notice of Intent To Fund Single Eligibility Award

##### A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the intent to fund fiscal year (FY) 2003 funds for a cooperative agreement program in the Republic of Tanzania for (1) the enhancement of antenatal care (ANC) services with emphasis on prevention of mother to child transmission (PMTCT) of HIV; and (2) the enhancement of blood safety with emphasis on preventing transmission of HIV, syphilis, and malaria. The Catalog of Federal Domestic Assistance number for this program is 93.941.

##### B. Eligible Applicants

Assistance will be provided only to the Department of Diagnostic Services (DDS) of the Ministry of Health (MOH) in Tanzania. No other applications are solicited.

The DDS is currently the only appropriate and qualified organization to conduct a specific set of activities supportive of the CDC Global AIDS Program's (GAP) goals for enhancing ANC services and blood safety in Tanzania for the following reasons:

1. The DDS is uniquely positioned, in terms of legal authority, ability, and credibility among Tanzanian citizens, to coordinate the implementation of national initiatives for PMTCT and blood safety.
2. The DDS has developed national PMTCT and blood safety guidelines, and strategic plans for enhancing PMTCT services and blood safety in Tanzania, which allows the DDS to immediately become engaged in the activities listed in this announcement.
3. The purpose of the announcement is to build upon the existing framework of health policy and programming that the MOH itself has initiated.
4. The MOH in Tanzania has been mandated by the Tanzanian constitution to coordinate and implement activities

necessary for the control of epidemics, including HIV/AIDS and STDs.

##### C. Funding

Approximately \$1,000,000 is available in FY 2003 to fund this award; \$500,000 for enhancing ANC services, and \$500,000 for blood safety. It is expected that the award will begin on or about September 1, 2003, and will be made for a 12-month budget period within a project period of up to five years. Approximately \$1,000,000 will be available for years two through five of the project. Funding estimates may change.

##### D. Where To Obtain Additional Information

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

For program technical assistance, contact: Eddas M. Bennett, Deputy Director, CDC Tanzania AIDS Program, National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention (CDC), 686 Old Bagamoyo Road, Dar es Salaam, Tanzania, Telephone: 255 222 667 8001 x4819, e-mail: [ebennett@tanccdc.co.tz](mailto:ebennett@tanccdc.co.tz).

Dated: June 1, 2003.

**Sandra Manning,**

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

[FR Doc. 03-17174 Filed 7-7-03; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Collection of Specimen Panels for Validation for Incidence Assays, Contract Solicitation Number 2003-N-00872

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting:

*Name:* Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Collection of Specimen Panels for Validation for Incidence Assays, Contract Solicitation Number 2003-N-00872.

*Times and Dates:* 7 p.m.-8 p.m., July 24, 2003 (Open); 8 a.m.-8:30 a.m., July 25, 2003 (Open); 8:30 a.m.-5 p.m., July 25, 2003 (Closed).

*Place:* The Westin Atlanta North at Perimeter Center, 7 Concourse Parkway, Atlanta, GA 30328, Telephone 770.395.3900.

*Status:* Portions of the meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

*Matters To Be Discussed:* The meeting will include the review, discussion, and evaluation of applications received in response to Contract Solicitation Number 2003-N-00872.

*For Further Information Contact:* Esther Sumartojo, Ph.D., Deputy Associate Director for Science, National Center for HIV, STD, and TB Prevention, CDC, 1600 Clifton Road, NE., MS-E07, Atlanta, GA 30333, Telephone 404.639.8006.

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 CDC and the Agency for Toxic Substances and Disease Registry.

Dated: June 27, 2003.

**Alvin Hall,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 03-17172 Filed 7-7-03; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 03N-0191]

#### Agency Emergency Processing Under OMB Review; Submission of Validation Data for Reprocessed Single-Use Devices

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information will be used by FDA to determine whether reprocessed single-use devices (SUDs) are substantially equivalent to legally marketed predicate devices. FDA is requesting this emergency processing under the PRA to implement the statutory provision under section 302 of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA).

**DATES:** Submit comments on the collection of information by August 7,