

conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at [www.ffiec.gov/nic/](http://www.ffiec.gov/nic/).

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than August 20, 2001.

**A. Federal Reserve Bank of Kansas City** (Susan Zubradt, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198-0001:

1. *First Western Bank Shares, Inc.*, Huron, South Dakota; to become a bank holding company by acquiring 100 percent of the voting shares of Marquette Bank Nebraska, N.A., O'Neill, Nebraska.

Board of Governors of the Federal Reserve System, July 20, 2001.

**Robert deV. Frierson,**

*Associate Secretary of the Board.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[Program Announcement 01150]

#### Expansion of Activities Supporting Coordination and Networking Among and Information Sharing and Networking Between Non-Governmental AIDS Service Organizations in the Republic of Zimbabwe; Notice of Availability of Funds

##### A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2001 funds for a cooperative agreement to improve and expand coordination, networking, and information sharing activities between and among non-governmental AIDS service organizations (ASOs) in Zimbabwe.

The U.S. Government seeks to reduce the impact of HIV/AIDS and related conditions in specific countries within sub-Saharan Africa, Asia, and the Americas through a recently funded Global AIDS Initiative. Through this program, CDC has initiated its Global AIDS Program (GAP) to strengthen capacity and expand activities in the areas of (1) HIV primary prevention; (2) HIV care, support, and treatment; and (3) capacity and infrastructure development, especially for

surveillance. Targeted countries represent those with the most severe epidemics and the highest number of new infections. They also represent countries where the potential for impact is greatest and where U.S. Government agencies are already active. Zimbabwe is one of these targeted countries.

To carry out its activities in these countries, CDC is working in a collaborative manner with other U.S. Government agencies (e.g., USAID), national governments and other partners to develop programs of assistance to address the HIV/AIDS epidemic. CDC's program of technical assistance to Zimbabwe focuses on several areas including strengthening surveillance and laboratory measures, scaling up promising prevention and care strategies, supporting behavior change communication projects, promoting communication and technology transfer, and other capacity building efforts.

Zimbabwe is experiencing one of the world's most severe AIDS crises that looms as a disaster of unprecedented proportions. Zimbabwe has one of the world's highest HIV prevalence rates among adults, and the proportion of children orphaned by AIDS is expected to reach 35 percent by 2010.

Zimbabwe has taken many positive steps to address the AIDS epidemic. It was one of the first governments in the world to negotiate a large World Bank loan for AIDS prevention in 1992.

The national response has generated many examples of creative programming and successful grassroots initiatives in the face of staggering adversity. In December 1999, the Government of Zimbabwe (GOZ) declared AIDS a national disaster, created a new ministerial-level, multi-sectoral National AIDS Council (NAC), announced a new National AIDS Policy and instituted an "AIDS levy" payroll tax to underwrite improved national AIDS prevention and care services.

However, despite these and others interventions, the prevalence of HIV infection appears to have increased substantially in Zimbabwe from 1997 to 2000, and the epidemic cannot yet be characterized as having stabilized.

High prevalence rates among women 15-19 yrs of age suggests that recent infections continue to be high, including among youth. In addition, Zimbabwe is facing economic and political crises which compete for attention with and directly impact current responses to the AIDS epidemic.

The response to HIV/AIDS in Zimbabwe needs to be significantly strengthened in several areas. The Government of Zimbabwe, in its effort to lead the public sector response, needs

to strengthen three public health activities and programs in areas such as surveillance, laboratory systems and services and access to voluntary counseling and testing (VCT). The response on the part of civil society can be characterized as aggressive but poorly coordinated. Activities of Zimbabwean non-governmental AIDS service organizations (ASOs) span the spectrum from care, prevention, training, education and advocacy. Literally hundreds of organizations have programs of work at village, district, regional and national levels. However, to date there has been little coordination of effort among these organizations, few efforts to evaluate coverage or reduced duplication of services, inadequate efforts to evaluate and help address resource mobilization requirements and relatively little done to address information exchange/communication needs. Improvements in these facets of the response to HIV/AIDS on the part of civil society are major unmet needs in Zimbabwe.

The purpose of this cooperative agreement is therefore to improve and expand coordination, networking, and information sharing activities between and among non-governmental ASOs in Zimbabwe.

These collaborative activities could profoundly impact the scope, coordination and intensity of the implementation the National AIDS Policy, which calls for multi-sectoral action on many fronts. Cooperative efforts could lead to significant improvements in coordination of HIV/AIDS prevention and care activities in all provinces, increased capacity building of ASOs, resource mobilization activities targeting HIV/AIDS ASOs across Zimbabwe and strengthened ties between organizations within civil society and government HIV/AIDS and related programs.

##### B. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations, non-governmental organizations with two years experience in HIV/AIDS, including facilitating information exchange and coordinating service activities between and among other non-governmental ASOs and relevant government agencies or other partner organizations in the majority of provinces of Zimbabwe.

##### C. Availability of Funds

Approximately \$300,000 is available in FY 2001 to fund this agreement. It is expected that the awards will begin on or about September 30, 2001 and will be made for a 12-month budget period

within a project period of three (3) years. Annual funding estimates may change. Continuation awards within the approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

All requests for funds, including the budget contained in the application, shall be stated in U.S. dollars. Once an award is made, the Department of Health and Human Services (DHHS) will not compensate foreign grantees for currency exchange fluctuations through the issuance of supplemental awards.

#### 1. Direct Assistance

Direct provision of equipment and supplies (e.g., vehicles, computer hardware/software, specific consumables) may be requested as direct assistance in lieu of this financial assistance.

#### 2. Use of Funds

Funds received from this announcement may not be used for the direct purchase of antiretroviral drugs for treatment of established HIV infection (with the exception of nevirapine in PMTCT cases and with prior written CDC approval), occupational exposures, and non-occupational exposures and will not be used for the purchase of machines and reagents to conduct the necessary laboratory monitoring for patient care.

No funds awarded under this announcement shall be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drugs.

Applicants may contract with other organizations under these cooperative agreements; however, applicants must perform a substantial portion of the activities (including program management and operations and delivery of prevention services) for which funds are requested.

The costs that are generally allowable in grants to domestic organizations are likewise allowable to foreign institutions and international organizations, with the following exception:

*Indirect Costs:* With the exception of the American University, Beirut, the Gorgas Memorial Institute, and the World Health Organization, indirect costs will not be paid (either directly or through a sub-award) to organizations located outside the territorial limits of the United States or to international organizations regardless of their location.

### D. 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. Strengthen Operational Capacity

(1) Assess needs of non-governmental ASOs in the areas of operational systems and capacity including: Monitoring and evaluation; communications management; design, assembly and dissemination of public information; prevention; information management and effective use of information to direct, monitor, and evaluate ongoing performance; physical plant; resource mobilization, and coordination and collaboration.

(2) Develop structured methods to improve operational systems.

(3) Develop a plan to assist Zimbabwe ASOs in assessing their operational capacity and their ability to (a) effectively carry out their goals and objectives; (b) coordinate the services of ASOs with, for example, the Zimbabwe government/MOH, National AIDS Council, and other partners; and (c) increase the responsiveness to donors, clients and other constituents.

##### B. Expand Coordination Capacity

(1) Determine need for, and conduct evaluation activities with non-governmental ASOs, for example, ASO service delivery patterns, service needs/requirements, impact analyses, resource mobilization needs.

(2) Plan provincial and national meetings and congresses to foster and improve coordination of ASO activities, information sharing, and assessment of needs and gaps in ASO services.

(3) Develop a plan for information exchange, resource mobilization, capacity building, and coordination of ASO activities at the provincial level in Zimbabwe.

##### C. Strengthen Network Communication and Information Exchange

(1) Support improvements to communication systems supporting non-governmental ASOs, government, and other partners, including training and support services for development of strategies for effective use of information, and efficient use of information and telecommunication technologies to implement those strategies.

(2) Support expansion of web development assistance provided to

non-governmental ASOs, government and other partners.

##### D. Provide Capacity Building Assistance to Zimbabwe ASOs

(1) Provide Capacity Building Assistance and service delivery support in priority interventions (to be defined in collaboration with CDC and other partners) to non-governmental ASOs, government and other partners directly or through small contracts.

#### 2. CDC Activities

(1) Collaborate as needed with the recipient on designing and implementing the activities listed above, including but not limited to the provision of technical assistance to develop and implement program activities, analyses, capacity building assistance.

(2) Monitor project and budget performance.

### E. Application Content

Please use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections of this document to develop your 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 25 (excluding the abstract, attachments and appendices) double-spaced pages, printed on one side, with one inch margins, and un-reduced font. Pages should be numbered, and a complete index to the application and any appendices must be included.

Please include a two-page, double-spaced summary of your proposed activities.

### F. Submission and Deadline

Submit the original and two copies of PHS 5161-1 (OMB Number 0920-0428). Forms are available at the following Internet address: [www.cdc.gov/od/pqo/forminfo.htm](http://www.cdc.gov/od/pqo/forminfo.htm) or in the application kit.

On or before August 24, 2001, submit the application to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

### G. Evaluation Criteria

The application will be evaluated against the following criteria by an independent review group appointed by CDC.

#### 1. Understanding of the Problem (20 Points)

Extent to which the applicant demonstrates a clear and concise

understanding of the nature of the HIV/AIDS epidemic in Zimbabwe, capacity building and coordination needs among non-governmental ASOs and other partners in Zimbabwe, and understanding of the broader network of supporting organizations and resources dedicated to facilitating the function of ASOs in Southern Africa. This specifically includes description of the public health importance of the planned activities to be undertaken and realistic presentation of proposed objectives and projects.

### 2. Technical and Programmatic Approach (25 Points)

The extent to which the applicant's proposal demonstrates an understanding of how to assess the needs of an open system with diverse ASOs and other partners including an overall design strategy and including measurable time lines.

The extent to which the proposal addresses regular monitoring and evaluation, and the potential effectiveness of the proposed activities in meeting objectives. This includes developing a plan to assist non-governmental ASOs in assessing their needs, gaps in services, and methods. The extent to which the applicant proposes a system for providing capacity building support to non-governmental ASOs in Zimbabwe.

### 3. Ability To Carry Out the Project (20 Points)

The extent to which the applicant demonstrates organizational capability to achieve the purpose of the project including experience networking with ASOs in Zimbabwe and familiarity with structure, function, resources and customs of Zimbabwe.

The extent to which the applicant has an existing, formal membership/network that includes the majority of provinces of Zimbabwe, as evidenced by membership and or dues paying lists.

### 4. Personnel (20 Points)

The extent to which professional personnel involved in this project are qualified, including documented evidence their knowledge of and experience in working with ASOs to promote effective HIV/AIDS care and prevention services by ASOs that deliver services directly.

The extent to which the composition of the applicant's key management and direct staff are indigenous to the population of Zimbabwe.

### 5. Plans for Administration and Management of Projects (15 Points)

The extent to which the composition of the applicant's board of directors reflects the indigenous population of Zimbabwe, other ASOs, and other relevant partners across Zimbabwe provinces.

The extent to which the applicant's charter, mission, and mandate reflects its role as a key national ASO networking organization. Adequacy of plans for administering the projects including understanding of their organizational capabilities and administrative infrastructure, for example, administrative and fiscal management systems.

### 6. Budget (Not Scored)

The extent to which itemized budget for conducting the project, along with justification, is reasonable and consistent with stated objectives and planned program activities.

## H. Other Requirements

### Technical Reporting Requirements

The recipient is required to provide CDC with original plus two copies of:

1. Written quarterly progress reports;
2. Financial status report, no more than 45 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.

4. 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 with the potential awardee, pre or post award, in order to review their business management and fiscal capabilities regarding the handling of U.S. Federal funds.

Send all reports to the program contact and the Grants Management Specialist, both 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. Some of the more complex requirements have some additional information provided below:

AR-14 Accounting System Requirements

### I. 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. section 242I], as amended. The Catalog of Federal Domestic Assistance number is 93.941.

### 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: Dorimar Rosado, 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: (770) 488-2782, E-mail: [dpr7@cdc.gov](mailto:dpr7@cdc.gov).

For program technical assistance, contact: Michael St. Louis, MD, Global AIDS Program (GAP), Zimbabwe Country Team, National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention (CDC), Zim-CDC AIDS Project Team, 38 Samora Machel Avenue, 2nd Floor, Harare, Zimbabwe, Telephone: 263 4 796040, 796048, Fax: 263 4 796032, E-mail: [stlouism@zimcdc.co.zw](mailto:stlouism@zimcdc.co.zw).

Dated: July 20, 2001.

### 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

### Food and Drug Administration

### Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

*Name of Committee:* Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on August 8, 2001, from 9:30 a.m.