2. Feasibility of Plan: 35 Points

(a) Infrastructure—Is the plan to guide or assist in the development of blood center infrastructure sound and reasonable?

(b) Blood collection—Is the plan to guide or assist in the development of blood collection facilities, including the development of blood donor recruitment networks, reasonable?

(c) Testing—Is the plan to guide or assist in the development of blood transfusion testing laboratories, including standard operating procedures and protocols, reasonable?

(d) Transfusion and Blood Utilization—Does the applicant's plan to develop or assist in the development of blood transfusion practice guidelines and a blood utilization review programs seem reasonable?

(e) Training—Does the applicant have the resources and a reasonable plan to develop, or guide the development of, a comprehensive training program in the basic principles and practices of blood banking and transfusion medicine?

(f) Monitoring and evaluation—Is the monitoring and evaluation plan feasible? Does the plan measure important indicators?

(g) Sustainability—Is the plan for sustainability reasonable and feasible?

3. Measures of Effectiveness: 10 Points

Do the measures of effectiveness address the number of blood units tested safe for transfusion-transmitted diseases and the number of persons receiving safe transfusions?

4. Plans for Collaboration: 10 Points

Is there a plan or strategy for effectively collaborating with the Ministries of Health or National Transfusion Services funded under CDC Program Announcement 04077?

V.2. Review and Selection Process: Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) staff, and for responsiveness by the National Center for HIV, STD, and TB Prevention. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified that their application did not meet submission requirements.

An interagency objective review panel will evaluate your application according to the criteria listed in section ''V.1. Criteria'' above.

In addition, the following factors may affect the funding decision:

- Geographic distribution.
- Percentage of staff who are citizens of the country in which services will be provided.

V.3. Anticipated Announcement and Award Dates: Award Date: March 25, 2004.

VI. Award Administration Information

Award Notices: Successful applicants will receive a Notice of Grant Award (NGA) from the USG Procurement and Grants Office. The NGA shall be the only binding, authorizing document between the recipient and USG. The NGA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

Administrative and National Policy Requirements: 45 CFR part 74 and part 92.

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: *http://www.access.gpo.gov/nara/cfr/cfr-table-search.html.*

The following additional requirements apply to this project:

- AR–4 HIV/AIDS Confidentiality Provisions
- AR–5 HIV Program Review Panel Requirements
- AR–6 Patient Care
- AR–9 Paperwork Reduction Act Requirements
- AR–10 Smoke-Free Workplace Requirements
- AR–11 Healthy People 2010
- AR–12 Lobbying Restrictions
- AR–14 Accounting System Requirements
- AR–16 Security Clearance Requirement
- AR–23 States and Faith-Based Organizations
- AR–24 Health Insurance Portability and Accountability Act Requirements
- AR–25 Release and Sharing of Data

Additional information on these requirements can be found on the CDC Web site at the following Internet address: *http://www.cdc.gov/od/pgo/funding/ARs.htm.*

Reporting Requirements

You must provide CDC with a hardcopy original, plus two copies of the following reports:

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. Semi-annual progress report, due 7 months after the beginning of each budget period. This report should contain the following elements:

(a) Progress on achieving objectives

(b) Modification or new activities

3. Financial status report, no more than 90 days after the end of the budget period.

4. Final financial and performance reports, no more than 90 days after the end of the project period.

These reports must be mailed to the Grants Management Specialist listed in the ''Agency Contacts'' section of this announcement.

VII. Agency Contacts

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

For program technical assistance, contact: Kenneth Clark, M.D., MPH, Project Officer, National Center for HIV, STD, and TN Prevention, Centers for Disease Control and Prevention, 1600 Clifton Rd, NE, MS E04, Atlanta, GA 30333, Telephone: 404–639–8057, E-mail: *kjc4@cdc.gov.*

For budget assistance, contact: Shirley Wynn, Contract Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770–488–1515, E-mail: *zbx6@cdc.gov.*

Dated: November 25, 2003.

Edward Schultz,

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

[FR Doc. 03–29892 Filed 11–28–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Health Resources and Services Administration

Rapid Expansion of Antiretroviral Therapy Programs for HIV-Infected Persons in Selected Countries in Africa and the Caribbean Under the President's Emergency Plan for AIDS Relief

Announcement Type: New.

Funding Opportunity Number: 04080.

Catalog of Federal Domestic Assistance Number: 93.941.

Key Dates: Application Deadline: December 31, 2003.

I. Funding Opportunity Description

Authority: This program is authorized under section 301(a) and 307 of the Public Health Service Act, [42 U.S.C. 241(a) and 242l] as amended and under Public Law 108–25 (United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003) [22 U.S.C. 7601].

Purpose: President Bush's Emergency Plan for AIDS Relief has called for immediate action to turn the tide of HIV/AIDS in Africa and the Caribbean. An important aspect of the President's bold vision is to treat at least two million HIV-infected persons with combination antiretroviral therapy (ART) within five years. This funding opportunity responds to the President's call for rapid, accountable, and sustainable action.

The primary purpose of this funding announcement is to rapidly expand ART for low-income HIV-infected persons. An additional intent is to develop sustainable indigenous capacity to continue these programs after the project ends. Funds will be awarded to organizations with excellent HIV programs that currently provide care or care and ART. Services should be delivered in a manner that is consistent with national plans and policies. The following countries are eligible: Botswana, Côte d'Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, Zambia.

Measurable outcomes of this program will be in alignment with the following performance goal for President Bush's Emergency Plan for AIDS Relief: Treat two million HIV-infected people in 14 countries in Africa and the Caribbean heavily afflicted by AIDS (see above). CDC expects to work in close collaboration with the Health Resources Services Administration (HRSA) in supporting awardee activities under this cooperative agreement.

This initiative is a coordinated effort led by the Office of the Global AIDS Coordinator at the Department of State and involves various U.S. Federal Government agencies including the Department of State, Department of Health and Human Services (HHS), Department of Defense and the U.S. Agency for International Development.

Activities

The recipient must manage a program to support all of the following activities in the countries in which they currently meet eligibility requirements. Awardee activities for this program are as follows:

Clinical Care

a. Diagnose HIV infection correctly.

b. Provide comprehensive care including appropriate prophylaxis and treatment for opportunistic infections (OI) including tuberculosis (TB) and sexually transmitted infections (STIs), according to national guidelines. If such guidelines do not exist, use World Health Organization (WHO) or other international guidelines.

c. Provide ART according to national guidelines and algorithms that cover when and how to initiate therapy, use first- and second-line regimens, and use regimens for special circumstances, such as pregnancy, co-infection with TB, and where appropriate, children.

d. Evaluate and manage adverse effects of drugs.

e. Maintain adequate clinical records.

f. Provide counseling and social support to ensure adherence to treatment regimens.

g. Provide referrals for additional care and support needs.

h. Provide monitoring and care for HIV-infected persons not yet eligible by medical criteria for ART.

Drug and Health Commodities Management

a. Select and procure appropriate drugs in the correct amounts in accordance with U.S. government policies and national and international law.

b. Develop and maintain ongoing quality assurance for secure and reliable storage and distribution systems, and prevent the diversion and theft of drugs and commodities.

c. Maintain record-keeping systems.

Laboratory Services

Ensure the availability and appropriate use of laboratory capabilities for diagnosing HIV infection, opportunistic infections, and other co-morbid events, and for appropriate evaluation of drug toxicities consistent with national guidelines. This includes access to: (1) Physical infrastructure; (2) trained staff; (3) equipment; (4) supplies and reagents; and (5) quality assurance.

Training

a. Assure training and continuing education to health care workers, such as doctors, nurses, clinical assistants, nurse practitioners, pharmacists, laboratory technicians, and community workers (including persons living with HIV/AIDS).

b. Training should address the diagnosis, treatment, and care of HIV.

c. Provide training to increase the capacity of indigenous staff.

d. Provide management training as needed.

Community Mobilization and Behavior Change

Limited funding in this award (no more than seven percent of the budget) is available for community mobilization and behavior change to promote the use of ART. These activities should include employment of people living with HIV/AIDS where appropriate. The specific goals of this activity include: (1) For those at risk of infection—encourage them to seek testing; (2) 2. For those not infected—reduce the risk of acquiring HIV and other STIs; and (3) For those infected—reduce the risk of HIV transmission and encourage care seeking behavior and adherence to therapy.

Monitoring and Evaluation

a. Implement a system for ongoing review and adjustment of program activities.

b. Measure uptake and clinical outcomes to assess impact, including monitoring for adverse outcomes, such as drug resistance at the population level in the populations being served.

c. Collect program indicators as recommended by national and United States Government (USG) guidelines, that have been or will be developed.

d. Assist in dissemination of evaluations and lessons learned from these programs.

In a cooperative agreement, HHS staff are substantially involved in the program activities, above and beyond routine grant monitoring. HHS will work under the guidance and supervision of the Office of the Global AIDS Coordinator at the Department of State.

CDC and HRSA Activities for this program are as follows:

a. Provide scientific and technical assistance in refining the plan.

b. Provide ongoing technical assistance in addressing problems encountered in implementing the plan, as well as for the delivery of an effective ARV treatment program through regular telecommunication and on-site support.

c. Assist in evaluating program operations and overall effectiveness of the program through the joint review of clinical operations and joint analysis of monitoring data.

d. Assist the awardees with sophisticated technical elements, such as ARV resistance monitoring, through direct support from CDC or by facilitating linkages with other national or international organizations.

II. Award Information

Type of Award: Cooperative Agreement.

CDC involvement in this program, including technical collaboration with and support from HRSA, is listed in the Activities Section above.

Fiscal Year Funds: 2004.

Approximate Total Funding: $115 million.

Approximate Number of Awards: Five or six.

Approximate Average Award: $17 million.

Floor of Award Range: $7 million.

Ceiling of Award Range: $25 million.

Anticipated Award Date: January 15, 2004.

Budget Period Length: 12 months.

Project Period Length: 5 years.

Throughout the project period, HHS's commitment to continuation of awards will be conditioned on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the Federal Government.

III. Eligibility Information

III.1. Eligible Applicants

Applications may be submitted by organizations that have experience in: (1) Directly providing clinical care for HIV-infected persons (including management of TB and other opportunistic infections, as well as clinical follow up), or directly providing such care plus treatment with ART, or (2) assisting in providing clinical care or care and treatment with ART through funding and technical assistance (need to show evidence of an operational presence in the countries your organization proposes to work). Eligible applicants must have provided these services for three or more years in at least three of the following countries: Botswana, Côte d'Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, and Zambia. Either United States (U.S.) or non U.S. organizations are eligible to apply.

No funds made available under this solicitation may be used to provide assistance to any group or organization that does not have a policy explicitly opposing prostitution and sex trafficking. This written statement of certification must be signed by authorized person(s) within the applicant group or organization, including the individuals submitting the application. No funds made available under this solicitation may be used to promote or advocate the legalization or practice of prostitution or sex trafficking. Nothing in the preceding sentences shall be construed to preclude the provision to individuals of palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and other commodities, including test kits, condoms, and, when proven effective, microbicides.

III.2. Cost Sharing or Matching

Matching funds are not required for this program.

III.3. Other

If you request a funding amount greater than the ceiling of the award range, your application will be considered non-responsive and will not be entered into the review process. You will be notified that your application did not meet the submission requirements.

If your application is incomplete or non-responsive to the requirements listed in this section, it will not be entered into the review process. You will be notified that your application did not meet submission requirements.

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.

IV. Application and Submission Information

IV.1. Address To Request Application Package

To apply for this funding opportunity use application form CDC 1246. Application forms and instructions are available on the CDC web site, at the following Internet address: *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) staff at: 770–488–2700. Application forms can be mailed to you.

IV.2. Content and Form of Submission

You must include a project narrative with your application forms. Your narrative must be submitted in the following format:

- Maximum number of pages: 40 (Note: Eligibility and budget narrative are not included in the page total). If your narrative exceeds the page limit, only the first pages which are within the page limit will be reviewed.
- Single-spaced.
- Font size: 12-point unreduced.
- Paper size: 8.5 by 11 inches.
- Page margin size: One inch.
- Printed only on one side of page.
- Held together only by rubber bands or metal clips; not bound in any other way.
- Written in English.

Your narrative should address activities to be conducted over the entire project period, and must include the following items in the order listed:

1. Eligibility: No Page Limit

Provide evidence that your organization meets the eligibility requirements for this funding announcement. Examples could include a copy of an agreement between your organization and a host country institution, annual reports, or registration as an operating entity within the countries you propose to work.

This should be the first topic addressed in your program narrative. If you do not provide adequate documentation, your application will be deemed ineligible and will not be reviewed. If you need to include substantiating documents, include these in the appendix under a section titled ''Eligibility.''

2. Need: 2 Page Max

Describe the need for treatment services in the catchment areas in which you intend to provide ART. Address the following:

a. Estimated number of infected persons in the catchment area where you intend to provide ART.

b. Estimated number of infected persons receiving ART in your proposed catchment areas and the number of persons receiving ART through your organization (if any) and the number of facilities your organization supports to provide ART (if any).

c. Number of persons with whom you intend to initiate treatment with ART and the number of facilities in which you will provide ART for each year of the next five years.

d. Provide this information in a table format: for columns—base and years 1 through 5; for rows—number of infected persons (baseline only), number receiving ART (baseline only), number receiving ART through your program (baseline only), number of facilities where ART is being provided (baseline only), the number of persons your organization intends to initiate treatment with ART for each of the next five years, and the number of facilities for each year.

e. Describe your proposed patient population, including socioeconomic status and gender.

3. Current HIV Care and Treatment Services: 16 Pages Max

Address the following and describe whether your organization or partnering organizations is responsible for these activities (Include supporting documents in the appendix under the heading, ''Current HIV care and treatment services.''):

a. Clinical care—

(1) Current services—Describe the types of facilities in which you are currently providing services (*e.g.*, hospital, clinic), locations, relationship to government health services, and the types of HIV related care and treatment provided. Also indicate any fees for services.

(2) Describe your strategies for diagnosis, treatment and prophylaxis for opportunistic infections, including TB. Also describe laboratory and clinical follow-up.

(3) If your program is currently providing ART, describe the criteria for initiation and continuation of ART and first- and second-line ART regimens. Also describe laboratory and clinical follow up as well as strategies to promote adherence. Indicate whether these are consistent with national guidelines.

b. Drug and health commodities—Describe your system to select, procure, store, track, distribute, and provide pharmaceuticals to patients, and measures to prevent the theft and diversion of drugs and commodities. Indicate sources for procurement of pharmaceuticals and laboratory supplies.

c. Laboratory services—Describe the following:

(1) Laboratory facilities for diagnosis and treatment of HIV, STIs, and opportunistic infections such as TB;

(2) Capability of performing CD4 tests at each facility including type of equipment used;

(3) Staff qualifications;

(4) Quality assurance measures.

d. Training activities—Describe training programs for HIV care and treatment, including laboratory services. Include information about course titles, types and numbers of persons trained, length of each course, training facilities, follow-up activities, and trainer qualifications.

e. Community mobilization and behavior change—Describe your activities to promote HIV testing in the proposed catchment areas and to provide behavioral change counseling to persons the program tests for HIV.

f. Monitoring and evaluation—Describe your current system to record program indicators, including patient outcomes.

4. Goals and Objectives: 2 Page Max

Address the following:

a. Provide goals for your project and measures of effectiveness by which you can assess the success of your program. One of these measures must be the number of HIV-infected persons to whom you will be providing ART by the end of each year of the project.

b. Describe major activities to achieve project goals and a timeline for implementation of the project in the first year and a more general timeline for four years.

5. Rapid Expansion of ART: 14 Pages Max

Describe your plans for increasing the number of infected persons who receive ART. Address the following areas:

a. Clinical care—Explain how you plan to increase the number of persons receiving ART and maintain or improve the quality of care provided in three or more of the eligible countries. Include protocols you will use. Provide an estimate of annual per patient cost for HIV treatment based on your total budget. Describe your policy for charging fees to patients. Explain how the proposed program will strengthen the national network for providing ART and is consistent with Ministry of Health (MOH) expansion plans.

b. Drug and health commodities—Describe how you plan to expand the drug management system to ensure appropriate treatment of the projected number of persons on ART.

c. Laboratory services—Describe how you will increase your HIV-related services. If you plan to perform CD4 counts or viral load testing for initiating or monitoring ART, describe plans to develop this capacity or to collaborate with others to do so.

d. Training—Describe your training needs including the number and type of staff that need to be trained and how the training will be accomplished. Describe how your program will ensure that training of indigenous personnel will occur within 5 years.

e. Community mobilization and behavior change—Describe the methods you will use to increase the number of persons who seek HIV testing and the methods you will use to increase the number of persons to whom you provide counseling. Describe your efforts to support adherence to therapy.

f. Monitoring and Evaluation—Describe your proposed monitoring and evaluation plan, including a list of key indicators to track program performance.

g. Sustainability—Applicants should develop a one-page description of capacity building activities for each year's work plan. Proposed activities must include capacity building as defined as activities promoting host country infrastructure development and strengthening of management, service delivery, and evaluation systems and clinical/cultural competency.

In order to accomplish sustainable systems development the following activities are suggested:

- Identify key stakeholders and engage potential in-country partners;
- Develop or expand a formal (preferably host country) advisory group to plan for on-going services;
- Define the components of care with other health or social service providers;
- Research funding sources; and
- Develop an exit plan.

The overall strategy and program must fit into National host country strategies including continuation of the program funding and staffing.

6. Management Plan, Staffing, and infrastructure: 6 Pages Max

Address the following:

a. Collaborating Organizations

(1) Describe which organizations you will financially support under this cooperative agreement and the role each will play.

(2) List the organizations with whom you intend to collaborate and what role each will play.

(3) Provide letters of support from these organizations as well as the MOH. These letters should be included in the appendix under a section titled, ''Letters of Support.'' The letters should indicate support for the goals and objectives of your proposed project and indicate what support they will provide, *e.g.*, referrals to your program.

b. Management plan—Provide an organizational chart and describe the responsibilities of key staff.

c. Staffing—Describe number and types of staff needed to treat the projected number of persons with ART. Indicate what percentage of clinical and senior management are citizens of the country in which services will be provided. Describe plans to increase these percentages. Also describe the number and types of new staff that will need to be hired in each country.

d. Infrastructure—Describe the physical facilities where services will be provided and the equipment needed.

7. Budget Narrative: No Page Limit

Guidance for completing your budget can be found on the CDC Web site, at the following address: *http://www.cdc.gov/od/pgo/funding/budgetguide.htm.*

You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal government. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access *www.dunandbradstreet.com* or call 1–866–705–5711.

For more information, see the CDC Web site at: *http://www.cdc.gov/od/pgo/funding/pubcommt.htm.*

If your application form does not have a DUNS number field, please write your DUNS number at the top of the first page of your application, and/or include your DUNS number in your application cover letter.

Additional information may be included in the application appendices. The appendices will not be counted toward the narrative page limit. This additional information includes: Curriculum Vitae, Resumes, Organizational Charts, Letters of Support, and other pertinent documents.

Additional requirements that may require you to submit additional documentation with your application are listed in ''VI.2. Administrative and National Policy Requirements''.

IV.3. Submission Dates and Times

Application Deadline Date: December 31, 2003.

Explanation of Deadlines: Applications must be received in the CDC Procurement and Grants Office by 4 p.m. Eastern Time on the deadline date. If you send your application by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If CDC receives your application 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, you will be given the opportunity to submit documentation of the carriers guarantee. If the documentation verifies a carrier problem, CDC will consider the application as having been received by the deadline.

This program announcement is the definitive guide on application format, content, and deadlines. It supersedes information provided in the application instructions. If your application does not meet the deadline above, it will not be eligible for review, and will be discarded. You will be notified that your application did not meet the submission requirements.

CDC will not notify you upon receipt of your application. If you have a question about the receipt of your application, first contact your courier. If you still have a question, contact the PGO–TIM staff at: 770–488–2700. Before calling, please wait two to three days after the application deadline. This will allow time for applications to be processed and logged.

IV.4. Intergovernmental Review of Applications

Executive Order 12372 does not apply to this program.

IV.5. Funding Restrictions

Funding restrictions, which must be taken into account while writing your budget are as follows:

1. 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 HHS/CDC officials must be requested in writing.

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

3. 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, the Gorgas Memorial Institute, 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.

4. 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.)

5. You must obtain annual audit of these HHS/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 HHS/CDC.

6. 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.

7. Use of these funds for the purchase of antiretroviral drugs, laboratory reagents, and laboratory equipment for antiretroviral treatment projects requires prior approval in writing by HHS/CDC officials.

8. Funds may be used only for activities associated with HIV/AIDS. HHS/CDC funds may be used for direct costs such as salaries; necessary travel; operating costs, including supplies, fuel, utilities, etc.; staff training costs, including registration fees and purchase and rental of training-related equipment; renovation of clinical or lab facilities; and purchase of HIV testing reagents, test kits, and laboratory equipment for HIV testing.

9. No funds made available under this solicitation may be used to provide assistance to any group or organization that does not have a policy explicitly opposing prostitution and sex trafficking. This written statement of certification must be signed by authorized person(s) within the applicant group or organization including the individuals submitting the application. No funds made available under this solicitation may be used to promote or advocate the legalization or practice of prostitution or sex trafficking. Nothing in the preceding two sentences shall be construed to preclude the provision to individuals of palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and other commodities, including test kits, condoms, and, when proven effective, microbicides.

10. No funds appropriated under this solicitation shall be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

IV.6. Other Submission Requirements

Application Submission Address: Submit the original and two hard copies of your application by mail or express delivery service to: Technical Information Management-PA 04080, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

Applications may not be submitted electronically at this time.

V. Application Review Information

V.1. Criteria

You 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. These should be included in your project narrative under ''4. Goals.''

Your application will be evaluated against the following criteria:

A. Current Capability: 80 Total

1. Clinical Care: 20

Does the applicant demonstrate significant experience in implementing or assisting HIV care and treatment programs in the proposed countries? Does the applicant describe technically sound clinical care protocols? Is the applicant currently providing ART?

2. Drug & Health Commodities: 15

Does the applicant describe all aspects of drug management? Do procedures appear to be adequate, including to prevent theft and diversion?

3. Laboratory Services: 15

Are facilities adequate? Are staff qualified? Are there adequate quality assurance measures in place? Is the lab capable of performing a broad range of tests? Can the lab perform CD4 tests?

4. Training: 10

Does the applicant have a history of providing training on a broad number of relevant topics to all levels of staff?

5. Community Mobilization and Behavior: 5

Does the applicant describe efforts to promote testing and plans to provide counseling? Did the applicant describe methods to increase the number of persons who seek HIV testing and methods to increase the number of persons to whom it will provide counseling? Did the applicant describe efforts to support adherence to therapy?

6. Monitoring and Evaluation: 10

Is there a M&E plan in place? Does the plan measure indicators that track program performance?

7. Sustainability: 5

Is the plan for sustainability reasonable and feasible?

B. Feasibility of Expansion Plan: 80 Total

1. Clinical care: 25

Does the applicant propose to provide ART in three or more of the eligible countries? Is the plan to increase the number of persons receiving ART feasible? Is the estimated cost per patient reasonable? Are plans to assure quality of care adequate? Does the applicant demonstrate consistency with national plans?

2. Drug & Health Commodities: 15

Are plans to provide services and assure quality adequate?

3. Laboratory Services: 15

Is the plan to increase laboratory services feasible?

4. Training: 15

Is the plan to expand training feasible? Does the training plan address the needs of the program? Does the applicant address training needs of indigenous staff?

5. Community Mobilization and Behavior: 5

Did the applicant describe how the program will increase the number of persons tested and counseled?

6. Monitoring and Evaluation: 5

Does the plan measure indicators that track program performance?

C. Organizational Structure, Management, and Staffing: 20 Total

1. Organizational Structure: 7

Is the proposed mix of organizations adequate to achieve program objectives? Were letters of support including those of the MOH provided?

2. Staffing: 8

Are the number and types of staff reasonable? Does the applicant provide a realistic sustainability plan?

3. Facilities: 5

Are the facilities adequate to provide the proposed services?

D. Measures of effectiveness: 10 Total

Do the measures of effectiveness address the number of persons receiving ART and clinical outcomes? Are timelines reasonable?

E. Budget: 10 Points

Is the budget reasonable for the proposed activities?

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) staff, and for responsiveness. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified that their application did not meet submission requirements.

An objective review panel will evaluate complete and responsive applications according to the criteria listed in the ''V.1. Criteria'' section above.

In addition, the following factors may affect the funding decision:

- Geographic distribution—to ensure that funding is not concentrated in any one catchment area.
- Cost sharing.
- Number of persons to be treated.
- No award will be made without the concurrence of the U.S. Embassy and the CDC representative in the country under consideration.

V.3. Anticipated Announcement Award Date

January 15, 2004.

VI. Award Administration Information

VI.1. Award Notices

Successful applicants will receive a Notice of Grant Award (NGA) from the CDC Procurement and Grants Office. The NGA shall be the only binding, authorizing document between the recipient and CDC. The NGA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

Unsuccessful applications will receive notification of the results of the application review by mail.

VI.2. Administrative and National Policy Requirements

45 CFR Part 74 and Part 92.

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: *http://www.access.pgo.gov/nara/cfr/cfr-table-search.html*

The following additional requirements apply to this project:

- AR–1 Human Subjects Requirements
- AR–4 HIV/AIDS Confidentiality Provisions
- AR–5 HIV Program Review Panel Requirements
- AR–6 Patient Care
- AR–9 Paperwork Reduction Act Requirements
- AR–10 Smoke-Free Workplace Requirements
- AR–12 Lobbying Restrictions
- AR–14 Accounting System Requirements

- AR–16 Security Clearance Requirement
- AR–23 States and Faith-Based Organizations
- AR–24 Health Insurance Portability and Accountability Act Requirements
- AR–25 Release and Sharing of Data

Additional information on these requirements can be found on the CDC web site at the following Internet address: *http://www.cdc.gov/od/pgo/funding/ARs.htm.*

VI.3. Reporting Requirements

You must provide CDC with an original, plus two hard copies of the following reports:

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.

f. Measures of Effectiveness.

2. Semi-annual progress report, due 7 months after the beginning of each budget period. This report should contain the following elements:

a. Progress on achieving objectives.

b. Modification or new activities.

3. Financial status report, no more than 90 days after the end of the budget period.

4. Final financial and performance reports, no more than 90 days after the end of the project period.

These reports must be sent to the Grants Management Specialist listed in the ''Agency Contacts'' section of this announcement.

VII. Agency Contacts

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

For program technical assistance, contact:

Tedd Ellerbrock, M.D., Project Officer, Centers for Disease Control and Prevention, Global AIDS Program, 1600 Clifton Road, NE, Mailstop E–04, Atlanta, GA 30333, Telephone: 404–639–8944, E-mail: *tellerbrock@cdc.gov.*, or

Joel Kuritsky, M.D., Project Officer, Centers for Disease Control and Prevention, Global AIDS Program, 1600 Clifton Road, NE, Mailstop E–04, Atlanta, GA 30333, Telephone: 404–639–8618, E-mail: *jnk2@cdc.gov.*

For budget assistance, contact: Diane Flournoy, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770–488–2072, E-mail: *dmf6@cdc.gov.*

Dated: November 25, 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 Medicare & Medicaid Services

[CMS–3070, CMS–10095, and CMS–10096]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Agency: Centers for Medicare and Medicaid Services, HHS. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a previously approved collection.

Title of Information Collection: Intermediate Care Facility for the Mentally Retarded or Persons with Related Conditions ICF/MR Survey Report Form (3070G–I) and Supporting Regulations at 42 CFR 442.30, 483.410, 483.420, 483.440, 483.450, and 483.460.

Form No.: CMS–3070 (0938–0062).

Use: The survey forms are needed to ensure provider compliance. In order to participate in the Medicaid program as an ICF/MR, a provider must meet Federal standards. The survey report form is used to record providers' level of compliance with the individual standard and report it to the Federal government. The collection includes the information collection requirements that ICF/MRs must meet.

Frequency: Annually.

Affected Public: Business or other for-profit, Not-for-profit institutions.

Number of Respondents: 6,763.

Total Annual Responses: 177,721,815.

Total Annual Hours: 6,841,538.

2. *Type of Information Collection Request:* New Collection.

Title of Information Collection: ''Detailed Explanation of Non-Coverage'' 42 CFR 422.626(e)(1), and ''Important Message of Non-Coverage'' 42 CFR 625(b)(1).

Form No.: CMS–10095 (OMB# 0938–NEW).

Use: Pursuant of 42 CFR 422.624(b)(1), providers in skilled nursing facilities, home health agencies, and comprehensive outpatient rehabilitation facilities must deliver to M+C enrollees a 2-day advance notice of termination of services. Per requirements at 42 CFR 422.626(e)(1), M+C organizations must deliver detailed notices to the QIO and enrollees upon request for appeal of the termination of services. These notices fulfill the regulatory requirement.

Frequency: Other: distribution.

Affected Public: Business or other-for-profit, Not-for-profit institutions, Federal Government, and Individuals or Households.

Number of Respondents: 22,247.

Total Annual Responses: 612,000.

Total Annual Hours: 68,000.

3. *Type of Information Collection Request:* New Collection.

Title of Information Collection: Medicare Health Survey (MHS).

Form No.: CMS–10096 (OMB# 0938–NEW).

Use: The Centers for Medicare and Medicaid Services has developed a survey, the Medicare Health Survey, that is similar to the Health Outcomes Survey (HOS). The main purpose of the MHS is to collect information that may be used to adjust Medicare payment. This approach has been tested for PACE (as mandated by BBA) and other organizations that serve frail populations and frailty adjusted payments will be made to PACE and certain demonstrations starting in 2004. CMS is currently investigating the feasibility of applying frailty adjustment to the M+C program in the future. To