AMENDMENT II (3/28/2012):

i) ***Pages 4 and 25 – The Application Deadline Date has been extended to April 16, 2012***

ii) ***Page 19 - The following language has been revised under Award Information:***
Approximate Current Fiscal Year Funding: $5,000,000
Approximate Total Project Period Funding: $37,000,000 (This amount is an estimate, and is subject to availability of funds and includes direct costs for international organizations or direct and indirect costs for domestic grantees for all years.)
Approximate Average Award: $2,500,000 (This amount is for the first 12 month budget period, and includes direct costs for international organizations or direct and indirect costs for domestic grantees.)
Ceiling of Individual Award Range: $5,000,000 (This ceiling is for the first 12 month budget period and includes direct costs for international organizations or direct and indirect costs for domestic grantees.)
Budget Year 2 Ceiling amount: $8,000,000
Budget Year 3 Ceiling amount: $8,000,000
Budget Year 4 Ceiling amount: $8,000,000
Budget Year 5 Ceiling amount: $8,000,000

AMENDMENT I (3/6/2012):

i) ***Page 32 - The following language has been added under <u>The 8% Rule:</u> Under PEPFAR, US Government agencies in Malawi, including CDC and USAID, coordinate to efficiently support implementation of Malawi's Health Sector Strategic Plan. The Office of the Global AIDS Coordinator has issued the following guidance to USG agencies in reference to the use of PEPFAR funds: "avoid duplication of resources programmed by different USG agencies to the same implementing organization for the same purposes (e.g., two USG agencies funding the same partner to provide the same assistance to orphans or antiretroviral treatment). This will minimize the burden on the partner as well as USG staff." As such, PEPFAR Malawi would like to avoid situations where different USG agencies program resources to the same implementing organization for the same purpose. This guidance and the USG partners and***

partner activities existing at the time will be considered when award selection(s) are made.

ii) Questions and answers:

1. ***Sequencing of deadlines for measurable outcomes (MO) is not always logical. Can applicant review the sequence according to its implementation plan?***
   - ***Please review the FOA and any restrictions or lack thereof on the sequence of MOs.***
2. ***Linked with question above, are all listed MO for 2013 expected to be part of this one year proposal?***
   - ***Applicants should follow the FOA instructions and purpose in developing their technical application'***
3. ***Outcome 3a is not specific: are we talking about 100% facilities or just high burden? If the latter is correct, will it not make more sense to replace 3a by 3c?***
   - ***3a. should be modified for clarity "A minimum of 5 facilities with fully functional integrated outpatient department, pharmacy, laboratory, inpatient, Antenatal, Maternity and Under 5, HIV Testing and Counseling, Tuberculosis modules by 2014.***
4. ***Can outcomes that are neither applicant's competency nor part of what applicant can subcontract be considered as assumption in the proposal? eg: 6c, 8d which are government's responsibility***
   - ***The applicant should describe how the applicant will work towards ensuring that MOs are achieved.***
5. ***Outcomes are over a period of 5 years and the proposal for one. Is it fair to assume that the applicant is expected to submit a 5 years plan as part of the narrative and submit a detailed implementation plan for one year as CDC will approve fund on annual basis? Shall the long term general plan be part of the narrative or be added in the appendices?***
   - ***The applicant will submit a 5 year plan as part of narrative and detailed implementation plan for one year***
6. ***Funds should not be used for research but yet elsewhere in the document it is said that HHS/CDC wants to promote research - Need for clarity***

- ***This is a non-research RFA***

7. ***Under Budget Justification p.25: is first budget period referring to the first year budget or any other period?***
   - ***This is the first 12 months***
8. ***Under funding restriction, is it a correct understanding that equipment, if clearly identified in the budget, is acceptable although it is also said that budget is not including equipment?***
   - ***Equipment must be clearly identified***
9. ***In terms of number of awardees, one document says there will be one and another says there will be 1-2. If there will be 2 awardees what mechanism will be put in place to avoid duplication?***
   - ***This will be discussed in the post-award phase***
10. ***8% rule- how much is Malawi's FY 2012 PEPFAR funding (excluding US Government & staffing costs)?***
    - ***The total funding is approximately $55 million***

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PART 1. OVERVIEW INFORMATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Federal Agency Name: Centers for Disease Control and Prevention (CDC)

Funding Opportunity Title: Improving Quality of Care and Health Impact through Sustainable, Integrated, Innovative Information System Technologies in Malawi under the President's Emergency Plan for AIDS Relief (PEPFAR)

Announcement Type: New – Type 1

Agency Funding Opportunity Number: CDC-RFA-GH12-1250

Catalog of Federal Domestic Assistance Number: *93.067*

Key Dates:

Application Deadline Date: ***April 16***, 2012 on Grants.gov, 11:59pm Eastern Standard Time.

Measurable objectives of the program will be in alignment with one (or more) of the following performance goal(s):

Measurable Outcome 1:

MO 1.1a: 90% of antiretroviral therapy (ART) clinics rated high burden sites should have comprehensive functional electronic medical records system to support patient care by 2017.

Outputs:

- Improved patient safety (e.g. reduce prescriptions, medication errors, avoid adverse drug events)
- Improved clinical efficiency (reduce duplicate tests)
- Increased throughput or decreased waiting time

Measurable Outcome 2:

MO 2a: 55% of high burden ART sites have registered and are managing over 2,500 patients with Electronic Medical Record (EMR) systems by 2013. High burden sites are defined by the Ministry of Health's HIV/AIDS department as an ART clinic/site that manages over 2,500 patients in a month.

MO 2b: 35% of patients who are alive and registered on the national ART program managed with electronic medical systems by 2013.

Outputs:

- EMR installed and maintained
- EMR upgraded and updated

Measurable Outcome 3:

MO 3a: Facilities with integrated outpatient department, pharmacy, laboratory, inpatient, HIV Testing and Counseling, and tuberculosis modules by 2014.

MO 3b: 70% of targeted sites with integrated EMR systems able to track defaulters, support referrals to other services, remote consultations, reminders and patient follow up by 2017.

MO 3c: Scale up to 30% of high burden sites with integrated modules by 2014.

MO 3d: Link 90% of facilities within catchment area providing maternal, neonatal and child health by 2017.

MO 3e: Link 50 facilities providing Antenatal, Maternity, Under 5, Early Infant Diagnosis (EID) and Prevention of Mother to Child Transmission (PMTCT) by 2017.

MO 3f: Uniquely follow up and monitor at least 33% of patients in the PMTCT program within the catchment area of the Kamuzu Central Hospital (central region of Malawi) across facilities by 2014.

Outputs:

- Integrated EMR modules developed and piloted
- Service provider compliance with patient management protocols reviewed to guide capacity building and inform policy, guidelines

- Patient referral pathway monitored to assess patient follow-up/tracking
- Software applications supporting facility-based programs for real time data collection developed

Measurable Outcome 4:

MO 4a: 70% of patients referred to another service actually access service within the recommended referral timeframe by 2015.

MO 4b: 15% of facilities with electronic information systems should interface with community information systems by 2014. Other than facility-based tools for collecting data, the basic standard registers at the community level are Village Health Register and Village Register for civil registration. However, Village Health Committees have come up with other interventions collecting information in log books on Maternal Health and Child Growth monitoring. Community information systems refers to the Ministry of Health's Village Health Register, National Registration Bureau Village Register, and other information tools devised by village health committees that can support community level maternal and child health surveillance.

MO 4c: 120 facilities with linked information systems with data flow to and from community based services supporting electronic referrals pre-ART to facility-based services, remote consultations, mobile data collection, sending reminders by 2017.

Outputs:

- Software developed supporting community linkages and capable of transferring information in real time
- Data use case to analyze functioning of community based activities supervised by facility
- Data available to analyze availability and accessibility of care within catchment area

Measurable Outcome 5:

MO 5a: 100 % of EMR sites where management has real time access to facility records by 2017.

MO 5b: 200 health care workers trained in EMR system use per year.

MO 5c: 25 staff trained in systems maintenance and basic troubleshooting per year.

Outputs:

- Staff trained including key cadres e.g. healthcare workers, data entry clerks, program managers
- Reference modules/ models and data dictionary developed

Measurable Outcome 6:

MO 6a: Production of standardized reports supporting decision-making, allocation of supplies, resources and planning based on information products in all sites using EMR by 2017.

MO 6b: Availability of integrated and consolidated data sources focused to collect data that is of local relevance in all sites using EMR by 2017.

MO 6c: Availability of the capacity for health workers to use data for planning and day-to-day decision making in all sites by 2017.

Measurable Outcome 7:

MO 7a: Availability of national data Quality Assurance (QA) and analysis in-service training curricula that encompasses all Essential Health Package (EHP) health services, programs and functions by 2014.

MO 7b: Availability of pre-service training modules on data analysis for health program management/ service delivery by 2015.

Outputs:

- Modules developed
- Job aids/ SOPs developed
- Pre- and in-service modules developed

Measurable Outcome 8:

MO 8a: 100% in-service trainings conducted as planned per year.

MO 8b: 2 assessments/ evaluations conducted to assess cadre specific competencies for data analysis per year.

MO 8c: 20% district data & analyzing reports to guide development of District Implementation Plans (DIPs) by 2013.

MO 8d: 20% Zonal Health Support Offices (ZHSO) utilizing Health Management Information System (HMIS) reports produced to guide Zonal Implementation Plan (ZIP) development by 2013.

Outputs:

- Program managers, ZHSO staff and Extended District Health Management Team (DHMT) trained on data quality checks and utilization for health program planning, implementation and monitoring
- Health workers trained on basic trend analysis and internal QA
- Performance based incentives awarded for data quality

Measurable Outcome 9:

MO 9a: Availability of national set of data standards and Health Level 7 application to support information exchange and inter-operability of disparate health information systems by 2015.

MO 9b: 30% of facilities connected to district, zonal and central level data warehouses by 2014.

Measurable Outcome 10:

MO 10a: Availability of the capacity to provide real-time public health reporting and surveillance, and improved monitoring of health trends in a given population at all levels by 2017.

MO 10b: Establish a central system to generate and manage unique patient identifiers issuing patient identities to all connected facilities in real time by 2013.

Outputs:

- National e-health information systems strategic plan, guidelines and SOPs developed, disseminated and implemented
- National data standards task force meetings convened to support implementation of the strategic plan minutes of meetings

Measurable Outcome 11:

MO 11a: Achieve interoperability at 30 % of facilities to create comprehensive patient records across multiple providers to successfully track and identify emerging diseases or other threats to the public's health by 2014.

MO 11b: 70% of targeted sites with integrated EMR systems able to track defaulters, support referrals to other services, remote consultations, reminders and patient follow up by 2017.

MO 11c: Establishment of a National Health Data Repository by 2017.

MO 11d: 70% central level directorates, departments, divisions with access to central data repository by 2015.

Outputs:

- Interoperability of data collection systems achieved
- Connectivity of routine data collection systems from district to national level piloted and implemented

Measurable Outcome 12:

MO 12: 50% of districts with integrated data warehouses at facility, district, zonal and central levels by 2017.

Outputs:

- Operational data warehouses installed at zonal/ district level
- Central data repository installed and functional with multiple databases including National Database of public and private facilities and service availability, National

HIV Database, National Unique Patient Identification System Integrated with Patient demographics databases

This announcement is only for non-research activities supported by CDC. If research is proposed, the application will not be reviewed. For the definition of research, please see the CDC Web site at the following Internet address: http://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf

PART 2. FULL TEXT OF THE ANNOUNCEMENT

I. FUNDING OPPORTUNITY DESCRIPTION

Statutory Authority:

This program is authorized under Public Law 108-25 (the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003) [22 U.S.C. 7601, et seq.] and Public Law 110-293 (the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008).

Background:

The President's Emergency Plan for AIDS Relief (PEPFAR) has called for immediate, comprehensive and evidence based action to turn the tide of global HIV/AIDS. As called for by the PEPFAR Reauthorization Act of 2008, initiative goals over the period of 2009 through 2013 are to treat at least three million HIV infected people with effective combination anti-retroviral therapy (ART); care for twelve million HIV infected and affected persons, including five million orphans and vulnerable children; and prevent twelve million infections worldwide (3,12,12). To meet these goals and build sustainable local capacity, PEPFAR will support training of at least 140,000 new health care workers in HIV/AIDS prevention, treatment and care. The Emergency Plan *Five-Year Strategy* for the five year period, 2009 - 2014 is available at the following Internet address: http://www.pepfar.gov.

The overarching purpose of this FOA is to fund activities to prevent or control disease or injury and improve health, or to improve a public health program or service. Recipients may not use funds for research. Certain activities that may require human subjects review due to institutional requirements but that are generally considered *not* to constitute research (e.g., formative assessments, surveys, disease surveillance, program monitoring and evaluation, field evaluation of diagnostic tests, etc.) may be funded through this mechanism.

Purpose:

Under the leadership of the U.S. Global AIDS Coordinator, as part of the President's Emergency Plan, the U.S. Department of Health and Human Services' Centers for Disease Control and Prevention (HHS/CDC) works with host countries and other key partners to assess the needs of each country and design a customized program of assistance that fits within the host nation's strategic plan and partnership framework.

HHS/CDC focuses primarily on two or three major program areas in each country. Goals and priorities include the following:

- Achieving primary prevention of HIV infection through activities such as expanding confidential counseling and testing programs linked with evidence based behavioral change and building programs to reduce mother-to-child transmission;
- Improving the care and treatment of HIV/AIDS, sexually transmitted infections (STIs) and related opportunistic infections by improving STI management; enhancing laboratory diagnostic capacity and the care and treatment of opportunistic infections; interventions for intercurrent diseases impacting HIV infected patients including tuberculosis (TB); and initiating programs to provide anti-retroviral therapy (ART);
- Strengthening the capacity of countries to collect and use surveillance data and manage national HIV/AIDS programs by expanding HIV/STI/TB surveillance

programs and strengthening laboratory support for surveillance, diagnosis, treatment, disease monitoring and HIV screening for blood safety.

- Developing, validating and/or evaluating public health programs to inform, improve and target appropriate interventions, as related to the prevention, care and treatment of HIV/AIDS, TB and opportunistic infections.

In an effort to ensure maximum cost efficiencies and program effectiveness, HHS/CDC also supports coordination with and among partners and integration of activities that promote Global Health Initiative principles. As such, grantees may be requested to participate in programmatic activities that include the following activities:

- Implement a woman- and girl-centered approach;
- Increase impact through strategic coordination and integration;
- Strengthen and leverage key multilateral organizations, global health partnerships and private sector engagement;
- Encourage country ownership and invest in country-led plans;
- Build sustainability through investments in health systems;
- Improve metrics, monitoring and evaluation; and
- Promote research, development and innovation.

The purpose of this program is to strengthen health information systems at the facility level to improve the quality, integration, and effectiveness of service delivery across care points within Malawi in collaboration with USG implementing partners, including the Ministry of Health and relevant non-governmental organizations. Facility level refers to a facility where patients encounter health care workers and information is recorded at the point of care for service delivered. Such facilities would include health posts, dispensaries, maternities, health centers, community and rural hospitals, district hospitals, and central hospitals. This program will build solid foundations of national electronic HIS infrastructure of reliable data sources for both Health Management Information System national reporting as well as support a reliable National Health Data Repository for surveillance and epidemiological activities.

While these systems will focus on HIV, they will be developed using a lifecycle continuum of care approach and cover other acute and chronic illnesses. Support will be provided to build country owned, sustainable and innovative integrated information systems that strengthen data collection, management and use at facility, district and national levels, and decrease the workload of healthcare workers.

Such systems will:

a) Improve the capacity to accurately collect patient level demographic, diagnostic and service delivery information to assist in management of individual patient care, one patient one record;
b) Improve the capacity to utilize information at facility, district and country-level to assist with clinic and program management and to inform national and sub-national program and policy development; and
c) Improve capacity to exchange standardized health information among public and private sector health facilities, care providers and information systems, ensuring inclusion of the following activities:
    - Development of central demographic registration system with capability to generate and assign unique identification code to patients through connected EMR systems.
    - Integrate and strengthen routine health information systems at the facility level: HMIS, Integrated Disease Surveillance and Response, and vital registration.
    - Improve the capacity to integrate services and expand access to health services building upon impressive results and momentum of coordinated multidisciplinary care, tracking and follow-up of individual patients using a National Patient identifier.

Program Implementation

Recipient Activities:

Partners receiving HHS/CDC funding must place a clear emphasis on developing local indigenous capacity to deliver HIV/AIDS related services to the Malawian population

and must also coordinate with activities supported by Malawian, international or USG agencies to avoid duplication. Capacity-building plans should address systems, policy, organizational and workforce requirements for strengthening sustainable indigenous capacity to respond to the epidemic. Partners receiving HHS/CDC funding must collaborate across program areas whenever appropriate or necessary to improve service delivery.

The selected applicant(s) of these funds is responsible for activities in multiple program areas.

The grantee will implement activities both directly and, where applicable, through sub-grantees; the grantee will, however, retain overall financial and programmatic management under the oversight of HHS/CDC and the strategic direction of the Office of the U.S. Global AIDS Coordinator. The grantee must show measurable progressive reinforcement of the capacity of health facilities to respond to the national HIV epidemic as well as progress towards the sustainability of activities.

Applicants should describe activities in detail that reflect the policies and goals outlined in the *Five-Year Strategy* for the President's Emergency Plan and the Partnership Framework for Malawi. The grantee will produce an annual operational plan, which the U.S. Government Emergency Plan team on the ground in Malawi will review as part of the annual Emergency Plan review-and-approval process managed by the Office of the U.S. Global AIDS Coordinator.

The grantee may work on some of the activities listed below in the first year and in subsequent years, and then progressively add others from the list to achieve all of the Emergency Plan performance goals as cited in the previous section. HHS/CDC, under the guidance of the U.S. Global AIDS Coordinator, will approve funds for activities on an annual basis, based on availability of funding and USG priorities, and based on documented performance toward achieving Emergency Plan goals, as part of the annual

Emergency Plan for AIDS Relief Country Operational Plan review-and-approval process.

Grantee activities for this program are as follows:

Activity #1: Improve the capacity to accurately collect patient level demographic, diagnostic and service delivery information in real-time using a point-of-care EMR system and develop innovative approaches to improve the quality of care at service delivery points.

Activity #2: Install and maintain a sustainable and low-cost, point-of-care EMR system capable of supporting continuum of care of patients at target health facilities and their catchment areas.

Activity #3: Scale up comprehensively a facility-wide EMR system within clinic settings to cover broader health services and improve quality of health service delivery:

Task 3.1: Integration of services and departmental linkages for easy access to complete patient record at every point-of-care within facility.
Task 3.2: Clinical linkages within and across facilities to coordinate multidisciplinary patient care using a one-patient one-record approach.

Activity #4: Link facilities to community-based health services through innovative technologies.

Task 4.1: Conduct capacity building (orientation training) of healthcare providers and assistant statisticians.

Task 4.2: Improve capacity to utilize data for decision making at facility, district, zone and national level.

Task 4.3: Develop training modules on data quality assurance systems and analysis.

Task 4.4: Build capacity at zone, district and facility level to analyze data on burdens of disease and patient outcomes.

Task 4.5: Improve capacity to exchange standardized health information among public and private sector health facilities, care providers and information systems.

Task 4.6: Support the development of national integrated health information systems (HIS).

Task 4.7: Strengthen connectivity and data exchange systems.

Task 4.8: Establish linked data storage systems at district, zone and national levels.

In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring.

CDC Activities:

The selected applicant of this funding competition must comply with all HHS/CDC management requirements for meeting participation and progress and financial reporting for this cooperative agreement (See HHS/CDC Activities and Reporting sections below for details), and comply with all policy directives established by the Office of the U.S. Global AIDS Coordinator.

In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring. CDC activities for this program are as follows:

1. Organize an orientation meeting with the grantee to brief it on applicable U.S. Government, HHS, and Emergency Plan expectations, regulations and key management requirements, as well as report formats and contents. The orientation could include meetings with staff from HHS agencies and the Office of the U.S. Global AIDS Coordinator.

2. Review and make recommendations as necessary to the process used by the grantee to select key personnel and/or post-award subcontractors and/or subgrantees to be involved in the activities performed under this agreement, as part of the Emergency Plan for AIDS Relief Country Operational Plan review and approval process, managed by the Office of the U.S. Global AIDS Coordinator.
3. Review and make recommendations to the grantee's annual work plan and detailed budget, as part of the Emergency Plan for AIDS Relief Country Operational Plan review-and-approval process, managed by the Office of the U.S. Global AIDS Coordinator.
4. Review and make recommendations to the grantee's monitoring-and-evaluation plan, including for conduct of routine data quality assurance processes and periodic data quality assessments and for compliance with strategic information guidance established by the Office of the U.S. Global AIDS Coordinator.
5. Meet on a monthly basis with the grantee to assess monthly expenditures in relation to approved work plan and modify plans, as necessary.
6. Meet on a quarterly basis with the grantee to assess quarterly technical and financial progress reports and modify plans as necessary.
7. Meet on an annual basis with the grantee to review annual progress report for each U.S. Government Fiscal Year, to evaluate grantee's performance (including quality of products and achievement of project goals and objectives), and to review annual work plans and budgets for subsequent year, as part of the Emergency Plan for AIDS Relief review and approval process for Country Operational Plans, managed by the Office of the U.S. Global AIDS Coordinator.
8. Provide technical assistance, as mutually agreed upon, and revise annually during validation of the first and subsequent annual work plans. This could include expert technical assistance and targeted training activities in specialized areas, such as strategic information, project management, confidential counseling and testing, palliative care, treatment literacy, and adult-learning techniques.
9. Provide in-country administrative support to help grantee meet U.S. Government financial and reporting requirements approved by the Office of Management and Budget (OMB) under 0920-0428 (Public Health Service Form 5161).

10. 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, evaluate program implementation, manage and analyze data, conduct quality assurance, present and possibly publish program results and findings, and manage and track finances.
11. Provide consultation and scientific and technical assistance based on appropriate, HHS/CDC and Office of the U.S. Global AIDS Coordinator documents to promote the use of best practices known at the time.
12. Assist the grantee in developing and implementing quality-assurance criteria and procedures.
13. Facilitate in-country planning and review meetings for technical assistance activities.
14. Provide technical oversight for all activities under this award.
15. Provide ethical reviews, as necessary, for evaluation activities, including from HHS/CDC headquarters.
16. Supply the grantee with protocols for related evaluations.
17. Supporting coordination with Ministry of Health and National Health Data Standards Group to develop governance structures such as technical implementing team and high level advisory group to support partner to develop interoperable systems.
18. Collaborate with Ministry of Health and other stakeholders to support partner to review organizational and environmental determinants that relate to the information culture within district and facilities, the structure of HIS, the roles and responsibilities of different actors and available resources for HIS.
19. Facilitate and work with Ministry of Health Central level and District Health Management teams to transfer ownership of Electronic Medical Records to Ministry of Health.
20. Provide technical and program support for other key objectives falling under the CDC-supported cooperative work plan, including the implementation of program evaluation projects.

II. AWARD INFORMATION

Type of Award: Cooperative Agreement.

Award Mechanism: U2G – Global HIV/AIDS Non-Research Cooperative Agreements

Fiscal Year Funds: FY2012

Approximate Current Fiscal Year Funding: ***$5,000,000***

Approximate Total Project Period Funding: ***$37,000,000*** (This amount is an estimate, and is subject to availability of funds and includes direct costs for international organizations or direct and indirect costs for domestic grantees for all years.)

Approximate Number of Awards: 1-2

Approximate Average Award: ***$2,500,000*** (This amount is for the first 12 month budget period, and includes direct costs for international organizations or direct and indirect costs for domestic grantees.)

Floor of Individual Award Range: None

Budget Year 2 Floor amount: None

Budget Year 3 Floor amount: None

Budget Year 4 Floor amount: None

Budget Year 5 Floor amount: None

Ceiling of Individual Award Range: ***$5,000,000*** (This ceiling is for the first 12 month budget period and includes direct costs for international organizations or direct and indirect costs for domestic grantees.)

Budget Year 2 Ceiling amount: ***$8,000,000***

Budget Year 3 Ceiling amount: ***$8,000,000***

Budget Year 4 Ceiling amount: ***$8,000,000***

Budget Year 5 Ceiling amount: ***$8,000,000***

Anticipated Award Date: September 30, 2012

Budget Period Length: 12 months

Project Period Length: Five years

Throughout the project period, CDC'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. Ceiling amounts in budget years 02-05 include additional funds for anticipated scale-up of existing activities.

Note: Applicants should only apply for the first budget period funding taking into consideration the first budget period floor and the first budget period ceiling.

III. ELIGIBILITY INFORMATION

Eligible Applicants

Eligible applicants that can apply for this funding opportunity are listed below:

- Nonprofit with 501C3 IRS status (other than institution of higher education)
- Nonprofit without 501C3 IRS status (other than institution of higher education)
- For-profit organizations (other than small business)
- Small, minority, and women-owned businesses
- Universities
- Colleges
- Research institutions
- Hospitals
- Community-based organizations
- Faith-based organizations
- Federally recognized or state-recognized American Indian/Alaska Native tribal governments
- American Indian/Alaska native tribally designated organizations
- Alaska Native health corporations
- Urban Indian health organizations
- Tribal epidemiology centers
- State 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)

- Political subdivisions of States (in consultation with States)
- Non-domestic (non-U.S.) entity
- Other

A Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a bona fide agent of a state or local government, a legal, binding agreement from the state or local government as documentation of the status is required. Attach with "Other Attachment Forms" when submitting via www.grants.gov.

PEPFAR Local Partner definition:
A "local partner" may be an individual or sole proprietorship, an entity, or a joint venture or other arrangement. However, to be considered a local partner in a given country served by PEPFAR, the partner must meet the criteria under paragraph (1), (2), or (3) below within that country:

(1) an individual must be a citizen or lawfully admitted permanent resident of and have his/her principal place of business in the country served by the PEPFAR program with which the individual is or may become involved, and a sole proprietorship must be owned by such an individual; or

(2) an entity (e.g., a corporation or partnership): (a) must be incorporated or legally organized under the laws of, and have its principal place of business in, the country served by the PEPFAR program with which the entity is or may become involved; (b) must be at least 51% for FY 2009-10; 66% for FY 2011-12; and 75% for FY 2013 beneficially owned by individuals who are citizens or lawfully admitted permanent residents of that same country, per sub-paragraph (2)(a), or by other corporations, partnerships or other arrangements that are local partners under this paragraph or paragraph (3); (c) at least 51% for FY 2009-10; 66% for FY 2011-12; and 75% for FY 2013 of the entity's staff (senior, mid-level, support) must be citizens or

lawfully admitted permanent residents of that same country, per sub-paragraph (2)(a), and at least 51% for FY 2009-10; 66% for FY 2011-12; and 75% for FY 2013 of the entity's senior staff (i.e., managerial and professional personnel) must be citizens or lawfully admitted permanent residents of such country; and (d) where an entity has a Board of Directors, at least 51% of the members of the Board must also be citizens or lawfully admitted permanent residents of such country; or

(3) a joint venture, unincorporated association, consortium, or other arrangement in which at least 51% for FY 2009-10; 66% for FY 2011-12; and 75% for FY 2013 of the funding under the PEPFAR award is or will be provided to members who are local partners under the criteria in paragraphs (1) or (2) above, and a local partner is designated as the managing member of the organization.

Host government ministries (e.g., Ministry of Health), sub-units of government ministries, and parastatal organizations in the country served by the PEPFAR program are considered local partners. A parastatal organization is defined as a fully or partially government-owned or government-funded organization. Such enterprises may function through a board of directors, similar to private corporations. However, ultimate control over the board may rest with the government.

Note: To be considered a local partner, the applicant must submit supporting documentation demonstrating their organization meets one of the three criteria listed above.

Required Registrations

Registering your organization through www.Grants.gov, the official agency-wide E-grant website, is the first step in submitting an application online. Registration information is located on the "Get Registered" screen of www.Grants.gov. Please visit www.Grants.gov at least 30 days prior to submitting your application to familiarize yourself with the registration and submission processes. The "one-time" registration process will take three to five days to complete. However, the Grants.gov registration process also requires that

you register your organization with the Central Contractor Registry (CCR) and DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) which will require up to at least 4 weeks to complete registration in its entirety. The CCR registration can require an additional two weeks to complete. You are required to maintain a current registration in CCR. CCR registration must be renewed annually.

Central Contractor Registration and Universal Identifier Requirements

Foreign entities only: Prior to registering for CCR, please follow the Special Instructions for acquiring a Commerical and Governmental Entity (NCAGE) Code: http://www.dlis.dla.mil/Forms/Form_AC135.asp.

All applicant organizations **must obtain** a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an AOR should complete the **US D&B D-U-N-S Number Request Form** or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a DUNS number.

Additionally, all applicant organizations must register in the Central Contractor Registry (CCR) and maintain the registration with current information at all times during which it has an application under consideration for funding by CDC and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later. CCR is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the CCR internet site at **www.ccr.gov**.

If an award is granted, the grantee organization must notify potential sub-recipients that no organization may receive a subaward under the grant unless the organization has provided its DUNS number to the grantee organization.

Cost Sharing or Matching

Cost sharing or matching funds are not required for this program.

Maintenance of Effort

Maintenance of Effort is not required for this program.

Other

If a funding amount greater than the ceiling of the award range is requested, the application will be considered non-responsive and will not be entered into the review process. The applicant will be notified that the application did not meet the eligibility requirements.

Special Requirements:

- Late submissions will be considered non-responsive. See section "V.3. Submission Dates and Times" for more information on deadlines.
- If the total amount of appendices includes more than 80 pages, the application will not be considered for review. For this purpose, all appendices must have page numbers and must be clearly identified in the Table of Contents.

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 a grant, loan, or an award.

Funding under this award will be subject to preferences based on programmatic needs and in-country strategic priorities. Applicants meeting the criteria specified in "Section V. Application Review Information" will receive additional points beyond the possible total of 100.

IV. Application and Submission Information

Submission Dates and Times

This announcement is the definitive guide on LOI and application content, submission, and deadline. It supersedes information provided in the application instructions. If the application submission does not meet the deadline published herein, it will not be eligible for review and the applicant will be notified the application did not meet the submission requirements.

Application Deadline Date: ***April 16***, 2012 ON GRANTS.GOV, 11:59pm Eastern Standard Time.

Applicants must download the SF424 application package associated with this funding opportunity from Grants.gov. If access to the Internet is not available or if the applicant encounters difficulty in accessing the forms on-line, contact the HHS/CDC Procurement and Grant Office Technical Information Management Section (PGO TIMS) staff at (770) 488-2700 email:pgotim@cdc.gov Monday-Friday 7:00am – 4:30pm U.S. Eastern Standard Time for further instruction. CDC Telecommunications for the hearing impaired or disabled is available at: TTY 1-888-232-6348.

If the applicant encounters technical difficulties with Grants.gov, the applicant should contact Grants.gov Customer Service. The Grants.gov Contact Center is available 24 hours a day, 7 days a week, with the exception of all Federal Holidays. The Contact Center provides customer service to the applicant community. The extended hours will provide applicants support around the clock, ensuring the best possible customer service is received any time it's needed. You can reach the Grants.gov Support Center at 1-800-518-4726 or by email at support@grants.gov. Submissions sent by e-mail, fax, CD's or thumb drives of applications will not be accepted.

Content and Form of Application Submission

All applicants are required to sign and submit CDC Assurances and Certifications that can be found on the CDC Web site at the following Internet address: http://www.cdc.gov/od/pgo/funding/grants/foamain.shtm

Print, scan and upload as an additional attachment into the application package.

Letter of Intent (LOI):
A letter of intent is not applicable to this funding opportunity announcement.

A Project Abstract must be completed in the Grants.gov application forms. The Project Abstract must contain a summary of the proposed activity suitable for dissemination to the public. It should be a self-contained description of the project and should contain a statement of objectives and methods to be employed. It should be informative to other persons working in the same or related fields and insofar as possible understandable to a technically literate lay reader. This abstract must not include any proprietary/confidential information.

A Project Narrative must be submitted with the application forms. The project narrative must be uploaded in a PDF file format when submitting via Grants.gov. The narrative must be submitted in the following format:

- Maximum number of pages: 25 (If your narrative exceeds the page limit, only the first pages which are within the page limit will be reviewed.);
- Font size: 12 point, unreduced, Times New Roman;
- Double spaced;
- Page margin size: One inch;
- Number all narrative pages; not to exceed the maximum number of pages.

Note: The applicant should take into consideration the Criteria listed in "Section V. Application Review Information" when composing the project narrative.

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

- *Project Context and Background (Understanding and Need):* Describe the background and justify the need for the proposed project. Describe the current infrastructure system; targeted geographical area(s), if applicable; and identified gaps or shortcomings of the current health systems and AIDS control projects;
- *Project Strategy - Description and Methodologies:* Present a detailed operational plan for initiating and conducting the project. Clearly describe the applicant's technical approach/methods for implementing the proposed project. Describe the existence of, or plans to establish partnerships necessary to implement the project. Describe linkages, if appropriate, with programs funded by the U.S. Agency for International Development;
- *Project Goals and Objectives:* Include the goals of the project and its SMART objectives (specific, measurable, achievable, relevant, and time-bound). These need to be consistent with the expected targets of the Country/Regional Operational Plan and for this Cooperative Agreement program as provided in the "Purpose" Section at the beginning of this Announcement;
- *Work Plan and Description of Project Components and Activities:* Be sure to address each of the specific tasks listed in the activities section of this announcement. Clearly identify specific assigned responsibilities for all key professional personnel;
- *Project Outputs:* List the products that will result from the activities to be implemented in this project and that are relevant to the objectives specified in the previous section (e.g., conduct data quality assessment once a year);
- *Project Outcomes:* Include the expected effects of project activities in the target populations and/or organizations (e.g., increased adherence to ART) that are relevant to the project goals and objectives. This will represent the project's effectiveness;
- *Performance Indicators:* Include measures that will show progress in the achievement of project goals and objectives (e.g., percent of health care workers who graduated from a pre-service training at the end of the reporting period)

- *Timeline* (e.g., GANTT Chart); and
- *Management of Project Funds and Reporting*. Reporting should also address quarterly reports and PEPFAR Semi-Annual (SAPR) and Annual (APR) progress reports.

Project Budget Justification:

With staffing breakdown and justification, provide a line item budget and a narrative with justification for all requested costs ***for the first budget period***. Be sure to include, if any, in-kind support or other contributions provided by the national government and its donors as part of the total project, but for which the applicant is not requesting funding.

Budgets must be consistent with the purpose, objectives of the Emergency Plan and the program activities listed in this announcement and must include the following: line item breakdown and justification for all personnel, i.e., name, position title, annual salary, percentage of time and effort, and amount requested.

The project budget justification must be included as a separate attachment of the application, not to be counted in the narrative page limit.

The recommended guidance for completing a detailed budget justification can be found on the HHS/CDC Web site, at the following Internet address: http://www.cdc.gov/od/pgo/funding/budgetguide.htm.

For each contract, list the following: (1) name of proposed contractor; (2) breakdown and justification for estimated costs; (3) description and scope of activities the contractor will perform; (4) period of performance; (5) method of contractor selection (e.g., competitive solicitation); and (6) methods of accountability. Applicants should, to the greatest extent possible, employ transparent and open competitive processes to choose contractors;

Additional information may be included in the application appendices. The appendices will not be counted toward the narrative page limit. **The total amount of appendices must not exceed 80 pages and can only contain information related to the following**:

- ***Curricula vitae*** of current key staff who will work on the activity, including the Principal Investigator and All Senior Staff;
- ***Job descriptions*** of all proposed key positions to be created for the activity;
- ***Applicant's Corporate Capability Statement***;
- ***Letters of Support*** (5 letters maximum) from the MOH and existing users of systems in Malawi;
- ***Evidence of Legal Organizational Structure;***
- ***If applying as a Local Indigenous Partner***, provide documentation to self-certify the applicant meets the PEPFAR local partner definition listed in "Special Requirements," Part III. ELIGIBILITY INFORMATION section of the FOA.
- Background information on the organization, such as governance systems, organizational chart, organization history, Board composition, and previous work in Malawi.

Additional information submitted via Grants.gov should be uploaded in a PDF file format, and should be named accordingly. i.e.: Letters of support should be named "letters of support"

Additional requirements for additional documentation with the application are listed in Section VII. Award Administration Information, subsection entitled "Administrative and National Policy Requirements."

Funding Restrictions

Restrictions, which must be taken into account while writing the budget, are as follows:

- All plans for data collection from persons or personal records and for laboratory specimen collection and testing that are expected to result in public reports will require protocols for technical review and review of institutional human subjects

protection considerations by CDC. Funds for implementing these activities will be restricted until all necessary institutional protocol approvals have been obtained. Funds for preparatory activities (e.g., protocol development, training, equipment, reagents, and site preparation) may be provided prior to protocol approval. To facilitate the early availability of funding, the budget and narrative should clarify which activities are preparatory.

- 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 injection of any illegal drug.
- Recipients may only expend funds for reasonable program purposes, including personnel, travel, supplies, and services, such as contractual.
- Awardees may not generally use HHS/CDC/ATSDR funding for the purchase of furniture or equipment. Any such proposed spending must be identified in the budget.
- The direct and primary recipient in a cooperative agreement program must perform a substantial role in carrying out project objectives and not merely serve as a conduit for an award to another party or provider who is ineligible.
- Reimbursement of pre-award costs is not allowed.
- 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.)
- 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.

- Foreign grantees are subject to audit requirements specified in 45 CFR 74.26(d). A non-Federal audit is required, if during the grantees fiscal year, the grantee expended a total of $500,000.00 or more under one or more HHS awards (as a direct grantee and/or as a sub-grantee). The grantee either may have (1) A financial related audit (as defined in the Government Auditing Standards, GPO stock #020-000-00-265-4) of a particular award in accordance with Government Auditing Standards, in those case where the grantee receives awards under only one HHS program; or, if awards are received under multiple HHS programs, a financial related audit of all HHS awards in accordance with Government Auditing Standards; or (2) An audit that meets the requirements contained in OMB Circular A-133.
- A fiscal Grantee 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.
- ADS funding restrictions which require submission of protocols will be submitted within six months of notification of such requirement, but no later than the end of the first budget year. Requests for exceptions to these deadlines will need to be submitted in writing to the Grants Management Officer.

  All protocol approvals **should be obtained** no later than the end of the second budget period after the award or Continuation has been made**,** provided that the Grantee submits their protocol no later than the deadline.
- Recipients may not use funds for research.
- Recipients may not use funds for clinical care.

The 8% Rule

The President's Emergency Plan for AIDS Relief (PEPFAR) seeks to promote sustainability for programs through the development, use, and strengthening of local partnerships. The diversification of partners also ensures additional robust capacity at the local and national levels.

To achieve this goal, the Office of the Global AIDS Coordinator (OGAC) establishes an annual funding guideline for grants and cooperative agreement planning. Within each annual PEPFAR country budget, OGAC establishes a limit for the total amount of U.S. Government funding for HIV/AIDS activities provided to a single partner organization under all grant and cooperative agreements for that country. **For U.S. Government fiscal year (FY) 2012, the limit is no more than 8 percent of the country's FY 2012 PEPFAR program funding (excluding U.S. Government management and staffing costs), or $2 million, whichever is greater.** The total amount of funding to a partner organization includes any PEPFAR funding provided to the partner, whether directly as prime partner or indirectly as sub-grantee. In addition, subject to the exclusion for umbrella awards and drug/commodity costs discussed below, all funds provided to a prime partner, even if passed through to sub-partners, are applicable to the limit. PEPFAR funds provided to an organization under contracts are not applied to the 8 percent/$2 million single partner ceiling. Single-partner funding limits will be determined by PEPFAR after the submission of the COP(s). Exclusions from the 8 percent/$2 million single-partner ceiling are made for (a) umbrella awards, (b) commodity/drug costs, and (c) Government Ministries and parastatal organizations. A parastatal organization is defined as a fully or partially state-owned corporation or government agency. For umbrella awards, grants officers will determine whether an award is an umbrella for purposes of exception from the cap on an award-by-award basis. Grants or cooperative agreements in which the primary objective is for the organization to make sub-awards and at least 75 percent of the grant is used for sub-awards, with the remainder of the grant used for administrative expenses and technical assistance to sub-grantees, will be considered umbrella awards and, therefore, exempted from the cap. Agreements that merely include sub-grants as an activity in implementation of the award but do not meet these criteria will not be considered umbrella awards, and the full amount of the award will count against the cap. All commodity/drug costs will be excluded from partners' funding for the purpose of the cap. The remaining portion of awards, including all overhead/management costs, will be counted against the cap.

Applicants should be aware that evaluation of proposals will include an assessment of grant/cooperative agreement award amounts applicable to the applicant by U.S. Government fiscal year in the relevant country. An applicant whose grants or cooperative agreements have already met or exceeded the maximum, annual single-partner limit may submit an application in response to this RFA/APS/FOA. However, applicants whose total PEPFAR funding for this country in a U.S. Government fiscal year exceeds the 8 percent/$2 million single partner ceiling at the time of award decision will be ineligible to receive an award under this RFA/APS/FOA unless the U.S. Global AIDS Coordinator approves an exception to the cap. **Applicants must provide in their proposals the dollar value by U.S. Government fiscal year of current grants and cooperative agreements (including sub-grants and sub-agreements) financed by the Emergency Plan, which are for programs in the country(ies) covered by this RFA/APS/FOA.** For example, the proposal should state that the applicant has $_____ in FY **2012** grants and cooperative agreements (for as many fiscal years as applicable) in ***Malawi***. For additional information concerning this RFA/APS/FOA, please contact the Grants Officer for this RFA/APS/FOA.

Under PEPFAR, US Government agencies in Malawi, including CDC and USAID, coordinate to efficiently support implementation of Malawi's Health Sector Strategic Plan. The Office of the Global AIDS Coordinator has issued the following guidance to USG agencies in reference to the use of PEPFAR funds: "avoid duplication of resources programmed by different USG agencies to the same implementing organization for the same purposes (e.g., two USG agencies funding the same partner to provide the same assistance to orphans or antiretroviral treatment). This will minimize the burden on the partner as well as USG staff." As such, PEPFAR Malawi would like to avoid situations where different USG agencies program resources to the same implementing organization for the same purpose. This guidance and the USG partners and partner activities existing at the time will be considered when award selection(s) are made.

Prostitution and Related Activities

The U.S. Government is opposed to prostitution and related activities, which are inherently harmful and dehumanizing, and contribute to the phenomenon of trafficking in persons.

Any entity that receives, directly or indirectly, U.S. Government funds in connection with this document ("recipient") cannot use such U.S. Government funds to promote or advocate the legalization or practice of prostitution or sex trafficking. Nothing in the preceding sentence shall be construed to preclude the provision to individuals of palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides. A recipient that is otherwise eligible to receive funds in connection with this document to prevent, treat, or monitor HIV/AIDS shall not be required to endorse or utilize a multisectoral approach to combating HIV/AIDS, or to endorse, utilize, or participate in a prevention method or treatment program to which the recipient has a religious or moral objection. Any information provided by recipients about the use of condoms as part of projects or activities that are funded in connection with this document shall be medically accurate and shall include the public health benefits and failure rates of such use.

In addition, any recipient must have a policy explicitly opposing prostitution and sex trafficking. The preceding sentence shall not apply to any "exempt organizations" (defined as the Global Fund to Fight AIDS, Tuberculosis and Malaria, the World Health Organization and its six Regional Offices, the International AIDS Vaccine Initiative or to any United Nations agency).

The following definition applies for purposes of this clause:

- Sex trafficking means the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act. 22 U.S.C. § 7102(9).

All recipients must insert provisions implementing the applicable parts of this section, “Prostitution and Related Activities,” in all subagreements under this award. These provisions must be express terms and conditions of the subagreement, must acknowledge that compliance with this section, “Prostitution and Related Activities,” is a prerequisite to receipt and expenditure of U.S. government funds in connection with this document, and must acknowledge that any violation of the provisions shall be grounds for unilateral termination of the agreement prior to the end of its term. Recipients must agree that HHS may, at any reasonable time, inspect the documents and materials maintained or prepared by the recipient in the usual course of its operations that relate to the organization’s compliance with this section, “Prostitution and Related Activities.”

All prime recipients that receive U.S. Government funds (“prime recipients”) in connection with this document must certify compliance prior to actual receipt of such funds in a written statement that makes reference to this document (e.g., “[Prime recipient's name] certifies compliance with the section, ‘Prostitution and Related Activities.’”) addressed to the agency’s grants officer. Such certifications by prime recipients are prerequisites to the payment of any U.S. Government funds in connection with this document.

Recipients' compliance with this section, “Prostitution and Related Activities,” is an express term and condition of receiving U.S. Government funds in connection with this document, and any violation of it shall be grounds for unilateral termination by HHS of the agreement with HHS in connection with this document prior to the end of its term. The recipient shall refund to HHS the entire amount furnished in connection with this document in the event HHS determines the recipient has not complied with this section, “Prostitution and Related Activities.”

Any enforcement of this clause is subject to Alliance for Open Society International v. USAID, 05 Civ. 8209 (S.D.N.Y., orders filed on June 29, 2006 and August 8, 2008) (orders gaining preliminary injunction) for the term of the Orders.

The List of the members of GHC and InterAction is found at:
http://www.usaid.gov/business/business_opportunities/cib/pdf/GlobalHealthMemberlist.pdf

Additional Submission Requirements

Electronic Submission

Submit the application electronically by using the forms and instructions posted for this funding opportunity on www.Grants.gov. If access to the Internet is not available or if the applicant encounters difficulty in accessing the forms on-line, contact the HHS/CDC, Procurement and Grant Office, Technical Information Management Section (PGO TIMS) staff at (770) 488-2700 Email:pgotim@cdc.gov Monday-Friday 7:30am -4:30pm for further instruction.

Note: Application submission is not concluded until successful completion of the validation process.

After submission of your application package, applicants will receive a "submission receipt" email generated by Grants.gov. Grants.gov will then generate a second e-mail message to applicants which will either validate or reject their submitted application package. This validation process may take as long as two (2) business days. Applicants are strongly encouraged check the status of their application to ensure submission of their application package is complete and no submission errors exists. To guarantee that you comply with the application deadline published in the Funding Opportunity Announcement, applicants are also strongly encouraged to allocate additional days prior to the published deadline to file their application. Non-validated applications will not be accepted after the published application deadline date.

In the event that you do not receive a "validation" email within two (2) business days of application submission, please contact www.Grants.gov . Refer to the email message

generated at the time of application submission for instructions on how to track your application or the Application User Guide, Version 3.0 page 57.

Applications must be submitted electronically at www.Grants.gov. Electronic applications will be considered as having met the deadline if the application has been successfully made available to CDC for processing from Grants.gov on the deadline date. The application package can be downloaded from www.Grants.gov. Applicants can complete the application package off-line, and then upload and submit the application via the Grants.gov Web site. The applicant must submit all application attachments using a PDF file format when submitting via Grants.gov. Directions for creating PDF files can be found on the Grants.gov Web site. Use of file formats other than PDF may result in the file being unreadable by staff.

Applications submitted through Grants.gov (http://www.grants.gov), are electronically time/date stamped and assigned a tracking number. The AOR will receive an e-mail notice of receipt when Grants.gov receives the application. The tracking number serves to document submission and initiate the electronic validation process before the application is made available to CDC for processing.

If the applicant encounters technical difficulties with Grants.gov, the applicant should contact Grants.gov Customer Service. The Grants.gov Contact Center is available 24 hours a day, 7 days a week, with the exception of all Federal Holidays. The Contact Center provides customer service to the applicant community. The extended hours will provide applicants support around the clock, ensuring the best possible customer service is received any time it's needed. You can reach the Grants.gov Support Center at 1-800-518-4726 or by email at support@grants.gov. Submissions sent by e-mail, fax, CD's or thumb drives of applications will not be accepted.

Organizations that encounter technical difficulties in using www.Grants.gov to submit their application must attempt to overcome those difficulties by contacting the Grants.gov Support Center (1-800-518-4726, support@grants.gov). After consulting

with the Grants.gov Support Center, if the technical difficulties remain unresolved and electronic submission is not possible to meet the established deadline, organizations may submit a request prior to the application deadline by email to the GMO/GMS [See Section VII "Agency Contacts"], for permission to submit a paper application. An organization's request for permission must: (a) include the Grants.gov case number assigned to the inquiry, (b) describe the difficulties that prevented electronic submission and the efforts taken with the Grants.gov Support Center (c) be submitted to the GMO/GMS at least 3 calendar days prior to the application deadline. Paper applications submitted without prior approval will not be considered.

If a paper application is authorized, the applicant will receive instructions from PGO TIMS to submit the original and two hard copies of the application by mail or express delivery service.

If a paper application is authorized, the applicant will receive instructions from PGO TIMS to submit the original and two hard copies of the application by mail or express delivery service.

Intergovernmental Review

Executive Order 12372 does not apply to this program.

V. Application Review Information

Eligible applicants are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the funding opportunity announcement GH12-1250. Measures of effectiveness must relate to the performance goals stated in the "Purpose" section of this announcement. Measures of effectiveness must be objective, quantitative and measure the intended outcome of the proposed program. The measures of effectiveness must be included in the application and will be an element of the evaluation of the submitted application.

Criteria

Eligible applications will be evaluated against the following criteria:

Ability to Carry Out the Proposal (30 points):

Does the applicant demonstrate the local experience in Malawi and institutional capacity (both management and technical) to achieve the goals of the project with documented good governance practices? (10 points)

Does the applicant have the ability to coordinate and collaborate with existing Emergency Plan partners and other donors, including the Global Fund and other U.S. Government Departments and agencies involved in implementing the President's Emergency Plan, including the U.S. Agency for International Development? (10 points)

Is there evidence of leadership support and evidence of current or past efforts to enhance HIV prevention? Does the applicant have the capacity to reach rural and other underserved populations in Malawi? Does the organization have the ability to target audiences that frequently fall outside the reach of the traditional media, and in local languages? To what extent does the applicant provide letters of support? (10 points)

Technical and Programmatic Approach (20 points):

Does the application include an overall design strategy, including measurable time lines, clear monitoring and evaluation procedures, and specific activities for meeting the proposed objectives? (5 points) Does the applicant display knowledge of the strategy, principles and goals of the President's Emergency Plan, and are the proposed activities consistent with and pertinent to that strategy and those principles and goals? (5 points) Does the applicant describe activities that are evidence based, realistic, achievable, measurable and culturally appropriate to achieve the goals of the President's Emergency Plan? (5 points) Does the application propose to build on and complement the current national response in with evidence-based strategies designed to reach underserved populations and meet the goals of the President's Emergency Plan? Does the application include reasonable estimates of outcome targets? (For example, the numbers of sites to be

supported, number of clients the program will reach.) To what extent does the applicant propose to work with other organizations? (5 points) The reviewers will assess the feasibility of the applicant's plan to meet the target goals, whether the proposed use of funds is efficient, and the extent to which the specific methods described are sensitive to the local culture.

Capacity Building (15 points):

Does the applicant have a proven track record of building the capacity of indigenous organizations and individuals? Does the applicant have relevant experience in using participatory methods, and approaches, in project planning and implementation? Does the applicant describe an adequate and measurable plan to progressively build the capacity of local organizations and of target beneficiaries to respond to the epidemic? (10 points) If not a local indigenous organization, does the applicant articulate a clear exit strategy which will maximize the legacy of this project in the intervention communities? Does the capacity building plan clearly describe how it will contribute to a) improved quality and geographic coverage of service delivery to achieve the "3,12,12[1]" targets of the President's Emergency Plan, and b) (if not a local indigenous organization) an evolving role of the prime beneficiary with transfer of critical technical and management competence to local organizations/sites in support of a decentralized response? (5 points).

Monitoring and Evaluation (15 points):

Does the applicant demonstrate the local experience and capability to implement rigorous monitoring and evaluation of the project? (5 points) Does the applicant describe a system for reviewing and adjusting program activities based on monitoring information obtained by using innovative, participatory methods and standard approaches? Does the plan include indicators developed for each program milestone, and incorporated into the financial and programmatic reports? Are the indicators consistent with the President's

[1] The President's Emergency Plan for AIDS Relief (PEPFAR) has called for immediate, comprehensive and evidence based action to turn the tide of global HIV/AIDS. As called for by the PEPFAR Reauthorization Act of 2008, initiative goals over the period of 2009 through 2013 are to treat at least three million HIV infected people with effective combination anti-retroviral therapy (ART); care for twelve million HIV infected and affected persons, including five million orphans and vulnerable children; and prevent twelve million infections worldwide.

Emergency Plan Indicator Guide? Is the system able to generate financial and program reports to show disbursement of funds, and progress towards achieving the numerical objectives of the President's Emergency Plan? (10 points) Is the plan to measure outcomes of the intervention, and the manner in which they will be provided, adequate? Is the monitoring and evaluation plan consistent with the principles of the "Three Ones[2]? "Applicants must define specific output and outcome indicators must be defined in the proposal, and must have realistic targets in line with the targets addressed in the Activities section of this announcement.

Understanding of the Problem (10 points):

Does the applicant demonstrate a clear and concise understanding of the current national HIV/AIDS response and the cultural and political context relevant to the programmatic areas targeted? (5 points) Does the applicant display an understanding of the Five-Year Strategy and goals of the President's Emergency Plan? To what extent does the applicant justify the need for this program within the target community (5 points)?

Personnel (5 points):

Does the organization employ staff fluent in local languages who will work on this project? Are the staff roles clearly defined? As described, will the staff be sufficient to meet the goals of the proposed project? If not an indigenous organization, does the staff plan adequately involve local individuals and organizations? Are staff involved in this project qualified to perform the tasks described? Curricula vitae provided should include

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[2] The Emergency Plan supports the multi-sectoral national responses in host nations, adapting U.S. support to the individual needs and challenges of each nation where the Emergency Plan is at work. Countries and communities are at different stages of HIV/AIDS response and have unique drivers of HIV, distinctive social and cultural patterns (particularly with regard to the status of women), and different political and economic conditions. Effective interventions must be informed by local circumstances and coordinated with local efforts. In April 2004, OGAC, working with UNAIDS, the World Bank, and the U.K. Department for International Development (DfID), organized and co-chaired a major international conference in Washington for major donors and national partners to consider and adopt key principles for supporting coordinated country-driven action against HIV/AIDS. These principles became known as the "**Three Ones**": - **one national plan, one national coordinating authority, and one national monitoring and evaluation system** in each of the host countries in which organizations work. Rather than mandating that all contributors do the same things in the same ways, the Three Ones facilitate complementary and efficient action in support of host nations.

information that they are qualified in the following: management of HIV/AIDS prevention activities, especially confidential, voluntary counseling and testing; and the development of capacity building among and collaboration between Governmental and non-governmental partners.

Administration and Management (5 points):

Does the applicant provide a clear plan for the administration and management of the proposed activities, and to manage the resources of the program, prepare reports, monitor and evaluate activities, audit expenditures and produce collect and analyze performance data? Is the management structure for the project sufficient to ensure speedy implementation of the project? If appropriate, does the applicant have a proven track record in managing large laboratory budgets; running transparent and competitive procurement processes; supervising consultants and contractors; using subgrants or other systems of sharing resources with community based organizations, faith based organizations or smaller non-governmental organizations; and providing technical assistance in laboratory or pharmacy management? (5 points). The grantee must demonstrate an ability to submit quarterly reports in a timely manner to the HHS/CDC office.

Budget (SF 424A) and Budget Narrative (Reviewed, but not scored):

Is the itemized budget for conducting the project, along with justification, reasonable and consistent with stated objectives and planned program activities? Is the budget itemized, well justified and consistent with the goals of the President's Emergency Plan for AIDS Relief? If applicable, are there reasonable costs per client reached for both year one and later years of the project?

If the applicants requests indirect costs in the budget, a copy of the indirect cost rate agreement is required. If the indirect cost rate is a provisional rate, the agreement should be less than 12 months of age. The indirect cost rate agreement should be uploaded as a PDF file with “Other Attachment Forms” when submitting via Grants.gov.

The indirect cost rate agreement does not apply to international applicants.

The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address: http://www.cdc.gov/od/pgo/funding/budgetguide.htm.

Funding Preferences (30 points):

In addition to direct consideration of findings from the Objective Review Panel, funding under this award will be subject to several preferences based on programmatic needs and in-country strategic priorities. **Applicants meeting the criteria set forth in these funding preferences will receive additional points beyond the possible total of 100 as follows:**

- A funding preference of 15 points will be applied to local and indigenous organizations.
- A funding preference up to 15 points will be applied to applicants who are vested in existing EMR Health Information System development efforts in Malawi and who are scaling up EMR systems under sanction of the MOH in MOH facilities. Applicants will receive three points for each zone in the Malawi Health System where they have implemented EMR in at least one district or central level hospital, with a preference up to 15 points total for implementation in all five zones in Malawi.

Review and Selection Process

Review

All eligible applications will be initially reviewed for completeness by the Procurement and Grants Office (PGO) staff. In addition, eligible applications will be jointly reviewed for responsiveness by HHS/CDC Division of Global HIV/AIDS and PGO. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified the application did not meet eligibility and/or published submission requirements.

An objective review panel will evaluate complete and responsive applications according to the criteria listed in Section V. Application Review Information, subsection entitled "Criteria". The panel may include both U.S. Federal Government and non-U.S. Federal Government participants.

Selection

Applications will be funded in order by score and rank determined by the review panel unless funding preferences or other considerations stated in the FOA apply.

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

- Funding preference will provided to local indigenous organizations.
- Funding preference will be applied to applicants who are vested in existing EMR Health Information System development efforts in Malawi and who are scaling up EMR systems under sanction of the MOH in MOH facilities.

CDC will provide justification for any decision to fund out of rank order.

VI. AWARD ADMINISTRATION INFORMATION

Award Notices

Successful applicants will receive a Notice of Award (NoA) from the CDC Procurement and Grants Office. The NoA shall be the only binding, authorizing document between the recipient and CDC. The NoA will be signed by an authorized Grants Management Officer and e-mailed to the program director. A hard copy of the NoA will be mailed to the recipient fiscal officer identified in the application. Any application awarded in response to this FOA will be subject to the DUNS, CCR Registration and Transparency Act requirements.

Unsuccessful applicants will receive notification of the results of the application review by mail and/or e-mail.

Administrative and National Policy Requirements

Successful applicants must comply with the administrative requirements outlined in 45 Code of Federal Regulations (CFR) Part 74 or Part 92, as appropriate. 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-8 Public Health System Reporting Requirements
- AR-9 Paperwork Reduction Act Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-12 Lobbying Restrictions
- AR-14 Accounting System Requirements
- AR-15 Proof of Non-Profit Status
- AR-20 Conference Support
- AR-21 Small, Minority, and Women-Owned Business
- AR-23 States and Faith-Based Organizations
- AR-24 Health Insurance Portability and Accountability Act Requirements
- AR-25 Release and Sharing of Data
- AR-26 National Historic Preservation Act of 1966 (Public Law 89-665, 80 Stat. 915)
- AR-27 Conference Disclaimer and Use of Logos
- AR-29 Compliance with E.O. 13513 Federal Leadership on Reducing Text Messaging While Driving, October 1, 2009.
- AR-30 Information Letter 10-006. – Compliance with Section 508 of the Rehabilitation Act of 1973

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

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

Reporting

Federal Funding Accountability And Transparency Act Of 2006 (FFATA): Public Law 109-282, the Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), requires full disclosure of all entities and organizations receiving Federal funds including grants, contracts, loans and other assistance and payments through a single publicly accessible Web site, USASpending.gov. The Web site includes information on each Federal financial assistance award and contract over $25,000, including such information as:

1. The name of the entity receiving the award
2. The amount of the award
3. Information on the award including transaction type, funding agency, etc.
4. The location of the entity receiving the award
5. A unique identifier of the entity receiving the award; and
6. Names and compensation of highly-compensated officers (as applicable)

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients: 1) information on executive compensation when not already reported through the Central Contractor Registry; and 2) similar information on all subawards/subcontracts/consortiums over $25,000.

For the full text of the requirements under the Federal Funding Accountability and Transparency Act of 2006, please review the following website:
http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_bills&docid=f:s2590enr.txt.pdf

Each funded applicant must provide CDC with an annual Interim Progress Report submitted via www.grants.gov:

1. The interim progress report is due no less than 90 days before the end of the budget period. The Interim Progress Report will serve as the non-competing continuation application, and must contain the following elements:
    a. Standard Form ("SF") 424S Form.
    b. SF-424A Budget Information-Non-Construction Programs.
    c. Budget Narrative.
    d. Indirect Cost Rate Agreement
    e. Project Narrative.
    f. Activities and Objectives for the Current Budget Period;
    g. Interim Financial Status Report (SF-269) for the current budget period;
    h. Proposed Activity and Objectives for the New Budget Period Program;
    i. Budget;
    j. Measures of Effectiveness, including progress against the numerical goals of the President's Emergency Plan for AIDS Relief for **Malawi**; and
    k. Pipeline Analysis – Expenditures versus budget as identified in work plan, description of challenges, and explanation of unexpected pipeline (high or low).

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

2. Quarterly Progress Reports – In addition to the Interim Progress Report and the Final performance and Financial Status Reports, quarterly reports are required 90 days after submission of the Final Performance and Financial Status Reports, and, 90 days after submission of the Interim Progress Report. Reports shall include:
    a. Activities and Objectives for the current quarter;
    b. Financial progress for the current quarter; and
3. Financial Status Report (SF 269) - An annual progress report, due no more than 90 days after the end of the budget period.

4. Final performance and Financial Status Reports - Due no more than 90 days after the end of the project period.

*Disclaimer: As of February 1, 2011, current Financial Status Report (FSR) requirements will be obsolete. Existing practices will be updated to reflect changes for implementation of the new Federal Financial Reporting (FFR) requirements.

These reports must be submitted to the attention of the Grants Management Specialist listed in the Section VIII below entitled "Agency Contacts".

Human Subjects Restrictions

Data collection protocols required for release of human subjects funding restrictions must be submitted to the DGHA Science Office within 6 months of notification of such restrictions, but no later than the end of the first budget year. Requests for exceptions to these deadlines will need to be submitted in writing to the Grants Management Officer.

All protocol approvals should be obtained no later than the end of the subsequent budget period after the award or continuation has been made, provided that the Grantee has not been granted an exception to the deadlines specified above.

VII. AGENCY CONTACTS

CDC encourages inquiries concerning this announcement.

For **programmatic technical assistance**, contact:

Allison Keller, Project Officer
Department of Health and Human Services
Centers for Disease Control and Prevention
CDC, P.O Box 30016
Lilongwe 3 Malawi
Telephone: +2651775188
E-mail: akeller@mw.cdc.gov

For **financial, grants management, or budget assistance**, contact:

Kathy Raible, Grants Management Specialist
Department of Health and Human Services
CDC Procurement and Grants Office
2920 Brandywine Road, MS: K-75
Atlanta, GA 30341
Telephone: 770-488-2045
E-mail: kraible@cdc.gov

For assistance with **submission difficulties,** contact:

Grants.gov Contact Center Phone: 1-800-518-4726.
Hours of Operation: 24 hours a day, 7 days a week. Closed on Federal holidays.
Email: support@grants.gov

For **submission** questions, contact:

Technical Information Management Section
Department of Health and Human Services
CDC Procurement and Grants Office
2920 Brandywine Road, MS E-14
Atlanta, GA 30341
Telephone: 770-488-2700
Email: pgotim@cdc.gov

CDC Telecommunications for the hearing impaired or disabled is available at: TTY 1-888-232-6348.

VIII. Other Information

Amendments, Questions and Answers (Q&As)

Applicants must submit their Q&As, if any, to the Project Officer listed under the Agency Contacts Section of this announcement no later than 15 days after the publication date in www.grants.gov. All amendment and Q&As will be published in grants.gov following the approval of CDC. No amendments or Q&As will be accepted past the due date.

For additional information on reporting requirements, visit the CDC website at: http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm.

Other CDC funding opportunity announcements can be found at http://www.grants.gov.