



Guidance on the Definition and Use of the Global Health Programs Account

A Mandatory Reference for ADS Chapter 201

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The guidance contained within this document – including legal requirements, policy requirements, congressional directives, and USAID guidance – is subject to change. Please make sure that the correct version of the guidance is being followed.

Questions should be directed to USAID’s Bureau for Global Health, Office of Policy, Programs, and Planning (GH/P3) at GHPAccount@usaid.gov.

GUIDANCE ON THE DEFINITION AND USE OF THE GLOBAL HEALTH PROGRAMS ACCOUNT

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ACRONYMS

| | | | |
|-----------------|---|-----------------|--|
| AAPD | Acquisition and Assistance Policy Directive | PwP..... | Prevention with People Living with HIV/AIDS |
| AB | Abstinence, Be faithful | ROP..... | Regional Operational Plan |
| ADS | Automated Directives System | RLO..... | Resident Legal Officer |
| AFR..... | Bureau for Africa | SCH..... | Supply Chain for Health |
| ART | Antiretroviral Treatment | S/GAC | Office of the U.S. Global AIDS Coordinator |
| ARV | Antiretroviral Drug | STI..... | Sexually Transmitted Infections |
| CBP..... | Child Blindness Program | TAACS.... | Technical Advisors in AIDS and Child Survival |
| CCM..... | Country Coordinating Mechanism | TB..... | Tuberculosis |
| CDC | Centers for Disease Control and Prevention | UNAIDS | Joint United Nations Programme on HIV/AIDS |
| CF | Commodity Fund | UNICEF | United Nations Children’s Fund |
| CMAM.... | Community Management of Acute Malnutrition | U.S..... | United States |
| COP..... | Country Operational Plan | USAID..... | United States Agency for International Development |
| COR | Contracting Officer’s Representative | VCT..... | Voluntary HIV Counseling and Testing |
| CRB | Contract Review Board | WCF | Working Capital Fund |
| CS | Child Survival | WHO | World Health Organization |
| DCOF..... | Displaced Children and Orphans Fund | WSH | Water Supply, Sanitation, and Hygiene |
| DOD | Department of Defense | XDR | Extensively Drug-Resistant |
| DOTS | Directly Observed Treatment, Short Course | | |
| EPP | Expedited Procedures Package | | |
| EPP | Expedited Procedures Package | | |
| F | Office of U.S. Foreign Assistance Resources | | |
| FAA | Foreign Assistance Act | | |
| FFP..... | Food for Peace | | |
| FP/RH | Family Planning/Reproductive Health | | |
| FSL | Foreign Service Limited | | |
| FTF | Feed the Future | | |
| GC..... | Office of the General Counsel | | |
| GFATM... | Global Fund to Fight AIDS, Tuberculosis and Malaria | | |
| GH..... | Bureau for Global Health | | |
| GHI | Global Health Initiative | | |
| GHP | Global Health Programs | | |
| HIDN | Office of Health, Infectious Diseases and Nutrition | | |
| HRH..... | Human Resources for Health | | |
| HTC | HIV Testing and Counseling | | |
| IDU | Injecting Drug User | | |
| IPR | Implementation Procurement Reform | | |
| MARP | Most-at-Risk Population | | |
| MDR | Multidrug-Resistant | | |
| MNCH | Maternal, Newborn, and Child Health | | |
| MCH | Maternal and Child Health | | |
| MOH | Ministry of Health | | |
| MVA | Manual Vacuum Aspiration | | |
| NGO..... | Nongovernmental Organization | | |
| NSP..... | Needle and Syringe Exchange Program | | |
| NTD | Neglected Tropical Disease | | |
| NTP..... | National TB Program | | |
| OE | Operating Expenses | | |
| OHA..... | Office of HIV/AIDS | | |
| OI..... | Opportunistic Infection | | |
| OP | Operational Plan | | |
| ORS..... | Oral Rehydration Salts/Solution | | |
| OU..... | Operating Unit | | |
| OVC | Orphans and Vulnerable Children | | |
| PAC..... | Post-Abortion Care | | |
| PEP | Post-Exposure Prophylaxis | | |
| PEPFAR.. | U.S. President’s Emergency Plan for AIDS Relief | | |
| PHDP | Positive Health Dignity and Prevention | | |
| PIOET.... | Pandemic Influenza and Other Emerging Threats | | |
| PLWHA .. | People Living with HIV/AIDS | | |
| PLWHIV . | People Living with HIV/AIDS | | |
| PMI..... | President’s Malaria Initiative | | |
| PMTCT... | Prevention of Mother-to-Child Transmission | | |
| PPL | Bureau for Policy, Planning, and Learning | | |
| PR | Principal Recipient | | |
| PRH..... | Office of Population and Reproductive Health | | |
| PSC | Personal Service Contract | | |
| PSCMS.... | Partnership for Supply Chain Management | | |

GUIDANCE ON THE DEFINITION AND USE OF THE GLOBAL HEALTH PROGRAMS ACCOUNT

I. SUMMARY

A. Purpose of the Guidance

The purpose of the Guidance on the Definition and Use of the Global Health Programs Account (Guidance) is to (1) provide comprehensive guidance to U.S. Agency for International Development (USAID) operating units (OUs) on the definition and use of the Global Health Programs (GHP) Account (2) provide reference documents to management, technical, program, and budget officers; and (3) delineate special considerations for programming the GHP Account.

Unless otherwise noted, the legislative and policy requirements contained in this guidance apply to the GHP Account. If funds from other accounts (e.g., Development Assistance or Economic Support Fund [ESF]) are used by USAID for health activities, then such use of those funds should also comply with this guidance.

Managers, technical, and financial officers must do careful planning, monitoring, and reporting (see Automated Directives System [ADS] Series 200 for detailed guidance), follow parameters set forth under the direction of Congress by the Office of U.S. Foreign Assistance Resources (F) and (for HIV/AIDS assistance) the Office of the U.S. Global AIDS Coordinator (S/GAC), and they must adhere to congressional earmarks and, as appropriate, to directives and other Agency guidelines.

To ensure that legislative and policy guidelines are followed, F and USAID's Office of Budget and Resource Management (BRM) are responsible for the appropriate allocation and tracking of GHP Account funds. The Bureau for Global Health (GH), in collaboration with Regional Bureaus, the Office of the General Counsel, the Bureau for Legislative and Public Affairs, BRM and F, takes the lead in (1) communicating issues on the GHP Account to the appropriate parties and (2) responding to external inquiries from Congress and others on the planning, implementing, and monitoring of the GHP Account funds assigned to USAID.

Scope, Definitions, Authorities, and Prohibitions

This guidance describes the statutory requirements and policies USAID applies to global health programs. This guidance will assist USAID/Washington and Missions to implement programs that make the most of every dollar invested" to achieve the agency's goals. It is important that OUs ensure they are familiar with relevant technical and initiative strategy, as well as Agency-wide reform efforts, including USAID Forward and new project design guidance.

In mid-January 2014, Congress passed the Consolidated Appropriations Act, 2014 (H.R. 3547), and the President signed it into law (P.L. 113-76) on January 17, 2014. Funds must be used

within the parameters set by Congress and by the Department of State and USAID's **Joint Strategic Plan for Fiscal Years 2014-2017**¹, S/GAC (for HIV/AIDS assistance), and this Guidance. Funds must then be applied to global, regional, and country needs.

The Role of the Operating Unit (OU)

OUs should **provide** this Guidance to partners implementing activities with GHP Account funds, particularly as this Guidance affects their planning, implementation, and monitoring and evaluation. Contractors, recipients, and grantees should be given documentation requirements (i.e., work plan requirements and program reports) in the scope of work and program description for acquisition and assistance instruments. OUs should ensure that scopes of work and program descriptions for new awards reflect this Guidance in the definitions and appropriate use of funds for activities covered by GHP Account funds.

Operating units are required to implement activities that comply with the guidance for their discrete funding allocations and to report accordingly. Managers as well as technical and financial officers must ensure that GHP funds are used for the purpose for which they are appropriated by following the parameters set forth by F, and adhering to this Guidance for congressional earmarks and directives and corresponding budget categories.

Modifications to the 2014 Guidance

- **New section added to each budget category to highlight priority goals, and**
- **Layout update to increase ease of reference with regard to policy and legislative restrictions and to ensure formatting consistency across all sections.**

B. Points of Contact

Direct general questions concerning the overall guidance to the Director of the Bureau for Global Health's Office of Policy, Programs, and Planning (GH/P3) at GHPAccountGuidance@usaid.gov.

II. Relationship between program elements and budget categories

USAID remains steadfast in its commitment to enhancing the integration of quality interventions with the broader health and development programs of the U.S. government, country partners, multilateral organizations, and other donors. Responding to global health challenges is a shared responsibility that cannot be met by one nation alone. USAID is part of an extensive global health community including governments and global partners working together with the primary goals to end preventable child and maternal deaths by 2035, create an AIDS-free generation, and

¹ United States State Department. "FY 2014-2017 Department of State and USAID Strategic Plan." <http://www.state.gov/documents/organization/223997.pdf>.

protect communities from infectious diseases. These goals were created to be attainable and align with Millennium Development Goals 4, 5, and 6, as set by the United Nations. USAID's approach will continue to save millions of lives while fostering sustainable health care delivery systems that can address the full range of developing country health needs. The United States will remain unremitting in its challenge to the global community that it continue to focus on building healthier, stronger, and more self-sufficient nations in the developing world.

A. Appropriate Elements under the Foreign Assistance Framework

The Health Program Area goal is “to contribute to improvements in the health of people, especially women, children, and other vulnerable populations in countries of the developing world, through expansion of basic health services, including family planning (FP); strengthening national health systems, and addressing global issues and special concerns such as HIV/AIDS and other infectious diseases.” This goal is primarily supported by activities funded with GHP Account funds. OUs develop operational plans specific to local conditions. Such operational plans include activities that are grouped into Program Elements used for summarizing and reporting on programs. The Program Elements specific to the health program area are:

- 3.1.1 HIV/AIDS
- 3.1.2 Tuberculosis
- 3.1.3 Malaria
- 3.1.4 Pandemic Influenza and Other Emerging Threats
- 3.1.5 Other Public Health Threats
- 3.1.6 Maternal and Child Health
- 3.1.7 Family Planning and Reproductive Health
- 3.1.8 Water Supply and Sanitation
- 3.1.9 Nutrition

The GHP Account also includes funding for vulnerable children, which may be programmed in the following elements of the Social Services and Protection for Especially Vulnerable Populations program area:

- 3.3.2 Social Services

Program Elements are subject to adjustment annually, and are included in the Foreign Assistance Standardized Program Structure and Definitions, available at <http://www.state.gov/f/c24132.htm>.

B. Budget Categories

As a matter of policy, the Agency utilizes the following categories for all health programs regardless of funding source. The relationship among the elements in the Foreign Assistance Framework and the six budget categories set forth in the Appropriations Act is below. Once funding is allocated to an element, only F has the authority to transfer funding between elements and only after consultation with Congress².

² This delegation of authority was published on January 20, 2012 and provides that State/F, under the Deputy Secretary for Management and Resources, provides for “continuous supervision and general direction of foreign assistance and approving the programming of foreign assistance [and manages] the integrated State/USAID foreign assistance budget process, ensuring that

Budget Categories³:

- **Maternal and Child Health** (MCH), which includes the following activities identified by Congress: polio and the GAVI Alliance.
Associated Program Element:
 - **3.1.6 Maternal and Child Health**

- **Nutrition**, which includes the following activity identified by Congress: iodine deficiency disorder (associated with the USAID/United Nations Children’s Fund [UNICEF]/Iodine Deficiency Disorder program and micronutrients/Vitamin A supplementation).
Associated Program Element:
 - **3.1.9 Nutrition**

- **HIV/AIDS**, which includes the following activity identified by Congress: microbicides, **Global Fund (GF), Joint United Nations Programme on HIV/AIDS (UNAIDS)**
Associated Program Element:
 - **3.1.1 HIV/AIDS**

- **Other Infectious Diseases**, which includes the following activities identified by Congress: pandemic preparedness, malaria, tuberculosis (TB), and neglected diseases.
Associated Program Elements:
 - **3.1.2 Tuberculosis**
 - **3.1.3 Malaria**
 - **3.1.4 Pandemic Influenza and Other Emerging Threats**
 - **3.1.5 Other Public Health Threats**

- **Family Planning/Reproductive Health**. There are no specific activities identified by Congress within this budget category.
Associated Program Element:
 - **3.1.7 Family Planning and Reproductive Health**

- **Vulnerable Children**, which includes the following activity identified by Congress: blind children.
Associated Program Element:
 - **3.3.2 Social Services**

GHP funds must be used only where their direct impact on health objectives and their optimal use provide adequate justification. For a detailed explanation of direct impact and optimal use requirements, please see Chapter III, Section 1.B, below.

the budget reflects our foreign policy priorities and coordinating with the Bureau of Resource Management and USAID to present and defend an integrated budget to the Office of Management and Budget and Congress.”

³ Budget Categories are as outlined in the U.S. Senate, Committee on Appropriations Report for H.R. 2055. Available at http://www.thomas.gov/cgi-bin/cpquery/?&dbname=cp112&sid=cp112rZaDq&refer=&r_n=sr085.112&item=&&&sel=TOC_102853&.

III. Allowable uses of funds for agency programming purposes

This chapter describes legal requirements and congressional directives as well as USAID requirements.

All legal requirements are mandatory. Congressional directives in the health sector are also treated as mandatory.

USAID guidance is issued to ensure effective, evidence-based programming and to increase consistency and predictability of operations. This guidance has been determined based on decades of experience in health programming and represents the best understanding of leading technical experts. Although Operating Units (OUs) should generally follow these practices, there are situations where an OU may wish to deviate from them or adapt them to particular situations, especially when such deviations correspond to the guiding principles of direct impact and optimal use. Please see Chapter IV for the procedures for deviating from USAID requirements.

1. General

A. Legal requirements and congressional directives

a. Statutory Authorities

Statutory authorities for use of the GHP Account are as follows:

- **Authorization Authority:** The GHP Account (formerly the GH/CS Account) is authorized by the Foreign Assistance Act of 1961, as amended, including amendments made in the 2000 Global AIDS and Tuberculosis Relief Act, the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003 (the United States President's Emergency Plan for AIDS Relief (PEPFAR) Authorization) and the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis and Malaria Reauthorization Act of 2008 (the PEPFAR Reauthorization). The PEPFAR Stewardship and Oversight Act of 2013 - (Sec. 2) Amends the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 to extend through FY2018 requirements that: (1) the Inspectors General of the Department of State and the Broadcasting Board of Governors, of the Department of Health and Human Services (HHS), and of the U.S. Agency for International Development (USAID) jointly develop oversight plans to combat global HIV/AIDS.
- **Appropriation Authority:** Funds from the GHP Account are appropriated in the annual Appropriations Act for the Department of State, Foreign Operations, and Related Programs. In terms of the scope of the legislation, the FY 2014 Appropriations Act authorizes global health activities, such as "(1) child survival and maternal health programs; (2) immunization and oral rehydration programs; (3) other health, nutrition, and water and sanitation programs that directly address the needs of mothers and children

and related education programs; (4) assistance for children displaced or orphaned by causes other than AIDS; (5) programs for the prevention, treatment, and control of and research on HIV/AIDS, tuberculosis, polio, malaria, and other infectious diseases including neglected tropical diseases, and for assistance to communities severely affected by HIV/AIDS, including children infected or affected by AIDS; and (6) family planning/reproductive health (FP/RH). ”

- **Notwithstanding Authority:** The notwithstanding authority in Section 7058 of the FY 2014 Appropriations Act allows USAID to use funds for “child survival activities or disease programs including activities relating to research on, and the prevention, treatment, and control of HIV/AIDS “... notwithstanding any other provision of law except for the provisions under the heading “Global Health Programs” and the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003” as amended.⁴ In other words, when required for program efficiency, USAID may carry out activities regardless of country prohibitions or certain procurement regulations, personnel regulations, competitive process standards, or other restrictions that would otherwise prohibit or restrict programming. Please note that utilizing the notwithstanding authority to provide GHP Account assistance applies specifically to provisions of law or regulation relevant to that program. The notwithstanding authority, however, does *not* extend to FP/RH activities. If OUs have questions about certain provisions of law related to activities funded under the GHP, they must consult with the **Resident Legal Officer** or the Office of the General Counsel (GC) before providing GHP Account assistance.
- **How to obtain Notwithstanding Authority:** A decision to rely on notwithstanding authority provides USAID legal flexibility, but such a decision must be carefully coordinated with appropriate offices in accordance with Agency policy and, with respect to HIV/AIDS activities, PEPFAR policy. OUs must prepare a memo requesting approval from their Bureau’s Assistant Administrator and obtain clearances from the Assistant Administrator of the Bureau for Global Health (if the operating unit is not within GH) and others as deemed appropriate by the approving Assistant Administrator. The approving Assistant Administrator may request clearance from the Assistant General Counsel for their Bureau, the relevant Regional Bureau, and the relevant Regional Bureau’s Assistant General Counsel. F is responsible for tracking OUs that make use of the notwithstanding authority. A copy of all memos relying on this global health notwithstanding authority should be sent to GC/GH for information.

b. Legislative Restrictions Regarding Abortion and Involuntary Sterilization Applicable to All Health Activities⁵

It is important for USAID staff to:

- Understand these restrictions and how they could potentially impact activities;

⁴ Please note that there is also Notwithstanding Authority contained in the Foreign Assistance Act. The scope of this FAA NWS authority is more limited than the 7058 authority, however, so health programs usually rely on 7058.

⁵ See also Annex V

- Ensure that agreements contain the current relevant standard provisions; and
- Ensure that partners are aware of these restrictions.

A number of restrictions regarding abortion and involuntary sterilization are set forth in Section 104(f) of the FAA and the annual Appropriations Act. These restrictions apply to all activities funded under the annual Appropriations Act, including FP/RH, MCH, HIV/AIDS, malaria, and other health activities. These legislative restrictions are reflected in the mandatory standard provisions of all USAID awards. See ADS 303 for the latest provisions for assistance awards and AAPD (Acquisition and Assistance Policy Directive) 08–01 for the latest provisions for contracts.

These restrictions include the following:

Helms Amendment (1973): USAID funds may not be used to pay for the performance of abortion as a method of family planning or to motivate or coerce any person to practice abortions. Under the Leahy Amendment, the term “motivate,” as it relates to family planning assistance, shall not be construed to prohibit the provision, consistent with local law, of information or counseling about all pregnancy options.

Siljander Amendment (1981): USAID funds may not be used to lobby for or against abortion.

Biden Amendment (1981): USAID funds may not be used to pay for any biomedical research that relates in whole or in part, to methods of, or the performance of, abortions or involuntary sterilization as a means of family planning. Epidemiological or descriptive research to assess the incidence, extent, or consequences of abortions is not covered by the amendment and is therefore permitted.

Additional provision relating to voluntary sterilization (1985): USAID funds may not be used to pay for the performance of involuntary sterilizations as a method of family planning or to coerce or provide any financial incentive to any person to undergo sterilization.

These legislative restrictions are repeated in the HIV, MCH, and FP/RH sections of this document to reinforce their relevance within the health element technical areas to which they most often apply.

B. USAID Guidance

GHP funds must be used only where their direct impact on health objectives and their optimal use provide adequate justification.

- **“Direct impact”** means that the results (outcome/impact) of an activity can be linked and measured (using health elements and health indicators) against the purposes for which the funds supporting the activity were appropriated, as defined in the Appropriations Act and the relevant House, Senate, and conference Reports and under the health element goal: “To contribute to improvements in the health of people, especially women, children, and other vulnerable populations in countries of the developing world, through expansion of basic health services, including family planning; strengthening national health systems,

and addressing global issues and special concerns such as HIV/AIDS and other infectious diseases.” Thus, the goal of the activity must include a specific and measurable health impact.

In addition, the justification for use of GHP funds rests solely on the expected health impact of the activity. The impact of an activity on other goals, even those as valuable to development as poverty reduction, economic growth or education, is not relevant in justifying the use of GHP funds. While activities in other sectors are likely to have positive impact on health, the selection of GHP-funded activities cannot take into account any impact outside of health.

- **“Optimal use of funds”** refers to the prioritization of the funding of an activity in terms of its effectiveness and efficiency. Activities that produce the greatest impact on the objective should be funded with the GHP Account funds over those that will show a lesser impact. This requires comparing the expected result of a planned activity with the best alternative and should be accompanied by monitoring and reporting on the achievement of those results. Effectiveness implies that there has been or there is some current analysis to determine that the proposed use of funds will likely achieve the greatest possible impact with the funding made available. Indicators and measurements exist for the different child survival and health interventions that have been legitimized by the peer reviewed literature, including such illustrative journals as, the Lancet, the Journal of Pediatrics, the New England Journal of Medicine, BMJ, and others. Efficiency implies that the proposed activity can be implemented in a way that maximizes results relative to inputs. Country factors, such as the severity and magnitude of the problem, overall developmental needs, program stage or maturity, relative cost- and program-efficiency of the intervention, and host country and other donor resources, help determine optimal use.

The following sections further define allowable uses of funds in each specific category, organized by health program initiative (Protecting Communities from Other Infectious Diseases, Ending Preventable Maternal and Child Deaths, and Creating an AIDS Free Generation). If an operating unit needs clarification or has a question about whether an activity falls within these parameters, it may contact, as appropriate, the Office Director of GH/P3 (GHPAccount@usaid.gov), its Regional Bureau Technical Officer for Health, the relevant Technical Office/Element Lead, S/GAC, the Office of the General Counsel, or the cognizant Resident Legal Officer or the Investing in People lead in F. See Chapter IV for further details and procedures for deviations from the USAID requirements.

a. Compliance

As in all Agency policy and procedures guidance detailed in the Automated Directives System (ADS), this Global Health Programs Account guidance is mandatory policy that guides the Agency’s health program and operations. USAID employees are responsible for complying with

the policy directives and procedures identified in this ADS.⁶

To assess compliance and identify opportunities for shifts in programming to maximize alignment of health program plans, the Bureau for Global Health conducts annual reviews of the Health Implementation Plans submitted by all OUs receiving GHP funding or ESF funds designated for health during the Operational Plan (OP) process. The Health Implementation Plans are reviewed concurrently with the OP as a whole. GH, along with regional bureaus, reviews all HIPs to ensure that they are aligned with the Agency's health goals and priorities and are using the highest-impact interventions as outlined in this guidance. Any compliance issues will be submitted to F as an OP significant issue via the OP comment process. Additionally, countries designated as MCH priority countries may not obligate GHP funds until they receive final approval of their HIPs from USAID's Bureau for Global Health. This review will focus on programmatic decisions and will not change country or element allocations. This is in addition to the overall FOP approval. For a detailed explanation of the Health Implementation Plan, including review criteria, please see Annex 14 of the Operation Plan: *Annex 14: Supplementary Guidance for Global Health (USAID only)*.

Further, USAID/Washington will conduct quality compliance assessments at least every two years for countries programming TB funds.

GOAL 1: ENDING PREVENTABLE CHILD AND MATERNAL DEATH

On June 14 - 15, 2012, over 80 countries represented by governments and partners from the private sector, civil society, and faith-based organizations participated in the *Child Survival: Call to Action* – a high-level forum convened by the governments of Ethiopia, India and the United States, in collaboration with the United Nations Children's Fund (UNICEF). The Call to Action challenged the world to reduce child mortality to 20 or fewer child deaths per 1,000 live births in every country by 2035. Reaching this historic target will save an additional 45 million children's lives by 2035. The June conference resulted in the signing of the "A Promised Renewed" pledge by governments and civil society partners. The pledge is a commitment to sharpen national plans for maternal and child survival, monitor results, and focus greater attention on the most disadvantaged and vulnerable members of society. It has resulted in a renewed global effort to end preventable child deaths that we now call *Committing to Child Survival: A Promise Renewed*.

USAID has expanded this goal and is working to end preventable child and maternal deaths (EPCMD) in 24 countries that account for 70% of child and maternal deaths globally. This work takes a comprehensive, integrated approach to addressing maternal and child survival – combining USAID's health program elements of MCH, FP/RH, Malaria, and Nutrition among others. There are five strategic shifts in which the 24 priority countries are encouraged to adopt and incorporate into their strategic planning for maternal and child survival:

- Increase efforts in the countries that account for the largest share of under-five deaths;

⁶ USAID. ADS Chapter 501, Sections 1, 2, and 3.1.1. Available here: <http://www.usaid.gov/ads/policy/500/501>.

- Reach the most underserved populations;
- Target priority causes of mortality with innovation efforts and interventions poised to go to scale;
- Invest beyond health programs to include empowering women and supporting an enabling environment; and
- Create transparency and mutual accountability at all levels, with strengthened commitment to common metrics for tracking progress.

On June 25, 2014, USAID and the Governments of Ethiopia and India, in collaboration with UNICEF and the Bill and Melinda Gates Foundation, hosted a forum of leaders from government, civil society, private sector, and others to celebrate the progress made since the launch of A Promise Renewed, examine the challenges that remain, and chart a way forward. The forum coincided with several related meetings that, taken together, will mark a watershed moment on global mobilization to end preventable child and maternal deaths. The forum also included the release of the Acting on the Call report, which highlights the global progress since the 2012 Call to Action and the remaining challenges, cross-cutting interventions, and finally USAID's approach in target countries.

For more on USAID's work to end preventable child and maternal deaths and USAID's response to President Obama's call from his State of the Union address, see: <http://www.usaid.gov/what-we-do/global-health>.

2a. MATERNAL AND CHILD HEALTH: GENERAL

This budget category corresponds to the element 3.1.6 Maternal and Child Health.

America's legacy in maternal and child survival is a proud one; three decades ago, USAID and the UNICEF launched a "child survival revolution" aimed at reducing the number of deaths among young children in developing countries. As a result, countless efforts and advances in technology culminated in a reduction of child deaths from nearly 12 million in 1990 to 6.6 million in 2012. There has also been a 45 percent reduction in maternal deaths in less than 25 years; the global maternal mortality ratio declined from 380 to 210 deaths per 100,000 live births at an annual rate of reduction of 2.6 percent between 1990 and 2013.

Despite this progress, significant work remains in order to accelerate progress to end preventable child and maternal deaths: increase coverage of high-impact interventions, strengthen the health systems that support these interventions, and to address equity gaps that are bottlenecks to progress. USAID is a leader among international donors in creating and sustaining the conditions necessary for countries to accelerate reductions in maternal and child mortality, with the generational goal of ending preventable child and maternal deaths.

A. Health Program Element Guide

Addressing maternal, newborn, and child drivers of mortality represents the core of Maternal and Child Health (MCH) program and the primary use of MCH funds. An MCH program supports country-led strategies and high-impact interventions to accelerate reductions in maternal and

child mortality.

Key maternal and child health outcome indicators for MCH funds include, but are not limited to: Maternal Mortality Ratio (MMR); Under Five Mortality Rate (U5MR); Newborn Mortality Rate (NMR); increased number of antenatal care (ANC) visits by skilled providers; increased births attended by a skilled doctor, nurse, or midwife; increased number of women giving birth who receive a uterotonic in the third stage of labor; increased percent of infants aged 0-5 months who are exclusively breastfed; increased percentage of children who receive vaccinations; increased percent of children under five with suspected pneumonia receiving antibiotics; increased percentage of households with soap and water at a handwashing station; increased percent of population using an improved sanitation facility; increased percent of population using an improved water source.

B. Priorities and Goals

Programs in MCH will focus on the drivers of Maternal, Newborn, and Under-Five mortality, which contribute most substantially to saving lives. The LiST tool is particularly useful to identify priority interventions and has been used by many countries in strategic planning efforts (as a stand-alone tool or through its incorporation into other international strategic planning tools such as the OneHealth tool). LiST analyses for USAID's priority MCH countries can be found in the Acting of the Call report

(http://www.usaid.gov/sites/default/files/documents/1864/USAID_ActingOnTheCall_2014.pdf).

OUs are strongly encouraged to review applicable legislation and Agency guidelines before programming this Program Element.

a. Allowable Activities: Priority Approach

Increase the availability and use of proven life-saving interventions that address the major killers of mothers and children and improve their health status, including effective maternity care and management of obstetric complications; newborn care; routine immunization; polio eradication; safe water, sanitation, and hygiene; and treatment of life-threatening childhood illnesses.

The following comprise the primary categories for programming MCH funds:

- ***Birth Preparedness and Maternity Services:*** Support registration of pregnancies, infection prevention, self-care practices, education about need for a skilled birth attendant and recognition of complications, identification and discouragement of harmful practices such as inadequate provision of food during pregnancy, development of individualized birth plans, constructive engagement of partners and families in support of pregnant women, community based-financing of deliveries, and organization for transport. Support facility-based and outreach services, improving the quality and equitable coverage of antenatal, delivery and postpartum care services, including periodic evaluation of the progress of pregnancy, labor support, use of the partogram, clean delivery, and use of a uterotonic or active management of the third stage of labor.
- ***Treatment of Obstetric Complications and Disabilities:*** Support education about

recognition of complications during labor, delivery and post-partum and treatment of obstetric complications by women, their partners and the community, such as post-abortion care, management of hypertension, induction or augmentation of labor, assisted delivery, blood transfusion, surgery (including cesarean section, repair of lacerations, and management of postpartum hemorrhage); and management of pregnancy-related disabilities including case identification, medical management of chronic problems such as anemia, and surgical repair and postoperative rehabilitation of obstetric fistula.

- ***Newborn Care and Treatment:*** Improve care of male and female newborns by identifying and treating serious infections and other neonatal complications, including immediate care at birth (resuscitation, thermal stabilization, cord care, early and exclusive breastfeeding), the provision of routine essential care, special care for low birth weight and premature infants, increasing family and health worker recognition of newborn danger signs, and increasing access to appropriate treatment when required.
- ***Immunizations:*** Strengthen routine immunization service delivery, increase equitable coverage and contribute to disease control strategies when appropriate, including improvement of planning vaccine forecasting and management, cold chain and logistics, vaccine-preventable disease surveillance, lab capacity and quality, injection safety, and non-polio specific immunization campaigns.
- ***Polio:*** Support planning, implementation and monitoring of supplemental immunization activities for polio eradication; improve surveillance for acute flaccid paralysis (AFP) and laboratory capacity for diagnosis, analysis and reporting; improve communication and advocacy; support certification, containment, post-eradication and post-certification policy development; improve information collection and use for continuous program improvement.
- ***Treatment of Child Illness:*** Increase boys' and girls' access to and utilization of appropriate treatment for diarrhea, pneumonia, and other potentially life-threatening childhood illnesses, including improved recognition of serious illness, community and facility-based treatment of uncomplicated pneumonia, recognition and treatment of severe and complicated pneumonia, Oral Rehydration Therapy, including oral rehydration salts (ORS), introduction and evaluation of zinc treatment, antibiotic treatment of dysentery, and management of persistent diarrhea.
- ***Household Level Water, Sanitation, Hygiene, and Environment:*** Increase household-level actions to prevent disease regardless of the state of public service infrastructure, including point-of-use water treatment, safe water storage and handling, improved sanitation, including its marketing and promotion, promotion of hand washing with soap, reduction of exposure to indoor smoke from cooking and to local sources of environmental toxins such as lead.
- ***Health Governance and Finance (MCH):*** Promote sustainable improvements in health outcomes for men/boys and women/girls by reducing key governance and financing constraints to the achievement of multiple health element objectives and the health area

goal overall. These include activities that reduce corruption; increase equity; improve efficiency and increase financial protection (especially for underserved populations), including in the context of financing, organization of services, facility construction/renovation, pharmaceutical management, and human capacity development and management.

- ***Anti-Microbial Resistance (MCH)***: Slow the emergence of antimicrobial resistance in child and maternal health. Improving pharmaceutical management will increase access to and the correct use of quality essential medicines for MCH priorities. This sub-element will also strengthen quality assurance of essential medicines, community case management for childhood illnesses, and development of treatment guidelines for priority childhood diseases.
- ***Host Country Strategic Information Capacity (MCH)***: Establish and/or strengthen host country institutions' management information systems (MIS) and their development and use of tools and models to collect, analyze and disseminate a variety of information related to the program element. These may include, but are not limited to MIS for government ministries or other host country institutions, needs assessments, baseline studies, censuses and surveys, targeted evaluations, special studies, routine surveillance, data quality assessments, and operational research. This sub-element may also include developing and disseminating best practices and lessons learned and testing demonstration and/or pilot models. Related training, supplies, equipment, and non-USG personnel are included.

b. Allowable Activities: Illustrative Examples

Allowable activities using funds for maternal health include those that contribute directly to the element 3.1.6 Maternal and Child Health. USAID encourages programs to consider the full continuum of care from mothers to newborns to children in order to ensure healthy families. Maternal health and survival are not limited to but typically begin with a focus on adolescent girls and women of reproductive age. Maternal interventions are also critical to ensuring newborn survival and other interventions focus on the newborn directly as well as infants and children up to 5 years of age. Allowable activities for this category are those that make a “direct impact” on improving maternal, newborn, and/or infant/child health and reducing maternal, newborn, and infant/child mortality (excluding those activities targeted at the prevention and treatment of malaria). Specific interventions include the following:

- *Increasing access to and use of quality maternal and reproductive health interventions at community, family, and individual levels* through educational preparation for childbearing; encouraging healthy behaviors and access to related health services; and modification of services to become more available, culturally appropriate, and effective.
- *Strengthening preparation for birth*, including antenatal care; planning for a safe delivery attended by a skilled, professional attendant; promotion of safe hygiene and good nutritional practices; recognition and treatment of complications; and planning for transport.

- *Promoting safe delivery and postpartum care*, including monitoring of labor and delivery, safe delivery, provision of uterotonics, and elimination of disrespectful and medically harmful practices; recognition, referral, and treatment of maternal and newborn complications; postpartum and neonatal care that includes identification and treatment of complications; and postpartum and neonatal preventive care, including counseling on proper rest, nutrition, breastfeeding, hygiene, and child spacing. (Child spacing is limited to those activities in which child spacing efforts are conducted as a part of a larger maternal health and child survival effort with the objective of improving maternal health and reducing infant and child mortality; no contraceptives may be purchased with MCH funds – see below).
- *Improving management and treatment of life-threatening obstetrical and newborn complications including hemorrhage, preeclampsia/eclampsia, sepsis, and post-abortion complications* by providing information to family and community members on complications of pregnancy and provision of obstetric first aid; strengthening referral systems, including communication and emergency transport; and timely, high-quality care for obstetric and newborn complications, including medical and surgical care.
- *Providing care for women who suffer from long-term disabilities as a result of pregnancy and birth*, including identification, treatment, and rehabilitation of women with obstetric fistula, anemia, and other significant medical, surgical, and mental health problems. Activities for prevention and repair of fistula may include: 1) prevention, 2) repair, 3) reintegration, and 4) monitoring and evaluation and research. The fistula program should be funded with a combination of funds from both the MCH and FP elements. A typical distribution of funds within a comprehensive fistula program would include 70 percent of funding from the 3.1.6 Maternal and Child Health element and 30 percent of funding from the 3.1.7 Family Planning and Reproductive Health element. FP funds should be focused on community-based prevention and post-repair counseling, while MCH funds should focus on obstetric prevention, including labor monitoring, cesarean section, and immediate catheterization, as well as surgical repair. Activities to prevent the occurrence of fistula may include supporting family planning to prevent unintended pregnancies, delaying marriage and first birth, and increasing community awareness of danger signs in pregnancy and delivery.
- *Improving long-term capacity and systems of local public and private sector institutions to provide quality maternal health care*, including diagnostic assessments; improved health policies; development and updates of standard treatment guidelines; use of data for decision-making processes; quantification, costing, rational management, and procurement (except where prohibited – see below) of commodities and services; sustainable supply and demand side maternal health financial incentives, such as performance-based incentives, user fees and exemptions, vouchers, franchising, insurance, and conditional cash transfers; improved capacity and use of health sector personnel and financial resources; and enhanced monitoring, evaluation, quality improvement, and accountability systems.

- *Expanding access to essential newborn care* to all newborns regardless of where they are born through community- and facility-based approaches. Activities will include community mobilization, encouraging health behaviors among mothers and other caregivers, mainstreaming essential newborn care (breastfeeding, warmth, clean cord care, and chlorhexidine where appropriate) and pre-discharge check-up of newborns in all health facilities, and home-based postnatal visit by a trained health worker if the newborn is unable to receive care in health facilities.
- *Improving the quality of sick newborn care in health facilities* including resuscitation, care of premature newborns (antenatal corticosteroids and kangaroo mother care), and management of infections. Ensuring that the referral system between the community and the health facility is functional and that facilities are staffed and equipped to treat sick newborns.
- *Immunization Program Priorities.* Appropriate use of MCH funds for vaccination activities will prioritize immunization activities recommended by a country's national immunization program that are aligned with USAID's efforts to end preventable child deaths. For the current vaccination schedule database, see here: http://www.who.int/immunization_monitoring/data/en/. In the event of a disease outbreak, a targeted immunization program to curb the spread of disease – for example, in a defined community, geographical area, or during a particular season – may be warranted. These limited efforts should take into account critical factors impacting program success, such as the level of health care access, the cost of vaccines, and any issues with vaccine availability and storage. Any support for campaign activities should be done with a view to strengthen the country's routine immunization system. Missions should consult with GH staff prior to programming resources for outbreak activities. As new vaccines are available, GH will provide updated guidance on the effectiveness of any new vaccine and its ability to further USAID's goal to end preventable child deaths. Specific program activities may include:
 - *Strengthening immunization systems for the delivery of priority, cost-effective intervention for the prevention of childhood mortality from vaccine preventable disease and disability.* Appropriate use of MCH funds would focus attention on the strengthening of routine immunization systems as well as the activities needed for the introduction of new vaccines. Areas of concentration include surveillance (activities range from laboratory intensification of specific circulating genotypes to training of community surveillance officers in the identification and reporting of diseases and syndromes); cold chain and vaccine logistics and management; health worker training; communication and behavior change strategies to promote better adoption of vaccines; support for policy and procedure development as well as regulatory responsibilities; improved supervision and personnel management; enhanced decision-making based on better data and data analysis; improved planning and monitoring and evaluation; financing and budgeting for immunization services; strengthening outreach services and other modes of service access; development and application of appropriate immunization technologies; operations research into new delivery approaches; and, support for

countries to apply for external support through the Global Alliance for Vaccines and Immunisation (GAVI) that are aligned with USAID efforts to end preventable child deaths. To enhance the impact of immunization resources, MCH funds should stress the improvement of coverage in an equitable manner through strategies such as RED (Reaching Every District) and should emphasize the expansion of national programs to include all appropriate vaccines and can be effectively absorbed into the national routine immunization system.

- *Targeting the major killers of children under-five – pneumonia and diarrhea – with a package of promotive, preventive, and curative services that can be delivered in the community, through outreach services, and through health facilities*, including facility-based case management and the integrated community case management with oral rehydration salts/solution (ORS) **with zinc** and with antibiotics for pneumonia as well as counseling on breastfeeding; water sanitation and hygiene interventions (see Chapter III.2b); and routinely recommended immunizations (e.g., rotavirus, pneumococcal vaccines). For regions with malaria, MCH funds may yield greater impact by leveraging interventions for integrated community case management of diarrhea and pneumonia with malaria activities by community health workers and outreach activities planned with malaria funding.
- *Enhancing the quality, availability, and sustainability of key child health interventions* through activities that improve planning, organization, and management of health systems and services; increase promotion and delivery of key interventions by communities; build in-country capacity; promote private sector service delivery; improve the use of health sector financial resources; enhance the availability and appropriate use of health commodities; and promote positive health policies.
- *Ensuring integration of MCH programs with other key health programs* including FP, Malaria, and Nutrition programs. For further guidance on program integration, see Chapter III.11.A.
- *Improving Gender Relationships*: Interventions to transform traditional gender norms that limit women and men's access to maternal, newborn, and child health information and services, including community mobilization and behavior-change interventions seeking to (1) improve couple communication and increase constructive male involvement in maternal health counseling and decision-making, (2) prevent or mitigate gender-based violence as related to maternal health and (3) give women a greater role in care and care-seeking for themselves and their newborns and children.
- *Developing, testing, and replicating priority environmental health interventions to prevent the spread of childhood disease* due to environmental factors. Such interventions include improving household-level water supply and sanitation, promoting good hygiene behavior, and controlling vector-borne diseases that represent important threats to children's survival or health. For more comprehensive guidance regarding allowable water, sanitation, and hygiene activities, see Chapter III.2b.

- *Identifying, testing, and introducing and expanding new approaches and technologies to promote maternal and child health and survival* including diagnostics, therapeutics, and mobile technologies.

c. Examples of Integration of Maternal and Child Health Activities Across Various Health Elements

Maternal and child health program activities are set within the reproductive, maternal, newborn, and child health continuum of care. While a focus on specific MCH outcomes should be the main focus, there are many examples of successful integration on MCH programs with other health programs in the health sector, including:

- Joint support of integrated community case management with Malaria program funds.
- Integration of maternal health programs with infectious disease programs, including strengthening the maternal health platform for the rollout of Option B+ HIV/AIDS treatment protocols, strengthening the antenatal care platform for safe delivery and prevention, care, and treatment of infectious disease.
- Integration of MCH programs with FP programs, including post-partum family planning, family planning in post-abortion care settings, integration of family planning in immunization days or child health visits.
- Joint support with HIV/AIDS, Malaria, and FP funds to strengthening supply chain systems for improved access to MNCH commodities.
- Joint approaches to health systems strengthening at the national, regional, district, and community level.

d. Special Considerations for Maternal and Child Health: Other Funding Considerations

Earmarks and Directives

Most appropriations bills establish specific funding levels for portions of the MCH portfolio, including GAVI, polio, and water, sanitation and hygiene. Specific interventions include the following:

Polio Eradication Activities

USAID has joined forces with other international, bilateral, and national efforts to eradicate polio. Intensive efforts are underway to interrupt virus transmission in endemic countries, maintain immunity in polio-free areas, and establish or maintain certification-standard surveillance in all countries. Polio directive funds must be used to directly support polio eradication activities, the primary purpose of the funding. In addition, a governing principle of USAID's polio strategy is to contribute to the eradication of polio in a way that strengthens health systems, particularly for the delivery of polio vaccines. **Some OUs will receive MCH funds specifically directed for use addressing polio.** Accordingly, polio directive funds may be used to support the following polio eradication interventions:

- Developing effective partnerships to support polio eradication and vaccination (e.g., interagency coordinating committees (non-governmental organization (NGO) participation);
- Strengthening immunization delivery systems as a secondary impact of investments in polio eradication (e.g., cold chain, communications, supervision);
- Improving timely planning, implementation and monitoring of supplemental polio immunizations (e.g., micro-planning, training, independent monitors);
- Improving acute flaccid paralysis surveillance and response (e.g., facility and community-based surveillance and laboratory diagnosis, Expert Review Committees);
- Supporting certification, containment, and post-certification policy development; and
- Improving timely dissemination and use of information to continuously improve the quality of polio eradication activities.

Missions should contact the USAID Polio Eradication Coordinator [Ellyn Ogden \(eogden@usaid.gov\)](#) and the Office Director of GH/Office of Health Infectious Diseases and Nutrition (HIDN) to jointly determine how best to program polio funds to assure specific activities are allowable under the directive and to maximize the impact of these funds toward achieving the polio eradication goals.

GAVI

Funds for GAVI are managed by the Bureau of Global Health through a pooled funding mechanism. Since FY01, USAID has contributed over \$1 billion to GAVI. GAVI's vaccine procurement agent is UNICEF, which delivers vaccines largely funded by the GAVI Alliance to countries at special GAVI-negotiated prices. GAVI also provides a few different types of cash grants to countries. One is the Health Systems Support grant (HSS) which, when considered as a percentage of the total health expenditure, is relatively small. Another small cash grant is provided to countries when they introduce a new vaccine; this is called the Vaccine Introduction Grant. This is a very small cash grant per target child that is made available to countries when they are introducing a new vaccine into their immunization program through GAVI support. Countries apply for New Vaccine Support (NVS) and Health Systems Strengthening (HSS) support to GAVI through applications. Most GAVI vaccines require some small level of co-finance per dose in order to receive GAVI funds. This limited funding is NOT meant to cover all the costs associated with a new vaccine introduction; rather, it is meant to be combined with national and country level donor funding and technical assistance to help offset immediate vaccine introduction costs (training, materials revisions, etc.) and prepare the immunization program for the upcoming changes. For details on the vaccines GAVI provides to countries, see here: <http://www.gavialliance.org/country/>. Operating Units are not expected to purchase vaccines, but may provide technical assistance to the rollout of GAVI programs that align with USAID's efforts to end preventable child deaths. **Operating units are expected to plan any bilateral programs to support immunization in a manner that is complementary to GAVI investments in country.** GAVI does not have country-level presence, and therefore relies on GAVI Alliance partners (including USAID, the UK Department for International Development, Norway, AusAID, Canadian CIDA, Swedish SIDA, France, the European Commission, Germany, Japan, Korea, and other donors) as well as WHO, UNICEF and World Bank country offices to provide technical assistance and other support to immunization programs that administer GAVI and non-GAVI purchased vaccines.

Key vaccines that countries may have introduced or may be introducing through GAVI in the near future that align with USAID goals to end preventable child deaths include:

- Pneumococcal conjugate (a vaccine against most bacterial pneumonia) that should be used in an integrated manner with pneumonia prevention and treatment education; and
- Rotavirus vaccine (a vaccine against a particularly prevalent form of deadly diarrhea), which like the vaccine mentioned above, should be introduced with training on diarrhea prevention and treatment.

C. Legal Requirements and Congressional Directives

a. Authority

USAID's Maternal and Child Health Program is authorized by the FAA of 1961, as amended.

b. Legal and Policy Requirements

i. *Legislative Requirements*

Legislative Restrictions Regarding Abortion and Involuntary Sterilization Applicable to All Health Activities⁷

It is important for USAID staff to:

- Understand these restrictions and how they could potentially impact activities;
- Ensure that agreements contain the current relevant standard provisions; and
- Ensure that partners are aware of these restrictions.

There are a number of restrictions regarding abortion and involuntary sterilization set forth in Section 104(f) of the FAA and the annual Appropriations Act. These restrictions apply to all activities funded under the annual Appropriations Act, including FP/RH, MCH, HIV/AIDS, malaria, and other health activities. These legislative restrictions are reflected in the mandatory standard provisions of all USAID awards. See ADS 303 for the latest provisions for assistance awards and AAPD 08–01 for the latest provisions for contracts.

These restrictions include the following:

Helms Amendment (1973): USAID funds may not be used to pay for the performance of abortion as a method of family planning or to motivate or coerce any person to practice abortions. Under the Leahy Amendment, the term “motivate,” as it relates to FP assistance, shall not be construed to prohibit the provision, consistent with local law, of information or counseling about all pregnancy options.

⁷ See also Annex V.

Siljander Amendment (1981): USAID funds may not be used to lobby for or against abortion.

Biden Amendment (1981): USAID funds may not be used to pay for any biomedical research that relates in whole or in part, to methods of, or the performance of, abortions or involuntary sterilization as a means of family planning. Epidemiological or descriptive research to assess the incidence, extent, or consequences of abortions is not covered by the amendment and is therefore permitted.

Additional provision relating to voluntary sterilization (1985): USAID funds may not be used to pay for the performance of involuntary sterilizations as a method of FP, or to coerce or provide any financial incentive to any person to undergo sterilization.

2b. MATERNAL AND CHILD HEALTH: WATER SUPPLY, SANITATION, AND HYGIENE

This budget category corresponds to the Maternal and Child health sub-element 3.1.6.8, Household Level Water, Sanitation, Hygiene, and Environment.

A. Health Program Element Guide

Lack of access to safe water and sanitation services and poor hygiene behaviors have direct health implications as over 700,000 children under five die from diarrhea each year.⁸ Nearly 90 percent of diarrhea is attributed to unsafe drinking water, inadequate sanitation, and poor hygiene⁹, and is preventable by known interventions.^{10,11} In addition, an estimated 45 percent of child mortality is associated with malnutrition¹², which can be exacerbated by chronic exposure to fecal pathogens in the environment, even in the absence of clinical diarrhea.¹³

USAID's 2014 Water and Development Strategy makes Water for Health a strategic objective to improve health outcomes through the provision of sustainable WASH. Key outcomes for the Strategy are:

- Increasing first time and improved access to sustainable water supply;
- Increasing first time and improved access to sustainable sanitation; and
- Increasing adoption of key hygiene behaviors.

The Strategy aims for more equitable access through explicitly targeting the poorest and most vulnerable, and encourages operating units to increase the proportion of WASH investments focused on sanitation services in both urban and rural settings.

⁸ WHO Diarrhoeal Disease Fact Sheet No. 330. 2013

⁹ WHO Facts and figures: Water, sanitation and hygiene links to health. 2004.

¹⁰ Waddington H et al. *Water, sanitation and hygiene interventions to combat childhood diarrhoea in developing countries*. The International Initiative for Impact Evaluation (3ie), 2009

¹¹ Cairncross S et al. Water, sanitation and hygiene for the prevention of diarrhoea. *International Journal of Epidemiology*, 2010

¹² The Lancet, Maternal and Child Nutrition Series, [Volume 382, Issue 9904](#), Pages 1550 - 1551, 9 November 2013

¹³ Ngure et al. 2014. Water, sanitation, and hygiene (WASH), environmental enteropathy, nutrition, and early child development: making the links. *Annals of the New York Academy of Sciences*.

Because of the disease burden associated with unsafe WASH, GHP funds should be used for activities that have a primary goal of reducing the prevalence of diarrheal diseases in groups for which diarrhea and/or undernutrition is a significant public health concern, primarily children under five and people living with HIV/AIDS. Additional specific guidance on the use of HIV/AIDS funds for water, sanitation, and hygiene activities is found in the HIV/AIDS Preventive Care Guidance for adults¹⁴ and children.¹⁵

Some OUs will receive MCH funds specifically directed to be used to support WASH activities. GHP funds should be used for WASH activities that are consistent with the “optimal use of funds” guidance of Chapter III.1.B. This includes efficiency not only among the various eligible WASH activities but also in considering efficiency of WASH interventions with respect to other approaches to achieve an identified health objective, such as the reduction of child mortality or improved nutrition. Typically, GHP/MCH WASH funds would be used to fund components of an operating unit’s overall WASH activity in combination with the United States Department of Agriculture (DA) or other funds, exploiting the comparative advantage of health activities as appropriate.

B. Priorities and Goals

The GHI target for WASH activities is to halve the proportion of people without sustainable access to safe drinking water and basic sanitation by 2015, as identified by the Millennium Development Goals.

a. Allowable Activities: Priority Approach

Key health-focused WASH interventions are those that increase access to and effective use of improved drinking water supply and sanitation facilities; increase water quantity per capita available for drinking and hygiene; ensure microbiologically safe drinking water quality at the household level; and improve handwashing practices.

b. Allowable Activities: Illustrative Examples

Illustrative WASH activities eligible for GHP funding include:

- *Increasing access to improved drinking water supply*, i.e., the availability of at least 20 liters per person per day from an “improved” source within one kilometer of the user’s dwelling. An improved source is one that is likely to provide safe water, including household connections to a water supply distribution network, public standpipes (connected to networked systems, or from a community well or surface water source), boreholes, protected dug wells, protected springs, and rainwater collection. Access to improved sources can be rural or urban, and may be provided through utilities, community-based systems, self-supply, and/or other long-term and permanent systems.

¹⁴ <http://www.pepfar.gov/guidance/c19728.htm>

¹⁵ <http://www.pepfar.gov/guidance/c19729.htm>

Unprotected wells, unprotected springs, rivers or ponds, vendor-provided water, bottled water, and tanker truck water are not considered improved drinking water supplies.

- *Increasing access to improved sanitation at the household level.* Sanitation facilities are considered improved if they are private and if they separate human excreta from human contact through means including connection to a public sewer, connection to a septic system, pour-flush latrines, simple covered pit latrines, and ventilated improved pit latrines. Access provided can be rural or urban, and may be provided through community-managed simplified systems, utility-managed central network systems, or self-supply.
- *Increasing access includes supply side interventions* like sanitation marketing; product development for water storage, toilets and latrines; value chain analyses to improve household access to water and sanitation products and services, and facilitating access to financing along the supply chain for products and services down to the household level.
- *Increasing access to public or shared improved sanitation facilities in communal or institutional settings* (e.g., health clinics, schools, public markets) if they adequately separate human excreta from human contact and have a sustainable management and maintenance system in place, and include handwashing facilities.
- *Creating demand at the household and community level for improved WASH products and services* (e.g., Community-Led Total Sanitation or other participatory approaches), and use of both health and non-health channels in a strategic approach to address barriers and support adoption of improved hygiene behaviors (goal is improved behaviors, not just increased awareness or knowledge).
- *Supporting availability of, access to, and correct and consistent use of products to collect, transport, treat and properly store drinking water at the household level or at other point of use in order to ensure the safe microbiological quality of drinking water.*
- *Supporting availability of and access to handwashing stations and soap, and promoting correct and consistent adoption of proper handwashing with soap at critical times to break routes of fecal-oral transmission.*

c. Integrated WASH Activity Examples

Other WASH-related activities are also eligible for partial GHP funding. The appropriate proportion of GHP funding will be determined by the extent to which the activity contributes to the health-focused WASH interventions described above. OUs are encouraged to consult with USAID/Washington, as described in Chapter III.11.A of this guidance, to help determine the appropriate fraction of GHP funding. These activities include:

d. Examples of WASH Activities Integrated Across Various Health Elements

- *Improving the quality of existing drinking water supply or sanitation services, including*

increasing the number of hours of water access per day or quantity of water available, improving the quality of water delivered, improving the maintenance of systems and reducing the number of days out of service, or increasing the number of household connections for people who already have access to a communal improved source.

- *Provision of multiple-use water services* that include both domestic drinking water supply and water supply for productive use needs of the community (e.g., small-scale agriculture/gardening/animal husbandry).
- *Protection of surface water and groundwater quality of potable water supply system from direct contamination prior to distribution to users*, including installation of barriers to prevent access to the water point by animals, people, or other contamination sources, or water quality protection activities where there is a credible, direct, and specific cause-effect linkage between the contaminating activity and the degradation of an otherwise high-quality drinking water source.
- *Institutional strengthening and reform* related to drinking water supply, sanitation, and hygiene, including capacity building of government and other key actors and organizational development, water supply, and wastewater utility governance/corporatization and utility reform.
- *Water and sanitation infrastructure financing*, including increased access to credit, strengthening of domestic private capital markets, and facilitating support from domestic financial institutions.
- *Small-scale community-managed wastewater collection and/or treatment infrastructure*.

GHP/MCH WASH funds can be integrated with governance, education, environment, or nutrition funds in support of the comprehensive package of interventions. The appropriate proportion of GHP funding will be determined by the extent to which the activity contributes to the health-focused WASH interventions described above. OUs are encouraged to consult with USAID/Washington, as described in Chapter III.11.A of this guidance, to help determine the appropriate fraction of GHP funding.

C. Legal Requirements and Congressional Directives

a. Authority

USAID's WASH activities are authorized by the Foreign Assistance Act of 1961, as amended. This guidance applies to the use of GHP funds appropriated to USAID.

b. Legal and Policy Requirements

i. Legislative Requirements

The primary source of guidance for WASH programming is the Paul Simon Water for the Poor Act of 2005 [Public Law 109-121¹⁶]. As amended to the Foreign Assistance Act, this legislation defines access to safe water and sanitation for developing countries as a specific policy objective of U.S. foreign assistance programs. Each year USAID, with the U.S. Department of State, is required to report to the U.S. Congress on progress achieved towards the goals of the Act. In addition, annual appropriations bills provide legal authority for Agencies to spend funds and include directives on amounts of USAID funding to be spent on WASH.¹⁷

Typically, GHP/MCH water directive funds would be used to fund components of an operating unit's overall WASH activity in combination with DA or other funds, exploiting the comparative advantage of health activities as appropriate.

ii. Policy Requirements

Missions and Operating Units are required to specify how planned and/or ongoing MCH/WASH activities meet their FY 2014 653(a) GHP (as well as other accounts) water directive allocation in the annual Operational Plan (OP) and include the WASH Key Issue. If a Mission determines it cannot align with the Water and Development Strategy, it must articulate a clear rationale to the Water Sector Council. The Agency Notice dated May 7, 2013, describes the "exceptions" process for Missions proposing new programs or activities that are not fully aligned with the Strategy.

Eligible activities under the directive should be linked to the achievement of the USAID Water and Development Strategy's intermediate results (IRs). IRs and corresponding FACTS indicators are noted in the Strategy Implementation Field Guide.¹⁸ To the extent possible, the use of common FACTS indicators under 3.1.8 and 3.1.6.8 are encouraged. Operating Units are required to report on GHP (and other accounts) water directive results annually to F through performance plan and reports (PPRs).

Additional specific guidance on the use of HIV/AIDS funds for water, sanitation, and hygiene activities is found in the HIV/AIDS Preventive Care Guidance for adults¹⁹ and children.²⁰ OUs considering use of GHP funds to support WASH activities as part of other program elements should also consult with USAID/Washington as described in Chapter III.11.A of this guidance to help ensure that such programs maximize health impact and are consistent with any other programmatic guidance.

The following categories of water-related activities are not eligible for GHP funding, because they are not directly associated with health-focused WASH outcomes described earlier in this

¹⁶ United States Cong. An act to Authorize the 'Senator Paul Simon Water for the Poor Act of 2005, December 1, 2005. 109th Congress. Washington: GPO. Available at <http://www.gpo.gov/fdsys/pkg/PLAW-109publ121/pdf/PLAW-109publ121.pdf>

¹⁷ The term "water directive" is used to refer to the more commonly used "water earmark." Congress prefers the use of the term "directive," and we are asked by Policy, Planning, and Learning (PPL) and Budget and Resource Management (BRM) to help in bringing its consistent use into practice in the Agency.

¹⁸ http://www.usaid.gov/sites/default/files/documents/1865/Strategy_Implementation_Guide_web.pdf.

¹⁹ <http://www.pepfar.gov/reports/guidance/c19728.htm>.

²⁰ <http://www.pepfar.gov/reports/guidance/c19729.htm>.

section:

- *Water resources management*, including management of water and associated natural resources, analysis of hydrologic resources and ecosystems, development of allocation strategies among multiple competing human demands for water resources, and water-resources-management governance structures.
- *Water productivity*, including economic or productive uses of water in agriculture, industry, commerce, services, or energy resources.
- *Water security*, including the management of trans-boundary or shared water resources.

3. NUTRITION

This budget category corresponds to the element 3.1.9 Nutrition.

A. Health Program Element Guide

At least 170 million children under age five, and one of three women in the developing world, suffer from undernutrition. The overarching goal for the nutrition element is to reduce child undernutrition by 20 percent across assisted food-insecure countries in conjunction with Feed the Future (FTF), the U.S. Global Hunger and Food Security Initiative. FTF funds support investments that tackle the root causes of hunger, improve food security, and permanently reduce the number of chronically hungry and malnourished. These efforts should complement nutrition activities that focus on prevention of undernutrition through integrated services that provide evidence-based interventions such as nutrition education to improve maternal diets, nutrition during pregnancy, exclusive breastfeeding, and infant and young child feeding practices; diet quality and diversification through fortified or biofortified staple foods, specialized food products, and community gardens; and delivery of nutrition services including micronutrient supplementation and community management of acute malnutrition.

Nutrition activities are primarily directed to pregnant women and children under the age of five with emphasis on the “1,000-day” window from pregnancy to the child’s second birthday.

B. Priorities and Goals

In May 2014, USAID’s Nutrition Strategy for 2014 through 2025 was launched. The new strategy provides a framework for USAID to set its policies and programs with the objective of improving nutritional outcomes, saving lives, building resilience, increasing economic productivity, and advancing development. Following a multisectoral approach, the strategy intends to:

- Contribute to the reduction of child stunting by 20% wherever we work (GHI target);
- In Global Health, Feed The Future, and Food for Peace intervention areas, reduce the number of stunted children by 2 million over five years; and
- In humanitarian crises, maintain Global Acute Malnutrition below 15%.

a. Allowable Activities: Priority Approach

Nutrition **programming** includes activities related to Individual Prevention Programs; Population-Based Nutrition Service Delivery (including micronutrient supplementation); and Nutrition Enabling Environment and Capacity. Activities are primarily directed toward pregnant women and children under the age of five with emphasis on the 1,000-day window from pregnancy to the child's second birthday.

The following listing comprises the primary categories for programming nutrition funds:

- **Individual Prevention Programs:** Improve maternal and child nutrition through prevention programs targeted to women, children under two, and the very poor. These activities may include but are not limited to: community-based social and behavior change communication programs that focus on key nutrition practices related to maternal nutrition, exclusive and continued breastfeeding, and appropriate infant and young child feeding; promoting consumption of fortified or biofortified staple foods and specialized food products; partnering with public and private sectors to ensure food quality and supporting food-based and woman-centered programs that improve dietary quality for women and children.
- **Population-Based Nutrition Service Delivery (including micronutrient supplementation):** Support delivery of nutrition services through sustainable platforms. This sub-element includes but is not limited to micronutrient supplementation programs, community management of acute malnutrition, production of fortified foods, and strengthening nutrition service delivery systems as part of primary health care systems.
- **Nutrition Enabling Environment and Capacity:** Strengthen institutions, policies, and practices that support sustained, locally led improvements in nutrition. Advance the capacity of public and private institutions to assess, plan, design, implement, monitor, and evaluate nutrition programs. This sub-element includes supporting an enabling environment and capacity strengthening specifically targeted to women and the very poor.

b. Allowable Activities: Illustrative Examples

Individual Prevention Programs: Activities eligible for GHP nutrition funding aim to improve maternal and child nutrition through prevention programs targeted to women, children under five with an emphasis on those under two, and the very poor.

These activities may include but are not limited to:

- Developing, strengthening, and/or expanding community-based social and behavior change communication programs that focus on key nutrition practices related to maternal nutrition, exclusive and continued breastfeeding, and appropriate infant and young child feeding;

- Promoting consumption of fortified or biofortified staple foods and specialized food products;²¹
- Facilitating and partnering with public and private sectors to ensure food quality and supporting food-based and woman-centered programs that improve dietary quality for women and children;
- Increasing community and household production of staples and quality foods like fruits, green and yellow vegetables, and animal proteins through community gardens, and poultry and livestock farming;
- Targeting and empowering women so that new farming skills, access to inputs and services, and increases in income translate into improved health and well-being of their children;
- Incorporating nutrition outreach and behavior change activities to ensure increases in both household production and income lead to the purchase and consumption of higher quality foods and feeding of young children;
- Working at national and local scale to improve fortification techniques and access to fortified foods in areas with significant micronutrient deficiencies;
- Analyzing effects of agriculture and food security policies and programs on nutritional status of mothers and children; and
- Developing, testing, and replicating priority environmental health interventions to prevent the spread of pathogens causing gastrointestinal diseases that contribute to undernutrition,.

Population-based nutrition service delivery including micronutrient supplementation: Food-based approaches and prevention programs should be coupled with targeted micronutrient supplementation and quality community-based nutrition services.

These activities may include but are not limited to:

- Strengthening nutrition service delivery systems as part of primary health care systems.
- Enhancing vitamin A supplementation for children 6–59 months and iron folic acid supplementation for pregnant women and children as part of anemia reduction packages (that include malaria prevention and treatment and deworming).
- Planning, budgeting, and cost analysis of micronutrient programs and service delivery and logistics.
- Supporting delivery of nutrition services through sustainable platforms, including the introduction and scale-up of community management of acute malnutrition (CMAM). This includes the timely detection and referral of cases with acute malnutrition in the community, outpatient treatment of those without medical complications, and inpatient treatment of those without appetite or with medical complications; improving the capacity of facilities as well as of communities to ensure that referrals of the most serious cases are handled effectively, building upon the CMAM platform to promoting

²¹ Any specialized food products procured should be of appropriate nutrient content for the intended consumers. This varies across populations, contexts, and age groups. Any questions pertaining to the appropriateness of specific food products should be directed to GH/HIDN/NUT.

participation and behavior change for long-term solutions to inadequate care and feeding practices, food insecurity, and other threats to public health.

- Facilitating and supporting the production of fortified foods through national and regional platforms. *This sub-element does not include zinc as treatment for diarrhea (included in 3.1.6.7).*

Nutrition enabling environment and capacity building: For prevention and service delivery activities to be effective and sustainable, adequate local capacity and an enabling environment are essential. Nutrition funding may support *galvanizing government and community commitment and capacity to address nutrition, especially of women, young children, and the very poor.*

These activities may include but are not limited to:

- Strengthening institutions, policies, and practices that support sustained, locally led improvements in nutrition;
- Advancing the capacity of public and private institutions to assess, plan, design, implement, monitor, and evaluate nutrition programs;
- Promoting high-level commitment, including financial and political resources, to nutrition at the national and local levels;
- Contributing to the development of sound nutrition policies or strengthening existing policies with clear multisectoral linkages; and
- Strengthening the translation of food and nutrition policies into action and implementation.

Gender activities are also an important component of nutrition programming and activities might address men's influence on women and children's nutritional status (i.e., customs such as the eldest male eating first, and decision-making regarding food expenditures and access to supplements, women's participation, and health care). Further, activities may target changing gender norms to involve men as responsible fathers for nutritional status improvement.

c. Integration of Nutrition Activities Within Other Health Program Element Activities

Nutrition activities are also closely linked with the maternal and child health element and the family planning and reproductive health element. Specific areas of cross element collaboration include reduction in maternal anemia as a contributing factor to reducing maternal mortality; increasing exclusive breast-feeding as a contributing factor to birth spacing and maternal mortality reduction; reducing child undernutrition as a significant contributor to overall child mortality; and the use of MCH and FP/RH funds to invest in integrating care across family planning, nutrition, and infectious diseases in particular as well as all health program areas.

C. Legal Requirements and Congressional Directives

a. Authority

USAID's Nutrition Program is authorized by the FAA of 1961, as amended.

b. Legal and Policy Requirements

i. Policy Requirements

USAID Nutrition Programs are aligned with the Feed the Future Initiative policy requirements; and in particular, contribute to the initiatives' *Improved Nutritional Status* Objective.

4. FAMILY PLANNING AND REPRODUCTIVE HEALTH

This budget category corresponds to the element 3.1.7 Family Planning and Reproductive Health (FP/RH).

A. Health Program Element Guide

USAID is a leader among international donors in creating and sustaining the conditions necessary for individuals to access safe, voluntary, and high quality family planning information and services. Consensus-based agreements negotiated at international conferences have highlighted the strong linkages among women's position in society, small family size, and women and children's health and well-being. As these agreements reaffirmed, family planning is a key component of reproductive health care.

Family planning represents the core of USAID's Family Planning and Reproductive Health (FP/RH) program and the primary use of FP/RH funds. An FP program should serve the objective of creating the necessary conditions for women and men to have the number and spacing of children that they desire. Such a program must be free of coercion of any kind and should offer assistance appropriate to low-resource settings to help individuals and couples attain their ideal family size.

Key family planning and reproductive health outcomes for FP/RH funds include, but are not limited to: correct, voluntary use of contraceptive methods; healthy **timing and** spacing of births; reduction of unmet need and unintended pregnancy; increased age at sexual debut and age at birth of first child; and reduced reliance on abortion as a method of fertility regulation.

USAID aims to advance and support voluntary family planning/reproductive health programs worldwide, and enable countries to meet the family planning needs of their people. This programming is guided by the following technical and cross-cutting priorities:

- **Healthy Timing and Spacing of Pregnancies**
- **Community-based Approaches**
- **Contraceptive Security**
- **Long-Acting Reversible and Permanent Methods**
- **FP/MCH integration**
- **FP/HIV integration**
- **Youth**

- Gender
- Poverty & Equity

B. Priorities and Goals

FP/RH programming aims to prevent 54 million unintended pregnancies, increase modern contraceptive prevalence by up to two percentage points each year, and reduce first births to women under 18 by 15 percent. Additional performance measures include: increasing the percent of births spaced 3 or more years apart; reducing the percent of births order five or higher; and increasing the percent of demand satisfied through modern contraception.

Family planning and reproductive health programming contributes to USAID initiatives of Ending Preventable Child and Maternal Deaths and Creating an AIDS-Free Generation. By expanding access to and use of voluntary family planning information and services, encouraging healthy timing and spacing of pregnancies, and providing post-abortion care, family planning can significantly contribute to a reduction in child and maternal deaths. In addition, by ensuring that women living with HIV who desire to have children have access to safe pregnancy counseling in order to protect their own health and reduce the risk of HIV transmission to their partners and children, family planning can significantly contribute to the prevention of mother-to-child transmission and the creation of an AIDS-Free Generation.

In addition, USAID is committed to global goals in the areas of family planning and reproductive health, including Family Planning 2020 (FP2020). FP2020 works with governments, civil society, multi-lateral organizations, donors, the private sector, and the research and development community to enable 120 million more women and girls to use contraceptives by 2020. In addition, USAID helped to launch the Alliance for Reproductive, Maternal and Newborn Health, a donor partnership that seeks to accelerate progress in achieving Millennium Development Goals four and five, which focus on improving maternal and child health outcomes. The partnership seeks to promote cost-effective use of resources, leverage resources to fill funding gaps, reduce duplication, and encourage sharing of best practices among partners.

a. Allowable Activities: Priority Approach

The following listing comprises the primary categories for programming FP/RH funds:

- ***Service Delivery:*** Expand sustainable provision of family planning services in clinical and non-clinical programs including those in the public, private, NGO, and private voluntary organization (PVO) sectors, and at the community level.
- ***Communication:*** Increase awareness of the availability of services, including through mass media, community mobilization, outreach, and/or national campaigns.
- ***Policy Analysis and System Strengthening:*** Create an enabling environment for effective FP/RH programs, including policy interventions (advocacy, dialogue, analysis, planning, finance, implementation, multi-sectoral engagement, attention to equity).

- **Health Governance and Finance:** Promote sustainable improvements in health outcomes by reducing key governance and financing constraints to the achievement of multiple health element objectives and the health area goal overall.
- **Host Country Strategic Information Capacity:** Establish and/or strengthen host country institutions' management information systems and their development and use of tools and models to collect, analyze and disseminate a variety of information related to the program element.

b. Allowable Activities: Illustrative Examples

The vast majority of FP/RH-designated funds should be used to support family planning activities, primarily through family planning information and services, including integration into other reproductive health or general health activities. USAID's approach to family planning includes the following activities:

- **Social and behavior change communication (SBCC)** is essential in creating informed demand for family planning products and services; improving the quality of client-provider interactions; and shaping the social norms that influence reproductive health behaviors. Activities in this area include strategically-designed mass media, community-level activities, and interpersonal communication, with attention to both individual and social barriers to behavior change. Priorities in this area include: consistent application of best practices, including audience segmentation, attention to relevant behavioral barriers, and explicit focus on social and normative factors; and strengthening the capacity of local organizations in SBCC design, implementation, and evaluation. There is a critical need for operations research and impact evaluations around SBCC for FP/RH, and for dissemination and application of the findings of such research. Programs should also prioritize innovation in behavior change research and programming, including exploration and application of proven and emergent practices from disciplines such as marketing, behavioral economics, and human-centered design.
- **Building a strong family planning workforce** by strengthening the policies and approaches needed to: implement task sharing, the introduction of new cadres and dedicated workers to expand the FP workforce; support pre-service, in-service and continuous professional development systems—this includes addressing FP-specific content as well as topics relevant to the provision of FP and other health services overall such as leadership and management, promoting gender equality & sensitivity of the workforce, and training providers to identify signs of gender-based violence; promote gender equality and women's empowerment within the FP and general health workforce; advance supply chain management workforce professionalization; strengthen human resources management systems for the health workforce. As noted, many activities to strengthen the FP workforce actually benefit the health workforce overall. Activities that benefit several health sectors (i.e., HIV/AIDS, MCH, FP, etc.) ideally, should be funded by each sector in proportion to the benefits to that sector. This can be achieved by partnering, pooling or leveraging funds from other sectors, agencies and donors, both private and public.

- *Improving the quality and effectiveness of counseling and service delivery approaches* through the provision of a broad range of contraceptive information, products and services in ways that help clients choose and correctly use the contraceptives that meet their lifestyle and reproductive needs for delaying, spacing or limiting. Illustrative priorities include support for multiple approaches to improving method choice, such as mobile outreach, task sharing, community-based distribution, and post-partum family planning; support for monitoring and data, including information about quality, method mix trends, and procurement; and implementation of best practices.
- *Supporting the purchase and supply of contraceptives and related materials*, including the purchase of contraceptive commodities and related equipment, commodity and logistics support, and the procurement of health commodities through local systems (consistent with President's Malaria Initiative and Office of Population and Reproductive Health guidance on the procurement of key, life-saving commodities, March 2012; <http://forward.inside.usaid.gov/content/guidance-and-policy-1>). Supply systems should ensure the long-term availability for clients of quality-assured contraceptives and other FP/RH supplies through public and private services. Priorities in this area include building a global supply, focusing on the in-bound supply for today and securing product pipelines for the future; national supply systems, including enabling human resources and leadership; data visibility; and strategic design of supply systems; and enabling environments, including engaged stakeholders, financing, and governance. As part of efforts to expand the contraceptive method mix, USAID Missions may procure Emergency Contraception through the Central Commodity Procurement system. In the case of condom procurement, one must consider the primary objectives of the program (HIV/AIDS or sexually transmitted infection (STI) prevention versus reducing unintended pregnancy) in determining the proper source of funds for their purchase (HIV/AIDS and/or FP/RH funds).
- *Strengthening the marketplace for family planning information and services*, through promotion and enhancement of contributions from all sectors, including the public, non-profit, and commercial sectors. Priorities in this area include market segmentation research; research to document and test effects of total market approach (TMA) planning and implementation on the FP market and use; testing and implementation of demand side or supply side initiatives for voluntary family planning to reduce financial barriers to access and to maximize use of available resources; supporting mobile outreach for long-acting reversible contraception and permanent methods (LARCs/PMs) for target populations; and expanding the role of the commercial sector in providing quality family planning information and services.
- *Expanding options for family planning and the quality of family planning information and services*, including biomedical research to develop and introduce new options for expanding contraceptive choice; and social science research to improve the organization and quality of family planning information and services. (Note that FP/RH funds may be used to pay for operations research activities that include broader health or non-health components or linkages, provided that the objective of the study is to improve family

planning and related reproductive health activities).

- *Supporting demographic surveys, surveillance tools, and project evaluations* for the collection, analysis, and dissemination of representative data on population, family planning need and use, and programmatic best practices. Appropriate activities include Demographic and Health Surveys, technical assistance related to censuses, related secondary data analysis that documents indicator trends, and impact evaluations of family planning activities that seek to improve access to high-quality family planning information and services.
- *Create a policy and governance environment that ensures equal access to family planning information and services for all populations.* Activities in this area include supporting policy change that fosters sustainable and equitable health systems through country ownership; building national and local level support for family planning, and capacity to meet FP/RH needs; strengthening civil society organizations to advance public health; promoting accountable and transparent governance; increasing government accountability for policy and funding commitments; strengthening the capacity of health stakeholders to promote equitable access to information and services; and strengthening of management systems, including information systems, human resources, supervision, training, and financial systems.
- *Contributing to the sustainability of family planning information and services,* including initiatives with the commercial sector and health and social insurance programs to leverage private resources for family planning; utilization of supply- and demand-side result-based financing mechanisms; mobilization of public sector resources to finance family planning information and services; measures to ensure reliable supplies of contraceptives; and policy and program actions to maximize the positive effects of health reform on family planning services.

c. Integration of Family Planning/Reproductive Health Activities

Innovations to promote FP information and services as part of a broader package of reproductive health care are crucial to fulfilling USAID's continuing commitment to reproductive health, and are encouraged. However, due to the integrated nature of some FP/RH programs, questions often arise about the requirements of joint funding from other Program Elements within the health program area or from other program areas or accounts.

There are two categories of integrated family planning activities included in this reference: 1) **Integration of Family Planning/Reproductive Health Activities with other health program elements;** and 2) **Integration of Family Planning/Reproductive Health Activities within non-health program elements.**

Integrated family planning activities support USAID family planning objectives but are not considered standalone family planning activities. Integrated family planning activities often strengthen or complement a family planning program, facilitate the achievement of family planning program objectives, or contribute to the results of a family planning activity.

Integrated activities often have similar key audiences as family planning activities and are co-located or require the skills of a single health services provider.

To help decide whether a non-family planning activity represents an appropriate use of FP/RH funds, the activity should satisfactorily address the criteria of **direct measurable impact in the reduction of unintended pregnancies and optimally used funds, as described in the introduction to this chapter, and programmatic linkage to existing family planning activities.**

In the case of both **categories of integration of** family planning/reproductive health activities, an integrated family planning activity funded by USAID requires joint funding of FP/RH-designated funds and non-FP/RH-designated funds. For example, the use of non-FP/RH-designated funds is required to help support integrated FP/HIV activities that also receive FP/RH-designated funds. Likewise, USAID funding for mentoring activities that are intended to keep girls in school by building their self-esteem while also modeling positive reproductive health behaviors requires joint funding from FP/RH-designated and non-FP/RH-designated accounts.

d. Integration of Family Planning/Reproductive Health Activities Within Other Health Program Element Activities

Reproductive health needs vary over the course of an individual's life. Therefore, FP/RH funds should be used to help countries provide women and men with the convenience of co-located or linked health services that respond to a broad set of reproductive health needs.

Research suggests that linking family planning with, HIV and STI prevention efforts, **maternal and child health care,** or broader youth development efforts is associated with improved client satisfaction, higher utilization rates, and sustained and satisfied use of family planning and related health or other services. Further, support for strengthened linkages between family planning and other reproductive health areas is consistent with the objectives of the Programme of Action adopted by the U.S. Government at the 1994 International Conference on Population and Development, which called for, *inter alia*, universal access to a full range of safe and reliable family planning methods and related reproductive health care. (See: <http://www.un.org/popin/icpd/conference/offeng/poa.html>). It is also consistent with Millennium Development Goal 5 to improve maternal health and Target 5b, achieve universal access to reproductive health. (See: <http://www.un.org/millenniumgoals/maternal.shtml>). **Illustrative activities include, but are not limited to:**

- **Integrating family planning and newborn, child and maternal health care. Illustrative activities include provision and education regarding post-partum family planning, increasing access to emergency obstetrical care, and integration of family planning with newborn and child health services, such as immunization drives.**
- **Post-Abortion Care (PAC):** PAC programs are an integrated service delivery model that includes maternal health and family planning activities. PAC programs should be funded with a combination of funds from both the MCH and FP/RH elements. USAID funds may be used to support PAC activities, regardless of whether the abortion was legally or

illegally obtained. However, no USAID funds may be used to purchase or distribute manual vacuum aspiration kits for any purpose. FP/RH funds should focus on post-abortion family planning counseling and services to prevent future unintended pregnancy; linking women to family planning and other reproductive health care, and PAC community awareness activities. MCH funds should focus on emergency treatment for complications of induced or spontaneous abortion; and community awareness of post-abortion danger signs and support to help women get emergency treatment.

- Integrating and coordinating family planning and HIV/AIDS activities. The integration of health programs, including HIV and family planning programs, is a priority for the U.S. Government and is outlined as a key strategy to strengthen existing foreign assistance programs. Integration of HIV and FP activities may be cost-effective and appropriate, depending on the country context, within PEPFAR-supported programs for prevention of mother-to-child transmission (PMTCT), care and treatment, services for key populations, and health systems strengthening. Illustrative programming opportunities that should be actively pursued include counseling and/or referrals to voluntary family planning services for women and men in HIV prevention, care and treatment programs; providing HIV prevention messaging and support, as well as HIV testing and counseling, within antenatal care, maternal and child health, and family planning programs for both men and women; ensuring access to a comprehensive range of contraceptive commodities for PLHIV who wish to delay or prevent pregnancy; developing and disseminating technical guidance materials related to HIV and FP integration; and strengthening the policy environment for appropriate integration of HIV and FP platforms and services.
- Please see Chapter 6. HIV/AIDS of this Guidance and consult the most recent annual Country Operational Plan Guidance and Technical Considerations document issued by S/GAC for extensive guidance on the use of PEPFAR funds for FP/HIV integrated activities. A partner that receives both PEPFAR and USAID FP/RH funds to conduct an integrated program is subject to the legal and policy requirements that govern both HIV/AIDS and FP activities because the partner is conducting both types of activities. PEPFAR funds may not be used to purchase family planning commodities; however, male and female condoms can be purchased using PEPFAR funds.
- Integrating youth family planning and reproductive health information and services with cross-sectoral youth development activities. Programs should incorporate approaches that are integral to ensuring optimal reproductive health behaviors and outcomes and that promote self-efficacy and responsibility by strengthening life-skills and creating enabling environments at the policy and community level. Within cross-sectoral activities that build young people's potential, capacities, and abilities, FP/RH funds should support youth access to comprehensive sexual and reproductive health information and services, including all methods of contraception to prevent unintended pregnancy, delay first pregnancy to at least age 18 and ensure birth to pregnancy intervals of at least two years. FP/RH funds should also support the reduction of young people's reproductive health risk behaviors and risk factors. Operating units should refer to the USAID Youth in Development Policy (http://www.usaid.gov/sites/default/files/documents/1870/Youth_in_Development_Policy)

[0.pdf](#)) for more information about integrating youth into development programming.

- Preventing and repairing fistula. Activities may include: 1) repair, 2) prevention, 3) reintegration, and 4) monitoring and evaluation and research. The fistula program should be funded with a combination of funds from both the MCH and FP elements. A typical distribution of funds within a comprehensive fistula program would include 70 percent of funding from the 3.1.6 Maternal and Child Health element and 30 percent of funding from the 3.1.7 Family Planning and Reproductive Health element. FP funds should be focused on community-based prevention and post-repair counseling, while MCH funds should focus on obstetric prevention and repairs and increasing community awareness of danger signs in pregnancy and delivery. Activities to prevent the occurrence of fistula may include supporting family planning to prevent unintended pregnancies, and delaying marriage and first birth.
- Integrating gender into family planning programs: Illustrative examples include interventions that transform traditional gender norms that perpetuate gender-based violence, including intimate partner violence, child marriage, and other harmful traditional practices; address barriers to access to quality family planning services; improve men's constructive involvement as supportive partners; support gender equity in strengthening health systems; promote men's use and support of contraceptives; support policies and laws in support of gender equality; and link to programs on girls' education, women's literacy, economic opportunities, access to productive resources, and social safety nets. Promoting gender equality in family planning and reproductive health programming is consistent with USAID's policy on Gender Equality and Female Empowerment (<http://www.usaid.gov/sites/default/files/documents/1870/GenderEqualityPolicy.pdf>) and GHI's principle of Women, Girls, and Gender Equality supplemental guidance.

e. Integration of Family Planning/Reproductive Health Activities with Non-Health Program Areas

OUs are encouraged to seek opportunities to develop mutually productive linkages with other health activities and development sectors such as education, democracy and governance, environment, microenterprise and income generation programs, and to those with specific gender objectives. Such linkages can serve multiple purposes. Often, they expand the entry points for introducing family planning information and services, particularly when coupled with HIV and child survival and maternal health services. In other instances, these multisectoral approaches help to reach underserved or nontraditional populations when family planning information provision and service delivery are coupled with conservation, natural resources management, and/or livelihoods development activities.

OUs implementing multisectoral activities should consult the Legislative Restrictions Regarding Abortion and Involuntary Sterilization Applicable to All Health Activities and the Legislative Restrictions on FP/RH Activities.

While FP/RH-designated funds can be used to support the FP/RH components of multisectoral activities, funds from non-FP/RH sources must be used to support activities that do not directly affect FP/RH outcomes.

Within an integrated family planning activity, non-family planning/reproductive health and non-health activities must be supported with non-FP/RH funds in combination with FP/RH-designated funds. Illustrative examples include, but are not limited to the following:

- *Non-Family Planning/Reproductive Health.* Addition of non-family planning products and promotion to a family planning social marketing campaign, for example, addition of ORS or insecticide treated bed nets can enhance a social marketing system that delivers and promotes family planning products. *Note:* FP/RH funds must not be used to pay for non-FP/RH products and their promotion. In this case, non-FP/RH-designated funds would pay for the non-family planning products and their promotion.
- *Education.* Pregnancy and dropout among schoolgirls are sometimes precipitated by poor school performance. Mentoring programs that help adolescent girls succeed in school while also providing them with reproductive health information and counseling combine the two forces that are needed to reduce dropout due to pregnancy. *Note:* Basic education activities must be paid for with funds that are designated for that purpose. FP/RH funds may not be used to support basic education activities.
- *Democracy and Governance.* Education and awareness-raising about reproductive issues, such as voluntarism in family planning programs, can be supported as a component of broader awareness-raising and education about women's rights.
- *Environment.* USAID has a longstanding congressional directive to provide family planning information and services in areas where population growth threatens biodiversity or endangered species. Allowable activities under these types of projects include: those that integrate family planning information dissemination and service delivery with biodiversity and conservation service delivery; community, regional, and national level planning activities that simultaneously examine environmental, demographic, and/or health factors; national, regional, and local level policy advocacy activities that identify relationships between population, health, and environment and advocate policy responses in both FP/RH and environment sectors; and research, awareness raising, or communications activities that highlight the relationship between population, health, and environment.
- *Microenterprise and Income Generation.* Linking family planning volunteers, including peer educators, to microenterprise and income generation activities. For example, FP/RH-designated funds may be used along with non-FP/RH-designated funds to subsidize small loans, training, or skills development activities that are directed to family planning volunteers or peer educators as rewards for length or quality of service. Also, income-generating activities may help to generate resources for FP/RH activities: for example, microfinance activities to assist women to sell FP and related health products.

- *Legal Counsel.* Linking family planning clients to sources of legal counsel about gender-based violence, child marriage, property, custody, and other rights of women.

C. Legal Requirements and Congressional Directives

a. Authority

USAID’s FP/RH Program is authorized by the FAA of 1961, as amended.²² Restrictions on the use of foreign assistance funds for FP/RH-related activities are clearly outlined in the annual Foreign Assistance Appropriations Act and USAID’s policy, and govern programming within all elements.

FP/RH activities are further governed by USAID’s policies on voluntarism and informed choice, including Policy Determination 3 (PD-3).

b. Legislative and Policy Requirements on Reproductive Health/Family Planning Activities

i. *Legislative Restrictions Regarding Abortion and Involuntary Sterilization*²³

There are a number of restrictions regarding abortion and involuntary sterilization set forth in Section 104(f) of the FAA and the annual Appropriations Act. These restrictions apply to all activities funded under the annual Appropriations Act, including FP/RH, MCH, HIV/AIDS, malaria, and other health activities. These legislative restrictions are reflected in the mandatory standard provisions of all USAID awards. See [ADS 303, Grants and Cooperative Agreements to Non-Governmental Organizations](#) for the latest provisions for assistance awards and AAPD (Acquisition and Assistance Policy Directive) 08-01 for the latest provisions for contracts.

These restrictions include the following:

Helms Amendment (1973): USAID funds may not be used to pay for the performance of abortion as a method of family planning or to motivate or coerce any person to practice abortions. Under the Leahy Amendment, the term “motivate,” as it relates to family planning assistance, shall not be construed to prohibit the provision, consistent with local law, of information or counseling about all pregnancy options.

Siljander Amendment (1981): USAID funds may not be used to lobby for or against abortion.

Biden Amendment (1981): USAID funds may not be used to pay for any biomedical research that

²² Section 104 (b) of the FAA of 1961, as amended, states that “In order to increase the opportunities and motivation for family planning and to reduce the rate of population growth, the President is authorized to furnish assistance, on such terms and conditions as he may determine, for voluntary population planning. In addition to the provision of family planning information and services, including also information and services which relate to and support natural family planning methods, and the conduct of directly relevant demographic research, population planning programs shall emphasize motivation for small families.”

²³ See also Annex V

relates in whole or in part, to methods of, or the performance of, abortions or involuntary sterilization as a means of family planning. Epidemiological or descriptive research to assess the incidence, extent, or consequences of abortions is not covered by the amendment and is therefore permitted.

Additional provision relating to voluntary sterilization (1985): USAID funds may not be used to pay for the performance of involuntary sterilizations as a method of family planning or to coerce or provide any financial incentive to any person to undergo sterilization.

There are additional legislative and policy requirements that apply to all family planning activities regardless of the source of funds. USAID supports the freedom of individuals to choose voluntarily the number and spacing of their children through family planning. Since its inception, USAID's FP/RH program has helped effect the conditions that make it possible for individuals to exercise this fundamental freedom. USAID places highest priority on ensuring that its FP/RH activities adhere to the principles of voluntarism and informed choice. The Agency considers an individual's decision to use a specific method of family planning or to use any method of family planning as being *voluntary* if it is based upon the exercise of free choice and is not obtained by any special inducements or any element of force, fraud, deceit, duress or other forms of coercion or misrepresentation. USAID defines *informed choice* to include effective access to information on family planning choices and to the counseling, services, and supplies needed to help individuals choose to obtain or decline services, to seek, obtain, and follow up on a referral, or simply to consider the matter further.

Through legislated requirements, presidential policy, and its own policies and practices, USAID has taken special measures to protect individuals against potential abuses and coercion in family planning programs. References to each of these legislative and policy requirements are included in a chart entitled "USAID Family Planning Requirements," attached as Appendix V. The following legislative and policy requirements are also generally reflected in the standard provisions of USAID awards for family planning. See ADS 303 for the latest provisions for assistance awards and AAPD 08-01 for the latest provisions for contracts. Further information about these requirements, including relevant guidance, can be found on USAID's Web site at <http://www.usaid.gov/what-we-do/global-health/family-planning/voluntarism-and-informed-choice>.

ii. Additional Legislative Restrictions

- ***Tiahrt***: The principles of voluntarism and informed choice are codified in the Tiahrt Amendment, which requires that USAID-assisted family planning projects meet certain standards of voluntarism. The Tiahrt Amendment was first included in the FY 1999 Appropriations Act, and has been included each year thereafter. Under the Tiahrt Amendment, voluntary service delivery projects receiving family planning assistance from USAID (including in the form of funds, commodities, technical assistance, or training) must meet five requirements:
 - Service providers or referral agents in the project must not implement or be subject to quotas, or other numerical targets, of number of total births, number of family planning acceptors, or acceptors of a particular method of family planning

(this provision shall not be construed to include the use of quantitative estimates or indicators for budgeting and planning purposes);

- The project must not include payment of incentives, bribes, gratuities, or financial rewards to (1) an individual in exchange for becoming a family planning acceptor or (2) program personnel for achieving a numerical target or quota of total number of births, number of family planning acceptors, or acceptors of a particular method of family planning;
 - The project must not deny any right or benefit, including the right of access to participate in any program of general welfare or the right of access to health care, as a consequence of any individual's decision not to accept family planning services;
 - The project must provide family planning acceptors comprehensible information on the health benefits and risks of the method chosen, including those conditions that might render the use of the method inadvisable and those adverse side effects known to be consequent to the use of the method; and
 - The project must ensure that experimental contraceptive drugs and devices and medical procedures are provided only in the context of a scientific study in which participants are advised of potential risks and benefits.
- *DeConcini Amendment*: Family planning assistance may only be available to voluntary family planning projects that offer, either directly or through referral to, or information about access to, a broad range of family planning methods and services.
 - *Livingston-Obey Amendment*: In awarding grants for natural family planning, no applicant shall be discriminated against because of such applicant's religious or conscientious commitment to offer only natural family planning, and all applicants must comply with the DeConcini Amendment.

iii. Policy Requirements

- *Policy Determination-3 (PD-3)*: In 1982, USAID issued a policy paper on population assistance, which clearly states its commitment to voluntarism in the provision of family planning services. The Population Policy of 1982, in Annex Policy Determination 3, includes specific requirements for USAID-supported programs that include voluntary sterilization. These requirements cover informed consent, ready access to other methods, and guidelines on incentive payments, which affect payments to acceptors, providers, or referral agents. The requirements of PD-3 are implemented in conjunction with the Tiahrt requirements. Further requirements that apply to voluntary sterilization include documentation of informed consent.
- *Post-Abortion Care (PAC)*: PAC programs are an integrated service delivery model that includes maternal health and family planning activities. PAC programs should be funded

with a combination of funds from both the MCH and FP/RH elements. USAID funds may be used to support post-abortion care activities, regardless of whether the abortion was legally or illegally obtained. However, no USAID funds may be used to purchase or distribute manual vacuum aspiration (MVA) kits for any purpose. FP/RH funds should focus on post-abortion family planning counseling and services to prevent future unintended pregnancy, linking women to family planning and other reproductive health care, and PAC community awareness activities. MCH funds should focus on emergency treatment for complications of induced or spontaneous abortion; and community awareness of post-abortion danger signs and support to help women get emergency treatment. (See the Chapter III.11.A on Integration for guidance on funding).

5. MALARIA

This budget category corresponds to the element 3.1.3 Malaria.

A. Health Program Element Guide

USAID's malaria program is designed to improve malaria prevention and control in order to reduce malaria related morbidity and mortality. This budget category has the goals of supporting the implementation of the President's Malaria Initiative (PMI), related malaria control programs, and malaria research activities to reduce malaria-related mortality. Funding will be used to develop effective malaria vaccines, new malaria treatment drugs, and targeted operations research.

B. Priorities and Goals

The GHI's target for malaria activities is to achieve and sustain universal coverage for all populations at risk with locally appropriate interventions for prevention and case management.

a. Allowable Activities: Priority Approach and Illustrative Examples

The President's Malaria Initiative (PMI) aims to lower the deaths related to malaria by 50 percent in 19 countries in Africa through various interventions that target the most vulnerable populations: pregnant women and children under the age of five.²⁴

The following listing comprises the primary categories for programming malaria funds:

- ***Diagnosis and Treatment of Malaria with Artemisinin-Based Combination Therapies:*** Improve availability of parasitologic diagnosis and equitable access to and appropriate use of artemisinin-based combination therapies (ACTs) to treat malaria, including provision of rapid diagnostic tests or microscopy supplies; drugs; logistic support for the

²⁴ The President's Malaria Initiative (PMI). "About PMI." <http://www.pmi.gov/about>.

delivery of drugs; informing and educating communities and health providers about improved diagnostic capacity and prescribing ACTs; training of health providers and supporting supervision including support for integrated community case management of malaria (iCCM); and monitoring of adverse effects.

- ***Insecticide-Treated Nets (ITNs) to Prevent Malaria:*** Improve access to and use of ITNs to prevent malaria, including provision of nets and re-treatment kits; logistic support for the delivery of ITNs; behavior change about use of ITNs; improved access to long-lasting nets and net treatment technology; and private sector marketing of ITNs.
- ***Indoor Residual Spraying (IRS) to Prevent Malaria:*** Expand the use of indoor residual spraying to prevent malaria, including purchase of insecticide and spraying equipment; logistic support; information/education for communities on upcoming spray campaigns; environmental assessments; and capacity to conduct entomological and epidemiologic monitoring.
- ***Intermittent Preventive Treatment (IPT) of Pregnant Women:*** Expand access to and use of IPT with sulfadoxine pyrimethanine (SP) via antenatal services in order to address malaria in pregnancy. Activities will include provision of SP; training of service providers; information, education, and communication (IEC) for women and their partners and for providers of IPT; and logistic support for the delivery of SP.
- ***Epidemic Preparedness, Surveillance, and Response:*** Help countries forecast, prepare for, detect, and respond to epidemics of malaria including entomologic and epidemiologic surveillance; procurement and equitable distribution of insecticide sprayers, and ITNs; and training of service providers.
- ***Malaria Research:*** Further the research and development of improved or new malaria interventions, including new malaria vaccine candidates, new malaria drugs, and new insecticide-based products. Also, targeted operations research to improve existing malaria interventions and their scale up in countries will be supported.
- ***Health Governance and Finance (HGF):*** Promote sustainable improvements in health outcomes for men/boys and women/girls by reducing key governance and financing constraints to the achievement of multiple health element objectives and the health area goal overall. These include activities that reduce corruption; increase equity; improve efficiency and increase financial protection (especially for underserved populations), including in the context of financing, organization of services, facility construction/renovation, pharmaceutical management, and human capacity development and management. HGF activities supported with malaria funding must demonstrate clear linkages between the activity and the contributions to achieving malaria control objectives and outcomes.
- ***Anti-Microbial Resistance:*** Address anti-malarial drug resistance, especially related to artemisinin-based combination therapies and other WHO-approved anti-malarial drugs. Multi-drug resistance is a particular threat in the Mekong Region and the Amazon Basin.

Activities include: helping countries to update and implement new malaria treatment policies, ongoing monitoring of malaria drug efficacy, addressing sub-standard and counterfeit drugs, and information and education for both consumers and health workers.

- **Host Country Strategic Information Capacity:** Establish and/or strengthen host country institutions' management information systems (MIS) and their development and use of tools and models to collect, analyze, and disseminate a variety of information related to the program element. These may include, but are not limited to MIS for government ministries or other host country institutions, needs assessments, baseline studies, censuses and surveys, targeted evaluations, special studies, routine surveillance, data quality assessments, and operational research. This sub-element may also include developing and disseminating best practices and lessons learned and testing demonstration and/or pilot models. Related training, supplies, equipment, and non-USG personnel are included.

For additional guidance on PMI technical guidance and training please refer to: <http://www.pmi.gov/resource-library/training-guidance>.

C. Legal Requirements and Congressional Directives

a. Authority

USAID's Malaria Program is authorized by the FAA of 1961, as amended, and the 2008 Tom Lantos and Henry J. Hyde Global Leadership against HIV/AIDS, Tuberculosis, and Malaria Act.

The Administrator's Executive Message (USAID/General Notice, issued 12/23/05) established the position and clarified the authorities of the U.S. Global Malaria Coordinator and fundamentally restructured USAID's malaria programs. The requirements listed in this notice were further reinforced in a subsequent Agency notice (USAID/General Notice, issued 3/6/08) and adopted as permanent foreign assistance law with the passage of the 2008 Tom Lantos and Henry J. Hyde Global Leadership against HIV/AIDS, Tuberculosis, and Malaria Act (Lantos/Hyde Act) Section 304, available here: <http://www.gpo.gov/fdsys/pkg/BILLS-110hr5501enr/pdf/BILLS-110hr5501enr.pdf>. These documents define the rules and requirements for the use of all USAID malaria funding – for programs that are part of PMI as well as those administered by USAID outside of PMI (sometimes referred to as PMI non-focus country or regional programs).

b. Legal and Policy Requirements

i. Legislative Requirements

GC has determined that the following, adapted rationale, developed based on the case of use of GHP funds in HIV/AIDS programs that include military, police, prison, and other law enforcement personnel as populations at risk of contracting and transmitting HIV/AIDS, can be applied to all USAID infectious disease programming. Please review the full language detailed in Section C.b.ii of this reference for additional considerations and requirements.

Combatting the spread of Malaria in Military, Police, Prisons, or other Law Enforcement Personnel: Section 531(e) of the Foreign Assistance Act of 1961, as amended, and general principles of appropriation law prohibit the use of economic assistance funds for military purposes. In addition, Section 660 of the FAA prohibits training or advice or financial support for police, prisons, or other foreign law enforcement forces. However, GC has determined that certain programs involving military forces or police, prison, or other law enforcement personnel would not be prohibited by these legal restrictions. In particular, participation by these groups in malaria programs might not be prohibited if they are participating not in their military or law enforcement capacity, but as a population group at risk of contracting and transmitting the disease more broadly within the population and the following conditions are met:

- a) The programs or activities in which the military or police, prison, or other law enforcement personnel would participate are part of a larger public health initiative to combat malaria, and exclusion of such group would impair the achievement of the initiative's public health objectives;
- b) The program for the military or police, prison, or other law enforcement personnel must be similar to that received by other population groups similarly situated in terms of malaria risk and prevention; and
- c) Neither the program or activities, nor any commodities transferred under the program can be readily adaptable for military or police, prison or other law enforcement personnel purposes.

Notwithstanding authority for assistance to police, prison, or other law enforcement personnel: The notwithstanding authority described in section III.1.A.a is available for assistance to police, prison, or other law enforcement personnel that does not meet the guidance above. This notwithstanding authority is *not* available for assistance to foreign militaries. For programs with foreign militaries that do not meet the guidance above, consideration should be given to the possibility of implementation by DOD.

In relying on notwithstanding authority for this purpose, OUs need to carefully review the facts of any proposed activity to ensure that the activity falls only within the scope of malaria activities permitted by other sections of this guidance. If an operating unit decides to rely on “notwithstanding” authority, the clearance procedures described below must be followed.

Moreover, OUs should be aware that certain activities relating to the spread of infectious disease involving prisoners, that do not involve support to prisons or prison personnel, may not fall within the prohibition of Section 660 at all, and therefore would not require the reliance on “notwithstanding” authority to fund. However, an activity that involves providing assistance to prison personnel or prisons, even for the benefit of prisoners, might fall under the prohibition of Section 660 and require the use of notwithstanding authority. If in doubt about the applicability of Section 660, contact your Resident Legal Officer or GC for assistance.

A decision to rely on notwithstanding to provide assistance to prisons, police, or other law enforcement personnel may raise sensitive policy issues. OUs must prepare a memo requesting approval from their bureau's Assistant Administrator and obtain clearances from the Assistant Administrator of the Bureau for Global Health (if the operating unit is not within GH), and

others as deemed appropriate by the approving Assistant Administrator. The approving Assistant Administrator may request clearance from the Assistant General Counsel for their bureau, the relevant regional bureau, and the relevant regional bureau's Assistant General Counsel. F is responsible for tracking OUs that make use of the notwithstanding authority. A copy of all memos relying on this global health notwithstanding authority should be sent to GC/GH for information.

ii. Policy Requirements

Pursuant to the authorities in the 2008 Lantos/Hyde Act and the USAID Administrator's Executive Messages of 2005 and 2008:

- The U.S. Global Malaria Coordinator has direct authority over both PMI and USAID non-PMI malaria programs and policy. The authorities, roles, and responsibilities of the Coordinator that are relevant to this guidance on the use of malaria funds include:
 - Direct oversight and approval of all malaria policies, planning, and budgeting;
 - Direct supervision over, and hiring authority for, all staff supported under malaria funding;
 - Approval of all malaria budget allocations to bureaus and countries, including minimum funding levels, as well as malaria staffing levels in bureaus and countries;
 - Approval of all malaria-related acquisition and assistance plans;
 - Approval of all malaria-related Monitoring and Evaluation (M&E) requirements and reporting requirements, with the authority to approve or disapprove any specific malaria-related M&E and reporting plans; and
 - Approval of all direct hire and non-direct hire travel to countries for malaria program support, regardless of the funding source.
- All USAID malaria programs will allocate a minimum of 43 percent of their funds for life-saving commodities (e.g., insecticide-treated mosquito nets, indoor residual spraying-related commodities, artemisinin-based combination therapies, sulfadoxine-pyrimethamine for intermittent preventive treatment of pregnant women, drugs for severe malaria, and diagnostic equipment and supplies). The U.S. Government Global Malaria Coordinator may waive this requirement if evidence shows that malaria commodity needs and gaps are fully funded by other funding sources.
- Budgets are set centrally by following recommendations of the U.S. Global Malaria Coordinator. Approval from the U.S. Global Malaria Coordinator is required for any change in approved budgets or to shift funding between sub-elements.
- The minimum annual funding level for country malaria programs or regionally managed country programs is \$2.5 million of malaria funds. When the consequences of this requirement are not in the best interest of the malaria program, the Coordinator may make exceptions on a case-by-case basis.

- In compliance with the Lantos/Hyde Act, all OUs are required to submit reports on activities implemented with USAID malaria funds on an annual basis.
- For PMI countries, the PMI Web site, <http://www.pmi.gov>, will include all procurement documents funded under PMI (e.g., contracts, grants). GH is responsible for managing this process, but PMI countries are required to submit all procurement documents (after redaction by the contractor/grantee).
- PMI country programs can use up to 2 percent of their annual budget for the hiring of additional Foreign Service Nationals, Mission cross-cutting programs, taxes and fees (e.g., Capital Security Cost Sharing, any “cost of doing business” and associated expenses) and other relevant administrative expenses. Dedicated country PMI staff (PMI resident advisors, PMI dedicated foreign service nationals (FSNs)) costs are not included within this 2 percent cap. All staffing and administration costs are subject to review and approval by the Coordinator.

GOAL 2: CREATING AN AIDS FREE GENERATION

On November 8, 2011, Secretary Clinton called on the world to join the United States in working to achieve the goal of an AIDS-free generation during an address at the National Institutes of Health in Bethesda, Maryland. According to the Secretary, an AIDS-free generation means that virtually no children are born with the virus; that as these children become teenagers and adults, they are at a far lower risk of becoming infected than they would be today, thanks to a wide range of prevention tools and, finally, that if they do acquire HIV, they have access to treatment that helps prevent them from developing AIDS and passing the virus to others.

6. HIV/AIDS

This budget category corresponds to the element 3.1.1 HIV/AIDS.

During his 2003 State of the Union Address, President Bush announced the creation of the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR), a 5-year, \$15-billion initiative to combat the global HIV/AIDS pandemic. In May 2003, President Bush signed into law the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003” (P.L. 108–25, the PEPFAR Authorization), which authorizes the activities of the Emergency Plan, including efforts in prevention, treatment, and care (including care for orphans and vulnerable children). During its first 5 years, the Emergency Plan set goals to support antiretroviral treatment (ART) for 2 million HIV-infected individuals, prevention of 7 million HIV infections, and care for 10 million people infected or affected by HIV/AIDS, including orphans and vulnerable children.

The law was reauthorized by the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008 (P.L. 110–293) (the PEPFAR Reauthorization). The Reauthorization provided scope, broadly, within the FY 2009–2013 appropriations (Section 301) for assistance to combat HIV/AIDS through procurement and distribution of HIV/AIDS pharmaceuticals and through integration of food

security and nutrition activities into HIV/AIDS prevention, treatment, and care activities. It revised requirements of the 5-year strategy to combat HIV/AIDS as it relates to mother-to-child transmission and care and treatment for family members and children orphaned by HIV/AIDS (Section 307). Finally, it requires more than half of the FY 2009–2013 appropriation for bilateral assistance be made available for (1) ART; (2) clinical monitoring of HIV-seropositive people not in need of ART; (3) care for associated opportunistic infections; (4) nutrition and food support for people living with HIV/AIDS (PLWHA); (5) other essential medical care for people living with HIV/AIDS (Section 403);²⁵ and (6) health systems strengthening. Further provisions are detailed throughout this section.

The law was again reauthorized by the PEPFAR Stewardship and Oversight Act of 2013 (P.L. 113-56). The Act extends existing authorities for five years and strengthens oversight of PEPFAR. It requires the State Department, USAID, and Health and Human Services (HHS) Inspectors General to coordinate on oversight and audit plans. The Act extends per-patient cost study reporting requirements and the 33 percent cap on U.S. contributions to the Global Fund. It updates annual PEPFAR reporting requirements. Finally, it extends funding requirements for the treatment of orphans and vulnerable children.

Under the PEPFAR Authorization and the PEPFAR Reauthorization, the U.S. Global AIDS Coordinator has authority to provide “oversight and coordination of all resources and international activities of the United States Government to combat the HIV/AIDS pandemic.”

A. Health Program Element Guide

Allowable activities for HIV/AIDS include those that contribute directly to prevention, care (including care for infected individuals and affected orphans and vulnerable children), and treatment of HIV/AIDS and those that build and strengthen sustainable, country-owned health systems in support of the global HIV/AIDS response. These goals require a comprehensive, locally-tailored approach that engages sufficient community, government, non-governmental organization (NGO), and donor resources in a consistent and complementary manner. The strategies should reflect the stage of the epidemic and focus efforts on “those most likely to contract or transmit” HIV.

The following guidance is directed to all programs providing HIV/AIDS assistance worldwide. All PEPFAR Country Operational Plan (COP) guidance referenced below can be found here: <http://www.pepfar.gov/reports/guidance/>.

The S/GAC provides guidance for HIV/AIDS activities worldwide through guidance documents, including annual Country, Regional, and Headquarters Operational Plans, which inform planning by interagency teams. Any additional guidance from S/GAC supersedes the related guidance contained in this document. For questions, please contact the Office Director of GH/Office of HIV/AIDS (OHA).

²⁵ United States Cong. An act to Authorize Appropriations for Fiscal Years 2009 through 2013 to Provide Assistance to Foreign Countries to Combat HIV/AIDS, Tuberculosis, and Malaria, and for Other Purposes, July 30, 2008. 110th Cong., 2nd sess. Washington: GPO. Available at: <http://www.gpo.gov/fdsys/pkg/BILLS-110hr5501enr/html/BILLS-110hr5501enr.htm>.

B. Priorities and Goals

On World AIDS Day, December 1, 2011, President Obama reiterated the U.S. commitment to PEPFAR and to evidence-based combination prevention. Specifically, the President committed PEPFAR to achieve the following targets by 2013:

- Treatment: PEPFAR will directly support more than 6 million people on ART – 2 million more than the U.S. Government’s previous goal.
- Voluntary medical male circumcision (VMMC): PEPFAR will support more than 4.7 million VMCMs in Eastern and Southern Africa.
- Condoms: PEPFAR will distribute more than 1 billion condoms.
- Prevention of mother-to-child transmission (PMTCT): PEPFAR will reach more than 1.5 million HIV-positive pregnant women with antiretroviral drugs to prevent them from passing the virus to their children.

a. Prevention of Sexual Transmission of HIV/AIDS

In August 2011, PEPFAR issued interagency guidance on implementation of programs to prevent sexual transmission in the policy document, “Guidance for the Prevention of Sexually Transmitted HIV Infections (August 2011),” available at <http://www.pepfar.gov/documents/organization/171303.pdf>. This new guidance replaces the ABC Guidance #1 which is no longer in effect. Like all PEPFAR guidance, the prevention of sexual transmission guidance applies to all funding used for HIV activities, including GHP (formerly Child Survival and Health Programs Fund and Global HIV/AIDS Initiative), Economic Support Funds, FREEDOM Support Act, Assistance to Eastern Europe and the Baltics, Andean Counterdrug Initiative, or Title II Funding.

The new guidance requires that, first and foremost, country programs should respond to the local epidemiology and social context. Programs should prioritize the most important modes of transmission and the highest incidence populations and geographic areas, and monitor the scope, coverage, and cost of prevention interventions on an ongoing basis.

Both the second PEPFAR five-year strategy and the 2011 prevention guidance emphasize the country “continuum of response,” i.e., the need for linkages across prevention, care, and treatment. Both documents also call for a combination prevention approach incorporating biomedical, behavioral, and structural approaches. The rationale is that no one intervention alone is likely to have sufficient efficacy to control the HIV epidemic, and that combining mutually reinforcing activities offers the greatest promise for significantly reducing HIV incidence.

Within a combination prevention approach, the guidance prioritizes five “core” interventions. These include: voluntary medical male circumcision (VMMC); comprehensive programming relating to condoms and to prevention for most-at-risk populations (MARPs) and for people living with HIV/AIDS (PLWHA), also referred to as positive health dignity and prevention (PHDP); and Preventing mother-to-child transmission of HIV programs. **The guidance**

indicates that scale-up of these “core” interventions should comprise the large majority of PEPFAR prevention funding. (In concentrated epidemics, the majority of funding should focus on comprehensive programming for MARPs.)

Additionally, the Prevention Guidance emphasizes the need for other complementary interventions. It underscores the over-arching importance of preventing sexual transmission, of treatment coverage, and of behavioral interventions to support uptake of high-impact interventions as well as reduction of risk behaviors. It recognizes that HIV testing and counseling (HTC) represent a crucial gateway for referral of HIV-infected persons to care and treatment and other HIV services. Additionally, the guidance identifies a safe blood supply, universal medical precautions, and school-based and non-school-based programs for youth as “foundational” systems for sustainable long-term prevention that may require only limited or no investments by PEPFAR. The guidance also recognizes the role of “critical enablers”: interventions that create an environment that maximizes the impact of HIV prevention activities. Finally, “innovations with evaluation” are promising interventions requiring further evaluation of impact prior to scale-up.

Secretary of State Clinton – in her remarks, *Creating an AIDS-Free Generation*, on November 8, 2011²⁶ – and President Obama – in his World AIDS Day remarks on December 1, 2011²⁷ – endorsed the importance of prioritizing interventions with the strongest evidence and the greatest impact. A worldwide cable, STATE 004105, Subject: Obama Administration: Achieving an AIDS-Free Generation, dated January 13, 2012, reinforces this message and elaborates on global targets for PEPFAR for the highest impact interventions: VMMC, condom procurement, treatment as prevention, and PMTCT. STATE 004105 calls for PEPFAR teams in countries with high rates of infection among adolescent girls and young women to prioritize evidence-based risk reduction activities for this population. It also calls on all countries, but especially those with concentrated epidemics, to make combination HIV prevention accessible to MARPs.

For more information, please see the current COP/Regional Operational Plan (ROP) Guidance and Technical Considerations.

b. Biomedical Prevention

Biomedical prevention includes activities for blood safety, safe injection, injecting and non-injecting drug users and male circumcision.

Injecting Drug Users (IDUs)

USAID is committed to supporting effective strategies to prevent the spread of the HIV/AIDS pandemic among IDUs. On July 10, 2010, PEPFAR released a revised technical guidance document on Comprehensive HIV Prevention for People Who Inject Drugs. This guidance

²⁶ Clinton, Hillary. "Remarks on 'Creating an AIDS-Free Generation'" Speech.

²⁷ Obama, Barack. "Remarks by the President on World AIDS Day." Speech. Web. Available at:

<http://www.whitehouse.gov/photos-and-video/video/2011/12/01/president-obama-world-aids-day#transcript>.

affirmed PEPFAR's support for comprehensive, evidence-based, and human rights-based HIV prevention programs for persons who inject drugs.

Funds for HIV/AIDS activities may support the following:

- Implementing HIV prevention and treatment interventions that benefit IDUs (specific prevention interventions that should be emphasized include: community-based outreach, needle and syringe programs [NSPs], but see text below on the restriction set by the FY 2012 Statement of Managers for NSPs), and medically assisted treatment.
- Training of health professionals to increase the capacity for delivering high quality health care services for IDUs, including training in drug-dependence treatment modalities;
- Monitoring and evaluation of programs and interventions through the use of standardized indicators developed by the World Health Organization (WHO), the United Nations Office on Drugs and Crime, and Joint United Nations Programme on HIV/AIDS (UNAIDS) for each core intervention component to monitor accessibility, availability, quality, coverage, and impact;
- Assessments of laws, policies, regulations, and barriers that impede the implementation of comprehensive HIV prevention programs and activities for IDUs to address such structural barriers; size estimation activities to help countries set targets for universal access to HIV prevention, treatment, and care for IDUs; rapid assessments using multiple qualitative and quantitative methods to better understand the behavioral and HIV transmission dynamics, and estimate coverage needs and costs to have an impact on the HIV epidemic; and activities to support removal of access barriers to comprehensive services for people who inject drugs;
- Operations research to identify the most effective interventions within each epidemic context, support delivery of high-quality services to clients, and evaluate innovative strategies to improve and strengthen comprehensive services for IDUs; and
- Commodity procurement of naloxone for preventing overdose deaths, and methadone/buprenorphine, when they are conducted as part of a comprehensive package of HIV and drug prevention and treatment services in line with local laws and policies. However, the U.S. Government should not supplant existing programs or services, but coordinate for evidence-based coverage, intensity, and scale.

In FY 2012, the Statement of Managers to the Appropriations Act added a statement reading, "No funds under [the Global Health Programs account] may be used for needle exchange programs in fiscal year 2012." Previously, as part of the FY 2010 appropriations process, the U.S. Congress lifted the ban on domestic funding for needle and syringe exchange programs. The FY 2014 Statement of Managers does not include a similar statement; however, as of the date of publication of this guidance, the Office of the Global AIDS Coordinator has not yet announced any new policy with respect to whether it will approve programs of these types. For guidance on using previous years' funding (i.e., FY 2011–FY 2012) for NSPs, please consult your Resident

Legal Officer (RLO) or the Office of the General Counsel. For FY 2014 funds, please consult with the appropriate TWG and your RLO or the Office of the General Counsel.

For further guidance, please see Comprehensive HIV Prevention for People Who Inject Drugs, Revised Guidance (July 2010), at <http://www.pepfar.gov/documents/organization/144970.pdf>.

c. Voluntary Medical Male Circumcision (VMMC)

VMMC has been shown to reduce men's risk of acquiring HIV through heterosexual intercourse by approximately 60 percent in three randomized controlled trials. Extended follow-up of trial participants has shown that VMMC's protective effect has been maintained or increased to over 70 percent. This finding is supported by over 50 ecological and epidemiological studies that show a strong link between VMMC and reduced HIV prevalence. In addition, biological studies have shown that high concentrations of cells in the foreskin are susceptible to HIV infection, which is one of the potential biological explanations of why VMMC may reduce HIV acquisition.

UNAIDS and PEPFAR have estimated that scaling up adult VMMC in men aged 15–49 years in 14 focus countries in southern and eastern Africa will require 20.3 million adult circumcisions in five years in order to reach 80 percent coverage of the eligible population. Mathematical modeling, using this level of coverage over the next 15 years, suggests there is the potential to avert up to 3.6 million new HIV infections and generate a potential cost savings of US \$16.5 billion.

In addition to the reduction in risk of HIV acquisition among circumcised men, VMMC provides other health benefits. Evidence shows that VMMC reduces some sexually transmitted infections (STIs), particularly ulcerative STIs, including chancroid, herpes and syphilis, as well as balanitis, phimosis, and penile cancer. One of the primary benefits of VMMC is that it has also been associated with a reduction in penile human papillomavirus, which is associated with cervical cancer in females. As more men are circumcised, women's likelihood of sexual exposure to HIV decreases, and their risk of HIV infection also declines. The indirect protection for women is substantial; modeling at levels of 80 percent circumcision coverage shows an approximately equal number of HIV infections will be averted in women as in men after 15 years.

Although VMMC has been shown to significantly reduce men's risk of acquiring HIV via heterosexual intercourse, VMMC does not provide complete protection from HIV. Behavioral data from the three VMMC randomized controlled trials show that circumcised men were no more likely to engage in high-risk sexual practices than uncircumcised men. Due to VMMC's partial protection from acquiring HIV, it is necessary for recently circumcised males to minimize any potential increase in risky sexual behaviors (known as risk compensation) following VMMC surgery. In order to ensure that VMMC surgery is provided as part of a comprehensive HIV prevention package, WHO recommends that all VMMC clients receive the minimum package of services, including:

- HIV Testing and Counseling (offer of);
- Screening and treatment for STIs;
- Promotion and provision of male and female condoms;

- Promotion of safer sex practices and risk reduction counseling; and
- Male circumcision (surgical removal of the foreskin).

In addition to WHO's minimum package of services, PEPFAR also recommends including additional components that ensure high quality VMMC services:

- Identifying and implementing active linkages of HIV-positive clients to care and treatment services in VMMC programming; and
- Assurance of voluntarism and informed consent within the VMMC context.

In the future, it is likely that simple, scalable, cost-effective nonsurgical medical devices that can be provided by minimally skilled health care workers will be an additional option for voluntary male circumcision. Two such devices have been developed, and initial studies of their safety and efficacy have been undertaken or are ongoing in selected countries. However, PEPFAR will not support the use of these or other devices until WHO provides normative guidance on their use for voluntary male circumcision, after more studies on the devices become available.

Provision of VMMC services should always be provided in a voluntary and coercion-free environment. Special consideration should be given to performance-based mechanisms to ensure that implementing partner performance measures, client and/or provider reimbursements, and other elements of performance-based financing are consistent with USAID's principles of informed choice and quality of care. Please contact your **Resident Legal Officer** for additional guidance on performance-based financing for VMMC.

For more information, please see the current COP/ROP Guidance and Technical Considerations.

d. Prevention of Mother-to-Child HIV Transmission

The 2008 PEPFAR Reauthorization sets a goal of providing access to PMTCT interventions to 80 percent of pregnant women in heavily affected countries. In the PEPFAR Reauthorization, Congress did not specify a target amount of funding for PMTCT. Nevertheless, in areas where prevalence is high (exceeding five percent in pregnant women), PMTCT programs are an important gateway to HIV/AIDS and other maternal/child health services. Missions are strongly encouraged to develop PMTCT activities. In order to use GHP funds to improve services for pregnant and postpartum women, Missions should be able to demonstrate a direct contribution to increased access to PMTCT services.

PMTCT funds should be used to increase focus on providing access to PMTCT interventions, supporting ART provision for treatment-eligible, HIV-positive pregnant women, and collecting and reporting data on the numbers of HIV-positive pregnant women initiating ART while pregnant, which is a required PEPFAR indicator. Ensuring this sub-group of HIV-infected women is appropriately screened and treated will dramatically reduce the risk of HIV transmission to infants and improve overall maternal health and child survival.

For more information, please see the current country operational plan (COP), Mini-COP, and Technical Consideration Guidance.

e. Orphans and Vulnerable Children Affected by HIV/AIDS

Support for orphans and vulnerable children (OVC) is integral to PEPFAR's wider efforts to mitigate the broad socio-economic impact of HIV/AIDS. In FY 2011, PEPFAR supported more than 4.1 million children with the majority of orphans and vulnerable children programming through USAID. While this is a substantial number, it still represents just a small portion of the estimated 16 million children who have lost one or both parents to AIDS. To underline the importance of expanding coverage, the PEPFAR Reauthorization reiterates that PEPFAR must devote at least 10 percent of program resources in prevention, care and treatment funding globally to OVC programs. With few exceptions, all countries/regions preparing a COP are required to meet this earmark. Programs not meeting this requirement must submit a justification for PEPFAR approval.

USAID programs with GHP funding for OVC affected by HIV/AIDS may include activities to:

- Strengthen families as primary caregivers of children. Highly encouraged are programs that are planned with the assistance of subject matter experts in the area of household economic strengthening and that aim to reduce the economic vulnerability of families and empower them to provide for the essential needs of the children in their care;
- Support the capacity of communities to create protective and caring environments;
- Support programs that establish strong linkages across the continuum of response and give special attention to mother-child pairs and children under five years-old. Such programs are also highly encouraged;
- Build the capacity of social service systems to protect the most vulnerable;
- Allocate resources for children according to need in the context of HIV/AIDS;
- Conduct operations research to identify program models that are effective, efficient, and sustainable; and
- Share lessons learned with local, national, and global partners.

Pediatric care and treatment are also priorities and should have their own dedicated funds. Funding for pediatric care and pediatric treatment will not be counted toward meeting the OVC budgetary requirement. For more information on programming for OVC, please refer to the current COP guidance, technical considerations, as well as the PEPFAR Orphans and Other Vulnerable Children Programming Guidance, available at <http://www.pepfar.gov/documents/organization/83298.pdf>.

f. HIV/TB

In countries or areas with a high burden of HIV/AIDS, the prevalence of HIV infection among patients in TB clinical settings is high, and thus patients in TB clinical settings are “high yield” for identification and referral for HIV prevention, care, and treatment. TB increases mortality in PLWHA and complicates management of treatment for HIV. With the additional specter of

extensively drug-resistant TB emerging among PLWHA both in communities and care settings, TB/HIV activities must be urgently scaled up.

Since TB is the leading infectious killer in people with AIDS, and TB, with proper therapy, is both preventable and curable for most individuals regardless of HIV status, addressing TB among HIV-infected persons is a high priority for HIV/AIDS care programs and may be supported using HIV/AIDS funds. Activities that may be supported include (but are not limited to):

- Screening of HIV-infected individuals (including individuals in PMTCT programs) for symptoms of active TB;
- Support for developing and refining referral systems for HIV-infected individuals to ensure that TB subjects have access to both diagnosis and treatment facilities and that they continue to access HIV care;
- Provision of HTC to all those with active or suspected TB—either within TB clinics or through referral mechanisms;
- Implementation of the “Three I’s” (isoniazid preventive therapy, intensified TB case-finding, and TB infection control) at HIV entry points as priority activities in TB/HIV;
- Development of systems to manage HIV/TB co-infected individuals in either integrated treatment and care programs or across multiple health care programs, including reporting systems to monitor the provision of TB/HIV services, TB-program effectiveness and multidrug-resistant TB in HIV-infected individuals;
- Coordinated planning, training, and monitoring and evaluation of TB/HIV collaborative activities; and
- Surveillance to measure the rate of TB and HIV co-infection.

HIV/TB collaborative activities are an important component of national level plans for both TB and HIV/AIDS. Assistance can be provided to help develop these plans, and PEPFAR resources for TB/HIV should support the priorities outlined in these plans.

To maximize the impact of U.S. Government investments and to avoid duplication, resources and support for HIV/TB activities should be coordinated with programs and funding from other sources, including GHP funds appropriated to USAID and grants from the Global Fund to Fight AIDS, TB and Malaria. The formation of interagency technical working groups and joint monitoring and technical assistance visits can help to facilitate this coordination.

For further information or guidance, please contact GH/OHA or see the current COP guidance for PEPFAR.

g. Counseling and Testing

HIV testing and counseling (HTC) is a critical intervention that serves as a linchpin connecting HIV prevention to HIV treatment and care. Strategic scale-up of HTC and successful linkages are critical for access to treatment, effective prevention interventions, and other services.

The U.S. Government and its partners are supporting the provision of routinely offered, provider-initiated counseling and testing in clinical settings, such as medical and surgical wards, outpatient departments, TB clinics, and at sites for VMMC, antenatal care (ANC), and sexually transmitted infections (STIs). Also, the U.S. Government is committed to increasing access to confidential HTC through community-based settings that include:

- Home-based HTC via index patient or door-to-door HTC;
- Mobile or outreach HTC targeting specific communities or populations; and
- Stand-alone Voluntary HIV Counseling and Testing (VCT).

The USG-supported HTC programs consider how national HTC guidelines, policies, and laws are aligned with international recommendations and guidelines, and address policy gaps where they exist, including those that impact stigma, promote quality HIV testing technologies, and support the uptake and availability of counseling and testing services.

U.S. Government programs that support HTC should also place renewed emphasis on ensuring successful linkage of HTC clients and patients with appropriate follow-up services, particularly HIV prevention services for HIV-negative persons identified through testing activities and HIV care, support, and treatment of HIV-positive persons. Early enrollment and retention in care are important to maximize the health and prevention benefits for people living with HIV.

For more information, please see the current COP Technical Considerations provided by PEPFAR Technical Working Groups.

h. Microbicide Research and Development for HIV/AIDS Prevention

USAID/Washington funds microbicide efforts through central agreements. Examples of activities include the following:

- Supporting the discovery, development, and preclinical evaluation of topical microbicides;
- Developing and assessing acceptable formulations and modes of delivery for microbicides, bridging knowledge and applications from the chemical, pharmaceutical, physical, bioengineering, and social sciences;
- Conducting clinical studies of candidate microbicides to assess safety, effectiveness, and acceptability in reducing sexual transmission of HIV and/or other STIs in diverse populations in international and domestic settings;
- Conducting basic and applied behavioral and social science research to enhance microbicide development, testing, acceptability, and use domestically and internationally; and
- Establishing and maintaining the appropriate infrastructure (including training) needed to conduct microbicide research domestically and internationally.

Missions may be asked by USAID/Washington for advice on local policies and assistance in coordinating HIV/AIDS prevention, care, and treatment program activities with clinical trial activities.

For more information on USAID's work in Microbicides, see: <http://www.usaid.gov/news-information/fact-sheets/hivaids-microbicides>.

i. Vaccine Research for HIV/AIDS

USAID/Washington funds vaccine research efforts through International AIDS Vaccine Initiative. USAID/Washington reviews partner performance to inform decision-making in funding research and development, including clinical trials, through central agreements. Examples of activities include: vaccine research and development including clinical trials; training of personnel in good clinical practices; preparing communities for vaccine trials; training for developing country journalists; policy efforts to encourage national governments to establish practical and effective public policies for accelerating HIV/AIDS vaccine development and testing; and policy efforts to ensure that once a vaccine is developed it is widely accessible in as short a time as possible.

Missions may be asked for advice by USAID/Washington on local policies and assistance in coordinating HIV/AIDS program activities with clinical trial activities.

j. Commodity Fund (CF)

Condom availability and use in most countries is inadequate, especially for those most-at-risk. The Commodity Fund helps fill this important gap. CF centrally funds condoms for HIV prevention and ensures their expedited delivery to countries. The fund is intended to increase condom availability and use by making condoms for HIV prevention available free of charge to other bilateral programs, subject to resource availability and program need, as elaborated below. It is expected that these condoms will be additive to country programs in an effort to expand HIV/AIDS activities and that Missions will not swap condom provision responsibilities with other donors such that availability and use remain unchanged.

Focus countries will need to budget and pay for the male and female condoms they need and will not be eligible to obtain them free of charge from the CF. Countries that submit COPs or mini-COPs are required to include male and female condoms as an activity/budget line item in their COPs. Focus countries are expected to use USAID's centralized procurement mechanism (Central Contraceptive Procurement Project, 936-3057) for all condom procurement.

If a Mission has funding constraints and limited options for obtaining needed condoms, it should consult GH/Office of Population and Reproductive Health (PRH)/ Commodities Security and Logistics Division (CSL). There may be some flexibility on a country-by-country basis to assist in a limited way or on an emergency basis. For focus countries, these expenses must be reimbursed to USAID/GH with GHP funds appropriated to the State Department. Missions should not reduce orders based on funding constraints without first corresponding with GH/PRH/CSL about program needs and possible assistance.

Both focus countries and Missions in other bilateral programs should follow the same ordering procedures as in prior years. Detailed ordering guidance has been sent separately to Missions.

For clarification on condoms, the HIV/AIDS budget category should not be used for the purchase of contraceptives *for family planning only* nor used to make up for shortfalls in the FP/RH category activities or in any other program. However, within the GHP Account, HIV/AIDS budget category funds may be appropriately used for purchasing condoms *for HIV/AIDS prevention*. Orders of male and female condoms for family planning programs only must be budgeted and paid for like other contraceptives with FP/RH funds.

k. Partnership for Supply Chain Management System (PfSCM)

Funded by PEPFAR, Supply Chain Management System (SCMS) brings together 14 private sector and non-governmental organizations under one contract to procure essential medicines and supplies at affordable prices; help strengthen and build reliable, secure and sustainable supply chain systems; and foster coordination of key stakeholders. The contract with PfSCM is unique, because PfSCM services and expertise are available to U.S. Government agencies, foreign governments, U.S.-Government-financed contractors, grantees, and other organizations doing HIV/AIDS work. Country teams are encouraged to use PfSCM because of the efficiency of centralized procurement and its expertise in supply chain management.

PfSCM purchases antiretroviral drugs (ARVs), other essential drugs, laboratory supplies and equipment (including rapid test kits), and other supplies, and equipment. Use of the PfSCM contract increases efficiency and reduces costs by volume purchasing and being a single point of contact for manufacturers and consumers. By leveraging the economies of scale created by U.S.-Government-pooled procurement, the SCMS program is currently at or below the lowest reported price for all ARVs, generic or innovator pharmaceuticals. All PfSCM team members are committed to developing the procurement and distribution capacity of host-country organizations. PfSCM assists countries in determining and implementing the most appropriate strategy for each supply chain component, whether managed internally or outsourced, to achieve best value. All U.S. Government agencies are encouraged to use the procurement services of the SCMS mechanism and to phase out other agreements for ARVs, other essential drugs, test kits and other laboratory supplies and equipment, and other commodities that lend themselves to centralized purchasing.

SCMS provides a full range of supply chain management services, including forecasting, quantification, overall management, warehouse and inventory control, procurement, freight and freight forwarding, quality assurance, information systems management, and in-country technical assistance and support. Technical assistance is available regardless of who is purchasing the commodities. Other donors, such as the Global Fund, also use PfSCM as procurement agent.

If you have questions, please contact the USAID Supply Chain for Health (SCH) team. More information about SCMS is available at <http://scms.pfscm.org/scms>. Please also see the current COP guidance for PEPFAR.

l. Working Capital Fund

The HIV/AIDS Working Capital Fund (WCF) is a congressionally authorized account that

facilitates the procurement of HIV/AIDS commodities. Funds deposited into the WCF become no-year funds and are co-mingled with other funds. This gives the Agency the flexibility to shift funds within the WCF to respond to changes in country needs so as to ensure protection against stockouts and to meet other program needs. GH/OHA/SCH manages the WCF and it is primarily used to fund the Supply Chain Management System program and its principal contractor, the Partnership for Supply Chain Management. The working Capital Fund can accept funds from any U.S. Government agency, foreign governments, multi-lateral organizations, and other public or private entities.

m. Adult and Pediatric Care and Treatment

According to the 2012 COP and Mini-COP Guidance:

Adult care and treatment comprises all facility-based and home/community-based activities for HIV-infected, adults, and their families (HIV-affected individuals) aimed at extending and optimizing quality of life for HIV-infected individuals from the time of diagnosis throughout the continuum of illness, through provision of clinical, psychological, social, spiritual, and other support for the prevention of onward transmission of the virus--using principles of prevention with people living with HIV (PwP) and positive health dignity and prevention (PHDP) services. Care and treatment programs should optimize early identification, linkage and retention and maximize access to antiretroviral care and treatment, while ensuring that quality services are delivered in a sustainable fashion. Clinical services should include evaluation for ART eligibility so that antiretroviral therapy can be initiated at the appropriate time; antiretroviral therapy, prevention and treatment of opportunistic infections (OIs), a preventative care package, and other HIV/AIDS-related complications, including malaria, diarrhea, and cryptococcal disease (providing access to commodities such as pharmaceuticals, insecticide treated nets, safe water, sanitation and hygiene interventions and related laboratory services), pain and symptom relief, and nutritional assessment, counseling and support; and screening to prevent cervical cancer. Adult care and treatment also includes the purchase, distributions, and management of OI drugs, excluding TB drugs.

Psychological and spiritual support may include group and individual counseling and culturally appropriate end-of-life care and bereavement services. Non clinical services provided within community platforms should include, but are not limited to: socioeconomic support including vocational training, economic strengthening and income-generating activities, social and legal protection, and training and support of caregivers, PLWHA support group members/leaders, community leaders, peer counselors, condom distributors, etc.; such services should be provided in addition to some already mentioned activities in the paragraph above where applicable.

Prevention services integrated into routine care in both facility and community settings must comprise prevention with positives (PwP)/Positive health Dignity and Prevention (PHDP services), which includes: behavioral counseling, and counseling and testing of family members.

The Office of the Global AIDS Coordinator has issued guidance on palliative care called, HIV/AIDS Palliative Care Guidance #1 for the United States Government in Country Staff and Implementing Partners, available here: <http://www.state.gov/documents/organization/64416.pdf>.

Pediatric care and treatment programs should address linkages with PMTCT, efforts to rapidly scale up early infant diagnosis through dry-blood spot/DNA Polymerase Chain Reaction (PCR) laboratory networks, training of health care workers in the provision of pediatric care and treatment and in other key aspects of pediatric care and treatment. Pediatric care and treatment programs comprise all health facility-based activities for HIV-exposed and HIV-infected children (<2 years and 2–14 years) and their families (HIV-affected individuals) aimed at extending and optimizing quality of life for HIV-infected children – from the time of diagnosis throughout the continuum of illness – through provision of clinical, psychological, social, spiritual and prevention services. Clinical services should include early infant diagnosis, appropriate counseling and testing for at-risk children and adolescents, antiretroviral therapy, prevention and treatment of OIs (excluding TB) and other HIV/AIDS-related complications including malaria and diarrhea (providing access to commodities such as pharmaceuticals, insecticide treated nets, safe water interventions and related laboratory services), pain and symptom relief, and nutritional assessment and support. A key component of clinical services is provision of the Preventive Care Package for children. Other services – psychological, social, spiritual, and prevention services – should be provided as appropriate. These services are provided within programs for OVC, and clinic-based partners should make linkages to OVC services and service providers to ensure continuum of care for these children. Pediatric care and treatment also includes the purchase, distribution, and management of OI drugs, excluding TB drugs. Readers are referred to the HIV/AIDS Preventive Care Guidance, which includes two sections: one, regarding programming for adults (<http://www.pepfar.gov/reports/guidance/c19728.htm>), and the other regarding programming for children ages 0–14 (<http://www.pepfar.gov/reports/guidance/c19729.htm>).

For more information, please also see the current COP or Mini-COP Guidance.

n. Injection Safety

HIV transmission in the health care setting can occur through unsafe injection practices that put both patients and providers at risk. Under PEPFAR I, Congress recommended that HIV/AIDS funds be used to support initiatives that reduce the spread of HIV in health care settings by making medical injections safer. S/GAC assigned this activity to be implemented by both the Centers for Disease Control and Prevention (CDC) and USAID. Beginning in FY 2004, through HIV/AIDS funds approved by S/GAC, USAID/Washington provided central funding for medical injection safety activities. Activities have included rapid assessments of current injection and phlebotomy practices; training programs and systems to improve provider skills and reduce needlestick injuries; occupational post-exposure prophylaxis (PEP); improved commodity security; procurement and management of safe-injection supplies and equipment; better treatment guidelines that emphasize oral medications where appropriate; strengthened health care waste management systems, especially for sharps; improved knowledge about injection safety and advocacy to reduce inappropriate demand for injections; and the development and implementation of national injection-safety plans and policies.

Current PEPFAR prevention guidance considers injection safety activities (encompassed under “universal precautions”) to be foundational programs that support systems for prevention in

every country. Nonetheless, significant vulnerabilities remain related to most aspects of injection safety, particularly waste management, PEP, and safe phlebotomy interventions. Please contact PEPFAR medical transmission technical working group members in OHA for further information and assistance.

o. Health Systems Strengthening and HIV/AIDS

Health systems strengthening is an important foundation for ensuring sustainability of service provision and other HIV/AIDS services and interventions. HIV/AIDS programs need to be supported by systems that develop and implement sound policies, provide pharmaceuticals and laboratory services, finance health services, assure quality and efficiency of care, manage the health workforce, and provide the required information to operate effectively.

- To address weaknesses in host-country leadership and management that make HIV/AIDS services less effective and waste resources, funds may be used for broad policy reform and system-wide approaches and for making management processes more transparent and accountable. Examples include improving donor coordination and strengthening local partner organizations, particularly in financial and program management, policy development, and leadership.
- Where financial systems are not adequate to reveal funding deficiencies for HIV/AIDS programs, funds may be used to improve planning-unit approaches to the allocation of resources. Examples include conducting focused expenditure reviews for HIV/AIDS in order to provide policymakers with a clearer understanding of the current strengths and weaknesses of financial arrangements for priority areas.
- Where weaknesses in pharmaceutical management limit access to treatment, funds may be used to support strengthening the capacity of host government institutions to develop policies and plan, manage, and implement HIV programs, including national procurement, logistics, and pharmacovigilance systems to ensure the quality, safety, and rational use of medicines such that desired therapeutic outcomes are achieved.
- Where weaknesses in information limit the availability and use of reliable and timely information for evidence-based HIV/AIDS policymaking and program management, funds may be used to support the collection, analysis, dissemination, and use of reliable and timely information. Examples include support to the development and use of harmonized core indicators for program planning, monitoring and evaluation; strengthening the quality of data sources, such as service records; addressing constraints to the use of information for program management; and implementing evaluations to assess the impact of program interventions.
- Where the lack of a well skilled, supported, and motivated workforce is a major barrier to scaling up HIV services, funds may be used to support pre-service and in-service training and institutional strengthening; strengthen health worker recruitment, retention, performance and productivity; and build country capacity in human resources for health

(HRH) planning and management and utilization of data for workforce decision-making. Examples include: e-health and mobile health activities.

Interventions in the following areas are also appropriate health systems strengthening activities:

- Strengthening leadership and the policy environment to reduce stigma and discrimination, including addressing key gender issues;
- Strengthening the role of the private health sector to leverage donor resources more efficiently, encourage mixed health systems, and enhance the sustainability of the HIV/AIDS response;
- Strengthening leadership and policy environment to expand access to HIV care and treatment services for children and documenting any positive outcomes from previous years' investments in this area (e.g., new policy or guidelines, new legislation, etc.);
- Strengthening the systems that support Global Fund grants at the country level. This may include working directly with the country coordinating mechanism (CCM) and/or the Prime Recipient in areas directly related to health systems strengthening in grant management and implementation.

Human resources for health are critical for a functioning health system. Effective health systems depend on a trained and motivated health workforce that can carry out the tasks and build the systems needed to achieve PEPFAR goals. These tasks include: HRH strategy development and workforce planning; human resource information systems; pre-service and in-service training and training for task shifting; performance assessments; retention strategies; twinning and volunteers; management and leadership development; and support for salaries.

Questions often arise regarding support for long-term training and the use of U.S. Government funds to pay salaries of staff in government facilities, or to pay salary supplements. The following guidance is pursuant to S/GAC's "Support for Host Government Staffing: PEPFAR Guidance (8/16/06)" and the FY 2012 Country Operational Plan Guidance.

Long-term training

PEPFAR funds may be used to support long-term training of health professionals such as medical doctors, nurses, pharmacists, medical social workers; auxiliary workers or "associate professionals" such as clinical officers, assistant or general nurses, and laboratory and pharmacy technicians; advanced degrees in disciplines such as public health, public administration, epidemiology, and pharmacology.

Long-term training may be supported within certain parameters:

- For each PEPFAR COP, other bilateral program, or operating unit, no more than 3.0 percent of annual HIV/AIDS budget levels or \$6,000,000 per year (whichever is less) may be used to support long-term training;
- The types of personnel eligible for long-term training are only those who are directly involved in HIV/AIDS service delivery or program management support;

- All personnel should have a requirement to serve in areas of need and to deliver HIV/AIDS services upon completion of their program; and
- A strong monitoring and evaluation component should be included in order to demonstrate the linkage to improved access to quality HIV/AIDS services.

Countries are encouraged to look at innovative approaches that leverage other resources from different donors, e.g., support the proportion of training that is HIV/AIDS-specific and ask other donors to support the remainder.

For more information, please refer to the most current COP or Mini-COP guidance. Please also see Chapter III.11.B on health systems/systems strengthening.

Salaries

USAID *shall not* pay for salaries of permanent civil service employees on public health institution payrolls. However, HIV/AIDS funds may be used by U.S. Government program contractors or grantees to pay for time-limited contractors to carry out activities essential to HIV/AIDS program goals. In addition, NGOs may hire personnel to be placed in the Ministry or other government health facilities or in their own organizations. USAID, through its contractors, also supports staff seconded to the Ministry of Health (MOH). U.S. Government teams and their implementing partners are urged to be cautious about paying salaries or other benefits that attract staff away from their current positions in local public and private agencies. In all cases, countries should develop a transition plan to ensure that contract staff can eventually be absorbed through sustainable long-term approaches using non-U. S. Government resources.

Payment of salary supplements, or “top-ups,” to host government employees is not permitted. However, it is permissible to pay bonuses or incentives to personnel (public or private sector) who meet performance-based criteria that are directly linked to achieving HIV/AIDS goals, e.g., working overtime to increase patient access or achieving quality performance targets above and beyond routine job requirements. Any performance-based financing scheme should first be implemented on a pilot basis and include monitoring and evaluation and reporting of results achieved as well as any broader impacts on service delivery. Successful models of performance-based health programs that can be applied to HIV/AIDS service delivery already exist in a number of countries.

In addition, there are a number of ways to motivate health care providers to stay on their jobs that do not involve financial-incentive schemes. HIV/AIDS funds may be used to support a number of these including:

- ART for health care providers and their families;
- Housing support in rural areas;
- Providing basic infection-prevention supplies to reduce fear of HIV infection;
- Improving morale and empowerment through continuing education courses, supportive supervision, and in-house support groups;

- Placing a human resource professional at service facilities to plan for ART scale-up, ensure a workplace prevention program, develop a training plan, and rework job descriptions to reflect current responsibilities for HIV/AIDS service providers; and
- Establishing better linkages with community groups that provide care for HIV/AIDS patients at home.

For further information or guidance, please contact GH/OHA, or see the current COP or mini COP guidance for PEPFAR.

p. Gender and HIV/AIDS

Gender inequality is a key driver of the HIV epidemic, and HIV disproportionately impacts those with less social status and power. Such disparities are the result of biological, structural, and cultural conditions that place women and girls at greater risk for acquiring HIV, such as gender norms that impact expectations and behaviors as well as differences in access to resources that limit prevention and mitigation of the disease. Men and boys are also affected by gender expectations that may encourage risk-taking behavior, discourage accessing health services, and narrowly define their roles as partners and family members. Often, gender norms around masculinity and sexuality not only create pressure to engage in risky sexual behavior, but also put men who have sex with men and transgender individuals at increased risk for HIV by creating additional stigma and discrimination that can prevent them from seeking or accessing services. The issues around gender and HIV/AIDS are complex, and can vary from one country to another; however, addressing these challenges successfully is critical to the achievement of HIV prevention, treatment, and care goals.

PEPFAR employs a two-pronged approach:

- Mainstreaming of gender into all prevention, care, and treatment programs; and
- Programming to address five cross-cutting gender strategic areas:
 - Increasing gender equity in HIV/AIDS activities and services;
 - Reducing violence and coercion; engaging men and boys to address norms and behaviors;
 - Increasing women’s legal protection; and
 - Increasing women’s access to income and productive resources, including education.

This approach is supported by the GHI Women, Girls and Gender (WGGE) Equality principle supplemental document as well as the Gender Equality and Female Empowerment Policy (<http://www.usaid.gov/sites/default/files/documents/1870/GenderEqualityPolicy.pdf>) and the National Action Plan on Women, Peace and Security.

Illustrative activities include (but are not limited to) interventions to:

- Work with communities, men and women to transform traditional gender norms that perpetuate gender-based violence, sanction cross-generational and transactional sex, and promote multiple sex partners;

- Address barriers to women’s and men’s access to quality PMTCT, counseling and testing, and care and treatment services, including adherence to treatment;
- Increase couple communication and men’s constructive involvement as supportive partners;
- Provide counseling that considers fear of negative outcomes, such as violence, on disclosure of HIV status, and as a deterrent to testing and to accessing services;
- Support family-centered care where appropriate;
- Promote non-stigmatizing support networks for women infected and affected by HIV/AIDS;
- Address the unequal burden of care on mothers/wives and other female household members; and
- Ensure inheritance and property rights for women and access to productive resources, e.g., linking income-generation, education, and microfinance as “wrap-around” interventions with care and support activities.

Activities should include collection of sex-disaggregated data and age-disaggregated data as applicable, and/or build the capacity of data systems to enable collection of sex-disaggregated data. For additional guidance on activities per program area and five gender strategic areas, please see the most current COP guidance. Please contact the USAID/OHA Gender Team for further information and assistance.

q. Support to the Global Fund to Fight AIDS, Tuberculosis and Malaria

The U.S. Government is the largest bilateral donor to the Global Fund, with more than \$6.079 billion in contributions to date. Over ten grant rounds, the Global Fund Board has approved \$22.6 billion for more than 568 grants in 150 countries. In order to ensure the most successful implementation of these grants, Mission staff should participate in CCMs and work closely with Global Fund Principal Recipients (PRs) and sub-recipients where possible. In August 2007, GH/OHA awarded a Global Fund technical assistance contract – later named Grant Management Solutions – to Management Sciences for Health and partners; this project has been replaced by the Global Fund Technical Support Project (GFTS 2.0). Global Fund PRs and CCMs in almost all countries are eligible to apply for technical assistance in governance and leadership, organizational development, program and financial management, procurement and supply management, and monitoring and evaluation and reporting. Additionally, many other USAID-funded partners provide technical assistance for strengthening Global Fund grant implementation, such as UNAIDS, STOP TB, Green Light Committee, and Roll Back Malaria. Missions are strongly encouraged to use their GHP funds to support technical assistance to Global Fund grants where appropriate. The USAID Global Fund Liaison and S/GAC’s Multilateral Diplomacy staff can answer questions about Global Fund policies and procedures as well as USAID and U.S. Government policies and procedures regarding the Global Fund.

r. Examples of Family Planning/Reproductive Health and HIV/AIDS Integrated Activities

The integration of health programs, including HIV and family planning programs, is a priority for the U.S. Government and is outlined as a key strategy to strengthen existing foreign

assistance programs under the [Global Health Initiative](#). USAID is a key implementing partner of the PEPFAR and provides leadership for the newly formed PEPFAR Interagency FP/HIV Task Force. Integrated services can ensure that all people living with HIV and AIDS have access to family planning services that support their fertility choices. USAID coordinates with other agencies at the country level to make integrated services available to the clients we serve.

PEPFAR funding may be used to support family planning and HIV/AIDS integrated programs, as described in PEPFAR guidance documents, including the Country Operational Plan Guidance and Technical Considerations (<http://www.pepfar.gov/reports/guidance/>). PEPFAR programs should be optimized as a platform on which to incorporate and integrate other essential health services for women, including the integration of HIV and voluntary FP services, aimed at safeguarding the rights of individuals living with HIV in reproductive decisions.

Integration of HIV and FP activities may be cost-effective and appropriate, depending on the country context, within PEPFAR-supported programs for prevention-of-mother-to-child transmission (PMTCT), care and treatment, services for key populations, and health systems strengthening. Illustrative programming opportunities that should be actively pursued are listed below, as appropriate:

- Provide counseling and/or referrals to voluntary family planning services for women and men in HIV prevention, treatment, and care programs. Provide HIV prevention messaging and support, as well as HIV testing and counseling, within antenatal care, maternal and child health, and family planning programs for both men and women;
- Ensure access to a comprehensive range of contraceptive commodities for PLHIV who wish to delay or prevent pregnancy;
- Monitor enrollment and receipt of services when referrals are made to capture linkages and ensure uptake of high-quality services including FP, maternal, neonatal and child health (MNCH) and primary care;
- Develop and disseminate technical guidance materials related to HIV and FP integration;
- Strengthen the policy environment for appropriate integration of HIV and FP platforms and services;
- Evaluate the efficiency and effectiveness of integrated HIV and FP service delivery;
- Support quality assurance efforts to improve integrated HIV and FP services;
- Conduct operational or implementation science research on effective integration approaches;
- Strengthen public health and primary health care systems, including commodity procurement, information systems, and logistics and distribution systems designed to improve the availability of HIV and FP commodities within integrated programs;
- Ensure that HIV and FP integrated program activities respect a client's right to make informed decisions about his or her reproductive life and that a full range of contraceptive options are available for those clients who wish to avoid pregnancy;
- Strengthen delivery of voluntary family planning services within PEPFAR programs to improve PLHIV's access to these services; and
- Document successful and promising approaches to integrated HIV and FP programs.
- Women living with and affected by HIV may refrain from seeking FP services and safe pregnancy counseling to avoid experiencing stigma and discrimination.

To help mitigate possible stigma and discrimination, USG-supported family planning and HIV/AIDS programs must adhere to the following principles:

- People living with HIV should be provided with comprehensive information on, and be able to exercise voluntary choices about their health, including their family planning choices.
- All individuals have a right to choose, as a matter of principle, the number, timing, and spacing of their children, as well as decide on the use of family planning methods, regardless of their HIV status.
- Family planning use should always be a choice, made freely and voluntarily, independent of the person's HIV status.
- The decision to use or not to use family planning should be free of any discrimination, stigma, coercion, duress, or deceit and informed by accurate, comprehensible information and access to a variety of methods.
- Access to and provision of health services, including antiretroviral treatment, for a person living with HIV should never be conditioned on that person's choice to accept or reject any other service, such as family planning (other than what may be necessary to ensure the safe use of antiretroviral treatment, e.g., drug interactions).
- Women living with HIV who wish to have children should have access to safe and respectful pregnancy counseling, antenatal, and childbirth services.

As part of comprehensive care for HIV and AIDS, field teams are expected to prioritize opportunities to use PEPFAR funds to support voluntary family planning and reproductive health (FP/RH) services. These services must meet an HIV prevention, treatment, or care purpose and/or link PEPFAR-funded activities with FP/RH activities funded from separate U.S. government accounts or other non-U.S. government sources of funds. As in years past, PEPFAR funds may not be used to purchase family planning commodities; however, male and female condoms can be purchased using PEPFAR funds.

HIV and FP integrated program activities must respect a client's right to make voluntary and informed decisions about his or her reproductive health. The principles of voluntarism and informed choice are prerequisites for good quality of care and must form the basis of integrated programs. These principles are articulated in legislative requirements that govern the use of U.S. government foreign assistance funds and [U.S. government FP assistance](#). In addition, as always, it is important to ensure that USG staff is aware of and properly implement the various legal and policy requirements that apply across U.S. foreign assistance at large, including [those related to abortion](#) and involuntary sterilization.

A partner that receives both PEPFAR and USAID FP/RH funds to conduct an integrated program is subject to the legal and policy requirements that govern both HIV/AIDS and FP activities because the partner is conducting both types of activities. Similarly, in accordance with current PEPFAR guidance, a partner that receives only PEPFAR funds to conduct both HIV/AIDS and FP activities must also comply with the legal and policy requirements applicable to both HIV/AIDS and FP activities.

Within an integrated HIV/AIDS and FP program, different organizations may be responsible for different types of activities, and therefore be subject to different legal and policy requirements. For example, a partner that receives funds solely for HIV/AIDS activities will not be subject to the [voluntarism and informed choice requirements](#). A partner that receives funds solely for FP activities will be subject to [the voluntarism and informed choice requirements](#) but will not be subject to the [HIV/AIDS requirements](#).

For additional information on HIV/AIDS and FP/RH integration, [policy guidance](#), including guidance on integrated activities by technical area, please consult the most recent annual Country Operational Plan Guidance and Technical Considerations document issued by S/GAC.

For additional information on USAID’s work in FP/HIV integration and programmatic best practices and resources, visit USAID’s new external Web page, “[Promoting Integration of Family Planning into HIV and AIDS Programming](#).”

C. Legal and Policy Requirements and Congressional Directives

a. Authority

USAID’s HIV/AIDS Program is authorized by the FAA of 1961, as amended.

b. Legislative Requirements

i. Legislative Restrictions Regarding Abortion and Involuntary Sterilization Applicable to All Health Activities²⁸

There are a number of restrictions regarding abortion and involuntary sterilization set forth in Section 104(f) of the FAA and the annual Appropriations Act. These restrictions apply to all activities funded under the annual Appropriations Act, including FP/RH, MCH, HIV/AIDS, malaria and other health activities. These legislative restrictions are reflected in the mandatory standard provisions of all USAID awards. See ADS 303 for the latest provisions for assistance awards and AAPD 08–01 for the latest provisions for contracts.

These restrictions include the following:

Helms Amendment (1973): USAID funds may not be used to pay for the performance of abortion as a method of family planning or to motivate or coerce any person to practice abortions. Under the Leahy Amendment, the term “motivate,” as it relates to family planning assistance, shall not be construed to prohibit the provision, consistent with local law, of information or counseling about all pregnancy options.

Siljander Amendment (1981): USAID funds may not be used to lobby for or against abortion.

Biden Amendment (1981): USAID funds may not be used to pay for any biomedical research that

²⁸ See also Annex V.

relates in whole or in part, to methods of, or the performance of, abortions or involuntary sterilization as a means of family planning. Epidemiological or descriptive research to assess the incidence, extent or consequences of abortions is not covered by the amendment and is therefore permitted.

Additional provision relating to voluntary sterilization (1985): USAID funds may not be used to pay for the performance of involuntary sterilizations as a method of family planning, or to coerce or provide any financial incentive to any person to undergo sterilization.

It is important for USAID staff to:

- Understand these restrictions and how they could potentially impact HIV/AIDS activities;
- Ensure that agreements contain the current relevant standard provisions; and
- Ensure that partners are aware of these restrictions

ii. Military, Police, Prisons, or other Law Enforcement Forces

In many HIV high-prevalence countries, military and law enforcement populations are known to be high-risk groups that have a direct influence on the HIV transmission dynamics in the general civilian population. With HIV prevalence in some militaries estimated at 40–60 percent, their potential to infect others is enormous. In other countries where HIV prevalence is not yet high, it is essential to head off such an extreme situation before it occurs. In both cases, failure to include such groups in HIV/AIDS activities will pose a severe threat to the health of the public at large and diminish the likelihood that any HIV/AIDS prevention and mitigation program could succeed. In certain circumstances, funds from the GHP Account may be used to address the spread of HIV/AIDS within populations of military forces, police, prison, or other law enforcement forces subject to the guidance below. Where possible, U.S. Department of Defense (DOD) HIV/AIDS experts should be consulted and engaged in programs addressing these population groups. For assistance that does not meet the requirements of the guidance below, such as when these personnel are participating in their military or law enforcement capacity, and not as a population group at risk of spreading the disease, contact your Resident Legal Officer or GC for assistance.

Assistance to foreign military or to police, prison, or other law enforcement personnel as a population group at risk of contracting and transmitting HIV/AIDS:

Section 531(e) of the Foreign Assistance Act of 1961, as amended, and general principles of appropriation law prohibit the use of economic assistance funds for military purposes. In addition, Section 660 of the FAA prohibits training or advice or financial support for police, prisons, or other foreign law enforcement forces. However, GC has determined that certain programs involving military forces or police, prison, or other law enforcement personnel would not be prohibited by these legal restrictions. In particular, participation by these groups in HIV/AIDS programs might not be prohibited if they are participating not in their military or law enforcement capacity, but as a population group at risk of contracting and transmitting HIV/AIDS more broadly within the population, and the following conditions are met:

- a) The programs or activities in which the military or police, prison, or other law enforcement personnel would participate are part of a larger public health initiative to combat HIV/AIDS, and exclusion of such group would impair the achievement of the initiative's public health objectives;
- b) The program for the military or police, prison, or other law enforcement personnel must be similar to that received by other population groups similarly situated in terms of HIV/AIDS transmission risk and prevention; and
- c) Neither the program or activities, nor any commodities transferred under the program can be readily adaptable for military or police, prison or other law enforcement personnel purposes.

GC has determined that this same rationale can be applied to all USAID infectious disease programming.

GC has emphasized that the requirement for similar programs (b above) means similar-in-subject content, e.g., how HIV/AIDS is acquired, how it is transmitted, and how transmission can be avoided. As long as the training and materials are designed to deal with such acceptable subjects, they meet the test. It is not required that there be one uniform set of training materials appropriate for use by military and also by the other groups in society, such as younger school children. Clearly, the language, content, and method of delivery could and should vary depending on the audience.

The Office of the General Counsel has also advised that it would be appropriate to have particular activities that are directed only toward the military or police, prison, or other law enforcement personnel as long as they are designed only to support HIV prevention and combat its transmission. A conference or design workshop attended only by military personnel may be funded for the frank discussion of HIV/AIDS among the military and how to combat it (e.g., an officer's responsibility to see that his subordinates are fully informed and are discouraged from engaging in high-risk behavior or from frequenting known high-risk establishments). Under the same HIV/AIDS country or regional program, a conference for village health workers on avoiding mother-to-child transmission may well exclude military personnel as it is not relevant to them. Both, however, are in pursuit of the broader goal and thus appropriate for USAID funding.

Therefore, it is appropriate and legally permissible to include the military, police, prison, or other law enforcement personnel in comprehensive HIV/AIDS programs when they are participating not in their law enforcement capacity but as a population group at risk of contracting and spreading the disease and the program meets the three legal criteria outlined above. Indeed, including those groups may well be critically important to the success of the programs. In the design and implementation of HIV/AIDS programs, it is also appropriate to have training sessions or materials focused specifically on individual groups as long as the activities are in pursuit of the overall program goal. Where possible, DOD HIV/AIDS experts should be consulted and engaged in programs addressing these groups, and in certain contexts with foreign militaries, it may be appropriate for DOD to implement these activities.

From a legal standpoint, a specific, written request or formal approval is not required if the guidance above is followed. However, OUs should be aware that, as a policy matter, the approval of bureaus or offices in USAID/Washington might be required before HIV/AIDS assistance is provided in accordance with the guidance above; therefore, Missions are asked to confirm procedures with their bureaus. Regardless of whether or not formal bureau or office clearance is required, OUs must document the decision to include military, police, prison or other law enforcement personnel in HIV/AIDS activities that are part of a larger public health initiative. Such documentation should explain how the personnel are participating as population groups at risk of contracting or spreading the disease; how the three legal criteria discussed above have been met; and how any bureau approval procedures have been followed. If there is substantial potential for controversy, or if there is confusion about applying the guidance above to determine whether inclusion of the military or police, prison, or other law enforcement personnel as part of a larger overall HIV/AIDS program is appropriate or authorized, please contact your Resident Legal Officer or GC advisors.

Notwithstanding authority for assistance to police, prison, or other law enforcement personnel: For assistance that does not meet the guidance above (please see conditions a through c beginning on page 76), if the assistance is to police, prison, or other law enforcement personnel, the use of notwithstanding authority described in section III.1.A.a may be available. However, this notwithstanding authority is *not* available for assistance to foreign militaries. For programs with foreign militaries that do not meet the guidance above, consideration should be given to the possibility of implementation by DOD.

In relying on notwithstanding authority for this purpose, OUs need to carefully review the facts of any proposed activity to ensure that the activity falls only within the scope of HIV/AIDS activities permitted by other sections of this guidance. As an example of an activity that might require use of notwithstanding authority, programs that aim to address gender-based violence and its role in the spread of HIV/AIDS may appropriately want to engage local police; however, if the engagement involves assistance to police in their law enforcement capacity, notwithstanding authority may be required. If an operating unit decides to rely on “notwithstanding” authority, the clearance procedures described below must be followed.

Moreover, OUs should be aware that certain activities relating to the spread of HIV/AIDS involving prisoners, that do not involve support to prisons or prison personnel, may not fall within the prohibition of Section 660 at all, and therefore would not require the reliance on “notwithstanding” authority to fund. However, an activity that involves providing assistance to prison personnel or prisons, even for the benefit of prisoners, might fall under the prohibition of Section 660 and require the use of notwithstanding authority. If in doubt about the applicability of Section 660, contact your Resident Legal Officer or GC for assistance.

A decision to rely on notwithstanding to provide assistance to prisons, police, or other law enforcement personnel may raise sensitive policy issues. OUs must prepare a memo requesting approval from their bureau’s Assistant Administrator and obtain clearances from the Assistant Administrator of the Bureau for Global Health (if the operating unit is not within GH), and others as deemed appropriate by the approving Assistant Administrator. The approving Assistant Administrator may request clearance from the Assistant General Counsel for their bureau, the

relevant regional bureau, and the relevant regional bureau's Assistant General Counsel. F is responsible for tracking OUs that make use of the notwithstanding authority. A copy of all memos relying on this global health notwithstanding authority should be sent to GC/GH for information.

iii. Prostitution and Sex Trafficking

Section 301 of the PEPFAR Authorization, entitled "Assistance to Combat HIV/AIDS", includes certain restrictions on the use of HIV/AIDS funds relating to prostitution and sex trafficking.²⁹

- Section 301 (e) prohibits the use of U.S. Government funds for HIV/AIDS activities to promote or advocate the legalization or practice of prostitution or sex trafficking.
- Section 301 (f) requires non-governmental organizations and certain Public International Organizations³⁰ receiving U.S. Government funds for HIV/AIDS activities to have a policy explicitly opposing prostitution and sex trafficking. This legal requirement is met when the organization signs its award, which includes a statement that the organization is opposed to the practices of prostitution and sex trafficking.
- Section 301(f) is the subject of litigation, including a Supreme Court decision, and is no longer enforceable against U.S. Organizations. However, the requirement remains applicable to non-U.S. NGOs. The litigation is ongoing; please contact your RLO or GC/GH if you have any questions regarding application of this requirement.

These provisions were left unchanged in the PEPFAR Reauthorization. USAID's AAPD 14-04 implements these provisions (<http://www.usaid.gov/work-usaid/aapds-cibs/aapd-14-04>). AAPDs are revised from time to time. Please make sure that the correct AAPD that implements the provision is being followed, and that the proper clauses are included in all relevant awards for HIV/AIDS activities.

USAID and its implementing partners may work with high-risk groups, such as people engaged in prostitution, as long as PEPFAR funds are not used to "promote or advocate the legalization or practice of prostitution and sex trafficking."

The following HIV/AIDS prevention, care, and treatment activities are specifically permitted by the PEPFAR Authorization: "provision to individuals of palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities,

²⁹ Section 301 includes the following provisions:

"(e) LIMITATION. – No funds made available to carry out this Act, or any amendment made by this Act, may be used 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.

"(f) LIMITATION. – No funds made available to carry out this Act, or any amendment made by this Act, may be used to provide assistance to any group or organization that does not have a policy explicitly opposing prostitution and sex trafficking."

³⁰ The FY 04 Appropriations Act amends Section 301(f) of the AIDS Authorization by exempting the Global Fund to Fight AIDS, Tuberculosis and Malaria, the World Health Organization, the International AIDS Vaccine Initiative and any 'United Nations agency' from that section. The Statement of Managers states that the conferees 'intend that for purposes of this provision, the World Health Organization includes its six regional offices: The Americas (PAHO); South-East Asia (SEARO); Africa (AFRO); Eastern Mediterranean (EMRO); Europe (EURO); and Western Pacific (WPRO).'"

including test kits, condoms and, when proven effective, microbicides." The Agency also supports the provision of other HIV/AIDS prevention activities, such as behavior change communication, to achieve risk reduction in people engaged in sex work.

iv. Condoms

Within the GHP Account, HIV/AIDS funds may be used appropriately for purchasing condoms for HIV/AIDS prevention (see Commodity Fund, Chapter III.6.B.j).

Since 2004, USAID's appropriations have included the following provision: "That information provided about the use of condoms as part of projects or activities that are funded from amounts appropriated by this Act shall be medically accurate and shall include the public health benefits and failure rates of such use."³¹ "This requirement means that information on condoms provided by USAID-funded programs should be consistent with the USAID Condom Fact Sheet available at: <http://www.usaid.gov/sites/default/files/documents/1864/condomfactsheet.pdf>."

v. Conscience Clause

Under section 301(d) of the Leadership Act, as amended, "An organization, including a faith-based organization that is otherwise eligible to receive assistance...for HIV/AIDS prevention, treatment, or care

- Shall not be required, as a condition of receiving such assistance:
 - (1) to endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS; or
 - (2) to endorse, utilize, make a referral to, become integrated with, or otherwise participate in any program or activity to which the organization has a religious or moral objection; and
- Shall not be discriminated against in the solicitation or issuance of grants, contracts, or cooperative agreements...for refusing to meet any [such] requirement."

USAID implements this requirement through clauses that must be included in solicitations and awards for HIV/AIDS activities. The clauses are set forth in AAPD 14-04 (<http://www.usaid.gov/work-usaid/aapds-cibs/aapd-14-04>). Please note that there is a version of the Conscience Clause standard provision that must be specifically printed in RFAs and RFPs for HIV/AIDS activities. Please work with your COs and AOs to ensure that all solicitations issued by your operating unit include this provision.

OUs should design solicitations following evidence-based and country-specific approaches to create the most effective program with the most efficient use of resources. Linkages and referrals – across HIV/AIDS services and between HIV/AIDS programs and other health or development

³¹ See, e.g., Consolidated Appropriations Act of 2004, Division D – Foreign Operations, Export Financing, and Related Programs Appropriations, Title II – Bilateral Economic Assistance, United States Agency for International Development, Child Survival and Health Programs Fund.

programs – to create multisectoral or comprehensive programs are frequently programmatically appropriate in order to achieve desired health outcomes.

An organization with a religious or moral objection to a specific component of a solicitation must raise its conscience clause objection no later than 15 calendar days before the end of the solicitation period. Ultimately, the organization may choose to submit a response that does not respond to all of the specified activities of a solicitation. AAPD 14-04 provides guidance on what actions to take if an organization raises a conscience clause objection.

vi. Earmarks and Directives

Complying with legislative earmarks and responsiveness to congressional reporting requirements must be carefully considered in a manner that takes into account the country/regional context and seizes every opportunity for integrated programming consistent with the Five-Year PEPFAR strategy and the imperatives of GHI. Under the PEPFAR Reauthorization and the policy directives of the State Department's S/GAC, the following budgetary requirements are currently in place for all HIV/AIDS-related funding. These requirements are clearly delineated each year in the PEPFAR COP Guidance issued by S/GAC. Country teams should refer to the most recent annual version of the S/GAC COP Guidance for current information on earmarks and directives related to HIV/AIDS funding.

vii. Expedited Procedures Package

On February 14, 2008, the Administrator approved the Expedited Acquisition and Assistance Procedures for USAID's Activities and Programs Related to the Prevention, Care, and Treatment of HIV/AIDS. This expedited procedures package (EPP) is effective through December 31, 2013, and includes the following components:

- Authorization for other than fully competitive procedures for the award or modification of assistance agreements
- Authorization for other than full and open competition for the award or modification of contracts
- Authorization for a general source, origin, and nationality waiver, including motor vehicles, ARVs, and other pharmaceuticals.

Procurement Executive's Bulletin 2008-05 provides guidance on the use of this EPP and relevant templates. Each year the GH/AA must reconfirm that the EPP is still required, which has been done each year. To expedite this reconfirmation process, all OUs who make use of the EPP must report when they have used it to the Deputy Director of the Office of HIV/AIDS. Contracting Officers/Agreement Officers must also report use to the Agency Competition Advocate.

Please see Chapter 4 Family Planning and Reproductive Health (FP/RH) of this document for extensive guidance on the use of FP/RH funds, including the use of FP/RH funds in an integrated program.

GOAL 3: PROTECTING COMMUNITIES FROM OTHER INFECTIOUS DISEASES

USAID funded programs are pivotal in the fight against tuberculosis, neglected tropical diseases, pandemic influenza and other emerging threats. Through targeted interventions for affected populations, as well as support of public private partnerships and the development of new technologies, USAID has made great strides in alleviating the burden of infectious diseases. These achievements result from close partnerships with host country governments, the private sector, faith-based institutions and civil society.

7. NEGLECTED TROPICAL DISEASES

This budget category corresponds to the element 3.1.5 Other Public Health Threats.

A. Health Program Element Guide

The USAID Neglected Tropical Diseases (NTD) Program was initiated in 2006 to achieve an integrated response to the control of neglected diseases that enhances coordination and effectiveness and maximizes the leverage of U.S. contributions.

The primary focus of NTD funding is on activities that control and/or eliminate the burden of NTDs that can be addressed with effective and wide-scale strategies such as mass drug administration with preventive chemotherapy and other proven interventions. GHI and the NTD Program target the following seven neglected tropical diseases: lymphatic filariasis (elephantiasis); schistosomiasis (snail fever); trachoma (eye infection); onchocerciasis (river blindness); and three soil-transmitted helminthes (hookworm, roundworm, and whipworm).

In support of the WHO NTD Road Map for the control and elimination of key NTDs by 2020, the USAID NTD Programs specifically supports:

- The elimination of onchocerciasis in Latin America;
- The elimination of lymphatic filariasis globally; and
- The elimination of blinding trachoma globally.

B. Priorities and Goals

The Global Health Initiative (GHI) target for NTD programming aims to have 100 percent of the global target population under treatment or completed treatment for lymphatic filariasis and trachoma.

a. Allowable Activities: Priority Approach

Neglected Tropical Disease funding corresponds to the Other Public Health Threats (OPHT) Sub-Element 3.1.5.1 Other Infectious Diseases.

Funding provided under the neglected tropical disease program is restricted to the following

diseases: Onchocerciasis, Schistosomiasis, Soil-transmitted helminthes, Lymphatic filariasis, and Trachoma.

b. Allowable Activities: Illustrative Examples

As reflected in the previous Congressional Budget Justifications and the 653(a), the NTD Program and the corresponding funds are allocated, programmed and managed centrally by the NTD Program Management Team within the Bureau for Global Health in order to target efforts to (1) best achieve the elimination goals established for the initiative, (2) coordinate with the various drug donation programs to ensure appropriate forecasting and production for USAID supported countries, (3) ensure integrated programming at the country level to achieve efficiencies, (4) comply with the reporting requirements of the NTD Program and (5) keep operating costs at a minimum.

In 2006 the Congress directed USAID (1) to propose the most effective uses of such funds to demonstrate the health and economic benefits of such an approach; and (2) to develop a multilateral, integrated initiative to control these diseases that will enhance coordination and effectiveness and maximize the leverage of U.S. contributions with those of other donors. Based on this congressional direction, the following summarizes the elements that the NTD Program Management Team has adhered to since 2006.

- All NTD allocations and related implementation plans must be negotiated, reviewed, and approved by the NTD Program Management Team in GH.
- All funding is notified by GH/HIDN/ID.
- The GH/HIDN/ID will coordinate and submit reporting requirements for NTD funds as it pertains to the Annual Performance Report and the Performance Plan and Report.
- The NTD Program Management Team has established coordination mechanisms with the Drug Donation Programs for the diseases targeted under the NTD Program. OUs must seek written approval from the NTD Program Management Team before buying pharmaceuticals for programs targeting lymphatic filariasis, schistosomiasis, trachoma, onchocerciasis, and soil-transmitted helminthes (hookworm, roundworm, and whipworm).

OUs in countries with overlapping NTD disease burdens (e.g., at least three diseases) that want to support the integration of mass drug administration may buy into centrally managed projects in GH.

C. Legal Requirements and Congressional Directives

a. Authority

USAID's Neglected Tropical Disease Program is authorized by the FAA of 1961, as amended.

b. Legal and Policy Requirements

i. Legislative Requirements

GC has determined that the following, adapted rationale, developed based on the case of use of GHP funds in HIV/AIDS programs that include military, police, prison, and other law enforcement personnel as populations at risk of contracting and transmitting HIV/AIDS, can be applied to all USAID infectious disease programming. Please review the full language detailed in Section C.b.ii of this reference for additional considerations and requirements.

Combating the spread of NTDs in Military, Police, Prisons, or other Law Enforcement Personnel: Section 531(e) of the Foreign Assistance Act of 1961, as amended, and general principles of appropriation law prohibit the use of economic assistance funds for military purposes. In addition, Section 660 of the FAA prohibits training or advice or financial support for police, prisons, or other foreign law enforcement forces. However, GC has determined that certain programs involving military forces or police, prison, or other law enforcement personnel would not be prohibited by these legal restrictions. In particular, participation by these groups in NTD programs might not be prohibited if they are participating not in their military or law enforcement capacity, but as a population group at risk of contracting and transmitting the disease more broadly within the population and the following conditions are met:

- a) The programs or activities in which the military or police, prison, or other law enforcement personnel would participate are part of a larger public health initiative to combat NTDs, and exclusion of such group would impair the achievement of the initiative's public health objectives;
- b) The program for the military or police, prison, or other law enforcement personnel must be similar to that received by other population groups similarly situated in terms of NTD risk and prevention; and
- c) Neither the program or activities, nor any commodities transferred under the program can be readily adaptable for military or police, prison or other law enforcement personnel purposes.

Notwithstanding authority for assistance to police, prison, or other law enforcement personnel: The notwithstanding authority described in section III.1.A.a is available for assistance to police, prison, or other law enforcement personnel that does not meet the guidance above. This notwithstanding authority is *not* available for assistance to foreign militaries. For programs with foreign militaries that do not meet the guidance above, consideration should be given to the possibility of implementation by DOD.

In relying on notwithstanding authority for this purpose, OUs need to carefully review the facts of any proposed activity to ensure that the activity falls only within the scope of NTD activities permitted by other sections of this guidance. If an operating unit decides to rely on "notwithstanding" authority, the clearance procedures described below must be followed.

Moreover, OUs should be aware that certain activities relating to the spread of infectious disease involving prisoners, that do not involve support to prisons or prison personnel, may not fall

within the prohibition of Section 660 at all, and therefore would not require the reliance on “notwithstanding” authority to fund. However, an activity that involves providing assistance to prison personnel or prisons, even for the benefit of prisoners, might fall under the prohibition of Section 660 and require the use of notwithstanding authority. If in doubt about the applicability of Section 660, contact your Resident Legal Officer or GC for assistance.

A decision to rely on notwithstanding to provide assistance to prisons, police, or other law enforcement personnel may raise sensitive policy issues. OUs must prepare a memo requesting approval from their bureau’s Assistant Administrator and obtain clearances from the Assistant Administrator of the Bureau for Global Health (if the operating unit is not within GH), and others as deemed appropriate by the approving Assistant Administrator. The approving Assistant Administrator may request clearance from the Assistant General Counsel for their bureau, the relevant regional bureau, and the relevant regional bureau’s Assistant General Counsel. F is responsible for tracking OUs that make use of the notwithstanding authority. A copy of all memos relying on this global health notwithstanding authority should be sent to GC/GH for information.

8. TUBERCULOSIS

This budget category corresponds to the element 3.1.2 Tuberculosis.

A. Health Program Element Guide

USAID is the lead U.S. Government agency in international tuberculosis (TB) programs. USAID provides bilateral assistance to national TB programs (NTPs) to support implementation and scale-up of their national strategic plans (NSPs) in accordance with the current international World Health Organization (WHO) STOP TB Strategy and future post-2015 strategy. USAID has been working in TB programs since the late 1990s and is the main funder of technical assistance globally. USAID provides assistance to countries for the fight against TB with a well-coordinated strategy that supports proven interventions and builds on lessons learned from global and country specific experiences. USAID programs work closely with international partners, particularly the Global Fund (GF), to ensure programs are well coordinated. While the Global Fund supports mainly the “bricks and mortar” of a NSP, USAID’s programs provide the “know-how” to ensure quality implementation of the government and GF resources. Strong national TB diagnostic, care, treatment and ultimately prevention services are essential in reducing mortality and the transmission of the disease, resulting in the saving of lives.

There are alarming increases in detection of drug-resistant TB (DR-TB) cases in countries that have trailed behind in implementing high quality TB programs. Initially, the failure to appropriately manage the use of first-line TB drugs drives the development of drug-resistant strains, but once those strains begin circulating in the community, the rates of drug-resistant TB among new cases rises. This trend threatens to reverse progress in halting the spread of the disease and increases the risk of further anti-microbial resistance. Strengthening basic TB services to provide high quality treatment and patient support to prevent resistance and finding and treating existing drug-resistant TB cases is a priority.

TB disproportionately affects vulnerable populations, such as migrants, people living in poverty or in crowded living and/or working conditions and poor ventilation—like miners and prisoners. HIV/AIDS, diabetes, malnutrition, and other health factors further affect a person’s vulnerability to TB. Additionally, the rise in global urbanization is leading to densely populated, overcrowded urban centers that contribute to the increase in the TB epidemic.

B. Priorities and Goals

USAID’s TB program contributes to the global goal of reducing TB prevalence to less than 50 cases per 100,000 by 2025 and decreasing TB mortality rate 75 percent by 2025 (compared with 2015).

The GHI’s targets are:

- By 2019, USG TB programs will increase case notification rate and the absolute number of notified cases (all forms of TB).
- By 2019, USG-supported countries will achieve and maintain at least 85 percent treatment success rate (all forms of TB) and successfully treat more than 3 million TB cases (all forms of TB) per year.
- By 2019, USG TB program will initiate on treatment more than 80,000 Multi-Drug resistant TB (MDR TB) cases per year.

National Tuberculosis Program’s NSPs that are consistent with the STOP TB Partnership Global Plan to STOP TB 2006–2015 and the STOP TB Strategy and the WHO post-2015 strategy should serve as the basis for planning for USAID assistance. USAID can help to develop these plans, and USAID assistance should support the priorities described in NSPs. In implementing TB programs, it is critically important that Missions coordinate with the National TB Program in-country to identify the most important role for USAID and is not supported by other donors, such as the Global Fund. At the same time, it is also important that TB funds are invested in approaches that are most likely to have impact on improved case detection and treatment outcomes for all forms of TB, including DR-TB and HIV associated TB.

USAID’s strategy also emphasizes expanding the involvement of private providers and private voluntary organizations/NGOs in TB care and treatment.

a. Allowable Activities: Priority Approach

Key programmatic outcomes for activities supported with TB funds should contribute to the decreased prevalence and mortality, increased case detection and notification rates, maintained or increased cure and treatment success rates, and decreased deaths and default rates for all people with TB and drug resistant TB (DR-TB). They should also map to NSP priorities at country level and leverage the impact of interventions supported by the Global Fund.

TB programs should contribute directly to improving case detection and treatment success rates

for both drug sensitive TB and drug resistant TB. There are four main USAID TB programs should utilize in support of these goals. First, TB funds should be used to support universal access to patient-centered care services for TB and DR-TB and TB/HIV including quality diagnosis, care and treatment among all public and private providers. Second, the programs should focus on prevention of transmission and disease progression through actively finding TB cases and the preventing the spread of the disease in congregate and community settings through active case finding, infection control and latent TB prevention. Third, USAID programs should develop and strengthen the underlying systems including TB policy and legal frameworks, TB laboratory networks, TB drug management systems, TB human resources, TB surveillance and monitoring and evaluation (M&E) systems, and involvement of partnerships and community. Lastly, the programs should support implementation of research to identify new tools for TB management and improve current services. Again, these activities should be planned and implemented in coordination with the Global Fund grants and contribute to the country's TB NSP.

The following listing comprises the primary categories for programming TB funds. USAID Washington (USAID/W) will conduct quality compliance assessments at least every two years. For a listing of illustrative activity examples please review section III.8.B.b.

- **Improved Quality Patient-Centered Care Services for TB, DR-TB, TB/HIV**

To reach our ultimate goal of a world free of TB, we must ensure universal access to quality diagnosis, treatment, and care for TB, DR-TB and TB/HIV. Universal access means that each individual “suspected” (meaning those that have symptoms and those that are at risk for TB) of having TB, DR-TB, or TB/HIV is aware of and able to use quality diagnostic and treatment services in an effective and efficient manner; access to these services will not result in catastrophic personal hardship to the individual or his or her household; and that high quality comprehensive service is available and tailored to the needs of the individual requiring care. In other words, this approach should focus on ensuring high quality services are readily available, service appropriate (accommodating and user-friendly) and affordable. The patients and their families should be involved and empowered in their care at every stage in the diagnostic and treatment pathway. This first objective also includes the strengthening of service delivery strategies to ensure universal access to TB diagnosis, care and treatment.

- **Prevention of Transmission and Disease Progression**

Prevention is one of the pillars of the global post-2015 strategy which was recently endorsed by the World Health Assembly (May 2014). Without accelerated action to prevent infection, transmission, and disease, the global community will not achieve significant reductions in TB morbidity and mortality, or in the epidemiological and socioeconomic burden of TB, and ultimately will not be able to eliminate TB. Prevention aims to interrupt *M. tb* transmission, and once infection is acquired, minimize progression to disease. The level of risk of transmission is affected by the prevalence of active infectious pulmonary disease in the community; the severity of TB disease; the frequency, intensity, and duration of exposure; and the presence of risk factors such as HIV, diabetes mellitus, overcrowding in congregate settings, among others. The prevention objective identifies main areas for interventions including prevention

strategies such as screening for TB and latent TB infection (LTBI), prevention and control of infection. The main goals aimed for are improved TB and LTBI detection and treatment, and reduction of TB transmission in health care, congregate and community settings.

- **Strengthened TB System Platforms**

TB services are implemented and delivered by existing health systems and provides the platform on which key TB prevention, diagnosis and treatment activities are introduced, expanded, and strengthened. The quality of the larger health system therefore, has a critical role in the provision of quality TB services. Effective national leadership and political commitment are essential to the development and successful implementation of the NSP. This support, coupled with engaged and coordinated partners and demand for quality services by affected communities are necessary to achieve goals and objectives. The engagement of partners from different sectors and interest groups enriches the national response to the epidemic and helps to ensure ownership, accountability, and sustainability. The involvement of affected communities raises awareness and creates a demand for services that are user-friendly and patient-centered. Lastly, it is critical to improve quality and availability of TB-related health systems including those for drug and laboratory policy and management, monitoring and evaluation (M&E), and human resources for health (HRH).

- **Accelerated Research**

Progress in the development and introduction of new tools and approaches to improved TB services, technologies and research has been limited due to lack of financial resources to support the research agenda. It is critical to develop innovative implementation approaches to address current diagnostic and treatment challenges, as well as basic science to advance our understanding of TB pathogenesis, and accelerate the development of new technologies and drugs. Simultaneously, we must strengthen existing and/or build platforms for introduction and scale-up of new diagnostic tools, medicines, and other technologies. At implementation level, enhanced operations and implementation research will provide the required evidence for policy and decision-making and improve the performance of the TB programs.

b. Allowable Activities: Illustrative Examples

Missions may use funding in the TB element to support activities in any or all of the areas described below. Missions may also support activities that strengthen TB and MDR-TB system platforms. In general, USAID should not support activities that are considered inherent government functions. These activities should be funded with domestic resources or, if this is not possible, the Global Fund. Missions should clearly identify USAID's comparative advantage and support activities that will result in impact in these areas.

Technical interventions of the WHO post-2015 Strategy

USAID programs support implementation of the WHO post-2015 strategy. The key elements of the new Strategy are summarized below and are also available at the following Web site:

http://apps.who.int/gb/ebwha/pdf_files/EB134/B134_12-en.pdf?ua=1

USAID's approach to TB includes the following activities:

- **Improved Quality Patient-Centered Care Services for TB, DR TB, TB/HIV:**
 - i. Service delivery strategies to ensure universal access:
 - a. Develop and implement service delivery strategies to maximize access to quality TB detection and treatment;
 - b. Engage leaders, special interest groups and individuals in the community to participate and feel a responsibility for early and active finding of TB, DR-TB and TB/HIV;
 - c. Engage private providers in intensified case finding for TB, DR-TB and TB/HIV among their clients; and
 - d. Develop and implement policies, guidelines, and norms to facilitate community involvement.
 - ii. Universal access to diagnosis:
 - a. Ensure the availability of comprehensive high quality TB diagnostic services including bacteriological, drug susceptibility, molecular, and radiological tests as well as other services as they become available. These should be decentralized, tailored to the needs and characteristic of the population/community served, and widely available in public, private, workplace/school, prison, and community settings free of charge or at subsidized costs; and
 - 1) Develop and implement TB and DR-TB diagnosis algorithms to guide the best combination and utilization of all available TB diagnosis tools (bacteriological, molecular and radiological).
 - 2) Strengthen TB diagnosis network capacity and develop linkages to treatment sites/facilities.
 - 3) Develop and implement an effective system for collecting and shipping specimens to public or private laboratories for TB diagnosis.
 - 4) Develop and implement an effective system for monitoring and maintaining the quality of TB diagnosis services in the network.
 - 5) Strengthen the capacity of private laboratories and/or private providers in TB bacteriological (smear microscopy, culture and drug susceptibility testing (DST)) and molecular diagnosis as well as HIV screening.
 - b. Ensure availability of treatment facilities sites for the management of TB, DR TB and TB/HIV (Ensure readily available access of all drug susceptible and drug resistant TB patients to appropriate treatment with quality-assured first and second line drugs).
 - 1) Development and scale-up of treatment facilities, sites and community-based approaches for TB treatment delivery.
 - 2) Integrate further DR-TB services in the general Directly Observed Treatment, Short Course (DOTS) framework.
 - 3) Scale-up of new treatment sites and development of patient-centered approaches for both adults and children.

- 4) Introduce novel tools and approaches in the management of DR-TB patients.
- 5) Provide universal access to treatment of drug susceptible and drug sensitive TB, using patient-centered approaches that minimize direct and indirect costs for patients.
- 6) Develop and implement community based or household support schemes to improve adherence.

- **Prevention of Transmission and Disease Progression**

- i. Targeted screening for active TB:

- a. Detect active TB via proactive measures in health care settings with individuals being seen for other illnesses that make them at higher risk for developing TB disease;
- b. Improve contact investigation and screening among high-risk groups and in high-risk congregate settings. Identify people at particularly high-risk of developing active TB disease in the future (e.g., people living with HIV/AIDS (PLHIV), undernourished, and diabetics);
- c. Identify people who are eligible for the treatment of latent TB infection (e.g., close contacts, PLHIV); and
- d. Prioritize individual and community-level risk factors and socio-economic determinants that need to be addressed to prevent TB in a given population.

- ii. Infection Control activities to minimize the risk of TB transmission within populations in health care and congregate settings.

- iii. Latent TB Strategies to diminish the risk of progression to disease through a post-exposure vaccine, improved LTBI detection, treatment implementation and adherence, and/or addressing the underlying clinical and population risk factors for progression.

- **Strengthen TB systems**

- i. Political Commitment and Leadership:

- a. Strengthen national TB governance including setting up management and policy leadership in the implementation and the monitoring of the NSP;
- b. Support adequate resource allocation for TB prevention and care, especially from domestic sources including social protection and other schemes to achieve universal health coverage;
- c. Use evidence and ongoing analysis to ensure effective use of resources; and
- d. Create linkages and approaches to ensure TB is appropriately addressed in social protection, poverty alleviation, and health areas relevant for TB.

- ii. Comprehensive Partnerships and Informed Community Involvement:

- a. Enhance coalition building with civil society and communities;
- b. Engage with private sector and private health providers;
- c. Improve coordination between all partners involved in the provision of TB services or otherwise engaged in implementation of the NSP at national level;
- d. Implement community empowerment strategies to demand quality TB services; and

- e. Engagement of end users, providers, and communities in development of TB delivery systems, policies and plans.
- iii. Drug Management Systems:
 - a. Intensify market shaping efforts for International Quality Assured (IQA) drugs and expansion of manufacturing capacity;
 - b. Strengthen the regulatory framework for quality and rational use of medicines; and
 - c. Build drug procurement and management capacities to avert “zero stock-outs.”
- iv. Data Quality, Surveillance, Monitoring and Evaluation:
 - a. Introduce a regulatory framework for case notification and vital registration;
 - b. Improve data collection, management, and analysis;
 - c. Strengthen program monitoring and evaluation for measuring impact;
 - d. Enhance integration of case management and surveillance systems; and
 - e. Improve use of data for decision-making.
- v. Human Resources Development:
 - a. Improve systems for development, retention and quality of TB related HRH;
 - b. Improve integrated disease management at primary level of care; and
 - c. Improve task shifting and support initiatives such as nurse-initiated management of TB/HIV and MDR-TB.
- **Accelerate Research:**
 - i. New tools and approaches developed and tested to prevent, detect and improve management of TB and DR TB;
 - ii. Activities to build the capacity and outcomes of operational research to influence policies and programs; and
 - iii. Improve performance of TB programs through Implementation Research.

In addition to supporting implementation of the post-2015 Strategy described above, funding in the TB element may be used to provide technical assistance to ensure the success of GF TB grants, including:

- Development of epidemiological assessments, national strategic plans and other documents needed to support implementation of quality TB services;
- Development of quality GF concept notes;
- Building technical, administrative and organizational capacity of Principal Recipients; and
- Development of implementation, procurement, supply management, and monitoring and evaluation plans for GF TB grants.

C. Legal Requirements and Congressional Directives

a. Authority

USAID's TB Program is authorized by the FAA of 1961, as amended. Restrictions on the use of foreign assistance funds for TB-related activities are clearly outlined in the annual Foreign Assistance Appropriations Act and USAID's policy, and govern programming within all elements.

b. Legislative and Policy Requirements

i. Legislative Requirements

GC has determined that the following, adapted rationale, developed based on the case of use of GHP funds in HIV/AIDS programs that include military, police, prison, and other law enforcement personnel as populations at risk of contracting and transmitting HIV/AIDS, can be applied to all USAID infectious disease programming. Please review the full language detailed in Section C.b.ii of this reference for additional considerations and requirements.

Combating the spread of Tuberculosis in Military, Police, Prisons, or other Law Enforcement Personnel: Section 531(e) of the Foreign Assistance Act of 1961, as amended, and general principles of appropriation law prohibit the use of economic assistance funds for military purposes. In addition, Section 660 of the FAA prohibits training or advice or financial support for police, prisons, or other foreign law enforcement forces. However, GC has determined that certain programs involving military forces or police, prison, or other law enforcement personnel would not be prohibited by these legal restrictions. In particular, participation by these groups in tuberculosis programs might not be prohibited if they are participating not in their military or law enforcement capacity, but as a population group at risk of contracting and transmitting the disease more broadly within the population and the following conditions are met:

- a) The programs or activities in which the military or police, prison, or other law enforcement personnel would participate are part of a larger public health initiative to combat tuberculosis, and exclusion of such group would impair the achievement of the initiative's public health objectives;
- b) The program for the military or police, prison, or other law enforcement personnel must be similar to that received by other population groups similarly situated in terms of tuberculosis risk and prevention; and
- c) Neither the program or activities, nor any commodities transferred under the program can be readily adaptable for military or police, prison or other law enforcement personnel purposes.

Notwithstanding authority for assistance to police, prison, or other law enforcement personnel: The notwithstanding authority described in section III.1.A.a is available for assistance to police, prison, or other law enforcement personnel that does not meet the guidance above. This notwithstanding authority is *not* available for assistance to foreign militaries. For programs with foreign militaries that do not meet the guidance above, consideration should be given to the possibility of implementation by DOD.

In relying on notwithstanding authority for this purpose, OUs need to carefully review the facts of any proposed activity to ensure that the activity falls only within the scope of Tuberculosis activities permitted by other sections of this guidance. If an operating unit decides to rely on “notwithstanding” authority, the clearance procedures described below must be followed.

Moreover, OUs should be aware that certain activities relating to the spread of infectious disease involving prisoners, that do not involve support to prisons or prison personnel, may not fall within the prohibition of Section 660 at all, and therefore would not require the reliance on “notwithstanding” authority to fund. However, an activity that involves providing assistance to prison personnel or prisons, even for the benefit of prisoners, might fall under the prohibition of Section 660 and require the use of notwithstanding authority. If in doubt about the applicability of Section 660, contact your Resident Legal Officer or GC for assistance.

A decision to rely on notwithstanding to provide assistance to prisons, police, or other law enforcement personnel may raise sensitive policy issues. OUs must prepare a memo requesting approval from their bureau’s Assistant Administrator and obtain clearances from the Assistant Administrator of the Bureau for Global Health (if the operating unit is not within GH), and others as deemed appropriate by the approving Assistant Administrator. The approving Assistant Administrator may request clearance from the Assistant General Counsel for their bureau, the relevant regional bureau, and the relevant regional bureau’s Assistant General Counsel. F is responsible for tracking OUs that make use of the notwithstanding authority. A copy of all memos relying on this global health notwithstanding authority should be sent to GC/GH for information.

9. PANDEMIC INFLUENZA AND OTHER EMERGING THREATS

This budget category corresponds to the element 3.1.4 Pandemic Influenza and Other Emerging Threats.

A. Health Program Element Guide

Over the past decade, the emergence and spread of a number of deadly infectious diseases in humans have heightened concern about the potential consequence of a pandemic. Pandemic diseases threaten public health, economic stability, and development efforts. USAID is an essential partner in a cross-U.S. Government effort to combat Pandemic Influenza and Other Emerging Threats (PIOET). A multisector PIOET Unit, housed in GH, coordinates all USAID PIOET planning, budgeting, and programming. In addition, the PIOET Unit coordinates all operational field activities with those of other U.S. Government departments and agencies as outlined in the U.S. National Strategy for Pandemic Influenza: Implementation Plan. USAID’s primary programmatic focus for PIOET is to limit the potential for the emergence of a pandemic by containing new diseases in animals, limiting human exposure to infected animals, minimizing the number of human cases, and ensuring adequate and appropriate response to a pandemic should it occur.

B. Priorities and Goals

Key outcomes for PIOET funds include, but are not limited to planning and preparedness, animal and human surveillance, animal and human response, and behavior change communication and messaging for increased public awareness and risk mitigation.

In early 2014, the USG agencies, including USAID, joined in an international effort in the launch of the Global Health Security Agenda (GHSa) (<http://www.globalhealth.gov/global-health-topics/global-health-security/ghsagenda.html>). At its core the GHSa Agenda recognizes infectious diseases, whether naturally caused, intentionally produced, or accidentally released, are among the foremost dangers to human health and the global security. Limited capacity in many countries to prevent, detect, and rapidly respond to these threats, and the added danger of terrorists using biological material and expertise to achieve their own objectives, are among the key reasons for a concerted international effort at a senior leadership level to accelerate progress toward GHSa. GHSa is constructed around nine objectives that contribute to: 1) Preventing and reducing the likelihood of outbreaks; 2) Detecting threats early; and 3) Responding rapidly and effectively. PIOET programming is fully integrated into all nine objectives of the GHSa framework and represents the development arm of this USG effort.

Additionally, PIOET programming aims to support, where appropriate, the capacities required by the International Health Regulations (http://www.who.int/topics/international_health_regulations/en/) and the World Organization for Animal Health's (OIE) International Guidelines.

a. Allowable Activities: Priority Approach and Illustrative Activities

The following listing comprises the primary categories for programming PIOET funds:

- ***Planning and Preparedness for Outbreak Response:*** Design national multisectoral PIOET plans and coordination mechanisms. Support will also be provided to ensure adequate response to contain animal outbreaks and plans for the possibility of future human cases.
- ***Animal and Human Disease Surveillance:*** Support passive and active surveillance for animal PIOET outbreaks, including enhancing in-country laboratory capacity, updating national surveillance strategies, linking animal and human surveillance efforts, and monitoring the health of wild bird and domestic poultry populations. Human surveillance also includes reporting incidence of human infections, researching primary modes of viral transmission, and strengthening communication and reporting pathways.
- ***Commodity Stockpile:*** Determine essential commodities, establish release triggers for mobilizing the stockpile, procure commodities, develop commodity deployment strategies, deploy commodities appropriately, and replenish stockpiles.
- ***Behavior Change Communications:*** Mobilize communication networks to prioritize PIOET efforts, design and implement communication strategies, broadcast PIOET

awareness and behavior change messages, train trainers in the appropriate use of commodities, and provide accurate material to communicators.

- ***Response to Disease Outbreak***: Respond to animal outbreaks, including: facilitating the deployment of rapid response teams; designing incentive schemes to report outbreaks, and implementing bio-security measures. This sub-element also includes collecting and transporting samples, and implementing containment measures (e.g., culling, vaccination, quarantine). Human response also includes training health workers about appropriate care models, implementing social distancing policies, facilitating humanitarian response to a pandemic, and promoting infection control.
- ***Health Governance and Finance (PIOET)***: Promote sustainable improvements in health outcomes for men/boys and women/girls by reducing key governance and financing constraints to the achievement of multiple health element objectives and the health area goal overall. These include activities that reduce corruption; increase equity; improve efficiency and increase financial protection (especially for underserved populations), including in the context of financing, organization of services, facility construction/renovation, pharmaceutical management, and human capacity development and management. Note: Operating Units should make efforts to report activities that address specific earmarks under other sub-elements, reserving the use of the health governance and finance sub-element for overarching activities that support multiple health elements.
- ***Host Country Strategic Information Capacity (PIOET)***: Establish and/or strengthen host country institutions' management information systems (MIS) and their development and use of tools and models to collect, analyze and disseminate a variety of information related to the program element. These may include, but are not limited to MIS for government ministries or other host country institutions, needs assessments, baseline studies, censuses and surveys, targeted evaluations, special studies, routine surveillance, data quality assessments, and operational research. This sub-element may also include developing and disseminating best practices and lessons learned and testing demonstration and/or pilot models. Related training, supplies, equipment, and non-USG personnel are included.

b. Multisectoral Integration of PIOET Activities

PIOET programing is inherently multisectoral in nature and requires, at a minimum, coordination across the human health, animal health and environmental fields. PIOET encourages collaboration across all sectors and sees ample opportunities to work with conservation, ecology, food security, climate change, natural resource management, and higher education. PIOET represents an emerging technical area and methods for working effectively across sectors are still being developed.

C. Legal Requirements and Congressional Directives

a. Authority

Section 7058 of the H.R.3547 - Consolidated Appropriations Act, 2014 “authorizes specified funds to be made available to combat a pandemic virus if the President reports to Congress that the virus is severe and is spreading internationally.”

On May 3, 2006, the Administrator approved an Action Memorandum entitled "Expedited Acquisition and Assistance Procedures for Activities and Programs Related to USAID’s Avian Influenza Pandemic Emergency Preparedness and Response Efforts," dated April 27, 2006. The latest extension expired in May 2012. A new, five-year, extension was approved by the Administrator on February 13, 2013. These procedures are in place for and are only to be used in the event of an emergency. For regular PIOET programming, general Agency procedures should be followed.

The original approved recommendations and associated determinations and findings related to this acquisition and assistance policy directive provided for:

- Contracts, Grants, and Cooperative Agreements – Authorization for Other than Fully Competitive Procedures. This has been included in all extensions.
- A general source and nationality waiver authorizing procurement of goods and services, including restricted commodities, from geographic code 935: any country (except foreign-policy restricted countries). This has been included in all extensions.

b. Legal and Policy Requirements

i. Legislative Requirements

GC has determined that the following, adapted rationale, developed based on the case of use of GHP funds in HIV/AIDs programs that include military, police, prison, and other law enforcement personnel as populations at risk of contracting and transmitting HIV/AIDs, can be applied to all USAID infectious disease programming. Please review the full language detailed in Section C.b.ii of this reference for additional considerations and requirements.

Combating the spread of Pandemic Influenza and Other Emerging Threats in Military, Police, Prisons, or other Law Enforcement Personnel: Section 531(e) of the Foreign Assistance Act of 1961, as amended, and general principles of appropriation law prohibit the use of economic assistance funds for military purposes. In addition, Section 660 of the FAA prohibits training or advice or financial support for police, prisons, or other foreign law enforcement forces. However, GC has determined that certain programs involving military forces or police, prison, or other law enforcement personnel would not be prohibited by these legal restrictions. In particular, participation by these groups in PIOET programs might not be prohibited if they are participating not in their military or law enforcement capacity, but as a population group at risk of contracting and transmitting the disease more broadly within the population and the following conditions are met:

- a) The programs or activities in which the military or police, prison, or other law enforcement personnel would participate are part of a larger public health initiative to combat PIOET, and exclusion of such group would impair the achievement of the initiative's public health objectives;
- b) The program for the military or police, prison, or other law enforcement personnel must be similar to that received by other population groups similarly situated in terms of PIOET risk and prevention; and
- c) Neither the program or activities, nor any commodities transferred under the program can be readily adaptable for military or police, prison or other law enforcement personnel purposes.

Notwithstanding authority for assistance to police, prison, or other law enforcement personnel: The notwithstanding authority described in section III.1.A.a is available for assistance to police, prison, or other law enforcement personnel that does not meet the guidance above. This notwithstanding authority is *not* available for assistance to foreign militaries. For programs with foreign militaries that do not meet the guidance above, consideration should be given to the possibility of implementation by DOD.

In relying on notwithstanding authority for this purpose, OUs need to carefully review the facts of any proposed activity to ensure that the activity falls only within the scope of PIOET activities permitted by other sections of this guidance. If an operating unit decides to rely on “notwithstanding” authority, the clearance procedures described below must be followed.

Moreover, OUs should be aware that certain activities relating to the spread of infectious disease involving prisoners, that do not involve support to prisons or prison personnel, may not fall within the prohibition of Section 660 at all, and therefore would not require the reliance on “notwithstanding” authority to fund. However, an activity that involves providing assistance to prison personnel or prisons, even for the benefit of prisoners, might fall under the prohibition of Section 660 and require the use of notwithstanding authority. If in doubt about the applicability of Section 660, contact your Resident Legal Officer or GC for assistance.

A decision to rely on notwithstanding to provide assistance to prisons, police, or other law enforcement personnel may raise sensitive policy issues. OUs must prepare a memo requesting approval from their bureau's Assistant Administrator and obtain clearances from the Assistant Administrator of the Bureau for Global Health (if the operating unit is not within GH), and others as deemed appropriate by the approving Assistant Administrator. The approving Assistant Administrator may request clearance from the Assistant General Counsel for their bureau, the relevant regional bureau, and the relevant regional bureau's Assistant General Counsel. F is responsible for tracking OUs that make use of the notwithstanding authority. A copy of all memos relying on this global health notwithstanding authority should be sent to GC/GH for information.

ii. Policy Requirements

The following summarizes the requirements that the PIOET Unit has adhered to since 2005:

- All PIOET allocations and all PIOET-related implementation plans must be reviewed and approved by the Director of the PIOET Unit.
- All PIOET funding is notified by GH/Office of Health, Infectious Diseases and Nutrition (HIDN)/PIOET.
- The use of Agency funds to purchase antivirals or human influenza vaccines (including Tamiflu, the brand name, Federal Drug Administration-approved antiviral medication produced by Roche) is prohibited, pursuant to the General Notice issued by the Administrator, entitled “Interim Budgetary Guidance for Reprogramming of Funds for Urgent Avian Influenza Related Activities,” dated November 3, 2005, and attached as Appendix IV.
- All OUs are required to submit reports on the status of PIOET activities to the PIOET Unit Director to meet congressional reporting requirements. Per PIOET Unit guidance, Missions will also be required to respond to queries on obligations and expenditures of PIOET funds.

10. VULNERABLE CHILDREN

In response to the legislative requirement set forth in P.L. 109–95, the U.S. Government Special Advisor and Senior Coordinator to the USAID Administrator for Children in Adversity has worked with an interagency team to develop a U.S. Government Action Plan on Children in Adversity, the first-ever whole-of-government plan to guide U.S. government foreign assistance to children. The goal of the Plan is to ensure that all children grow up within protective family care and free from deprivation or danger. The Plan’s core objectives enable greater U.S. Government coherence and accountability for whole-of-government assistance to vulnerable children.

A. Health Program Element Guide

The Vulnerable Children budget category usually includes the following line items: Displaced Children and Orphans Fund (DCOF), Blind Children, and Other Vulnerable Children. This budget category corresponds to the sub-element 3.3.2.1 Vulnerable Children.

a. Allowable Uses of Funds for Vulnerable Children

Based on experience gained over the past 15 years, the Agency is pursuing a strategy whereby allowable uses for funds reserved for “vulnerable children” support a set of programs designed to address the critical *needs of children most at risk* as well as to *address disabilities, family separation*, and other problems that can put children at risk. Family reunification is a primary objective for children outside of family care. At the center of this strategy are programs that strengthen the capacity of families and communities to address the physical, social, educational, and emotional needs of children in crises. Children that have been identified as requiring special attention include: (1) children displaced, orphaned or otherwise severely affected by the consequences of complex emergencies, armed conflict (including child soldiers), and natural

disasters; (2) separated children who are outside the care of their parents or normal guardians; and (3) children with disabilities. For more information on children affected by HIV/AIDS, please see Chapter III.6.B.e

b. Displaced Children and Orphans

The Displaced Children and Orphans Fund directive within the Vulnerable Children budget category provides financial and technical assistance for the care and protection of vulnerable children who are outside of family care or are at risk of losing family care and protection.

DCOF supports the delivery of services, the provision of technical support, and system development to improve the safety and well-being of highly vulnerable children (under 18 years of age) and the (re)integration of those who are outside of family care. DCOF seeks to build upon and strengthen the capacities of families and communities to protect and care for their own children. DCOF seeks to strengthen national and sub-national child protection systems, with a view toward improving the safety and wellbeing of highly vulnerable children. DCOF expects funded activities to contribute to the evidence base for the most appropriate and effective practices for ensuring appropriate care, protection, and development of highly vulnerable children.

DCOF places strong emphasis on strengthening family and community capacity for identifying and responding to the special physical, social, educational, and emotional needs of these children.

The following are illustrative of allowable activities:

- Documenting, tracing, and reuniting children (including former child soldiers) separated from their families and supporting their family and community reintegration;
- Mobilizing communities and strengthening families to care for and protect their most vulnerable children;
- Working with host country governments and others to strengthen formal and informal components of child protection systems, ranging from family strengthening through policy and programmatic reform; and
- Strengthening the economic capacities of highly vulnerable households, with the aim of preventing children's unnecessary separation and facilitating their reunification and reintegration.

c. Blind Children

The blind children budget category within vulnerable children is administered centrally by the Nutrition Division within GH/HIDN. Referred to as the Child Blindness Program (CBP), this directive sits within the Social Services element and seeks to provide technical assistance and grants to organizations working with children and vulnerable populations who are blind or have low vision.

CBP supports the improved delivery of quality eye care services to children and other vulnerable

populations: e.g., refugees, with limited access to sight-saving services. CBP has a competitive grant-making process with multiple grant categories to support service delivery and operations research. The comprehensive approach taken by CBP to address child blindness includes training and capacity building to strengthen local eye and health care staff, screening for prevention and surgical and nonsurgical treatment of eye conditions such as cataracts, refractive error, and low vision, and expanded education and rehabilitation support for visually impaired children with no medical treatment option. Research carried out under the program has led to an expanded global understanding of programmatic approaches for large-scale pediatric eye care interventions.

Allowable activities include the following:

- Support eye care and health organizations to establish public-private service delivery partnerships as well as family and community focused service models;
- Establish effective referral networks to ensure children and other vulnerable populations have access to the spectrum of care needed for healthy vision;
- Expand and facilitate a learning agenda on innovative and improved ways to reach those affected by blindness and provide sustainable services to them;
- Develop appropriate service protocols and methods for screening patients and improve public understanding and sensitivity to the needs of the visually impaired;
- Provision of low-vision equipment for those in need (e.g., glasses, canes, magnifying glasses); and
- Provision of technical equipment needed for medical procedures as well as training required for medical professionals for treatable forms of blindness and low vision.

NOTE: Activities specifically targeting Children Affected by HIV/AIDS are *not* appropriate uses of Vulnerable Children funds. All activities specifically addressing Children Affected by HIV/AIDS must be funded by HIV/AIDS funds.

B. Legal Requirements and Congressional Directives

Earmarks and Directives: Most appropriations bills include earmarks or directives designating funding for vulnerable children.

In 1989 Congress initiated a requirement for the use of Child Survival funds for programming to benefit children without adequate family care and has continued this requirement as a directive, indicating a specific amount each year. This has been referred to as the **Displaced Children and Orphans Fund (DCOF)**. Since it was initiated, DCOF has focused on opportunities to advance the state of the art in approaches and programming for highly vulnerable children, especially those without adequate family care. Through a strong learning agenda, DCOF has successfully leveraged the impact of these funds throughout the Agency. Please also refer to the Notwithstanding Authority guidance in Chapter III.1.A.a.

Public Law 109-95: *The Assistance to Orphans and Other Vulnerable Children in Developing Countries Act of 2005* was signed into law in November 2005 to respond to the global orphans and vulnerable children crisis. It calls for the U.S. Government response to the crisis to be

comprehensive, coordinated, and effective. USAID is the lead agency under the Act, with the Bureau for Global Health serving as the locus of P.L. 109–95 leadership and management and the home of the U.S. Government Special Advisor and Senior Coordinator to the USAID Administrator on Children in Adversity.

In 2009, a secretariat was established to implement the legislative requirements specified under P.L. 109–95. In the FY 2012 Senate Foreign Appropriations Bill, the Senate Committee “encourage[d] USAID to institutionalize the secretariat established in Public Law 109–95 and note[d] the important interagency efforts of the Special Advisor ... and Secretariat.”

In response to this language, USAID has formed a Center of Excellence on Children in Adversity, housed in the Bureau for Democracy, Conflict, and Humanitarian Assistance.

11. CROSS-CUTTING PROGRAM AREAS

The following guidance describes technical and policy guidance that applies across all health program area discussed in this guidance.

A. Integration

Integration has been defined as “the organization, coordination, and management of multiple activities and resources to ensure the delivery of more efficient and coherent services in relation to cost, output, impact, and use (acceptability).”³² Integrating programs and services is not a standalone goal, but rather a method of achieving improved and sustainable health outcomes. Accordingly, the development hypothesis for integrated programming should be well articulated during the project design process. This includes a clear theory of change that explains how the integrated activity components are both necessary and sufficient to achieve the intended outputs, intermediate outcomes, outcomes and impact. Linkages in this theory of change should be supported by evidence from either the local context or other similar settings. If insufficient evidence exists about the relationship between integrated programming activities and the intended results, OUs may decide to begin with a pilot or proof-of-concept program that can be adapted and scaled up depending on the results. Regardless of the current level of evidence supporting integrated programming, all projects should include a robust monitoring and evaluation plan to assess short- and long-term progress, including considerations about unintended consequences and changes in the contextual environment.

While these design and programming approaches are common to USAID’s processes, they remain particularly important for integrated programs where intuitive linkages may or may not occur in practice. For example, USAID-commissioned Cochrane Reviews on integration of family planning, maternal and child health, nutrition, and HIV services found that service integration was feasible across a variety of models, settings and target populations. While most

³² WHO HIV, FP/RH, MNCH Technical Working Group, March 2011.

studies demonstrated an improvement in outcomes, other studies showed mixed or no effects.³³ A variety of factors can inhibit service integration including stakeholder needs and perceptions, provider skills and capacity, community attitudes and beliefs, and health system characteristics.

a. Co-Programming Across Various Elements Within the Health Program Area

Co-programming for a single intrasectoral health program requires joint funding from the relevant elements across the health program area, funded by the GHP Account. For example, an antenatal clinic that also provides voluntary counseling and testing for HIV/AIDS should, as a guide, be equally funded through the maternal and child health element and the HIV/AIDS element. Roughly, if the clinic devotes approximately 75 percent of its resources to providing maternal and antenatal care and approximately 25 percent to VCT, the amount of MCH and HIV/AIDS funds must be equivalent to their respective balance of activities in the clinic. Often OUs may seek to balance the spread of funds in a particular project by prioritizing funds available rather than intended use. Following this guidance, an HIV/AIDS PMTCT project laying out activities planned, generally, to be 75 percent HIV/AIDS goals related and 25 percent maternal health goal related should ensure the amount of MCH and HIV/AIDS funds are equivalent to their balance in the project.

As described in Chapter III above, a number of legal restrictions apply to HIV/AIDS and family planning programs, respectively. In an integrated program that includes both HIV/AIDS activities and voluntary FP activities, any partner that receives U.S. Government funding for both purposes must comply with the respective requirements applicable to each activity. However, in an integrated program, different organizations may be responsible for different types of activities, as not all organizations will necessarily do both voluntary family-planning and HIV/AIDS activities. Any partner that receives funds solely for HIV/AIDS activities is thus not subject to the requirements applicable to family planning activities. If you have any questions about the applicability of the requirements, please contact your cognizant RLO or GC backstop. Please also see section III.6.B.r, “Integrated Family Planning and HIV/AIDS Activities.”

Planning for integrated programming requires consideration of country plans and policies, an analysis of the benefits and costs of integration, local epidemiologic and health surveillance data, timing and sequencing of services, and other factors. The GHI Paper on Integration offers an exploratory Integration Scoping Tool OUs may find useful in planning in their intrasectoral integration approach. The tool should not be considered normative guidance and is instead meant to be a starting point for thinking about the scope of integration and the policy and programming implications within a country. The three elements contained in the tool and intended to guide the scoping exercise are:

- An overarching question for each of five functional domains (policy, program/organization, system support strategies, services, and health promoting behaviors);

³³ Kennedy C, Lindegren ML, Brickley DB, Kennedy G, Horvath T, Azman H, Butler LM, Creanga AA, Spaulding A (2011). Integration of maternal, neonatal and child health and nutrition, family planning and HIV: Current evidence and practice from a systematic Cochrane Review. Washington, D.C.: PEPFAR, CDC, and USAID.

- A series of features or characteristics for each functional domain; and
- A determination of the extent to which the function is present: fully, partially, or not at all.

OUs will benefit from using the tool in consultation with stakeholder groups representing civil society, the private sector, the public sector, and the donor community.

b. Multisectoral Programming

The integration of health sector activities with activities in other sectors – such as non GHP-funded water and sanitation, education, food security, agriculture, economic growth, microfinance, and democracy and governance – can potentially achieve high-yield gains for health.³⁴ Element-specific considerations for multisectoral programming are included in the relevant chapters of this guidance.

c. Co-Programming of GHP Funds with Other Program Areas and/or Accounts

Under certain circumstances, GHP funds may be used with other account funds in a single integrated program. For an example, please see the case of Nepal described below under item “v. *Examples of Health and Democracy, Human Rights and Governance Program Integration.*” However, GHP funds must be used for the purposes intended by Congress as detailed in this guidance, and must be accounted for and reported separately. The above equivalency rule applies to multisectoral programming, and Missions must clearly document how the percentage breakdown among the various types of funds was determined and how GHP funds are being used. Again, where such a breakdown might be difficult to determine, Missions are encouraged to contact USAID/Washington Bureau for Global Health P3 for assistance. Missions will also be required to disaggregate GHP-funded and other activities in Congressional Notifications and in annual reporting.

d. Co-Programming Using Food for Peace (FFP) — P.L. 480 Title II

GHP funds may be used in conjunction with P.L. 480 Title II food security resources to provide a more complete maternal/child health, nutrition, or HIV/AIDS activity. OUs are encouraged to work with Agency partners to strategically program activities funded by GHP funds with those supported by Title II resources. In that effort, OUs are reminded that while the activity areas may overlap, each resource must be used within its specified activity area (either GHP or Title II). Title II resources are provided to cover the cost of commodity procurement, ocean transportation, and where applicable, inland transportation for all Title II activities. For emergency activities, Title II resources may be provided to cover costs associated with internal transport, storage, and handling costs. For Title II non-emergency (development) activities, OUs with FFP and GHP activities are encouraged to consider the integration of GHP activities with those from Title II where they would be mutually supportive. Where activities are integrated, the Title II component may also receive direct Title II support with either Section 202(e) or monetization resources when they are available. Both programs must be reported separately.

³⁴ Global Health Initiative Principle Paper on Integration in the Health Sector. Ibid.

e. Examples of Health and Democracy, Human Rights and Governance Program Integration

The 2013 USAID Strategy on Democracy, Human Rights and Governance (DRG) includes an objective to improve development outcomes through the integration of democracy, human rights, and governance principles and practices across USAID's development portfolio. Integrating core DRG principles, goals, and approaches across USAID's development portfolio, as well as building country ownership, are essential to improving development outcomes. Sustainable improvements in food security, health, education, economic growth and trade, and environmental protection require improvements in rule of law, policy formulation and implementation, public financial management, public accountability, and citizen participation. At the same time, advances in health, education, and economic growth can be leveraged to promote better governance.

As USAID Missions have employed integrated approaches in addressing socioeconomic development challenges, increasingly evidence has shown a promising linkage between the integration of DRG principles and practices into socioeconomic programming, improvements in sectoral governance and improvements in the delivery, management and oversight of services targeted by these programs. In Nepal, the integration of DRG approaches into HIV/AIDS programming, which included capacity development activities targeting local civil society organizations (CSO) and human rights advocacy training for local CSOs, played a key role in improving the governance and management of HIV/AIDS services and fostering a more inclusive HIV/AIDS response. In Guinea, where the Mission undertook a multi-sectoral approach to improving health, education, agriculture, and natural resource management outcomes through an emphasis on enhancing democratic governance practices by government and civil society stakeholders, an evaluation found that the integration of political reform and service delivery programming was mutually reinforcing, contributing not only to more transparent and accountable governance practices, but also to the greater utilization of services and improved resource mobilization in targeted sectors.

B. Health Systems/Systems Strengthening³⁵

In addressing health systems issues, allowable activities for uses of GHP funds relate to the Agency's health objectives and the principle of assuring the long-term accessibility, efficiency, effectiveness, quality, equity, and sustainability of programs.

USAID's health systems investments include the following:

- Assist countries to develop robust, well-managed health systems that ensure adequate coverage of the population with high impact, safe, and high quality health promotion, disease prevention and health care services;

³⁵ Please also refer to Chapter III.6.B.o for detailed guidance on programming for Health Systems Strengthening under PEPFAR.

- Gain sustainable system improvements resulting from increased linkages between health systems and other sectors;
- Accelerate progress in achieving global health and poverty goals; and
- Contribute to significant improvements in broad-based economic growth and engage more in the global economy, partly as a result of sustained country health system capacity.

The quality, equity and efficiency of a health system is essential to ensuring the health and well-being of individuals, families, communities, and nations. Promoting health, preventing disease, and treating illnesses in developing countries is dependent on a well-functioning health system. Achieving progress in areas such as family planning, maternal and child health, nutrition, and infectious diseases and HIV/AIDS is challenging in an environment of weak, poorly functioning health systems.

Achieving gains in our global health goals areas requires sustained emphasis and focus on health systems strengthening, and in particular supporting countries to contribute expanding local resources to domestic health programs in a manner that ensures transparency, accountability, and impact of their health systems investments. Impact means increasing service coverage; strengthening financial protection; and improving access to more equitably all socioeconomic sectors of the population. The basic assumption is that as economies grow so too, should the share of funding allocated locally for health. By promoting sustainable self-financing to improve national health systems USAID builds on its legacy in global health and development. Recognizing the strategic potential to increase country capacity to expand services to those who need them most and thereby improve health outcomes, USAID endeavors to support countries in maximizing opportunities to increase local financing for health.

USAID may provide technical support for sustainable health financing, drawing on Agency-wide expertise in health financing and economics, democracy and governance, and economic growth disciplines. Solutions to support domestic resource mobilization for local health systems should be tailored to each country context and involve a unique mix of health financing approaches. Underpinning this approach is the core analytics to monitor and evaluate the progress in each approach area.

a. Examples of the USAID Health Systems Approach

Health systems interventions typically use systems thinking and focus on processes to enhance countries' overall health status, contribute to results in the USAID Health and Social Services Elements, and improve health system performance. USAID programs can assist countries in strengthening health systems, for example, in the following ways (among others):

- Ensuring quality, equity, effectiveness, and financial sustainability of health programs in the context of decentralization and other major reforms, including strengthening transparency and accountability (typically addressed as leadership and governance);
- Improving and reforming health-related policies;

- Supporting the development of institutions through measures such as: formulation and coordination of policy (i.e., rules and norms in the policy making process); rules and norms shaping efficient and effective delivery systems for goods and services; and development of motivated and effective staff for rulemaking and enforcement;
- Establishing fair, efficient, and equitable financing to protect access by the poor to health programs by expanding domestic sources of financing, improving cost controls and rationalizing application of user fees, privatization, and risk pooling arrangements including health insurance programs;
- Strengthening health promotion and disease prevention programming and improving health communication to promote healthy behaviors and health supporting environments, and wide use of services;
- Reorganizing health sectors, including realignment of roles within the health sector, such as redefining which institutions promote health, prevent disease, and deliver health care services, make policies, and set standards on financing services and supplies;
- Strengthening health information systems and resources to inform the making of better health policy, management decision-making, and monitoring and analysis of program activities;
- Introducing and institutionalizing modern evidence-based process improvement approaches, as an integral part of health services;
- Strengthening health workforce and human resources management, often with progressive decentralization and work at the community level;
- Involving the private sector, including faith- and community-based organizations, actively in the provision of health care;
- Strengthening medical products and commodity management systems to improve access to affordable, safe, and efficacious medicines and health commodities of assured quality through activities that promote good governance in pharmaceutical operations, best procurement practices, the appropriate use of medicines, patient safety through enhanced pharmacovigilance systems, and efficient distribution systems, including the use of commercial sector partners, to ensure that desired therapeutic outcomes are achieved;
- Developing new and improved technologies and approaches to effectively plan and deliver quality child survival and health services; and
- Supporting health systems research in areas such as the following: strengthening health systems interventions for advancing priority health services; advancing methodologies to measure health system strengthening and performance; and promoting knowledge translation and utilization for health systems strengthening.

b. Funding Considerations

At this time, there is no directive or special budget category for health systems development or capacity strengthening. Health systems activities may be funded from any health element and. All health elements can support element-specific and cross-cutting health systems activities that benefit the Program Element objective (e.g., an element-specific activity, such as national health accounts in order to carry out HIV/AIDS resource tracking). For cross-cutting health systems activities, programs can be funded by pooling contributions from multiple health elements. For example, a cross-cutting activity to improve drug distribution could be funded from MCH, Family Planning, and HIV/AIDS funds.

For further information or assistance, Missions should contact staff members of the GH Office of Health Systems.

C. Health Systems Strengthening and Fragile and Conflict-Affected States

The goal of USAID's Fragile States Strategy is "to guide USAID's efforts in reversing decline in fragile states and advancing their recovery to a stage where transformational development progress is possible." To support this goal, USAID staff will need to explore how health development assistance can address key risk factors associated with state fragility and determine how health programs can be implemented to make the greatest possible contribution to a country's stability, resilience, and recovery and, at the same time, achieve the purposes for which the funds were appropriated.

The guiding principles of using GHP funds to achieve "direct impact," and the Agency's responsibility to assure "optimal use" of GHP funds, still apply in fragile state environments (see below). Mission staff will therefore need to develop program approaches that deliver situation-appropriate health programs in ways that also contribute to reconstruction and stability objectives, while respecting existing earmarks and directives.

a. Allowable Uses of Funds for Fragile States

The guidance in this section on rebuilding countries applies to the use of GHP funds appropriated to USAID. In order to use GHP funding for these activities, the activities should meet two established criteria: "direct impact" and "optimal use of funds." "Direct impact" means that the results of the activity can be linked and measured directly (using the health elements and standard indicators) against the purposes for which they were appropriated, as defined in the appropriations bill and the relevant House, Senate, and Conference Reports, and under the health element goal: "To contribute to improvements in the health of people, especially women, children, and other vulnerable populations in countries of the developing world, through expansion of basic health services, including family planning; strengthening national health systems, and addressing global issues and special concerns such as HIV/AIDS and other infectious diseases." "Optimal use of funds" means ensuring that those activities that are most

effective and efficient in reaching significant, critical populations, and/or providing sustainable community-based services receive priority for funding. Under the direct impact and optimal use of funds criteria, activities undertaken with GHP funds in fragile environments and during stabilization and reconstruction actions should contribute to the effective use and delivery of the interventions for which those funds were appropriated, as referenced in Chapter III of this Guidance. Such activities should be linked to health outcomes as well as stabilization and reconstruction objectives. Further, the Agency-wide Building Resilience to Recurrent Policy and Program Guidance was released December 2012 and can be referenced: http://www.usaid.gov/sites/default/files/documents/1866/Policy%20&%20Program%20Guidance%20-%20Building%20Resilience%20to%20Recurrent%20Crisis_Dec%202012.pdf. Programming guidance outlined in the policy should be adhered to as relevant.

In addition to what is outlined in Chapter III of this guidance on the recommended uses of GHP funds, please consider the following guidance.

Health sector governance activities

Rebuilding countries are characterized by weak governance and lack of capacity and/or willingness on the part of the government to work together with public and private providers and the community to deliver services. Strengthening the ability of national, local, and community institutions to manage a country's resources and affairs in a manner that is open, transparent, accountable, equitable, and responsive to the needs of the people is an important goal of programming in fragile environments.

The following activities may be funded when they directly impact the delivery and use of services for the directive and sub-directive areas for which the funds used were appropriated:

- Expanding and institutionalizing health services, including but not limited to:
 - Establishing or strengthening the delivery of services and the procurement of pharmaceuticals and medical supplies, including supply chain management;
 - Drafting national health policy and promoting legislation and regulation³⁶;
 - Improving infrastructure and institutional capacity to deliver services and manage health programs;
 - Strengthening corruption prevention;
 - Training, quality assurance, and human resource development of health sector workers;
 - Establishing fair, efficient, and equitable health sector financing; and
 - Strengthening national and local level management, information, financial systems, and leadership training/development for health services.

- Reestablishing or strengthening basic health services with particular attention to previously underserved, socially marginalized, and vulnerable populations in ways that promote longer-term re-engagement with national governments and building capacities of national governments to use health resources effectively.

³⁶ The Siljander Amendment (1981) prohibits USAID funds being used to lobby for or against abortion.

- Building the capacity of public sector institutions and strengthening the relationship between government institutions and nongovernment providers at all levels in the health sector by:
 - Assuring that nongovernment organizations in the health sector are aligned with the national government and contribute to building state capacity; and
 - Strengthening the capacity of local NGOs to engage with and be accountable to government (where feasible) and to implement and report on health programs.

- Increasing the participation of civil society, local government, and community institutions in health activities by:
 - Increasing the role of communities in planning, decision-making, and resource management for health activities;
 - Strengthening organization and capacities of communities and local government;
 - Supporting the provision of health empowering information to families and communities;
 - Supporting the development of local mechanisms to monitor health status and plan effective responses; and
 - Increasing accountability and responsiveness of local health authorities.

Multisectoral programming

Many of the factors that drive state fragility are rooted in the political, security, economic, or social sectors. Development efforts to address grievances in these factors in rebuilding countries that have limited absorptive capacity presents a major challenge – particularly in post-conflict situations. USAID health officers are encouraged to seek opportunities to develop mutually productive linkages with other sectors such as education, democracy, and governance, and economic development. For example, in a post-conflict situation both the agriculture and education sectors may be investing in strengthening district governments to provide services to vulnerable populations; GHP funds could be used to develop a consistent approach to strengthening health sector governance at the district level. Use of a common governance model would decrease duplication of effort among the sectors and contribute to aid efficiency and effectiveness.

While GHP funds should be used to support the GHP components of multisectoral activities, funds from non-GHP sources must be used to support activities that do not directly affect GHP outcomes. Examples of multisectoral activities that can be funded with GHP funds include the following:

- Support for the health component of a larger government-wide decentralization, corruption-prevention, or management strengthening activity;
- Addition of child survival, maternal health, or family planning education component to employment, income generation, or agricultural programs;
- Support for food aid programs that increase the nutritional status of households; and
- Provision of field guidance and training in high-impact child survival interventions in complex emergencies.

D. USAID Forward

USAID Forward is focused on partnership building, innovation, and an enhanced emphasis on evaluation policy within the Agency. More specifically, the three primary goals aim to:

- Deliver results on a meaningful scale through a strengthened USAID;
- Provide sustainable development from high-impact partnerships and local solution; and
- Identify and scale up innovative breakthrough solutions to intractable development challenges.

Local solutions, formerly known as Implementation and Procurement Reform (IPR), is an initiative that enhances assessment and implementation tools, procurement policies, and partnership strategies in order to improve sustainability. The vision for *Local Solutions* is societies that own, resource and sustain inclusive and accountable development. The Bureau for Global Health fully supports this vision and is working to achieve global health targets in ways that build partner country ownership and foster sustainability. As countries continue to advance in their economic development and improve health indicators, the GH Bureau anticipates that partner countries will want to explore, with the donor community, plans for building more self-sufficiency in the health sector.

The Bureau for Global Health fully supports programming that:

- Achieves and sustains our commitment to health targets;
- Supports a country's public health and development objectives;
- Complements and reinforces the approach taken by the broader donor community;
- Leverages global investments in multilateral partners, such as the Global Fund, and GAVI;
- Promotes greater efficiency and value for money; and
- Fosters transparency, accountability, and sustainability.

Use of country systems and local organizations should be explored, where its design and implementation support these objectives, mitigate programmatic and fiduciary risk, and are in accordance with applicable USG and USAID requirements.

a. Procurement Reform

USAID Forward gave the Agency new tools and approaches for improving sustainability in USAID health programs through new partnerships and a focus on strengthening local capacity and systems. USAID continues to change its business processes to increase direct grants and contracts with more and varied local partners where appropriate, including partner country systems and local not-for-profit and for-profit organizations. The objectives are to:

- Strengthen partner country capacity to improve aid effectiveness and sustainability by increasing use of reliable partner country systems and institutions to provide support to

partner countries. (See [ADS 220, Use and Strengthening of Reliable Partner Government Systems for Implementation of Direct Assistance](#); and further detail below under item A.)

- Increase use of reliable partner country systems and institutions that meet certain minimum standards; and
 - Enhance USAID governance programs in order to provide further support to partner countries in strengthening public accountability, including public financial management and procurement systems.
- Strengthen local civil society and private sector capacity to improve aid effectiveness and sustainability by working closely with USAID implementing partners on capacity building and local grant and contract allocations. (See [ADS 303](#), [ADS 310](#), and [ADS 312](#).)
 - Increase the percentage of total program obligations for direct grants or contracts with local not-for-profit and for-profit organizations;
 - Increase the number of local civil society and private sector partners receiving direct support from USAID;
 - Work closely with implementing partners to ensure that all programs strengthen the capacity of local organizations either directly or indirectly; and
 - Build metrics and targets for local capacity-building objectives into implementing partner agreements.
- Increase competition and broaden USAID’s partner base by increasing the number of prime contract awards and percentage of total dollars obligated to U.S.-based small and disadvantaged businesses and small NGOs (while decreasing the number and value of large pre-competed contracts). (See [ADS 321](#).)
- Use U.S. Government resources more efficiently and effectively, by increasing the number of fixed-price contracts where feasible and appropriate, decreasing the use of “high-risk” procurement methods, and harmonizing procurement approaches with other U.S. Government agencies working in the same substantive areas. (See [ADS 302](#) and [ADS 303](#).)
 - Increase the number of fixed-price contracts where feasible and appropriate;
 - Decrease the use of certain procurement methods that Office of Management and Budget has classified as “high risk” when more cost-effective contract alternatives are available (e.g., single award contracts, ensuring both more continuous competition and more entry points for potential private sector partners);
 - Consider setting policies with caps on salaries and other cost containment measures for contractors and grantees;
 - Harmonize procurement approaches with other U.S. Government agencies working in the same substantive areas, such as HIV/AIDS, Maternal Child Health, etc.; and

- Reduce by one third the number of times a contract must be reviewed by the Contract Review Board (CRB) and increase significantly the threshold for using the CRB depending on the contract officer's warrant.
- Strengthen collaboration and partnership with bilateral donors and multilateral and international organizations to increase synergies and avoid duplication. (See [ADS 308](#) and [ADS 351](#).)
 - Strengthen USAID's ability to collaborate with and leverage benefits from other bilateral donors, multilateral organizations and international organizations, where comparative advantage and expertise can be brought together to deliver effective and efficient foreign assistance; and
 - Strengthen USAID's ability to focus its development efforts in particular sectors or areas and avoid duplication with development activities carried out by other donors.

b. USAID Guidance on Local Procurement of Global Health Commodities

On March 30, 2012, the President's Malaria Initiative and Office of Population and Reproductive Health released guidance on the procurement of key, life-saving commodities, which lays out specific criteria for local procurement of malaria and family planning/reproductive health (FP/RH) commodities. In addition to the Public Financial Management Risk Assessment, which assesses fiduciary risks, USAID Missions considering government-to-government agreements or agreements with local non-governmental, including private sector, organizations to procure malaria or FP/RH commodities are required to conduct an additional programmatic risk assessment and develop an associated risk mitigation strategy.

c. Government to Government (G2G)

Obligation Requirements for G2G Activities:

The FY 2014 Appropriations Act states that funds appropriated under that Act, including Global Health Programs funds, may be made available for direct Government to Government assistance.” However, such funds may only be made available for such assistance if:

- Each implementing agency or ministry to receive assistance has been assessed and is considered to have the systems required to manage such assistance and any identified vulnerabilities or weaknesses of such agency or ministry have been addressed and:
 - The recipient agency or ministry employs and utilizes staff with the necessary technical, financial, and management capabilities;
 - The recipient agency or ministry has adopted competitive procurement policies and systems;

- Effective monitoring and evaluation systems are in place to ensure that such assistance is used for its intended purposes;
 - No level of acceptable fraud is assumed; and
 - The government of the recipient country is taking steps to publicly disclose on an annual basis its national budget, to include income and expenditures;
- The recipient government is in compliance with the principles set forth in section 7013 of this Act;
 - The recipient agency or ministry is not headed or controlled by an organization designated as a foreign terrorist organization under section 219 of the Immigration and Nationality Act;
 - The Government of the United States and the government of the recipient country have agreed, in writing, on clear and achievable objectives for the use of such assistance, which should be made available on a cost-reimbursable basis; and
 - The recipient government is taking steps to protect the rights of civil society, including freedom of association and assembly.³⁷

Comprehensive guidance regarding the policies and procedures that must be followed when disbursing funds directly to partner governments, including risk management practices that apply to G2G assistance and the mechanisms that are available for financing G2G assistance, is set forth in [ADS 220, Use of Reliable Partner Country Systems for Direct Management and Implementation of Assistance](#).

i. Congressional Notification (CN) Requirements

Section 7031(a)(2) of the FY 2014 Foreign Operations Appropriations Act requires Congressional notification before the obligation of FY2014 funds for direct government-to-government assistance. OUs should refer to the State/F guidance on issuing a Congressional Notification and consult and confer with their cognizant RLO regarding any Congressional Notification requirements for G2G assistance.

ii. State Department Policy Guidance

The State Department issued a cable on September 4, 2012 setting forth policy guidance on government-to-government programming in the health sector. On September 21, 2012, OGAC issued interagency FAQs on implementation of the policy as it relates to PEPFAR-funded activities. Missions that support PEPFAR-funded activities should review that guidance.

In addition, pursuant to the Secretary of State's mandate in the September 4, 2012 policy guidance, USAID and CDC jointly issued provisions and procedures to be used for PEPFAR and other health activity G2G agreements when funding is provided directly to a partner country's government. "Technical Guidance for Government-to-Government Mechanism and Support for Global Health Programs" (henceforth/herein referred to as the technical guidance for G2G health

³⁷ FY 2014 Foreign Operations Appropriations Act, Section 7031(a)(1).

agreements) on February 1, 2013. For GHP Funds, the technical guidance for G2G health agreements set forth standardized award terms, protocols and processes to be used by USAID and CDC in cost-based and fixed amount G2G agreements for (1) PEPFAR funds, or (2) non-PEPFAR health funds in countries where either CDC or USAID seeks to engage for the first time with government-to-government funding. The standardized award terms have subsequently been memorialized in the Development Objective Agreement/Bilateral Project Agreement health template and Implementation Letter health template which are mandatory references to ADS 220. In addition, on February 1, 2013, USAID issued a document containing information on when and how to follow the new technical guidance for applicable USAID G2G agreements in health.

d. Nonproject Assistance

In FY 2012, the Appropriations Act language was amended so that it no longer contains a prohibition on nonproject assistance that had been included in previous years. Under program assistance (or “nonproject assistance”), contributions by USAID help to alleviate constraints to development that are policy or resource based. There are two types of program assistance in use by USAID: “Sector Program Assistance” and “General Budget (or Balance of Payments) Support.” The distinguishing feature of program assistance is the manner in which USAID resources are provided. Under program assistance, USAID provides a generalized resource transfer, usually in the form of foreign exchange (hard currency, e.g., U.S. Dollars), or sometimes in the form of commodities to the partner country. Individual transfers of funds are dependent on the completion of performance actions by the partner government and funds are only disbursed after program actions have been completed.³⁸ However, the FY 2012 Statement of Managers notes that the “conferees understand that USAID does not intend to enter into additional funding arrangements of this type, and agree with that position.” In the health sector, USAID, in consultation with Congress, may consider the use of “Sector Program Assistance” when results and milestones are clearly articulated. Reliance on “General Budget Support” should be rare. While this type of assistance is not statutorily prohibited, direct budget support³⁹ often limits USAID’s ability to hold a partner government accountable for results. Other forms of government-to-government funding, such as reimbursable assistance are preferred by Congress.

For more information on Local Solutions for GH at USAID/Washington, please contact the GH/AA’s office.

e. Monitoring and Evaluation Policy

USAID’s monitoring and evaluation goals and guidance provide Operating Units with guidance on best practices to ensure well-designed programs are implemented and meet the needs of target populations in the developing countries where the Agency operates. The policy can be accessed:

³⁸ G2G Policy [September draft].

³⁹ Direct budget support can be defined as a type of resource transfer in which funds are channeled directly to recipient governments. The recipient uses its own procurement and accounting systems, and the funds are not linked to projects (http://pdf.usaid.gov/pdf_docs/PNADE110.pdf).

<http://www.usaid.gov/ads/policy/200/203>.

E. Construction of Facilities

Although USAID has legal authority to perform both construction and improvements, USAID usually prefers to avoid using health funding for new construction. This is based on the view that the construction of facilities is resource-intensive and does not ordinarily result in *optimal use* of GHP funds. Optimal use is defined throughout this guidance as those activities that are most effective and efficient in reaching significant, critical populations and/or providing *sustainable* community-based services. This requires balancing the use of funds for construction against other factors, such as the severity and magnitude of the problem, overall developmental needs, program stage or maturity, relative cost- and program-efficiency of the intervention, and host country and other donor resources. USAID's Bureau for Global Health, Office of Policy, Programs, and Planning (GH/P3) should be consulted via GHPAccountGuidance@usaid.gov before any construction activities commence.

Please refer to the Agency's updated policy on construction issued on April 3, 2012: <http://notices.usaid.gov/notice/22805>. PEPFAR has also issued FY 2014 COP Guidance, which provides the latest guidance on programming construction activities using HIV/AIDS funding (section 7.5.1, Construction/Renovation for HIV/AIDS Assistance Projects only): <http://www.pepfar.gov/documents/organization/217765.pdf>.

F. Gender

Promoting gender equality in health programming is consistent with USAID's policy on Gender Equality and Female Empowerment, which articulates three overarching outcomes:

- Reducing gender disparities in access to, control over, and benefit from resources, wealth, opportunities and services;
- Reducing gender-based violence and mitigating its harmful effects on individuals; and
- Increasing the capability of women and girls to realize their rights, determine their life outcomes, and influence decision-making in household, communities, and societies.

Allowable activities for this category are consistent with those outlined in the Global Health Initiative's principle on Women, Girls, and Gender Equality supplemental guidance (http://www.ghi.gov/principles/docs/wgge_principle_paper.pdf). Illustrative examples include (but are not limited to) interventions that:

- Work with communities and men and women to transform traditional gender norms that perpetuate gender-based violence including intimate partner violence, child marriage, and other harmful traditional practices;
- Address barriers to women's and men's access to quality health services, including structural barriers such as inadequate transportation;
- Improve couple communication, joint decision-making, and men's constructive involvement as supportive partners;
- Monitor, prevent, and respond to gender-based violence;

- Strengthen health systems to meet the health needs of women/girls and men/boys; support gender equity in health care workforce development; and implement gender-sensitive information systems;
- Engage men, boys, and communities to transform harmful notions of masculinity, promote men’s use and support of health services and commodities, reduce their use of violence, and encourage men’s equitable interaction with their partners, families and children;
- Work with government, civil society, and champions to promote policies and laws in support of gender equality and health, and support public awareness and debate on relevant issues;
- Ensure full access to a range of commodities, including access to Emergency Contraception and Post Exposure Prophylaxis;
- Link across sectors to address social, economic, legal, and cultural determinants of health, including programs on girls’ education, women’s literacy, economic opportunities, access to productive resources, and social safety nets.

For more information, please visit the GH Intranet site on Gender Equality and Health, or contact the GH Gender Team:

<http://ghintranet.usaid.gov/GHNET/Pages/GHOffices/CCFA/GenderEquality/Index.aspx>.

G. Salary Payments⁴⁰

With respect to payment of salaries, GHP funds may be used by U.S. Government program contractors or grantees to pay for time-limited contractors to carry out activities essential to health program goals. In addition, NGOs may hire personnel to be placed in the Ministry or other government health facilities or in their own organizations. USAID, through its contractors, also supports staff seconded to the Ministry of Health (MOH). U.S. Government teams and their implementing partners are urged to be cautious about paying salaries or other benefits that attract staff away from their current positions in local public and private agencies. In all cases, countries should develop a transition plan to ensure that contract staff can eventually be absorbed through sustainable long-term approaches using non-U. S. Government resources.

Payment of salary supplements, or “top-ups,” to host government employees is not permitted. However, it is permissible to pay bonuses or incentives to personnel (public or private sector) who meet performance-based criteria that are directly linked to achieving program goals, e.g., working overtime to increase patient access or achieving quality performance targets above and beyond routine job requirements.

For further information or guidance, please contact your cognizant **RLO**.

⁴⁰ See State Department Cable # 119780 (April 15, 1988; Unclassified) for further guidance and references: <http://www.usaid.gov/sites/default/files/documents/1868/220mac.pdf> and <http://www.usaid.gov/sites/default/files/documents/1868/119780.pdf>.

H. Antimicrobial Resistance (AMR) Containment

Activities funded to achieve the reduction of antimicrobial resistance, may include (but are not limited to):

- Interventions designed to “preserve the effectiveness of currently available antimicrobials,” including educational activities such as formal and continuing education (pre- and in-service training, seminars and workshops for health professionals);
- Curricular development involving concepts of AMR and rational use of antimicrobials;
- Development of printed and other media-based materials (clinical literature, newsletters, radio and TV spots, flyers, videos) and face-to-face approaches for practitioner and public awareness on appropriate treatment-seeking behavior, self-medication and adherence to recommended therapy;
- Other behavior change and communication strategies;
- Establishment of drug information centers to provide accurate, up-to-date and unbiased drug information/materials;
- Support for global and regional AMR advocacy and containment networks and country-level approaches;
- Managerial activities involving the design and implementation of standard tools to promote rational medicine selection, procurement and use such as formularies, pharmacoconomics, limited procurement lists, standard diagnostic and treatment guidelines, and drug utilization reviews;
- Promotion of proven approaches to facilitate effective uptake of new treatment technologies and practices;
- Drugs and Therapeutics Committees;
- Infection control programs;
- Efforts to develop pharmaceutical management capacity and appropriate financing and incentive schemes for improved access to and use of medicines; and
- Regulatory activities such as strengthening regulatory authority capacity, quality control laboratories, and quality assurance mechanisms such as drug registration and surveillance systems to detect counterfeit and substandard medicines.

AMR containment activities should be included in their respective elements (e.g., Malaria, MCH).

I. Surveillance and collection and use of health information to respond to endemic and epidemic infectious diseases

Activities funded for surveillance and response to epidemic and endemic disease may include (but are not limited to):

- Strengthening epidemiological surveillance and response capacity by improving collaborating partnerships;
- Improving the use of surveillance and health data to respond to disease threats and improve programs;
- Expanding capacity building, including training and improved laboratory capacity, including performance in diagnostic techniques for new and re-emerging pathogens; and

- Developing and using improved tools, including rapid diagnostics, policy tools, data gathering tools, and strengthened field epidemiology capacity and the understanding of disease patterns and trends.

Surveillance activities should be included in their respective elements (i.e., Malaria, MCH).

12. ADMINISTRATIVE/MANAGEMENT COSTS

A. Health Program Element

Agency regulations on the appropriate use of operating expense and program funds for administrative and management positions are found in ADS 601, Funding Source Policy. ADS 601 is applicable to the use of GHP Account funds, and Missions must carefully review costs where there may be doubt about the proper source of funding. Regarding funding sources, E601.5.7 states:

“In most instances the appropriate funding source will be clear, particularly viewed in conjunction with the examples provided in the Mandatory References to this policy. In cases where it is not clear which funding source is to be used, the cognizant technical office or other requesting office, after consultation with the cognizant GC, as appropriate, must document the funding source decision. Such documentation will be in the form of a statement that the requestor has reviewed the scope of work and determined that the appropriate source of funding is (identify funding source).”

Missions should consult health officers, either in Missions or in USAID/Washington, when GHP funds are used for administrative and/or management costs. If any doubt remains as to whether a cost should be funded by Operating Expenses (OE) or GHP Account funds, OUs are urged to err on the side of caution and to use OE funds.

Use of Objective 6:

It is important for OUs to ensure that overhead costs allocated to specific positions (for example, office leases and utilities, building maintenance, warehouse costs, etc.) are properly funded, support the direct impact and optimal use of GHP funds, and that the GHP Account bears its fair share of these costs (see [E601.5.8b](#)). As with every Program Element, OUs must ensure that those costs that are considered cross-cutting truly do fall within this category and that all Program Elements within the portfolio are equally supporting the costs. OUs should clearly document the justified funding amounts. For additional guidance on the use of program funds for cross-cutting program support expenses, please see the Operational Plan Guidance and associated Annex, “Operating Unit Management Costs and Program Support,” including any subsequent changes to the Foreign Assistance Standard Program Structure and Definitions.

For complete policy guidance on determining appropriate funding sources, see the following documents:

ADS 601: Funding Source Policy
<http://www.usaid.gov/ads/policy/600/601>

Mandatory Reference ADS 601maa: Cost of Doing Business
(<http://www.usaid.gov/ads/policy/600/601maa>)

Foreign Service Limited (FSL): The Appropriations Act includes a provision that funds may be made available to “hire and employ individuals in the United States and overseas on a limited appointment basis pursuant to the authority of sections 308 and 309 of the Foreign Service Act of 1980.” This provision requires that the number of FSLs hired in any fiscal year may not exceed 175. The authority to hire individuals under this provision may only be used to the extent that an equivalent number of positions that are filled by personal services contractors or other non-direct hire employees of USAID, who are compensated with funds appropriated to carry out part I of the Foreign Assistance Act of 1961, including funds appropriated under the heading “Assistance for Europe, Eurasia and Central Asia” are eliminated.

PEPFAR Funds: The PEPFAR authorization authorizes USAID to use PEPFAR funds for administrative expenses of the Agency. Please consult with GC or your RLO for further guidance.

13. ENVIRONMENTAL REGULATION

Please consult and follow ADS 204: Environmental Procedures. All program planning must include an environmental impact analysis to ensure that projects protect environmental resources in developing countries. Environmental actions approach preservation and mitigation of project impacts via three main steps: (1) environmentally sustainable design or planning, (2) Environmental Impact Assessment, and (3) environmental monitoring and mitigation implementation. Environmentally sustainable design and environmental planning begin at the early stages of project development. Environmental Impact Assessments evaluate the project itself to determine what impacts remain and the best approach to mitigate and manage the impacts. Environmental monitoring and mitigation implementation ensure that mitigations and conditions determined during the environmental impact analysis are implemented and documented in a manner consistent with plan.

IV. PROCEDURES FOR DEVIATIONS FROM THE GUIDANCE

This document describes legal requirements and congressional directives, as well as USAID guidance.

All legal requirements are mandatory.

USAID guidance is issued to ensure effective, evidence-based programming, and to increase consistency and predictability of operations. This guidance is determined based on decades of experience in health programming and represents the best understanding of leading technical experts. If an OU seeks clarification or has a question about whether an activity falls within the parameters of the requirements, the OU should seek additional guidance by contacting GH/P3, who will coordinate a review and response with the GH Technical Lead, Regional Bureau Technical Officer, GC/Washington, or the cognizant **Resident Legal Officer**, as appropriate.

Although OUs should generally follow these practices, there are situations where an OU may wish to deviate from them or adapt them to particular situations, especially when such deviations correspond to the guiding principles of “direct impact” and “optimal use.” There is a two-phase process for requesting a deviation from this Guidance.

Phase I: When an OU wishes to deviate from USAID guidance, the OU must hold a technical consultation, organized by the Office Director of GH/P3, which must include representatives from the relevant Regional Bureau, GH, the Bureau for Legislative and Public Affairs, GC/Washington or the **Resident Legal Officer**, the Bureau for Policy, Planning, and Learning (PPL), and the Office of the Director of U.S. Foreign Assistance/Investing in People. The technical consultation should be documented in an Information Memorandum to the File from the OU. Ideally, the parties will reach a consensus on technical grounds. If all parties reach consensus, then the Information Memorandum will serve as documentation, and the OU is free to proceed with the requested program. See Appendix VI for a sample template for documenting technical consultations.

Phase II: If and only if a mutual agreement cannot be reached, an arbitration will be held. The Assistant Administrator of the relevant regional bureau should write a split decision Action Memo to the Administrator of USAID. This action memo should include a detailed description of the activity, how it directly contributes to the relevant health area and element objectives, and the expected results. It should outline the pros and cons of moving ahead with the proposed activity, and the relevant external considerations (including political, diplomatic, and programmatic considerations). PPL will convene an intra-agency committee with the appropriate policy, technical, program, and budget personnel to review the request and recommend approval or disapproval.

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