

# Systems for Improved Access to Pharmaceuticals and Services (SIAPS)

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## ACRONYMS

ADDO	Accredited Drug Dispensing Outlet
AIDS	Acquired Immune Deficiency Syndrome
AMfM	Affordable Medicines for Malaria
AMR	Antimicrobial Resistance
AO	Agreement Officer
AOTR	Agreement Officer's Technical Representative
ART	Antiretroviral therapy
ARV	Antiretroviral medicine
BEO	Bureau Environmental Officer
CA	Cooperating Agency
CFR	Combined Federal Regulations
CHS	Child Survival and Health
COP	Country Operational Plan
DFID	Department for International Development (British Aid)
DTC	Drugs and Therapeutics Committees
EA	Environmental Assessment
ECS	Environmental Capability Statement
EML	Essential Medicines List
EMMP	Environmental Monitoring and Management Plan
ESR	Environmental Status Report
FIP	International Pharmaceutical Federation
FP	Family Planning
FP/RH	Family Planning/Reproductive Health
GDF	Global Drug Facility
GFATM	Global Fund to fight HIV/AIDS, Tuberculosis and Malaria
GGM	Good Governance for Medicines
GH	Global Health Bureau
GHI	Global Health Initiative
GIS	Geographic Information System
GLC	Green Light Committee
GMP	Good Manufacturing Practices
GPS	Global Positioning System
HAI	Health Action International
HIDN	Health Infectious Disease and Nutrition
HIS	Health Information System
HIV	Human Immunodeficiency Virus
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome
HRH	Human Resources for Health
HS	Health Systems
HSS	Health Systems Strengthening
IEC/BCC	Information, Education and Communication/Behavior Change Communication
IEE	Initial Environmental Examination
IR	Intermediate Result
ISO	International Organization for Standards

ISoP	International Society of Pharmacovigilance
M&E	Monitoring and Evaluation
MCH	Maternal and Child Health
MDGs	Millennium Development Goals
MeTA	Medicines Transparency Alliance
MOC	Ministry of Commerce
MOF	Ministry of Finance
MOH	Ministry of Health
NGO	Non-government Organization
NICRA	Negotiated Indirect Cost Rate Agreement
OAA	Office of Assistance and Acquisitions
OGAC	Office of the U.S. Global AIDS Coordinator
OHA	Office of HIV/AIDS
OMB	Office of Management and Budget
PEPFAR	President's Emergency Plan for AIDS Relief (US)
PHN	Population, Health and Nutrition
PIEE	Programmatic Initial Environmental Examination
PMI	President's Malaria Initiative
PMIS	Pharmaceutical Management Information System
PMP	Performance Monitoring Plan
PRH	Population and Reproductive Health
QDDR	Quadrennial Diplomacy and Development Review
RFA	Request for Applications
RH	Reproductive Health
SHOPS	Strengthening Health Outcomes in the Private Sector Project
SIEE	Supplemental Initial Environmental Examination
SLMG	Sustainable Leadership, Management, and Governance Program
SPS	Strengthening Pharmaceutical Systems Program
TA	Technical Assistant/Assistance
TB	Tuberculosis
UN	United Nations
USAID	United States Agency for International Development
USFDA	United States Food and Drug Administration
USG	United States Government
WHO	World Health Organization

## **SECTION I - PROGRAM DESCRIPTION**

### **A. Introduction**

Collectively comprising one of the basic building blocks of health systems, Medical Products, Vaccines and Health Technologies are essential for successful implementation of priority health interventions pursued in all nine USAID Health Elements. References in this RFA to “pharmaceuticals” and “medicines” are interchangeable and include medicines, vaccines, equipment, supplies and diagnostics.

The goal of the new Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program of the Health Systems Division of the Office of Health, Infectious Diseases and Nutrition (HIDN) is to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. The SIAPS objective is to promote and utilize a systems strengthening approach consistent with the Global Health Initiative (GHI) that will result in improved and sustainable health impact. To this end, the SIAPS guiding framework and result areas reflect a comprehensive set of dynamic relationships among five health systems building blocks (governance, human resources, information, financing, and service delivery), with a Medical Products Building Block overlay to provide technical content and identify substantive areas of concern. This represents a significant advance over the technical approach of predecessor programs.

SIAPS expands the prevailing product availability paradigm to include a continuum of activities that embraces all pharmaceutical management functions, including supply chain, to patient-centered pharmaceutical services such as counseling to promote adherence to therapy, and pharmacovigilance to ensure patient safety and therapeutic effectiveness. SIAPS solutions will optimize investments in the pharmaceutical sector by the USAID health program elements and donors, address the immediate challenges of ensuring availability of essential medicines, yield measureable results, and demonstrate sustainable systems strengthening. Developing corresponding supportive roadmaps and guidance, and tools to support measurement of success from a health systems strengthening perspective, are among the key activities expected under SIAPS technical leadership and research.

SIAPS will help countries ensure that valuable resources are not wasted through mismanagement and that desired health outcomes are achieved from effective pharmaceutical services. Indeed, pharmaceutical management system weaknesses and failures are among the leading causes of health system inefficiencies (WHO, 2010). They can also contribute to the emergence of antimicrobial resistance (AMR), increased health system costs, and the need for more expensive medicines and prolonged treatments, in addition to posing significant public health risks with global health implications (Nugent, et al., 2010).

SIAPS will support application of proven approaches and methods and enhance the ability of USAID missions to apply USG policy on the use of partner country systems as outlined in the *Quadrennial Diplomacy and Development Review (QDDR)*. SIAPS will also support GHI’s “whole-of-government” approach and collaborate with all USG agencies and offices with expertise in global health activities to achieve common goals and targets. This includes the Department of State (DOS), Office of the Global AIDS Coordinator (OGAC), Health and

Human Services (HHS), the Center for Disease Control and Prevention (CDC), the US Food and Drug Administration (USFDA), and the Millennium Challenge Corporation (MCC), among others.

## **B. Background**

This section presents the overarching framework guiding HIDN pharmaceutical system strengthening efforts and describes the relationship of SIAPS to other USAID health projects. It also reviews the relevance of new key USG policies and initiatives, including the USG Foreign Assistance Framework and the Global Health Initiative (GHI), to the SIAPS design and core operating principles.

### **Foreign Assistance Framework**

The USG strategy for development and foreign assistance has the overall goal of “helping to build and sustain democratic, well-governed states that will respond to the needs of their people and conduct themselves responsibly in the international system.” As part of this goal, the Foreign Assistance Framework identifies *Investing in People* as one of five priority objectives. *Investing in People* includes improving global health and involves all Health Elements: HIV/AIDS, Tuberculosis (TB), Malaria, Avian Influenza (AI), Neglected Tropical Diseases, Maternal and Child Health, Family Planning and Reproductive Health, and Water Supply and Sanitation.

The Foreign Assistance objectives recognize that improving the health of populations contributes to increased workforce productivity and economic growth, while improving governance leads to a stronger civil society and social stability – all of which provide an environment necessary for citizens to achieve their full potential.

Health challenges and issues vary from country to country depending upon the burden of disease and the stage of development of health systems. Therefore, USAID’s strategies and approaches must be customized and tailored to the situation at the country-level based on an assessment of political commitment, technical opportunities, priorities, funding, and sustainability concerns. The USG Foreign Assistance Framework provides a useful perspective by identifying various classes of countries: Rebuilding, Developing, Transforming and Sustaining Partnership countries. The health context in these categories of countries needs to be considered in designing solutions to address pharmaceutical management constraints and build sustainable systems.

### **Health Systems Strengthening**

According to the World Health Organization (WHO, 2007), a health system consists of all organizations, people, and actions whose primary intent is to promote, restore, or maintain health. Health systems strengthening is defined by WHO as any array of initiatives and strategies that leads to better health through improvements in one or more of the six health system components or building blocks: governance and leadership; human resources; information systems; health financing; medical supplies, vaccines, and technology; and service delivery.

Health system strengthening is therefore a continuous evidence-based process of implementing sustainable changes in policies and management arrangements within the health sector for the purpose of achieving good health outcomes. The USG, primarily through PEPFAR, HHS, CDC, and USAID, is a contributor to health system strengthening and capacity building through disease-specific programs and across all of the health system components. The USG is also a significant provider of pharmaceutical products that support expanded prevention and treatment programs for HIV/AIDS, TB, and malaria, as well as for family planning and reproductive health (USAID, 2009). To support achievement of the health-related Millennium Development Goals (MDGs), USG programs, together with other global health initiatives, have contributed to a rapid and dramatic increase in the availability of resources and medicines and other health commodities in developing countries.

However, in the last decade, the increased availability of pharmaceuticals has not been accompanied by a commensurate improvement in health system performance. According to WHO's 2010 *World Health Report*, three important known sources of health system inefficiency are directly related to pharmaceutical management: the underuse of generics and higher than necessary prices for medicines, the use of substandard and counterfeit medicines, and the inappropriate and ineffective use of medicines. The latter is often associated with the emergence of AMR, increased risk to patient safety, and poor health outcomes.

Desired health outcomes from medication use cannot be assured without the provision of patient-centered pharmaceutical services. This means that human resources must be available with the requisite skill sets and competencies to perform a variety of pharmaceutical management functions and services that run through the supply chain to prescribing, patient counseling, dispensing, and monitoring the patient for adherence to treatment regimens, safety, and adverse events -- in addition to investigating the reasons for treatment failure. Information systems need to be designed to support these activities, financial resources mobilized, and governance structures and policies designed and implemented accordingly. Constraints in all of these areas explain why unprecedented increases in the availability of funds for pharmaceutical procurement through global health initiatives are not necessarily translating into the achievement of ambitious treatment targets and sustainable improvements in health systems.

The longer term implications of the increased availability of pharmaceutical products as regards health system strengthening and performance are still emerging and require better understanding. Moreover, new medical treatments and other technological advancements will be introduced in the coming years that will likely require rethinking strategic approaches and interventions to ensure the effective and efficient management and use of medicines. SIAPS will have a critical role in contributing to the global understanding of pharmaceutical system strengthening and the development of more coherent and robust approaches to health system programming and performance.

### **The Global Health Initiative (GHI)**

The Global Health Initiative (GHI), announced in 2009, aims to help USG partner countries achieve improved health outcomes through strengthened health systems. The GHI endorses approaches that incorporate the following principles: increased impact and efficiency through strategic coordination and integration; woman- and girl-centered approaches; strengthening and

leveraging partnerships, multilateral organizations, and private contributions; country ownership and country-led plans; improved metrics, monitoring and evaluation; and the promotion of research and innovation (<http://www.pepfar.gov/ghi/>).

GHI efforts to maximize sustainable health impacts are intended to support achievement of the Millennium Development Goals. The following Health Element-specific goals and targets have been defined for the GHI:

- **HIV/AIDS:** The U.S. President's Emergency Plan for AIDS Relief (PEPFAR) will: (1) support the prevention of more than 12 million new HIV infections; (2) provide direct support for more than four million people on treatment; and (3) support care for more than 12 million people, including five million orphans and vulnerable children.
- **Malaria:** The President's Malaria Initiative (PMI) will reduce the burden of malaria by 50 percent for 450 million people, representing 70 percent of the at-risk population in Africa, and expand malaria efforts into Nigeria and the Democratic Republic of Congo.
- **Tuberculosis (TB):** Save approximately 1.3 million lives by reducing TB prevalence by 50 percent. This will involve treating 2.6 million new TB cases and 57,200 multi-drug resistant cases of TB.
- **Maternal Health:** Save approximately 360,000 women's lives by reducing maternal mortality by 30 percent across assisted countries.
- **Child Health:** Save approximately three million children's lives, including 1.5 million newborns, by reducing under-5 mortality rates by 35 percent across assisted countries.
- **Nutrition:** Reduce child under-nutrition by 30 percent across assisted food-insecure countries, in conjunction with the President's Feed the Future Initiative.
- **Family Planning and Reproductive Health:** Prevent 54 million unintended pregnancies by meeting unmet need for modern contraception. Contraceptive prevalence is expected to rise to 35 percent across assisted countries, reflecting an average two percentage point increase annually. First births by women under 18 should decline to 20 percent.
- **Neglected Tropical Diseases (NTDs):** Reduce the prevalence of seven NTDs by 50 percent among 70 percent of the affected population, and eliminate onchocerciasis in Latin America by 2016, lymphatic filariasis globally by 2017, and leprosy.

USAID recognizes that gender plays an integral part in development and health outcomes, since men and women have different societal roles, behaviors, and expectations that may affect their access to health, information, education, and productive resources. The USAID goals to address gender, equality, and health issues are to:

- Ensure equitable access to essential health services at facility and community levels;
- Increase the meaningful participation of women and girls in planning, design, implementation, monitoring, and evaluation of health programs;

- Monitor, prevent, and respond to gender based violence;
- Empower adolescent and pre-adolescent girls by fostering and strengthening their social networks, educational opportunities, and economic assets;
- Engage men and boys as clients, supportive partners, and role models for gender equality;
- Promote policies and laws that will improve gender equality and health status and/or increase access to health and social services
- Address social, economic, legal and cultural determinants of health through a multi-sector approach;
- Utilize multiple community-based programmatic approaches, such as behavior change communication, community mobilization, advocacy, and engagement of community leaders/role models to improve health for women and girls;
- Build the capacity of individuals, with a deliberate emphasis on women, as health care providers, caregivers, decision-makers throughout the health systems, from the community to national level;
- Strengthen the capacity of institutions -- which set policies, guidelines, norms and standards that impact access to, and quality of, health-related outreach and services -- to improve health outcomes for women and girls and promote gender equality.

SIAPS is expected to build on the contributions and advances to Health Element programs made by SPS and other predecessor programs and support health system strengthening through prioritized activities that are both “health element driven” and “shared” or cross-cutting. Through research, innovation and evaluation, SIAPS will contribute to the evidence base for a pharmaceutical system strengthening framework with country ownership as a necessary condition. Activities will be carried out in close collaboration, coordination and partnership with country governments, local civil society, international organizations, and other donors, in line with the new *USG Presidential Policy Directive on Global Development* and the *First Quadrennial Diplomacy and Development Review (QDDR)* (<http://www.state.gov/s/dmr/qddr/>).

### **GHI Plus**

The GHI has launched an intensified effort in a subset of up to 20 "GHI Plus" countries that will receive additional technical, management, and financial resources to accelerate the implementation of GHI, including integrated programmatic interventions and investments across infectious diseases, maternal and child health, family planning, and health systems-related activities. SIAPS support to GHI Plus countries is expected to contribute to lessons learned which are intended to inform future decision-making regarding the best use of programmatic inputs across all USG agencies and partners. SIAPS contributions to the GHI Plus country activities will also support the goals of programmatic accountability and sustainability through robust monitoring and evaluation.

### **Smart Integration and Best Practices at Scale in the Home, Community and Facilities (BEST)**

BEST is an action plan that will be the principal mechanism in USAID-supported programs for contributing to the GHI’s goals for family planning, maternal and child health, and nutrition (FP/MCH/N). It was launched with the recognition that despite our knowledge of high-impact

interventions, coverage remains unacceptably low. It assists countries to implement “smart integration” in key areas where it makes technical, financial and cultural sense. Consultations with relevant USG agencies and other donors are expected to yield more integrated approaches to assisting partner countries in executing their national health plans. SIAPS will contribute to the development of locally relevant and appropriate “smart integration” models and BEST programs requiring the availability of essential medicines and corresponding pharmaceutical services.

### **USAID Forward Initiative**

USAID Forward (<http://forward.usaid.gov/>) is an initiative based on the QDDR that reflects a reform agenda with the intent to modernize the way USAID works. Under USAID Forward, USAID is changing its business processes—contracting with and providing grants to more and varied local partners, and creating true partnerships to create the conditions for sustainable development. The guiding SIAPS framework supports this initiative through activities that build and strengthen the capacity of governments and local institutions and organizations to make the most cost-effective use of resources, including promoting mutually beneficial public-private partnerships. To support USAID Forward strategies, SIAPS will make optimal use of appropriate technologies, research and innovation, knowledge-sharing and evaluation opportunities to achieve expected results.

### **Relationship to Other Global Health Programs**

SIAPS complements other GH mechanisms working in the area of the Medical Products Building Block. While implementing activities in coordination with these other mechanisms, SIAPS will focus more broadly on comprehensive pharmaceutical system strengthening and will contribute to the further development of USAID’s larger health systems strengthening strategy.

- The **Strengthening Pharmaceutical Systems (SPS) Program** is a first generation system strengthening program. It is predominantly field-based and provides technical support that embraces supply chain management as well as other SPS technical areas with a focus on the expansion and scale-up of prevention and treatment programs. SPS has been at the forefront in developing new tools and approaches supporting all the Health Elements, including access to medicines and pharmaceutical services for post-partum hemorrhage, childhood diarrhea, acute respiratory infections, malaria, TB, and HIV/AIDS programs. SPS has provided guidance to all the major global health initiatives including the Global Fund, the Global Drug Facility (GDF), the Green Light Committee (GLC), Roll Back Malaria, and the Stop TB Partnership.
- The **Promoting the Quality of Medicines (PQM)** program helps assure the quality and safety of priority medicines by strengthening medicines quality assurance in developing countries. The PQM technical mandate narrowly focuses on strengthening national medicines quality assurance systems; supporting international pre-qualification mechanisms and selected manufacturers to increase the supply of quality-assured medicines of relevance to priority USAID health programs; detecting counterfeit and substandard medicines in the supply chain; and, providing technical leadership and global advocacy regarding the importance of medicines quality assurance.

- **Supply Chain Management Systems (SCMS)** is designed to provide one-stop shopping for HIV/AIDS-related commodities and supplies for HIV/AIDS programs that are funded by PEPFAR. SCMS also assists in improving capacity of national supply chains to ensure long-term sustainability of distribution systems in participating countries.
- The **USAID/DELIVER** Project works with partner country governments and non-governmental and private voluntary organizations to develop, strengthen, and operate safe, reliable, and sustainable supply systems to provide essential health supplies through public and private services.
- The goal of the **Strengthening Health Outcomes through the Private Sector (SHOPS)** program is to increase the role of the private sector in programs that address family planning (FP)/reproductive health (RH), HIV/AIDS, and other health information, products, and services. It aims to support the expansion of public sector health services by increasing private sector involvement to serve those who can pay for private health services and medicines.
- The **Central Contraceptive Procurement (CCP)** project provides a mechanism for consolidated USAID purchases of contraceptives, including condoms, and the independent testing of these products.

In addition to working with other programs that relate directly to the Medical Products Building Block, SIAPS will also work with GH programs that focus on other health systems building blocks, including:

- **Health Systems 20/20** aims to improve health financing, governance and operations and build sustainable developing country institutional capacity in these areas. HS 20/20 helps to increase access to PHN priority services by implementing evidence-based approaches to reduce financial barriers, increase financing for health, and ensure that health resources are rationally allocated to maximize health impact.
- The **Health Care Improvement project (HCI)** uses modern improvement methodologies adapted from the US health care system to identify and test changes in health care that may improve clinical quality, efficiency, and patient-centeredness. HCI provides a range of services related to other quality improvement strategies, most notably the establishment of improvement collaboratives.
- The **CapacityPlus** program aims to improve the quality of health services in the developing world by strengthening the health care workforce to help reach the MDGs. In countries where both CapacityPlus and SIAPS work, the programs will coordinate on issues of HRH policy and planning, including strengthening HR management and information systems, and improving HRH workforce development, including pre-service, in-service, and continuing professional education programs.

- The **Sustainable Leadership, Management and Governance program (SLMG)** supports health systems strengthening by addressing the gap for sustainable leadership, management, and governance capacity of health care providers, program managers, and policy makers to implement quality health services at all levels of the health system. SIAPS will complement the efforts of SLMG and will contribute to the development of best practices and lessons learned, in particular with respect to developing the capacity of in-country organizations and institutions to assume greater responsibility for strengthening pharmaceutical systems.
- The **MEASURE Evaluation Phase III** program works to strengthen routine health information systems, to build capacity in host country institutions, to develop new tools and methodologies, and to conduct evaluation research. In addition, it facilitates the coordination of monitoring and evaluation and routine health information system strengthening efforts.

### C. Program Goal, Objective and Result Areas

The SIAPS goal is to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. The SIAPS objective is to promote and utilize a systems strengthening approach consistent with the Global Health Initiative (GHI) that will result in improved and sustainable health impact. SIAPS will provide “next generation” technical leadership and assistance to developing countries in pharmaceutical system strengthening with a deliberate focus on patient-centered services and health outcomes for all Health Elements. Importantly, SIAPS will assist USAID and partner countries to reconcile the long-term goals of country ownership, system strengthening and sustainability with the immediate requirements for continuing scale-up and expansion of prevention and treatment programs without adversely affecting health outcomes.

As described earlier, the SIAPS result areas address the intersections of five health systems components (governance, human resources, information, financing, and service delivery) and the ways they interact with the Medical Products Building Block to expand access to quality pharmaceutical products and effective pharmaceutical services. As SIAPS develops its technical program, it will identify issues associated with each health system component and consider its necessary contribution to potential interventions supporting the different Health Elements.

For example, for the design and implementation of a pharmacovigilance system, SIAPS will systematically consider governance issues such as transparency and accountability in processes and structures, prevailing medicines laws and regulations, and professional practice standards; human resource issues such as the availability of supportive training programs and materials on how to identify and address preventable medicines-related problems; information systems requirements for linking product management with patient issues and timely data collection, analysis and interpretation at all levels of the health systems; operational costs and financial sustainability opportunities and constraints; and development of systems to monitor adherence to therapy, assess adverse events, identify medication errors, and detect product quality issues.

The specific SIAPS results areas are:

- a. *Strengthen pharmaceutical sector governance:* The governance capacity of all pharmaceutical sector actors -- including Ministries of Health, regulatory authorities,

managers, providers, civil society organizations, and professional and trade associations, among others -- impacts on the ability of the pharmaceutical system to achieve its objectives. Strong and effective governance frameworks can assure that appropriate medicines policies and standards are in place and implemented to safeguard public health, combat corruption, promote efficiency, and ensure equitable access to quality medicines and services through both the public and private sectors. Best practices for pharmaceutical management incorporate the principles of good governance such as transparent processes that allow for accountability and responsiveness to stakeholders, and participatory approaches to decision-making and priority-setting that promote inclusiveness.

- b. *Build individual, organizational, and institutional capacity for pharmaceutical supply management and services:* The supply of qualified personnel to meet the demand for public sector pharmaceutical supply management and services is insufficient under the current models of care due to attrition caused by disease burden, burnout, competition with the private sector, brain drain to other countries, and the time required for educating and training traditional health cadres. Expanded, enhanced, and complementary approaches are needed to address the short, medium and longer term human resource needs of health systems. In addition, the pharmaceutical management capacity of institutions, organizations and networks must be strengthened to support local empowerment, sustainability, and country ownership.
- c. *Address the information for decision-making challenge in the pharmaceutical sector:* Having reliable and timely financial, human resource, service delivery, pharmaceutical product and patient data readily available for decision-making is a hallmark of an effective pharmaceutical management system. Policy-makers, managers, pharmacy and health workers at all levels of the health care system require information to anticipate needs, use resources wisely, identify interventions to correct or improve performance, and to ensure achievement of desired health outcomes. Significant challenges need to be addressed including harmonizing existing national and international data and information requirements and assuring effective communications, knowledge management, and utilization of system information.
- d. *Strengthen financing strategies and mechanisms to improve access to medicines:* Addressing financing issues from a pharmaceutical system strengthening perspective must include not only patient level financial barriers to access to medicines, but also issues related to the efficient use of existing resources for procurement and other pharmaceutical management functions. Resource mobilization to support increased coverage, enhanced service delivery, and access to care and treatment for the most vulnerable populations must be addressed as well.
- e. *Improve pharmaceutical services to achieve desired health outcomes:* Effective pharmaceutical services require a patient-centered focus and systems in place to support product availability, report adverse events, and monitor therapeutic effectiveness. Systems are also needed for better case management and follow-up, integrated laboratory services, active surveillance of selected medicines and patient cohorts, and adherence approaches that improve treatment outcomes. In addition, strategies and implementation plans may be

needed for the effective introduction and use of new diagnostics, fixed-dose combinations therapies, vaccines, and other health technologies.

#### **D. Statement of Expected Results**

SIAPS is expected to generate measurable results that demonstrate improved cost-efficiencies and contributions to sustainable health systems strengthening that are clearly linked to health outcomes. The focus of SIAPS is on enhancing pharmaceutical services through patient-centered solutions while continuing to support essential supply chain functions and medical products supply security.

#### **Intermediate Result 1: Pharmaceutical sector governance strengthened**

WHO identifies governance as the most influential of the six components of a health system (WHO, 2007). Governance is defined as the process of decision-making and the process by which decisions are implemented (UNESCAP, n.d.). Improving governance in health systems has been shown to reduce corruption and is associated with more effective relations among stakeholders, including donors and host-country counterparts, suppliers and clients, and providers and patients (Hussman, 2011) and has been demonstrated to impact positively on health outcomes (Gupta, et al., 2000).

The various decisions and actions taken as regards the management of pharmaceuticals and provision of pharmaceutical services are exercises in governance. They include the determination of health priorities, the delineation of roles to be played by the public and private sectors and the allocation of resources to assure the availability of pharmaceutical products and services. With respect to the pharmaceutical sector, governance issues necessarily involve the ministries from different sectors including Ministries of Health (MOH), Education (MOE), Commerce (MOC), and Finance (MOF), among others. Stakeholders also include the research-based industry, generic manufacturers, wholesalers, distributors, professional and trade associations, drug sellers, educational institutions, media, health care providers and consumers, regulators and enforcers.

Governance issues impact on all aspects of pharmaceutical management systems. Unfortunately, many developing countries have weak pharmaceutical sector governance structures and regulatory frameworks and/or lack the requisite infrastructure (including information systems) and human or financial resources to adequately support them. Weak governance capacity in the pharmaceutical sector is associated with a lack of transparency and accountability, vulnerability to corruption, and an inability to account for the use of scarce resources. Strengthening governance in the pharmaceutical sector involves improving the capacity of governing bodies and stakeholders to carry out their respective roles and responsibilities in assuring access to medicines in accordance with “good” governance principles.

#### **Expected Results:**

- More effective governance structures to support pharmaceutical system strengthening
- Pharmaceutical policies and legislation promote equitable and sustainable access to safe and efficacious medicines of assured quality

- Decreased vulnerability of the pharmaceutical sector to corruption

### **IR 1.1 Good governance principles embodied across all health systems components**

Strengthening pharmaceutical management systems necessarily requires addressing governance issues across all of the health system components. For example, with respect to human resources, low salaries, inadequate staffing, and poor work conditions can contribute to poor performance and cause staff to engage in theft and other corrupt practices. Clear standards, job descriptions, and ongoing supervision all play a part in addressing poor performance and managing problems such as absenteeism. Similarly, incentives for good performance and defined disciplinary actions for misconduct and transgressions are also governance issues. Further, educational activities should promote adherence to codes and standards of pharmacy practice to help assure effective pharmaceutical services.

The exercise of good governance also requires timely access to reliable information by the appropriate stakeholders. For example, the lack of inventory information makes supply management difficult, including the identification and control of theft or fraud. Entities tasked with providing oversight may be undermined if the necessary data is not available or not reliable, or if they are unable to interpret it correctly. Information, once available, needs to be published and disseminated in ways that allow stakeholders and civil society groups to utilize it to monitor processes and assess overall performance and progress toward targets, thereby promoting transparency and accountability.

Weak governance is also often manifested in poor allocation of resources, misappropriation and/or mismanagement of funds. This may occur at all levels of the health system. Reporting and auditing (of medicines and assets) may not occur due to lack of or noncompliance with statutory requirements or weak enforcement capacity. Unreliable financing systems due to poor governance diminish the credibility of the health system, waste scarce resources, and fail to address priority public health needs.

Activities to support achievement of this Sub IR will be reflected in interventions to support all components of health system strengthening as they impact on access to quality pharmaceutical products and services.

#### **Expected results:**

- Paradigm for good governance in pharmaceutical systems strengthening developed
- Increased stakeholder acceptance of harmonized approaches for good governance in medicines

#### **Illustrative activities:**

- Work with the MOH, MOF, MOE, professional and trade associations, and other stakeholders to develop appropriate governance frameworks and mechanisms to support work force effectiveness, information system responsiveness and accountability, equitable financing schemes, and quality pharmaceutical products and services

- Provide global technical leadership on good governance in medicines

### **IR 1.2 Improved medicines policies, legislation, regulations, norms and standards**

Since the publication of WHO's guidance on how to develop and implement National Medicines Policies in 1998, the majority of countries have not only developed and implemented their policies but most have also updated them within the last ten years. However, countries often need assistance to conduct systematic reviews of their policies in light of new health priorities, consideration of factors influencing access to medicines (e.g., international trade laws and national tax and tariff structures), existence of more effective medicines and other health technologies, and improved case management and clinical practices. SIAPS will focus on enhancing the effectiveness of governance structures and stakeholders through support for enabling legislation and updated practice norms and standards. This will enable health systems to better incorporate new life-saving medicines and health technologies such as vaccines for malaria (USAID, 2009) and address existing and emerging public health challenges (Samb, et al., 2010).

Legislation supports implementation of national medicines policies and includes provision for the establishment of national regulatory agencies responsible for assuring that only products meeting acceptable standards of quality, safety, and efficacy are registered and available in a country. Although there is great interest in increasing participation of the private sector in increasing access to medicines, many countries lack the requisite pharmaceutical legislation to ensure effective licensing and oversight of retail outlets and service providers. Many countries also lack adequate regulation regarding manufacturing, clinical trials and post-marketing surveillance to monitor medicine quality and safety. Ministries of Health interested in outsourcing pharmaceutical operations or contracting for services from the private sector require appropriate supportive legislation.

To be effective, laws and regulations should also set out legal sanctions. Opportunities for abuse increase when policies are not coherent, roles and responsibilities are ill-defined, and when conflicting interests are not addressed. SIAPS is not expected to address judicial reforms but it is expected to help support Ministries of Health to enhance governance in the pharmaceutical sector and advocate for necessary changes.

#### **Expected results:**

- National medicines policies updated and reflect best management and clinical practices
- Private sector enabled to improve access to quality medicines and services

#### **Illustrative activities:**

- Assist in developing and updating national medicines policies, standard treatment guidelines and essential medicines lists
- Assist national drug regulatory authorities strengthen drug registration systems, including developing expedited review procedures

- Develop criteria for government contracting out for pharmaceutical management operations
- Work with professional and trade associations, Ministries of Health and regulatory authorities to develop accreditation programs for pharmaceutical services
- Assess the policy environment and support development of policies and SOPs to address health care waste management

### **IR1.3 Transparent and accountable pharmaceutical management systems**

Estimates globally indicate that corruption siphons off 10 to 25% of public procurement spending on medicines (WHO/GGM, 2008), thereby diminishing medicine availability often for the most vulnerable populations. Poor governance can therefore be costly for governments and, when it leads to the consumption of contaminated, counterfeit or substandard products, harmful for its citizens. According to the International Medical Products Anti-Counterfeiting Taskforce, “many countries in Africa and parts of Asia and Latin America have areas where more than 30% of the medicines on sale can be counterfeit” (WHO/IMPACT, 2008). This means that they are deliberately mislabeled with respect to identity and/or source.

Good governance is not solely the responsibility of central governments or other official bodies. At each level of the health care system, various organizational entities and managers make decisions and take actions in the process of managing pharmaceuticals and providing pharmaceutical services. Given the global health concern with this issue, WHO’s program for Good Governance for Medicines (GGM) has provided international support for good governance to 26 countries. Working closely with Ministry of Health representatives and civil society, GGM seeks to promote public discourse on the issues of corruption, enhanced transparency and accountability, and reforms in public sector operations (Baghdadi-Sabeti and Serhan, 2010). Together with the World Bank, WHO also supports the complementary work of the UK Department for International Development (DFID)-led Medicines Transparency Alliance (MeTA). With a country-specific focus, MeTA implements a multi-stakeholder approach to engage in policy dialogue on transparency and efficiency issues relating to the availability and affordability of medicines.

The focus of this Sub IR is on the operational aspects of pharmaceutical systems and services. Efforts will aim to improve management procedures to support implementation of laws and regulations to ensure transparency, allow for responsible oversight, and promote accountability. These may include working with structures responsible for licensing manufacturers, importers, distributors and retail outlets; pharmacy and therapeutics committees at national, local or institutional level that advise on the selection of medicines; procurement boards that develop contract specifications and manage the tender process including the evaluation of bids and the award of contracts; and committees responsible for overseeing audit functions, internal controls, and financial reporting processes (e.g., Lewis, 2009; Vian, Savedoff and Matthisen, 2010). System strengthening activities may also include developing a conflict-of-interest policy and whistle-blower protection regulation as they relate to pharmaceutical operations.

#### **Expected results:**

- Roles and responsibilities for implementing medicines policies, laws and regulations specified
- Governance structures promote stakeholder involvement and oversight

**Illustrative activities:**

- Assist in developing modern and transparent procurement policies and procedures, including prequalification of suppliers
- Help establish a supplier performance monitoring and evaluation mechanism
- Support development of national and community level health advocacy programs
- Work with local watchdog organizations and journalists to develop their capacity for monitoring government pharmaceutical management operations
- Promote an inclusive and participatory approach to strategic planning

**IR1.4 National pharmaceutical sector development plans are strategic and evidence-based**

This Sub IR focuses on governance as it relates to the process of planning for the development of the pharmaceutical sector. Building on the strategic vision expressed in national medicines policies, the planning process results in a roadmap to guide investments over time based on the achievement of defined milestones and targets. The roadmap or master plan must be developed in a participatory and inclusive manner, taking into consideration the multi-sector context in which pharmaceutical systems operate and the often conflicting interests of numerous stakeholders. In addition, given the interrelatedness of health system components, pharmaceutical system strengthening activities may not yield immediate or obvious results.

Therefore, to advocate for continued political commitment and investments, policy makers and planners will benefit from a shared understanding of the roadmap and shared expectations for achievement of milestones. This requires the development of a pharmaceutical system strengthening framework supported by validated metrics that is consistent with a larger health system strengthening model and measurement strategy (WHO, 2010).

**Expected results:**

- Pharmaceutical system strengthening investments are based on clearly defined goals, priorities and targets
- Framework and metrics developed for pharmaceutical systems strengthening

**Illustrative activities:**

- Assist in conducting pharmaceutical sector assessments to inform development plans and policies and identify technical assistance needs

- Assure consideration of proven approaches and best practices in strategic plan development
- Assist in assessing the financial and human resource implications of pharmaceutical systems strengthening and in developing a phased master plan
- Assist in developing monitoring and evaluation efforts to track progress on implementation of strategic plans

**Intermediate Result 2: Capacity for pharmaceutical supply management and services increased and enhanced**

Many developing countries are experiencing a critical lack of trained personnel to support the demand for health services. Attrition in the public sector caused by disease burden, burnout, competition with the private sector, brain drain to other countries, and the time required for educating and training traditional health cadres (i.e., pharmacists, nurses, physicians) all contribute to the lack of qualified personnel. Staffing requirements for pharmaceutical management are no exception. According to the International Pharmaceutical Federation’s 2009 *Global Pharmacy Workforce Report*, evidence from developing countries indicates that there is a shortage of human resources to perform critical pharmaceutical-related activities at each level of the health system.

In addition to staffing shortages, pharmaceutical system strengthening challenges related to human resource capacity include the limited ability of educational and training institutions to prepare staff adequately and the ineffective use of existing private sector resources. The focus of this Intermediate Result is on implementing short-, medium- and long-term sustainable solutions to this multifaceted human resource challenge. Interventions will target public and private sector service delivery providers and provider networks, managers, training and educational institutions, health and pharmaceutical management organizations, and Ministries of Health.

**Expected results:**

- Ministries of Health are able to effectively manage their pharmaceutical systems
- Countries have a sustainable supply of qualified managers and health workers for pharmaceutical management operations
- Improved implementation of prevention and treatment programs supported by US Presidential Initiatives, USAID Health Elements, and global health initiatives

**IR 2.1 Pharmaceutical management capacity of individuals, institutions, organizations and networks strengthened**

Basic pharmaceutical management skills are generally not taught as part of pre-service training of most health workers and managers so they acquire these skills through on-the-job or in-service training, if at all. Additionally, health workers may receive only *ad hoc* and non-standardized training on the proper use of management tools such as stock cards, patient registers and charts, standard treatment guidelines, and adverse event reports, including the use of these tools for analytical purposes (e.g., ABC/VEN analysis and drug utilization reviews) and for improving

management and clinical practices. Similarly, supervisory capacity to identify and correct poor pharmaceutical management practices and promote good ones is weak and lacks institutional support, including the requisite technical training (c.f., Trap et al., 2001; Waako, 2009).

An important emphasis of SIAPS is the promotion of patient-centered pharmaceutical services, recognizing that pre-service education in most countries is largely inadequate in this regard. Although there is growing recognition of the potential contribution of medication use counseling and monitoring on patient outcomes (Nkansah et al., 2010), most locally trained faculty in particular have not been formally exposed to these concepts. They lack the competence to provide training on topics such as patient safety and therapeutic outcomes monitoring, the generation, access to and use of patient and product information, counseling on medication use and adherence, and identifying adverse medication-related events.

Continuing education programs are also needed to ensure that public and private sector providers stay abreast of important developments in health and pharmaceutical services, including guidance on the appropriate disposal of pharmaceutical waste. The content for these programs should be based on objective and unbiased materials and delivered by qualified faculty in their respective clinical or practice areas. Important collaborators in these efforts are the various professional associations that, together with regulatory and licensing bodies, define and support implementation of practice standards.

In addition to developing the capacity of individuals in their respective professional domains, activities to support this Sub IR will address the human resource capacity constraints that impede the ability of Ministries of Health, pharmaceutical and health management organizations and provider networks to carry out their roles and responsibilities effectively in ensuring access to quality pharmaceutical products and services. Various approaches and techniques will be required, including direct side-by-side training or “shadowing.” Activities to support achievement of this Sub IR will target Ministries of Health, health providers and managers working at all levels of the health system in the public and private sectors responsible for carrying out or supervising pharmaceutical management operations.

**Expected results:**

- Health workforce better prepared in pharmaceutical management and services
- Institutional capacity to perform pharmaceutical management operations strengthened

**Illustrative activities:**

- Develop pre-service and in-service pharmaceutical management training materials for health workers at all levels of the health system and help facilitate training
- Support training of faculties of medicine, nursing and pharmacy in AMR containment, appropriate medicines use, and therapeutic outcomes monitoring
- Promote the professionalization of supply chain managers and service providers

## **IR 2.2 Local institutions and organizations provide pharmaceutical services and TA in pharmaceutical system strengthening**

Over the last several decades, USAID has made large investments in training as part of technical assistance programming for various aspects of pharmaceutical management, including supply chain, procurement and rational medicines use. Although there are some local NGOs and other institutions that have acquired experience and expertise in pharmaceutical management, they are few in number and often lack the internal management and administrative capacity to directly manage donor or local government contracts.

In keeping with the intent and spirit of GHI, SIAPS will strengthen the ability of promising local organizations to effectively perform pharmaceutical functions and services for their constituents and stakeholders, thereby increasing the effectiveness of ongoing technical assistance provided by the USG and other international donors.

For organizations, capacity building may relate to almost any aspect of their work: governance, mission and strategy, partnerships and collaboration, administration (including human resources and financial management), program development, implementation, and evaluation. This may also involve evaluating the need for new management structures, processes and procedures.

### **Expected results:**

- Local organizations and institutions contracted as implementers of pharmaceutical systems strengthening efforts and services
- Government outsourcing of pharmaceutical management functions increased where and when appropriate

### **Illustrative activities:**

- Develop the capacity of selected local institutions to provide pharmaceutical management technical assistance at the country or regional levels
- Develop performance-based contract management capabilities and tools
- Provide assistance to organizations to manage and implement grants and contracts for pharmaceutical functions and services from government and private sector entities

## **IR 2.3 Innovative and proven approaches for human resource capacity building adopted and implemented**

The traditional approaches of training and educational institutions to address human resource capacity needs in pharmaceutical management have clearly been insufficient. The combined pressures to increase coverage rates for treatment and prevention programs and the need to provide staff with the necessary knowledge and skills to use new medicines and other health technologies appropriately have resulted in unique challenges for service provision and supply chain management. At the facility level, for example, staff shortages are in evidence. Advances in state-of-the-art prevention and treatment practices often require that health workers take on

additional responsibilities without being relieved of existing ones. The introduction of integrated services and home-based care models, as well as the increased need for medication use counseling for ART patients, require rethinking how best to meet workforce requirements without compromising management responsibilities or quality of care.

Complementary approaches are required to ensure that short-, medium-, and long- term human resource needs are addressed. These may include developing new cadres of health workers or assigning pharmaceutical management functions to other staff working at the health facility level through task shifting. For example, immediate staff shortages have been addressed through the creation of pharmacy assistant and pharmacy technician programs. However, to facilitate continuing education opportunities and career advancement, and to encourage retention, such programs should be linked with professional schools of pharmacy. For example, successful task shifting approaches must be incorporated into long-term human resource planning and institutionalized in educational programming.

The last decade has seen a rapid expansion of various mobile technologies in areas previously marginalized by the lack of electricity and telecommunications infrastructure. Innovative solutions will derive from the application of new and existing technologies to distance learning and knowledge management. These opportunities can dramatically increase health worker access to new skills building and refresher training and can also facilitate more localized training and reduce disruption and expense by not removing staff from their posts.

Activities in support of this Sub IR will include working closely with Ministries of Health to identify urgent human resource needs, design competency-based solutions, and support implementation. This may include updating or revising position descriptions, standard operating procedures, and job aids for health workers as well as supervisors. It may also involve upgrading and expanding the pool of existing education and training programs and institutions to support compliance with new practice standards and requirements.

**Expected results:**

- Non-traditional health cadres support pharmaceutical management functions
- Coverage and quality of training programs enhanced

**Illustrative activities:**

- Adapt training materials and approaches for eLearning/eHealth
- Support development of accreditation programs for pharmaceutical management training
- Assist MOH and other stakeholders to design task-shifting strategies and tools, including job aids and Standard Operating Procedures
- Work with professional and trade associations, educational institutions, and medical and pharmacy faculty to develop and implement continuing education programs on pharmaceutical management

### **Intermediate Result 3: Information for decision-making challenge in the pharmaceutical sector addressed**

The lack of accurate, relevant, and timely data that government and public health officials must use to make informed decisions to support access to quality pharmaceutical products and services continues to be a rate limiting factor hampering the development of more effective and efficient health systems. Having reliable product and patient data readily available can make the difference between an inefficient system that experiences stock outs, costly emergency procurements, and poor service utilization and an efficient system that can anticipate its needs, identify corrective, system strengthening interventions, use its scarce resources wisely, and achieve desired health outcomes.

The challenges and opportunities associated with meeting evolving information needs often derive from advances in medicine, changes in health services organization and management models, and available technology. For example, in some countries, contractors, cooperating agencies, and donors have established multiple vertical supply chains to assure the availability of critical program-specific products and services. Each supply chain is generally accompanied by management tools that use different formats even though much of the data collected are the same. Another problem arises when data collected is similar but not compatible because of different parameters or definitions. Although harmonization or integration of these information systems would support increased efficiencies and country ownership, this effort is often hindered by the incompatibility of existing technologies used by the various players over time.

Information-related needs and solutions are fundamentally driven by national health and medicines policy goals and objectives. Several health reform initiatives, for example, have generated additional information system challenges by devolving decision-making responsibilities for financial and supply management to the lower levels of the health system. Technical assistance will be needed to assist countries to develop information management strategies that are appropriate and scalable, while helping to inform decisions about the best use of human and financial resources in support of effective and efficient supply chain operations and pharmaceutical care services.

#### **Expected results:**

- Improved access to accurate and timely pharmaceutical management information
- Countries are able to measure the performance of their pharmaceutical systems
- Countries use information to enhance delivery of pharmaceutical services

#### **IR 3.1 Pharmaceutical management information systems (PMIS) support both products and patients**

Pharmaceutical management information systems (PMISs) allow for the integration of product-focused logistics management and patient-specific information systems. PMIS supports the delivery of quality pharmaceutical products and services and facilitates the achievement of optimal health outcomes. An effective PMIS also complements broader health information systems (HIS) and supports the monitoring and evaluation of health system performance.

Establishing a PMIS requires that the Ministry of Health exercise good governance in designing and building the platform that enables system-wide information sharing. Governance is also required when creating, adopting and maintaining information systems and standards to support pharmaceutical management functions such as selection, procurement, inventory management, medicines use, and pharmacovigilance. The governance function will have to engage active participation and support from a variety of stakeholders, including donors, policy makers, and health services managers and providers at all levels.

The management of pharmaceuticals and pharmaceutical services involves numerous health and non-health agencies, many of which operate myriad systems for collecting, maintaining, analyzing and sharing data and information critical to carrying out their respective missions. Creating the capacity to share information and data among and between agencies (e.g., between the MOH and MOF, and among the various logistics departments within the MOH), levels of government (e.g., central, provincial and local MOH representatives) and services (e.g., tertiary, secondary and primary care facilities and the referral systems that link them), and a variety of disciplines (e.g., logisticians, physicians and pharmacists) requires overcoming established barriers to data exchange (Akbari et al., 2008). Therefore, representatives of the various agencies, disciplines and levels of government must be able to agree to a unified strategy for achieving interoperability without compromising their primary objectives for collecting information. Clearly, these are not exclusively technical issues that can be addressed by programmers and data processing managers.

Activities addressing this Sub IR will include support for planning and implementing integrated pharmaceutical management information systems that incorporate both products and patients through approaches that account for the multifaceted array of political, organizational, legal, technical, cultural, and personnel issues that must be addressed.

**Expected results:**

- Complementary PMIS enhances health management information system
- Supply chain system performance data support continuing availability of medicines
- Managers have access to and use data to assess potential medicines use problems

**Illustrative activities:**

- Work with MOH and partners to develop common platforms for collecting and sharing data on supply chain management, prescribing, dispensing, adherence and patient outcomes
- Develop links between laboratory supply information systems and pharmaceutical management information systems
- Develop information systems to support medicines use needs for community-case management and down-referral systems

**IR3.2 Innovative and proven tools broadly available and used**

When used appropriately, as one key component of a comprehensive strategy to strengthen pharmaceutical systems, information technology tools have the potential to reduce workload, support supply chain management functions, and increase the efficiency and quality of pharmaceutical services. However, if promoted as a panacea and a “quick fix,” without adequate consideration of all the relevant factors in the local reality, sustained improvements are rarely achieved.

Over the years, a plethora of data collection and information management tools have been developed to support all pharmaceutical management functions as they relate to different disease-specific programs. Tools have been developed to support pharmaceutical management for malaria, tuberculosis, and childhood illnesses, among others. Many of these tools were based on the same basic pharmaceutical management principles, generate similar if not identical performance indicators, and have been implemented successfully in a variety of practice settings in different countries. However, they do not necessarily support pharmaceutical management in facilities offering integrated services. These differences, although apparently subtle, limit their utility for broader application.

Activities in support of this Sub IR will include distilling basic elements from disease-specific approaches and tools and, working closely with governments, donors, cooperating agencies, and other stakeholders, harmonize them and thereby increase their utility and use. To complement these efforts to make optimal use of existing resources, tools will be adapted to new mobile and internet-based technologies to increase their reach, especially to remote areas. In addition, available tools should facilitate timely and reliable access to data and a variety of information from scientific and technical references to support clinical analysis and decision making (e.g., Pearson et al., 2009; McMahon, 2008). To facilitate the aggregation and dissemination of data across countries and to support the information needs of national and international stakeholders, open source platforms (e.g., [www.openlmis.org](http://www.openlmis.org) or [www.villagereach.org](http://www.villagereach.org)) should be considered in the development of all new computer-based applications.

#### **Expected results:**

- Improved communications between service providers and supply chain managers for improved program implementation
- Web-based tools support patient and medicines management

#### **Illustrative activities:**

- Genericize and/or harmonize existing disease-specific pharmaceutical management tools
- Support adaptation of traditional data collection to mHealth collection devices (mobile phones or other portable device) and the corresponding software platforms
- Develop decision-making tools (e.g., clinical algorithms) with visual image information and communication capabilities
- Integrate the use of GIS and GPS with mobile technologies to support pharmacovigilance and inventory management functions

### **IR 3.3 Strategic information on pharmaceutical systems strengthening available and used**

As with overall health system strengthening initiatives, there is no generally recognized framework or corresponding metrics that can describe the impact of pharmaceutical system strengthening activities. From a health systems strengthening perspective, a well-designed and implemented pharmaceutical management information system will complement the broader health information system and contribute information to support the monitoring and evaluation of health system performance. Similarly, in principle, performance measures obtained from the HIS, PMIS and other data sources can be used to evaluate progress on pharmaceutical system strengthening and guide decision-making regarding future system strengthening investments.

The primary aim of this Sub IR is to support the development of a robust conceptual framework to describe pharmaceutical system strengthening and the corresponding metrics that will permit for the measurement of improvements over time. This framework will be developed in close collaboration with other relevant partners, support initiatives to increase access to and use of pharmaceutical system performance data (e.g., Cameron, et al., 2009; Management Sciences for Health/WHO, n.d., GFATM, n.d.), and will take into consideration advances in health systems strengthening and analysis efforts (e.g., WHO, 2010a; Bitran, et al., 2010). The pharmaceutical systems strengthening framework will also be used to support development of SIAPS work plan activities and to track and assess the outcomes and impact of work plan implementation.

#### **Expected results:**

- Pharmaceutical system performance findings guide investments
- PMIS used for performance-based monitoring and evaluation

#### **Illustrative activities:**

- Develop a framework and metrics to measure pharmaceutical system strengthening
- Contribute to/advance the global dialogue on measuring pharmaceutical systems strengthening in particular, and health systems strengthening in general
- Monitor outcomes of system strengthening activities, derive lessons learned, document and disseminate findings

#### **Intermediate Result 4: Financing strategies and mechanisms strengthened to improve access to medicines**

Estimates are that as much as a third of the world's population lacks access to essential medicines and that the greatest barrier to access is the lack of adequate financing (WHO 2004). Medicines often represent the single largest portion of household out-of-pocket health care expenses, and medicines can account for as much 40% of national health budgets in developing countries. Countries with growing populations with chronic illnesses such as HIV/AIDS are particularly challenged in this regard. Activities under this IR will help countries expand access to essential medicines and pharmaceutical services through the cost-effective use of existing financial resources and resource mobilization.

Financing health services in general is challenging because multiple stakeholders are involved at the global, national and local levels and, while they depend on each other, they also often have competing interests (Dinovska, et al., 2009). This is particularly evident with respect to the dual role of medicines as a part of health service delivery and as a consumable commodity on the open market. The affordability of medicines and the choice of financing mechanisms for public health purposes are influenced by this dual role and various related trade and market factors, such as taxes, tariffs, and commercial margins. Such issues impact on the prices that governments and consumers pay for medicines. They also highlight the need for strong governance and management capacity to support equitable access, including affordability, to essential medicines.

How well the MOH can make use of an existing recurrent budget for medicines can make the difference between increasing coverage to more people and even increasing the scope of medicines provided, or risking stock outs of essential medicines. For example, while many Ministries of Health can evaluate the results of pharmaceutical procurement, they are often unable to determine and evaluate the operational costs of their pharmaceutical management systems. A cost analysis would help to identify opportunities to increase efficiencies and reduce costs by outsourcing pharmaceutical management operations to the private sector.

In recent years countries have benefitted from resources provided through global health initiatives, including grants and in-kind contributions of medicines. SIAPS will facilitate coordination and collaboration among donors and partner countries and also help ensure that funds are effectively mobilized to provide needed medicines and support pharmaceutical services.

#### **Expected Results:**

- Equitable access to essential medicines and services
- Expanded access to quality medicines and pharmaceutical services through the public and private sectors

#### **IR 4.1 Financial barriers reduced**

Prices can be a barrier to access where people must pay directly out-of-pocket for their medications. In some countries, this can account for as much as 80-90% of household health expenditures (WHO, 2010b). In recent years, thanks to efforts of Health Action International (HAI), WHO, and the Medicines Transparency Alliance (MeTA), there has been increased advocacy for countries to review their medicines pricing policies and to widely share price information from both the public and private sectors (e.g., Cameron, et al., 2009). Governments need to understand and monitor the components of medicines prices and policy options should be assessed against access criteria to assure that equity concerns are addressed and priority health needs are met.

Because most countries cannot afford free access to medicines, they employ different mechanisms to share the financial burden with patients. A variety of cost-sharing, cost-recovery, and risk pooling approaches have been developed and used in the public sector, such as user fees and revolving drug funds, but success has been mixed. In addition, financing mechanisms with a

product focus frequently do not consider other costs to the patient for access to medicines such as transportation to health facilities and pharmacies and the time spent traveling and waiting for service. Lessons learned highlight the impact of poor governance capacity, lack of sufficient protection for the very poor, and vulnerabilities arising from stagnant or declining local and global economies.

Countries with a substantial formal labor market are moving towards developing health insurance systems and are including pharmaceutical benefits programs that contract with private sector vendors to provide products and care in support of public health goals. Locally appropriate financing schemes such as community-based insurance funds have been experiencing some success, especially when they employ incentives related to cost control and quality of care practices, including rational prescribing, dispensing, and use mandates. A similar scheme was developed and is being rolled out in Tanzania with the provision of pharmaceutical services by Accredited Drug Dispensing Outlets (ADDOs), demonstrating that the concept is also relevant to health systems in countries with a large informal labor market. Such examples, however, are few and serve to highlight the need for more evidence of the impact of similar programs and initiatives on access to and use of medicines (Faden, et al., 2011).

The focus of this Sub IR is on the patient or customer and reducing financial burden with respect to the price of quality essential medicines and costs of pharmaceutical services.

**Expected result:**

- Affordability of medicines and pharmaceutical services improved

**Illustrative activities:**

- Support national and community-based insurance funds to develop pharmacy benefits programs
- Assess factors contributing to the pricing of medicines in the private sector and make recommendations to promote affordability
- Identify viable cost-sharing and cost-recovery mechanisms

**IR 4.2 More efficient use of existing resources**

Public health systems in developing countries are often characterized as inefficient and in need of modernization and better incentives to stimulate cost-saving behaviors. Given constrained health and pharmaceutical budgets, making the most of existing financial resources is critically important and opportunities for improved resource allocation and use must be identified and maximized.

Technical efficiency can be improved throughout the pharmaceutical supply system. According to WHO (2010), three important known sources of health system inefficiency are directly related to poor pharmaceutical management practices. In procurement, where the most resources are expended, competitive international tendering can result in significant savings for most essential medicines. For example, in South Africa, after extensive policy dialogue based on an assessment

of procurement practices, the use of international price benchmarking led to a 53% reduction in tender prices for antiretroviral medicines (ARVs) in 2011.

Likewise, accurate needs forecasting and quantification also have efficiency implications in terms of potential waste and expiry due to overstocks or costs associated with expensive emergency orders in the event of stock outs. Analyses of fixed and variable costs associated with the warehousing and transportation of supplies may also reveal savings by outsourcing these functions to commercial enterprises, preferably with performance-based approaches. “Savings” gained from such technical efficiencies could be reallocated to expand service coverage, or to increase the scope of pharmaceutical services.

Decisions regarding allocative efficiency refer to the tradeoffs of placing more resources in one area or program at the expense of another. Within the MOH, examples of such decisions include how much to spend on primary, secondary, and tertiary care, or whether to spend additional program funds on TB control or treatment versus malaria treatment. SIAPS will assist in these analyses.

Activities to support this Sub IR will seek to improve both technical and allocative efficiencies in the public sector supply systems of developing countries.

**Expected results:**

- Improved allocation of resources for procurement and pharmaceutical management-related operations
- Efficiencies achieved through strategic investments in pharmaceutical system improvements

**Illustrative activities:**

- Conduct financial analyses to project future budgetary requirements for medicines needs resulting from on-going and expanding treatment programs
- Assess the impact of the introduction of new health technologies
- Design and help implement payment for performance schemes for pharmaceutical services
- Conduct options analysis to enhance system performance and efficiencies, including contracting out pharmaceutical management operations
- Identify opportunities to leverage disease-specific funding sources to support pharmaceutical system strengthening

**IR 4.3 Additional financial resources are generated**

Government budgets are usually under great political and financial pressure to demonstrate that resources are used efficiently. Rather than address the issue directly, this reality provides a powerful incentive to seek additional resources, whether financial (e.g., budget increases, grants and loans) or in-kind (e.g., medicines or other commodities). SIAPS will work with

governments to document the most egregious sources of inefficiency while also identifying opportunities to increase resources available for pharmaceutical system strengthening activities and increased provision of pharmaceutical services.

Grants-based multilateral initiatives, including the GFATM, GAVI, AMFm, and UNITAID, among others, now dominate the donor financing scene. Other important donors include private foundations such as the Clinton Foundation, and the Bill and Melinda Gates Foundation. SIAPS assistance will include support to partner countries to prepare grant applications, in addition to advocating for investments in product quality assurance, supply chain management, pharmacovigilance, and pharmaceutical services.

Since the advent of global health initiatives, there have been significant improvements at the country level to coordinate and collaborate among donors and between donors and partner country governments. SIAPS will work closely with the MOH in these countries to map pharmaceutical system strengthening needs and help identify and access available resources, including opportunities to forge effective public-private partnerships.

#### **Expected results:**

- Countries expand treatment programs to reach previously underserved groups
- Realistic costing framework for pharmaceutical services developed

#### **Illustrative activities:**

- Provide technical support to prepare GFATM Procurement and Supply Management plans and access grants through GFATM and other international health initiatives
- Identify opportunities for public-private partnerships
- Map donor investments and identify pharmaceutical system needs to facilitate coordination and the most effective use of investments

#### **Intermediate Result 5: Pharmaceutical services improved to achieve desired health outcomes**

Activities carried out in support of this IR will address both supply chain issues to ensure the availability of quality essential medicines and the supporting services required to ensure that medicines are used appropriately, that patient safety is assured, and that desired health outcomes are achieved. Together, these are the objectives of a comprehensive and integrated pharmaceutical system. Best practices and validated tools and approaches exist to address many of the issues involved. However, continued research is needed to identify the most cost-effective combination of well-tested methods to measure and improve the quality of pharmaceutical services, adherence to treatment protocols, and patient safety in the private sector and in various practice settings such as community-based care (c.f., Beney, Bero and Bond, 2000; Machado, 2007; Gianino, et al., 2008). Activities carried out under this IR will also support containment of the emergence and spread of antimicrobial resistance.

**Expected results:**

- Essential medicines are available for health programs
- Health systems support patient-centered care
- Antimicrobial resistance (AMR) is recognized as a serious public health threat

**IR 5.1 Availability of pharmaceuticals improved**

Operational weaknesses in supply chain systems persist in many countries. Many of these become manifest when new prevention, care and treatment programs are introduced or when established programs seek to expand or go to scale (e.g., Barker et al., 2010). In countries with very fragile supply chains, the immediate requirements of health element programs to ensure the availability of critical medicines and supplies will necessarily take priority over activities with longer term system-strengthening objectives. The focus is to ensure that best practices and management standards are successfully introduced and implemented throughout the supply chain, from selection, procurement, warehousing and transportation activities to “the last mile” level. Achieving international credibility through ISO 9000 certification, for example, demonstrates implementation of best management practices associated with product availability (Lo, Yeung and Cheng, 2009).

As mentioned earlier, planning for supply chain improvements should seek to take advantage of existing human, infrastructure and financial resources and make optimal use of information technologies in both the public and private sectors as appropriate. Planning should consider the long view and the potential for and vulnerabilities associated with future growth and expansion, including the challenges associated with the introduction of new technologies and products (e.g., diagnostics, new vaccines, and fixed dose and pediatric formulations). Activities under this Sub IR will also include providing technical assistance for the successful design and implementation of integrated health programs when and where appropriate (e.g., Legido-Quigley, et al., 2010). This may include supporting “smart” integration. A key criterion for supply chain improvements will include the extent to which they are sustainable and promote country ownership.

Lastly, given the limitations of public sector systems, approaches utilizing the private sector to improve access to quality medicines and services must be explored and exploited as the private sector remains a source of largely untapped potential.

**Expected results:**

- Organizational structures improved for more effective supply chains
- Strategies and approaches for integration of new health technologies and products adopted
- Expanded use of the private sector

**Illustrative activities:**

- Assess public sector supply chain capacity and operations and identify necessary system improvements
- Support opportunities to achieve ISO certification for supply system components
- Work with national counterparts to design and implement innovative approaches for enhanced use of the private sector for service delivery
- Assist national authorities to integrate new medicines and diagnostic tools

**IR 5.2 Patient safety and therapeutic effectiveness assured**

Medicines are often approved for marketing without a full understanding of their safety profile. In countries with mature pharmacovigilance systems that include manufacturer responsibility for post-marketing surveillance, potential problems associated with medicines use can be identified and addressed relatively quickly. A particular challenge now faces donors and countries with respect to the large volume of medicines being made available through various global health initiatives. New medicines for HIV/AIDS and malaria are rapidly entering less-protected markets and are being used by large population groups for which the safety profile is incomplete. Indeed, most of the medicines concerned are used where systems are not fully developed for the detection, assessment and prevention of adverse drug events. Much remains to be learned about the safety and therapeutic implications of expanded medicines use in these countries.

The WHO, USFDA, and selected other partners have acknowledged this as a serious concern and responsibility, but much remains to be done in terms of advocacy and financial support. To this end, the GFATM recently included provisions for pharmacovigilance activities in new grant applications. Countries will need support to help think through how best to approach the design and implementation of patient safety and pharmacovigilance programs. Internationally recognized guidance and consensus based on proven frameworks do not exist, so experience gained under SIAPS will contribute to that body of knowledge (e.g., Morris et al., 2004 and 2006). Activities under this Sub IR should consider and continue collaborations with the ongoing efforts of important international stakeholders such as the WHO Programme for International Drug Monitoring, the Uppsala Monitoring Centre in Sweden, and the International Society for Pharmacovigilance (ISoP).

To complement this system building agenda, regional and local USG-supported initiatives in Africa, Asia, and Latin America should also include promotion, introduction, and expansion of infection control programs, Drugs and Therapeutics Committees (DTCs), and other proven institutional interventions that help assure patient safety and good health outcomes.

**Expected results:**

- Pharmacovigilance systems established and operational
- Infection control programs implemented

**Illustrative activities:**

- Implement adverse drug events and causal assessment reporting systems
- Coordinate and collaborate with WHO, ISoP, GFATM and other global initiatives to advance the pharmacovigilance and patient safety agenda
- Document lessons learned and best practices in implementing comprehensive pharmacovigilance programs in developing countries
- Help establish and capacitate national-level and hospital-based DTCs and infection control units

**IR 5.3 Medication use improved**

Strategies to improve medicines use can be characterized as educational, managerial and regulatory. Educational strategies assume that better information and understanding of issues will influence appropriate behavior. They include training of prescribers through formal and continuing education programs, supervisory visits, seminars and workshops regarding DTCs and rational medicines use, as well as other activities implemented to support IR 2. Managerial strategies, on the other hand, are intended to guide and encourage appropriate behaviors through the use of formularies, essential medicines lists to guide procurement, structured drug order forms, standard treatment guidelines, as well as insurance schemes and pharmacy benefits programs that restrict prescribing options. Financial incentives that influence behavior change, such as reimbursements for medicines only for approved indications, price setting, and capitation, are addressed under Sub IR 4.1. Regulatory strategies (see IR 1) focus on creating legal barriers such as controlling the sale of medicines and restricting prescribing rights.

SIAPS will also address the particular medicines challenges presented by new care management models that have emerged in recent years. For example, community case management for childhood illnesses requires health workers to assume greater responsibility for the management and use of additional and more potent medicines (CORE Group, 2010). Similarly, chronically ill patients, such as those with HIV/AIDS, and tuberculosis, are increasingly expected to assume greater responsibility for the management of their therapies through home-based care programs, and providers must forge stronger partnerships with patients to assure uninterrupted therapies in systems implementing down-referral approaches. In many cases, organizations managing pharmacy benefits are not fully prepared to analyze and use the prescribing information available to them to identify and address medicines use problems (Faden, et al., 2011). To address these issues, health care management organizations and institutions, practitioners, patients and communities require supportive enabling environments and information for more appropriate, safe and judicious use of medicines.

**Expected results:**

- Health workers empowered to provide patient-centered pharmaceutical services
- Health care organizations implement medicines use review programs

- Patients empowered to better manage their therapies

**Illustrative activities:**

- Support the implementation/scaling-up of community case management for malaria and childhood illnesses
- Ensure effective prevention and patient care and treatment through down-referral systems for antiretroviral therapy (ART) and referral networks for maternal health, and TB/HIV programs
- Strengthen the capacity of health care organizations and institutions to monitor prescribing practices and implement corrective interventions
- Expand use of IEC/BCC messages and strategies in the public and private sectors for providers and patients on responsible self-medication and adherence to recommended treatment regimens

**IR 5.4 Pharmaceutical services standards defined, adopted and implemented**

The focus of this Sub-IR is on the need to formalize quality standards for patient-centered pharmaceutical services, or pharmaceutical care, as an important tool to facilitate consistent application of treatment modalities associated with positive health impact. It complements activities that address product quality assurance and supply chain management improvements.

Although most health systems in developing countries acknowledge the importance of a patient focus in medication management, most Ministries of Health and professional associations have not adopted an operationalized definition of pharmaceutical care as a recognized standard for pharmacy practice. The value of having a shared and formalized understanding among government, providers and patients is in large part related to governance and concerns with equity and social justice. As a practical matter, standards can be harnessed in accreditation programs and used as incentives in financing and reimbursement schemes (see IR 4.2) to support improved access to quality pharmaceutical care.

The process for developing standards must adhere to the same general principles of good governance discussed under IR1. Inclusiveness, transparency, and effective participation in the process are of particular relevance. Standards should be based on up-to-date clinical and management evidence, allow for accountability, and be applicable to both public and private sector providers. To have “teeth,” accreditation programs can be established and managed by an independent body. An important requirement for effective accreditation programs is access to reliable data on compliance as well as supportive programs to help facilities achieve standards.

Activities under this Sub-IR will encompass the development of practice standards for patient-centered-care at various levels as well as adoption by relevant authorities. Where appropriate, SIAPS will also include provide support to establish or strengthen accreditation bodies.

**Expected results:**

- Minimum standards for patient-centered pharmaceutical services established for public and private sectors

**Illustrative activities:**

- Work with governments and national professional associations to develop harmonized standards for pharmaceutical services
- Design medicines use components of accreditation programs for primary care facilities and pharmacies in the public and the private sectors

**IR 5.5 Emergence of antimicrobial resistance (AMR) slowed**

There is a growing concern with the emergence of AMR, especially multi-drug resistance, due to inappropriate treatment, supply interruptions, and/or lack of adherence to the full course of treatment. Overcoming the impending public health crisis that may result if AMR is left unchecked will require comprehensive, multipronged strategies to reduce the emergence of antimicrobial-resistant organisms, as described in WHO's "policy package" to combat AMR (Leung et al., 2011), with the hope that new medicines will enter the drug development pipeline.

Although addressing AMR issues is considered in many aspects of pharmaceutical system strengthening, including support for institutional and non-disease specific interventions, activities under this Sub-IR will focus on developing subsystems for improved case management and follow-up, laboratory services, adherence approaches that improve treatment outcomes, and the effective introduction and use of existing and new fixed-dose combinations therapies and vaccines. Strengthening current surveillance, data collection, prevention and control, and research capabilities to better understand, track, and contain the emergence and spread of AMR are also essential. Lessons learned and evidence gleaned from these experiences will help inform global initiatives, research agendas and advocacy activities.

At the country level, "ownership" of AMR issues and corresponding responses will require the active participation of local advocacy groups and coalitions representing all stakeholders, including providers, local research and educational institutions, industry, civil society and government authorities. Similarly, coordination with and support for global and regional AMR networks and initiatives are expected (e.g., ReAct, the International Network for Rational Use of Drugs, the Center for Global Development, the Regional Pharmaceutical Forum in East Africa, and the Ecumenical Pharmaceutical Network, among others).

**Expected results:**

- Global, regional, and country level AMR coalitions established
- Cross-cutting AMR interventions supported
- Framework to identify the health system costs of AMR developed

## Illustrative activities:

- Work with country stakeholders and institutions to develop evidence-based strategic plans for AMR containment
- Promote global and regional advocacy on AMR issues
- Document the impact and cost-effectiveness of AMR interventions

## E. Core Operating Principles

The following core operating principles are in alignment with the Global Health Initiative and govern the over-arching framework within which SIAPS will work. They also provide the operational parameters that will be critical for the program's success while providing the frame of reference against which success will be evaluated. The program should incorporate the complementary principles as decisions are made regarding the modalities of implementation for proposed activities.

- **Build on and strengthen existing systems**, when and where appropriate, to improve buy-in and acceptance from local governments and counterparts, the potential for sustainability, the scalability of health programs, and cost effectiveness from both a financial and human resource capacity perspective. This will include the integration of the private sector into the development of locally relevant strategies for increasing access to medicines and pharmaceutical services. There may be circumstances that require by-passing existing systems to accomplish immediate health services goals but these will not likely be considered long-term solutions to pharmaceutical systems strengthening.
- **Support integration**, where programmatically sound, across disease-specific areas and across supply chain actors and functions, and between commodity donation and technical assistance programs, to minimize redundancy and waste and optimize use of existing resources. In this regard, specific pharmaceutical system issues to be addressed may require adjusting the prevailing national medicines policy and regulations to allow for use of medicines by health workers at different levels, including the private sector, assessing supply chain capacity to support integration, making corresponding improvements, and supporting the development of human, information and financial resource management systems.
- **Build/strengthen the capacity of local organizations** to address both immediate and long-term sustainability of pharmaceutical systems. SIAPS will identify promising organizations to strengthen their governance, technical competence, financial systems, and monitoring and evaluation capabilities in pharmaceutical management such that they can become providers of technical assistance and training as well as implementers of USG-supported programs. If found to be cost effective, they could also be contracted to perform pharmaceutical management operations currently being undertaken by governments and could also expand access to quality pharmaceutical products and services.
- **Support country-led coordination** and the underlying goal of country-ownership by working with partner country governments and other relevant governing bodies, including

civil society organizations, to build their capacity to dialogue effectively with each other and donors, cooperating agencies and other stakeholders on national health priorities, proposed solutions and strategies, and resource requirements. This includes donor mapping, a shared understanding of pharmaceutical system strengthening needs, supporting collaborative work planning, and contributing to country-led coordination efforts.

- **Continually monitor and evaluate** to assess achievement of the SIAPS program’s goal, objective and results. This includes measurement of the effectiveness and cost-effectiveness of interventions and strategic approaches. To be consistent with and supportive of other core operating principles, the corresponding and requisite information systems should build on existing systems where appropriate, develop local capacity, and contribute to a common monitoring and evaluation framework.
- **Develop improved performance metrics** to assess pharmaceutical system performance, sustainability, the impact of investments, alternative options to carry out pharmaceutical functions and operations, and the achievement of desired health outcomes.
- **Harmonize tools, approaches and metrics** to avoid duplication of effort, reduce redundancy and the burden on partner countries, support coordination, facilitate management and implementation activities, assure information compatibility, and promote efficiency in the use of resources to strengthen pharmaceutical systems.
- **Share knowledge and information** among projects, agencies and other partners to create the evidence base required to validate conceptual frameworks and operational models for measuring and benchmarking pharmaceutical system performance and strengthening. Effective knowledge management will be a key activity throughout the life of the program, requiring a comprehensive strategy for sharing reports and work plans, studies, lessons learned, best practices, and success stories on an on-going basis with USG agencies, implementing organizations, partner country governments, other donors, multinational organizations, and international stakeholders.

## **F. Program Tasks**

To achieve the results that USAID expects and to manage this program effectively, three tasks are essential – global technical leadership, research and innovation, and field support. The applicant may identify other tasks. The successful applicant will have to demonstrate an understanding of the way USAID provides funding for this work and establish a plan for working within this funding system, particularly as regards field support. USAID mission staff and the AOTR will be involved with the development of work plans in response to field support funding.

### **Technical leadership:**

Establishing and maintaining global technical leadership in pharmaceutical management will be an overarching principle for SIAPS. A primary objective will be to assist USAID in its role of influencing global health initiatives to adopt best practices and proven tools, approaches, and

interventions to improve the availability and use of quality pharmaceutical products and services, thereby also improving aid effectiveness. Expected technical leadership results include:

- A continuing and enhanced USAID leadership role in strengthening health system performance by providing technical guidance and direction related to the Medical Products Building Block, in defining and promoting evidence-based approaches in pharmaceutical system strengthening. This will include supporting policy dialogue and harmonization on priority technical issues and facilitating coordination among donors, multilateral organizations, and implementing partners.
- Effective operational relationships maintained with other USG and USAID cooperating agencies and contractors, international and developing country partner organizations such as WHO, the Global Fund, Global Drug Facility (GDF), Green Light Committee (GLC), other bilateral donors, private voluntary and non-governmental organizations, foundations, universities, and other U.S. and host country government agencies, among others.
- Best practices and lessons learned in program implementation identified, documented, disseminated, and promoted for all SIAPS technical areas, as well as related benchmarking approaches to systematically measure and assess pharmaceutical system performance.

### **Research and Innovation:**

SIAPS will focus on operations research that builds the evidence base for new or adapted interventions and approaches to improve the functioning of pharmaceutical systems, developing and applying cost-effective tools and approaches to improve access to and use of quality medicines and pharmaceutical services. Key results include:

- Enhanced efficiency of health systems through engagement of the private sector for the provision of medicines and essential pharmaceutical services. The private sector is underutilized in many developing countries. Understanding the current roles and performance of the private sector, formal and informal, and how to harness its potential, can lead to the design of more efficient, effective, and sustainable solutions to increasing access to pharmaceutical products and services.
- Sustainability of affordable and quality services promoted through appropriate financing strategies and mechanisms. In particular, there is a dearth of information on the performance of alternative financing mechanisms with respect to assuring access to medicines and quality pharmaceutical services, especially to the poor.
- Continued research to identify the best and most cost-effective combination of well-tested methods to measure and improve the quality of pharmaceutical services, adherence to treatment protocols, and patient safety in various practice settings including community-based care.
- Operational challenges identified and approaches developed for a country-led and country-owned approach to transitioning projects to scale. Often, well-financed projects implemented as pilots in small regions for a defined population appear (and may be)

successful. However, since their potential for scalability was not a primary consideration in the initial design, there is a need to understand what is required to transition innovative pharmaceutical management interventions to scale and make them sustainable, including at the community level. This will necessarily include understanding financial requirements and making commitments accordingly.

- Methods and approaches developed to improve and harmonize metrics for measuring, monitoring and benchmarking pharmaceutical system performance and the impact of investments in support of the Global Health Initiative. This will involve direct engagement with various international and national stakeholders as well as participation in various fora such as the Access to Medicines Research Network under the Alliance for Health Policy and Systems Research (<http://www.who.int/alliance-hpsr/projects/medicines/en/index.html>).

### **Support to the field:**

SIAPS will help move forward USAID health systems strengthening strategies and plans and address critical country-specific or regional pharmaceutical management problems by applying proven approaches and best practices. Implementation modalities will seek to promote country ownership, accountability, and sustainability in systems changes. Examples of country-level results include:

- Effective governance in the pharmaceutical sector established such that appropriate medicine policies and standards are in place and implementation strategies and plans are clearly defined to protect the public health, minimize opportunities for corruption, and to promote equitable access to quality medicines and services through the public and private sectors.
- Improved efficiencies in supply chain functions, expanded use of generics, reduced prices for medicines, and more appropriate use of medicines.
- Comprehensive systems-oriented strategies and approaches established in SIAPS countries for pharmacovigilance that encompass the full spectrum of medicine safety – product quality, adverse drug reactions, and medication errors – using a range of surveillance methods.
- Human resource constraints reduced by modernizing curricula to include pharmaceutical management pre-service education, applying task-shifting strategies for new health cadres, and conducting in-service training for existing health workers, as well as strengthening the capacity of health systems to plan for workforce requirements.
- Information technology tools (paper-based, computers, and software programs) implemented and workload reduced, supply chain management functions improved, and the efficiency and quality of pharmaceutical services increased.

### **G. Gender Considerations**

The ability to identify and address gender constraints is an important element in the design of appropriate and sustainable programs that support equitable access to health services. Gender norms and the imbalance in power dynamics between men and women are often reflected within

health systems and institutions. Often, men have greater opportunities for continuing education and training, and are consequently in the highest positions of leadership and management. Practices related to recruitment, training, retention, and promotion for health providers and managers often reveal gender-related constraints as well as opportunities. The recipient will consider these issues in activities as a governance concern in general, and in human resource and institutional and organizational capacity building activities.

## **H. Monitoring and Evaluation**

The SIAPS Program Performance Monitoring Plan (PMP) will include a clearly defined Results Framework with indicators, baselines and targets for output, outcome, and impact level monitoring. The PMP will be aligned with the Global Health Initiative principles and the Agency's High Priority Performance Goal for Global Health. It will include benchmarks for program performance over the course of the five-year implementation period and contain metrics to assess country ownership and the sustainability of successful interventions introduced with program support.

The PMP will allow for monitoring activity progress toward targets and benchmarks in annual work plans that have been developed with the responsible Bureau or Mission and reviewed and approved by the AOTR. The plans will specify the expected pharmaceutical systems improvements that will be realized through the program's investments, as well as the means by which outputs, outcomes, and impacts will be measured.

For field support programs under this award, the recipient will reach agreement with the Mission's Activity Manager on a country-specific PMP, including expected outcome indicators (e.g., adoption of a national pharmaceutical sector strategic plan, establishment of accredited training programs, improved prescribing practices) and performance targets, and will report progress accordingly. PMPs developed for field support programs will reflect SIAPS program Intermediate Results and Sub IRs and will contribute to the overall SIAPS PMP, including supporting the development of a robust conceptual framework describing pharmaceutical system strengthening.

The SIAPS Program will be subject to evaluation to demonstrate the impact of interventions on pharmaceutical availability, services and health outcomes. The recipient will be responsible for the collection of baseline data. Baseline data will be obtained that correspond to the program's goal, objective and results areas as specified in the Performance Monitoring Plan (see USAID Evaluation Policy, p.8). When appropriate, baseline data (resulting from studies or other sources) should be sex-disaggregated as appropriate and used to establish reference points. The AOTR will ensure that the recipient collects the relevant baseline data, and that this documentation can be accessed for a future impact evaluation of the program. Key evaluation questions will also be identified to help determine the program's contributions to pharmaceutical system improvements. These evaluation questions, to be confirmed in consultation with the AOTR, should be included in the PMP.

The Recipient will be responsible for conducting a mid-term program review during the third year of implementation to address both descriptive and normative questions, to include: 1) the extent to which the SIAPS program goal, objective and Intermediate Results were met, the

reasons for the variance per available baseline data, and how the review's findings can further inform SIAPS implementation; 2) program achievements and whether expected results occurred; 3) how the program was implemented in terms of core operating principles; and 4) other questions that are pertinent to program design, management and operational decision-making.

Given that this program will contribute to all Health Elements and thus receive earmarked funding, the program must have the capacity to report results and monitor indicators specific to each HIDN pathway and to each mission performance monitoring plan. The recipient will be called upon to provide these data yearly in the annual report and for USAID portfolio reviews.

## **I. Knowledge Management**

An important requirement for the recipient of this award is to demonstrate the ability to capture and synthesize the experience gained through program implementation. The recipient will be required to develop a Knowledge Management Plan that describes how it will systematically capture, synthesize and share information about program activities, lessons learned and best practices among all stakeholders. The plan will describe how data and information about program activities will be used to inform decision-making, advocacy, and policies at the country level. In addition, summary results, program accomplishments and experiences will be presented in analyses and products that inform and advance the state-of-the-art. The recipient will collaborate with international organizations and partners in the documentation and transfer of key products and findings to assure that new information, knowledge and experiences are available to all relevant audiences in a timely and user-friendly format. The Knowledge Management Plan will be negotiated and approved by the AOTR as part of the annual work plan.

## **J. Reporting Requirements**

### **i. Technical Reports**

The recipient shall submit the following plans and reports to USAID: annual work plans, quarterly performance monitoring reports, summary annual reports of accomplishments and major issues requiring attention, and a final report. Reports shall be timed and formatted so that they can provide USAID Bureaus and Missions with useful information required for their reporting requirements.

Quarterly and annual performance monitoring reports shall present in narrative and quantitative form the progress made in achieving planned results as well as the resources expended in accomplishing progress to date. The planned timeline and achievements for every activity shall be presented for USAID country, regional and global programs, including recommended follow-up actions regarding future program directions to support further improvements; important issues, problems and recommendations; and documentation of the use of funds and effort in the execution of activities through this cooperative agreement. The exact format of the quarterly and annual reports will be determined in collaboration with the AOTR. Two copies of the reports will be required.

USAID requires, 90 days after the completion date of the Cooperative Agreement, that the Recipient submit a final report that includes an executive summary of the Recipient's accomplishments in achieving results as well as conclusions about areas in need of future

assistance; an overall description of the recipient's activities and attainment of results by country or region, as appropriate, during the life of the Cooperative Agreement; an assessment of the progress made toward accomplishing the program goal, objective and expected results; important research findings, comments and recommendations, and a fiscal report that describes how the recipient's funds were used.

**ii. Distribution of Reports**

The recipient shall submit an original and one copy of the final report to the Technical Advisor and the AOTR and one copy to the USAID Development Experience Clearinghouse: E-mail (the preferred means of submission ) is : docsubmit@dec.cdie.org. The mailing address via US Postal Service is:

Development Experience Clearing House  
8403 Colesville Road  
Suite 210  
Silver Spring, MD 20910

**iii. Financial Reporting**

Financial reporting requirements will be in accordance with 22 CFR 226

**iv. Environmental Compliance Planning and Reporting**

The Recipient must develop and secure USAID clearance of the Supplemental Initial Environmental Examination (SIEE) prior to funding any country level activities

All ongoing and planned country level activities must include an initial environmental examination under this cooperative agreement.

This examination will be done in collaboration with the USAID AOTR, the Mission Environmental Officer, and the Bureau Environmental Officer (BEO).

A complete environmental mitigation and monitoring plan (EMMP) or a program mitigation and monitoring (M&M) plan shall be prepared by the recipient as part of the program work plan and integrated into each annual work plan, or the monitoring plan can be included as part of the PMP. An EMMP is a table of conditions and measures to implement those conditions—see the PEE EMMP Section (attached).

This plan shall describe how the recipient will, in specific terms, implement all PEE and/or Environmental Assessment (EA) conditions that apply to proposed program activities within the scope of the award.

The EMMP M&M Plan shall include monitoring the implementation of the conditions and their effectiveness.

The results of the EMMP will be reported to the AOTR and the BEO annually, no later than November 1 of each year and can be included as an annex to the annual report.

v. Cost-containment

The agreement recipient will not be expected or funded to produce and disseminate a large number of publications, especially publications that do not play a role in the strategic transfer of knowledge and experiences to improve access to and use of quality medicines and pharmaceutical services.

Likewise, the recipient will not be charged with developing an at-scale communications program based on mass access media as this technical expertise is available through another Bureau-wide communications program.

**K. Reference Documents**

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## **SECTION II - IMPLEMENTATION ARRANGEMENTS**

### **A. Anticipated Award Schedule**

The program is expected to be awarded on or about August 30, 2011.

### **B. Eligibility Criteria**

To be eligible to receive this Cooperative Agreement, an organization must:

- Be a U.S. based-non-profit, for profit, or private voluntary organization or an Institution of Higher Education registered with USAID (as defined in 22 CFR part 228);
- Have managerial, technical, and institutional capacities to achieve the results outlined in this program description; and
- Propose to contribute from their own, private, or local sources no less than 7.5 percent of the amount of funds obligated by USAID for the implementation of this program over the course of the agreement.

### **C. Implementation Mechanism**

The program is a Cooperative Agreement with a five-year term. The Health Systems Division of GH/HIDN will manage the program. The program may receive both USAID core and field support funds from a variety of accounts and earmarks.

Applicants are encouraged to propose creative, collaborative partnerships with other U.S. and/or international organizations, NGOs, private voluntary organizations, and firms to implement activities under this program. Inclusion of local organizations of partner countries, faith-based organizations (FBOs) and small business is highly desirable. Proposing at least one new partner in response to this RFA is also highly desirable. "New partners" are defined as organizations that have never received Bureau for Global Health funding as either a direct or sub-recipient. Under this definition, organizations that have been directly funded by a USAID Mission bilateral program or have received USAID Regional Bureau funding will be considered a new partner. Partnerships should be of manageable size with relationships and responsibilities clearly defined.

### **D. Staffing**

The Applicant is expected to develop a comprehensive staffing plan that enables achievement of all Intermediate Results under the SIAPS program and demonstrates an appropriate balance of skills and accountability. The professional staff proposed should possess complementary experience that reflects a combination of strong management as well as specific technical expertise and competencies. The staffing level may be increased or modified over time if needed to provide effective support to field programs as they come on stream, rather than from the onset of the award. Key Personnel under the program include: Program Director; Deputy Program Director; Finance and Operations Director, and Performance Monitoring and Evaluation Specialist. In addition, the Applicant is requested to identify up to five (5) Core Technical Staff, consistent with the overall staffing plan.

## **E. Financial Plan**

The estimated USAID funding ceiling for this Cooperative Agreement is \$198 million over the five-year implementation period, contingent on availability of funds. The program can accept funds from any earmark or account. Activities under this Agreement will conform to relevant policies, laws, and guidance on use of the funds provided.

As indicated in Section II B, there is a 7.5 percent cost sharing requirement for the Cooperative Agreement. Such funds may be mobilized from the prime recipient, other multilateral, bilateral, and foundation donors, and host governments, local organizations, communities and private businesses that contribute financially, and in-kind, to implementation of activities at the county level. Indirect costs, if any, are to be included in these totals.

It is the intent of the U.S. government to make one award for this five-year period. The Government, however, reserves the right to fund more than one application, depending on the relative technical merit, relative cost of proposals received, and availability of funds, or to make no award. The Agreement Officer is the only USAID official or representative of the Government authorized to change any terms and conditions of the Cooperative Agreement.

## **F. USAID Management**

USAID shall be substantially involved during the implementation of this Cooperative Agreement in the following ways:

- Approval of annual work plans and all modifications that describe the specific activities to be carried out under the Agreement;
- Approval of the performance monitoring plan. USAID will be involved in monitoring progress toward achievement of the goal, objective and expected results during the course of the Agreement;
- Approval of the knowledge management plan;
- Review of quarterly technical progress reports and financial reports;
- Approval of Key Personnel and any changes;
- Review and approval of all field support work plans by USAID Mission staff and the AOTR;
- Approval of all US domestic and international travel on a quarterly basis quarterly; and
- As appropriate, other monitoring as described in 22 CFR 226.

The Cooperative Agreement for SIAPS will be managed by the Health Systems Division, Office of Health, Infectious Diseases and Nutrition, within the USAID Bureau for Global Health (GH/HIDN/HS).

The Cooperative Agreement will have one GH/HIDN/HS AOTR and a Technical Advisor (TA). The AOTR and TA will work in collaboration with AOTRs and COTRs for other projects that work in supply chain management, health systems strengthening, leadership and governance, service delivery, financing, information systems, capacity building and the private sector, and Mission bilateral programs to assure the provision of appropriate and non-duplicative technical assistance to the field.

Management of funds and technical content related to GH global leadership priorities or to HIV/AIDS, MCH, nutrition, NTDs, malaria, or TB will include technical input as appropriate.

## **G. Management Reviews and Evaluations**

The Annual Work Plan will form the basis for a joint management review by USAID and SIAPS program staff to review program directions, achievement of the prior year work plan objectives, and major management and implementation issues, and to make recommendations for any changes as appropriate.

At any time during program implementation, USAID may conduct one or more evaluation(s) to review overall progress, assess the continuing appropriateness of the program design, and identify any factors impeding effective implementation. USAID will utilize the results of the evaluations to recommend any mid-course changes in strategy and to help determine appropriate future directions. Site visits to SIAPS field programs may occur anytime after the initial six-month period.

## **SECTION III – COOPERATIVE AGREEMENT APPLICATION FORMAT**

### **A. General Instructions**

Applicants are expected to review, understand, and comply with all aspects of this RFA. Failure to do so will be at the Applicant's risk.

The successful Applicant for this RFA will be awarded a Cooperative Agreement with USAID. Applications in response to this RFA should respond directly to the terms, conditions, specifications, and provisions of this RFA. Applications not conforming to this RFA may be categorized as non-responsive, thereby eliminating them from further consideration.

Applicants should submit one original plus six (6) copies of a technical application and one original plus two (2) copies of the cost/business application, in English. Applications should reference the total proposed funding level and the estimated cost-share on the cover page. In addition to hard copies, technical and cost/business applications should be submitted on one (1) CD ROM each in Microsoft Word 2010 and Excel 2010 respectively.

All copies of the technical and cost/business applications must be separately placed in sealed envelopes clearly marked on the outside with the words "RFA No. SOL-OAA-11-000064" with the contents indicated: e.g., "Technical, and/ or Cost/Business (as appropriate) Application".

Any application with data not to be disclosed should be marked with the following legend:

"This application includes data that shall not be disclosed outside the U.S. Government and shall not be duplicated, used, or disclosed in whole or in part for any purpose other than to evaluate this application. If, however, a cooperative agreement is awarded to this Applicant as a result of or in connection with the submission of this data, the U.S.

Government shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting cooperative agreement. This restriction does not limit the U.S. Government's right to use information contained in this data if it is obtained from another source without restriction. The data subject to this restriction are contained in sheets [insert numbers or other identification of sheets]."

Mark each sheet of data you wish to restrict with the following legend: "Use or disclosure of data contained on this sheet is subject to the restriction on the title page of this application."

Any prospective applicant desiring an explanation or interpretation of this RFA must request it in writing. Questions should preferably be sent within two weeks of issuance of the RFA to allow a reply to reach all prospective applicants before the submission of their applications. Oral explanations or instructions given before award of a Cooperative Agreement will not be binding. Any information given to a prospective applicant concerning this RFA will be furnished promptly to all other prospective applicants as an amendment of this RFA, if that information is necessary in submitting applications or if the lack of it would be prejudicial to any other prospective applicants.

## **B. Submission Deadline and Instructions**

Applications are due to USAID by **June 22, 2011, 1700 Eastern Standard Time**. Applications which are submitted late or incomplete run the risk of not being considered in the review process.

All applications must be submitted through [www.grants.gov](http://www.grants.gov). Because Grants.gov registration may take some time, all prospective applicants are strongly encouraged to begin this process as early as possible in order to complete all steps prior to the submission deadline.

In addition to applying through [www.grants.gov](http://www.grants.gov), applicants should submit hard copies of both their technical and cost applications in accordance with the instructions above to:

*Via US Postal Service or Courier:*

Sam Kraegel  
USAID Office of Acquisition & Assistance  
M/OAA/DCHA/AFP, Rm 524-I, SA-44  
1300 Pennsylvania Ave., NW  
Washington, DC 20523

*Via hand-delivery:*

Sam Kraegel  
USAID Office of Acquisition & Assistance  
M/OAA/DCHA/AFP, Rm 524-I  
Federal Center Plaza  
301 C Street, SW  
Washington, DC 20024

Advance notice of 24 hours must be given for all hand-delivery requests. Requests specifying a date and time should be sent to [skraegel@usaid.gov](mailto:skraegel@usaid.gov).

Any questions concerning this RFA shall be submitted in writing via email to [skraegel@usaid.gov](mailto:skraegel@usaid.gov), with copy to [smcelrath@usaid.gov](mailto:smcelrath@usaid.gov) and reference the RFA number in the subject line. Answers to all questions received by the time specified will be issued as an amendment to the RFA. For all inquiries and questions, please provide a contact person's name,

phone number and email address. To allow adequate response time, questions must be received by May 27, 2011; 1700 Eastern Standard Time.

Award of any resultant cooperative agreement(s) cannot be made until funds have been fully appropriated, allocated, and committed through internal USAID procedures. While it is anticipated that these procedures will be successfully completed, potential applicants are hereby notified of these requirements and conditions for award. Applications are submitted at the risk of the applicant; should circumstances prevent award of a cooperative agreement, all preparation and submission costs are at the applicant's expense.

### **C. Preparation Guidelines for the Technical Application**

All applications received by the deadline will be reviewed for responsiveness to the specifications outlined in these guidelines and the application format. Section IV, "Evaluation Criteria," addresses the technical evaluation procedures for the applications. Applications that are submitted late or are incomplete will not be considered for award.

Applications shall be submitted in two separate parts: (a) technical and (b) cost or business application, following the instructions listed in the first part of this section.

The application will be prepared according to the structural format set forth below. Applications must be submitted to the location indicated in the cover letter accompanying this RFA by the date and time specified.

Technical applications should be specific, complete and concise. The Application should demonstrate the Applicant's capabilities and expertise with respect to achieving the goals of this program. The technical application should fully respond to the technical evaluation criteria found in Section IV.

Applicants shall provide the names of the key individuals responsible for preparing the technical application, the specific sections of the proposal to which each contributed, and the approximate percentage of the final document developed by each individual.

Applicants should retain for their records one copy of the application and all enclosures that accompany their application. Erasures or other changes must be initialed by the person signing the application. To facilitate the competitive review of the applications, USAID will consider only applications conforming to the format prescribed below.

USAID requests that applications be kept as concise as possible. Technical Applications are limited to 45 pages (12 point single-spaced type, 1 inch margins), not including the cover page, executive summary, appendices, figures and tables. Shorter applications are encouraged. USAID requests that applications provide all information required by following the general format described below.

A USAID Technical Evaluation Panel will evaluate the technical applications in accordance with the evaluation criteria in Section IV. The format of the technical application should follow the outline and order of the technical scoring criteria according to the guidelines provided below.

The suggested format for the technical application is:

**i. Cover Page**

Include program title, RFA number, name of organization(s) submitting application, contact person, telephone and fax numbers, e-mail, and address.

**ii. Executive Summary (1-3 pages)**

Briefly describe how the Applicant(s) proposes to apply the SIAPS core operating principles and achieve the program's goal, objective and five Intermediate Results. Indicate the technical and managerial resources of the Applicant's organization and explain how the overall program will be managed.

**iii. Technical Application Format (maximum 45 pages)**

This section represents the technical portion of the RFA. Applications should be kept as concise and specific as possible. The technical portion of the application shall be no more than 45 pages, excluding figures, tables, and attachments. The technical application should be organized in the order of the evaluation criteria found in Section IV.

Content of the Technical Application – Instructions

**a. Technical Approach (suggested 30 pages)**

- i. Understanding and overall quality of proposed strategies, approaches, and interventions: (suggested 18 pages)*

Applicants should describe how they propose to overcome the challenges described in Program Description to achieve the objective of this program—to assure the availability of quality pharmaceutical products and effective pharmaceutical services for the achievement of desired health outcomes for the different Health Program Elements. Applicants should demonstrate how they will assist USAID and partner countries to achieve the long-term goals of country ownership, system strengthening, and sustainability while supporting the continuing scale-up and expansion of prevention and treatment programs. As regards the five results areas described in the RFA, Applicants should present an overview of how they will accomplish each Intermediate Result and sub-Intermediate Result using specific illustrative activities. Applicants should focus on identifying innovative and viable strategies and approaches for the achievement of stronger and more efficient pharmaceutical systems, drawing from their own experiences or lessons learned from successful relevant efforts to promote sustainable improvements in partner country government health systems. The success of the SIAPS program will hinge on the extent to which its core operating principles are reflected in the development of strategies, approaches and implementation plans.

In this section, Applicants should also describe strategies for building on and strengthening local organizations, networks and institutions and collaborating with other USAID Cooperating

Agencies (CAs) and projects involved in related efforts. Specifically, Applicants should describe how they will involve local partners in program implementation and ensure capacity building of in-country organizations and institutions that will facilitate country ownership and responsibility for interventions, thereby increasing the sustainability of pharmaceutical systems.

*ii. Case Studies: (suggested 9 pages)*

Applicant responses to the two case studies should be no more than nine (9) pages as part of the 45 page limit.

**Case Study 1:** Under the Global Health Initiative, building sustainability through health systems strengthening is one of the seven basic principles. SIAPS core operating principles are in alignment with the GHI. As explained in the Program Description, SIAPS intends to move beyond the conceptual framework of the health systems building blocks to a strategic model for planning and implementation of interventions to assure the availability of quality pharmaceutical products and effective pharmaceutical services. To this end, the SIAPS result areas reflect a set of intersecting dynamic relationships among five health system building blocks (governance, human resources, information, financing, and service delivery), with a Medical Products Building Block overlay that provides technical content and areas of focus to support sustainable improvements in pharmaceutical systems and the achievement of desired health outcomes. Applicants should describe their vision how to operationalize this approach for more effective and efficient pharmaceutical systems strengthening.

**Case Study 2:** Applicants should choose a developing country where they possess knowledge or experience that is facing pharmaceutical system challenges and describe how they would apply their overall approach, as described in Case Study 1, in the selected country. This should include a brief background of the country situation, including how they will identify gaps and develop programmatic improvement approaches. What illustrative activities does the Applicant propose for this country? How will the Applicant collaborate with USG agencies, contractors, international stakeholders, and local organizations to promote and implement pharmaceutical systems strengthening efforts? Applicants should also address partner country government constraints to effectively manage increased resources and assume a requisite leadership role. Applicants are encouraged to identify evidence-based tools and approaches appropriate to the country context, as well as the indicators that will be used to monitor results.

*iii. Program Tasks: (suggested 3 pages)*

The SIAPS program is expected to carry out three essential tasks – global technical leadership, research and innovation, and field support. Applicants should explain how they will assist USAID to advance a systems strengthening perspective to improve the availability of quality pharmaceutical products and effective pharmaceutical services through the use of evidence-based tools, approaches, and interventions. As per the SIAPS research agenda, Applicants should address utilizing the untapped potential of the private sector, developing financing mechanisms for expanded access to medicines and services, and improving system performance metrics, among other issues of relevance to systems strengthening, sustainability and scaling up of effective interventions. As regards field support, Applicants should clearly explain how they will elicit USAID technical inputs, including how they will be responsive in a timely manner to

requests for assistance across the broad range of technical areas outlined in the Program Description, and how they will address the challenge of pharmaceutical system strengthening with Health Element funding. Applicants must also describe how lessons learned in program implementation will be systematically identified, documented, disseminated and used to support scale-up of best practices.

**b. Key Personnel and Other Staff (suggested 7 pages)**

Applicants should propose four (4) Key Personnel and five (5) Core Technical Staff that demonstrate an appropriate balance of technical skills and experience required to ensure achievement of the five Intermediate Results outlined in the Program Description. Key Personnel and Core Technical Staff should also possess strong management skills, developing country expertise, and experience collaborating with key stakeholders in other organizations, as well as the ability to support and supervise staff. Key Personnel and Core Technical Staff qualifications are specified in Section IV “Evaluation Criteria.”

The Applicant should provide a staffing plan that presents a complement of other staff that, together with proposed Key Personnel and Core Technical Staff, addresses all of the program’s critical technical, financial management, administration, and implementation requirements. The Applicant should use in-country and south-to-south human resources whenever possible while pairing them judiciously with external SIAPS staff and consultants. The staffing plan will include the following information that may be included in annexes and therefore does not count against the Applicant’s page limit:

- The proposed configuration of Key Personnel and Core Technical Staff positions and an explanation of functions and responsibilities, and corresponding position descriptions;
- An explanation of how additional technical expertise will be obtained with attention to cost-containment while avoiding unnecessary staffing. Staffing charts are also to include the percentage of staff time on the program;
- A matrix of relevant programmatic and technical skills and experience necessary to implement the Applicant’s plan that shows how all proposed staff (including short-term consultants) meet SIAPS program requirements;
- An annex including letters of commitment and resumes (three pages maximum) including a half page summary of qualifications for all candidates for Key Personnel and Core Technical Staff;
- Summary biographical statements (no more than one page each) of other technical and administrative personnel that are considered important to the implementation of the program.

**c. Management (suggested 2 pages)**

Applicants should propose a management plan consistent with this program’s technical complexity, the broad range of USG and external stakeholders, the evolving international health environment, program implementation at various levels, and expectations for collaboration and transparency. The management plan should be highly functional and efficient in response to

tight budgetary constraints and the need to achieve results in countries. It should also provide specific, operational and effective measures to address all elements set forth in the RFA instructions.

USAID will entertain proposals from a single organization that possesses the breadth of technical and country-specific knowledge, expertise and experience required to successfully implement this program or from partnerships of organizations or groups that would contribute to the accomplishment of the program's goal and objective. In either case, Applicants should describe how they will be organized and managed to minimize non-productive costs to the government and ensure success in achieving the five SIAPS Intermediate Results.

The Applicant should describe the proposed management and administrative structure, policies and practices for overall implementation of the program including personnel, financial and logistical support, and coordination, and how responsibility and lines of authority will be managed within the program and across any proposed partnerships. An organizational chart should be provided.

The management plan should also describe how the program will relate to and respond to USAID/Washington and to USAID Missions. Applicants should specifically describe how they will be responsive in a timely manner to USAID Missions requesting support for the broad range of technical areas outlined in the Program Description.

The Applicant should describe plans for rapid start-up of the program, including plans for accessing and deploying key personnel and essential technical staff to support the implementation of the technical program and meet USAID/Washington and USAID Mission needs while avoiding excess staffing.

USAID expects that all Key Personnel and Core Technical Staff be located at the program headquarters; Key Personnel should be full time with the program. Further, USAID strongly recommends that the SIAPS program headquarters be located in the Washington D.C. metropolitan area.

In an annex to the technical proposal, Applicants should demonstrate that they meet or exceed the Eligibility Criteria (Section II B "Eligibility Criteria") provided in the RFA.

#### **d. Monitoring and Evaluation (suggested 3 pages)**

Applicants should propose a preliminary PMP, including indicators, to track progress toward achievement of the program goal, objective and each of the five Intermediate Results as outlined in the Program Description. The PMP should be aligned with Global Health Initiative principles and the Agency's High Priority Performance Goal for Global Health and address metrics for country ownership as well as the sustainability of successful interventions introduced with program support. It should also include clearly defined benchmarks for program performance over the course of the five-year implementation period.

Applicants should describe how indicators will be regularly collected and reported to facilitate results reporting. Given that multiple Missions and Bureaus may contribute funds toward a

particular country program or activity, Applicants should describe how they will monitor technical and financial indicators and report results specific to each unit providing core and other funds into the Award.

Applicants should describe how baselines will be established, including gender-specific measures, how baselines and other data provided by the PMP and any other proposed specific studies to monitor particular aspects of activities would be used to make mid-term corrections or other changes, and how the overall outcomes and impact of program activities will be assessed. Applicants should also propose key evaluation questions that would capture SIAPS contributions to selected health outcomes and pharmaceutical system improvements.

Additionally, Applicants should describe how SIAPS program performance measures will be incorporated into a conceptual and operational framework that describes a dynamic model for sustainable pharmaceutical system strengthening. Applicants should also describe how they will engage with other USG programs, partners, and international stakeholders in the development of this framework.

**e. Knowledge Management (suggested 1 page)**

Applicants should describe a systematic and cost-effective approach to knowledge management that supports program monitoring and evaluation, as well as the sharing and critical review of data and information about program activities, lessons learned, and best practices among stakeholders at the country and global levels. Applicants should also describe how they will collaborate with relevant international organizations and partners to ensure the timely and effective transfer and exchange of knowledge and experience to further the state-of-the-art.

**f. Institutional Capacity (suggested 2 pages)**

Applicants (and each constituent organization that is proposed to implement at least 20% of the value of the program) should provide evidence demonstrating an institutional capacity to manage complex and multifaceted worldwide technical assistance programs and achieve measurable results in the technical areas of pharmaceutical system strengthening relevant to this RFA. Evidence should demonstrate:

- A volume and content of work indicating an aptitude and capacity to implement a complex program of this magnitude
- Successful financial performance, including efficient management of resources
- Success in indigenous capacity building through technical assistance resulting in the transfer of knowledge and skills
- Successful approaches that promote country-ownership and sustainability
- Development and application of innovative approaches and strategies to address pharmaceutical management deficits or weaknesses
- Ability to monitor and evaluate performance with the use of appropriate indicators
- Ability to establish effective partnerships with international global health programs and initiatives

**g. Past Performance (attachment)**

As an attachment, please provide three (3) past performance references for any current or recent awards, contracts, grants, and/or cooperative agreements financed by international development organizations (e.g., governmental, philanthropic and/or commercial), that are similar in subject matter, size, scope and complexity to the technical description of this RFA. References should include the following information: name and address of the organization for which the work was performed; current telephone number and email address of responsible representative from the organization for which the work was performed; contract/grant name and number (if any), annual amount received for each of the past three years and beginning and end dates; and a brief description of the project.

USAID reserves the right to obtain and assess past performance information from other sources, including those not named in this application.

**D. Environmental Compliance**

The Foreign Assistance Act of 1961, as amended, Section 117 requires that the impact of USAID's activities on the environment be considered and that USAID include environmental sustainability as a central consideration in designing and carrying out its development programs. This mandate is codified in Federal Regulations (22 CFR 216 [http://www.usaid.gov/our\\_work/environment/compliance/22cfr216.htm](http://www.usaid.gov/our_work/environment/compliance/22cfr216.htm) ) and in USAID's Automated Directives System (ADS) Parts 201.5.10g and 204 (<http://www.usaid.gov/policy/ADS/200/>), which, in part, require that the potential environmental impacts of USAID-financed activities are identified prior to a final decision to proceed and that appropriate environmental safeguards are adopted for all activities.

To demonstrate their capability to meet all environmental compliance requirements, applicants will submit an Environmental Capability Statement (ECS) presenting their approach to achieving environmental compliance and management, i.e., how they will implement the Programmatic Initial Environmental Examination (PIEE) (attached). This statement, which should be limited to ½ -1 page, must include:

- The Applicant's approach to developing and implementing any 22 CFR 216 documentation including provisions for an Environmental Monitoring and Management Plan (EMMP)2 to be updated and revised throughout the life of the award as detailed in the annual Environmental Status Report (ESR) and
- The Applicant's approach and staff that will provide necessary environmental management expertise. This will include examples of past experience of environmental management of similar activities and technical expertise of identified individuals.

Applicants must specify anticipated costs for implementing and monitoring the environmental compliance activities in the budget and to describe these costs in detail to the degree possible in the budget narrative.

## E. Cost/Business Application

The Cost or Business Application is to be submitted as separate document/package from the technical application. Certain documents are required to be submitted by an applicant in order for an Agreement Officer to make a determination of responsibility. However, it is USAID policy not to burden applicants with undue reporting requirements if that information is readily available through other sources. As instructed above, Applicants should submit their Cost Application electronically through the [www.grants.gov](http://www.grants.gov) website in addition to two (2) hard copies of their Cost Application and one (1) copy on CD ROM, formatted in Word 2010 and Excel 2010. While there is no page limit for this section, applicants are encouraged to be as concise as possible, while still providing the necessary detail and including the following:

1. A summary budget in US Dollars for each of the five years of the proposed activity, providing the total estimated costs for implementation of the program the organization is proposing. For the purposes of this illustrative budget, the applicants should assume that the program will begin slowly with funding during the first year estimated at roughly \$25 million.

Over the course of the Agreement, in addition to USAID funds, Applicants are expected to contribute from their other sources, no less than 7.5 percent of the amount obligated by USAID for the implementation of this program, over the life of the project.

Contributions can be either cash or in-kind and can include contributions from the U.S. NGOs, local counterpart organizations, project clients, and other donors (not other USG funding sources). Information regarding the proposed cost-share should be included in the SF 424 and the Cost Matrix as indicated on those documents. The cost-share should be discussed in the budget narratives to the extent necessary to realistically access these sources and funds and the feasibility of the cost-sharing plan. Applications that do not meet the minimum cost-share requirement are not eligible for award consideration. It should be noted that there is no separate/additional evaluation criteria category for cost-share because cost-share is included within cost-effectiveness.

2. Detailed budgets for each of the five years of the proposed activity with an accompanying budget narrative to facilitate USAID's determination that costs are allowable, allocable, and reasonable. Detailed budget notes and supporting justification of all proposed budget line items which provide in detail the total costs for implementation of the program the organization is proposing should be included. Information for the detailed budget must then be included on Standard Form 424, which can be found at the following website: <http://www.usaid.gov/forms/sf424.pdf>.

The budget shall include (as applicable):

- a. The breakdown of all costs associated with the program according to costs of, if applicable, headquarters, regional and/or country offices;
- b. The breakdown of all costs according to each partner organization or subcontractor/subgrantee involved in the program;
- c. The costs associated with external, expatriate technical assistance and those associated with local in-country technical assistance;

- d. The breakdown of the financial and in-kind contributions of all organizations involved in implementing this Cooperative Agreement;
  - e. Potential contributions of non-USAID or private commercial donors to this Cooperative Agreement;
  - f. A procurement plan for commodities.
3. If the Applicant has established a consortium or another legal relationship among its partners, the Cost/Business application must include a copy of the legal relationship between the parties. The agreement should include a full discussion of the relationship between the Applicants including: identification of the Applicant with which USAID will treat for purposes of Agreement administration; identity of the Applicant that will have accounting responsibility; how the Agreement effort will be allocated; and the express agreement of the principals thereto to be held jointly and severally liable for the acts or omissions of the other.
  4. A copy of the latest Negotiated Indirect Cost Rate Agreement if your organization has such an agreement with the US Government.
  5. Applicants which do not currently have a Negotiated Indirect Cost Rate Agreement (NICRA) from their cognizant agency shall, upon request from the Agreement Officer, also submit the following information:
    - a. Copies of the applicant's financial reports for the previous 3-year period, which have been audited by a certified public accountant or other auditor satisfactory to USAID;
    - b. Projected budget, cash flow and organizational chart; and
    - c. A copy of the organization's accounting manual.
  6. Applicants may be required to submit additional evidence of responsibility if deemed necessary for the Agreement Officer to make a determination of responsibility. The information submitted should substantiate that the Applicant:
    - a. Has adequate financial resources or the ability to obtain such resources as required during the performance of the award.
    - b. Has the ability to comply with the award conditions, taking into account all existing and currently prospective commitments of the applicant, nongovernmental and governmental.
    - c. Has a satisfactory record of performance. Past relevant unsatisfactory performance is ordinarily sufficient to justify a finding of non-responsibility, unless there is clear evidence of subsequent satisfactory performance.
    - d. Has a satisfactory record of integrity and business ethics; and
    - e. Is otherwise qualified and eligible to receive a cooperative agreement under applicable laws and regulations (e.g., EEO).
  7. Required certifications, assurances, and other statements for the prime and sub-recipients. These forms may include:
    - Assurance of Compliance with Laws and Regulations Governing – Nondiscrimination in Federally Assisted Programs

- Certification Regarding Lobbying
  - Prohibition on Assistance to Drug Traffickers for Covered Countries
  - Certification on Terrorist Financing
  - Certification of Recipient
  - Key Individual and Participant Certifications Narcotics Offence and Drug Trafficking
  - Certification Of Compliance With The Standard Provisions Entitled “Condoms” And “Prohibition On The Promotion Or Advocacy Of The Legalization Or Practice Of Prostitution Or Sex Trafficking
  - Survey On Ensuring Equal Opportunity For Applicants
8. Applicants that have never received a cooperative agreement, grant or contract from the U.S. Government may be required to submit, upon request from the Agreement Officer, a copy of their accounting manual. If a copy has already been submitted to the U.S. Government, the applicant should advise which Federal Office has a copy.

## **SECTION IV – EVALUATION CRITERIA**

### **A. Overview**

Each technical application submitted in response to this RFA will be evaluated in relation to the evaluation factors set forth in this solicitation and which have been tailored to the requirements of this RFA to allow USAID to choose the highest quality application.

The Government intends to evaluate applications and award an agreement without discussions with Applicants. However, the Government reserves the right to conduct discussions if later determined by the Agreement Officer as necessary. Therefore, each initial offer should contain the Applicant’s best terms from a cost or price and technical standpoint.

### **B. Acceptability of Proposed Non-Price Terms and Conditions**

An offer is acceptable when it manifests the Applicant's assent, without exception, to the terms and conditions of the RFA, including attachments, and provides a complete and responsive proposal without taking exception of the terms and conditions of the RFA. If an Applicant takes exception to any of the terms and conditions of the RFA, then USAID will consider its offer to be unacceptable. Applicants who wish to take exception to the terms and conditions stated within this RFA are strongly encouraged to contact the Agreement Officer before doing so. USAID reserves the right to change the terms and conditions of the RFA by amendment at any time prior to the Applicant selection decision.

The criteria presented below have been tailored to the requirements of this RFA. Applicants should note that these criteria serve to: (a) identify the significant areas that Applicants should address in their applications and (b) serve as the standard against which all applications will be evaluated. To facilitate the review of applications, Applicants should organize the narrative sections of their applications in the same order as the selection criteria.

The technical applications will be evaluated in accordance with the Technical Evaluation Criteria

set forth below; thereafter, the cost application of all Applicants submitting a technically acceptable application will be opened and costs will be evaluated for general reasonableness, allowability, and allocability. To the extent that they are necessary (if award is made based on initial applications), negotiations will be conducted with all Applicants, whose application after discussion and negotiation has a reasonable chance of being selected for award. An award will be made to responsible Applicants whose applications offer the greatest value, cost reasonableness, and other factors considered.

Award will be made based on the ranking of proposals according to the selection criteria identified below.

### **C. Evaluation Criteria**

USAID will award to the one Applicant whose proposal best meets the Program Description and represents the best value to the U.S. Government, all factors considered. Technical proposals for the SIAPS program will be evaluated and scored based on the following points. The maximum number of points available is 100.

#### **1. Technical Approach (40/100)**

The extent of the Applicant's responsiveness to each of the bullets below will be evaluated by the technical review committee in determining the overall score. The bullets below are in descending order of importance and will not be individually scored.

##### **a. Understanding and overall quality of proposed strategies, approaches, and interventions (21/40)**

- The application conveys a clear understanding of the Program Description and a proposed strategy and approach for addressing the key issues and challenges facing partner country government health systems, applying sound knowledge and best practices, and achieving specific results through effective interventions that are feasible, efficient, sustainable, and have potential to be scaled-up.
- The application reflects an in-depth grasp of pharmaceutical systems strengthening, including governance, human resource, information, financing and service delivery issues, as they contribute to sustainable systems improvements, institutional capacity development, country ownership, more advanced performance metrics, and desired health outcomes, including an appreciation of how support for FP/RH, HIV/AIDS, malaria, TB, and MCH, and other health areas can be used to achieve broader pharmaceutical systems strengthening.
- The application describes demonstrated approaches for improving access to quality pharmaceutical products and effective pharmaceutical services through more efficient supply chain management systems, monitoring of patient safety, adherence, and therapeutic effectiveness, and support for interventions to contain the emergence and spread of antimicrobial resistance, as well as innovative uses of the private sector and local organizations to improve access to medicines and services and for the performance

of pharmaceutical management functions and operations.

- The proposed approach for building the capacity of local organizations and institutions in pharmaceutical management and pharmaceutical service delivery improvement and expansion incorporates planning and implementation, monitoring of the capacity development process, and the fostering of stakeholder involvement and local ownership.
- The proposed approach describes the active engagement of a variety of partners at the global level, including USG agencies, donors, WHO, professional associations and initiatives, and entities such the Global Drug Facility, the Green Light Committee, ReAct, AMDS, RBM, Stop TB, and, at the local level, partner country governments, NGOs, the private sector, educational and training institutions, and professional health and trade associations, to develop political commitment and leverage funding and other resources to support collaboration, coordination, and country-led programs for pharmaceutical systems strengthening and improved health outcomes.

**b. Case Studies (13/40)**

- The Applicant demonstrates a holistic understanding of pharmaceutical systems and how to operationalize the SIAPS approach to system strengthening, including strategic planning, selection of interventions, and their implementation to assure the availability of quality pharmaceutical products and effective pharmaceutical services. (Case Study 1)
- Proposed interventions for the selected country case study are evidence-based, feasible, and measurable, and approaches to building institutional and human resource capacity and strengthening pharmaceutical systems are sustainable, innovative and appropriate for achieving favorable health impact. (Case Study 2)
- Proposed activities reflect the importance of strategic collaboration in building the capacity of partner country government entities from a technical, managerial, accountability and leadership perspective and their ability to assume responsibility for management and oversight of their pharmaceutical systems. (Case Studies 1 and 2)
- Proposed plans demonstrate realistic approaches to address the need to develop the capacity of local organizations to carry out pharmaceutical-related functions, roles, and responsibilities in support of public health goals. (Case Studies 1 and 2)
- Proposed approaches reflect understanding of the diverse nature of relationships and partnerships that need to be fostered with USG-funded activities and those of other donors, international stakeholders and health initiatives. (Case Studies 1 and 2)

**c. Program Tasks (6/40)**

The Applicant demonstrates a clear and comprehensive understanding of the program tasks in this RFA and indicates how it will address the challenges and requirements involved in providing field support (including how it will engage with USAID Mission staff and the AOTR in the work planning process), exercising global technical leadership, and conducting research.

## **2. Key Personnel and Other Staff (36/100)**

### *Qualifications of the Program Director (9/36)*

The proposed Program Director shall be responsible for oversight, administration, supervision and management of all aspects of cooperative agreement performance. S/he must have strong leadership qualities, extensive developing country experience, broad technical and management expertise, and demonstrated success in executive level management of large, complex USG technical assistance activities in developing countries, as reflected by at least eight (8) years of experience in addressing pharmaceutical systems strengthening issues. To be effective, the proposed Director must possess international credibility as a technical leader in pharmaceutical and supply chain management, access to medicines, and pharmaceutical service delivery, and have experience coordinating and collaborating with other USG-funded cooperating agencies and contractors, Mission PHN staff, partner country government officials, and other donors and international stakeholders. Strong interpersonal, writing and oral presentation skills in English are required, and fluency/proficiency in a second language is highly desirable. Performance as an effective decision-maker and competence supervising professional and support staff must be demonstrated. A Master's Degree (or equivalent) in Pharmacy, Public Health, Health Policy, or related field is required.

### *Qualifications of the Deputy Director (6/36)*

The proposed Deputy Director must have at least six (6) years of experience in implementing activities related to pharmaceutical systems strengthening in developing countries. As an operational oversight manager, demonstrated competence in managing and providing technical assistance in key areas of pharmaceutical systems (such as product selection, forecasting, procurement, distribution, rational use, AMR and pharmaceutical services, etc.) is required. S/he must have demonstrated executive level qualities, broad technical and management expertise and experience, and strong interpersonal, writing, and oral presentation skills, with fluency/proficiency in a second language highly desirable. Experience with one or more disease-specific programs (e.g., HIV/AIDS, malaria, TB, etc.) is highly advantageous. S/he must have a Master's Degree in public health or a clinical discipline relevant to pharmaceutical systems strengthening.

### *Qualifications of the Finance and Operations Director (4/36)*

The proposed Finance and Operations Director must be experienced in USAID or international budgeting, financial management, and oversight for health programs implemented in developing countries. S/he must have at least six (6) years of relevant experience, broad technical financial and management expertise, and strong interpersonal, writing, and oral presentation skills. S/he must have a Master's Degree in Business Administration or be a Certified Public Accountant or have a related advanced degree or experience. Education and/or experience relevant to the field of financial management, accounting, auditing, and management for international public health is highly desirable. Experience working with cooperative agreements with multiple funding sources in developing countries is also highly desirable.

### *Qualifications of the Performance Monitoring and Evaluation Specialist (4/36)*

The proposed Performance Monitoring and Evaluation Specialist must have a firm command of M&E issues with respect to health and/or pharmaceutical systems strengthening, capacity building, and development of performance metrics and frameworks to benchmark systems improvements and achievement of results. S/he must have at least five (5) years of experience designing, implementing, and supervising M&E efforts for multi-country, pharmaceutical system or other health programs. S/he must have demonstrated analytical skills and experiences to identify and evaluate best practices and state-of-the-art approaches and must be able to develop the capacity of SIAPS program staff in setting goals and objectives, identifying outputs, outcomes, and impacts, and collecting and using indicator data. This would include designing a data collection, analysis and indicator-based reporting framework to support demonstration of pharmaceutical system strengthening. In addition, s/he must possess strong writing and organizational skills for reporting on program and study results. S/he must have an advanced degree in public health or a related discipline.

#### *Qualifications of the Core Technical Staff (7/36)*

The Applicant is requested to identify up to five (5) Core Technical Staff, consistent with the overall staffing plan, that are considered essential to achieving the results of the program. They should possess a mix of technical skills, competencies, and Health Element knowledge necessary for all aspects of pharmaceutical systems strengthening as described in this RFA. The Core Technical Staff should also demonstrate strong management skills, developing country expertise, and experience collaborating with key stakeholders in other organizations, as well as the ability to support and supervise staff.

#### *The Complement of Other Staff (6/36)*

The staffing pattern and the number and type of other positions proposed are responsive to the program's technical, financial management and administration requirements and are consistent with the Applicant's proposed approach with an optimal configuration for efficiency and cost containment. The proposed staff demonstrate technical expertise and experience regarding the different Health Elements and in the different areas of pharmaceutical system strengthening as described in the RFA. The Applicant is strongly encouraged to identify qualified staff from the respective countries and regions to support the implementation of the SIAPS program, thereby contributing to rapid program start-up, enhancement of local capacity, and fostering of country ownership.

### **3. Management (8/100)**

The extent of the applicant's responsiveness to each of the bullets below will be evaluated by the technical review committee in determining the overall score.

- Program management and administrative structures, policies and practices for overall implementation, including personnel, financial, and logistical support; the role and level of effort for staff supporting these functions; and a realistic plan for monitoring the technical and financial activities and reporting on results.

- Plans for rapid start-up of the program, including the first year plan of activities and timeline, and responsiveness to technical requests from USAID/Washington and/or USAID Missions, including how the program will manage a complex set of activities in multiple countries and regions of the world, and balance competing demands from USAID/Washington and USAID Missions.
- How the applicant will establish lines of authority and divide responsibilities and funding among partners to manage and implement activities; how the applicant will work with local partners, other USAID programs, and other implementing organizations to achieve results; and how management is structured in a way that is mutually reinforcing, not duplicative, efficient and effective in the use of technical and financial resources.

#### **4. Monitoring and Evaluation (8/100)**

The extent of the Applicant's responsiveness to each of the bullets below will be evaluated by the technical review committee in determining the overall score.

- The application presents a comprehensive PMP that clearly outlines its approach to monitoring and evaluation consistent with Global Health Initiative principles and the Agency's High Priority Performance Goal for Global Health and that addresses metrics for sustainability and country-ownership.
- The PMP specifies key performance indicators and delineates ambitious but achievable performance targets and benchmarks for achieving the life of program results as outlined in the Program Description. The PMP also specifies relevant evaluation questions to capture the impact of program contributions on key outcomes that may be attributed to program activities.
- The PMP specifies a realistic and cost-effective methodology for the collection of high quality baseline data (including data collected from surveys or other methods as appropriate), is responsive to the requirements of various funding units, allows for disaggregation of data by gender, and can inform a subsequent impact evaluation.
- The proposed approach for developing a comprehensive and operational pharmaceutical system strengthening framework is inclusive, realistic and feasible.

#### **5. Knowledge Management (2/100)**

The extent to which the proposed approach to knowledge management is cost-effective and supports systematic program monitoring and evaluation, as well as the sharing and critical review of data and information about program activities among stakeholders at the country level. The proposed approach also promotes the timely transfer and exchange of knowledge and experience, engages international organizations and partners, and will ensure that lessons learned and best practices are used to further the state-of-the-art.

#### **6. Institutional Capacity (3/100)**

The extent to which the proposal demonstrates the Applicant’s institutional capacity and competence to creatively plan, implement, monitor, and report on the broad range of pharmaceutical system strengthening activities described for each SIAPS result area described in this RFA for both USAID/Washington and country-funded programs.

**7. Past Performance (3/100)**

The extent to which the Applicant (and each constituent organization that is proposed to implement at least 20% of the value of the program) demonstrates a proven track record of developing and implementing programs similar in size and scope to the current RFA that achieve documented results in relevant technical areas, as evidenced through the references provided.

**Summary:**

Technical Approach	40 points
Key Personnel and Other Staff Management	36 points
Performance Monitoring and Evaluation	8 points
Knowledge Management	2 points
Institutional Capacity	3 points
Past Performance	3 points
<b>TOTAL</b>	<b>100 points</b>

## **SECTION V - ANNEXES**

Annex A: Standard Form 424: <http://www.usaid.gov/forms/sf424.pdf>

Annex B: Mandatory Standard Provisions for U.S. Nongovernmental Recipients:  
<http://www.usaid.gov/policy/ads/303/303mab.pdf>

Annex C: Branding and Marking Plan

Annex D: Programmatic Initial Environmental Examination (PIE) for the SIAPS Program