Subject: Leader with Associates Cooperative Agreement Number 306-A-00-11-00532-00 with Management Sciences for Health, (MSH) under Leader Award Number GHN-A-00-07-00002-00.

Dear Mr. Reynolds:

Pursuant to the authority contained in the Foreign Assistance Act of 1961, as amended, the U.S. Agency for International Development (hereinafter referred to as “USAID” or “Grantor”) hereby provides to Management Sciences for Health (herein after referred to as “Recipient” or “MSH”) the sum set forth in Section A.3 of this Award to provide support for the program described in Attachment B of this Award entitled “Program Description.”

This Award is effective as of the date of this letter and shall apply to commitments made by the Recipient in furtherance of program objectives for the period described in Section A.2 of this Award. USAID shall not be liable for reimbursing the Recipient for any costs in excess of the obligated amount.

This Award is made to the Recipient on condition that the funds will be administered in accordance with the terms and conditions as set forth in the attachments listed under my signature below, which together constitute the entire Award document, and to which your organization has agreed.

Please sign the original and each copy of this letter to acknowledge your receipt of this Award, and return the original and all but one copy to the Agreement Officer.

Sincerely,

[Signature]

Office of Acquisition and Assistance
Attachments:

A. Schedule
B. Program Description

ACKNOWLEDGED: [Redacted]

Management Sciences for Health

By: [Redacted]

Name: [Redacted]

Title: [Redacted]

Date: 30 August 2011
ACCOUNTING AND APPROPRIATION DATA

A. GENERAL

1. Total Estimated USAID Amount
2. Total Obligated USAID Amount
3. Tax I.D. Number
4. DUNS Number
5. LOC Number

B. SPECIFIC

1. MAARD Number: 306-MAARD-11394
2. Amount: $1,000,000.00
3. Appropriation: 72-1910/111031-90
5. Program Area: A11
6. Program Element: A053
7. EOCC: 4100201
8. CO Reference No.: 306-SOAG-306-05-0007.00—1
9. CO Reference Line No.: 63
10. Total Amount: $3,600,000.00

C. PAYING OFFICE

M/FM/CMP-LOC/Unit
USAID/ Washington
RRB 7.07-107, 134
1300 Pennsylvania Avenue
Washington D.C, 20523
Email: loc@usaid.gov

D. ADMINISTRATIVE OFFICE

(a). Agreement Officer (AO)
Afghanistan Office of Acquisition and Assistance
USAID/Afghanistan
Great Massoud Road
Kabul

(b). Agreement Officer Technical Representative (AOTR)
Office of Social Sector Development
USAID/Afghanistan
Great Massoud Road
Kabul
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ATTACHMENT A – SCHEDULE

A.1 PURPOSE OF AWARD:

The purpose of this Award is to provide support for the program described in Attachment B of this Award entitled “Program Description.”

A.2 PERIOD OF AWARD:

(a) The effective date of this Award is the date of the cover letter, and the estimated completion date is August 27, 2015.

(b) Subject to the terms and conditions of this Award, allowable costs incurred by the Recipient shall be reimbursable during the period beginning on August 28, 2011 and ending on the estimated completion date.

(c) As indicated in Section A.3 (b) below, this Award shall be incrementally-funded. The obligated amount set forth in Section A.3 (b) below is anticipated to be sufficient through approximately March 30th, 2012. The Recipient is authorized to continue expending obligated funds, if available, beyond that date, but not after the estimated completion date set forth in Section A.2 (a) above.

A.3 AMOUNT OF AWARD AND PAYMENT:

(a) The total estimated amount of this Award for its full period, as set forth in Section A.2 (b) above, is

(b) The amount of $4,600,000.00 is obligated for the purposes of this Award. USAID is not required to reimburse the Recipient for any costs in excess of this amount, nor is the Recipient required to continue performance or incur costs in excess of this amount (including actions/costs under the termination and suspension provisions of 22 CFR 226.60-62). If, pursuant to 22 CFR 226.25(c)(4), the Recipient requests additional USAID funding and USAID determines not to provide such additional funding, the Agreement Officer will, upon written request of the Recipient, terminate this Award pursuant to 22 CFR 226.61(a)(2).

(c) Payment shall be made to the Recipient via Letter of Credit in accordance with the procedures set forth in A. GENERAL (5), 22 CFR 226.22, and 22 CFR 226.52.

(d) Until such time as the obligated amount shall equal the total estimated amount of this Award, additional increments of funds may be obligated by USAID through a unilateral modification to this Award, subject to availability of funds, successful performance by the Recipient, possible evaluation of the program, program priorities at the time, and the requirements of 22 CFR 226.25.

A.4 AWARD BUDGET:

(a) Summary Budget

(b) The following is the Award Budget for the total estimated amount of this Award (see Section A.3 above) for its full period (see Section a.2 above). The Recipient may not exceed the total
THE BUDGET

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Total Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Salaries and Wages</td>
<td>$1,429,082</td>
<td>$2,608,649</td>
<td>$2,858,770</td>
<td>$2,952,664</td>
<td>$9,849,165</td>
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<td>Consultants</td>
<td>$23,956</td>
<td>$20,623</td>
<td>$22,361</td>
<td>$7,992</td>
<td>$74,932</td>
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<td></td>
<td>Overhead</td>
<td>$823,004</td>
<td>$1,102,711</td>
<td>$1,134,602</td>
<td>$1,054,941</td>
<td>$4,115,258</td>
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<td>Travel and Transportation</td>
<td>$758,274</td>
<td>$955,617</td>
<td>$969,525</td>
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<td>$3,662,989</td>
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<td>Allowances</td>
<td>$227,179</td>
<td>$378,896</td>
<td>$368,695</td>
<td>$287,192</td>
<td>$1,261,962</td>
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<td>Training</td>
<td>$223,290</td>
<td>$210,610</td>
<td>$217,126</td>
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<td>Equipment</td>
<td>$458,376</td>
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<td>$0</td>
<td>$458,376</td>
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<td>Other Direct Costs</td>
<td>$1,204,993</td>
<td>$841,781</td>
<td>$1,083,542</td>
<td>$1,119,593</td>
<td>$4,249,909</td>
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<td></td>
<td>Grand Total</td>
<td>$5,148,154</td>
<td>$6,118,887</td>
<td>$6,654,621</td>
<td>$6,578,274</td>
<td>$24,499,936</td>
</tr>
</tbody>
</table>

(1) Prior Approval Required for Transferring Funds among Cost Categories by More Than 10% of Total Estimated Amount.

In accordance with 22 CFR 226.25(f), the Recipient may not transfer funds among cost categories by more than 10% of the total estimated amount of this Award (see Section 1.3 above) without the prior written approval of the Agreement Officer. Approval is also required for other budget revisions. Even if the budget revision is within the 10% restriction described herein.

(2) Prior Approval of Certain Revisions to Budget Plan

In accordance with 22 CFR 226.25(b), the Recipient shall request prior approval from the USAID Agreement Officer for the specific budget revisions described in 22 CFR 226.25(c) (1) through (c) (8).

A.5 INTERNATIONAL TRAVEL:

The following international trips are approved. Recipient shall seek USAID | Afghanistan Agreement Officer (AO) approval for any additional international travel not included or anticipated in the approved budget. In accordance with Standard Provision "INTERNATIONAL AIR TRAVEL AND TRANSPORTATION" (JUN 1999).

<table>
<thead>
<tr>
<th>Name</th>
<th>Origin</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>No. of Trips/Year</th>
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<td>1</td>
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<td>2</td>
<td>1</td>
<td>1</td>
<td>0</td>
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</tbody>
</table>
The USAID Afghanistan AOTR shall provide concurrence for all budgeted international travel prior to the initiation of travel. MSH will submit a quarterly report for all international staff for the AOTR’s concurrence. No Business class travel is approved under the Award.

A.6 SUB-AWARD, TRANSFER, OR CONTRACTING-OUT OF ANY WORK (OTHER THAN THE PURCHASE OF SUPPLIES, MATERIAL, EQUIPMENT, OR GENERAL SUPPORT SERVICES)

Pursuant to 22 CFR 226.25(c)(8), prior approval is required for the sub-award, transfer, or contracting-out of any work hereunder (other than the purchase of supplies, material, equipment, or general support services), unless it was described in the Recipient’s application (see Attachment B of this Award) and funded in the approved budget of the award. Except as indicated above all other contracts sub-awards, transfers, and sub-grants must have the prior approval of the Agreement Officer.

A.7 REPORTING AND EVALUATION:

(a) Financial Reporting

(1) Reporting of Expenditures

(1) Financial reporting requirements shall be in accordance with 22 CFR 226.22 regarding Advance payments. Either paper copies or electronic copies (scanned PDF document) may be submitted, but not both.

(2) In accordance with 22 CFR 226.52, the SF 425 or SF-425a Federal Financial Report forms are used to report actual expenditures and are required on a quarterly basis. The Recipient shall submit these forms in the following manner:

(3) The SF-425a (if necessary) must be submitted via electronic format to the U.S. Department of Health and Human Services (HHS) (http://www.dpm.psc.gov) within 45 calendar days following the end of each quarter. A copy of this form shall also be submitted at the same time to the Agreement Officer Technical Representative (AOTR).

(4) One copy of the SF-425a (as appropriate) must be submitted to the Agreement Officer Technical Representative and to Office of Financial Management at kabulfinancialreport@usaid.gov. These reports shall be submitted within 30 calendar days from the end of each quarter, except that the final report shall be submitted within 90 calendar days from the estimated completion date of this Award.

(5) In accordance with 22 CFR 226.70-72, the original and two copies of all final financial reports shall be submitted to the USAID/Washington M/FM/CMP-LOC Unit. The electronic version of the final SF-425a may be submitted to HHS in accordance with paragraph (a) (2) (A) above.
(b)  (1) Programmatic Reporting
(2) Program Planning Reports

Program Planning Reports:

1. Future Activity Report (FAR): No more than a paragraph detailing planned program efforts for the upcoming 2-3 weeks. The submission would be COB on Saturday and cover the significant planned activities starting a week after that Saturday covering up to 2-3 weeks after that Saturday.

2. Weekly Activity Report: No more than a paragraph detailing key activities and project achievements of the past week. The submission would be COB Wednesday for activities for the previous week.

3. Not later than 60 days from the effective date of this Award, the Recipient shall submit three hard copies to the AOTR of a draft annual work-plan, covering the first year of this Award. The work-plan shall include the activities planned to be conducted, the site(s) where they will be conducted, benchmarks/milestones and annual performance targets; the outputs/outcomes which the Recipient expects to achieve; and the inputs planned to be provided by the Recipient, during the work-plan period. Included shall be an explanation of how those inputs are expected to achieve the outputs/outcomes and benchmarks/milestones.

4. Not later than 60 days prior to the beginning of each subsequent year, the Recipient shall submit three copies to the AOTR of draft annual work-plans for each subsequent year. The work-plans shall include the activities planned to be conducted, the site(s) where they will be conducted, and benchmarks/milestones; the outputs/outcomes which the Recipient expects to achieve; and the inputs planned to be provided by the Recipient, during the work-plan period. Included shall be an explanation of how those inputs are expected to achieve the outputs/outcomes and benchmarks/milestones.

(c) Monitoring and Evaluation (M&E) Plan

Within one month, the implementer will submit a monitoring and evaluation plan for USAID to review and approve. The plan will clearly demonstrate how project activities will address needs and reach goals. This will include benchmark statistics, intermediate and full project targets with quantifiable measurements and descriptive indicators that provide context.

(i) Not later than 60 days from the effective date of this Award, the Recipient shall submit three copies to the AOTR of a draft M&E plan. The M&E plan shall include a detailed plan for managing the collection of data in order to monitor performance and report thereon. The M&E plan shall specify the source, method of collection, and schedule of collection for each datum required; and assign responsibility for collection to a specific partner, team, or individual. The M&E plan shall also describe critical assumptions. Also included must be performance baseline data that describe the prevailing conditions of a beneficiary population and/or the situation at the onset of the program, the magnitude of the problem and/or the needs that the Recipient's program will address, performance indicators (including appropriate rationale and justification therefore), and numerical performance targets delineated by the U.S. Government's fiscal year (i.e., AOTR per October 1st - September 30th) or part thereof. If disaggregated data are required, the M&E plan must be capable of accomplishing this. If disaggregated data are not feasible, the M&E plan (including performance indicators) must assess impact on disaggregated populations indirectly. The AOTR will provide comments within 30 days, and the Recipient shall then submit three copies of the final M&E plan within 15
days of receipt of the AOTR's comments to the AOTR for approval. The AOTR shall review the draft annual work-plan, and shall provide comments within 30 days from receipt. Thereafter, the Recipient shall submit three copies of the final work-plan within 15 days of receipt of the AOTR's comments to the AOTR for approval. The M&E plan must be approved by the AOTR.

(3) Performance Monitoring Reports

(A) Notifications

The Recipient shall submit one copy to the AOTR and one copy to the Agreement Officer of notifications (in writing), as follows:

(i) Developments which have a significant impact on the activities supported by this Award; and

(ii) Problems, delays, or adverse conditions which materially impair the ability to meet the objectives of this Award. This notification shall include a statement of the action taken or contemplated, and any assistance needed to resolve the problem.

(B) Quarterly Program Performance Reports

(i) The Recipient shall submit one copy of a concise and brief quarterly program performance report to the AOTR. Electronic submissions are preferred over hard-copy.

(ii) Reporting periods are calendar quarters.

(iii) The due-date for these program performance reports is not later than 30 days after the end of each reporting period. However, if the reporting period ends before 45 days from the effective date of this Award, or less than 30 days from the estimated completion date of this Award and this Award are not being extended, no submission shall be required. All other reporting requirements shall, however, apply.

(iv) At a minimum, these reports shall include the following:

- A comparison of actual accomplishments, both for the reporting period and cumulatively, with the established goals and objectives, and expected results; the findings of the investigator; or both. Data (both qualitative and quantitative) must be presented using established baseline data and indicators, and be supported by a brief narrative. Whenever appropriate and the output of programs or projects can be readily quantified, such quantitative data should be related to cost data for computation of unit costs;

- Reasons why established goals were not met (if applicable), the impact on the program objective(s), and how the impact has been/will be addressed; and

- Other pertinent information including, when appropriate, success stories (if available) which illustrate the direct positive effects of the program; how unforeseen circumstances affected overall performance compared to original assumptions (if applicable), how activities were accordingly adjusted or re-targeted; and analysis and explanation of cost overruns or high unit costs.

(B) Annual Program Performance Reports
(i) The Recipient shall submit one copy of a concise and brief annual program performance report to the AOTR. Electronic submissions are preferred over hard-copy.

(ii) Reporting periods are the anniversary dates of this Award.

(iii) The due-date for these program performance reports is not later than 90 days after the end of each reporting period. However, if the reporting period ends before 90 days from the effective date of this Award, or less than 90 days from the estimated completion date of this Award and this Award are not being extended, no submission shall be required. All other reporting requirements shall, however, apply.

(iv) At a minimum, these reports shall include the following:

- A comparison of actual accomplishments, both for the reporting period and cumulatively, with the established goals and objectives, and expected results; the findings of the investigator; or both. Data (both qualitative and quantitative) must be presented using established baseline data and indicators, and be supported by a brief narrative. Whenever appropriate and the output of programs or projects can be readily quantified, such quantitative data should be related to cost data for computation of unit costs;

- Reasons why established goals were not met (if applicable), the impact on the program objective(s), and how the impact has been/will be addressed; and;

- Other pertinent information including, when appropriate, success stories (if available) which illustrate the direct positive effects of the program; how unforeseen circumstances affected overall performance compared to original assumptions (if applicable), how activities were accordingly adjusted or re-targeted; and analysis and explanation of cost overruns or high unit costs.

(4) Final Report

(A) The Recipient shall submit one copy of an annual and/or final results report to the AOTR. Electronic submissions are preferred over hard-copy. These results reports shall cover the period October 1st through September 30th of each year, or parts thereof. If this Award expires during the reporting period, the Recipient shall submit a final report not later than 90 days after the estimated completion date. Otherwise, the Recipient shall submit an annual report not later than December 31st. These annual and final results reports shall emphasize quantitative as well as qualitative data that reflect results, shall measure impact using the baseline data and indicators established for the program, and shall, at a minimum, include the following:

- Number of beneficiaries targeted during the reporting period;

- Number of beneficiaries reached during the reporting period;

- Cumulative number of beneficiaries targeted to date;

- Cumulative number of beneficiaries reached to date;

- Total numbers of beneficiaries targeted and reached to date;

- A description of assessments and surveillance data used to measure results;
• Success stories and an explanation of successes achieved, constraints encountered, and adjustments made for achieving program objectives;

• A discussion of the overall performance of the program, including details of any discrepancies between expected and actual results and any recommendations for improving the design of the program;

• Overall cost effectiveness, with particular attention paid to cost savings and/or cost overruns, and other significant cost impacts such as major exchange rate fluctuations or other types of inflation shall be detailed;

• A comparison of actual accomplishments, both for the reporting period and cumulatively, with the established goals and objectives, and expected results; the findings of the investigator; or both. Data (both qualitative and quantitative) must be presented using established baseline data and indicators, and be supported by a brief narrative. Whenever appropriate and the output of programs or projects can be readily quantified, such quantitative data should be related to cost data for computation of unit costs;

• Reasons why established goals/targets were not met (if applicable), the impact on the program objective(s), and how the impact has been/will be addressed; and

• Other pertinent information including, when appropriate, success stories (if available) which illustrate the direct positive effects of the program; how unforeseen circumstances affected overall performance compared to original assumptions (if applicable), how activities were accordingly adjusted or re-targeted; and analysis and explanation of cost overruns or high unit costs.

• MSH shall also provide a copy of all programmatic reports to the AOTR for the leader agreement at USAID/Washington.

F. Closeout Plan:

30 days prior to the completion date of the Cooperative Agreement, the Recipient shall submit a Closeout Plan to the Agreement Officer and AOTR. The closeout plan shall include, at a minimum, an illustrative Property Disposition plan; a delivery schedule for all reports or other deliverables required under the Agreement; and a time line for completing all required actions in the Closeout Plan, including the submission date of the final Property Disposition plan to the Agreement Officer’s Technical Representative. The closeout plan shall be approved in writing by the Agreement Officer.

A.8 TITLE TO AND USE OF PROPERTY:

Title to property financed under this Award or provided by USAID shall vest in the Recipient, subject to the following requirements regarding the use, care, accountability, maintenance, and disposition thereof:

(a) Tangible Property

(1) Equipment
“Equipment” means an article of tangible non-expendable personal property having a useful life of one year or more and a per-unit acquisition cost (purchase price) of $5,000 or more. Equipment is subject to the requirements set forth in 22 CFR 226.34.

(2) Supplies and Other Expendable Equipment

“Supplies and other expendable equipment” means items of tangible personal property that do not meet the definition of “equipment” in paragraph (a) (1) above. Supplies and other expendable equipment are subject to the requirements set forth in 22 CFR 226.35.

(3) Real Property

“Real property” means land, land improvements, structures, and appurtenances thereto. Real property is subject to the requirements set forth in 22 CFR 226.32.

(b) Intangible (Intellectual) Property

“Intangible property” means, but is not limited to, copyrights, inventions and patents, and data first produced under this Award. Intangible property is subject to the requirements set forth in 22 CFR 226.36.

A.9 AUTHORIZED GEOGRAPHIC CODE:

The authorized geographic code for procurement of goods and services under this award is 000.

A.10 INDIRECT COSTS:

Pursuant to the Standard Provision set forth in the Leader Award entitled “Negotiated Indirect Cost Rates - Provisional (Non-profits),” an indirect cost rate or rates shall be established for each of the Recipient’s accounting periods which apply to this Award. Pending establishment of final or revised provisional indirect cost rates, allowable indirect costs shall be reimbursed on the basis of the following negotiated provisional rate(s) and the appropriate base(s):

<table>
<thead>
<tr>
<th>Period</th>
<th>Employee Direct Labor + Accrued Holiday, Vacation and Sick Pay</th>
<th>Consultant Fees + Direct Labor (as used) Holiday, Sick and Vacation Pay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final</td>
<td>07-01-07 - 07-06 - 08</td>
<td>07-01-08 - 06-30 - 09</td>
</tr>
<tr>
<td></td>
<td>79.62%</td>
<td>80.62%</td>
</tr>
<tr>
<td>Final</td>
<td>07-01-09 - 06-30-10</td>
<td>81.61%</td>
</tr>
<tr>
<td>Provisional</td>
<td>07-07 - Until Amended</td>
<td>07-08 - 10</td>
</tr>
<tr>
<td></td>
<td>81.00%</td>
<td>40.00%</td>
</tr>
</tbody>
</table>
A.11 RESTRICTIONS ON FUNDING FOR LAW ENFORCEMENT:

None of the funds made available through this grant shall be used to provide training or advice, or provide any financial support, for police, prisons, or other law enforcement forces. The only exception to this restriction is activities that enhance professional capabilities to carry out investigative and forensic functions conducted under judicial or prosecutorial control. The Grantee shall consult with USAID before relying on this exception.

A.12 SUBSTANTIAL INVOLVEMENT UNDERSTANDINGS:

It is understood and agreed that USAID will be substantially involved during performance of this Award as set forth below. The AOTR is not authorized to provide any approvals which would constitute: (1) a change to the scope or objectives of the program described in Attachment B of this Award, which may only be approved by the Agreement Officer; (2) a change to the Award budget set forth in Section A.4 above, unless the Agreement Officer's approval is not required for said budget changes pursuant to 22 CFR 226.25; or (3) an unauthorized commitment as defined in ADS-303.3.18.

1. Approval of specified key personnel
   The following position has been designated as key to the successful completion of the objectives of this award. In accordance with the Substantial Involvement clause of this award, the personnel is subject to the approval of the USAID Agreement Officer’s Technical Representative (AOTR). The Recipient agrees to notify USAID at least 30 days in advance of the diversion of any personnel filling such positions identified below. Further, the Recipient agrees to notify USAID as soon as possible of the removal of any personnel filling such positions identified below.

<table>
<thead>
<tr>
<th>Position</th>
<th>Person</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
</tr>
</tbody>
</table>

2. Substantial Involvements
   i. Approval of Recipient Program Planning Reports and Performance Monitoring Reports per Section: A.7;
   ii. Approval of Sub-Recipients and Sub-Awards;
   iii. Approval of Annual Work Plans; and
   iv. Approval of Key personnel

3. Sub-Recipients and Sub-Awards:
   Pursuant to 22 CFR 226.25(c)(8), whereby the Agreement Officer must approve the sub-award, transfer, or contracting-out of any work under this award an award (except for the purchase of supplies, material, equipment, or general support services) that are not described in the Attachment B of this Award and funded in the approved Award Budget (see Section 1.4 above), the Agreement Officer hereby delegates authority to the AOTR to approve the selection of sub-recipients (as defined in 22 CFR 226.2) and the substantive provisions of the sub-awards (as
defined in 22 CFR 226.2). The AOTR's approval of the substantive provisions of the sub-awards is limited to technical and programmatic matters only; such approval shall not extend to contractual, administrative and financial provisions, which must be in accordance with the terms and conditions of this Award unless otherwise approved, in advance and in writing, by the Agreement Officer.

4. Collaborative Involvement in Selection of Advisory Committee Members:
The AOTR must approve the selection of advisory committee members, and may choose to become a member of such committee. Advisory committees shall only concern themselves with technical and programmatic issues, and not with "contractual, administrative and financial matters."

A.13 ASSOCIATE COOPERATIVE AGREEMENT:

This is an Associate cooperative agreement which has been issued under the MSH Leadership with Associates (LWA) cooperative agreement number GHN-A-00-07-00002-00. This award supports the same program objectives described in the LWA. The original LWA agreement was signed on July 11, 2007. All Mission or Bureau issued awards must be completed within 5 years of the expiration date of the LWA.

A.14. SCHEDULE A AND STANDARD PROVISIONS:

The Schedule A clauses and the Standard Provisions of the Leader Award apply to this Associate Award unless otherwise stated herein.

A.15 RESOLUTION OF CONFLICTS:

Conflicts between any of the Attachments of this Award shall be resolved by applying the following descending order of precedence:

A.16 REPORTING OF FOREIGN TAXES (March 2006):

A. The Recipient must annually submit a report by April 16 of the next year.
B. Contents of Report. The report must contain:
   a) Contractor/Recipient name.
   b) Contact name with phone, fax and email.
   c) Agreement number(s).
   d) Amount of foreign taxes assessed by a foreign government [each foreign government must be listed separately] on commodity purchase transactions valued at $500 or more financed with U.S. foreign assistance funds under this agreement during the prior U.S. fiscal year.
   e) Only foreign taxes assessed by the foreign government in the country receiving U.S. assistance are to be reported. Foreign taxes by a third party foreign government are not to be reported. For example, if an assistance program for Lesotho involves the purchase of commodities in South Africa using foreign assistance funds, any taxes imposed by South Africa would not be reported in the report for Lesotho (or South Africa).
   f) Any reimbursements received by the Recipient during the period in (iv) regardless of when the foreign tax was assessed and any reimbursements on the taxes reported in (iv) received through March 31.
   g) Report is required even if the Recipient did not pay any taxes during the report period.
h) Cumulative reports may be provided if the Recipient is implementing more than one program in a foreign
country.

C. Definitions. For purposes of this clause:

a) "Agreement includes USAID direct and country contracts, grants, cooperative agreements and interagency
agreements.

b) "Commodity" means any material, article, supply, goods, or equipment.

c) "Foreign government" includes any foreign governmental entity.

d) "Foreign taxes" means value-added taxes and custom duties assessed by a foreign government on a
commodity. It does not include foreign sales taxes.

D. Where. Submit the reports to: electronic to kabulfinancialreport@usaid.gov and point of contact at the
Embassy, Mission or FM/CMP as appropriate, see b. below]

E. Sub agreements. The Recipient must include this reporting requirement in all applicable subcontracts, sub
grants and other sub agreements.

F. For further information see http://www.state.gov/m/rm/cl0443.htm.

Attachment A – Schedule 22 CFR 226
Attachment B - Program Description
Attachment C - Standard Provisions
SPECIAL PROVISIONS:

A.17 SECURITY:

The Recipient shall comply with all Government of the Islamic Republic of Afghanistan (GIRoA) and U.S. Government civilian/military agency security policies and orders (COM/FRAG) as they relate to Recipient's activities under this Cooperative Agreement.

Recipient is advised that, as a result of Presidential Decree #82, security requirements for this Cooperative Agreement must be coordinated through the Afghan Ministry of Interior's Afghanistan Public Protection Force (APPF). At the time of award of this Cooperative Agreement, procedures for obtaining security are in transition and Recipient shall closely monitor APPF procedural requirements and implement changes. Recipient shall initiate discussion with APPF regarding security requirements as soon as possible. The APPF will require Recipient to prepare and submit information on several forms. After receipt, APPF will discuss Recipient's specific security requirements in a personal interview. At the time of award of this Cooperative Agreement, the contact persons for this process is Major General Sayed Kamal (Sadat), Director General of Public Protection, 0799-340-490 and 0700-145-575, E-mail generalSadat@yahoo.com (Note: Mr. Sadat is more comfortable communicating in Dari). USAID's, Safety and Security Office will assist with the process and may be reached at kabulaidso@usaid.gov.

The Recipient shall be responsible for providing all life-support and security services required for its personnel deployed to project locations except when it is expressly stated in individual task orders that such facilities and services are to be provided by other means. The Contractor responsibilities shall include all life support, communications, and transportation of materials, personnel, and equipment to work sites. The Recipient may be required to provide the same life-support and security services for USAID personnel when so specified. In addition, the Recipient shall be responsible for maintaining the security of its personnel, materials, and equipment.

The Recipient shall prepare a comprehensive safety and security plan pertaining to all aspects of its activities and the activities of its employees in the performance of all work related to this Cooperative Agreement as well as the off-duty activities of its employees, as those activities relate to performance of contract work, serving in Afghanistan or elsewhere within the region as it relates to performance of the work. The Recipient shall continuously monitor and update this comprehensive safety and security plan by means of qualified and competent staff of personnel. The Recipient shall work closely with and establish liaison and cooperate with all authorized and appropriate safety and security organizations and entities for the protection and safety of its operations and employees.

A.18 NON-FEDERAL AUDITS:

In accordance with 22 CFR 226.26, the Recipient and its sub-recipients are subject to the audit requirements contained in the Single Audit Act Amendments of 1996 (31 U.S.C. 7501-7507) and OMB Circular A-133. The Recipient and its sub-recipients must use an independent, non-Federal auditor or audit organization which meets the general standards specified in generally accepted government auditing standards (GAGAS) to fulfill these requirements.
A. 19 USAID DISABILITY POLICY (DEC 2004):

1. The objectives of the USAID Disability Policy are:

a) to enhance the attainment of United States foreign assistance program goals by promoting the participation and equalization of opportunities of individuals with disabilities in USAID policy, country and sector strategies, activity designs and implementation;
b) to increase awareness of issues of people with disabilities both within USAID programs and in host countries;
c) to engage other U.S. government agencies, host country counterparts, governments, implementing organizations and other donors in fostering a climate of nondiscrimination against people with disabilities; and
d) To support international advocacy for people with disabilities. The full text of the policy paper can be found at the following website: http://www.usaid.gov/about_usaid/disability/.

2. USAID therefore requires that the Recipient not discriminate against people with disabilities in the implementation of USAID funded programs and that it make every effort to comply with the objectives of the USAID Disability Policy in performing the program under this grant or cooperative agreement. To that end and to the extent it can accomplish this goal within the scope of the program objectives, the Recipient should demonstrate a comprehensive and consistent approach for including men, women and children with disabilities.

A. 20 EXECUTIVE ORDER ON TERRORISM FINANCING (FEB 2002):

The Recipient is reminded that U.S. Executive Orders and U.S. law prohibits transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the responsibility of the Recipient to ensure compliance with these Executive Orders and laws. This provision must be included in all Subcontracts/subs awards issued under this contract/agreement.

A.21 FOREIGN GOVERNMENT DELEGATIONS TO INTERNATIONAL CONFERENCES (JAN 2002):

Funds in this agreement may not be used to finance the travel, per diem, hotel expenses, meals, conference fees or other conference costs for any member of a foreign government's delegation to an international conference sponsored by a public international organization, except as provided in ADS Mandatory Reference "Guidance on Funding Foreign Government Delegations to International Conferences" or as approved by the AO.

A.22 BRANDING STRATEGY AND MARKING PLAN:

"Marking Under USAID-Funded Assistance Instruments," the Recipient's Branding Strategy and Marking Plan will be approved after award.

A.23 HOST COUNTRY TAXES AND DUTIES:

The Recipient is advised that equipment, materials, and funds introduced into Afghanistan under the USAID program are exempt from customs duties and taxes of every kind. Accordingly, and in accordance with the applicable U.S. Government cost principles (see 22 CFR 226.27), such costs are unallowable and may not be charged to this Award.
or paid with funding provided hereunder. If the Recipient is assessed any such charges, the Recipient shall bring the proposed assessment to the immediate attention of the Agreement Officer and USAID/Kabul.

A.24 DATA BASE REPORTING REQUIREMENTS:

USAID/Afghanistan uses a management information system to track program and project information for all mission-funded activities. The purpose of this database is to track and monitor development projects, while maintaining coordination between USAID/Afghanistan, USAID/Washington, Congress, implementing partners, the Government of Afghanistan, and other donors. This reporting process supports the Government of Afghanistan’s requirement that USAID provide information to the Ministry of Finance in order to track ongoing and completed donor-sponsored development activities.

The Recipient shall provide at least a quarterly update of information on the activities under the award by entering this information into the USAID/Afghanistan management information system. The Recipient shall enter information via an internet website. USAID will provide the URL address, and a user ID/password. The Recipient shall name one person as the primary point of contact for this information system, who will receive training from the USAID Database Manager to utilize the system. A comprehensive user manual, which will be provided after award, provides detailed information on the required information and processes needed for managing the information in USAID/Afghanistan information system.

A.25 HOMELAND SECURITY PRESIDENTIAL DIRECTIVE (HSPD-12) (SEP 2006):

In response to the general threat of unauthorized access to federal facilities and information systems, the President issued Homeland Security Presidential Directive-12. HSPD-12 requires all Federal agencies to use a common Personal Identity Verification (PIV) standard when identifying and issuing access rights to users of Federally-controlled facilities and/or Federal Information Systems. USAID is applying the requirements of HSPD-12 to applicable assistance awards. USAID will begin issuing HSPD-12 “smart card” IDs to applicable recipients (and recipient employees), using a phased approach. Effective October 27, 2006, USAID will begin issuing new “smart card” IDs to new recipients (and recipient employees) requiring routine access to USAID controlled facilities and/or access to USAID’s information systems. USAID will begin issuance of the new smart card IDs to existing recipients (and existing recipient employees) on October 27, 2007. (Exceptions would include those situations where an existing recipient (or recipient employee) loses or damages his/her existing ID and would need a replacement ID prior to Oct 27, 2007. In those situations, the existing recipient (or recipient employee) would need to follow the PIV processes described below, and be issued one of the new smart cards.)

Accordingly, before a recipient (including a recipient employee) may obtain a USAID ID (new or replacement) authorizing him/her routine access to USAID facilities, or logical access to USAID’s information systems, the individual must provide two forms of identity source documents in original form and a passport size photo. One identity source document must be a valid Federal or state government-issued picture ID. (Overseas foreign nationals must comply with the requirements of the Regional Security Office.) USAID/W recipients (and recipient employee) must contact the USAID Security Office to obtain the list of acceptable forms of documentation, and recipients working in overseas Missions must obtain the acceptable documentation list from the Regional Security Officer. Submission of these documents, and related background checks, are mandatory in order for the recipient (or employee) to receive a building access ID, and before access will be granted to any of USAID’s information systems. All recipients (or employees) must physically present these two source documents for identity proofing at their USAID/W or Mission Security Briefing. The recipient (or employee) must return any issued building access ID and
remote authentication token to USAID custody upon termination of the individual's employment with the recipient or completion of the award, whichever occurs first.

The recipient must comply with all applicable HSPD-12 and PIV procedures, as described above, as well as any subsequent USAID or government-wide HSPD-12 and PIV procedures/policies, including any subsequent applicable USAID General Notices, Office of Security Directives and/or Automated Directives System (ADS) policy directives and required procedures. This includes HSPD-12 procedures established in USAID/Washington and those procedures established by the overseas Regional Security Office. In the event of inconsistencies between this clause and later issued Agency or government-wide HSPD-12 guidance, the most recent issued guidance should take precedence, unless otherwise instructed by the Agreement Officer.

The recipient is required to include this clause in any sub-awards (including subcontracts) that require the sub-awardee or sub-awardee employee to have routine physical access to USAID space or logical access to USAID's information systems.

A.26 SPECIAL PROVISION FOR PERFORMANCE IN AFGHANISTAN (JULY 2010):

All recipient personnel deploying to Afghanistan under grants or cooperative agreements with a performance period over 30 days or valued at more than $100,000 must be accounted for in the Department of Defense maintained Synchronized Pre-deployment and Operational Tracker (SPOT) system. Information about SPOT is available at http://www.dod.mil/bta/products/spot.html as well as from the Agreement Officer (AO) or Agreement Officer’s Technical Representative (AOTR). Recipient shall register those individuals requiring SPOT-generated Letters of Authorization (LOAs) in SPOT before deploying any employees or consultants to Afghanistan. If individuals are already in Afghanistan at the time the recipient employs them, the recipient must enter each individual upon his or her becoming an employee or consultant under this award. Personnel that do not require LOAs are still required to be accounted for in SPOT for reporting purposes either individually or via an aggregate methodology. The recipient must maintain and keep current all employee and consultant data in SPOT. Information on how individual and/or aggregate tally registrations will be made in SPOT is available from the Agreement Officer (AO) or Agreement Officer’s Technical Representative (AOTR).

Recipient performance may require the use of armed private security personnel. To the extent that such private security contractors (PSCs) are required, recipients are required to ensure they adhere to Chief of Mission (COM) policies and procedures regarding the operation, oversight, and accountability of PSCs. PSCs will be individually registered in SPOT.

Under this award, the term “PSC” includes any personnel providing protection of the personnel, facilities, or property of a recipient or sub recipient at any level, or performing any other activity for which personnel are required to carry weapons in the performance of their duties. As specific COM policies and procedures may differ in scope and applicability, recipient is advised to review post policies and procedures carefully in this regard and direct any questions to the Embassy Regional Security Office (RSO) via the Agreement Officer’s Technical Representative.

Any exception to these policies must be granted by the COM via the RSO. A copy of any exception must be provided to the AO and AOTR. COM policies and procedures may be obtained from the RSO via the Agreement Officer’s Technical Representative. Recipient is also advised that these policies and procedures may be amended from time to time at the post in response to changing circumstances.
Recipient is advised that adherence to these policies and procedures is considered to be a material requirement of this grant/cooperative agreement. The recipient must include this provision in all sub-awards at any tier or contracts under their grant/cooperative agreement.

Recipient is reminded that only the Agreement Officer has the authority to modify the Notice of Award. Recipients shall proceed with any security guidance provided by the RSO, but shall advise the Agreement Officer and the Agreement Officer’s Technical Representative of the guidance received and any potential cost or schedule impact.

A.27 SERIOUS INCIDENT REPORTING IN AFGHANISTAN (DECEMBER 2010):

The implementing partner is responsible for reporting all serious incidents during performance of the award. This reporting shall apply to the prime implementing partner and all sub-awardees regardless of the tier (subs of subs and lower, etc). In addition to reporting, the prime is responsible for ensuring timely investigation of all serious incidents and maintaining on file all records of reported serious incidents.

A serious incident is defined as any of the following against an employee paid for with US Government funding or on a USAID funded worksite regardless of the tier of the employee:

1. Death of an individual,
2. Discharge of a firearm with the intent to cause bodily injury or the use of an instrument with the intent of causing serious bodily harm to an employee,
3. The detention of an employee against their will.

Implementing partners shall provide initial notification to the USAID Safety and Security Office (SSO), either orally or by email, of any serious incident - as soon as practical if it practical if it cannot be done immediately. The emails shall be sent to: KabulAIDSSO@usaid.gov. This notification must provide as many details as are known at the time about of the incident.

Within 24 hours of the incident, the implementing partner shall submit a more formal written incident report. The prime partner shall provide the report to the SSO and will concurrently send a copy to the USAID Cognizant Contracting/Agreement Officer’s Technical Representative (AOTR) and the Agreement Officer (AO).

The initial written report shall include the award number, the name of the company, location where the incident occurred (Latilon or MGRS), time when the incident occurred, a brief description of the events of the incident, details about any known casualties and a point of contact for the company.

The implementing partner shall provide a follow-up comprehensive written report of events surrounding the incident within 96 hours when greater details are known. Additionally, if a serious incident which involves an employee wounded in action (WIA) who later succumbs of the wound(s), the partner shall notify the SSO within 24 hours of the death of the individual.

A.28 GENDER INTERGRATION REQUIREMENTS (DECEMBER 2010):

USAID programs must address the needs and protect the rights of women and girls in Afghanistan. Therefore, USAID requires recipients to undertake efforts to prevent discrimination and violence against women and girls, provide economic and leadership opportunities, increase participation of women in the political process, improve security for women and girls, promote education, health and well-being, and other efforts designed to directly benefit women and girls. The Recipient shall integrate assistance to women into all aspects of development, planning, programming and implementation, as a part of this assistance program. Such integration shall contribute to the three
pillars of development outlined in the ten-year National Action Plan for the Women of Afghanistan (NAPWA) 1) Security; 2) Government, Rule of Law, and Human Rights; and 3) Economic and Social Development. The Recipient shall establish the necessary implementation, management and reporting systems to separately track and report to USAID data on female beneficiaries and measurable impacts of activities intended to address the needs of women and girls. It is expected that the relevant indicators on female beneficiaries and impacts of activities on the needs of women and girls will vary by project. However, relevant indicators may include items such as:

1) The total number of women and girls supported through the agreement on a quarterly basis through Afghan Info;

2) Number of women accessing basic services, including education and health;

3) Number of interventions leading to increased employment and economic opportunities for women, as well of number of beneficiaries;

4) Number of interventions resulting in increased participation of women in government and civil society;

5) Number of activities supporting legal rights and public access for women; and,

6) Outcomes for women who have benefited from the agreement. The Recipient shall refer to USAID/Afghanistan’s comprehensive Performance Management Plan (PMP) for complete list of gender indicators. To the extent possible, indicators applicable to the agreement will be disaggregated by gender.

A.29. USAID AFGHANISTAN IMPLEMENTING PARTNER NOTICES:

The Recipient of this award shall comply with and adhere to all USAID Afghanistan Implementing Partner Notices. Copies of the notices are provided to implementing partners at the time of issuance. Copies are also available upon request from your cognizant Agreement Officer.

A.30. ASSOCIATE AWARDS:

1. This Cooperative Agreement is being issued under a Leader/Associate type award. The Leader/Associate agreement covers worldwide activities and provides that Missions and Bureaus may fund “Associate” Grants or Cooperative Agreements under the leader Agreement. No further competition or waiver of competition is required for any Associate award. Competition was considered met during the initial Leader RFA process. In this manner, USAID missions or bureaus may fund specific awards without further competition.

2. Associate Awards must be awarded before the expiration date of the Leader Cooperative Agreement. All Mission or Bureaus-issued Associate awards must be completed no later than five years after the expiration date of the Leader Cooperative Agreement. There is no stated dollar limit on the total amount of Associate Awards which may be issued under the Leader Agreement. The Leader Agreement and each individual associate award will specify the total award for that instrument.

3. Associate awards, while subject to the Standard Provisions, will not include the Standard Provisions in the Associate award document. The Mandatory Standard Provisions of the Leader agreement shall automatically apply to the Associate Awards. The “Required” as “Applicable” standard provisions shall also apply automatically to the Associate Awards, unless the cognizant Associate Agreement or Grant Officer adjusts the “Required as Applicable” Standard Provisions from those included in the Leader Agreement, if appropriate.
4. Associate Award numbering shall be independent of the Leader Agreement award number. Bureaus or missions shall assign their own Associate Award Numbers.

5. Associate Cooperative Agreements “Substantial Involvement” provisions will be defined in its terms. Such substantial involvement must be consistent with the Program Description in the Leader Agreement as well as the Program Description of the particular Associate Cooperative Agreement.

6. Prior to award of an Associate Grant/Agreement, the recipient must affirm that certifications provided prior to award of the Leader agreement remain valid, or provide new certifications.

7. Associate award cost sharing requirements may vary from the Leader Agreement cost-sharing requirement, at the determination of USAID.

8. The cognizant mission or bureau issuing an Associate Award shall be responsible for the administration of that Award.

A.31. AFGHANIZATION:

The recipient will be evaluated on the selection of qualified Afghan Key and non-key personnel to improve Afghan participation in the implementation of the MSH/SPS project, to foster greater AID Effectiveness, to facilitate local buy-in and to increase Afghanization of program activities. If an expatriate Chief of Party is identified, the Recipient should identify a Deputy Chief of Party that can be trained to assume the Chief of Party role.

The key personnel specified above are considered to be essential to the work performed hereunder. Prior to replacing any of the specified individuals, the Recipient shall immediately notify both the Agreement Officer and Agreement Officer’s Technical Representative (AO-TR) reasonably in advance and shall submit written justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. No replacement of key personnel shall be made by Recipient without the written consent of the Agreement Officer.

A.32. VETTING:

I. 4-14.001 (the Contracting Officer shall modify as appropriate for assistance awards)

Information for Non-US contractors, subcontractors, and key individuals.

(a) The contractor must complete and submit the “USAID Information Form” in appendix B. for:

(i) If it is a non-U. S. entity;

(ii) Each subcontractor or subcontractor of a subcontractor, regardless of the tier, that is a non-U.S. entity; or

(iii) Each key individual that is a non-U.S. entity.

(b) For purposes of this clause, the following definitions apply:

“Non-U.S. entity” means (1) any non-US citizen or non-permanent legal resident of the United States: or (2) any entity that is not formed in the United States or for which 50% or more of the equity is owned or controlled by persons who are not U.S. citizens or permanent legal residents of the United States.

“Key individuals” means (i) an individual or entity owning 10% or more equity stake in the organization, whether publically- or privately-held: (ii) principal officers of the organization’s governing body (e.g., chairman, vice chairman, treasurer or secretary of the board of directors or board of trustees); (iii) the principal officer and deputy principal officer of the organization (e.g., executive director, deputy director, president, vice president); (iv) the program manager or chief of party for the USA ID-financed program; and (v) any other person with significant responsibilities.
for administration of USAID financed activities or resources.

(c) The requirements of paragraph (a) of this clause must be completed at prior to the Government's acceptance of the contract and following that, at the earlier of:

(i) Once a year; or
(ii) When there is a change or addition to any entity or person identified in paragraph (a).

(d) USAID reserves the right to rescind approval for a sub-award in the event that USAID subsequently becomes aware of information indicating that the sub-award is contrary to U.S. law or policy prohibiting support for terrorism, or facilitating criminal activity. In such cases, USAID's Contracting Officer will provide written instructions to the recipient to terminate the sub-award.

(End of Provision)

II. 4-14.002 (Assistance Awards shall use the ATC as set forth in Appendix D)

Certification Regarding Provision of Support to Persons Engaged in Terrorism

(a) By entering into this contract, the contractor certifies, to the best of its knowledge and belief that:

1. The Contractor, to the best of its current knowledge, did not provide, within the previous ten years, and will take all reasonable steps to ensure that it does not and will not knowingly provide, material support or resources to any individual or entity that commits, attempts to commit, advocates, facilitates, or participates in terrorist acts, or has committed, attempted to commit, facilitated, or participated in terrorist acts, as that term is defined in paragraph 3.

2. The following steps may enable the Contractor to comply with its obligations under paragraph 1:

a. Before providing any material support or resources to an individual or entity, the Contractor will verify that the individual or entity does not (i) appear on the master list of Specially Designated Nationals and Blocked Persons, which list is maintained by the U.S. Treasury's Office of Foreign Assets Control (OFAC) and is available online at OFAC's website: http://www.treas.gov/offices/otff/ocaf/sdn/ldsn.pdf, or (ii) is not included in any supplementary information concerning prohibited individuals or entities that may be provided by USAID to the Contractor.

b. Before providing any material support or resources to an individual or entity, the Contractor also will verify that the individual or entity has not been designated by the United Nations Security (UNSC) sanctions committee established under UNSC Resolution 1267 (1999) (the "1267 Committee") [individuals and entities linked to the Taliban, Osama Bin Laden, or the Al Qaeda Organization]. To determine whether there has been a published designation of an individual or entity by the 1267 Committee, the Contractor should refer to the consolidated list available online at the Committee's website: http://www.11n.org/Docs/sc committees/1267/1267ListHng.htm.

c. Before providing any material support or resources to an individual or entity, the Contractor will consider all information about that individual or entity of which it is aware and all public information that is reasonably available to it or of which it should be aware.

d. The Contractor also will implement reasonable monitoring and oversight procedures to safeguard against assistance being diverted to support terrorist activity.

3. For purposes of this Certification:
a. "Material support and resources" means currency or monetary instruments or financial securities, financial services, lodging, training, expert advice or assistance, safe houses, false documentation or identification, communications equipment. Facilities, weapons, lethal substances, explosives, personnel, transportation, and other physical assets, except medicine or religious materials.*

b. "Terrorist act" means-
   (i) An act prohibited pursuant to one of the 12 United Nations Conventions and Protocols related to terrorism (see UN terrorism conventions Internet site: http://untreaty.iai.org/English/Terrorism.asp); or
   (ii) An act of premeditated, politically motivated violence perpetrated against noncombatant targets by sub-national groups or clandestine agents; or
   (iii) Any other act intended to cause death or serious bodily injury) to a civilian, or to any other person not taking an active part in hostilities in a situation of armed conflict, when the purpose of such act, by its nature or context, is to intimidate a population, or to compel a government or an international organization to do or to abstain from doing any act.

c. "Entity" means a partnership, association, corporation, or other organization, group or subgroup.

d. References in this Certification to the provision of material support and resources shall not be deemed to include the furnishing of USAID funds or USAID-financed commodities to the ultimate beneficiaries of USAID assistance, such as recipients of food, medical care, micro-enterprise loans, shelter, etc., unless the Contractor has reason to believe that one or more of these beneficiaries commits, attempts to commit, advocates, facilitates, or participates in terrorist acts, or has committed, attempted to commit, facilitated or participated in terrorist acts.

e. The Contractor's obligations under paragraph 1 are not applicable to the procurement of goods and/or services by the Contractor that are acquired in the ordinary course of business through contract or purchase, e.g., utilities, rents, office supplies, gasoline, etc., unless the Contractor has reason to believe that a vendor or supplier of such goods and services commits, attempts to commit, advocates, facilitates, or participates in terrorist acts, or has committed, attempted to commit, facilitated or participated in terrorist acts.

(b) By entering into this contract, the Offeror acknowledges that it has a continuing obligation and shall notify the Contracting Officer within 72 hours in writing if it has intentionally or unintentionally taken any actions that have the result and effect of being inconsistent with the certification in subsection (a) of this clause.

(c) The certification in paragraph (a) of this provision and the requirement to update the contracting officer as to a change in status as set forth in paragraph (b) are material representations upon which reliance was placed when making award. If it is later determined that the Offeror knowingly rendered an erroneous certification, or did not notify the contracting officer in writing of a change in such certification, in addition to other remedies available to the Government, the Contracting Officer may terminate the contract resulting from this solicitation for default.

(End of provision)

III. Restrictions on certain foreign purchases (June 2008)

(a) Except as authorized by the Office of Foreign Assets Control (OFAC) in the Department of the Treasury, the Contractor shall not acquire, for use in the performance of this contract, any supplies or services if any proclamation, Executive order, or statute administered by OFAC, or if OFACs implementing regulations at 31 CFR Chapter V, would prohibit such a transaction by a person subject to the jurisdiction of the United States.
(b) Except as authorized by OFAC, most transactions involving Cuba, Iran, and Sudan are prohibited, as are most imports from Burma or North Korea, into the United States or its outlying areas. Lists of entities and individuals subject to economic sanctions are included in OFAC’s List of Specially Designated Nationals and Blocked Persons at http://www.treas.gov/offices/enforcement/ofac/sdn. More information about these restrictions, as well as updates, is available in the OFAC’s regulations at 31 CFR Chapter V and/or on OFAC’s website at http://www.treas.gov/offices/enforcement/ofac.

(c) The Contractor shall insert this clause, including this paragraph (c), in all sub-contracts.

[In addition to the clauses set forth above, the following clause shall be included in any contract, grant or cooperative agreement awarded by USAID (i.e. USAID prime awards only)]

(d) Before awarding any grant or similar instrument, the Contractor/Recipient shall obtain from the proposed sub-awardee the certification required under USAID’s Acquisition and Assistance Policy Determination 04-14 (AAPD 04-14), “Certification Regarding Terrorist Financing Implementation E.O. 13224 (Revision 2)

(End of provision)
ATTACHMENT B – (MSH) PROGRAM DESCRIPTION

Executive Summary:

In this application, the Strengthening Pharmaceutical Systems (SPS) Program has developed a four-year plan to provide technical assistance to address specific constraints hampering health program development in Afghanistan and contributes to the U.S. Agency for International Development (USAID) | Afghanistan’s strategic objective: a better educated and healthier population. This program is designed to improve the regulatory system, supply chain management, human resource capacity, pharmaceutical services, and information systems. Under the proposed SPS/Afghanistan program and in line with the USAID/Afghanistan objectives and the Ministry of Public Health’s (MoPH) strategic plans, SPS will focus on health systems strengthening in the pharmaceutical sector using the core principles and approaches below.

Core Principles and Approaches:

The SPS Program is recognized for helping countries successfully strengthen supply chain management to help increase access to essential medicines, and also address a wide range of pharmaceutical management issues that help improve overall health outcomes, such as governance, standards for pharmaceutical services, pharmacovigilance, rational medicine use and antimicrobial resistance, integrating new health technologies, and the role of the private sector. SPS widely shares the strategies, interventions, and materials developed as part of its work with other SPS countries to adapt and use.

- Base country-specific technical assistance on a sound, evidence-based situational analysis of the strengths and weaknesses of the pharmaceutical management system;
- Implement the program of work with a focus on solving immediate problems and demonstrating results while contributing to longer-term system strengthening and developing the knowledge and skills of in-country institutions and partners;
- Use systematic, generic tools and solutions as much as possible while meeting customized client needs to improve access to and use of medicines of assured quality;
- Be responsive to client requests for assistance while simultaneously ensuring consistency with the program’s objectives and intermediate results;
- Promote coordination of donor and host-country provision of medicines for population, health, and nutrition programs; and
- Provide the best advice based on global experience and lessons learned, a firm understanding of USAID policies and regulations relating to pharmaceuticals, as well as an understanding of host country government policies, regulations, and practices.

Using these core approaches, SPS will meet the stated results in each of the five technical objectives as follows:
Strengthen the Regulatory System:

A functional drug regulatory system is required to ensure the safety, efficacy, and quality of medicines. The initial step of strengthening the capacity of medicines regulation is to establish a common understanding of the priority needs and agree on a regulatory framework through consensus building. Key challenges in Afghanistan include a lack of access to technical expertise related to regulating medicine and processed food products, poor coordination and communication among existing departments, and inadequate human resource competency needed to achieve a functioning regulatory body.

MS H proposed interventions to achieve this objective include:

• Support the MoPH by developing and implementing strategies to establish a functional regulatory framework, taking into account existing systems and resource constraints;
• Help the MoPH create and implement a plan for the development and update of required laws, regulations, and policies to support the regulatory system;
• Assist the MoPH with all consensus-building processes necessary to secure the support of all stakeholders to strengthen the regulatory system;
• Support the MoPH with the development and implementation of a comprehensive strategy and implementation plan to address medicines quality assurance and secure buy-in of stakeholders, including the private sector supply chains;
• Work with General Directorate of Pharmaceutical Affairs (GDPA) to improve the quality of products and services in private sector pharmacies and drug shops; and
• Help the GDPA improve pharmaceutical waste management.

Improve supply chain management and commodity security to assure product availability

With the current Tech-Serve project due to end, pharmaceutical supply chain activities need to continue uninterrupted. Moreover, persistent stock shortages indicate room for improvement, and for the long term, the MoPH’s capacity and resources to oversee medical supply activities fall short of what it needs to assume full responsibility without threatening the security of the medicine supply system. Without adequate MoPH capacity, planning beyond the life of donor support is difficult.

SPS has also been helping the MoPH establish a Coordinated Procurement and Distribution System (CPOS) to address issues such as information sharing and efficient use of available resources and to provide the MoPH with a clearer picture of the structure and effectiveness of the pharmaceutical supply system.

SPS proposes the following activities:

• Develop a detailed transition plan for the integration of Tech-Serve drug management staff, infrastructure, and responsibilities into SPS/Afghanistan;
• Help build the GOP’s institutional capacity to assume responsibility for procurement, storage, and distribution;
• Help establish and implement a system of good governance to ensure transparency and efficiency in supply chain management and commodity security, particularly procurement practices;
• Assist the members of the CPOS committees with the development and implementation of strategies and technical interventions to assure product quality and availability;
• Provide technical assistance to support the development of a quantification system to support procurement planning; and
Support the MoPH with developing and implementing a system to coordinate and standardize an information system to manage the procurement and supply of medicines and health commodities. Build human resource capacity for effective service delivery.

SPS has been partnering with MoPH and GDPA to build capacity in pharmaceutical systems strengthening, management, and services. However, to carry out the activities in this application, we need to comprehensively examine and strengthen all aspects of pharmaceutical human resources development across all areas of the pharmaceutical sector. Therefore, this objective is cross-cutting in its approach and links to the other four technical objectives.

SPS will conduct an assessment that will characterize the human resources situation in the country's pharmaceutical sector and guide the development of interventions. Proposed activities in support of this objective include:

- Help build MoPH capacity to make plans related to pharmaceutical sector human resources;
- Assist the MoPH to improve pharmaceutical sector human resources management (recruitment, retention, and job descriptions);
- Help the MoPH develop and implement a human resource strategy (training plan);
- Provide technical assistance to develop pharmaceutical management training materials and implement associated training; and
- Provide technical assistance to the pharmacy education institutions to incorporate modern pharmaceutical management concepts in their curricula.

Enhance pharmaceutical services to achieve desired health outcomes.

Comprehensive pharmaceutical services are critical to a health care system and to achieving good health outcomes. Historically, Afghanistan's pharmaceutical services have been minimally developed and delivery has been a low priority. Challenges to providing pharmaceutical services include (among others) the lack of education and knowledge among prescribers and dispensers at all levels of the health care system. However, recent advocacy efforts have helped highlight the importance, and the MoPH is now strongly supporting the idea of improving pharmaceutical services, especially those that promote rational medicine use.

SPS proposes the following set of interventions to support pharmaceutical services and rational medicine use:

- Provide technical assistance to MoPH and standard treatment guideline working groups to develop and roll out treatment guidelines to primary health facilities and hospitals;
- Support development of adequate training materials for pharmaceutical services that target prescribers and dispensers;
- Support the appropriate functioning of national, regional, provincial, and institutional drug and therapeutics committees to oversee the implementation of rational medicine use strategies and interventions;
- Improve the capacity of GDPA, non-governmental organizations (NGOs), and health facilities to support the provision of pharmaceutical services in the public and private sectors; and
- Assess the existing elements of the Afghanistan pharmacovigilance and adverse drug reaction systems and suggest phased interventions.
Address the information for decision-making in the pharmaceutical sector.

An effective pharmaceutical management information system (PMIS) is able to synthesize the large volume of data generated by pharmaceutical management operations. It then processes the data into information for use in planning activities, estimating demand, allocating resources, and monitoring and evaluating pharmaceutical management operations. This information is often in the form of key indicators. Staff at all levels should have appropriate indicators to monitor both their own performance and that of the units for which they are responsible. Such indicators would need to be developed for the Afghanistan system in coordination with the health management information system. An essential function of a PMIS is to improve accountability. Much of the recording and reporting in a PMIS is intended to create an audit trail for products as they enter or leave a pharmaceutical supply system. A PMIS should also have a mechanism to provide feedback to the reporting centers and stakeholders.

Interventions include:

- In collaboration with other relevant U.S. and Afghan government partners and counterparts involved in both supply chain and health management information systems, support the development and implementation of a comprehensive PMIS for the recording, reporting, analysis, and presentation of patient- and product-related data to support decision making;
- Provide continued support to the paper-based and other existing forms of management information systems as required; and
- Ensure collation of information related to medicine use outcomes (such as adherence indicators, adverse drug reactions) for pharmaceutical policy, medicine selection decisions, and treatment options.

To achieve the program objectives, MSH proposes an organizational structure that will ensure adequate linkages with MoPH counterparts at the central and peripheral levels and with other implementing partners and stakeholders critical in health services delivery. The SPS/Afghanistan team will be led by a Chief of Party, Zafar Omari. Since 2005, Mr. Omari has worked for MSH to strengthen pharmaceutical management in Afghanistan - first with the REACH project, then as a Deputy Program Manager for Tech-Serve, and now as the Country Team Leader for SPS.

MSH, a non-profit organization with 39 years' experience in more than 100 countries, has successfully carried out technical assistance, capacity building, and systems development in family planning/reproductive health, maternal health, child health, pharmaceutical management, and prevention and mitigation of infectious diseases such as HIV/AIDS, tuberculosis, and malaria. In addition, MSH has a history of working effectively to achieve results in the challenging Afghanistan environment.

SPS Health Systems Strengthening Strategy

Management Sciences for Health's (MSH) application responds to the Request for Application issued by U.S. Agency for International Development (USAID)/Afghanistan for the Strengthening Pharmaceutical Systems (SPS) Associate Award for Afghanistan. USAID/Afghanistan developed the program description to implement a four-year program focusing on the following five technical areas:

- Strengthen the regulatory system;
- Improve supply chain management and commodity security to assure product availability;
- Build human resource capacity for effective service delivery;
- Enhance pharmaceutical services to achieve desired health outcomes; and
- Ensure collation of information related to medicine use outcomes (such as adherence indicators, adverse drug reactions) for pharmaceutical policy, medicine selection decisions, and treatment options.

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Address the information for decision-making challenge in the pharmaceutical sector.

This new program is intended to build on the strengths of existing USAID/Afghanistan programs and form part of the Agency's health systems strengthening support to Afghanistán.

SPS develops country-specific technical strategies to improve pharmaceutical management by developing capacity within a country's frame of reference and by fostering collaboration between countries and institutions within those countries.

SPS widely shares the strategies, interventions, materials, and lessons learned among SPS countries to ensure that all SPS programs learn from each other and adapt and apply the most successful tools and approaches.

Below are the core principles that make up MSH technical approach. Each includes a discussion of each challenge and MSH experience in addressing it through the Leader with Associate and where applicable the tangible results.

Basing Country-Specific Technical Assistance on a Sound, Evidence-Based Situation Analysis of the Strengths and Weaknesses of the Pharmaceutical Management System.

SPS and the MSH Center for Pharmaceutical Management believe strongly that technical assistance strategies must be based on a clear understanding of the system-specific problems that reduce access to medicines and the root causes of those problems.

MSH approach involves a structured survey in collaboration with stakeholders, combining political mapping with an assessment of the capacities of existing public, commercial, and non-governmental supply chain systems. We then work with stakeholders to identify and implement the most cost-effective strategies to solve existing problems to assure that appropriate high-quality medicines are available where and when patients need them.

SPS has completed more than 20 full pharmaceutical system assessments worldwide and multiple other targeted assessments on child health, HIV/AIDS, tuberculosis (TB), and malaria programs, all based on MSH broad view of the pharmaceutical system (figure 1).

SPS has worked with over 40 countries to strengthen specific aspects of their pharmaceutical management systems based on these assessments.
collaborated on initiatives. An example of this is the Notice about the development of an inventory management and distribution tool.

By the end of 2020, more than 600 stakeholders, including government officials, civil society, and private sector representatives, were involved in the design and implementation of the tool.

The most recent resource-constrained countries can use the Notice about the development of an inventory management and distribution tool. We provided technical assistance to counterparts to gain more in-depth understanding of how to achieve meaningful results.

In addition, SPS /Ethiopia is now engaged in establishing and strengthening DTCs in Ethiopia, for example, SPS will continue to support the DTCs, with USAID / Ethiopia and the Ethiopian government's Pharmaceutical Supply Agency (PFSA), to achieve their objectives.

The Notice about the development of an inventory management and distribution tool has been revised to include how to use and train trainers in inventory management and distribution.

Figure 1. The Pharmaceutical System
improving treatment adherence, among others. Nationally, regionally, and facility staff as interventions.

Institutional framework that mandates action for national rollout. The extended

Providing the Best Advice Based on

DELIVER, Supply Chain USAID Ethiopia context and with mandate and assure the sustainability of their interventions after we are gone.

Government country experiences.

are developed in options analysis which identifies the problems around access to medicines and their root causes. Then interventions technically interventions are designed to fit within host-country policies and regulations. Where appropriate,

As noted above, weak oversight. To tackle these issues,

In process, pharmaceutical management strengthening issues, involvement demonstrates MoH recognition of host countries amend regulations and policies to national standards for pharmaceutical systems strengthening in Kenya. For example, training curricula on various aspects of pharmaceutical management, such as commodity management, pharmacovigilance, supportive supervision, and quantification have been adopted on a national level. In some cases, the best approach is to implement existing systems and tested and proven in other countries; in other cases, the best approach may be to develop country-specific technical strategies based on a collaborative assessment and

The SPS Policies and Regulations Relating to Pharmaceuticals, as

SPS tools with missions and other stakeholders, based on lessons learned from many other

SPS countries.

SPS/USAID has produced a document that outlines

SPS and DFID help

PharmaDex for drug registration, RxSolution for inventory management, Quantimed for dispensing drugs, and SPS/PATH for diagnostics.

The SPS Program Leader with Associate is managing core software for country programs implement and use as representatives of other partners and other platforms to effectively implement their

MSH System, and other partners to use this platform to effectively implement their

MSH Phannaceutical quantification and cost estimations, and e-TB Manager for TB medicine and case management.

The

tools are currently available for drug registration, RxSolution for inventory management, Quantimed for dispensing drugs, and SPS/PATH for diagnostics.

Equipment and personnel are in place, and facilities are online. In some cases, the best approach is to implement existing tools that are best suited to the country context, while

SPS/PATH tries to find the most cost-effective solution to

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When appropriate, SPS tools are harmonized based on a cross-cutting system strengthening approach to incorporating different disease-specific frameworks (i.e., HIV/AIDS, malaria, TB, maternal and child health) into each software tool. For instance, RPM Plus's original Antiretroviral Dispensing Tool was expanded to become the EDT, which manages dispensing for all medicines. Adherence indicators have now been added in accordance with the International Network for the Rational Use of Drugs Initiative on Adherence to Antiretrovirals and WHO guidelines. The new version of the EDT is being used in Ethiopia and in Namibia, SPS finalized EDT-mobile specifications and architecture—a version for field use that would be available to Afghanistan. PharmDex, RxSolution, and e-TB Manager have all been upgraded and expanded to include new features, to interface more easily with other software systems and web-based tools, and to serve users in other languages in addition to English. For example, EDT has been translated into French and e-TB Manager is available in English, Spanish, French, Russian, Ukrainian, Bahasa, Armenian, Azerbaijani, and Chinese.

Promoting Coordination of Donor and Host-Country Provision of Medicines for Population, Health, and Nutrition Programs

MSH, through its Center for Pharmaceutical Management projects and the SPS Leader award, has developed cordial relationships with virtually every international organization and agency working in the field of pharmaceutical and supply chain management, and we have a proven history of successfully engaging donors and other stakeholders at all levels—global, regional, national, and local. For example, SPS partnered with the Global Fund to Fight AIDS, Tuberculosis and Malaria to develop the pharmaceutical and health products management profile tool and revise its local funding agent and principal recipient assessment and report tools. The Global Fund will require countries making future grant applications to use the new country profile to provide a more standardized, structured, and informative overview of the pharmaceutical system required to manage essential medicines and health supplies. As part of the collaboration, we helped the Global Fund introduce the tool at a workshop in West Africa, and we serve as a technical assistance resource to directly assist countries when requested. Through this activity, SPS is helping coordinate Global Fund activities at the country level, thereby helping decrease bottlenecks that might limit countries' ability to provide medicines. SPS carefully cultivates MSH ties and partnerships at global and national levels, knowing that collaboration with a wide variety of stakeholders—even competitors—is the best and most efficient way to accomplish program goals.

Implementing the program of work with a focus on solving immediate problems and demonstrating results while contributing to longer-term system strengthening and developing the knowledge and skills of in-country institutions and partners

As mentioned, the SPS technical strategy is based on identifying the most urgent problems that restrict a country's access to medicines and working with stakeholders to develop strategies to solve those problems. However, SPS plans its technical activities based on the goal of long-term strengthening of the overall pharmaceutical management system, and SPS understands that building in-country technical and management capacity is the only route to sustainable system strengthening.

Building local capacity strengthens in-country leadership to improve quality of services provided and ensure sustainability. MSH capacity-building model (figure 2) describes nine separate but interdependent components of capacity. MSH uses needs assessment methodology to determine at which of these levels interventions will have the biggest impact, be most powerful, and be efficient. When training is required to build capacity, MSH believes that the optimal approach places responsibility for implementing best practices learned in the hands of local staff.
When USAID/Kenya approached SPS to provide technical support for the Kenya Medical Supplies Agency (KEMSA), which has had a history of corruption and mismanagement, KEMSA was again embroiled in controversy, dealing with the removal of its entire management team. Through Millennium Challenge Account funding, SPS was asked to help KEMSA get through its immediate crisis, but also, in the longer term, to help improve KEMSA's transparency and accountability in the health sector, provide technical assistance to identify weaknesses, and make recommendations for further system strengthening to accomplish KEMSA's mission as outlined in their 2007-2010 business plan.

SPS conducted a comprehensive assessment of KEMSA which resulted in short-, mid-, and long-term recommendations. Both the KEMSA Board of Directors and the Ministerial Task Force adopted the recommendations for implementation. As a result, SPS has worked with KEMSA to build system-wide governance strengthening approaches such as department-specific standard operating procedures and key performance indicators. For example, a result of one of the short-term recommendations to improve transparency was SPS helping KEMSA expand its website to allow public visibility of commodity delivery schedules and tender prices.

Afghanistan Technical Strategy Overview of SPS/Afghanistan Activities:
In 2008, the USAID Mission invited MSH's SPS Program to render technical assistance and support to the Government of Afghanistan's MoPH to improve the pharmaceutical system. In October 2008, SPS established a country office in Kabul, and since then, SPS has been working closely with the MoPH to (1) improve the use of medicines, (2) build MoPH's capacity to manage pharmaceutical services, (3) build the capacity of the MoPH to ensure the quality of pharmaceutical products, (4) establish a coordinated procurement and distribution system, and (5) design a system for USAID procurement of pharmaceuticals to be used after the conclusion of the Tech-Serve Project.

Since establishing the country office, SPS has assisted the MoPH in Afghanistan with pharmaceutical management interventions at both national and peripheral levels. At national level, SPS has provided technical assistance to the...
Institutions to integrate the components of pharmaceutical management into General competent medicines coordinating mechanisms are in and quality of medicines. Key effective, and of appropriate drug reactions monitoring, and developing measurable distribution, and management information systems. At the through a facilities functions must work in concert to protect from the Coordinated pharmacovigilance activities. MSH activities are an initiative of the Government of Afghanistan with the aim of ensuring that appropriate medicines, especially those related to regulatory authority, and appropriate enforcement are needed to ensure the safety, efficacy, and quality.

To measure progress toward these objectives, MSH is proposing activities for the Associate Award that contributes to the Coordinated pharmaceutical system staffed with more technical support decision making, enhance the government of Afghanistan's health better educated population. To achieve five objectives described in the Request for Assistance to address specific constraints hampering development of pharmaceutical management information systems that maximize the purchasing power of donor funds and resources, and coordinated process.

1. Strengthen the technical human resource capacity for effective service delivery. SPS will leave peripheral level, SPS, and developing curricula and conducting training in pharmaceutical management for pharmacy staff.

2. Strengthen the supply chain management and commodity security to assure product availability.

3. Address the information for decision-making. SPS will leave the Coordinated Procurement System that can support the country's strategies for improving access to the Essential Package.

4. Build and institutional capacity, develop systems and institutional capacity, and increase capacity to carry out hazardous population. SPS will leave the Coordinated Procurement System that can support the country's strategies for improving access to the Essential Package.

5. Address the information for decision-making. SPS will leave the Coordinated Procurement System that can support the country's strategies for improving access to the Essential Package.
The GDA, under the supervision of the MoPH, has the primary mission of providing equitable pharmaceutical services for all people in Afghanistan in the public and private sectors.

In addition, the National Food and Medicines Board (NFMB), established in October 2009, is a stand-alone, independent board with jurisdiction over the quality of food and medicines. The NFMB is not situated within the MoPH or the GDA, but it does report directly to the Minister of Public Health.

The NFMB is comprised of individuals from several institutions, including the relevant ministries, international and national organizations, associations, the private sector, and academia.

Other entities that are part of the regulatory system include the Avicenna Pharmaceutical Institute, which previously produced generic pharmaceuticals, but has new terms of reference that focus primarily on improving pharmaceutical management and supporting rational medicine use.

The Pharmaceutical Enterprise is a semi-autonomous entity under MoPH that is now tasked with developing Afghanistan's pharmaceutical and health supply manufacturing sector and importing selected products.

In April 2010, SPS conducted an initial assessment of the regulatory components, capacities, and legislative structures related to medicines and processed foods in the country. Initial findings revealed a lack of comprehensive regulatory structure pertaining to medicines and processed foods. The establishment of NFMB was expected to provide guidance on the technical aspects of regulating medicines and processed food products; however, because of the lack of access to technical expertise and poor coordination among relevant departments, the board has been unable to fulfill its expected role.

SPS proposed three options for a functional regulatory agency:

- Keep the NFMB intact and strengthen its technical capacity;
- Support the existing regulatory entities within MoPH, while establishing one enforcement agency for both medicines and processed food products; and
- Establish an independent Afghan food and drug regulatory body.

The assessment report and options are still under review.

Sub-objective (i). Strengthen medicines regulatory capacity

A functional drug regulatory system is required to ensure the safety, efficacy, and quality of medicines. The initial step of strengthening the capacity of medicines regulation is to establish a functional structure through consensus building.

Key challenges identified in the SPS assessment include a lack of access to technical expertise related to regulating medicines and processed food products, poor coordination and communication among existing departments, and little human resource competency needed to achieve a functioning regulatory body.

Proposed interventions:

1. Support the MoPH by developing and implementing strategies to establish a functional regulatory framework taking into account existing systems and resource constraints:

   - Based on the option chosen to establish a functioning regulatory agency, identify, develop and implement the components required for a regulatory system/framework for medicines and processed food products;

   - Use the results from the previous assessment to map current roles and responsibilities of MoPH departments involved in the regulatory functions;

   - Use the results of the GDA functional analysis described under Objective 2 to determine stakeholders' functions, resources, capacity, skill set, decision-making points and mechanism, and communication and...
reporting mechanism; based on results, identify possible scenarios/options to develop functional structure to regulate medicines to fit with the agreed upon option; Based on the GDPA analysis, develop an action plan to establish the regulatory structure. To do this, SPS will use existing structures and resources as much as possible to build local capacity, complement ongoing initiatives without duplication, and leverage existing and potential resources; and Facilitate the consensus-building process through strategic planning meetings to help the MoPH/GDPA reach agreement with stakeholders on the implementation strategies, intervention priorities, and implementation timelines for the action plan.

Support the MoPH to create and implement a plan for the development and update of required laws, regulations, and policies to support the regulatory system. This intervention has three parts: developing a new national medicine policy (NMP), strengthening the regulatory environment, and establishing standardized enforcement mechanisms.

A. Help MoPH and GDPA review and revise the 2003 NMP to form the foundation for all future pharmaceutical activities. The current NMP is lacking several major components, and many of the bodies named in the policy no longer exist, such as National Medicines Authority and the Medicines Information Center. In addition, the current NMP does not address the private sector, which plays a large role in the country's pharmaceutical sector. SPS will work with the existing NMP task force to carry out the following activities:

- Follow World Health Organization (WHO) guidelines on revising the NMP, which will link the NMP update to the functional analysis outcomes. The functional analysis will help to identify which section of GDPA will be responsible for disseminating, promoting, and updating the NMP;
- Facilitate widespread stakeholder consultation; ensure the NMP's conformity with international standards and national health care policies; and
- Help MoPH produce, publish, disseminate, and institutionalize a comprehensive NMP that covers public and private sectors and address all aspects of pharmaceutical affairs.

B. Help MoPH and GDPA strengthen the regulations and standards on product quality, pharmacy facilities, and human resource qualifications. SPS will:

- Identify areas from the NMP where standards need to be developed or updated;
- Use the results of a private sector survey (Objective 1.ii) and human resource assessment (Objective 3.i) and the existing quality assurance assessment to inform standard setting in the areas of pharmacy facilities and human resources;
- Collaborate with the Kabul University Pharmacy School to revise curriculum to meet new standards (see Objective 3.i); and
- Provide technical support to professional bodies, industry, academia, and government regulatory department, to ensure dissemination and implementation of the standard regulations.

C. To help MoPH and GDPA strengthen and standardize regulatory enforcement, SPS will:

- Use findings from the private sector survey to develop regulatory enforcement techniques and structure at each level, identify regulatory enforcement resource and capacity requirements, and define the government's role in enforcing regulations in the private sector;
Define the role of authorities and the status of enforcement agencies through consultation and consensus-building workshops;

Develop enforcement implementation plan and identify priority areas; and

Under the coordination of NMFB, build consensus on implementation scheme with other stakeholders before launching implementation in priority areas.

3. Assist the MoPH with all consensus-building processes necessary to secure the support of all stakeholders to strengthen the regulatory system

SPS will collaborate with the MoPH by:

- Engaging relevant stakeholders in the consensus-building processes, including private and public sectors, professional organizations, and industries. As previously described, this will be built into all activities such as defining the regulatory framework and developing and updating laws, regulations, and policies;

- Working with stakeholders to develop a systematic process to reach consensus; and

- Documenting the consensus-building process around regulatory matters. For example, SPS will establish a guidance document on how to revise the NMP. Such documentation will be critical for transparency, as reference in case of ambiguity, for training, and to help sustain the system.

Expected Results:
The expected results of the activities under this sub-objective will include—

- Regulatory framework that describes the structure of a functional regulatory body;

- Action plan that guides the establishment of the regulatory body and its different sub-systems with clear steps that responsible parties have agreed to take;

- Reduction in the percentage of unregistered drug products in the public and private sectors;

- Revised NMP that addresses current issues in Afghanistan's pharmaceutical sector;

- Strengthened regulatory standards for products, drug outlets, and workforce in the pharmaceutical sector;

- Increased numbers of warehouses, facilities, and drug outlets that meet minimum requirements according to national standards; and

- Standardized enforcement measures with guidelines.

Sub-objective (ii). Strengthen the quality assurance system to assure the quality of pharmaceutical products in the public and private sectors

Several reports suggest that Afghanistan is a "pharmaceutical dustbin" of substandard, counterfeit, adulterated, and diverted medicines, as well as a transit point for such medicines to the entire region.

Because some medicines are very expensive and therefore prone to counterfeiting, the establishment of a viable and sustainable market protection system through regulatory processes is essential. These processes must be capable of preventing the circulation of substandard medicines, as well as detecting unacceptable products. In addition, the discovery of manufacturers or suppliers of products which fail to meet established standards must result in appropriate legal actions and deterrent penalties for unscrupulous manufacturers and suppliers;
Proposed Interventions:

1. Support the MoPH with the development and implementation of a comprehensive strategy and implementation plan to address medicines quality assurance and secure buy-in of stakeholders.

The findings of a recent medicines quality assurance assessment and testing study (n = 348 medicine samples) by SPS show that medicines in the public and private sectors of Afghanistan mostly (91 percent) comply with established international pharmacopeia standards, especially in USAID-supported public facilities which have more stringent quality assurance systems. However, failing medicines (n = 33) were found in private pharmacies (24 percent) and private hospitals (18 percent), where the supply chain may not be well regulated or have a reliable quality assurance system. Though the testing study was not set up to quantify the magnitude of supply chain problems in different settings, MSH assume that a higher risk could exist in that less-regulated segment.

Interventions to build a sustainable quality assurance system require a competent and independent national medicines regulatory authority, with strong political backing and a clear mandate to enforce medicines regulations. Afghanistan lacks functional and operational structures, procedures, and policies to properly regulate the pharmaceutical sector for quality assurance and build on successes. There is no good manufacturing practices (GMP) inspectorate or national GMP guidelines. In addition, the country has little capacity to test pharmaceuticals for quality, which opens the door to the circulation of substandard and counterfeit drugs. Assessments of the Afghanist pharmaceutical sector clearly indicate the need for establishing a medicines quality assurance technical committee that will lead the development of a comprehensive quality assurance strategy and implementation plan.

MSH propose helping the MoPH to:

- Establish a quality assurance technical committee for pharmaceutical products and develop terms of reference for the committee;
- Produce a road map for a viable and sustainable quality assurance strategy;
- Use data and information from the supply chain, private sector, and CPOS surveys and other pharmaceutical sector assessments to identify interventions;
- Identify and provide analytical equipment at the provincial level that will be most appropriate to conduct post-marketing surveillance;
- Establish priority areas for short-, medium-, and long-term interventions;
- Develop and finalize a three-year quality assurance strategy and implementation plan; and
- Conduct a quality assurance strategy and implementation plan stakeholder meeting.

2. Provide technical assistance to the MoPH to develop and implement a program to improve the quality of products provided through the supply chain.

In Afghanistan, the size, value, and complexity of the pharmaceutical market, the number of stakeholders and international donors involved, and the high levels of anticipated risk in the current supply system require coordinated attention. Furthermore, the Afghanistan Public Health and Nutrition Sector Strategy: 2010-2013 stresses the need for a program to assure the quality of medicines nationwide. A recent pharmaceutical sector qualitative study by SPS shows that although policies, legislation, and regulations exist, implementation is weak due to insufficient budgets, infrastructure, and human resources. Furthermore, Afghanistan does not have any mechanism or system for monitoring medicine quality, adverse drug reactions, or medication errors. Initially, discussions with the MoPH and others focused on quality control, which involves...
laboratory testing of pharmaceutical samples. While testing is a valuable tool, SPS proposed to help develop and implement a more comprehensive quality assurance program that addresses all activities that influence the pharmaceutical product quality from pre-importation to patient use.

A comprehensive system requires the involvement of multiple actors across both public and private sectors. SPS has already provided the necessary technical assistance and support to the MoPH to plan and implement an extensive desktop review of the pharmaceutical sector, establish a medicines quality assurance taskforce, and conduct medicines testing study and a medicines quality assurance assessment.

Under this Associate Award, SPS proposes to help the GDPA and MoPH/Health Law and Regulation Directorate (HLRD) to:

- Implement and evaluate the developed medicines quality assurance strategy at the end of each year;
- Identify and address new risks in medicines supply chain each year;
- Develop and implement a national quality assurance policy;
- Develop a medicines quality assurance surveillance strategy and an implementation plan;
- Develop and implement a communication strategy regarding medicines quality assurance;
- Develop and implement a mechanism for updating major stakeholders on medicines quality assurance issues;
- Make substantial contributions to quality assurance issues in a national pharmaceutical master plan;
- Thoroughly review the registration/licensing/inspection process for pharmaceutical companies, medicines, and establishments;
- Develop a strategy and implementation plan for a pharmaceutical pre-qualification system for the public sector;
- Develop and implement a capacity-building plan for quality assurance activities;
- Develop and maintain a quality assurance database and recording system; and
- Train technical staff in medicine quality assurance including appropriate training for inspection.

3. Work with GDPA to improve the quality of products and services in private sector pharmacies and drug shops

As in other countries, Afghanistan’s private sector plays a vital part in providing the public with access to essential medicines; however, little reliable information is available to inform policy and decision making to engage and regulate the sector within the overall health care system. Numerous laws and regulations already exist for retail pharmacy outlets in Afghanistan. In recent years, however, the high rate of expansion in urban areas has outstripped the regulatory authorities’ ability to enforce regulations, while rural areas still suffer a severe shortage of pharmacy outlets.

Given the importance of this sector, SPS proposes gaining a better understanding of the current situation and developing interventions to raise the quality of products and services provided in the private retail pharmaceutical sector. As a first step, SPS will assess the retail pharmacy sector and associated supply chains, which will form the foundation for developing interventions customized to Afghan conditions. To address the national and provincial governments’ immediate concerns about the over-supply of retail drug outlets, SPS will also work with GDPA to improve its licensing system for pharmacies and drug shops.

SPS activities to strengthen the private sector include:

- Helping MoPH appoint a task force to manage the survey process and policy development;
• Providing technical assistance to the GDPA to assess the private wholesale and retail sectors, including determining the number of companies and shops, locations, size, source of products, prices, quality of service and products, ownership, and staffing;

• Based on the findings, helping GDPA identify intervention options that meet priority needs related to regulation, standards, and enforcement;

• Identifying other stakeholders, such as professional associations, to play a role in regulation, inspection, or accreditation; and

• Facilitating the review of the licensing system and working with GDPA to revise, develop, and implement improvements to the current system.

Helping the GDPA improve pharmaceutical waste management

Many health managers in the public sector retain their damaged, deteriorated, and expired products in their inventories until a disaster strikes. In addition, expired products are repackaged for sale or as a donation, so they can be taken off their inventories without having to admit to purchasing excess products. At present, Afghanistan has no pharmaceutical waste management program. The MoPH recently destroyed about 300 tons of counterfeit, low-quality, and expired medicines. The MoPH/GDPA needs to establish a technical task force to lead the process of developing a pharmaceutical waste management program and a safe disposal system for the country.

Designing and implementing a successful pharmaceutical waste management program is a highly interdisciplinary process that focuses primarily on how the national regulations apply to hazardous and non-regulated hazardous pharmaceutical waste management. The process also includes performing a medicines inventory review and exploring how waste can be minimized. Such a review would establish a baseline to estimate waste management costs and track progress over time and identify ideas for reducing the waste stream. Another challenge is choosing a method to communicate information to stakeholders about waste management.

The most successful implementation programs involve carefully staged rollouts, developed with the participation of all stakeholders. Under this Associate Award, SPS proposes to assist the MoPH in:

• Creating a functional pharmaceutical waste management technical task force;

• Developing and disseminating a national policy/guidelines for pharmaceutical waste management including roles and responsibilities;

• Developing a strategy and action plan for pharmaceutical waste management; and

• Developing standard operating procedures and work instructions to dispose of pharmaceutical waste.

Expected Results:

As a result of the interventions proposed under this objective, MSH expects the following results within the GDPA, HLRD, NFMB, and other relevant agencies involved in medicine quality assurance:

• Roles and responsibilities defined for quality assurance activities;

• A national quality assurance policy in place and functioning;

• Improved ability of GDPA, HLRD, and other relevant agencies to manage quality assurance activities more efficiently in both public and private sectors as illustrated through increased government oversight and responsibilities;

• Increased number of pharmaceutical products tested for quality;
Objective 2. Improve supply chain management and commodity security to assure product availability.

Through the REACH and Tech-Serve projects, USAID has worked to assure an adequate supply of essential medicines to 8 to 10 million people in 13 provinces since 2003, with support possibly expanding into additional provinces. With the Tech-Serve project due to end in September 2011, however, activities need to continue without interruption. Moreover, stock shortages indicate room for improvement, and for the longer term, the MoPH's capacity and resources to oversee medical supply activities falls short of what it needs to assume full responsibility without threatening the security of the medicine supply system.

If MoPH does not develop the required capacity, planning beyond the life of donor support is difficult.

Since October 2008, SPS has been helping the MoPH establish the CPOS to begin addressing issues such as information sharing and efficient use of available resources and to provide the MoPH with a clearer picture of the structure and effectiveness of the pharmaceutical supply system. Furthermore, in 2009, SPS evaluated the Central Medical Store (CMS) as part of an initial, broad supply options analysis for USAID and MoPH.

Sub-objective (i). Strengthen pharmaceutical supply management for BPHS and EPHS providers to assure an uninterrupted supply of essential medicines and health commodities:

The primary activities to achieve this sub-objective relate to the seamless transition of responsibilities from Tech-Serve to SPS and investigating and implementing options to decrease stockouts and ensure the supply of essential medicines and commodities for the short and long term.

Proposed Interventions:

1. In collaboration with Tech-Serve, develop a detailed transition plan for the integration of Tech-Serve drug management staff, infrastructure, and responsibilities into SPS: To ensure that the current supply service is not disrupted, SPS proposes to assume full responsibility for in-country pharmaceutical management operations no later than August 2011, before the end of the Tech-Serve project. SPS will also work very closely with USAID DELIVER, which will assume responsibility for procurement following Tech-Serve closure, to ensure effective coordination and to prevent supply disruptions.

SPS will develop and implement a detailed transition plan in collaboration with Tech-Serve to integrate all Tech-Serve drug management staff and responsibilities into SPS. In addition, MSH will coordinate operations with DELIVER to ensure effective pharmaceutical procurement and logistics activities. SPS's specific activities related to the transition plan will start upon project award and include:

• Development and coordination of documentation and quantifications required to facilitate medicine procurement by USAID partners;
• Production of a detailed work plan and budget for the transition of drug management operations from Tech-Serve to SPS including transfer of staff, warehousing, stocks/inventories, and equipment;
• Establishment of contact and modus operandi with DELIVER (USAID's procurement partner) to ensure effective procurement and international logistics operations in Afghanistan;
• Submission of a plan and budget for the transition of drug management operations to USAID for review and modify based on feedback;
• Collaboration with Tech-Serve to implement all handover activities;
Receipt of physical stock from Tech-Serve; Start oversight of information technology systems and databases; and Assumption of operational control of medicines and medical commodity supply activities.

2. Provide technical assistance to ensure an uninterrupted supply of essential medicines and health commodities to BPHS and EPHS providers, including the development of a quantification system to support procurement planning.

SPS recognizes the achievements of USAID-supported drug supply activities since they were initiated in 2003. However, opportunities for improvement exist—such as decreasing stock-outs. Making the drug supply system more flexible and upgrading drug management systems and staff skills at health facilities will help reduce stock-outs.

In addition, distributing medicines to health facilities based on actual demand will also contribute to reducing waste and stock-outs. In the first year of the program, SPS will conduct a survey to collect data needed to evaluate the feasibility and appropriateness of a range of options including—

• Holding provincial buffer stock;
• Local purchasing by provincial authorities and/or health facilities to supplement central supply;
• Establishing systems to track stock in facilities and manage internal transfers between health facilities;
• Procuring through Afghan importers to supplement international procurement, with appropriate safeguards for product quality; and
• Moving to a more demand-based supply system for health facilities.

Reducing the lead time of the international supply component of the USAID-funded supply system could also improve service levels. In collaboration with USAID DELIVER, SPS will look into increasing the number of scheduled international deliveries to Afghanistan; consolidating stock in another country in the region, such as India, and airfreighting into Kabul regularly; and operating a bonded store at the Kabul airport and clearing customs there.

Sustained improvements will only be possible if systems are strengthened at service delivery level. Therefore, MSH will work to strengthen and standardize pharmaceutical supply chain systems at provincial and health facility level by—

• Providing funds to refurbish select provincial warehouses in support of supply chain improvements;
• Providing technical assistance to review current provincial and health facility drug management policies and procedures in collaboration with NGOs and provincial health authorities;
• Identifying needed infrastructure and equipment upgrades and helping develop a plan to address these requirements;
• Developing and implementing standardized pharmaceutical management policies and operating procedures at provincial and health facility levels;
• Training pharmacy staff in supply chain management, such as inventory management and storage (see also Objective 3.i.3); and
• Providing ongoing training and mentoring to pharmacy staff to develop their ability to supervise and support drug management activities at health facilities.

Through a combination of such interventions, SPS will target reducing stock outs from the percentage established as a baseline in the first year of project target facilities. MSH will also designate annual benchmark figures to reach.
the longer term, SPS will evaluate the need for and feasibility of broadening the SPS-supported supply system to incorporate donor-funded NGOs. A more integrated supply system would not only help NGOs address some of their problems, but would also increase the efficiency of the BPHS and EPHS supply system and eventually the broader public health system. SPS understands that donor programs designed to strengthen the CMS, such as that financed by Canada International Development Agency, will need to be taken into account when planning long-term options. Because of the physical and operational difficulties of strengthening the CMS to the point where it can function as the hub of a national supply service, SPS will consider alternative approaches, including the potential for the SPS supply operation to form the basis for a private sector-based MoPH supply system in the longer term.

In addition to the need to look outside the CMS for supply solutions, SPS understands that the MoPH needs support in the broader area of pharmaceutical supply management. The CPOS process, for example, is an important initiative that is setting out a long-term strategic plan for the public pharmaceutical system. More immediately, SPS recognizes that the MoPH should assume increasing responsibility for operational activities as their resources and capacity increase, perhaps through a strengthened GDPA. This is consistent with both the CPOS process and USAID's desire to transition operational responsibilities to the MoPH. As a first step, SPS will work with the MoPH to identify a cadre within the Ministry to be responsible for essential medicines quantification and procurement planning. SPS will work with this group to develop their quantification and procurement planning skills through a phased process beginning with formal training in quantification and procurement planning. Involvement with real-time SPS planning and quantification activities will deepen the group's understanding and skills. Over time, as this process proceeds through a combination of formal and on-the-job training and system development, the MoPH quantification and planning group will assume greater responsibility in this area. SPS's objective will be for GDPA to assume full responsibility for quantification and procurement planning by the end of the Associate Award. To achieve this objective, SPS will:

- Help MoPH develop expertise and organizational/administrative capacity in quantification and procurement planning;
- Facilitate the adaptation or development of appropriate systems and tools for quantification and procurement planning;
- Develop and implement formal and hands-on training for MoPH staff taking on responsibility for quantification and procurement planning;
- Support the maintenance and update of mechanisms and procedures for receiving and processing stock and consumption reports from health facilities and warehouses;
- Support and maintain the process for preparing procurement quantities;
- Develop and implement good storage practices and tools to support stock management at all levels of the health system; and
- In collaboration with Tech-Serve and MoPH, prepare final orders to be placed under the current procurement mechanism. Over time, a MoPH supply planning group together with the CPOS could form the nucleus around which the MoPH will become the focal point for coordination, oversight, and strategic leadership to the public health supply system.

3. Provide technical assistance for an operational plan to build the institutional capacity of the GDPA to assume responsibility for procurement, storage, and distribution.
GDPA is currently restricted in its ability to manage and make decisions related to the pharmaceutical supply system by the lack of clearly defined functions and responsibilities within the GDPA and between GDPA and other MoPH departments. The problem is further compounded by GDPA's deficit of needed expertise, infrastructure, and resources. If GDPA is to provide leadership in pharmaceutical management, it will have to build its human and physical resources and strengthen its decision making and management capacity.

To achieve this objective, SPS will work with GDPA and MoPH staff to:

- Continue conducting a functional analysis of GDPA to:
  - Clarify roles and responsibilities of existing GDPA departments/units in relation to each other, other departments and directors (e.g., Pharmaceutical Enterprise, General Directorate of Administrative Affairs, and CMS), donors, and NGOs (functional analysis already begun in previous fiscal year);
  - Assess GDPA systems, staffing, and resources in relation to its functions and goals;
  - Address operational issues covering all major functional areas, including Avicenna Pharmaceutical Institute, Pharmaceutical Enterprise Department, pharmaceutical planning, procurement and registration, inspection and evaluation, and narcotics and controlled substances; and
  - Recommend the skills mix required in each GDPA department for effectively carrying out responsibilities, including identifying training and skill development needs and how best to meet them.

- Develop a three-to-five year operational plan with GDPA managers and staff to:
  - Establish priority areas of responsibility;
  - Detail goals and objectives in relation to building capacities and improving performance in those priority areas;
  - Determine human, financial, and other resources (infrastructure, transport, information technology, etc.), and potential government or donor sources needed for implementation;

- Develop a one-year work plan detailing key interventions, targets and milestones, activities, and human and financial resources needed for implementation

- Initiate a process for conducting an internal assessment at the GDPA and train key staff members to be responsible for this assessment

In addition to contributing to Objective 2.i by building GDPA decision making and management capacity, this activity will also contribute to Objective 3.i by building institutional capacity.

Expected Results:
Under this sub-objective, SPS expected results include:

- A smooth transition of responsibilities from Tech-Serve to SPS based on a detailed transition plan;
- Increased public supply chain efficiency based on implementation of public-private options analysis recommendations;
- Standardized policies and procedures in place for pharmaceutical procurement, storage, and distribution;
- Reduced lead times for pharmaceutical procurements;
- Decreased medicine stock-outs in target areas;
- Increased availability of quality-assured pharmaceutical products in Afghanistan;
- Improved staff skills in pharmaceutical management in the public and NGO sectors;

In addition to the tasks outlined, SPS will work with GDPA and MoPH staff to:

- Conduct an operational audit of pharmaceutical management to:
  - Identify gaps and inefficiencies in current processes;
  - Develop recommendations for improving operational efficiency;
  - Implement targeted interventions to address identified issues;

- Develop a training plan for GDPA staff, including:
  - Identifying training needs based on operational audit findings;
  - Developing training programs and curricula for identified needs;
  - Conducting training sessions with GDPA staff;

- Establish a sustainable institutional framework to:
  - Ensure continuity of pharmaceutical management activities;
  - Facilitate the transfer of knowledge and skills from SPS to GDPA staff;
  - Promote ongoing learning and improvement in pharmaceutical management practices.
• Development and documentation of a quantification system to support procurement; and
• Responsibilities for quantification and procurement transferred to MoPH

Sub-objective (ii).

Strengthen coordination among the international donor community, the MoPH, and other relevant stakeholders through a CPOS: USAID, the World Bank, and the European Commission provide most financial and technical support to implement the BPHS and EP HS, while various other donors and organizations make key niche contributions. Mechanisms for managing pharmaceuticals and reporting requirements vary by donor. In 2008, USAID and the MoPH asked SPS to help establish a CPOS in Afghanistan to address the lack of coordination, information sharing, transparency, and appropriate use of resources among the different pharmaceutical sector players. Based on 30 stakeholder interviews in 2009, GDPA and SPS identified the co-existence of parallel procurement and distribution mechanisms as part of vertical public health programs (e.g., TB). The potential risks include different reporting mechanisms for different stakeholders (with the same information), incomplete/fragmented management information systems, and lost opportunity to access better prices through pooling procurement.

In addition, GDPA and SPS also identified 86 donors and NGOs involved in the pharmaceutical sector with each stakeholder functioning differently at different levels. For example, some donors procure medicines directly, while others provide funding to NGOs for the procurement of medicines. In 2009, 80 meeting participants agreed that a CPOS needed to be established based on a sound operational model. A CPOS task force with 13 stakeholder representatives was established to develop the CPOS governance framework with technical assistance from SPS. In 2010, 100 stakeholders reviewed and approved the proposed CPOS governance framework and determined the next steps for implementation. The CPOS is comprised of a National Management Commission and three permanent committees: Data and Information Committee (DIC), Advisory Committee for System Strengthening, and Commodity Security Committee. This year, the three committees met to clarify roles and responsibilities, confirm the technical leader of each committee, and clarify priority activities in a formal work plan for each committee beginning October 2010.

As a mechanism for developing a system of governance, stakeholders agreed on the proposed structure of the CPOS as outlined in Figure 3 below, where the National Management Commission is responsible for the CPOS activities, while GDPA works in close consultation. The National Management Commission is headed by a president who is currently the Deputy Minister of Public Health for Policy and Planning. The National Management Commission consists of permanent members that are the major donor agencies in Afghanistan's pharmaceutical sector. The General Assembly includes organizations involved in the procurement and distribution of pharmaceuticals and health commodities in Afghanistan. The CPOS Coordinator will be independently recruited and seconded to the MoPH and will serve as a liaison between the National Management Commission and the various CPOS committees.

SPS proposes sponsoring CPOS meetings until it becomes institutionalized within the MoPH.
1. Provide technical assistance to establish and implement a system of good governance to ensure transparency and efficiency in supply chain management and commodity security:

SPS will facilitate a working relationship between key staff at the MoPH/GDPA with major stakeholders with the goal of building GDPA leadership, management, and technical capacity. Over the life of the Associate Award, SPS will work with partners to carry out the following steps:

• Recruit a CPOS Technical Coordinator whose focus will be to facilitate and where possible guide the system's operations and ensure performance and efficient communication among CPOS members. The CPOS Technical Coordinator will be seconded to the MOPH and will be directly supervised by the President, who is the Deputy Minister of Public Health for Policy and Planning with the technical oversight and supervision of SPS;

• Assure that the Technical Coordinator has developed sufficient working relationships with CPOS members and GDPA management and staff to help GDPA start overseeing CPOS implementation. The result will be improved and effective working relationships among the GDPA, partner agencies of the CPOS committees, and MoPH officials over the next three years;

• Provide support to the Technical Coordinator as he or she works with GDPA to ensure adequate information flow among the MoPH, GDPA, General Directorate of Administrative Affairs, relevant ministries, public programs, donors, and key partners related to the pharmaceutical management for BPHS and EPHS programs;

• Review and modify the CPOS structure and operations based on the evaluation of the work done by the CPOS committees, if needed;

• Collaborate with the MoPH/GDPA to develop and implement a strategic plan of action to institutionalize the CPOS with the MoPH assuming full technical, operational, and financial responsibility for the system, including funding for the CPOS Technical Coordinator position;

2. Provide technical assistance to the members of the CPOS committees and their sub-committees with the development and implementation of strategies and evidence-based technical interventions to assure pharmaceutical product quality and availability:
In 2009, CPOS stakeholders expressed the need for standardized procurement and distribution guidelines for pharmaceuticals. The Advisory Committee for System Strengthening will lead the development of such guidelines, which will describe procedures from selecting appropriate medicines to monitoring supplier performance. In addition, this committee will collaborate with other CPOS committees to share information, such as the performance of suppliers, to assure pharmaceutical product quality and availability.

SPS will provide technical assistance to the CPOS committees by:

- Helping assess current procurement and distribution procedures of the MoPH, relevant stakeholders, and agencies funded by the three major donors and giving findings to GDPA to develop national procurement and distribution guidelines;
- Working with the Advisory Committee for System Strengthening to ensure endorsement and implementation of these guidelines among stakeholders;
- Establishing mechanisms to obtain feedback on the draft guidelines, using feedback to revise as necessary, and identifying bottlenecks to implementation;
- Helping the CPOS share information on product suppliers, prices, and supplier performance to assure an uninterrupted supply of quality-assured products. The CPOS Technical Coordinator will facilitate information sharing among CPOS members; and
- Exploring options for pooled procurement with CPOS stakeholders (NGOs) as part of the broader work conducted on strengthening the national supply chain.

While the development of draft guidelines for procurement and distribution is ongoing, MSH needs to characterize how pharmaceuticals and commodities are quantified. As described in Objective 2.i, the MoPH will appoint a quantification committee whose members will be trained in general quantification techniques and in methods used by the Tech-Serve program. They will participate in the review of Tech-Serve forecasts planned for March/April 2011 and be involved in making decisions on any changes to those forecast quantities. During this period, SPS will review and revise Tech-Serve methodologies as required and incorporate these changes into the process. In addition, MSH will review the methodologies of other groups such as NGOs and begin to draw them into the coordinated process. Eventually, MSH plans to work with the Commodity Security Committee to oversee this process.

SPS will work with the quantification committee to accomplish the following activities:

- Assess stakeholders' methods and tools for quantification and forecasting; based on findings, develop a package of options for best practices in quantification and forecasting and present options to CPOS stakeholders;
- Implement capacity-building programs for relevant procurement staff on procurement, quantification, forecasting, tendering, contracts with suppliers, and receipt of products; and
- Implement programs with the customs department on a short-term clearance mechanism to avoid expiry, damages, and late delivery, and to monitor product quality; support the development of a memorandum of understanding between customs and wholesalers.

Support the MoPH with the development and implementation of a system to coordinate and standardize the collection, reporting, and analysis of essential data required to manage the procurement and supply of medicines and health commodities:

The CPOS DIC will work with stakeholders to establish the minimum amount of data needed to oversee and coordinate pharmaceutical management at the national level. Part of the CPOS mandate is to promote good...
governance, which requires the easy availability of data. Objective 5.i describes the development of the PMIS in more detail.

SPS proposes working with the DIC to accomplish the following key activities:

• Identify the required indicators for selection, procurement, distribution, and use of pharmaceutical products and reporting requirements in the country;

• Develop a standard data collection and reporting system; decide on data to be collected based on the identified information requirements and indicators;

• Design formats and procedures of data collection, processing, reporting, and dissemination of information;

• Train CPOS staff on how to use the system and the information it generates for decision making.

Expected Results: Expected results from this sub-objective include the following:

• Increased technical ability among CPOS committees to coordinate procurement and distribution activities among donors;

• Procurement, inventory, and distribution data readily available to CPOS members and adequately used for planning and decision-making; and

• Increased number of commodities that are included in one national coordinated procurement plan among donors/partners.

Objective 3. Build human resource capacity for effective service delivery: SPS has been partnering with MoPH and GDPA to build capacity in pharmaceutical systems strengthening, management, and services. However, to carry out the activities in this application, MSH need to comprehensively examine and strengthen all aspects of pharmaceutical human resources development across all areas of the pharmaceutical sector. Therefore, this objective is cross-cutting in its approach and links to the other objectives: (1) strengthening the regulatory system, (2) improving supply chain management and commodity security to assure product availability, (3) enhancing pharmaceutical services to achieve desired health outcomes, and (4) addressing the information for decision-making challenge in the pharmaceutical sector.

SPS is currently conducting a human resource assessment to characterize the human resources situation in the country’s pharmaceutical sector. This assessment is supported with current funding and will be complete by June 2011.

Sub-objective (i): Building institutional and human resource pharmaceutical management capacity:

The MoPH and GDPA report that because information on pharmaceutical human resources has not been updated and is unreliable, they have no comprehensive picture of the availability, location, or practice area of pharmaceutical human resources in the country. In addition, low salaries and lack of job prospects deter pharmacists and pharmacy assistants from being recruited to and retained in the public workforce. Untrained personnel provide a significant proportion of pharmaceutical services, especially in the private sector.

The approach to human resource capacity building can be classified into three areas: planning, management, and development. Human resources planning focuses on developing a strategic approach to workforce planning and strengthening human resources information systems. The activities under human resource management use various
measures to improve the recruitment and retention of staff and identify and address factors that affect performance.

Human resource development focuses on the education and training needs of the staff needed for the country's workforce. The proposed interventions will be implemented after the human resources assessment has been conducted and a pharmaceutical human resources strategic framework developed.

SPS will initiate activities across these three areas after the human resources assessment findings become available.

Proposed Interventions:
The RF A's illustrative interventions are critical for the human resources development; however, MSH also proposes two complementary interventions related to human resources planning and management.

1. Help build MoPH capacity to plan pharmaceutical sector human resources

The interventions will focus on three components: strategic human resources planning, strengthening human resources information systems needed for planning, and identifying human resource needs.

- Through collaborative meetings, support the MoPH Human Resources Department to develop a pharmaceutical human resources framework and a short- and long-term pharmaceutical human resources strategic plan. The strategic plan will be integrated with the broader MoPH health sector human resources strategic plan. Specific activities include:
  - Defining roles and responsibilities of various types of health workers in managing pharmaceuticals and providing pharmaceutical services; incorporating task-shifting to account for a shortage of pharmacists and requiring specific competencies to address gaps.
  - Training and other interventions to enhance health workers' competencies and improve the quality of services provided. This strategy is particularly applicable in regions lacking trained pharmaceutical workers.
  - Identifying approaches to increase staff retention to ensure the investment made on education and on-the-job training of new workers.
  - Supporting the GDPA and MoPH to translate the human resources strategic plan into annual operational plans.

- Strengthen and update the existing pharmacist and pharmacy assistant registration system and improve human resources information reporting between training institutions, facilities, and MoPH.

- Use the assessment findings to enable the MoPH and GDPA to quantify and forecast workforce needs in both private and public pharmaceutical sectors over the next five years, taking into account workload requirements and associated budgetary constraints.

2. Assist MoPH to improve pharmaceutical sector human resources management (recruitment, retention, and job descriptions)

SPS proposes working with MoPH Human Resources Department and MoPH/GDPA to:

- Draft guidance for developing job descriptions in pharmaceutical sector services;
- Review, update, and revise job descriptions;
- Identify strategies to improve personnel recruitment and retention; and
- Use the assessment findings to help MoPH and GDPA develop strategies to address identified barriers in the work environment that influence performance.

3. Assist the MoPH with the development and implementation of a human resources strategy (training plan) to address the deficiencies in education and training:

- Draft a human resources strategy and training plan to address identified deficiencies in education and training.
In collaboration with MoPH at the central and provincial levels and NGOs involved in providing pharmaceutical sector training and relevant training institutions, SPS will:

- Help develop training plans based on the identified learning needs of pharmaceutical personnel;
- Identify competency gaps across the pharmaceutical sector, help MoPH implement the training plan to address gaps, and work with NGOs and training institutions to conduct training workshops based on identified needs in pharmaceutical supply chain management and pharmaceutical services, such as dispensing and counseling (see also Objective 2.i.2);
- Help ensure that the capacity building and training strategy incorporates ongoing and future SPS training activities and materials to strengthen pharmaceutical management and service delivery in the following areas: supply chain management, pharmaceutical management information systems, rational medicine use, the regulatory system, and quality assurance of medicines.

4. Provide technical assistance for development of pharmaceutical management training materials and implement training for pharmacy staff on the relevant aspects of pharmaceutical management:

Most pharmacists in Afghanistan manage few supply-related activities (ordering, stocking) and provide almost no professional services, such as patient counseling, prescription verification and labeling, or providing drug information. Improving pharmaceutical ordering and stocking and other inventory management will result in better distribution and availability of medicines in the pharmacy, and promote patient understanding of appropriate medicine use.

It is clear that training alone will not change behavior or provide the skills needed for these pharmacists to improve their performance. Training plays a role in capacity building provided there is adequate pre-training needs assessment, periodic monitoring, and post-training evaluation to determine effectiveness.

SPS will work with GDPA and the private sector to develop and implement a capacity building program for pharmacists in the public and private sectors. Activities include:

- Conducting a baseline evaluation to document basic indicators on ordering, receiving, storage, dispensing practices, patient communication, etc. to provide a way to measure improvement;
- Conducting training needs assessment for targeted pharmaceutical personnel, starting with the pharmacists employed by GDPA;
- Reviewing and adapting existing SPS training materials on pharmacy services and basic pharmaceutical management (used in other countries) to the Afghan context, conducting training in targeted facilities to test materials and methodology.

GDPA and SPS will facilitate:

- Providing follow-up support including periodic coaching, mentoring, idea generation, and encouragement.
- Follow-up will be provided in cooperation with GOPA;
- Collaborating with GDPA to revise training materials and follow-up mechanisms and providing training and capacity building to other public health facilities in Kabul and other provinces including hospital pharmacies throughout Afghanistan;
- Providing technical assistance to MoPH and Kabul University Pharmacy School to develop in-service and continuing education training programs and short-term and certificate courses in response to competency development needs in pharmaceutical management and service delivery; and
- Collaborating with the MoPH and Kabul University Pharmacy School to establish a continuing education center that builds capacity in the pharmaceutical workforce.
5. Provides technical assistance to the pharmacy education institutions for the incorporation of modern pharmaceutical management concepts in their curricula.

Pre-service education for physicians and pharmacists on rational medicine use, pharmaceutical management, and AMR is vital. Pre-service education will ensure that professional staff has the necessary background and basic understanding of medicine use concepts and practices before entering the public health system. Currently, the Faculty of Pharmacy at Kabul University has little in the way of medicine use/AMR and pharmaceutical management courses, but they are very interested in revising the curriculum to include such material. SPS has similar experience working with universities in Rwanda and Zambia to revise medical and pharmacy curricula. MSH proposes activities based on MSH successes in those countries.

SPS proposes working with the MoPH, Ministry of Higher Education, Kabul University Pharmacy School, and the pharmacy assistant school to:

• Review the existing curriculum to identify what is needed related to rational medicine use, AMR, and supply chain management;
• Determine the actual content being covered, the hours of exposure, the teaching-learning methods used, etc. through a systematic self-assessment by the faculty. SPS will provide tools for conducting the self-assessment;
• Hold a workshop to develop the appropriate curriculum content, teaching-learning methods, and the amount of time required; determine what topic areas of rational medicine use, AMR, supply chain management, and other topics will be included in related disciplines;
• Assemble a wider group of stakeholders to review content; this wider review will improve the content quality and also increase buy-in for the materials;
• Provide orientation/training to teachers on the finalized modules;
• Monitor the extent of implementation of the module/additional content and identify further support needed; and
• Help the MoPH create community-based pharmacy assistant training programs in the provinces.

Expected Results:
The expected results under this sub-objective include:

• Human resource strategic framework and planning in place;
• Updated human resources database and strengthened information system for reporting human resource information;
• Forecast of workforce needs for three to five years;
• Guidance document(s) on how to develop job descriptions;
• Strategic plan for recruitment and retention;
• Training plan based on needs assessment findings developed and launched;
• Increased percentage of pharmacy staff that have minimum education and training requirements;
• Increased number of facilities with minimum number of qualified staff on hand;
• Increased percentage of pharmacy personnel who have the skills to provide medication counseling;
• Revised and adopted curricula in academic and training institutions that reflect rational medicine use, AMR, and medicine management topics and coursework; and
Pre-service and post-service training programs available that will help improve medicine use in the Afghanistan healthcare system.

Objective 4: Enhance pharmaceutical services to achieve desired health outcomes:

- Comprehensive pharmaceutical services are critical to a healthcare system and to achieving good health outcomes. Pharmaceutical services include those actions that lead to rational medicine use, such as appropriate prescribing, dispensing, and patient counseling. Afghanistan's deliveries of pharmaceutical services historically have been a low priority and are minimally developed. Challenges to providing pharmaceutical services include (among others) the lack of education and knowledge among prescribers and dispensers at all levels of the healthcare system. However, recent advocacy efforts have helped highlight the importance, and the MoPH is now strongly supporting the idea of improving pharmaceutical services, especially those that promote rational medicine use;

- The MoPH/SPS medicine use study of March 2009 illustrated overuse and mis-prescribing of antimicrobials in primary health care facilities. Physicians do not follow treatment protocols and use multiple antibiotics in multiple doses over extended periods when a single dose of an antibiotic would suffice. This irrational use may contribute to increased morbidity and mortality. In addition, the indiscriminate use of antimicrobials leads to AMR and threatens the treatment of many infectious diseases in Afghanistan. The financial burden from irrational medicine use and AMR is difficult to estimate, but can be considered high in this low-resource country.

- Patients lack understanding of basic health principles and medicine use. Consultation times and dispensing times are extremely low, so patients do not receive adequate counseling on their medical conditions and treatment regimens. Facilities are poorly staffed and healthcare professionals are generally underpaid, which is a significant challenge for providing high-quality pharmaceutical services. In addition, a large and growing private healthcare sector promotes the availability of medicines of questionable quality and readily provides them to anyone for a price with or without prescriptions.

SPS's previous technical assistance has resulted in:

- Development of a national Drug and Therapeutics Committee (DTC) within GDPA with terms of reference and an action plan;

- Development of DTCs in five hospitals that have now received MoPH guidelines and protocols on medicine and which have helped draft formulary lists;

- Draft of key health messages forming the basis for public service announcements on rational medicine use, AMR, and responsible self-medication;

- Formation of a standard treatment guidelines (STG) working group at GDPA and initiated the development process of STGs for primary health. The STG group has members from MoPH medical departments, GDPA, Kabul Medical University, and the Afghanistan Physicians Association;

- Curriculum review and reform at Kabul University Faculty of Pharmacy to incorporate rational medicine use, AMR, and pharmaceutical management concepts;

- Collaboration with the Health Services Support Project and GDPA to review and revise their training programs for rational medicine use; and

- Training on pharmaceutical management for hospitals and NGOs and to the Kabul University School of Pharmacy faculty and students.
Subjective (i): Provide assistance to promote more effective pharmaceutical services, rational medicine use, and medicines safety. Under this sub-objective, SPS will build on the achievements realized under the Leader Award and will continue to work with partners to expand piloted interventions and introduce other effective interventions to promote rational medicines use in Afghanistan.

Proposed Interventions:

1. Improve the organizational capacity of GDP A, NGOs, and health facilities to support the provision of pharmaceutical services in the public and private sectors:

   As mentioned throughout the application, the overall organizational capacity of GDP A is very poor, which limits their ability to establish and sustain rational medicine use activities and interventions. GDP A has a limited number of trained professionals, and the department has a low priority within MoPH. SPS will explore opportunities to engage GDP A, Avicenna Pharmaceutical Institute, selected NGOs, and private sector health facilities/associations to be counterparts in the development and implementation of rational medicine use activities.

   SPS proposes to work closely with these organizations to improve their capacity to assess, develop, implement, and monitor interventions that strengthen pharmaceutical services and improve rational medicines use.

   SPS will work with GDP A to:

   • Promote GDP A involvement in the establishment and sustainability of DTCs, which provide a mechanism at national and facility levels to address pharmaceutical services and rational use issues.

     GDP A will help SPS develop DTC training materials; GDP A staff will serve as training facilitators for DTC training; GDP A staff will be active in the DTC follow-up activities including developing terms of reference and action plans for the DTC to carry out and support the DTCs' implementation of action plans; and GDP A will continue its membership on the National DTC, which provides a vision for and oversight to rational use activities and policy.

   • Develop and disseminate STGs to all primary health facilities.

     GDP A staff will actively participate in the development of STGs for primary health care and hospital facilities; GDP A will attend meetings of the STG working group and support the development of individual STG monographs; GDP A will collaborate with SPS to train on the use of STGs and rational medicine use in the public and NGO sectors; and GDP A will participate in the monitoring and evaluation of STG use.

   • Increase GDP A staff capacity to address human resource challenges and implement and maintain training programs by involving them in the training needs assessments and curriculum development processes described in Objective 3.i.

   • Work with GDP A staff to continue SPS's current work developing appropriate rational use messages for the general public and disseminating them through mass media.
SPS will work with the private sector (such as professional associations) to:

- Develop and implement continuing medical education programs in areas such as AMR and rational medicine use (see also Objective 3.i)
- Develop and distribute printed education materials for private pharmacists and drug sellers

SPS will work with NGOs to:

- Develop supply chain and rational medicine use training materials and courses for staff (see also Objective 2.i.2)
- Ensure that NGOs implement STGs
- Develop hospital formularies where needed and assure appropriate implementation

2. Support the appropriate functioning of national, regional, provincial, and institutional DTCs to oversee the implementation of rational medicine use strategies and interventions

WHO’s Global Strategy for the Containment of Antimicrobial Resistance cites DTCs as a critical intervention to improve the use of medicines in hospitals and primary care clinics. DTCs manage the selection of medicines for the formulary, evaluate the use of medicines, and implement strategies to improve medicine use throughout the health care system. DTCs ensure that treatments are in accordance with available STGs. Such activities lead to the procurement of safe and cost-effective medicines and improved use of medicines, which enhance health outcomes and contain AMR.

SPS contributes to the promotion of DTCs in two ways—through training initiatives and follow-up support. Comprehensive training programs teach healthcare professionals about how DTCs function in hospitals and primary health clinics and create advocates for rational medicine use at all levels of the health system. Regular follow-up support ensures that DTCs are functioning and addressing specific medicine use issues and problems.

In Afghanistan, SPS will:

- Continue supporting the national DTC’s oversight of interventions to improve the use of medicines in the country, including the implementation of local DTCs
- Support the development of guidelines and implementation of DTCs at key hospitals in Afghanistan
- Continue supporting the current five functioning local DTCs as they develop individual hospital formulary lists and identify medicine use problems within the hospital and develop institutional strategies to address problems
- Develop and implement six new DTCs in USAID-supported hospitals. This process includes a stakeholders analysis, development of a comprehensive training plan, selection of key participants from each hospital, approval by hospital and provincial directors, and a five-day training program. The DTCs will develop individual terms of reference, action plans, and follow-up activities during training
- Collaborate with national DTC and GDPA to provide continuous technical assistance and support to all hospitals with DTCs. This assistance includes ensuring the availability of all MoPH STGs, essential drug lists, licensed drug lists and other important policies on medicine use; providing drug information references when necessary; developing a formulary list; establishing monitoring programs to identify medicine use problems and developing interventions to improve use

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Implementing interventions to address medicine use problems including medicine use evaluations and education programs on rational medicine use; Ensuring that STGs and standard policies/procedures are followed (national and local) through regular review of important medical conditions including pneumonia, TB, malaria, diarrheal disease, and others; - Assuring the appropriate use of antimicrobials at all DTC hospitals by standard guidelines and procedures and by instituting drug use evaluations for commonly used medicines; and • Expand DTCs to key provincial and district hospitals throughout Afghanistan after DTCs have been successfully implemented at the 11 supported hospitals. GDPA will have primary responsibility of launching these DTCs and providing the necessary follow-up to ensure effective operations. 3. Assess the existing elements of the Afghan pharmacovigilance and adverse drug reaction systems and support the development of a comprehensive approach: Pharmacovigilance is a system to monitor the safety and effectiveness of medicines and other pharmaceutical products. The pharmacovigilance system aims to protect patients through the efficient and timely identification, collection, and assessment of adverse drug reactions and by communicating risks and benefits to support decision making about medicines at various levels of the health care system. Poor quality medicines, adverse drug reactions, and medication errors have enormous impact on health. Not only do these problems increase morbidity and mortality, but they contribute to higher health care costs and patient mistrust in the health system, driving many patients away from traditional health care. A comprehensive pharmacovigilance system should include all entities and resources that protect the public from medicines-related harm, whether in personal health care or public health services. Pharmacovigilance programs should monitor events that may be related to product quality, medication errors, and adverse drug reactions. A key component to the system is to monitor events, but also to use this information to prevent further adverse events at the health facility level. To address the pharmacovigilance system in Afghanistan, MSH will base MSH step-by-step strategy on the SPS conceptual framework and indicator-based pharmacovigilance assessment tools. Key collaborators will include NDT, GDPA, and the MoPH Department of Curative and Diagnostic Medicine. MSH expects additional involvement from WHO, academic institutions, and medical associations. Specific SPS activities include the following: • Work with MoPH to assess the status of any medicine safety activities in Afghanistan and assess the country's capacity to phase in pharmacovigilance activities using SPS's pharmacovigilance assessment methodology that covers all aspects of the pharmacovigilance framework: people, functions, and structures; • Work with in-country stakeholders to identify and analyze options to begin building a local pharmacovigilance framework and to develop feasible and sustainable approaches that are based on the assessment results and customized to Afghanistan's regulatory capacity and priorities and resource availability. SPS will work with national partners to identify and prioritize appropriate interventions to implement at health facility level, public health program level, and national level; and • As time and resources allow, help develop and implement the identified pharmacovigilance-related interventions in collaboration with in-country stakeholders and collaborating partners. 4. Provide technical assistance and support to MoPH and standard treatment guidelines working groups to develop and roll out STGS to primary health facilities and hospitals:
A fghanistan has STGs for a few medical conditions, but most healthcare providers in the primary health system have no protocol to guide treatment decisions. This leads to varying treatment regimens—many irrational. The development and use of STGs is a well-known intervention to improve the use of medicines and ultimately improve patient outcomes. STGs should form the basis of education and training for healthcare providers at all levels, including pre-service and in-service curricula. In addition, STGs contribute to procurement integrity by limiting the number of recommended medicines.

STGs are currently being prepared for primary health facilities; however, developing hospital guidelines is very different because they need to be written for more highly trained and experienced practitioners. Therefore, the stakeholders to develop and implement hospital STGs will be different from those needed for primary health, but the development process will be similar. The hospital STG activities will start after the completion of the primary health guidelines.

To promote the development and dissemination of STGs for primary health care facilities first, the hospitals, SPS will-

- Provide technical assistance and support to GDPA and the national DTC to continue the draft and review of STGs for primary health/hospitals and ensure that the draft reflects MoPH standards, WHO recommendations, and approved references;
- Help the STG working groups (one for primary health and one for hospitals) institute a rigorous review of all STG monographs to ensure accuracy, reliability, and usability at the primary health/hospital levels;
- Help pilot the STGs at three primary health care centers/three hospitals and incorporate any final changes in the STGs;
- Conduct validation workshops to gain consensus for final publication and dissemination;
- Provide support for final editing of the guides and publication of pocket-sized books;
- Provide support to translate the STG manuals into Dari and Pashtu;
- Collaborate with MoPH, European Union, World Bank, and NGOs to institute a comprehensive dissemination program to district, provincial, and regional levels;
- Oversee dissemination including formal MoPH launch, advocacy, and extensive training including a training of trainers approach. Monitoring and supervision for adherence to approved standards will be implemented for all primary health facilities. DT Cs at major hospitals will be responsible for implementing and monitoring of the use of their guidelines.

5. Support development of adequate training materials for pharmaceutical services and outpatient pharmacy management.

USAID’s Health Service Support Project is currently providing training for physicians and pharmacists in rational medicine use. SPS core funding through the AMR portfolio provided technical support and guidance to SPS Afghanistan to review the curricula and make recommendations to make the training program more effective for the target audience. Based on the recommendations, the training course is being revised. Under Objective 2.i, MSH describe specific activities related to pharmaceutical management training for providers at the facility level; in addition, other sections of the application cover training, including Objective 3.i on capacity building. Under this activity, SPS will-
Collaborate with GDPA and the Health Service Support Project to review and make recommendations to revise the rational medicine training course;

- Complete all training module revisions, including case studies, participant guides, and activities;
- Work with the Health Service Support Project to carry out the training courses already been scheduled through September 2011;
- Help transition the responsibility for the rational medicine use course to GDPA and start providing the course quarterly to primary health physicians, pharmacists, midwives, and community health workers; and
- Institute follow-up activities for trainees including site visits, review of training concepts, and application of rational medicine use concepts.

**Expected Results:**

SPS expects the following results from the activities under this sub-objective:

- GDPA, NGO, and private sector staff that is trained and capable of the development, implementation and follow-up of rational medicine use activities in their health facilities;
- More of the general public aware of the dangers of irrational medicine use;
- Functioning DTCs at 11 hospitals; hospital formularies that are used for ordering and prescribing of all medicines resulting in improved medicines selection; improved prescribing practices and medicine use based on routine DTC monitoring;
- All DTCs able to document improvement in pharmaceutical services at their facility;
- Assessment of Afghanistan's pharmacovigilance system and recommendations on interventions to phase in to improve patient medication safety;
- Percentage of prescribers in select health facilities complying with revised STGs;
- Health care practitioners from all provinces having attended an updated rational medicine use training course, resulting in their enhanced knowledge of rational use concepts and practices; and
- Greater percentage of patients who receive information on how to take medicines correctly.

**Objective 5. Address the information for decision-making challenge in the pharmaceutical sector**

SPS defines a PMIS as an information system that integrates pharmaceutical, logistics, and patient data collection and processing and presentation of information that help staff at all levels of a country's health system make evidence-based decisions to manage pharmaceutical services.

An effective PMIS is able to synthesize the large volume of data generated by pharmaceutical management operations. It then processes the data into information for use in planning activities, estimating demand, allocating resources, and monitoring and evaluating pharmaceutical management operations. This information is often best reported in the form of key indicators. Staff members at all levels should have appropriate indicators to monitor both their own performance and that of the units for which they are responsible. Such indicators would need to be developed for the Afghanistan system in coordination with the health management information system (HMIS).

Another important function of a PMIS is to improve accountability. Much of the recording and reporting in a PMIS is intended to create an audit trail for products as they enter or leave a pharmaceutical supply system. A PMIS should also have a mechanism to provide feedback to the reporting centers and to stakeholders.

Currently in Afghanistan, donors (e.g., USAID, World Bank, European Commission) procure and manage most pharmaceuticals through NGOs. Operational levels collect disparate pieces of information to meet specific donor reporting needs. Because the government has little direct pharmaceutical management responsibility, local management capacity is very limited, and the PMIS has no central data point; for example, the government does not
systematically collect data on pharmaceutical commodities supplied through the CMS or Pharmaceutical Enterprise.

To create a sustainable PMIS that is independent of donor support, a pool of professionals will need to be trained and mobilized to design, implement, and maintain a PMIS.

The pharmaceutical commodity flow in Afghanistan is extensive and complex, but there is no parallel information flow. For example, no mechanism exists to track how many medicines are actually brought into the country by the donors or importers from the private sector and whether these drugs conform to national quality standards. There is also no database to verify the registration of the medicines.

Sub-objective (i). Strengthen pharmaceutical management information systems to support evidence-based decision-making:

MoPH's General Directorate of Policy and Planning recently included a PMIS in its strategic plan for 2009-2013 and has engaged GDPA in discussions regarding the system's development. Based on GOPA's request, USAID has committed its support to this initiative.

SPS will help MoPH design a comprehensive PMIS to be housed at the DIC computing facility and use it to make informed decisions regarding pharmaceutical management. SPS will work toward strengthening existing systems and adding new components only when necessary. Most importantly, SPS will ensure the development of local capacity, so that the new systems are sustainable.

Proposed Interventions:

1. In collaboration with other relevant U.S. and Afghan government partners and counterparts involved in both supply chain and HMIS, support the development and implementation of a comprehensive PMIS for the recording, reporting, analysis, and presentation of patient- and product-related data to support decision-making:

   Stakeholders and staff at every level and position use information to make decisions that affect the overall functioning of a pharmaceutical supply system. Therefore, a critical aspect of the system is its ability to address users' needs.

   SPS proposes using the existing CPOS to collaborate on the content and scope of PMIS. As previously described, the CPOS is a mechanism for sharing information among stakeholders to enable the Government of Afghanistan to manage pharmaceuticals and related products more efficiently and effectively. The DIC under the CPOS includes representation from relevant pharmaceutical management stakeholders. SPS will use the experience, knowledge, and authority of this committee to decide on the PMIS indicators and other data requirements. This strategy will help ensure that local stakeholders will take ownership of the PMIS design process, which is instrumental in its success.

   The current HMIS gathers data from community, health posts, clinics, and hospitals throughout the country, processes it, and generates information. The resulting information is shared at both provincial and central levels, where its meaningful analysis can help shape both local and national response and improve Afghan health services.

   The impressive reporting rates from BPHS and EPHS are over 90 percent and 80 percent, respectively. The HMIS unit has a pool of around 200 master trainers who continually train the health facilities and NGOs on HMIS procedures. The HMIS also has an established mechanism to validate data quality.

   Because the HMIS system is currently functional, SPS will explore using this channel to collect pharmaceutical commodity data required by CPOS rather than creating a parallel system. Currently, HMIS calculates one indicator to measure the stock-out of essential drugs at the health facilities. This system will be expanded to include more indicators that are relevant to pharmaceutical management.
• Formulate a strategy to collaborate with HMIS and other stakeholders to implement the PMIS;

• Collect additional data on medicine management (e.g., consumption, stock position, near expiring medicines) as identified by DIC;

• Consolidate the data at provincial level and produce essential reports;

• Design feedback reports to the reporting centers;

• Consolidate data at national level and produce essential reports;

• Design information, analysis, and presentation systems that facilitate decision making (e.g., comparison of consumption among different geographical regions, morbidity vs. medicine use pattern, cost of expiry);

• Conduct training needs analysis;

• Train potential master trainers;

• Train all relevant staff on the use of the PMIS; and

• Train all relevant staff on using PMIS information to make informed decisions.

This strategy of collaborating with the HMIS has several advantages regarding cost, turnaround time, and sustainability. Because the HMIS has national coverage, and other international organizations support its operation, there would be an opportunity to share costs with HMIS stakeholders in developing PMIS.

SPS will provide support to the HMIS Department to add PMIS components to its scope, including:

• Computer hardware and other equipment at the provincial and central level to handle additional PMIS functions;

• Minor office refurbishment at the provincial level; and

• Trained human resources at the provincial and central levels to validate data and supervise/train reporting centers on using the PMIS (SPS will also explore the possibility of training existing HMIS trainers in PMIS).

The DIC will analyze data and reports produced at the central HMIS to report to the CPOS coordinator or other CPOS committees. The DIC will have technical staff members who will coordinate with HMIS and produce reports as CPOS requires. The DIC computing facility will be housed at GDPA.

2. Provide continued support to the paper-based and other existing forms of management information systems as required.

As mentioned, SPS will work toward strengthening management information systems—including those that are paper-based—rather than creating new systems, unless absolutely necessary. SPS will follow these steps to strengthen existing systems and incorporate them into the new PMIS—

• Hold a stakeholder workshop to identify indicators to cover selection, procurement, distribution, and use; identify data elements and reporting frequency through a participatory process (DIC will contribute to this activity);

• Study the set of formats for both data recording and reporting and manual and automated procedures, and assess if the current manual formats are sufficient to collect the required data listed above; ensure the formats are easy to use and have written instructions; continue support in using manual formats if no modifications are required;

• Provide technical assistance to modify manual formats if necessary and help develop instructions to use them if they do not exist;

• Meet with stakeholders to finalize formats and procedures;
• Develop new manual forms and pilot in two provinces (including conducting orientation) them before putting them in use;
• Conduct training need analysis;
• Provide training on the use of the manual formats as necessary; and
• Provide training on the analysis and use of the information SPS will recommend automating PMIS components when appropriate, based on the availability of adequate physical infrastructure and human capacity.

In any case, automation will follow only after the successful implementation of a paper-based system.

3. Ensure collation of information related to medicine use outcomes (such as adherence indicators, adverse drug reactions) for pharmaceutical policy, medicine selection decisions, and treatment options:

Getting the medicine to the health facilities is only half the job. Information related to rational medicine use, including treatment adherence and adverse drug reactions, informs corrective interventions and even treatment policies. For example, the discovery of a prevalent adverse drug reaction can result in new treatment recommendations.

In this intervention, SPS will -
• As time and resources allow, consider incorporating a component into the PMIS to facilitate analysis of drug prescribing patterns and other data related to rational medicine use, such as adherence;
• As time and resources allow, consider incorporating a component into the PMIS to provide data for pharmacovigilance (medicine safety), including tracking and analyzing adverse drug reactions;
• Complete the ongoing effort to develop a database for medicine registration. Information from this database will serve as a valuable reference for medicine selection and procurement decision making;
• Conduct a training need analysis for planned new systems; and
• Train trainers and users on the new information systems

Expected Results:
As a result of the activities under this sub-objective, SPS expects to have in place a new PMIS; figure 4 shows the conceptual flow of information among data processing centers. The DIC/CPDS will clearly play the important role of identifying the information needs in collaboration with other CPOS committees. The existing HMIS system will provide additional data related to medicine while new pharmacovigilance and drug registration sub-systems, as they are developed, will provide vital information on adverse drug reactions and medicine regulatory information.
Figure 4. Proposed PMIS Information Flow for Afghanistan

Other expected results include the following:

• Availability of key pharmaceutical information needed for planning and decision-making especially for quantification, procurement, and inventory control;
• Availability of information on type and quantity of medicines being imported by the government, donor agencies, and local importers to facilitate pipeline analysis;
• Strengthened paper-based management information systems that are incorporated into overall PMIS;
• Increased percentage of facilities that submit reports on time;
• Increased accuracy of PMIS reports from facilities;
• Increased number of provinces that submit reports on time;
• Increased accuracy of PMIS reports from provinces;
• Ability of MOPH staff providing pharmaceutical services at all levels to use PMIS for pharmaceutical management decision making; and
• Improved product tracking ability resulting in increased availability of essential products at health facilities.
Under the Leader Award, SPS has developed a monitoring and evaluation (M&E) framework that has been applied to all portfolios since the start of the program. MSH will apply the same framework for the Afghanistan Associate Award.

Key components of this framework include annual work plan development, performance monitoring plan (PMP), and program reporting.

- **Work Plan Development**
  Mark Morris, who is based at the SPS headquarters in the United States, will provide project support by working closely with the in-country Chief of Party to develop detailed, country-specific annual workplans. Plans will be developed in consultation with designated staff at the USAID/Afghanistan Mission and with MSH counterparts and partners, ensuring a mutual understanding of objectives, expectations, and activities. The collaborative process ensures that work plans address critical health elements and that progress can be measured based on standard indicators.

  Work plans will include a brief narrative describing background, technical objectives, planned activities, timelines, and expected results. Sound technical principles and activity-level budgeting guide the work plan development process. A performance monitoring matrix will facilitate activity tracking. Work plans will specify how planned activities correspond to health sub-elements as well as to intermediate and program results. The plan will also specify expected products, output targets, and outcomes at the activity level.

- **Performance Monitoring Plan**
  To complement the work plans, the Afghanistan team will also develop and implement a detailed PMP, which follows USAID guidance. The PMP tracks performance over the life of the program and focuses on measuring progress through indicators. The plan will not only provide a basis for accountability, but also demonstrate impact of the interventions.

  MSH will develop an indicator protocol reference sheet for each indicator that addresses its definition; baseline value; annual benchmarks; the how, when, and by whom the data will be collected and processed; and reported. The measured results will in turn be used for evidence-based decision making by the program itself, USAID/Afghanistan, and the MoPH. The table below shows an example of indicators that could be used to monitor and evaluate program effectiveness.

  With oversight from headquarters, the M&E Specialist will manage the PMP, which is meant to be an up-to-date document that facilitates proactive management and programmatic decision making by supporting performance improvement and identifying state-of-the-art tools, approaches, best practices, and lessons learned that could then be used to plan subsequent activities. The PMP also supports program accountability because of its focus on data quality and data management.

**Strategic Monitoring System and Reporting:**

Use of SPS's existing web-based Strategic Monitoring System will help simplify planning and management for the Afghanistan Associate Award. Managed by the SPS Deputy Director and maintained by the Program Associate for Monitoring and Reporting, the system is accessible to all management staff, including those in the field, and allows managers to document progress toward defined outcomes and track progress through to activity completion.

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The Strategic Monitoring System supports annual progress reporting by categorizing portfolio information and defining data about tasks, activities, resources, and products. The system allows users to conduct cross-program and cross-activity searches, correlations, and gap analyses, and to report on contributions toward SPS intermediate results.

In addition to reports generated by the Strategic Monitoring System, the in-country Chief of Party will work with his SPS headquarters contact to assure that all other Mission-specific reporting requirements are adequately met. SPS will document lessons learned and best practices, share them with USAID, and disseminate them through appropriate channels.
ATTACHMENT C - STANDARD PROVISIONS

Add the following provisions under attachment C.

1. Central Contractor registration and Universal Identifier (OCTOBER 2010)
2. Reporting Sub awards and executive compensation (OCTOBER 2010)
3. Trafficking in persons (OCTOBER 2010)
4. Per Section A.15 SCHEDULE A AND STANDARD PROVISIONS: The Standard Provisions of the Leader Award apply to this Associate Award.

Complete details of the above standard provisions may be obtained at the following link.