HEALTH POLICY PROJECT

Capacity Assessment of the Afghan Ministry of Public Health to Implement a New Private Health Sector Regulation: A Legal Analysis and Design for Strengthening Regulatory Effectiveness

JANUARY 2013

This publication was prepared by Michele Forzley for the Health Policy Project.

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EXECUTIVE SUMMARY

Introduction

During the post-Taliban era, the Government of the Islamic Republic of Afghanistan (GIRoA) devised a national development strategy that aims to increase growth in the market economy. In this environment, Afghanistan's private health sector has experienced rapid growth. Currently, Afghanistan has approximately 150 private hospitals, 90 private drug producers and importers, and many private diagnostic and other types of health centers. According to 2011 National Health Accounts, in 2008-2009, 76% of total health spending, or $760 million, was spent in the private sector, almost all of which was from out-of-pocket expenditures by individuals.

Over the last five years, the Ministry of Public Health (MOPH) has been actively developing a framework to regulate the health sector, including the burgeoning private sector. The MOPH is also considering how to establish an environment to improve the delivery of private health services and enhance the coordination between the public and private health sectors. These themes of integrating the private sector into the health system and the evolution of the Ministry of Public Health from a service provider to a steward of the health sector are echoed key policy documents, including the Ministry's Strategic Plan 2011-2015, the National Health and Nutrition Policy 2012-2020 and the National Policy for Private Sector 2009-2014.

In August of 2012, the GIRoA took another major step towards regulating the private sector when its Cabinet passed a law titled Private Health Center Regulation (PHCR).[1] However, the MOPH's capacity for effective regulation is understood to be weak. Therefore, the USAID-funded Health Policy Project (HPP) conducted a structural assessment of the MOPH in relation to implementation of the mandates in the PHCR and the private health sector strategic documents, to document MOPH strengths and weaknesses and to facilitate a MOPH plan for addressing gaps and strengthen its regulatory effectiveness. This report describes the findings from an assessment of the MOPH's capacity to implement the new law and proposes a design to build this capacity.

Methodology

The framework for private sector development is strongly grounded in the MOPH policy direction to be the *steward* of the health sector through mechanisms, actions and effective regulation.[2] These are stated to include strengthening institutional and organizational capacity at central and provincial levels for better leadership, administration and management—in other words, to govern and effectively regulate. Without good stewardship, it would be difficult, if not impossible, to fulfill the MOPH commitment to maintain an environment that is conducive for private sector to deliver health services which are now understood to be essential and for private sector services to be of good quality. With the enactment of the PHCR, the MOPH role as steward and regulator of the private sector is now grounded in a legal framework that establishes the MOPH as the authority to regulate private health care centers and the boundaries and outline of the key features of the acts of stewardship.

Since the PHCR is a law and is the starting point for the role of MOPH as regulator of private health centers, a legal analysis, conducted through a desk review and stakeholder interviews served as the

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method or foundation for this assessment. The resulting capacity building recommendations to strengthen the MOPH to govern, steward, and regulate the private sector stem from what the PHCR, a law, directs the MOPH to do. Supplementing the PHCR are other national laws—most importantly, the Public Health Law which establishes the MOPH and its basic duties, responsibilities, authority and relationship to other government ministries and branches. Also important are the policy documents noted above.

The method for this assessment was unusual in the realm of health sector assessments, which generally do not include a legal document or its analysis or use as the basis for assessment. What is important about this manner of assessing capacity is that this assessment looked at regulatory capacity to implement a law. Heretofore, health sector capacity was considered from a quantitative perspective (for example, the number of staff per patient) and the clinical perspective (how well are medical staff providing health care services in relation to existing standards). Regulatory capacity or *effectiveness* is more than and different from clinical competence. This study therefore looked at regulatory effectiveness from its starting point, which is the legal infrastructure that authorizes the regulator to act. For the field of health sector governance to mature, this approach must become elemental to every assessment and capacity building plan. This assessment is one of the first to consider this dimension of regulatory capacity. Since there are few, if any, health sector assessments that relate to the legal foundation of a ministry of health, no available assessment tool could be deployed. Thus, legal analysis was used to devise a set of questions related to the capacity of the relevant MOPH departments to implement the actions the PHCR assigns to each.

Key Findings

The MOPH is committed to good governance; however, the assessment found a number of areas for strengthening its regulatory effectiveness. First, the MOPH must strengthen its internal understanding of how a private sector successfully functions. This will require business basics, health care administration and regulatory expertise, which are not well developed in this ministry or others around the world in a similar transition. However, these can be learned and are the topics recommended in as part of the capacity building.

The assessment also identified a need to build systems, such as licensing, in a manner that results in a smooth, transparent process that welcomes private sector investment, delegates authority down the system and reduces opportunities for corruption. Designing an application form that is approved by the Minister is an easy mechanism to accomplish the removal of several of the 17 steps now necessary to get a license. To do this, the Minister must delegate, and lower level staff must be given more authority to act within appropriate procedures and oversight.

There is also a need to create a review body for MOPH decisions, since there is presently no independent review process of decisions made by departments (such as those on whether a hospital license application is complete, or whether a health center is in compliance). The lack of review process creates an opportunity for corruption and establishes a power imbalance by giving the Minister and heads of units and departments greater power than is appropriate. Having an independent review body will demonstrate a commitment to transparency, oversight and integrity.

This assessment was designed to also identify gaps and weaknesses. The main gap is that the MOPH has not taken time to learn the content of the PHCR, nor to determine what it has to do to realign itself to meet its new obligations and assign tasks to the relevant departments. Thus, the MOPH must be trained on the content of the PHCR and develop a plan for its implementation. In addition, as mentioned, the MOPH must be trained in other areas that are needed for effective regulation, such as basic business skills, finance, hospital administration, good inspection practices, and on rule of law.

ABBREVIATIONS

ACCI	Afghan Chamber of Commerce and Industry
AISA	Afghan Investment Office
APHA	Afghan Private Hospital Association
AIDC	Aid Coordinating Office
BPHS	Basic Package of Health Services
DM&E	Directorate of Monitoring and Evaluation
EHU	Environmental Health Unit
EPHS	Essential Package of Hospital Services
GD	General Directorate
GDCM	General Directorate for Curative Medicine
GDHR	General Directorate for Human Resources
GDP&P	General Directorate for Policy and Planning
GDPA	General Directorate for Pharmaceutical Affairs
GDPM	General Directorate for Preventive Medicine
GIHS	Institute of Health Sciences
GLP	Good Laboratory Practices
GPP	Good Pharmacy Practices
HACCP	Hazard Analysis & Critical Control Points
HMIS	Health Management Information System
HPP	Health Policy Project
HR	Human Resources
ICD 10	International Classification of Diseases Tenth Edition
IR	International Relations
ISO	International Standards Organization
JCI	Joint Commission International
LI	Legislation and Regulation Implementation Directorate
MOI	Ministry of Interior
MOJ	Ministry of Justice
MOPH	Ministry of Public Health
NAC	Norwegian Aid Committee
NGO	Non-governmental organization
NPDs	National Policy Documents
NDS	National Directorate of Security
OPSC	Office of Private Sector Coordination
PHCR	Private Health Center Regulation
PPP	Public Private Partnership
PU	Policy Unit
QC	Food and Drug Quality Control Department
TOR	Terms of Reference
UNFPA	United National Family Planning
USAID	United States Agency for International Development

INTRODUCTION

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METHODOLOGY

The methodology used to conduct the assessment was legal analysis and stakeholder interviews. However, while there are some models and tools available to guide legislative drafting, there are none to guide an assessment of this type. Therefore, the consultant engaged for this assessment designed interview questionnaires, which were informed by the legal analysis of the PHCR and national policy and other legal documents, including laws on non-governmental actors and investment. The policy documents reviewed included the MOPH's National Health and Nutrition Policy 2012-2020 and its Strategic Plan 2011-2015, the National Policy for Private Sector 2009-2014, the Strategic Plan to Support the National Policy and related Action Plan of February 2012, collectively referred to here as national policy documents, or NPDs. The assessment took into consideration the structural elements of the entire health system, the roles of various departments in relation to the private sector regulation and its implementation, and MOPH stewardship goals, as well as quantitative dimensions such as organograms, staff numbers and qualifications, and unit terms of reference in general and in relation to the new regulation.

[3] The PHCR is given the appellation of a regulation, but it is also referred to as a law. Generally, legal instruments named legislation are laws passed by a parliament; when named a *regulation*, it is a legal instrument enacted by a ministry but having the effect of a law. In Afghanistan, the Cabinet is also empowered to enact a law called a regulation.

Data collection took place from November 11- December 4, 2012 in Kabul, following remote desk top analysis. Over 27 formal interviews were conducted with MOPH staff in departments relevant to regulation of private sector, and numerous informal interviews of HPP and Office of Private Sector Coordination (OPSC) key staff. Annex D provides a list of interviews conducted. Various documents were also collected, including department *taskheel* (organograms), staffing profiles and data on number, type and location of private health centers. These were provided to HPP and OPSC staff and not included in this report. The document collection was not completed as some informants have not delivered requested documents to date, some are not yet translated from Dari to English and additional informants were not available to be interviewed due to schedule conflicts.

Following the assessment, a capacity building workshop was held to both validate the findings from the assessment and to build consensus on a proposed capacity building plan. Informants not available for interview were also invited to the capacity building workshop.

Workshop Planning

On November 26, 2012 Deputy Minister Dr. Ahmad Jan Naeen was briefed on preliminary findings and the proposed plan for a workshop. After agreement, the workshop was scheduled and invitations sent to all informants and others. The purpose of the workshop was to present and validate preliminary findings and recommendations, to prioritize next steps and build consensus on a proposed capacity building plan. Another important purpose of this workshop was to demonstrate and explain the Planning Book described next. The Planning Book is the document designed to present consultant's ideas and to capture MOPH input so both can be integrated into the final capacity building plan which is in essence the PHCR implementation plan. The Planning Book is a primary component of the design of the capacity building plan. The Planning Book was created in Excel format and contained sections organized by the units identified in the PHCR as responsible for particular functions, with a section for MOPH senior leadership and for functions otherwise allocated by the other laws most notably the Public Health Law and by operational necessity such as legal and Health Management Information Systems unit (HMIS). Copies of the Workshop version of the Planning Book and workshop presentation are included at Annexes E and F.

The Workshop

The workshop was held on the afternoon of December 2, 2012. Prof. Forzley and Dr. Saadat presented the findings, their interpretation and recommendations for next steps. Participants received copies of the actual full text of the PHCR, the Planning Book, the outline of PHCR articles by function and relevant MOPH unit.

The workshop participants were in agreement with the following schedule and plan:

- The Planning Book with MOPH input was due to be delivered to OPSC by December 22, 2013. This accelerated timeline was determined by the workshop participants.
    - Participants will submit Planning Books to OPSC (Dr. Saadat) for collection, review by OPSC, law department, and relevant senior Ministry staff.
    - Planning Books will outline work to be done by each standalone department or in concert with relevant departments to improve and streamline processes to support the regulation.
- Participants expressed strong interest in a multiple-day training and planning event to include the urgent items of licensing, learning on the regulation and the private sector, business and finance and others and for consultant to guide the implementation of the Planning Book.
- All participants will begin to implement actions in the Planning Books and start tracking progress.
- Participants strongly expressed interest for a Second Implementation Workshop to review and assess progress February/March 2013 and for training on PHCR and other topics noted in this report.

Post Workshop Actions

After the workshop, consultant held internal meeting for the purpose of debriefing the HPP, MOPH and OPSC teams. Consultant submitted to HPP a draft report and capacity building plan on December 20, 2012. The draft report contained Planning Book Suggestions and a Proposed Timeline for each unit of MOPH with a role in the PHCR as identified in the report of findings. MOPH completed the Planning Book as decided during the workshop and it was delivered to consultant in early January 2013. The Planning Book Suggestions originally in the draft of this report are now integrated with the Planning Book with MOPH input. A comprehensive Planning Book will be delivered to HPP with the final version of this report. Given the sensitive nature of the content, any decisions on the dissemination of the Planning Book will be made by HPP and MOPH.

The content is sensitive as there are a number of policy and structural decisions to be made in order to implement the Planning Book content. Some of the work to do this can occur during the anticipated second workshop.

OVERVIEW OF THE PRIVATE HEALTH CENTER REGULATION

In August 2012, (effective date solar calendar 5/21/1691), the Cabinet of Afghanistan approved the Private Health Center Regulation. Though called a regulation (*mukararah*) and not passed by Parliament, this legal instrument is a law under the Afghanistan legal system. This nomenclature is unusual; in many countries the term *regulation* is used for a legal instrument enacted by a ministry, also known as an administrative regulation. A regulation is a sub-national law and has the same force and effect of law, but is generally enacted outside of parliament and within the technical expertise of the relevant ministry to elaborate, add details or other dimensions necessary for a piece of legislation to be implemented.

The PHCR has a limited scope. By its own language, PHCR is only applicable to private health centers which are defined as hospitals, clinics, physical therapy centers and radiology centers. It does not apply to pharmacies or any other health actor that might be found in the private sector. It is national in scope; therefore, it is also applicable to provincial health centers and includes those owned and operated by individuals, entities, nationals and foreigners.

The regulation gives legal authority to the MOPH to regulate private health centers with three main mechanisms, including (1) how they are licensed, monitored, and sanctioned for non-compliance with requirements; (2) the conditions under which a private health center can be licensed and licensure maintained; and (3) the requirement to comply with established or new MOPH standards.

FINDINGS

Department/units' roles and capacity in relation to the private sector

One of the goals of this assessment was to conduct a baseline and structural assessment to identify the key departments/units relevant to the implementation of the PHCR. In this section, findings are presented by department or unit in relation to each function prescribed in the regulation. A chart referencing the specific articles of the PHCR, duties and related procedures or functions, organized by the relevant MOPH department/unit, is included at Annex A.

Like any legal instrument, not all details are included in its articles. Instead, some of the functions, authorities, roles, or mandates are found in another body of law, such as the Afghan Public Health Law, the laws on NGOS or investment or in a policy statement, or are implicit and understood as the role of a regulator. For example an implicit function of a regulator is to enforce a law under its jurisdiction. Finally, a law such as the PHCR is not the appropriate place for certain types of regulatory mechanisms,

such as the level of sanction applicable to a violation of a law, so these are not within its text; instead the MOPH is directed to draft another regulatory document from the options available under the Afghan legal system and those common to all health systems or is referred to another law explicitly or implicitly as is the case for sanctions. The types of regulatory documents under the Afghan legal system are listed and described in Box 1.

Under the regulation, a number of functions are designated, including: licensing, monitoring and evaluation and control, health management information systems, authority to adopt bills, procedures and guidelines to better implement the regulation, authority to discipline and punish breaches of the regulation, and the establishment of three commissions to resolve conflicts, medical disputes and to determine fees. The PHCR does not specify all the MOPH units responsible for implementing each particular function; instead, it refers simply to "MOPH" to do what the regulation requires (as is typical for laws) and leaves the MOPH to undertake its role according to its technical capacity. While the Afghan Public Health Law was not available during the assessment, it is assumed that it authorizes the MOPH, under its general authority as a ministry, to regulate the health sector and that other regulatory means and measures would be found in its terms. It is within this general regulatory authority that the role of stewardship is found and rightfully placed as a prime objective in the National Health and Nutrition Policy 2012-2020 and other NPDs.

The Senior Management and Leaders of MOPH: Office of the Minister and all Deputy Ministers, Directors of General Directorate:

The role of MOPH senior management and leaders is not specified in the PHCR; rather, it derives from the Afghan Public Health Law and all NPDs. These reflect national policies from sectors other than health that support the private sector, and they also reflect the MOPH's transition from a service provider to a modern regulator. In this regard, NPDs mandate MOPH senior management and leadership to develop its role as steward of the health sector. The NPDs provide these clear goals and these elements of a framework in which to move ahead:

- *"Strengthen institutional and organizational capacity: better leadership, administration and management*
- *Maintain an environment conducive for private sector to deliver services*
- *Develop and apply mechanisms for effective regulation through: information systems, expansion of quality services with model for participatory assessment, motivation and sanction*
- *At central and provincial levels*
- *Principles: oversight, transparency, accountability and legitimacy*[4]

The MOPH leadership has strong policy documents and is devoting high-level attention to the process of transforming itself into a modern regulator. Moreover, it has highlighted the importance of meeting the health needs of Afghans and is moving ahead to integrate the private sector as its partner to meet these needs. The MOPH is currently in the process of implementing the PHCR, which grants it the powers and legal mechanism to regulate private health centers.

The MOPH has also undergone an assessment of its overall institutional capacity as the regulator of the entire health sector by an EU funded project in addition to this assessment which specifically and only focused on its capacity to regulate the private sector.[5] The willingness to be assessed and take action in response to findings is a strength and key element of the *practice of capacity building.* Assessment is essential to strengthening institutional and organizational capacity, which is part of the role of

[4] The National Health and Nutrition Policy 2012-2020 of the Ministry of Public Health, Section 3: Policy Directions.
[5] Technical Cooperation Mapping and Institutional Reorganization Debrief PowerPoint, 28 May 2012, J Roos, G Kroes and L Sales.

stewardship.[6] Studies on regulatory effectiveness indicate that higher quality regulatory governance is associated with superior outcomes and that good institutions are able generate future good policy decisions out of their experience with past good policy decisions.[7] In this regard, the MOPH is on a good path to being a good institution and modern regulator.

As MOPH considers the proposed organization changes as suggested in the EU study and its own internal reorganization plans, its role as the regulator of the private health sector should be considered. It is not recommended that entirely separate departments are created to regulate the private health sector as this approach will create unnecessary layers of the system that will have to be managed. More importantly, if the private health sector is to become the major provider of health services it should be integrated as much as possible into the health system and not treated as a separate entity though its specific needs should be taken into account.

Gaps and Weaknesses

Given that the PHCR was just a few months old at the time of this assessment and the explicit function of stewardship of a private sector is a new role for MOPH, this section on gaps and weaknesses and others throughout this report should not be viewed as criticism but more as suggestions for steps to be taken in order to efficiently implement the regulation. Nonetheless, the importance of the areas identified in this section should not be underestimated both for their role in regulating the private health sector and in terms of the MOPH's role as steward of the entire health sector.

Stewardship: The MOPH is undertaking its role as steward by seeking guidance on the implementation of the PHCR. If there is a gap in this regard, it is that this work was not conducted prior to the submission of the PHCR text to the Ministry of Justice (MOJ) and presentation to the Cabinet. Had this been done, the text might have had been different and reflected the capacity of the MOPH. In addition, departments/units have not been given direction from the senior management on how to proceed, and departments/units are not familiar with the text and responsibilities as provided by the PHCR.

This gap was filled to some extent during the capacity building workshop on December 2, when the General Directorate (GD) of Policy and Planning and the GD of Curative Medicine took the lead in directing units to complete the Planning Book by December 22, and a committee was established to consider the matter of reorganizing the licensing department among other work streams.

In addition to seeking expert guidance and technical assistance when necessary, another dimension of leadership/stewardship is to ensure that senior leadership speaks with one clear voice on the importance of any policy or regulation. It is noteworthy that the Minister of Health herself did not attend the workshop on private sector, nor did the legal advisor, the director of HMIS or anyone from General Directorate of Pharmaceutical Affairs (GDPA). Without clear direction from MOPH senior leadership as to what is to be done, it will be difficult to fully implement the regulation in a systematic manner.

Finally, the PHCR leaves open the naming of a lead unit or team to establish three commissions (two for conflict resolution and one for fee determination) and draft related procedures and terms of reference for each, as referred to in Articles 22, 23, 40 and 24. These commissions have not yet been established. There

[6] Rosensweig, Fred. March 2012 *Organizational Capacity Building:* Lessons to Strengthen Health Systems. Brief, Bethesda, MD Abt Associates. Health Systems 2020. See also *Lessons Learned in Organizational Capacity Building for Health Systems Strengthening*, Health Systems 20/20.
[7] Department of Economics School of Social Sciences Regulatory Effectiveness: *The Impact of Good Regulatory Governance on Electricity Industry Capacity and Efficiency in Developing Countries*. John Cubbin, Jon Stern, City University and London Business School London Business School Discussion Paper Series No. 04/04. See also Rodrik, Subramanian and Trebbi (2002) for a recent survey of the literature on studies of cross-country growth performance.

does not appear to be any substantial issues around the dispute setting commissions other than the overall need for procedures and a review process.

However, the fee setting commission has raised concerns that were strongly expressed by the private sector through the Afghan Private Hospitals Association (APHA) and echoed by the OPSC. The main element of the concerns is that private hospital operators do not want to have their pricing regulated and that this freedom was part of the original draft of PHCR before it was processed for approval by the Cabinet. The MOPH can seek an amendment to the PHCR to remove the relevant provisions. If the amendment route is not successful and a fee-setting body is required, without any amendment, the MOPH can establish clear guidelines for its operation that reflect business principles on which a strong private sector can flourish. While the concerns around fee setting are appreciated, the MOPH is within its authority to expand the work of the commissions required by PHCR or integrate their functions work with other activities underway. Some examples follow. Strengthening the transparency of the private health sector, MOPH could, as part of the fee commission, require that health center fees are posted in various public places so patients can compare and select providers – a benefit to patients who are paying out pocket for services. Moreover, since there is a MOPH HMIS plan to integrate ICD-10 coding into MOPH data collection, it is possible that fee-setting commission can relate its fee determinations to ICD-10 codes, a step that will result in robust fee and other health services and statistical data across the entire health sector. Finally, services could be standardized according to treatment guidelines and identified with specific codes which will permit comparison across providers and provide data for the ministry with which to plan and understand morbidity and mortality trends in Afghanistan.

Respect for rule of law and role of law and lawyers: Implementing the PHCR means implementing a law. Effectively implementing a law requires an understanding of the text itself, its scope, its requirements and mandates, as well as the implications for the MOPH. The MOPH has not distributed the PHCR to its senior management, and leaders have not had any meetings to discuss its content nor to plan for implementation. At a most basic level, there can be no respect for rule of law if the law is unknown to the MOPH. Of the people interviewed, only one person in the OPSC had a copy of the law at hand. Some managers did not even know the law had passed or that their department was specifically referenced in it. The next section of this report on the office of legal advisor details particular steps to be taken in regards to implementing the law.

The absence of respect for rule of law and need to have the guidance of a lawyer was demonstrated by several situations observed during the assessment. The first is the frequent reference to corruption. Simply put, senior management should include integrating anti-corruption initiatives into all departmental work and a mandating a zero tolerance policy for corruption. Supporting this will be the establishment of review systems for all decision points in the system, especially for licensing, monitoring and evaluation and legislative implementation, the three commissions, and any sanctions procedures. Such a review system does not exist now. To reflect good rule of law practice, a review systems must delegate authority away from the top levels of management and leadership to an independent body or department established to serve as an internal administrative review body. Second, it will be essential to involve the MOPH legal department in the implementation of PHCR, starting with review of PHCR to confirm the findings of this report and the directions and suggestions within it. This review can and will support the elimination of the duplications, overlaps and conflicts between the directorates of Monitoring and Evaluation, Legislation Implementation and Food and Drug Quality Control Departments. These conflicts and areas for clarification are described in this report.

Finally, the work of the Directorate of Monitoring and Evaluation Department (DM&E) is not grounded in any law or regulation. The PHCR only states that DM&E is to be engaged in monitoring and evaluation. DM&E operations are guided entirely by the procedures and checklists they create. DM&E is to monitor compliance with standards, which may certainly reflect good practices; however, the processes

by which they operate are not grounded in law. In comparison, the Legislation and Regulation Implementation Directorate activities are bound by whatever law they enforcing. This is not so for M& E which currently has free reign in its work. This situation should be corrected.

Inter and Intra-ministerial coordination and alignment: The private health sector is, to some extent, a new set of stakeholders for the MOPH. While there are many private sector health actors in Afghanistan, the PHCR is a modern regulation in the post-Taliban era and is in place concurrently with a national economic policy. As such, to properly regulate the private health sector, it will be necessary for some—especially MOPH senior leadership—to learn about the private sector to be able to regulate it in a way that is conducive to its growth and success. MOPH has taken steps to become more expert in private sector operations and has opened a channel of communications through a public-private forum.

Nonetheless, both the MOPH's and private health sector stakeholders' gaps in knowledge around the private sector are substantial and will need to be mitigated so that unanticipated problems do not arise. For example, during the assessment, a focus group meeting was held with private hospital owners, who were asked, "What is your gross profit margin?" None could readily answer this basic financial question.

The PHCR mandates the establishment of a commission to determine fees, which will require that hospital owners to make a case for the fees they wish to charge. While this article of the PHCR is the subject of great discussion and will likely be amended, until it is amended, its implementation is a requirement. Thus, the commission, its members, and its procedures must reflect an understanding of what it takes to operate a business so that decisions on fees are not disconnected from basic business principles on which successful businesses are built. MOPH senior leadership, the commission members and the private sector hospital owners must learn about basic business principles in order to successfully deliver quality health care within a financial framework that allows business to survive and thrive so as to attract the investment needed to run health centers that meet national and international standards.

The MOPH will have to coordinate at both the intra- and inter-ministerial levels to ensure that regulatory interventions are aligned with basic business principles and the policy objections in NPDs such as the intention to create an environment that is conducive to the private sector. For instance, other ministries and governmental units, such as the police, are involved in the licensing process. The MOPH must coordinate with the Ministry of Higher Education to smooth the process to obtain education certificates for health professionals; with the police for background checks, with municipalities on land transfer so that hospitals can be built in property other than rental units (which makes owners reluctant to invest to meet minimum required standards); and so on. All ministries and governmental units should be aligned with the existing national economic policies on the private sector and thus coordination, in theory, should not be a problem. But as the private sector is not widely accepted as the preferred path by all in decision making positions across the government as reported during this assessment, there may be a need for the MOPH senior leadership to advocate on behalf of private health at inter-ministerial and intra-ministerial levels.

This coordination will be especially important to the amendment process of the PHCR. The MOPH must have the support of the MOJ and/or the enough Cabinet members (through the direct amendment route) so that desired amendments are not derailed. In this regard, good relations with the Minister of Commerce, AISA and the trade association are also important. As a business-focused actor, the Afghanistan Chamber of Commerce and Industry (ACCI) will also be very helpful because they are well-versed in the realm of the private sector and should be natural allies on changes to the PHCR, and they can provide useful counsel on regulating the private sector.

BOX 1: Types of legislation *in Afghanistan in hierarchical order:*

Constitution

Canon*; national legislation enacted by Parliament.*

Mukararah *(regulation) enacted by the Cabinet and imitated by a ministry.*

Tarzal Amal *(another kind of regulation) issued by the ministry and usually of a procedural nature.*

Liha *(an SOP) issued by a department of a ministry, Liha and tarzal amal can be used to deal with a problematic area of mukararah, or canon.*

Management Documents; *non-legal but binding as referenced in legal documents. Includes standards, checklists, guidelines, internal principles (ousool), and codes of conduct.*

The Office of Legal Advisor and lawyers in MOPH

Every function of the MOPH has one or more legal implications and all have some degree of legal authorization, yet there is only one lawyer, referred to as the legal advisor, who serves as counsel to the ministry as a whole; one lawyer in the Legislative Implementation sub-unit that processes violators (the other person is a pharmacist); and a law student in the Policies Unit responsible for drafting regulations, *liha* and *tarzal amal* and managing the process for their approval or amendment with the MOJ and Cabinet. Of the 16 staff in the Audit department, which monitors the expenditure of ministry money, one or more may be a lawyer. This needs to be confirmed, as the Audit unit may become relevant to the PHCR if a private actor is the recipient of ministry funding—for instance, if the MOPH contracts out to a private hospital, which is a likely possibility.

These two lawyers and one law student, excluding those who may be in the Audit unit are responsible for important legal functions. They are not considered part of a law department, and they work independently of each other. None of the departments/units with functional responsibility under PHCR have access to a lawyer; moreover, as the legal advisor alone cannot handle all the legal affairs of the MOPH, let alone assist the office of the Minister of Health. The Office of the Legal Advisor has proposed to the Minister to place legal advisors in the MOPH *tashkeel*, recommending the addition of 4-6 or more attorneys overall, each of whom would be assigned a work portfolio that reflects the functional aspects of the MOPH as a whole, and at least one to oversee the work related to the private sector. The need for an additional lawyer and overall supervision of the lawyers in the Legislative Implementation unit that prosecutes violators is particularly critical, as this unit has the power to close a hospital, and there is little-to-no procedure that reflects due process or any review process of the decision made by this unit.

It is recommended to develop a legal department, with lawyers assigned to each department/ function but sitting in one office as a team so that they are not isolated in the system and can backstop each other. Moreover, such a legal department will benefit from continuing legal education and learning on legal aspects of a regulatory agency. A key regulatory function is to appreciate the legal implications of programs, policies and plans. This will require available legal expertise to review programs, policies and plans and to provide input as to their legal implications and recommendations on what legal steps should or must be taken to effectuate those plans. Staff not trained in the profession of law should not be expected to interpret law, as this is unlicensed practice of law. No institution with integrity should allow this.

One example of a current legal matter is that the Minister has asked Office of the Legal Advisor to establish a committee to finalize the standards for private hospitals. This is important as there are several functions, including licensing, sanctions, accreditation and renewal of license, that relate to the variety of standards PHCR lists and which are noted Box 2. Moreover, the advice of legal counsel should guide

decision-making of the two main senior management bodies of the MOPH; the High Council and the Executive Board, and the legal counsel should have direct access to the Minister without intervention by anyone, including a Chief of Staff.

Amendment of a mukararah

A major pending matter is the possible amendment of the PHCR. Amendment may be needed to address PHCR components that are objectionable to the private sector and MOPH. These aspects include the fee setting commission, the fees at inception and renewal and the accreditation requirement. While these are detailed later in this report, in the section on OPSC, it is important to note that the capacity to amend a law is an essential regulatory function no matter the subject of the amendment or why it is needed. So here, we consider the process under Afghanistan law and the capacity of the MOPH to execute the amendment process. The MOPH has four options. The first option is to implement the regulation in its current approved form, until the PHCR is amended.

The second option is to draft a regulatory instrument such as a *liha* or *tarzal amal* that interprets the PHCR so that it can be implemented and surmount the objectionable content. One example of this is the timing of compliance with standards and licensing which can be phased in rather than required all at once. This is explained in this report in more detail as are other examples of solutions to parts of PHCR considered by some as objectionable.

The two paths to amendment are the third and fourth options, but of all persons interviewed, including those involved in preparing for the amendment, only the legal advisor knew of both. One is to form a committee in the GD Policy and Planning to lead the redrafting. Once the committee has completed its work, a letter is sent from the MOPH to the MOJ outlining the desired amendments and for further action. On receipt, the MOJ will consider the amendments and make recommendation to the Cabinet. There is one lawyer in MOJ responsible for health matters, and he prepares the request for the Executive Board of the MOJ. After the MOJ Board meets, the letter moves to another MOJ (*Takneed*[8]) department, which drafts a letter to be signed by the Minister of Justice, which is then sent to the General Directorate of Law of the Cabinet. This process can take a year. At present, a letter is being drafted by the MOPH to explain the objections to certain articles that are viewed as inconsistent with the national strategy on private sector. Thus, if this route is taken, there is a long period before the amendment, if successful, will be in place. During this period, the MOPH must implement the PHCR as enacted and approved by the Cabinet.

The fourth option is direct amendment done at Cabinet level and presented by the Minister of Health. In this approach the Minister places the idea of amendment on the Cabinet agenda according to the required procedure. This path avoids the steps at the MOJ and has the advantage that, before the Cabinet meeting to discuss the amendment, the Minister can gather support among other Cabinet members to ensure success. This is reported as a fast-track approach.

Development of a tarzal amal, liha and other management documents

PHCR Article 52 is clear that the MOPH can adopt bills, procedures, and guidelines to better implement the regulation. Some of these documents are legal in nature; the types of legal documents under the Afghan legal system are described in Box 1. Some are policy documents and some are management documents such as standard operating procedures (SOPs). Even if a document is not legal in nature, such as an SOP or policy document, because it is mandated or directed by the law, it takes on a different status and effect if its terms are breached in some way. This is because the law references the current version of

[8] This word needs to be confirmed.

the SOP or other document, in which case its terms are integrated by reference. The clearest example of this is the MRS, which are required for licensure and can be the grounds for legal action if they are breached in a substantial way.

These legal documents are drafted by the relevant department according to its needs and presented to the Executive Board for approval and signature by Minister. One problematic area of the PHCR is the requirement of accreditation, because there is currently no accreditation body and efforts towards this over the past three years have not resulted in the formation of this body. A *tarzal amal* could be written to direct internal procedures and, in the case of accreditation, a *tarzal amal* could provide for accreditation by an international organization such as ISO or JCI until a domestic body is available. Nonetheless only the legal advisor knew this, and he had not been consulted by any unit on this topic.

The fact that a viable solution to a problem with the implementation of the PHCR was available but no one had considered asking the legal advisor is a cause for concern, as all relevant units are positioned to or are already in the process of drafting new guidelines, checklists, and SOP to implement its terms. To ensure these documents are consistent with the NPDs and are not duplicative in nature between departments and functions, it is suggested that a drafting group be formed, which includes representatives from each relevant MOPH unit, and a legal review is conducted during the drafting phase.

Internal Review Process

There does not appear to be a clear process to review decisions made by a department, except to go back to the decision-maker—generally, the director. In the Directorate of Legislative Implementation, for example, if a punishment is imposed, such as a fine or closure, and a hospital operator is in disagreement with the punishment, the only recourse is for the operator to approach the director who signed off on the punishment. There is no process for notice, or hearing or other opportunity to defend a claim of wrongdoing. There is an urgent need to review all the processes related to law enforcement activities in this unit and any others in MOPH that can make decisions about a person or entity that is not staff. There are procedures under the Civil Service Law to consider the complaints of staff, but this law will not apply to the any party in the private sector.

General Directorate of Policy and Planning (GDP&P)

The General Directorate of Policy and Planning (GDP&P) is the unit of MOPH where the OPSC, HMIS and Policies Unit (PU) are situated, along with other units that provide support to the planning function. This GD has approximately 33 staff persons comprised of 12 staff in health care financing who have either an MD or MPH, a planning directorate of 33 persons with 1 or 2 staff with doctorate degrees and the rest with a BA in planning and management and administrative staff. The HMIS unit has 5 staff and a director who has an MD. There is 6 staff in the Public-Private Partnership (PPP) unit, 4 in OPSC and 3 in the new Aid Coordinating Unit.

The GDP&P and its sub-units are vital to the practical implementation of all aspects of the new regulation, solving problems and coordinating across the MOPH. This directorate will lead the critical stewardship functions of coordination, identification and removal of duplication, ensuring that planning is undertaken as necessary, in processing the amendments to the regulation as needed and in drafting and enacting one or more of the range of legal instruments available to it as a regulatory agency (see Box 1). The directors of the GDP&P and the OPSC attended and participated in the half-day capacity workshop and will remain instrumental in organizing next steps in response to the Planning Book (Annex E) recommendations. Their attendance and immediate response to the workshop and Planning Book recommendations reflects their awareness of their role and capacity to fulfill it. The GDP&P director took charge of the planning process suggested during the workshop and was in agreement on the priority

of redesigning the licensing process. He mandated all units to complete the Planning Book ten days earlier than proposed and established a working group to look at licensing. In fact, all units completed the Planning Book, and this input has been merged with the final Planning Book to be supplied to the MOPH for its use and determination of how to disseminate it publicly.

The PHCR was approved by the Cabinet in August 2012 and requires compliance within a year by all private health centers. This means that the MOPH must be ready to implement the PHCR/in the process of implementation by August of 2013. Though the terms of the regulation were negotiated with the private health sector (for which it is reported there was consensus), when the draft subsequently went to the Ministry of Justice, changes were made to it that are causes of concern for the private health sector and MOPH. These changes are in reference to the license fees in Art.6, the fee setting function in Art. 24, the renewal license fees in Art. 10 and the accreditation requirements of Art. 11 (especially since there is no standing accreditation body). Informants also raised the concerns of the lack of financial support in the form of loans or other mechanisms to build or renovate a hospital and the fact that an investment in a private hospital would be illiquid as a consequence of the deposit requirements under Art. 6. These requirements could be met with a bond, if possible, under the Afghan financial system, but the MOPH will have to coordinate with the financial sector, a function the GDP&P will have to fulfill. Given that there is a widespread lack of understanding about the private sector in the MOPH and among the members of the private health sector providers, resolving these concerns and others may be slow.

Though there is clarity in the GDP&P about the perceived problems with the regulation, at the time of the assessment, there was no plan to resolve the problems or to implement the regulation. For example, one fundamental dimension of implementation is licensing, but reports were conflicting regarding what to do with the approximately 200 applications pending at the time of the new regulation. The licensing unit indicated it had asked for direction, and the GDP&P indicated it had directed that all pending applications must comply with the new regulation. This is but one example of the many ways in which the GDP&P must lead the process and be clear to all units on what they are to do. Another example is the GDP&P did not have good data on existing health centers and has no idea on the number of potential or pending applicants. Thus they had no idea of the quantity of work they were facing in the months ahead. There can be no good governance in the absence of information. This information problem may be solved by a World Bank study to be completed in the first half of 2013 that will inventory all private health centers in Afghanistan, thus creating a comprehensive data set.

With regard to a plan to implement the regulation, the workshop conducted in December 2012 and the related capacity building design described in this report were essentially structured to provide the space for the GDP&P and related MOPH staff to focus on planning, problem solving, and implementation. Given the short time frame to comply with the regulation, several key functions will require immediate attention in the months until August 2013. These are to:

1. Revise the licensing process.
2. Grade the standards so these are phased in over three years, establish a process for applying the standards and relate a level of license to the phases (this is detailed in the section on licensing in this report) so that existing health centers have time to upgrade and renovate health centers.
3. Clarify and inform pending applicants on their obligations under the new regulation.
4. Collect data on existing health centers (where they are located, nature of services, number of beds, and other information useful to describe these actors) and pending applicants and undertake a survey on compliance with standards.
5. Coordinate and streamline the work of the Legislation and Regulation Implementation Directorate (LI), the Food and Drug Quality Control Department (QC) and DM&E responsible for monitoring and evaluation.

6. Finalize and establish an accreditation body by August 2015.[9]
7. Ensure that all standards, procedures, guidelines and checklists are consistent with the goals of the regulation and national policies.
8. Prepare checklists as per Article 47 to
    - evaluate quality and quantity of health care services and standards,
    - classify and accredit private health centers and
    - implement the provisions of the PHCR.
9. Amend the PHCR as needed.
10. Establish the commissions.

Office of Private Sector Coordination (OPSC)

Established in 2009 by the USAID-funded Communication for Behavior Change: Expanding Access to Private Sector Health in Afghanistan (COMPRI-A) Project, the MOPH OPSC unit is responsible for acting as a coordinating body between the public and private health sectors; to oversee the development and implementation of the National Policy for the Private Health Sector and its associated strategic plan, and to strengthen the partnership between public and private sector. Since its inception, the OPSC has accomplished several policy and practical initiatives, and has terms of reference (TOR) and an action plan. Composed of a director, two managers, a PPP Unit and one administrative person, the OPSC is actively involved in all matters related to the relationship between the MOPH and the private sector. Key staff in this unit are physicians and none have private sector or business experience. The following are the assessment findings and recommendations relevant to OPSC.

The OPSC is a good facilitator of communications and can be said to be successful as the "ear" of the private sector and its "voice" to the MOPH. It has been successful in identifying several obstacles to the growth of the private sector but has yet to coordinate a plan to remove these obstacles. It has coordinated the development of a draft MRS, but it has yet to finalize these with requisite approvals and disseminate or coordinate their implementation. The functions of inspection, supervision and sanctions for non-compliance in relation to the MRS and other standards as noted in PHCR must also be coordinated with the relevant directorates responsible for the function of monitoring and evaluation discussed later in this report. Moreover, levels of non-compliance are not yet determined, nor is there a plan to bring all private health centers into compliance over a period of time reasonable for improvements to happen.

Other MOPH functions required by the PHCR that are not *currently* under review by the OPSC to ensure that the plan of implementation reflects the main policy objectives[10]:

- Licensing , monitoring and evaluation, law enforcement and food and drug quality control, policy formation unit, HMIS, legal unit, capacity building unit within the Directorate of Human Resources
- Key departments noted in the PHCR have not been involved in planning and coordination to ensure policy objectives are achieved. A more direct relationship and interaction with these departments in the form of the OPSC acting as an ombudsman internal to MOPH will be helpful.

Streamlining and transparency are goals the OPSC can assist with by coordinating the establishment of a one-stop door (or shop) for information on the private health sector, including the dissemination of all

[9] An accreditation body is not necessary until health centers have been licensed for three years. Since no health center is currently licensed under the new PHCR, there is no need for the accreditation body until three years later. Thus, August 2015 is proposed but this date can be flexible depending on when the first health center is licensed under the new law.

[10] Policy objectives are: to strengthen institutional and organizational capacity, to maintain an environment conducive for private sector to deliver services and to develop and apply mechanisms for effective regulation specifically information systems and expansion of quality services according to the model for participatory assessment, motivation and sanction.

policy, legal and other documents such as application forms in English, Dari and Pashto. At a minimum, the OPSC should be heavily involved in organizing the translation of these documents and the supply of these in paper and online through the MOPH web site, although a decision will have to be made by senior leadership where the one-stop door will be situated. It may logically fit in both licensing and the OPSC, given the role the OPSC has in terms of PPPs for which many of the same documents and actors will be involved. The documents will be free of charge online, but a small charge can be imposed for a hardcopy package of documents to cover the costs of their provision. Since it is anticipated that non-Afghan hospital investors will consider operation in Afghanistan, the documents must be translated to relevant languages.

The OPSC has successfully built a PPP Unit and fully staffed it with six persons. However, there is a need to "think" through the connection between the draft PPP regulation, the PHCR and other relevant laws and regulations, such as the law on non-governmental organizations and investment and any other laws, policies, procedures or other documents that may be drafted at a later time.

Finally, to date, the OPSC has no representation from the pharmaceutical sector, and there is little coordination of the work between health centers subject to the PHCR and the pharmaceutical sector and the parts of the MOPH, such as GDPA.

Health Management Information Systems (HMIS)

The MOPH HMIS unit is responsible for developing reporting systems to provide information for decision making and for monitoring of services. The HMIS unit is comprised of 17-18 persons, with health systems information, and IT expertise. It plans to make an on-line system for Kabul and build a database system for provincial health centers for reporting purposes and to collect health data. The system is to be linked to ICD-10, and a patient master index and an electronic patient record is to be created.

The HMIS unit is in the GDP&P and is responsible under PHCR Articles 34, 35, and 36 for recordkeeping and reporting to MOPH. The PHCR does not identify what is a reportable condition or requirements for other vital and health statistics. It is likely that articles of the Public Health Law specify these requirements, but as an English copy of the Public Health Law was not available, it was not possible to confirm this during the assessment. It will be important to streamline reporting requirements and require the same data from the public and private sectors as may be mandated by the Afghan Public Health Law to ensure robust data sets. The private health sector should also be responsible for reporting and recordkeeping in compliance with national law and national health policies so that the MOPH has information across the system from both the public and private sectors.

From a practical perspective, the HMIS s director, also a doctor, did not know there is a new PHCR and that it had implications for his work. The director was familiar with what the private health sector is reporting under the old system but had no current plan to include the private sector in the systems the unit was building. Moreover, when the PHCR was shown to the director, particularly Articles 34- 36, he was surprised that no one had shown this to him or discussed the implications for his work stream. He was certain that it was necessary for the definitions of private health centers to be amplified so he could build robust datasets. The HMIS unit should be involved in digitizing the licensing department, as it has the IT expertise to do so and clarity on what data sets are in existence. This department has an expatriate consultant, Chris Bishop, who is a medical epidemiologist from New South Wales and is working with the director to build the health information system.

GD Curative Medicine

The GD of Curative Medicine (GDCM) is where the Private Health Sector Services Department, which is responsible for licensing, is located. This department's licensing function is a pivotal function of the PHCR and is in need of urgent attention so that the MOPH can respond to the requirements of the PHCR. This reality was clearly understood by the director of this GD and that of Policy and Planning who both supported taking immediate action. And indeed they took immediate action by replacing the director, and by finding a larger and more appropriate space for the department and two computers. More importantly they undertook to revise the licensing process and requested assistance and guidance on how to do so.

Licensing

The Private Sector Health Services Department has been registering private health centers and will continue to do so under the new regulation. It is responsible for registering new applicants, reregistering existing health centers and confirming registration on renewal or after some event such as a punishment, accreditation, sale or merger, or change of location.

The department is located in the basement of the MOPH in a room that houses all the paper records of license applications. It has one director and one manager for provincial affairs and a staff of 16 people. There is one computer on which staff take turns. There is barely enough room to move in the room where these men work. No one in the department speaks English. The director of this department was clear on what he needs: space to have proper files storage; a copy machine, computers and training on how to use them and modern management know-how to deal with the legal and practical aspects of the license application process.

Currently the licensing process includes 13 steps (though some report there are 17 steps) and is reported to take about a month, once all documents are in order. There is no standard application form, no set of instructions, no guidance on the process, no digital forms; all information is passed in the oral tradition. Given that the PHCR is effective now; there are an estimated 200 applications pending under old system, and approximately 300 existing private health centers that have to be relicensed by August 2013, including approximately 104 Kabul and 200 in provinces. There is currently no plan on how to manage these. It is essential to reform this department and focus attention on the process immediately.

Table 1 arrays the current process with suggestions on streamlining or reducing the steps. The process is currently under review as per direction of the directors of the GDs on Curative Medicine and Policy and Planning. In addition to streamlining the process, the staff configuration of the department may need to be changed. This assessment considered the current composition of the department in relation to the tasks. As the process and responsibilities of this department are reconfigured, it will be necessary to consider staff changes.

These suggestions and observations will be helpful in the streamlining and potential staff reconfiguration process. First and foremost, the department current operates more like a recordkeeping facility, given that its main function is to check off a list of required documents for licensing and store these in binders in the licensing department office. The recordkeeping function is essential and will be useful in this department in the future. This department should become digital: maintaining digital records of applications, digital copies of documents and an off-site physical location for the paper records. Moreover, a tracking system for pending applications and one for tracking renewal cycles for existing licensees will be useful. The PHCR requires a three-year renewal; in addition, there are several other events such as sale, suspension, relocation and others that cause the operator to renew the license. These changes in circumstances must be integrated into the system. As none of the staff reported a strong computer literacy, this will be an important capacity building area.

Finally, the GDCM must account for the fact that licensing under PHCR is accorded when the three main components are met: these are that an applicant meets the (1) *conditions* for an establishment in Article 6 and an owner in Article 5or the *conditions* for a health center in Article 8, (2) the *provisions* of the regulation itself which are numerous and listed throughout its text and finally (3) MOPH *standards* as described in Box 2. It is commonly misunderstood that the MRS are the only standards to be met before licensure. This is discussed below in more detail. Here it is important to note that the licensing process must reflect the *conditions*, *provisions* of PHCR and *all the standards*.

TABLE 1: License process

Current step	*Suggested reforms and rationale*
Prepare a request to Minister - bazaar writers	Develop a standard application form that is approved by Minister to eliminate this step. Make the form available in paper and electronically on the web and by email on request. Include a set of instructions, and list of conditions and standards to be met.
Minister sends approval to GD Curative Medicine	Eliminate this step. The process of application is where a determination is made whether an applicant is qualified for a license.
Department of Private Sector Health Services opens a file	A file number can be assigned when the application is submitted with all required documents.
Applicant collects and submits many documents.	Here is opportunity to build an electronic bridge or other cooperation with other departments, especially those that license health care professionals. Is there a way to build a common electronic platform where the licensing department can look to confirm diplomas?
Diploma of the director/applicant- for confirmation by Min of Higher Ed	Reduce this step
ID card from PO dept. to confirm applicant not a criminal	
Staff licenses – nurses, docs etc are verified – personal tax payment is checked	Eliminate personal tax payment requirement, as if there is non –payment, the license may be revoked. If it is not revoked, then it can be assumed (or should be) that the tax payment is made. Eliminate the submission of staff licenses, as the hospital director should be obligated to confirm these as part of a hiring standard. These can be checked during an inspection for compliance with standards.
DM&E construction department inspects building	
Equipment is installed	
AISA license	This should be also conducted by some electronic confirmation process developed with AISA
Pay license fee to financial directorate of MOPH bring receipt to office	Financial directorate can develop a system to avoid this step
Legislative Implementation issues license	The licensing department should issue the license once all conditions and requirements of the regulation
Minister signs the license	Or her designee, such as the Director of Curative medicine

Box 2: PHCR Articles that refer to standards

Article: 5- establishment of private health centers

Article 8 – standards for health center buildings

Article 10 – for licensure

Article 18 - with regard to the employment of health care workers

Article 20 - with regard to uniforms and necessary clothing to meet infection control standards and other applicable standards

Article 25 - health standards; named standards in the article and standards for diagnosis, treatment according to national and international standards

Article 28 - standards for identity cards

Article 31 - standards for electronic equipment, medical records, and hospital health information system

Article 32 - standards for hospital kitchens

Article 34 - standards for medical records

Article 47 - checklists for the standards under this regulation

Licensing, Standards and Timelines

The provisions and conditions for licensure are explicitly stated within the PHCR articles. However, the regulation also refers to *standards* in a number of places. Box 2 lists the PHCR articles that refer to standards that either exist or need to be drafted. The regulation does not require all new standards. Where existing standards are sufficient, these can be applied to the private health sector. In fact, there is good reason to have the same standards for the public and private health sectors. This will lead to a real minimum or baseline for all health care centers. Private health centers can supplement baseline standards as part of their marketing strategies.

Standards development is done by committees, often with international experts, but it is not clear that guidelines are available in terms of the process, or other requirements, such as reference to international standards such as HACCP (Hazard Analysis and Critical Control Points) for food, ISO for health facilities, good pharmacy practices (GPP) , good lab practices (GLP), etc. Collection of these should be undertaken for reference and incorporation by reference so that not every standard has to be newly established.

This assessment included coordination with other assessment teams. In this regard, this assessment considered the MRS and its related checklist, as these are integral to the licensing process and were the only standards available for review during the assessment. Though effort was made to determine the number of standards in process, the only set of standards that were possible to obtain were the MRS. It was reported that standards on buildings, treatment protocols and other standards were in under development, as were related checklists, but no other set of standards were obtained. The presentation of the MRS was planned for November 28, 2012, but as the MOPH had no answer to the objectionable articles in the PHCR (fee setting, license fees, accreditation), a decision was made to postpone the meeting. It is reported that to become final or "legal," the standards are signed by the minister after review by a technical advisor group (TAG). This has not yet been done.

The MRS is organized under the topics of leadership, workforce, environment, clinical care, and quality and safety. In addition to collecting all standards in process, it will be necessary to include a determination of whether the proposed MRS are sufficient to address all the standards required in the regulation as noted in Box 2.

Currently, hospitals are in homes or rental buildings. The main concern raised about the standards is how to manage the pre-existing health centers and bring these into compliance with the new standards and the regulation. This subject is addressed in this section. What is not addressed here is the need for land titling so that hospital owners can purchase or have property rentals for a long enough period to justify the

investment required to meet standards. This will require cooperation with provincial governments which are apparently responsible to 'sell' land.

The PHCR requires that the MOPH enforces its terms immediately upon its effective date (21/5/1691), and that, under Article 49, it re-licenses all private health centers in existence prior to the regulation within one year. Licensing under the new regulation, Article 5, is contingent on meeting the provisions of the regulations, its conditions and MOPH standards. This means that to relicense hospitals, the standards must be available so operators can comply. The MOPH must be able to apply the standards, whatever they may be, in addition to the draft MRS.

It is urgent that a plan for this process is established as early as possible, since the timeline for completion is August 2013, unless there is an extension of time to implement the regulation or another approach is taken. As the success of the amendment process is uncertain, it is advisable to undertake another approach. Moreover, as the potential exists for many hospitals to be unable to meet all the standards immediately, there is good reason to phase in the standards and related licensing status and have a plan to bring these into compliance with the new standards and the regulation over a period of several years.

A suggested approach is to develop a grade system for the standards by categories or phases; possible phases could be essential (patient and staff safety), intermediate and final. Achieving compliance by any health center wishing to obtain a license within the first year of the effective date of the regulation could be the first phase of implementation of PHCR, since it is doubtful that many private health centers can meet all the MRS or all other standards by August 2013, but all that will be allowed to operate must be able to meet the essential standards or be closed. If the regulation is extended, this timing can be adjusted. The grades of compliance can also be coordinated with licensing:

a. Essential – preliminary license
b. Intermediate- pending
c. Final – final and point at which accreditation must occur or three years after license if regulation is not changed.

Generally, it is within the existing power of the MOPH to implement a legal instrument such as this regulation according to a procedure that is made public. This position should be confirmed by the legal advisor of the MOPH, who may advise that a *tarzal amal* or *liha* is required to provide for the phased-in licensing as suggested here. However, as the nature of the standards are entirely within the control of the MOPH, it also has the option to impose a reduced level of standards for the balance of this solar year and adding a second level and so on over the next two years. This approach will allow the MOPH to build its capacity to inspect, allow time for the private health sector to upgrade operations, and will allow time for the creation of the accrediting body.

Finally the World Bank plans to conduct a survey of private hospitals, to be completed by May 31, 2013. According to this assessment, there are approximately 300 existing private health centers and 200 applications filed prior to the new regulation that must be processed. It is not known how accurate these numbers are, but in any event, with less than 8 months before the August 31, 2013 deadline, the number of existing health centers alone would demand more than 1-2 inspections per day to check on all facilities. Thus, deploying the World Bank survey team to count health facilities and to inspect according to the standards will yield a powerful data set by June 2013. It was suggested that the survey team include inspectors to measure compliance with whichever standards they use and to use some inspectors from the current teams in LI and DM&E. Using some foreign expert inspectors will be a way to not only get the work done in a timely manner but also such expert inspectors can train current inspectors on the standards and good inspection practice. Moreover, it will be essential to include on the inspectors on the teams that represent the various capacities relevant to the standards, such as medical engineers to inspect equipment,

etc. Once the standards are completed, it will be possible to determine the nature of the expertise required. The MOPH should consider negotiating this arrangement with the World Bank as part of the survey.

Function of Monitoring and Evaluation: Two Directorates and One Department

This section of the report refers to the function or activities of monitoring, evaluation and control and is the title of Article 45 of the PHCR. Within the MOPH, there is also a Directorate of Monitoring and Evaluation, which is not to be confused with the function of monitoring and evaluation and control PHCR assigns to two directorates and one department named in Article 45. Article 45 states that the

1. "Directorate of Monitoring and Evaluation (DM&E) is to monitor and evaluate clinical, support and utility services provided by private sector,
2. Legislation Implementation Ensuring Directorate (LI) shall supervise the implementation of this regulation and that the
3. Food and Drug Quality Control Department (QC) shall control pharmaceutical activities and the kitchen and dining room of private sector health centers."

These two directorates and one department are discussed as a group in this section on monitoring, evaluation and control as their respective activities are grouped and interconnected in Article 45 of the law and therefore also in the actual work of monitoring and evaluation. Each has a role to play in overseeing various aspects of private health centers. Because these roles are not clearly defined in the regulation and are to some extent overlapping in the text itself, it is important for these three directorates/departments to be coordinated as soon as possible so their respective roles and responsibilities are made clear. Duplication, confusion, overlap and lack of required competencies with these units were also reported during the assessment. Coordination must be done by the Minister or her designee to whom the three units report. Accordingly, this report contains suggestions for each separate department/directorate and for joint activities (JOINT Planning Book Page For DM&E, LI, and QC) that lead to coordination between these departments/directorates and with others in the MOPH, most importantly the GDCM on standards and with GDP&P. It may also be advisable to merge LI and DM&E units. With regard to QC, suggestions are provided later in this section.

This assessment revealed that there are technical and managerial weaknesses in these directorates/departments and none has fully prepared to fulfill their function regarding the private health sector. Most notably none have reviewed the PHCR or organized any meetings to discuss with each other how to implement it. None has any process for review of their decisions, none have trained their teams on private sector, there are no checklists ready for inspections nor have they participated in the drafting of the standards from which the checklists are to be developed. There is a lack of clarity on the scope of their respective authorities and the differences on what each is to inspect. Inspection is the fundamental action MOPH takes to monitor, evaluate and control actors in the health sector, yet there is little to no oversight of inspection to determine if there is any improvement in the health services or the degree to which corruption is causing inspections and monitoring to be an ineffective activity.

After the functions of these units are coordinated, there is much to do to prepare these units for the functions they will perform within regards to the private health sector so that each unit can operate with technical proficiency, be managed and supervised with legitimacy and MOPH stewardship policy goals can be achieved. The most important of these are the principles of *oversight, transparency, accountability and legitimacy*. Unless the separate units can settle their boundary differences so that there is no overlap or duplication, the senior MOPH leadership will have to intervene to do so.

Directorate of Monitoring and Evaluation (DM&E)

This directorate is identified in PHCR Article 45 as responsible for monitoring and evaluation of clinical, support and utility services provided by private health facilities. Utility services include kitchen and dining room activities. Clinical, support and utility services are defined in Article 3 of the regulation. DM&E was formerly under the GDP&P and now reports directly to the Minister.

The Directorate of DM&E has 62 staff, mostly doctors and pharmacist, and is organized into three sub-departments, one each for monitoring, evaluation and construction Monitoring is described as a systematic checkup and response to non-punishable conditions such as not having a document posted, as compared to a punishable offense that might include having expired or smuggled medicine or not having a pharmacist present. Currently, the DM&E conducts evaluations of private health centers and public sector hospitals in Kabul and the 34 provinces to monitor the Basic Package of Health Services (BPHS) and Essential Package of Hospital Services (EPHS). It uses a checklist to monitor hospitals and other checklists to also monitor pharmacies, labs, and equipment. Monitoring and evaluation is conducted every three months for BPHS and EPHS. Reports are sent to the hospital but not published. If the condition is serious, the report is sent to the LI, which has mechanisms for punishment. The Directorate of DM&E offers guidance on how to remedy non-compliance. The director reports that the work of his inspectors is monitored by HR, and he also has input on the performance of his *amireen.* He reports that there is no corruption as the inspectors have a salary, plus overtime and per diem. Each quarter, they have two trips to provinces.

DM&E reports that a new private health sector *mudirat* (a unit in the directorate) was formed in response to the PHCR. It is in the process of making a plan for the private sector. Currently, the acting director of private health sector monitoring and evaluation *mudirat* is creating a checklist for private health facilities. The head of the Directorate on DM&E, Dr Khalid reports that staff generally know requirements under the old Taliban rule but they need to be trained on the new standards, on developing SOPs (*liha* on measurements, as he says) and on procedures (*tarzal amal*).

The PHCR sets up a conflict between DM&E and QC on utility services, as it places responsibility on kitchen and dining room activities under QC without any further distinction, which are defined as utility services under PHCR. Utility services are under the supervision of DM&E. Interestingly, it was reported that there is no law in Afghanistan on foods, so it is not clear on what basis the departments will monitor and evaluate food in the private health centers' kitchens and dining rooms. Another conflict exists for DM&E, which reported it oversees the Environmental Health Unit (EHU) in the GDCM. It is not clear why the Director of the GDCM would not be responsible to oversee a unit in its directorate. EHU monitors barbers, butchers, hotels, among other entities and is reported to have an ongoing conflict with QC department over which unit has priority in the taking of samples. These are examples of conflicts in the law itself and how these units are operating that clearly should be resolved as soon as possible. Unless these units can solve these conflicts and clarify what each is to do under PHCR, it will be necessary for the Minister or Deputy Minister to intervene.

Legislation Implementation Ensuring Directorate

The Legislation Implementation Ensuring Directorate (LI) has 52 inspectors who are pharmacists or doctors, and one database manager who also does IT for the directorate. Counting the director and administrative staff and the 6-8 inspectors in each of the provinces, the directorate has about 250 persons working in it. None speak English. There is a *tashkeel* for the unit. Mainly composed of inspectors, LI is responsible for inspection and licensing of pharmacies, solo medical practitioner offices (MDs), diagnostic centers (labs, sonograms, EKG), health care workers, issuing import licenses for foods and

public and private hospitals. However, one informant stated that the Diagnostic Department licensed labs, X-ray and diagnostic imaging centers. This potential conflict needs to be addressed.

Under Article 45 of PHCR, LI has the function of supervising the "*implementation of this regulation", although* implementation is not described in the PHCR. Even though the function is limited to the activity of monitoring and evaluation, LI is not given any priority over the other two directorates in Article 45, nor is there much overall definition of what each is to do. It must be assumed until further investigation that the function is more fully described in the Public Health Law and is done according to the role the department has been filling until now in terms of private and public sector hospitals and health centers. Even the LI director could not fully explain the differences between the work of this directorate and that of DM&E.

Unlike DM&E, LI has a sub-unit that has the authority to punish non-compliance with the law. DM&E refers cases of severe non-compliance to LI for further action. In the case of acts of minor non-compliance, DM&E reports that it endeavors to upgrade the performance of the health actor.[11] The LI sub-unit is staffed by one lawyer and one pharmacist, but its work is not coordinated or supervised by the MOPH legal advisor. LI can impose punishments including fines, closure, license revocation, or refer an owner for prosecution to the High Court in the event of criminal behavior. Presumably, but not clearly stated in the PHCR, this unit will be responsible for PHCR Article 37 titled "Discipline for Breach," which refers to Afghanistan Public Health Law Article 32, Para. 2 on punishment. Punishments can include warning, fines, suspension, and closure. The relationship between the Public Health Law and the PHCR with respect to punishment and related procedures needs to be clarified. In addition, as stated earlier, there is no system to review the decision of this unit. For instance, if a hospital is in disagreement with the punishment, the only recourse is to go to court, if national law permits. Court is a time-consuming and not necessarily satisfactory means to address grievances. In the case of the private health sector, since one of the sanctions is loss of licensure and closure of operations, this can also be extremely expensive for the operator and create gaps in hospital coverage for patients.

The LI directorate has a number of *liha* and *tarzal amal* prepared under the old rules. Each of the 34 provinces has a representative from this department. The basic structure of the directorate is as follows: the Director and five *mudiriat*, a unit on assessment and control of foods, a unit on professional medical practitioners, a unit on service providers, a unit for producers, pharmacies, and hospitals, a unit on the laws and regulations (punishment) and a unit for Health Certificates. Yet another conflict regarding food appears, as M& E states it has control, but the PHCR gives this authority to QC. The LI directorate is the only one that has a database of registered health providers, which was provided during the assessment, though it is in Dari. This database needs to be centralized so QC, LI, DM&E and any other MOPH unit can access its content.

LI and DM&E describe their differences as follows: the LI looks to the requirements of the law or regulation and has a check list it uses for its work. DM&E refers to its checklist which is only described to be for technical matters. Both departments claim there is no duplication between their respective checklists. Both claim the checklists are public and available to the head directors of provinces, and that hospitals know their content. Yet when asked how a potential hospital operator could find a copy of the checklists, the reply was that query was made to the DM&E department or LI. This is not an example of transparency, and these checklists and other forms of guidance should be made public in the one-stop door to be established in paper and on the web.

[11] The scope of this upgrade activity is unknown as DM&E was not able to provide information on how health actor performance was improved. Moreover, the details on the differences between severe and minor non-compliance are not stated in the PHCR, nor could DM&E or LI offer much guidance on the differences except as reported in this paper. This is an area for further research.

The LI director has the view that his unit and the DM&E unit should be merged and he claims he tried to accomplish this in the past. He is concerned about corruption, the gaps and weaknesses in the regulations, and difficulty to implement the regulations against former commanders and community leaders – more so in the provinces as compared to Kabul. He is concerned about the safety of his inspectors in the provinces; one of his inspectors was killed in Kandahar. He sees his department facing a big challenge as it does not receive donor support. Were he to have funding, he would use it to strengthen his HR functions, build capacity, obtain vehicles (transport) and increase salaries. He has developed his own system to fight corruption by motivating his staff through religious leaders and following sharia, by making examples of wrong behavior and good and using a system to crosscheck procedures. He motivates also by sending three persons per year to the Haj.

He is also concerned about the accreditation requirement of the new regulation, given the poverty, different ethnic groups, and opportunity for corruption. He expressed a need to have accreditation, but that is premature and time is needed to build the ability of private health centers to comply with new standards.

The LI director would like to organize training for his department on a number of topics, including training on the PHCR itself, hospital management, HR resources, epidemiology, supervision and leadership, laws and regulations, international law, how to conduct an inspection, pharmaceutical management and health finance, modern methods against corruption, hospital management training, technical subjects such as pharmaceutical production (GMP) imports, equipment installation, medical technologies, management and administration of departments, how to supervise, capacity building of provincial health units, about health law and regulation. He also cited logistical needs: vehicles or transportation for staff, stationary, computers, IT, and copy machines.

Other informants reported there is political interference by members of Parliament who intervene in certain cases where current standards are being applied but enforcement is not continued due to this interference. There is also a gap in performance of the LI and DM&E units, which are supposed to send a report to the deputy minister who takes decision and then sends it to LI, which implements the law. Both departments are reported to take action without the step of going to the Deputy Minister. In the view of some informants, there is tremendous duplication between the LI and DM&E departments at central and provincial levels, as well as interference and corruption. This is highly likely as there is lack of clarity on the supervision of inspectors and their powers. As the inspectors are now inspecting hospitals four times a year, there is tremendous risk and likelihood of corruption across the system in both the public and private sectors. In the case of corruption, the payment is only part of the problem. The real issue is that the health facilities are not improved or operating within standards. Finally, the LI is seen as not having the capacity to do apply the new standards, not having good procedures and its TOR must be revised. It is recommended that at train-the-trainer (TOT) approach is taken to first strengthen the central level inspectors and then have some train the provincial inspectors.

Food and Drug Quality Control Department

The Food and Drug Quality Control Department (QC) is responsible to control *pharmaceutical activities and the kitchen and dining room of private sector health centers*. The duplication regarding food and kitchen services was noted earlier. Essentially, this department is the national laboratory and quality control lab for food, drugs, cosmetics and water. With the PHCR, this unit will now also test food and kitchens in private health centers. It tests chemical, biological, physical, toxicological, and macro biological conditions. It is responsible to sample imports at Customs and in the market place.

The director of this department reported some history of how the MOPH was structured. Prior to the war, Afghanistan produced 120 essential medicines; however, during the war, the manufacturing equipment and motors were looted. Now only five medicines (tablets and syrups) and sterile water are produced.

Before the war, all regulatory functions related to the pharmaceutical sector (including food, cosmetics and water) were under one directorate. Now there are several units in MOPH that regulate this sector. Private pharmacies, for example, are regulated by three units: the GDPA (pharmaceutical affairs), DM&E and LI. This duplication and over-regulation should be streamlined. It was reported that there is an ongoing conflict between this lab unit and the EHU, which is reported to conduct sampling itself and, in that process, is contaminating samples.

The main barriers to the QC department functioning well in terms of the private health sector are related to the conflicts in the scope of its responsibilities as compared to other units. It also has a substantial need for technical training on good laboratory practices and to be sufficiently equipped, staffed and have sufficient supplies to conduct its testing. These needs are no different than what are necessary for this lab to function well in terms of the public sector. MOPH cannot function correctly without its national lab, and all steps should be taken to address the needs of this department immediately. The risks of failing to do so are greater than what can happen to the private sector. If food, water and medicines are not of good quality, efficacy and safety, people can become ill, not get well as they should or, worse yet, die.

The QC has 36 staff and is expecting 49 more lab technicians. According to the director of the QC department, there is a need for a standard building that has proper exhaust system, sufficient space, and space for reagents and supplies, such as glassware. It also needs a procurement unit that is responsive to its needs. The procurement unit is not buying what the lab needs, which is glassware, reagents and equipment. The lab sends its specification to procurement, but it does not have a sufficient prequalified list of vendors. It goes for lowest cost without regard to the requisite specifications.

The QC seeks training on the equipment it has and needs. It also seeks vehicles and wants to conduct post-market surveillance. The lab director did not seem to know she could ask an equipment provider to deliver training on equipment, nor that in the procurement process, training and maintenance, supply and repair and cold chain or other requirements could be specified. She mentioned the MOPH does not manage cold chain (important for vaccines) well and this was especially important when the power went out. It is possible for the health centers to have a backup generator and that vaccines/medicines that require cold chain storage are kept there.

General Directorate for Human Resources

The General Directorate for Human Resources (GDHR) reported that a formal plan to restructure the MOPH tashkeel is intended to be completed (or commenced; this was not clear) by March 2013 (1392). The restructuring aims to address the overlaps between DM&E and LI, Internal Audit and GDPA and those between the curative and prevention departments. The biggest challenges identified are to have MOPH deliver clear direction for departments including guidelines, SOPs, standards, for each section and unit of each department and that these should be rationalized across the entire system, and to solve the challenges that everyone wants their 'benefits' more than to recognize the law. Decree 45 is said to address this, but as no English copy was available, it is not possible to confirm here.

It was reported that according to Decree 45, every ministry is to have a plan to combat the matter of benefits (in essence, corruption). Another challenge as reported is the sale of positions. There is also no system to track job placements and a lack of proper mapping of departments. These challenges and plans to restructure the MOPH are important and will aid the process of transforming the ministry into a modern regulator. In terms of private sector implementation, it will be important for GDHR to keep the private health sector under consideration as plans are drawn and implemented and for GDP&P to coordinate as much as possible with GDHR as the Planning Book is finalized, approved and implemented.

It is notable that GDHR did not participate in the capacity workshop but did submit a page for itself in the Planning Book. This was welcome, as GDHR in effect provides a service to MOPH departments as compared to providing health care services and public health expertise for the citizens of Afghanistan. It is important to the overall functioning of the MOPH, which can only operate with humans fulfilling its functions.

Ghazanfar Institute of Health Science (GIHS)

GIHS is a semi-governmental entity with five members from the government, and UNFPA, USAID, Aga Khan University, and the Norwegian Aid Committee. It operates a school in Kabul that graduates nurses, pharmacists, midwives, and lab, X-ray and radiology technicians. Each year, it graduates 350 students from Kabul, and has approximately 800 enrolled students in Kabul and 650 in the provinces. There are 46 total private non-GIHS schools, 18 of which are in the provinces; these graduate about 200 students a year. These non-GHIS schools may be an additional resource as the private health sector is developed.

The director of GIHS used to be a gynecologist but now runs the Afghan Accreditation Board for Midwives. The midwives assessment process has three phases; first a baseline assessment, a second nonbinding assessment that includes recommendations for improvement in anticipation of the third phase, which is a binding three months before accreditation. These phases provide opportunity for midwives to learn how to improve and prepare for accreditation. This approach is a good model for moving existing hospitals towards compliance with standards and towards accreditation. Currently, GIHS accredits private schools which, according to the *liha*, must be affiliated with a hospital. In the Article 44 of the PHCR, there is an option to become a teaching hospital but no obligation to be affiliated with a school, either public or private. This issue may be one for a *liha* to require the affiliation as is typical for teaching hospitals in other parts of the world.

The experience of this director will be very helpful to the later stages of regulation of the private sector when she will be a main player in the medical council, once formed, which is expected to be the accreditation body.

Afghan Private Hospitals Association and private health sector owners and managers

The director of the APHA described Afghanistan's general a lack of experience with a private health sector. He has sent a letter to the MOPH and the Office of the President stating a list of conditions for the environment in which the private sector would like to operate. The conditions are:

1. Standard buildings and land to purchase so operators can buy and build on land they own. In this regard, municipalities have the authority to sell land but there are apparently unresponsive.
2. 3-5 years tax holiday,
3. Stable electricity (or generators),
4. Interest free loans,
5. Supervision and constructive feedback from DM&E, LI
6. Freedom from corruption or illegal intervention,
7. Due process before closure or punishments,
8. Just one unit to conduct monitoring - clarify what DM&E and LI do and avoid duplication and to have APHA involved (either directly or via its appointee),
9. Clarify mistakes in the PHCR. For example, regarding ambulances, what are the standards for these?
10. Combine LI and DM&E and inspection unit of GDPA,
11. Provide advertising rules,
12. Provide a good example of a hospital in the public sector: MOPH should demonstrate cleanliness and compliance with standards,
13. Need a medical waste system and incinerator,

14. Want friendship not violence, and
15. Address the implementation dimensions that are outside the health sector.

Private providers expressed pleasure with MOPH's support thus far but also disappointment that their expectations have not been met. They have difficulties with the new regulation and licensing staff and find the structural requirements difficult to meet, particularly given that they are only able to rent buildings. This problem can be solved with longer leases and/or to have the municipalities sell the land on favorable terms to qualified hospital operators. They are also concerned that they do not know the procedures, as there is a need for transparency.

When asked their gross profit margins, no private provider could readily answer this, nor could they answer what their gross revenues are. The private sector and the MOPH are in urgent need for training courses on basic business skills, accounting, management, and pricing (if they are to present fees to the committee, they need to know if the fees they want are sufficient to cover operating expenses plus capital improvements, equipment replacement, etc. The committee that reviews prices needs to understand this, too.). They also expressed a need for medical engineers.

DESIGN FOR CAPACITY BUILDING

The design for capacity building is presented here by these charts which reference the Planning Book. Note: As the Planning Book is designed as an internal document, the version with additions and edits by MOPH and the author is not made a part of this report as an Annex. Only the original workshop version is included. The version with MOPH input does contain suggestions on who will implement each aspect and whether an outside resource is needed to complete each task. A final determination of whether outside resources are needed and their source remains to be made.

Capacity Building Plan	***Notes***
Dec. 2, 2012 All participants were provided Planning Book • The Draft Planning Book is designed to guide discussion on how to implement the Private Health Center Regulation by the MOPH departments relevant to its implementation and to provide an overview of the planning by all departments to the General Directorate of Policy and Planning and OPSC. • Assessment findings and implementation suggestions for each unit were embedded in the Draft Planning Book. • To supplement the Draft Planning Book, proposed elements/framework/steps/questions were provided participants along with an outline of the regulation by function and related provision and article. The structural elements are reflected in the Draft Planning Book.	Consultant to deliver Final Report on **December 20** with additional guidance for Planning Books based on assessment findings for MOPH to consider in revisions to Planning Book. • Assessment findings and implementation suggestions for each unit were embedded in the Planning Book suggestions in the Final Report. Final Planning Books to be submitted **by December 22, 2013 t**o OPSC (Dr. Saadat) for collection, review by OPSC, law department, and relevant senior Ministry staff. Work to be done by each standalone department or in concert with relevant departments. Consultant to review and provide comments on Planning Books and revise capacity building plan accordingly. **January 2013**. .
February/March 2013 Second Capacity Building and Planning Workshop	Consultant to prepare and deliver training and facilitate Planning Book implementation
April/May 2013 Third Second Capacity Building and Planning Workshop to review and assess progress and continue training.	Consultant to prepare and deliver training and facilitate Planning Book implementation
June/July 2013 Hold **Forth** Capacity Building and Planning Workshop/Train on Topics	Consultant to prepare and deliver training and facilitate Planning Book implementation
2014/2015 Topics/Tasks	To be determined during workshops what the steps to be taken in these years.

Capacity Building Plan Training Topics and Schedule

Group	***Topics*** (Topics may or may not be related to tasks but are topics necessary for overall performance)
1 **March 2013**	What is the national policy on private sector and what is a private sector? What is an environment conducive to a private sector? Learning the content of the Private Health Center regulation - what does it mean for each department, unit and staff of MOPH? Line staff- administration and management of responsibilities under PHCR, SOPs*, liha, tarzal amal* How to draft a SOP, *liha, tarzal amal*
2 **April to June 2013**	Good inspection practices, train inspectors on standards, Role of and rule of law and anti-corruption strategies Regulatory Effectiveness: limits and scope of regulatory powers Effective policy implementation Leadership and management Hospital Management Basic accounting and finance for business
3 **June/July-December 2013**	Good laboratory practices Train on legal issues for regulators Train inspectors in M &E and LI on private sector (central level) and train the trainer program for provincial health department training Deliver provincial health department training on all topics, and train inspectors HMIS integration and train private hospital staff
4 **2014/2015**	Training as needed

Measures of Regulatory Effectiveness and Capacity Building Program

National Indicators	**Baseline/2012**	**2013**
Confirm, adjust and approve these indicators		100%
Determine Indicators for 2014 and 2015		100%
Per cent of senior staff in attendance at workshops on private health sector	60%	100%
Completion of Planning Books	40%	100%
Reporting indicators as determined in Planning Books	0	70%
Availability of rules, instructions, applications on line and in a one stop window at MOPH in English and Dari	0%	100%
Distribution of PHCR and amendments to all senior staff	25%	100%
Compile and harmonize all relevant regulations, disseminate copies	0	50%
Compile and approve all standards applicable to private health sector	25%	100%
Design and implement MOPH SOP to enforce regulations, align and restructure departments to avoid duplication, overlap, unnecessary inspections, clarity of meaning and applicability for all parties	50%	
Implement interdepartmental coordination	25%	100%
Every process (licensing, DM&E, LE, MRS, admin review) of PHCR to have SOP, training, review of Planning Book and performance by senior management team	0	100%
Map geographic distribution and scope of services of public and private hospitals	40%	100%
Integrated HMIS system AND intervention 5 (Nat strategic plan) develop evidence of and measure private sector contribution to MOPH health goals	0	50%
Conduct leadership and management training for all senior ministry staff	0	50%
Conduct training of all MOPH staff on what is the private health sector and what makes a conducive atmosphere	0	100%
Formal process for notice and comment from private health sector on all regulatory documents and process to disseminate final rules on line, newspaper and in paper at one stop window	0	50%
Complete Tasks and Topics Group 1, 2, 3	0	100%
Complete plan to conduct workshops for Tasks and Topics Group 4		100%
Start plan to conduct workshop on Tasks and Topics Group 5		100%

LIMITATIONS OF THIS ASSESSMENT

The observations and recommendations in this report are limited by three factors, all of which can be addressed going forward. As stated above, the PHCR establishes the legal framework for the regulatory authority, responsibility and role of the MOPH in relation to the private sector—but it does not provide all the legal authority for the MOPH to comprehensively fulfill its role. There are other laws and documents, such as the Afghan Public Health Law, which were not available in English during this assessment. That certain aspects of the role of the MOPH as regulator could not be confirmed or clarified is a limitation of this study, but one that can be easily rectified during subsequent phases of the work going forward.

The second limitation of this study is that the time allotted to its completion allowed for a good review but not a complete review. The main reason is logistics: it was simply not possible to meet all concerned parties due to scheduling. Persons important to an understanding of the Afghan system but with whom meetings were not held included the health legal advisor in the MOJ, Afghanistan Investment Support Agency (AISA), the capacity building department in HR, the General Directorate on Pharmaceutical Affairs, the Independent Administrative Reform and Civil Service Commission, the members of the Health Committee of Afghanistan Chamber of Commerce and Industry (ACCI), and the Afghanistan National Medicines Services Organization (ANMSO). These persons and others can be interviewed as progress is made on more urgent aspects of the implementation of the PHCR.

The third limitation is that the MOPH is a dynamic entity. The capacity building plan, though final in January 2013, will be the subject of further revision and adaptation as the MOPH exercises its regulatory authority and implements the PHCR.

The transition from service provider to a regulator requires careful detailed planning and adequate time. More importantly, it requires political commitment, technical know-how, and perseverance through the errors and by capitalizing on the successes.

ANNEX A. FUNCTIONS AND DEPARTMENTS: REFERENCES TO PHCR ARTICLES

What functions are required of the MOPH according to the PHCR in relation to Private Health Centers?

Purpose and Scope

A. Purposes: Article: 1 and 2:
    1. Provide better health care services
    2. Establish, manage and coordinate affairs related to private health centers
    3. Monitor activities of private health sector

    [Note: The regulation does not have to include a reference to the role of the MOPH as a regulator; it has the authority and responsibility in its general authorization.]

B. Scope: Who can the MOPH regulate as per the PHCR?
    Article 3, 7, 8, and 9: Scope: Definitions and Classifications of hospitals
    Private Health Centers; hospitals, clinics, physical therapy centers and radiology centers; each further defined.

C. MOPH Functions according to PHCR and MOPH as steward

General Role of Steward for MOPH- Minister and Senior Staff

1. National Health Policy 2012-2020:
    a. Strengthen institutional and organizational capacity: better leadership, administration and management
    b. Maintain an environment conducive for private health sector to deliver services
    c. Develop and apply mechanisms for effective regulation through: information systems, expansion of quality services with model for participatory assessment, motivation and sanction
    d. At central and provincial levels
    e. Principles: oversight, transparency, accountability and legitimacy
2. Health Law: To *regulate*: to control, organize, command, systematize, coordinate, take charge of, make plans for, put in order. Done by law, regulation, policy, procedure, forms, and management. According to the principles of good and universal principles of rule of law.
3. Specific actions under PHCR:
    a. Amend PHCR to as needed
    b. Establish commissions Articles 22,23,24
    c. Establish independent, internal review body with oversight on all decision making by departments, commissions, committees
    d. Coordination with other national policies and strategies, especially national economic policy.

Licensing and Renewal

Articles 5, 6, 10, 16 How to establish a private health center
    a. Who can apply? 18 years, no crime conviction, good reputation, agrees to observe the regulation and MOPH standards.
    b. Make application to MOPH –
        i. Complete conditions of the PHCR and MOPH standards
        ii. Having an investment license
        iii. Present required bank statements

iv. Describe activities – general or specialty
v. Pay required license fee and deposit

c. Article 10: Renewal; every three years after evaluation and payment half license fee.
d. Article 11: Accreditation: after three years by evaluation board. Risk: loss of license.
e. Article 17: Approve change of location
f. Article 41: Integration – MOPH procedures
g. Article 42: Sale or transfer of Property
h. Article 43: Discontinuation of Activities
i. Article 49: Existing health centers are to renew licenses within one year

Monitoring, Evaluation and Control

Article 45:

a. Directorate of Monitoring and Evaluation to monitor and evaluate clinical, support and utility services provided by private sector
b. Legislation Implementation Ensuring Directorate shall supervise the implementation of this regulation
c. Food and Drug Quality Control Department shall control pharmaceutical activities, kitchen and dining room of private sector
d. Article 47: MOPH to prepare checklists to
    i. evaluate quality and quantity of health care services and standards,
    ii. classify and accredit private health centers and
    iii. implement the provisions of this regulation

Health Management & Information Systems

Articles 34, 35, 36: Record keeping and reporting to MOPH; see also Public Health Law for vital statistics, reportable diseases, more.

Legal Mechanisms and Actions

Article 52: Adopt bills, procedures, and guidelines to better implement the regulation

Discipline and Punish

Article 37: Discipline for Breach of PHCR, see also Article 32, Para. 2 of the Public Health Law includes: warning, fines, suspension, and closure.

Commissions: Conflict Resolution and Fee Determination

Establish and Conduct Conflict resolution Commissions; Kabul and provinces

a. Conflict resolution Commission- as per MOPH procedures
b. Medical Disputes solving commission- as per MOPH procedures
c. Commission for determining Fees for health care services, (see also Article 40) - as per MOPH procedures

ANNEX B. REFERENCE MATERIALS BY TOPIC

Accreditation

Implementation Agencies

- Joint Commission International
- Council of Health Services Accreditation of South Africa (COHSASA)
- Quality Assurance Project (USAID-funded; QAP)

Other Resources

- International Society for Quality in Health Care (ISQua)
- International Organization for Standardization (ISO)

Additional Reading

- Accreditation and other external quality assessment systems for healthcare. Montagu. DFID 2003
- Elephant in the Room: Integrating the Private Sector in Quality Improvement Mechanisms (ppt). Berg. 2006
- Toolkit for Accreditation Programs. Shaw 2004
- Quality and Accreditation in Health Care Services, A Global Review. Shaw 2005

Assessment tools

- World Justice Project Rule of Law Index: Factor 6 Regulatory Effectiveness Questions and Scoring
- Health Systems 2020 Framework for Assessing Organizational Capacity for Health Systems Strengthening
- Health System Assessment Approach: How to Manual Version 2.0 Health Systems 2020 2012
- OECD Methodology for Assessing National Procurement Systems Version 4.0 2006 and later versions
- Health Systems 20/20. April 2012. Learning from the Health Systems Assessment Approach. Brief. Bethesda, MD: Abt Associates Inc.
- Taking the Pulse of Policy- Policy Implementation Assessment Tool, Health Policy Initiative
- The Art of Moving from Policy to Action LESSONS LEARNED From the USAID Health Policy Initiative 2005-2010
- Private Participation in Health Services, Harding and Preker, World Bank, Chapter 2 on Conducting private sector assessments
- Specific tools for different parts of the system: sources include MSH Health Manager's Toolkit http://erc.msh.org/toolkit.

- *A tool for assessing management capacity at the decentralized level in a fragile state* by NewbranderW et al, Int. J Health Plann. Mgmt. 2001. See also: Thinking Strategically About Alliances

Capacity Building

- Organization for Economic Cooperation and Development (OECD), Shaping the 21st Century: The Contribution of Development Cooperation (May 1996).

- The African Capacity Building Foundation (ABCF), "Capacity Building in Africa Transcends MDGs," http://www.acbfpact.org/capacity-building-in-africa-transcends-mdgs.aspx (accessed May 2011).

- Milèn A, What Do We Know about Capacity Building? (Geneva: World Health Organization, June 2001).

- Wubneh M, "Building Capacity in Africa: The Impact of Institutional, Policy, and Resource Factors," African Development Review 15, no. 2–3 (December 2003): 165–198.
- Ministerial Leadership Initiative for Global Health, Country-Led Development in Health: Practical Steps Forward (May 2011).

- Baser H, Hauck V, Land T, Capacity Change and Performance: Capacity Development: Between Planned Interventions and Emergent Processes (ECDPM, March 2009).

- Potter C, Brough R, Systemic Capacity Building: A Hierarchy of Needs (Oxford, UK: Oxford University Press, 2004, Health Policy and Planning).

- Fukuyama F, State-Building: Governance and World Order in the 21st Century (New York: Cornell University Press, 2004).

- Israel A, Institutional Development: Incentives to Performance (Baltimore and London: Johns Hopkins University Press, 1987).

- Aarthi Rao, Amanda Folsom, Caroline Pang. Designing Development Programs to Build Capacity Emerging Experience from the Results for Development Institute, 2011.

- Challenges Encountered in Capacity Building: Review of Literature and Selected Tools AIDSTAR II AIDS Support and Technical Assistance Resources

ANNEX C. QUESTIONNAIRES

GD Policy and Planning Survey

1. How does this department coordinate the implementation of the PHCR?
2. How many departments or units are involved?
3. Does this department have a list of all private health centers in existence now and an idea of how many applicants there will be for new entrants?
4. Does this department have data on optimum distribution and capacity of hospitals and clinics for serving the current and future needs of the Afghan population? Is there a plan to limit the number of licenses to the number of health centers necessary for health of Afghans?
5. Is there a plan to improve the mix and increase the quality of the services and products which Afghan consumers purchase from the private health sector or delivered by the public sector directly or with contract in and out mechanisms?
6. How many check lists relevant to private health centers are being developed now in the MOPH? Who is developing them and are there drafts available?
7. Is there a strategic plan to manage the initial roll out phase of the PHCR? Ongoing operation, integration of PPPs and assessment and review of PHCR implementation?
8. What is the plan to transform the Nat Public Health Institute into a research and training institute?
9. What is the plan to establish the MOPH Private Facilities Unit as mentioned in the National Policy for Private Health Sector?
10. What measures will you use to evaluate the performance of the MOPH as a whole in terms of implementing the PHCR? How will you measure these goals?
    a. increased progress toward achievement of the millennium development health goals,
    b. increased geographic coverage with basic health services and related products,
    c. increased access to basic health services and related products through decreased production costs and efficiently targeted subsidies,
    d. increased quality of basic health services and related products,
    e. decreased waste caused by inappropriate utilization of health services and products,
    f. increased effective coverage of preventive and promotional services achieved through the contracting out of initiatives, and appropriate subsidies, where presently uncovered,
    g. increased community and individual participation and ownership of the health system, and
    h. increased protection from catastrophic health expenditure for non-essential services through the growth of insurance schemes (risk pooling).
    i. BPHS and EPHS Basic Package of Health Services and Essential Packages of Hospital Services.

Licensing Department:
Survey of private health providers: inpatient/outpatient hospitals, outpatient clinics, medical offices, diagnostic centers, laboratories, specialized care centers.
For Kabul and provinces, please provide the following information:

1. Geographic area and its population
2. Year of data
3. % population urban
4. %population rural
5. Total # of private health centers by type
6. % licensed
7. Number of applications pending for private health center licenses under prior regulation and under new regulation; further information on these; where located and type
8. Number of licenses due for renewal in the next 12-24 month

Please describe the department:

1. Total number of staff
2. Staff structure, job descriptions, department organization diagram
3. Educational background of department managers and director
4. # computers per staff member
5. Procedure for review and determination of a license application: does the unit inspect applicants? How does it verify information on application? Does it coordinate with Implementation of Laws and Regulation Directorate (ILRD)
6. Is there an SOP for the application process?
7. What is the review process for an applicant who is unhappy with the results?
8. Is the application available electronically?
9. Is there any written guidance on standards for private health centers? Is it available electronically?
10. How long does it take to get a license approved?
11. What are the mechanisms to avoid corruption in the office?
12. Is there a supervisory review process of the work of staff?
13. Can you issue a provisional license?
14. What other permits must a private hospital obtain before opening doors?
15. What is your plan to handle the pending applications in relation to the new regulation?

Directorate of Monitoring and Evaluation Survey

Please provide the following:

1. An organization chart for the department
2. A description of the number of staff, their skills, duties and qualifications
3. A copy of the job descriptions for staff
4. A description of the mission of the department generally and in relation to the private health center regulation.
5. Does the department have SOPs for conducting monitoring and evaluation on the private health sector? Is there guidance for the application of the checklists?
6. Is there supervision of the staff? Performance reviews?
7. What are the measures to prevent corruption?
8. What are the measures in case corruption is found?
9. Does the department maintain record on improvements in the health centers as a result of its work?
10. How does this department work with the Directorate on Legislation and Regulation Implementation?
11. What are the capacity building needs of the department in terms of private health centers?

HR Department Survey

Please provide the following:

1. A department organization chart identifying the senior managers, their names, job descriptions and academic degrees or other training and skills.
2. Total # of staff in each unit of the department
3. Please describe how the department determines the capacity building needs of staff.
4. Please describe your understanding of the needs and plan for building capacity in relation to the private health center regulation:
    a. in terms of the licensing department,
    b. the Legislation Implementation department,
    c. the department of policy and planning, the Food and Drug Control Dept. and
    d. the Directorate on Monitoring and evaluation
5. How does this department interface with the Afghan Public Health Institute? What are the differences?

Directorate of Health Implementation Laws and Regulations Survey

Please provide the following:

1. An organization chart for the department
2. A description of the number of staff, their skills, duties and qualifications
3. A copy of the job descriptions for staff
4. A description of the mission of the department generally and in relation to the private health center regulation.
5. Does the department have SOPs for conducting monitoring and evaluation? Is there guidance for the application of the checklists?
6. Is there supervision of the staff? Performance reviews?
7. What are the measures to prevent corruption?
8. What are the measures in case corruption is found?
9. Does the department maintain record on improvements in the health centers as a result of the monitoring and evaluation?
10. How does this department work with the Directorate on Monitoring and Evaluation?
11. What are the capacity building needs of the department in terms of private health centers?

ANNEX D. ALPHABETICAL LIST OF INFORMANTS

N	Name	Position	Department/Org
1	Abdurahimzai, Bashir Ahmad	Officer	Provincial Health Dept. Private Sector Licensing Manager
2	Ahmadi, Ziaulhaq	Legal Advisor	Advisors Office- MOPH
3	Alnoor, Hedayat	Advisor to GDCM	Curative Medicine General Directorate
4	Ashraf, Miya Ahmad	Acting General Director Curative Medicine(GDCM) & Hospital Reform Coordinator	Curative Medicine General Directorate Hospital reform Department
5	Azimi, Sayed Yaqoub	Head	HMIS department
6	Azizi, Kimia	Director and Chairperson	Ghazanfar Institute of Health Sciences (GIHS) and Accreditation Board of Afghan Nursing & Midwives (AMNEB)
7	Bishop, Chris	Consultant	LMG/MSH-HMIS
8	Fahim ,Mohammad Osman	Legal Expert	HPP/PPP
9	Faizi, Sher Mohammad	Officer	Monitoring of Private Sector
10	Ikram, Mohammad Nasir	Senior Advisor	Monitoring & Evaluation Directorate
11	Kamel , Sayed Ibrahim	Director	Legislation Implementation Ensuring Directorate
12	Khalid, Ibne Amin	Director	Monitoring & Evaluation
13	Mudassir, Enayatullah	Advisor	APHA
14	Naeem ,Ahmad Jan	Deputy Minister Policy & Planning	MOPH
15	Naimi , Najibullah	DM&E Coordinator	MOPH-OPSC-HPP
16	Nasrat, Karim	Head	Private sector organizing unit(Licensing)
17	Qadir, Abdul Qadir	General Director	Policy, Planning & International Relations-MOPH
18	Rahimi, Yousuf Ali	Technical Advisor	Curative Medicine General Directorate
19	Saadat ,Sayed Shafi	Head of	MOPH-Office of Private sector Coordination(OPSC)
20	Sayed , Ghulam Dastagir	Senior Health Specialist	World Bank
21	Sayedi ,Omar Zaman	Deputy Team Leader	FGI/HPP
22	Sears, Kathleen	Team Leader	FGI/HPP
23	Shahir, Ihsanullah	General Director	Human Resources- MOPH
24	Shokohmand,Ahmad Shah	Advisor	Deputy Minister of Health Services Provision
25	Sultani, Kamela	Director	Food & Drug Quality Control-MOPH
26	Tokhi, Amin Tokhi	Director	Afghanistan Private Hospital Association(APHA)
27	Zamani, Khan Mohammad	Head	Public Private Partnership Unit-MOPH-HPP

ANNEX E. WORKSHOP PLANNING BOOK, DECEMBER 2012

MOPH Unit/ Topics/Activities	Lead	Other MOPH Unit	By MOPH resources/other ministries	By HPP	Other resources: WB, EU, other donors, consultants	Completion Timeline
Minister, High Council, Executive Board, Deputy Ministers, Senior Management and Leadership						
Build respect for rule of law, zero tolerance for corruption; disseminate the PHCR, conduct training on its content, refer to legal department for explanation and clarification	HE. Minister	All	X	X		Constant
Mandate and manage department and unit plans with task to implement PHCR as guided by Planning Book content, including interdepartmental coordination	Deputy Minister	GDP&P, LI, M&E, QC, Licensing, GDCM, others	X	X		2/2/13 and commence
Align and restructure departments to avoid duplication, overlap, unnecessary inspections, settle conflicts on responsibility of departments and directorates	Deputy Minister	GDP&P, LI, M&E, QC, Licensing, GDCM, others	X	X		3/3/13
Engage donors for support to supplement internal capacity	GD P&P	International Relation dept	X	X		3/7/12
Establish commissions and administrative review board	GD P&P	GDCM, Legal, LI, Audit	X	X		3/30/13
Oversee process of amendment of PHCR as needed, determine what is to be amended	GDP&P	Legal, PU, OPSC	Minister, Cabinet, MOJ	X		Ongoing, complete by 8/ 2013
Approve Final MOPH Planning Book, timelines and indicators				X		3/20/13
Monitor and evaluate progress towards implementation over a three year period, adjust plans as needed and as information is available				X		Periodic and at least annually

Legal Advisor						
Topics/Activities	**Lead**	**Other MOPH Unit**	**By MOPH resources/other ministries**	**By HPP**	**Other resources: WB, EU, other donors, consultants**	**Completion Timeline**
Compile and harmonize all relevant regulations, disseminate copies, oversee process of translation to English and Pashto	Legal Advisor	PU, Lawyers from Audit, LI, OPSC	MOJ Health lawyer	X	X	3/3/13
Provide legal review and advice on all implementation documents	X		MOJ Health lawyer			ongoing
Draft framework and guidance on formal process for notice and comment from private sector and other stakeholders (including other ministries) on all regulatory documents, and SOP/COI for PHCR Commissions , approve SOP other Legal implementation documents from all departments	X	PU, and relevant departments	MOJ Health lawyer	X		3/6/13
Draft/clarify administrative review process of departments/directorate decisions,	Legal advisor	LI, M&E, Audit, PU	MOJ Health lawyer	X		3/6/13
Present admin review process to High Council and Exec. Bd. For approval						3/23/13
Add legal capacity - 4-6 lawyers, admin and finance staff build competencies	Minister, GDP&P, GDHR	Political Support and Tashkeel amendment	X		X	7/1/13
Office space, supplies and transportation	Minister	GDP&P	X			
Professional training on legal aspects of a regulatory agency	X	all lawyers in MOPH	X	X		3/18/13

GD Policy & Planning: Office of Private Sector Coordination (OPSC)						
MOPH Unit/ Topics/Activities	**Lead**	**Other MOPH Unit**	**By MOPH resources/other ministries**	**By HPP**	**Other resources: WB, EU, other donors, consultants**	**Completion Timeline**
Coordinate interdepartmental cooperation and alignment with communication tools, conducting face to face meetings), facilitate second workshop(s) on PHCR for March 2013	OPSC	GD P&P, GDCM, Dep. Minister	X	X		2/25/13
Compile documents, guidelines and policies relevant to the PHCR, identify and maintain a list of documents such as liha that need to be created for effective regulation of private sector	OPSC	Legal Advisor, all units	X	X		3/1/13
Procurement: Proper space, office equipment, computers , transportation and photocopy machine	OPSC	ALL	X			ongoing
Review and facilitate approval and implementation of Planning Book sections, assemble into Final Planning Book	OPSC	ALL	X	X		12/2/12-3/20/13
Upgrade knowledge about the private sector	OPSC	ALL				3/6/13
Facilitate the establishment of One Stop Door/Shop	OPSC					3/9/13
Facilitate staff capacity development	OPSC, APHI					continuous
Coordinate with M& E, LI, QC, GDCM in check list and MRS and all PHCR standards development and their implementation and roll out; Integrate MRS with WB survey and collaborate in WB survey as means to test standards and checklist and acquire data on private health sector	OPSC	PU, LI, QC, M&E, GDCM, GDP&P, AIDC				2/15/13
Coordinate the development of a bridge plan for hospitals to be in compliance with MRS and other PHCR standards	OPSC	GDCM, LI, M&E, QC, licensing, GDP&P	X	X		8/1/13
Expand and amendment of organizational structure(tashkeel). (Ex: promotion as directorate instead of department and promotion of coordinators positions to heads, and assistance to manager (mudir)	GD Policy & Planning	GDHR	X	X		

also creation of pharmaceutical and medical equipments affairs position, employment of a legal expert in private sector coordination unit). *Note: This item was not consultant's suggestion. It was suggested by OPSC and is subject to the approval process.*						
Establish HMIS requirements for private sector	HMIS	OPSC	X	X		3/12/13
Coordination and collaboration on preparing necessary SOPs and ToR (Liha) for private sector	OPSC	GDCM, PU, relevant units	X	X		3/6/13
Cooperation and coordination with other related departments on establishment and development accreditation board	GD P&P	GDHR, GDCM	X	X	X	9/1/13
Coordination for participation of private sector in national public affairs such as: EPI, TB and RH public-private partnership activities. *Note: This item was not consultant's suggestion.*	OPSC					

HMIS						
MOPH Unit/ Topics/Activities	**Lead**	**Other MOPH Unit**	**By MOPH resources/other ministries**	**By HPP**	**Other resources: WB, EU, other donors, consultants**	**Completion Timeline**
Develop integrated HMIS system including completion of intervention 5 (Nat strategic plan), develop evidence of and measure pvt. sector contribution to MOPH health goals	HMIS		X		X	ongoing
Map geographic distribution and scope of services of public and private hospitals, id gaps in BPHS and EPHS with results of WB Survey (5/31/13)	HMIS		X	X		7/1/13
Develop guidelines and requirements for reporting system of private health centers; ensure compliance with Afghan Public Health Law on vital statistics and mandatory reporting	HMIS	Legal Advisor	X	X		3/12/13
Registration of private health centers and distribution of codes	HMIS	Licensing , OPSC	X	X		7/1/13
Staff training on data analysis, and other data topics relevant to private sector	HMIS		X	X		7/1/13
Conduct HMIS training for private health centers' representatives	HMIS		X	X		8/1/13
Employment of HMIS or consultant for private hospitals			X	X	X	as needed

Policy department						
Review, compile of laws, regulations, SOPs, guidelines and polices of private sector	Legal Advisor	PU				3/5/13
Recommend to GDP&P how to better coordinate international best practices on private sector with national private sector policies and ensure MOPH regulations, and management documents such as SOP, liha and others are in harmony	PU	Legal Advisor, LI, M&E, GDP&P, OPSC	X	X		3/18/13
Logistics: proper place for conducting meetings, furniture and equipments, laptops, color printers and photocopy machine	GDP&P		X			ongoing
Staff training			X	X		ongoing

GD Curative Medicine/Licensing						
MOPH Unit/ Topics/Activities	**Lead**	**Other MOPH Unit**	**By MOPH resources/other ministries**	**By HPP**	**Other resources: WB, EU, other donors, consultants**	**Completion Timeline**
A. Standards						
Manage and coordinate development of all standards/checklists required by or important to the PHCR	GDCM	OPSC, all other relevant units	x	X		3/11/13
Manage restructuring of licensing unit, determine placement of One Stop Door/Shop in conjunction with GDP&P	GDCM	OPSC, licensing		X		3/9/13
B. Licensing Unit						
Streamline application process!!	GDCM	licensing, OPSC				12/3/12
One Stop Door/Shop: make available standards, PHCR, other relevant laws and information such as instructions, application forms, on line and at physical one stop door *Note: Steps for One-Stop Door include: establish instructions and an application, translate all documents into English and Pashto, set up web site page for document download, find office to house materials, determine logistics needs for space, staff, telephone line for inquiries, equipment, pricing of copies of materials and coordination with PPP Unit, among others, needs to be determined as this item is planned*	OPSC	GD CM	X	X		3/9/13
Prepare SOP(Liha) for licensing procedure, application form and instructions, approval by appropriate director or deputy minister	GDCM	licensing, OPSC	X	X		3/16/13
Staff training on PHCR, computer, management, English	Licensing					ongoing
Incentive pay for key staff of department *Note: This item was not consultant's suggestion.*	Licensing					ongoing

JOINT Planning Book Section for M&E, LI, and QC						
MOPH Unit/ Topics/Activities	**Lead**	**Other MOPH Unit**	**By MOPH resources/other ministries**	**By HPP**	**Other resources: WB, EU, other donors, consultants**	**Timeline**
Text in red needs to be clarified such as correcting for common acronym according to acronym table accompanying this PB and final report.						
Review PHCR	All departments	All departments	X	X		Mar-13
Coordinate with teams across MoPH and DRAFT ALL STANDARDS as required by PHCR and draft related comprehensive checklists ; with particular attention to avoiding overlap and duplication	Drafting Group is GDP&P/OPSC, LI, M&E, QC, GDCM	GDCM, HMIS, LI, M&E, QC, GDPA, EHU, GCMU, GDPM	X		X	Mar-13
Field test standards and check list in Kabul and 2-3 provinces and report to drafting group for final edits	M&E, LI, QC	GDP&P, GDCM, OPSC, EHU	x	X	X	Jun-13
Present for approval TAG and Executive Board for final approval	Dep. Minister	Drafting Group	X			Jun-13
Translate and publish standards and checklists in English, Pashto and Dari	GDP&P/OPSC	Drafting Group and translators	X			Jul-13
Develop a database of all private health centers	HMIS	LI, M&E, QC	X	X		Nov-13
Plan and begin implement training for central and provincial staff	LI, M&E, QC	HR	X	X	X	Mar-14
Cooperate with team that is developing an accreditation board	Drafting group	GDP&P, GDCM	X			Aug-13

Monitoring and Evaluation Directorate						
MOPH Unit/ Topics/Activities	**Lead**	**Other MOPH Unit**	**By MOPH resources/other ministries**	**By HPP**	**Other resources: WB, EU, other donors, consultants**	**Timeline**
Identify staff weakness in areas of technical competencies that will be required for all PHCR standards and source training on these and good inspection practices and conduct training on these and PHCR	M&E, OPSC, LI	OPSC, LI	X			3/2/13
Clarify and establish SOP on respective duties of amirs and mudirs on administration and management of responsibilities under PHCR	M&E					3/2/13

Legislation and Regulation Implementation Directorate(LI)						
MOPH Unit/ Topics/Activities	**Lead**	**Other MOPH Unit**	**By MOPH resources/other ministries**	**By HPP**	**Other resources: WB, EU, other donors, consultants**	**Timeline**
Establish procedures for LI for enforcing legislation and regulations relevant for private sector, with emphasis on participatory assessment as noted in NPDS	LI, Legal Advisor	Law enforcement unit of LI, possibly MOJ, Police, and National Directorate of Security (NDS)	Police and NDS	**X**		3/10/13
Draft relevant PHCR documents such as liha	LI	CMGD				3/10/13
Identify staff weakness in areas of technical competencies that will be required for all PHCR standards, and legal requirements and source training on these and good inspection practices and conduct training on these and PHCR		CDGD,M&E D and LI	Ministry of Finance	X	SPS	3/10/13
Enhance of professional knowledge of LI personnel; consider modern law enforcement techniques, new technologies for monitoring and evaluation of health service delivery (attend meetings & seminars)	MOPH- LI	GDHR,APHI	MOJ, Police, NDS		X, Interpol, UN others	10/7/13
Assess logistics needs for transportation, staff, computers, space, etc.	MOPH	GDP&P	X		X	8/1/13
Cooperation and coordination with Police and NDS	LI	Ministry of Interior and NDS	X			Continuous
Develop anti-corruption strategies and procedures to prevent and punish offenders, coordinate with national anti-corruption programs outside MOPH	LI	Police & NDS. Legal advisor, national anti-corruption departments	X	X		Continuous

Drug and Food Quality Control (QC)						
MOPH Unit/ Topics/Activities	**Lead**	**Other MOPH Unit**	**By MOPH resources/other ministries**	**By HPP**	**Other resources: WB, EU, other donors, consultants**	**Timeline**
Draft relevant PHCR documents	QC	LI , OPSC		X		3/9/13
Identify staff weakness in areas of technical competencies that will be required for all PHCR standards, and legal requirements and source training on these and good LAB practices and conduct training on these and PHCR for central and provincial staff	QC		X		X SPS	3/9/13
Develop and implement Quality Assurance Standards for medicines in the private health centers pharmacies. *Note: The below would be standards or procedures and were removed from Planning Book as these are not implementation plans but rather technical aspects. I6 saved them here for the QC department to refer to what they wrote in the Planning Book.* *All medication in the health center requires analyzed certificate. (A) The Original analyze certificate, if medication is bought form the manufacturing company; (B) A copy of analyze certificate from MOPH-Drug and Food Lab Department, if the medication bought from wholesalers; (C) Getting sample randomly for Lab Test according SOP from each Batch of Pharmacies; (D) Payment of fees to (6001 account of government) for Lab test of sampling; (E) Ensure of quality and sterilized of medical equipment; (F) Sampling of water by chemical water test of Private health centers. (Parasitological and Virology); (G) Payment of fees for water test in the (6001 government account); (H) Sampling of food testing while any incident of poisoning or spoiling happens (Bacteriology and Toxicology) ; (J) Quality and Safety control of foods and kitchen equipments of PHC by (Lumi PD-10 N tester) (K) Ensure of quality and sterilized of medical*	QC	GDPA	X		USAID/SPS	10/13/13

equipments.						
Develop standards for food/kitchens and dining rooms in health centers	GDCM	QC, OPSC, GDCM, EHU	X		X	8/1/13
Staff Technical training on food microbiology and food toxicology, water virology and parasitology	QC	GDHR, APHI	X	X	X	8/1/13

Environmental Health Directorate						
MOPH Unit/ Topics/Activities	**Lead**	**Other MOPH Unit**	**By MOPH resources/other ministries**	**By HPP**	**Other resources: WB, EU, other donors, consultants**	**Timeline**
Coordinate with Food and Drug Quality Control, settle conflicts over food/kitchen/dining room/ sampling responsibilities	GDP&P	EHU, QC, OPSC, Legal Advisor	X	X		3/10/13
Establish drinkable water quality and sampling procedures	EHU	QC	X			8/1/13
Establish standards for radiation protection for staff and patients	EHU	GDCM	X			3/11/13
Monitoring of safe drainage of toilets from by consideration of sanitation private hospitals	EHU					3/10/13
Conduct training course for capacity building of staff	EHU	GDHR, APHI			X	ongoing
Management of IEC materials for environmental health	EHU				X	ongoing

General Directorate of Pharmaceutical Affairs *Note: GDPA role for these activities is unclear to consultant; further discussion with and comment from them is needed to finalize.*						
MOPH Unit/ Topics/Activities	**Lead**	**Other MOPH Unit**	**By MOPH resources/other ministries**	**By HPP**	**Other resources: WB, EU, other donors, consultants**	**Timeline**
Participation in establishment of vaccination department, professional vaccinator recruitment, carrying, storing and cold chain of vaccines	Narcotic drug control department	GDPM	X			Continuous
Verification, agreement and administrative proves of establishment of pharmacies, recruitment of pharmacist and relevant affairs	Drug institutions office	GDCM	X			
Active participation in selection and supply of drug, equipments, instruments and needed medical materials	Registration and licensing office	GDCM	X			Continuous
Active participation and establishment of DTC committees	API	M&E,OPSC		X		30/12/2015
Capacity building, mutual understanding in responsibilities, related standard procedures (private sector staff)	API	GDHR/APHA		X	SPS	30/12/2015

GDHR- Specialty Program Directorate *Note: GDHR role for these activities is unclear to consultant; further discussion with and comment from them is needed to finalize.*						
MOPH Unit/ Topics/Activities	**Lead**	**Other MOPH Unit**	**By MOPH resources/other ministries**	**By HPP**	**Other resources: WB, EU, other donors, consultants**	**Timeline**
Conduct regular evaluation commission in licensing for foreigner health providers of private health centers according to existing SOP (Laiyha) of MOPH	Specialty Directorate	GDHR,OPSC	X			Continuous/ during recruitment or contract
Conducting training programs for orientation and introduction of update standards, treatment protocols and other specialty topics including research methods	Specialty Directorate	GDHR		X		25/03/2013-25/03/2014
Monitoring & evaluation of professional knowledge and skills of private hospitals specialists based on a SOP(Laiyha)	Specialty Directorate	GDHR,M&ED,LIED,OPSC		X		Periodic
Ensuring avoidance of medical specialists simultaneous work at public and private health facilities during official hours and hiring of two staff members under the Specialty Directorate for the same purpose.	Specialty Directorate	LIED,M&ED,GDCM & OPSC			X	25/03.2013 Continuous
Accreditation of private health centers from the specialized health services point of view according a ToR (Laiyha) and employment of a committee for processing documents	Specialty Directorate	GDHR,GDCM,OPSC and Medical council		X		25/03/2013 Periodic

ANNEX F. WORKSHOP PRESENTATION

HEALTH POLICY PROJECT

Workshop on Stewardship: Capacity Building to Implement Private Health Center Regulation

Office of Private Sector Coordination
and
Prof. Michele Forzley JD, MPH
Health Policy Project
12.2.12 Kabul, Afghanistan

USAID

Our plan for today

- Introduction: the private sector
- Orient to the PHCR and validate assessment findings
- Deep dive: licensing – use the planning worksheet
- Hear the proposal for capacity building: do we agree?
- Break-out session: each department to complete worksheet
- Discussion and close meeting

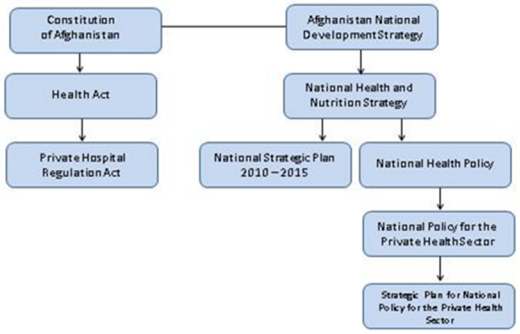
2

Private Sector and Health

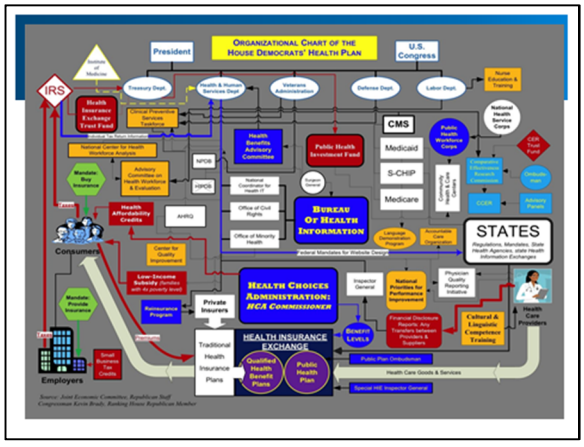
- What is the national policy on private sector and why?
- What is the private health sector? ***All health care services*** provided by entities other than the government.
- What is an atmosphere conducive to a private sector?
  - Ease of starting a business
  - Transparent rules, equal application, fair review process
  - *Tension is normal:*
  - *If both sides are unhappy the rule is good.*

3

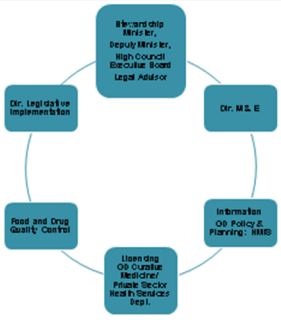
Current Policy & Legal Framework for the Private Health Sector



4



Structure and function of MoPH Units



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MoPH Stewardship Vision: *quantity and quality services*

- Principles: oversight, transparency, accountability and legitimacy
- Strong institutional and organizational capacity: good leadership, administration and management
- An environment conducive for private sector to deliver good *quality* services in sufficient *quantity*
- Effective regulation
  - Information systems,
  - participatory assessment, motivation and sanction
  - At central and provincial levels

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Good governance

- Government bound by the law – even the minister!
- Fair and equal application of the law.
- Procedures:
  - Fair
  - Decision makers do not review their decisions! A separate independent body must do so. Set one up.
  - Transparent and organized according to canon, mukararah, tarzal amal, liha, forms etc- all transparent, easy to find.
- ZERO tolerance of corruption.

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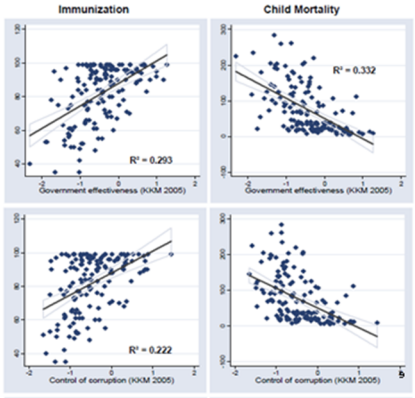
WHY?

Figure 1. Relationship between corruption indices and health outcomes



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Findings

- What are the functions MoPH must perform and who must perform them?
- Findings on the capacity of MoPH to implement the regulation
  - Strengths
  - Gaps
  - Weaknesses
- What is needed to build capacity?

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Findings on the capacity of MoPH to implement the regulation

- Strengths: direction of Minister, Deputy Minister, policies, strategies, regulation, focus - GD P&P:OPSC
  - Attention to building the vision of stewardship
- Gaps: awareness $^{1/2}\sqrt{}$, integration, action
- Weaknesses:
  - Old ideas, conflict, duplication
  - New plans, SOP, procedures, review process & rule of law
  - Coordination , consistency internal/external

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Deep Dive: Licensing

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Licensing : every grain goes to the mill

- ~200 applications pending under old system
- ~300 existing private health centers: must comply 12 months from 21.5.1391 = effective date of regulation
- Renewals, reinstatements: all go back to licensing
- Which units are involved?
  - Office of the Minister
  - GD Curative Medicine Dept of Private Sector Health Services = Licensing
  - Directorate of Legislative Implementation
  - GD Administration and Finance
  - AISA
  - M&E Construction Unit
  - Ministry of Education
  - Police Department

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Findings: 17 Steps to get a license:

- 1. Prepare a request to Minister - bazaar writers
- 2. Minister sends approval to GD Curative Medicine
- 3. Department of Private Sector Health Services opens a file
- 4. Applicant collects
  - Diplomas- for confirmation by Min Ed
  - ID card for PO dept confirm not a criminal
  - Staff licenses – nurses, docs etc are verified – tax payment is checked
  - M&E construction dept inspects building
  - Equipment is installed
  - AISA license
  - Pay license fee to financial directorate of MoPH, bring receipt to office
- 5. Legislative Implementation issues license
- 6. Minister signs the license

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Vision: One Stop Door For private sector

- Application form/instructions
- Information on what happens
- List of necessary documents
- A person who answers questions and an ombudsman
- Copy regulation, MRS, other standards: English, Dari, Pashto.
- Phone number, web site – for foreign and domestic investors
- Licensing office: space, computers, filing system, coordination with M& E and Legislation Implementation
- Guided by principles - international expectations

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Tasks and Timeline: Planning Book

- All: complete Planning Book
  - Draft today
  - Final by January 3, 2013
    - to OPSC Dr. Saadat for review
  - Implement by February 7, 2013
  - Workshop: Review/assess March 7, 2013
- Findings and suggestions for each unit
- Proposed elements/framework/steps/questions

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Questions and Discussion

Tashakar

Inshallah ashufaq baadeen

Tamanyate Niek!

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