USAID
FROM THE AMERICAN PEOPLE

FINDING MIDDLE GROUND: MAKING BETTER USE OF THE AFRICAN PRIVATE HEALTH SECTOR THROUGH MORE EFFECTIVE REGULATIONS

November 2009

This publication was produced for review by the United States Agency for International Development. It was prepared by Rich Feeley, Barbara O'Hanlon, Angela Stene, and Yuksel Sezgin for the Private Sector Partnerships-*One* project.

PSP-*One*
PRIVATE SECTOR PARTNERSHIPS FOR BETTER HEALTH

Technical Report

Technical Report Series: PSP-*One* Technical Report Series addresses important issues relating to the private sector's role in reproductive health and family planning. Papers in the series may discuss lessons learned and best practices, highlighting PSP-*One* technical areas.

Recommended Citation: Rich Feeley, Barbara O'Hanlon, Angela Stene and Yuksel Sezgin. November 2009. *Finding Middle Ground: Making Better Use of the African Private Health through More Effective Regulations*. Bethesda, MD: Private Sector Partnerships-*One* project, Abt Associates Inc.

Download: Download copies of PSP-*One* publications at: www.psp-one.com

Contract/Project No.: GPO-I-00-04-00007-00

Submitted to: Patricia Mengech, CTO
Bureau of Global Health
Global Health/Population and Reproductive Health/Service Delivery Improvement
Center for Population, Health and Nutrition
Bureau for Global Programs, Field Support and Research
United States Agency for International Development

Abt Associates Inc.■ 4550 Montgomery Ave, Suite 800 North ■
Bethesda, Maryland 20814 ■ Tel: 301/913-0500■ Fax: 301/652-3916
■ www.PSP-One.com ■ www.abtassoc.com

In collaboration with:
Banyan Global ■ Dillon Allman and Partners ■ Family Health International ■ Forum One Communications ■ IntraHealth International ■ O'Hanlon Consulting ■ Population Services International ■ Tulane University's School of Public Health and Tropical Medicine

FINDING MIDDLE GROUND: MAKING BETTER USE OF THE AFRICAN PRIVATE HEALTH SECTOR THROUGH MORE EFFECTIVE REGULATIONS

CONTENTS

Acronyms ..... **v**

Acknowledgments ..... **vii**

Executive Summary ..... **ix**

1. Introduction **1**

1.1 The Challenge 1
1.2 About This Report 2

2. The Role of Stewardship **3**

2.1 Problems That Must Be Addressed 3
2.2 Finding The Balance: Too Much or Too Little Regulation 5

3. Definitions of Key Terms And Concepts **7**

3.1 Legal Basis and Authority To Regulate 7
3.2 Levels and Instruments of Regulations 7

4. Moving From Regulatory Design To Enforcement **11**

4.1 Examaning The Legal Framework Governing The Private Sector 12
4.2 Assessing The Effectiveness of Regulatory Enforcement 14

5. Critical Regulatory Issues To Examine **17**

6. Common Regulatory Problems In African Countries **27**

6.1 Vaguely Defined Scopes of Practice 27
6.2 Failure To Accommodate Human Resource Shortages 28
6.3 Overly Restrictive Regulations In Private Health Facilities 30
6.4 Excessive Regulatory Roadblocks That Do Not Benefit Patients 31
6.5 No Effective Avenue To Address Patient Complaints About Poor Quality 32
6.6 Poor Enforcement Mechanisms and Practices 33

7. Securing Local Ownership In Policy Reform **35**

8. Conclusions **39**

Annex A: Examination of Nigerian Regulations **41**

Annex B: Examination of Kenyan Regulations **511**

Bibliography **59**

LIST OF FIGURES

Figure 1: Assessing the Legal and Regulatory Environment: A Step Analysis 12
Figure 2: Consultative Process Structure (Illustrative) 35

ACRONYMS

ADR	Adverse Drug Reaction
ART	Antiretroviral Therapy
ARV	Antiretroviral
CME	Continuous Medical Education
EU	European Union
FBO	Faith Based Organizations
FP	Family Planning
IFC	International Finance Corporation
NGO	Non-Governmental Organizations
MCH	Maternal and Child Health
MOF	Ministry of Finance
MOH	Ministry of Health
MOP	Ministry of Planning
RH	Reproductive Health
TB	Tuberculosis
USAID	United States Agency for International Development
US	United States
WHO	World Health Organization

ACKNOWLEDGMENTS

The authors Rich Feeley, Barbara O'Hanlon, Angela Stene, and Yuksel Sezgin wish to thank Patricia Mengech and Ishrat Hussein of USAID, for their leadership and support in addressing policy conditions enabling private provision of Reproductive Health and Family Planning services in Africa. Their insightful comments helped guide the production of this report. The authors are also grateful to Pamela Riley of the Abt Associates-led PSP-*One* project for her careful review and helpful comments.

EXECUTIVE SUMMARY

INTRODUCTION

Governments in sub-Saharan Africa face many complex and difficult challenges in meeting the health needs of their populations. Although sub-Saharan Africa accounts for 11 percent of the world's population and 24 percent of the global burden of disease, the region commands less than 1 percent of global health expenditures (WHO, 2006). To improve public health, African governments must marshal all the resources available in the health sector - public and private alike. African governments and donors increasingly recognize that achieving equity in access to health care requires engaging the commercial and non-profit private health sector through partnerships.

Africa's public and private sectors both have roles to play in expanding access to priority health services to underserved populations. The government must play an active role as a steward, facilitating public-private collaboration through an enabling policy environment. An effective regulatory framework that encourages greater private sector participation in public health is a balancing act: it must consider the market realities of the private health sector while at the same time ensuring expanded coverage of quality health services.

The Africa Bureau for Population, Health and Nutrition of the U.S. Agency for International Development (USAID) funded this report to highlight how changes in the legal and regulatory environment can facilitate expanded access to family planning (FP) and reproductive health (RH) services through Africa's private health sector. Using laws and regulations from three Africa countries - Ethiopia, Kenya and Nigeria - this report presents a "road map" on how to review the most important laws governing the private sector, as well as key issues to assess. Although the report focuses on policy reforms to increase private sector participation in the overall health system, these changes will also benefit critical health services such as FP, RH, Maternal and Child Health (MCH) as well as HIV/AIDS.

FINDING MIDDLE GROUNG THROUGH GOVERNMENT STEWARDSHIP

One of the government's key stewardship functions is to create a supportive environment for public and private health sector collaboration. Policies, laws, and regulations are important instruments for this purpose. However, many underlying factors must be addressed. They include:

- Mutual distrust between the public and private sectors
- Outdated, inadequate or counterproductive regulation
- Ineffective enforcement
- Little reward or encouragement for higher quality care or better access
- Lack of understanding of public-sector business requirements by the public sector

The challenge is to find a middle ground that considers both sectors' perspectives and concerns and imposes the proper degree of regulation. Reaching a middle ground requires consulting all the parties affected by the regulation and integrating their perspective and concerns while ensuring patient safety and protection. Too much regulation can inhibit private sector interest, while insufficient regulatory enforcement can expose patients to dangerous medical care and unsafe medicines. Stewardship entails striking the right balance of the appropriate degree of regulation and adequate enforcement, given institutional capacity and budgetary constraints.

MOVING FROM REGULATORY DESIGN TO ENFORCEMENT

Assessing the regulatory system of any country requires an understanding of several layers of the legal and regulatory environment. The legal framework consists of two main components: the design or content of the regulatory environment (the policy context), and the implementation (the enforcement capacity) set forth in the laws. This report outlines a step-by-step process for assessing the regulatory system.

Understanding the Policy Context:
Step One: Review the constitution and health policy framework
Step Two: Review the language of the health statutes
Step Three: Review the regulations adopted under the statutes
Step Four: Identify conflicts and inconsistencies to harmonize policies, laws and regulations
Assessing Enforcement Capacity:
Step Five: Assess enforcement capacity
Step Six: Review complaints, licensing actions and sanctions
Step Seven: Consolidate enforcement procedures

Policymakers considering legislative reform must take into account the timing and duration of the reform. Factors to consider include:

- ***Expect to make a long-term commitment.*** Thorough legal and regulatory reform may take years. There are few shortcuts in democratic policy reform. Consensus building takes time and is required to mobilize support to enact and then enforce the reforms. However, the opportunity to update the laws often occurs only once in a generation. When the opportunity for legal reform presents itself, it is important to address all necessary regulatory changes at once.

- ***Determine how recently regulations have been updated.*** Rules that have been adopted recently will be harder to change. If the rules have not been amended in years, it may be possible to lobby for a general rewrite that includes multiple changes.

- ***Know the timeframe of the legislative cycle and work within it.*** Parliamentary and cabinet procedures have a timetable with important deadlines. Understanding the legislative cycle and key deadlines can increase the effectiveness of a reform strategy.

- ***Review the general process for modifying regulations.*** This information will determine one's strategy and timeframe to reform regulations.

LEGAL AND REGULATORY CHECKLIST

The majority of constraints to a greater private sector role are related to seven core legal and regulatory areas governing:

- Health professional licensing requirements
- Facility requirements for public and private sector health care providers
- The Licensing of pharmacists and other professionals
- Facilities supplying pharmaceuticals
- The Supply of Pharmaceuticals
- Consumer and patient protection
- Enforcement mechanisms and capacity of the regulatory institutions

This report contains a detailed regulatory checklist based on these seven core areas (Table 1 in the document).The checklist highlights what to look for in regulations that affect the private sector, and strategies to create an enabling environment for improved participation.

COMMON REGULATORY PROBLEMS IN AFRICAN COUNTRIES

In reviewing policy environments across several Sub-Saharan countries, six common regulatory problems emerge. They are:

Vaguely defined scopes of practices within or between health professions. Inadequately defined professional boundaries – including ambiguous scopes of practice, overlapping scopes between health professions, and policies or practices that create conflicting scopes for private versus public health workers - create problems in the health sector. Key among these problems are turf battles between professions and conflicts between the public and private sectors. Regulatory strategies to minimize these kinds of conflicts include: 1) delegating authority to the appropriate professional licensing body to define the scope of practice for the profession; 2) establishing a mechanism to resolve conflicts among professions; 3) giving clear authority to appropriate health cadres to conduct a particular activity or procedure; 4) granting permission for private practitioners to be licensed when working within the agreed scope of practice; 5) ensuring that facility licensing laws and staffing regulations mirror professional scopes of practice, and 6) permitting modification of prescribing requirements based on new diagnostic and other technologies.

Failure to accommodate human resource shortages. Frequently, facility regulations require the presence of health professionals, such as physicians, who are in short supply. This requirement restricts a licensed facility operated by other skilled, licensed professionals from operating in underserved parts of the country. For example, clinics in Zambia require a full-time physician to supervise private sector nurses, while in Kenya, only fully licensed pharmacists can dispense essential drugs such as antibiotics or painkillers. First, regulations must make clear provisions for sub-categories of professional (e.g., nurse aide or pharmacist's assistant). Second, the regulations should be flexible, allowing different health cadres to assume greater responsibilities as new evidence and tools emerge. This kind of task-shifting maximizes the potential of key health professions - such as nurses, midwives, and paraprofessionals - who are the frontline providers for underserved population groups.

Overly restrictive regulations in private health facilities. There can be too much, or too little, regulation governing physical facilities. Highly detailed, prescriptive regulations raise the cost of medical care without adding benefits to patients. But regulations that are silent on truly critical elements create risks. Requirements for physical facilities and equipment should be scaled to the type of practice performed and level of service offered in the facility. For example, a simple consulting room might not require a facility license, because the attending health professional's licensure would include requirements for basic sanitation (that in a larger facility, would be mandated at the facility-level).

More advanced facility requirements would be applicable to clinics that conduct diagnostic or minor invasive procedures, and a third, more advanced licensure class would be reserved for facilities offering full-scale outpatient surgery or diagnostic services. Scaling facility licensing to types of practice will reduce a significant financial barriers to private nurses, midwives, and clinical officers who provide essential services such as FP. Ethiopia offers a good example of clear facility licensing scaled to types of practice.

Excessive regulatory roadblocks that give no patient benefits. A classic example of unnecessary legal barriers occurs in the regulation of pharmaceuticals, where a country that offers a relatively small market requires re-licensing - perhaps even new clinical trials - before permitting a product on the market even though this product has been approved and licensed for several years in another reputable jurisdiction. This is particularly wasteful when the product has already been licensed for several years in other countries having a sound licensing process. The simplest answer to such excessive filing requirements would be to accept licensing by another country (US, Japan, EU) as the basis for issuing a new product registration.

Lack of an effective patient grievance process. Few countries examined for this document have consumer protection laws, but African policymakers are increasingly aware of the need to integrate the consumer's voice. Patient grievance systems are critical for highlighting areas in the health system that require oversight. Legal and regulatory reform must create mechanisms that allow consumers to express their grievances and perspectives on health care issues. Nongovernmental organizations (NGOs) often play the role of "watchdog" on this issue. Another strategy is to include nonprofessionals in disciplinary committees that hear complaints of unprofessional or negligent conduct. This safeguard avoids the problem of "regulatory capture," which can occur when health professionals avoid carrying out disciplinary action against their own colleagues.

Lack of effective enforcement of the laws and policies governing the health sector. In most of the developing world, the laws are better than the enforcement process. The top five reasons why regulations are not effectively implemented are: 1) inadequate political will and budgetary resources assigned to enforcement; 2) low priority given to enforcement within Ministries of Health (MOH); 3) insufficient mechanisms to weed out corruption; 4) cumbersome procedures for disciplining or sanction health providers; and 5) inadequate investigation of patient complaints.

CONCLUSIONS

Main lessons that donors and practitioners should consider when planning or executing a legal and regulatory reform include the following:

Policy reform is a balancing act. For policies to be effective, a government must balance market realities of the private sector with the concerns of the public sector to expand access to quality services to underserved groups. Active stewardship involves soliciting stakeholder input - from public and private health providers as well as consumers - to reach a middle ground between too much and too little regulation.

Time and timing are critical factors in legal reform. Policymakers and donors considering legislative reform must expect to make a long-term commitment to ensure meaningful change. Both time and timing play a role: 1) Reform itself is a long-term process. The parliamentary passage of any new legal reform may take several months, but setting the stage for effective implementation may take years. 2) Rules that have been adopted recently will be harder to change. Older legal codes will likely have a backlog of changes desired by regulated parities, creating an opportunity for general reform that

includes multiple changes. 3) Parliamentary and cabinet procedures have timetables with important deadlines. Knowledge of the legislative cycle and key deadlines will inform the reform strategy.

The majority of regulations affecting private sector participation are centered in seven areas. Although the legal framework governing health systems is highly complex, there are seven main regulatory themes that influence the ability of the private health sector to deliver quality health services. These include the laws and regulations governing: 1) health professional licensing; 2) facility licensing requirements; 3) licensing of pharmacists and related professionals; 4) drug facility licensing; 5) the quality of the drug supply; 6) consumer protection; and 7) enforcement mechanisms and capacity. Focusing on these seven areas can greatly maximize existing private sector resources.

Enforcement has been neglected in policy reform. In many developing countries, the laws are better than the enforcement system. Policymakers, health practitioners, and international donors must bear in mind that regulatory change is just one side of the equation, and that enforcement merits more attention. The processes for regulatory assessment and reform proposed in this report present ideal opportunities to strengthen enforcement policies and practices. However, reforming enforcement systems will require *political commitment* to ensure that the reforms actually occur, *adequate resources* to properly staff and fund the regulatory agency's activities, and *skilled management and trained staff* to fulfill the scope of enforcement policies and implement the changes in policies and procedures.

Local ownership is critical for the long-term success of legal reform. Changing laws or regulations is a long-term investment, requiring years of work to yield results. A participatory and inclusive process can help foster political support and stakeholder buy-in. This local ownership is needed to manage political roadblocks and opposition created during any major shifts in legal and regulatory reform and to ensure that policy reforms reflect the concerns and perspectives of all actors in the health sector, and increase the likelihood of implementation after the policy changes are approved.

Now is the moment to introduce the consumer voice into African legal and regulatory frameworks. Policymakers and professional associations increasingly recognize the importance of integrating patient rights and consumer protection within law and policy. Since significant regulatory changes may occur only once in a generation, it is opportune to include consumer concerns within current initiatives in Kenya, Zambia, and other countries where vital policy and legislative updates are underway.

1. INTRODUCTION

Governments in Africa face many complex and difficult challenges in the effort to meet the health needs of their populations. As in many developing countries, policymakers in Africa must confront serious health care challenges - particularly the unmet need for modern methods of contraception, the HIV/AIDS pandemic and high rates of maternal and child mortality – with limited resources. To maximize the potential of all available resources, it is vital that that African governments act as leaders of regulatory reform to encourage and improve health care provision by the private sector.

1.1 THE CHALLENGE

Sub-Saharan Africa accounts for 11 percent of the world's population and 24 percent of global burden of disease, yet commands less than 1 percent of global health expenditures (WHO 2006). Even with the great influx of donor funds through initiatives such as the Global Funds to fight AIDS, Tuberculosis and Malaria, the Presidential Malaria Initiative, and the 2005 G8 Summit commitment, most African countries will allocate fewer funds than the amount recommended by WHO standards (US$30- 40 per capita) required to achieve universal primary care coverage, family planning (FP), and maternal and child health (MCH). Most African governments will not achieve the Abuja Goal of allocating 15 percent of their national budgets to health, as set forth in April 2001 (Govender et al. 2008).

To improve public health, African governments must marshal all the resources available in the health sector - public and private alike. African governments and donors increasingly recognize that achieving equity in access requires engaging the private sector[1] - both not-for profit and commercial - through partnerships. The private sector in Africa provides a complementary means to expand health services, products and infrastructure. Box One provides several reasons why African government may want to engage the private health sector. However, the private health sector is a not a panacea. Africa's public

Box One: Reasons to Engage the Private Health Sector in Africa

- **THE PRIVATE SECTOR ALREADY PLAYS A LARGE ROLE IN FINANCING HEALTH CARE.** A significant proportion of people seek health care in the private sector. In Africa alone, nearly 50 percent of those who seek care outside the home go to a private provider. About half of the $16.7 billion spent on health in sub-Saharan Africa in 2005 was spent in the private sector (IFC 2007).
- **WHEN OFFERED A CHOICE, CONSUMERS OFTEN PREFER THE PRIVATE SECTOR**. Household decision-makers in African countries often choose private providers because they respond more fully to patients' needs.
- **THE PRIVATE SECTOR ALSO DELIVERS SERVICES TO THE POOR.** Significant proportions of marginalized populations receive care from private, for-profit providers of modern medicine. This includes populations from the poorest quintiles (from 44% in Ethiopia to 64% in Nigeria) and from rural populations (30% in Madagascar to 62% in Uganda) (IFC 2007).
- **THE PRIVATE HEALTH SECTOR CAN INCREASE THE SCOPE AND SCALE OF SERVICES.** In many sub-Saharan countries, private-sector entities own and manage upwards of 40 to 50 percent of a country's health infrastructure and are often the primary employer of healthcare professionals (Sulzbach 2009; O'Hanlon et. al. 2009). Many of these services are located in remote and rural areas. The public sector can extend its reach through contracts with these facilities.

[1] For the purpose of the report, the private health sector is defined as for-profit (both informal and formal) and non-profit (NGOs, FBOS, etc) entities delivering health services and products.

and private sectors both have roles to play in expanding access to priority health services by underserved populations. While the private sector is increasingly seen as a critical resource for achieving public health objectives, the government must play an active role as a steward. In this role, the government facilitates public-private collaboration through an enabling policy environment reflected through supportive regulation and positive incentives. An effective regulatory framework that encourages a greater private sector role in public health is a balancing act: it considers the market realities of the private health sector while ensuring expanded coverage of quality health services.

1.2 ABOUT THIS REPORT

USAID's Africa Bureau for Population, Health and Nutrition funded this report to highlight how changes in the legal and regulatory environment can create a supportive environment to expand access to FP and reproductive health (RH) services through private sector in Africa. The report aims to provide a framework for African policymakers and other key stakeholders who are undertaking legal and regulatory reform in the health sector. The primary audiences include:

- *African Ministries of Health* (MOH). The report guides the reader through a process for systematically examining a country's regulatory framework.

- *In-country stakeholders.* Associations of health professionals, health-focused nongovernmental organizations (NGOs) and faith based organizations (FBOs), leaders in the private health sector, and consumers' groups have a critical role to play during the reform process.

- *International donors.* The report maps out the technical resources, level of commitment, and time requirements needed to implement regulatory change and strengthen enforcement capacity.

Using laws and regulations from three Africa countries - Ethiopia, Kenya and Nigeria - the report develops a "road map" on what laws to review and interpret. Although the report focuses on policy reforms to increase private sector participation in the overall health system, these changes will also benefit critical health services such as FP, RH, MCH, and HIV/AIDS.

The report focuses on the range of policies and regulations that can influence the private health sector's role and includes the following:

1. A description of the role of stewardship in African governments to address common realities underlying regulations and to maximize the comparative advantage of each sector.

2. A set of tools to facilitate a legal and regulatory analysis including a) definition of key terms and concepts, b) a step-by-step process for conducting assessments, c) critical questions to ask, d) a comprehensive checklist of key regulatory characteristics to evaluate, and e) two country examples with illustrative regulatory language.

3. An overview of common regulatory problems and policy strategies that African countries have used to address them.

4. Recommendations on how to facilitate reform.

2. THE ROLE OF STEWARDSHIP

One of the government's key stewardship functions is to create a supportive and effective environment for public and private health sector collaboration. Under ideal circumstances, governments can use regulations to maximize use of public and private sectors assets and create confidence and trust for mutual collaboration. Ineffective or outdated regulations on the other hand, can perpetuate mistrust between the sectors or create roadblocks that impede the overall performance of the health sector. The Rockefeller Foundation sponsored a report on public and private sector perceptions of each other (Hozumi et al. 2008).[2] This section highlights some of this report's key findings and highlights many non-regulatory factors that the public sector reformer must consider.

2.1 PROBLEMS THAT MUST BE ADDRESSED

Mutual mistrust between public and private sectors. Ideology plays a very important role in shaping the public sector's views of the private sector. Most health care workers, employed by the public health sector believe that the government has moral obligation to provide free or affordable health care to the poor. Many public sector representatives claim a higher moral ground vis-à-vis the private sector, believing that the public sector is entrusted with the well-being and interest of the poor, which are neglected by the for-profit providers. Entry of the profit-driven private actors into the field of public health, some believe, would provide only a marginal benefit while creating greater inequities between people who can afford private health care and those who cannot. Some also argue that the for-profit sector has no interest in providing preventive basic health care, which is what the poor need most, but narrowly focuses on curative services, which only the rich can afford.

Representatives from the private health sector, on the other hand, mistrust the public sector as too restrictive and protective of state-run programs and institutions. The regulatory agency (usually the MOH) is often a provider of health services, and may charge fees and compete directly with regulated private providers. Sometimes public facilities are given specific exemptions from requirements that are applied to private providers offering similar medical care. Even where the regulatory function is separate from the direct operation of health services, private providers suspect regulators of giving preference to public sector services, while failing to understand the economic realities of private practice. For example, commenting on the ongoing struggle between the private and public health care providers in Thailand, some observers described the situation as a turf war through which the Ministry of Public Health sought to protect the handful of responsibilities left under its jurisdiction (Hozumi et al. 2008).

Outdated, inadequate or counterproductive regulation. Medical knowledge continues to advance, while legislation and regulation in the health care system may be frozen for years or decades at a time. Just five years ago, it would be hard to imagine a system in which nurses initiate and manage treatment with antiretroviral (ARV) drugs. Yet the scale of the HIV/AIDS epidemic and the shortage of physicians in Africa have prompted more countries to allocate these responsibilities to properly trained nurses, and outcomes research on these nurse-run programs is encouraging. Thus a regulation

[2] With support from the Rockefeller Institute, the Program for Appropriate Technology in Health (PATH) prepared an analysis of attitudes and perceptions towards the private sector. Technical Paper No. 2: Landscape Analysis of Global Players' Attitudes Toward the Private Sector in Health Systems and Policy Levers that Influence These Attitudes. October 2008.

prohibiting nurses from prescribing ARVs could quickly become a barrier to national HIV/AIDS treatment goals.

Regulations must also specify required procedures. For example, clinical regulations that do not explicitly require sterilization of instruments or single use syringes deny inspectors the power to reduce nosocomial infections. The regulatory reformer must constantly question whether current rules actually address the biggest risks to patients, or if they reflect outdated medical and public health findings.

Ineffective enforcement. As a general rule in developing countries, the laws and regulations are better than the reality. Both public and private health sector representatives interviewed in the Rockefeller-sponsored study were quick to note that most developing countries lack the legal and institutional capacity to set up a regulatory environment to monitor private sector providers and ensure their compliance with certification requirements, professional and ethical standards, or pricing (Hozumi et al. 2008).

For example, penalties and procedures to control counterfeit drugs may be clear in the Official Gazette, but the marketplace remains full of counterfeit drugs sold by unlicensed sellers. Many factors could explain this - too few, or corrupt, inspectors, or lack of laboratories to verify the contents of a labeled package. Or perhaps there is no government agency directed to prosecute sellers of counterfeit drugs, or no lawyers assigned to carry cases through the courts.

Regulation may also be ineffective because of failure of leadership, or because enforcement of regulations is assigned to an entity that has been "captured" by the group being regulated. For example, if licensing of physicians is delegated to a medical society, there may be little enthusiasm for pursuing claims of incompetence against a ranking (or even rank and file) member of the society. An analysis of necessary reforms must focus on the system for enforcing the rules as much as on the rules themselves.

Little reward or encouragement for higher quality care or better access. As a governmental tool, regulation is better at defining (and ideally, restricting) harmful practices than encouraging continuing quality improvement. But regulatory reforms can offer carrots, as well as sticks. For example, private health care facilities meeting more than minimal standards might qualify for public-private partnerships that would expand their business - receiving contracts to provide government-supported benefits, for example, or obtaining donor-funded drugs or vaccines that they can provide to their patients at no cost. In a number of African countries such as Zambia, Uganda, Kenya, and Ethiopia, compliance with special certification standards has enabled trained private providers to access free ARVs for their AIDS patients.

But creating a reward system that fosters quality will require overcoming some common misperceptions about the private sector by the public sector. Although the quality of private sector services varies from very high levels to extremely low, most public sector representatives interviewed in the Rockefeller study viewed the private sector to be more interested in financial and economic gain than the patients' well-being. Also, many public sector interviewees believed that private sector providers tend to prescribe unnecessary drugs, conduct unsafe operations, and charge excessive prices while skimping on quality. Others stated that private providers often renege on their promise to provide services to the needy and cannot be trusted to provide free services to the poor (Hozumi et al. 2008).

Lack of understanding of business requirements. Private sector interviewees in the Rockefeller study commonly believed that the public sector lacks understanding of the economic and business realities that confront the private sector. Many said that because the public sector does not understand the privates sector's concerns, limitations, and interests; it cannot create the incentives and conditions

needed to encourage private sector participation in public-private partnerships. Such partnerships must be seen to benefit both sides. But as some private providers note, the government usually insists that the private sector should enter partnerships without much expectations of profit or economic gain, merely acting with nationalistic or philanthropic motivations to do their part in helping the poor (Hozumi et al. 2008).

2.2 FINDING THE BALANCE: TOO MUCH OR TOO LITTLE REGULATION

The challenge for effective public-private partnerships is to find a middle ground that considers both sectors' perspectives and concerns. Comments from both sectors in the Rockefeller study show that it is possible to find a middle ground. Although most public sector respondents opposed the idea of the "free-market" in health care, they were also very receptive to the idea of limited public-private partnerships, provided that they were properly regulated and controlled by public agencies. The report also adds that most public sector representatives have a pragmatic and instrumentalist approach to public-private partnerships and view them as means to other ends, such as meeting governmental public health goals or Millennium Development Goals (MDGs), rather than simply achieving greater privatization of services.

Many private sector respondents in the Rockefeller study regarded the public sector as too restrictive and protective, but said that they did not favor a completely unregulated market. Lack of regulation creates as many problems for the private sector as it does for the public sector. In fact, regulation serves the interest of private sector providers, because it encourages providers to be accountable to professional standards, thereby preserving the reputation and success of their business model.
All parties interviewed for the study - private and public providers as well as patients - seem to agree on the necessity of regulation in the health sector, but not on the nature and degree of regulation. Representatives from both sectors argued that to ensure a fair and effective regulatory system, the government must seek their input in the process of creating regulatory mechanisms, and make sure that supervisory bodies include representatives of both sectors for a fair and effective system (Mackintosh 2007; Hongoro and Kumaranayake 2000).

Reaching a middle ground requires consulting all parties affected by the regulation to integrate their perspective and concerns and ensure patient safety and protection. Too much regulation can inhibit private sector interest, while insufficient regulatory enforcement can expose patients to dangerous medical care and unsafe medicines. For appropriate stewardship, governments must find the right balance between too much and too little regulation and ensure adequate enforcement, given institutional capacity and budgetary constraints.

3. DEFINITIONS OF KEY TERMS AND CONCEPTS

The term "regulation" is often applied loosely to a spectrum of governmental powers and functions designed to implement control over private sector activities. Before addressing the problems that arise from excessive, inadequate, or ineffective regulation, it is best to clarify the legal basis for regulating the private sector in health care, and to differentiate the different levels of authority that underlie the actions of a regulatory body. In seeking to reform a regulatory regime, it is important to understand what legal instruments may need to be modified, replaced or enforced.

3.1 LEGAL BASIS AND AUTHORITY TO REGULATE

All governments have constitutional powers and ethical responsibility to protect citizens from harm caused by the actions of other citizens. This is often referred to as "police power" and gives the government the power to protect patients who may be unable to judge the qualifications or quality of a health care provider, or the efficacy or safety of a drug or medical device. Regulation refers to a spectrum of governmental powers and functions designed to protect citizens by establishing the requirements for entering medical practice, running a health facility, or marketing a new pharmaceutical.

Governments also have the power to structure markets and the economy to foster patient safety and facilitate broader access for the poor. This enables the state to impose conditions on medical providers, services, or prices for medical care or drugs. The state may bolster publish health and social welfare through publicly funded benefit programs (a national health or health insurance system) or by requiring individuals or employers to provide health insurance coverage. Government regulations also comprise the financial or quality standards ancillary to these social protection powers; or these standards may be seen as contractual requirements (supplementing the minimum requirements for medical providers) for doing business with the state or state-sponsored insurer. In states with large, public-sponsored insurance plans, standards for participation may be more meaningful levers of influence than basic regulations - particularly when financial compensation is directly tied to meeting these conditions.

3.2 LEVELS AND INSTRUMENTS OF REGULATIONS

Analyzing the regulatory regime for health care requires a common definition of policy levers and instruments for regulation. These levers of influence fall along a hierarchy, beginning with policy and extending through legislation and regulation to the specific details on inspectors checklists or contracts between a national health insurer and individual provider.

- **Policy.** This is a statement of government intent. It may have constitutional backing and the force of the law, or it may be an unenforceable vision for the future. A constitutional commitment to free medical care, for example, may prevent the government from setting formal charges for public clinics, but it does not inhibit informal payments or privately-paid medical practice where public health care funding is inadequate. A policy statement on public-private partnerships for health may provide guidelines for negotiating such arrangements, but absent implementing legislation, the policy has no authority to prohibit less desirable partnerships, or to encourage desirable teaming arrangements.

- **Legislation (Statutes or Laws).** Legislation puts a policy into effect. Once passed by the law-making body (usually a legislature or parliament, but sometimes an autocratic individual leader), legislation gives authority to a specific government agency to establish laws or rules governing the operation of a health provider or facility. The legislation may be general, delegating the authority to establish specific standards to an administrative body. Or it may be very specific, incorporating detailed standards directly in the law or legislative language. The latter approach is less flexible, and makes amending the law more difficult and time-consuming than repealing or modifying a regulation. Legislation, statutes and laws are generally synonymous.

- **Regulation.** This term is usually applied to the detailed standards adopted by the Government within the framework of a particular statute. Regulations issued under the legislation must be consistent with its terms. Courts may void any regulation that exceeds the authority granted by the statute. The designated government agency defines the regulations, incorporating and elaborating standards set in legislation. Democracies usually publicly disseminate the draft, accept public comment, and modify it prior to putting the regulations into effect. For example, new legislation may authorize the MOH to require continuing medical education (CME) as a condition of renewing a doctor's license. The Ministry then defines the number of hours of CME required, the conditions for approving a CME course, and the manner of confirming attendance. Similarly, a law requiring that all clinics have "adequate" facilities may be operationalized by publishing regulations that specify the minimum size and staffing, number of rooms, sterilization equipment, diagnostic devices, etc.

  Regulations are usually issued by the same agency that actually conducts inspections or reviews and enforces sanctions for the violation of the standards. However, in some legal systems, the regulations must be approved by a higher authority (the Cabinet or Chief Executive) before they are enforceable.

- **Implementation and Inspection Guidelines.** Regulations often leave grey areas in the definitions of what a regulated provider must do, or is allowed to do. These grey areas may be addressed by the inspectors, who receive authority from the regulatory agency to enforce the regulations (or terms of contract). For example, a pharmacy regulation may require that the pharmacist keep a copy of every prescription signed by a physician authorized to prescribe a certain controlled class of drugs. But the regulation does not list the authorized providers, or the form of the prescription. The regulatory agency will issue periodic updates of a list of authorized physicians, or it may give inspectors a sample prescription form which, in effect, becomes the norm for all prescriptions. A provider denied a license due to violation of these guidelines might be able to challenge the guidelines as being inconsistent with the underlying statutes or regulations. But the provider would bear a difficult legal burden, as courts typically grant discretion to the agency and its inspectors to "address the grey areas" to enforce regulations.

  Implementation guidelines do limit inspector discretion, and therefore restrict an inspector's ability to solicit a bribe to overlook an alleged violation. However, guidelines that are too detailed may impose additional costs on the regulated provider that do not translate to improving enforceable patient safety.

- **Conditions of Participation in Government-Reimbursed Benefit Programs.** In countries where the government health service or national health insurer contracts with medical providers, the terms of such contracts are often viewed as "regulations." This is the case even if the contract terms are negotiated with an organization of providers (as is done with the contract between the National Health Service and general practitioners in Britain). In other words, the individual provider cannot vary the terms of the national contract. In this respect, the contract terms are as rigid, and as proscriptive as a regulation. The method of enforcement, however, is different. For violations of a

regulation, the provider will be sanctioned and potentially lose his or her license and right to practice, or will be fined and allowed to produce evidence that corrective action has been taken. A contract, however, is tied to financial compensation. A provider who violates a contract's terms will lose the ability to receive payment compensation for caring for publicly-supported patients, but would not necessarily be prohibited from continuing in medical practice.

- **Additional Incentives.** While legal controls may lead to penalties or sanctions if they are not met, incentives can be used to affect the price, quantity, or quality of a specific product or service. Subsidies, donated goods (equipment), shared training, or even tax breaks and low-cost credit for private sector health investments are all examples of instruments the government could use to encourage specific private sector investments in public health services. Government-provided utilities such as water, electricity, or sanitation services could be given at a discount or free of charge to clinics or providers to encourage greater access and supply of essential health services for the poor.

4. MOVING FROM REGULATORY DESIGN TO ENFORCEMENT

Assessing the regulatory system of any country requires an understanding of several layers of the legal and regulatory environment. The legal framework consists of two main components: 1) the design or content of the regulatory environment (the policy context), and 2) the implementation (the enforcement capacity) set forth in the laws. This section describes a step-by-step process for moving from designing regulations to implementing and enforcing them. Before beginning the complex process of assessing and reforming regulations and their enforcement, it is important to understand the time-intensive nature of regulatory reform. Thorough legal and regulatory reform may take years. There are few shortcuts in democratic policy reform. Yet the opportunity to upgrade the laws often may occur only once in a generation. Below are several fundamental principles for policymakers and donors considering regulatory reform:

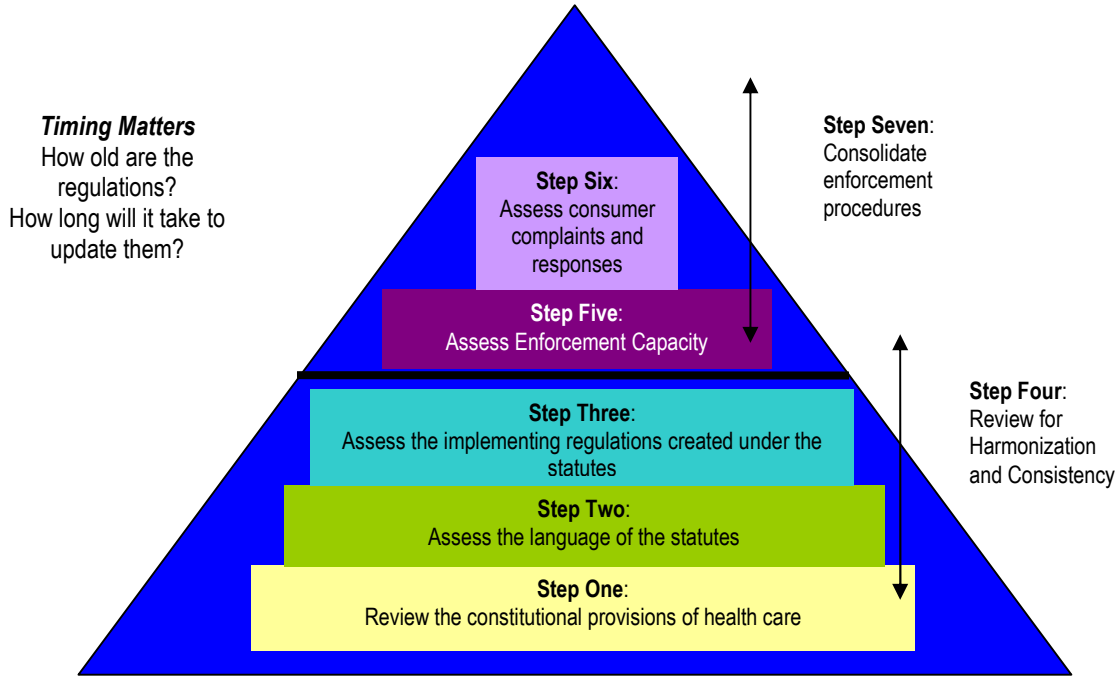
- **Expect to make a long-term commitment.** The analytical and mechanical steps (drafting, revising, and codifying the law) are the quickest phases in the reform process, taking upwards of 4 - 6 months. Consensus building also takes time, but is required to mobilize support for enacting and enforcing the reforms. Consulting with stakeholders and negotiating new legal language adds several more months to the process. Parliamentary approval can only move as fast as the democratic procedure. Donors and policymakers must be prepared for a long journey if they wish to produce meaningful change.

- **Determine how recently regulations have been updated.** Rules that have been adopted recently will be harder to change. If the rules have not been amended in years, there may be a backlog of changes desired by regulated parties and it will be possible to form a coalition to lobby for a general rewrite that includes multiple changes.

- **Know and work with the legislative cycle.** Parliamentary and cabinet procedures have timetables with important deadlines. Understanding the legislative cycle and key deadlines can increase the effectiveness of a reform strategy.

- **Review the general process for modifying regulations.** It is important to find out if there is a requirement for a draft and public comment? At what point can input be taken from the regulated providers or professions? Is there a Medical Council or other body that proposes changes in the regulation, or is the authority to update the regulations solely vested in the responsible agency MOH?) Answers to these questions will determine the strategy and timeframe for reforming regulations.

FIGURE 1: ASSESSING THE LEGAL AND REGULATORY ENVIRONMENT: A STEP ANALYSIS



4.1 EXAMANING THE LEGAL FRAMEWORK GOVERNING THE PRIVATE SECTOR

Step One: Review the constitution and policy framework. The first step in the legal analysis involves assessing whether there is a constitutionally guaranteed right to health care, or more specifically, "free" medical care. Does policy encourage or discourage private provision of medical care? Is there a policy that permits, or prohibits, dual practice (after-hours work in the private sector) among health professionals employed by public facilities? Box Two lists questions to ask while reviewing laws.

Box Two: Questions to Ask in Reviewing Existing Laws

- What groups (individuals, facilities, and products) are specifically covered by the statute? How is the regulated entity defined?
- Which requirements are explicit in the statute, and where are the specifics left to implementing regulation?
- What penalties or sanctions are defined for violation of the rules?
- What agency is given the power to adopt regulations under the statute? Does the same agency have the power to enforce the rules?
- Does the statute specify any aspects of the ***process*** for enforcing the regulations: the frequency of inspections or license renewal, the qualifications of inspectors, the procedure for responding to complaints? Does the statute permit unannounced inspections, or is it silent on this issue?
- Does the statute specify the process for sanctioning those who violate the rules (specification of charges, hearings and the right to present evidence, procedures for appeal)?
- Does the statute provide penalties for those who pretend to be licensed? Loss of license is no sanction for an individual who was never entitled to apply for a medical license in the first place.

Step Two: Review the language of the statutes: It is important to review the actual language of the statutes (often with the help of a local lawyer), and not just accept a verbal paraphrase of the laws. The "conventional wisdom" about the requirements of a law often differs from what the language actually says.

Step Three: Review the regulations adopted under the statutes. In most countries, regulations should have been published in an *Official Gazette*, but copies may be difficult to find. Often, regulated providers have never seen a copy of the regulations that govern them, although extracts may be published by a professional society or interest group. Wherever possible, the original regulation and any extracts or "how to comply" guides should be reviewed. Box Three describes questions to ask about the language and provisions of laws under review.

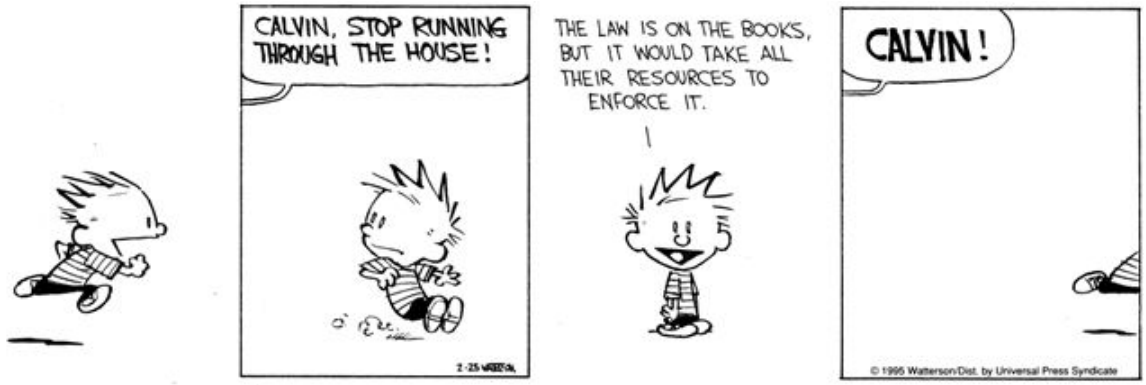
Box Three: Questions to Ask in Reviewing Regulatory Language and Provisions

- Do the regulations create subsets of the regulated profession/facility/product to which different standards apply?
- How specific are the regulatory standards? Are they written at a level of detail that is only questionably related to fundamental quality and patient protection?
- Do the rules require facilities, equipment or practices not normally found in a facility of the regulated class, even if that facility is generally perceived as adequate?
- Do the rules incorporate other requirements by reference-for example, respect for patient's right defined in a separate law? A requirement for a "business" license as a prerequisite to receiving a license as a health facility?
- Do the rules use terms like "adequate" or "satisfactory" that provide wide latitude to the inspector who determines compliance?
- Do the rules require that the licensee have facilities, training or equipment not currently required in most other jurisdictions? If the rule is relatively new and the requirement is critical to quality care, this may be positive development. However, if the requirement has been in place for some time but not adopted in other jurisdictions, should it be a candidate for elimination?
- Do the rules specify a process for reporting inspection results and correcting violations?

Step Four: Identify conflicts and inconsistencies. Any legal and regulatory review includes an analysis to identify conflicts or inconsistencies between the different policy instruments. Harmonization among the laws is critical to avoid needless bureaucratic barriers to getting licensed (at the facility and professional level). For example, if patient's rights are referenced in one part of the law, the rules should integrate reference to them as well as the procedures in which they are addressed. If a requirement for a "business" license is a prerequisite to receiving a license as a health facility, the law should make this clear wherever licensing is discussed. Without this harmonization of the laws, aspiring private practitioners may find themselves in a costly and time-consuming dilemma where a business license is needed to obtain a clinic license, but the former cannot be issued until the clinic license is approved.

Consistency ensures that licensees have requirements for facilities, training or equipment that are required (and quality centered) in most other jurisdictions. If there is an exception, the rule may be a relatively new positive development that improves quality of care. But if the requirement has been in place for some time but not adopted in other jurisdictions, it may be a candidate for elimination, particularly if it adds cost or administrative barriers to providers or facilities.

4.2 ASSESSING THE EFFECTIVENESS OF REGULATORY ENFORCEMENT



Step Five: Assess enforcement capacity. Written regulations may be quite different from what is actually enforced by inspectors in the field. While reforms may focus on changes in the statute or regulations, it is important to understand the enforcement process "on the ground" before developing a reform strategy. The reformer needs to look at the system for monitoring the regulated entities, as well as the process by which sanctions are actually enforced against violators.

Few regulations are self-enforcing. In most developing countries, it is not too hard to find health facilities operating without a license, or licensed facilities that are clearly in breach of important aspects of the regulations. The reformer should carefully review the monitoring process (see Box Four).
Terms such as "adequate" or "satisfactory" provide wide latitude to the inspector, and could present problems if the rules are not consistent, or if the inspectors do not give clear guidance on how these terms are interpreted.

Box Four: Questions to Ask in Assessing Enforcement Capacity

- The number and location of inspectional staff
- The adequacy of records containing the location and characteristics of the licensed entities or individuals
- The qualifications and training of inspectors or complaint investigators
- The scheduled and actual frequency of routine inspections
- Procedures for controlling the quality of inspections (preventing corruption)
- The number of complaint-based or "unannounced" inspections
- The number of enforcement actions undertaken and concluded

Step Six: Review systems for complaints, licensing actions, and sanctions. Besides looking at system-wide data (where available) on these aspects of the inspectional process, the reform process should examine the handling of a few complaints or prominent licensing actions. All of this should be undertaken before recommending major changes in statutes or regulations. It may be that regulations are adequate and reasonable, but enforcement absent or capricious. In that case, the reformer should focus on improving the enforcement system, not on changes in the regulations.

Complaints can be a key element of any regulatory system. Not all consumer complaints indicate a violation of the regulations, but they are often a leading indicator of real problems. Another strategy is to include non–professionals, such as consumers, on disciplinary committees that hear complaints of

unprofessional or negligent conduct. This safeguard avoids the problem of "regulatory capture," which can occur when health professional avoid raising disciplinary action against their own health profession or colleagues. For this reason, it is important to understand how complaints about medical providers are handled.

Inspections and complaints are the intelligence system for regulatory enforcement, but they must be complemented by a credible process for sanctions. A full regulatory analysis includes an assessment of what happens to negative complaint and inspection findings. Key questions to ask are listed in Box Five.

Box Five: Questions to Ask About How Consumer Complaints on Medical Providers Are Handled

- Is there a clearly identified place to register a complaint against a medical provider? Is this well publicized? Can the complaint be filed without traveling a great distance?
- Is there a government agency (preferably the regulatory agency) specifically charged with assessing the complaint?
- Are inspections conducted when a complainant provides credible evidence of a regulatory violation or danger to the public health?
- Is there a written record of the complaint and the findings?
- What happens if the complaint is justified? How is complaint information used in the enforcement process? Do valid complaints lead to disciplinary measures within a reasonable period of time?

The regulatory reformer should pragmatically look at strategies to strengthen enforcement: How many actions (as a percentage of the estimated number of providers) have been taken in the previous five years, and what was the average processing time? In systems where regulation is ineffective, rather than excessive, the problem may lie more with the sanction apparatus than with the basic statutes or regulations. In one African country, the backlog of medical licensure cases is almost a decade long. In this context, attention to the enforcement process may be much more important than updating the regulatory requirements.

Box Six: Questions to Ask about Sanctions

- What agency is assigned to obtain the sanction? Can the regulatory agency with primary responsibility actually remove or limit the license, or collect a fine? Or must a court or other government agency actually order the sanction?
- What provisions are provided for evidentiary hearings on the allegations? In general, the licensed entity should have a chance to present evidence, but in less than a full -scale trial.
- Are there multiple levels of decisionmaking required before a sanction is imposed? For example, does a sanction ordered by a Professional Responsibility subcommittee of a Medical Council have to be reviewed by the full Council before implementation? In reality, is the process so cumbersome that few sanctions are imposed? Can the process be short-circuited in the event of a serious public health threat?
- Does the responsible agency have sufficient dedicated legal staff to pursue the enforcement actions recommended by the regulatory agency? Are more lawyers or hearing officers required?
- Do sanctions tend to be overturned on judicial appeal? What do such appeals say about the process?

Step 7: Consolidate enforcement procedures. Streamlining the enforcement process may be the most important reform of all. Sanctions should be based on a single hearing conducted by a designated disciplinary committee, or at most by the action of the full licensing body based upon the findings of an independent hearings officer with access to professional testimony on the applicable standard of care. Duplicate hearings by the full licensing board should never be required, and sanctions should be imposed without waiting for court approval. Appeal to the courts by an aggrieved licensee should be possible, but on narrowly limited grounds, and only after the sanction is imposed. Since competent lawyers are critical to effective enforcement, including the closure of non-licensed facilities or quacks, the country

should create a special unit of lawyers to support all of its health regulatory agencies, or designate a special group within the Ministry of Justice that puts a high priority on this function

Lastly, regulatory reformers also need to look at the bottom line. Governments must be prepared to supplement license revenues with tax funds and to finance regulatory agencies with adequate funds to carry out its scope, including inspections and enforcement. This means that the Ministry of Finance, as well as the MOH, must support regulatory reforms that will strengthen enforcement capacity.

5. CRITICAL REGULATORY ISSUES TO EXAMINE

There are seven core areas that directly influence private sector capacity to deliver essential health services such as FP and RH, MCH, and HIV/AIDS.[3] These areas are summarized in Box Seven.

Box Seven: 7 Core Areas Affecting Private Role in Essential Health Services and Products
✓ Laws and regulations governing **health professional licensing**
✓ **Facility requirements and licensing** for public and private sector healthcare providers
✓ Laws and regulations governing **pharmacists and other related professional licensing**
✓ Laws and regulations governing **facilities supplying pharmaceuticals**
✓ Laws and regulations government governing **supply of pharmaceutical**
✓ Laws and regulations **protecting consumers**
✓ **Enforcement** mechanisms and capacity

In the past, enforcement has been the weakest link in regulatory assessments and reforms. The checklist that follows addresses this shortfall by including issues related to enforcement capacity and mechanisms.

The multi-page checklist summarizes the main areas outlined above and provides the following details:

- What elements are important to look for both in the policies, laws and statutes as well as enforcement?
- What is the impact of the current laws and regulations?
- What strategies have been used to create a favorable policy environment and improve enforcement?

The checklist below numbered in a sequence parallel with that of the table above. The "A" section within each element focuses on laws and regulations, while the "B" section focuses on enforcement of these laws.

[3] It is important to note the checklist is not designed to be an exhaustive list of all the legal and regulatory aspects of a health system but instead focuses on other critical areas that can inhibit or motivate private sector participation in basic health services. In addition to better integrating the private health sector, they also strengthen the overall health system.

The Kenya and Nigeria[4] legal and regulatory review country case studies (see Annexes One and Two) applied the checklist to examine all the relevant laws, policies and regulations - when available - influencing private sector provision. This comprehensive analysis was supplemented with examples of regulatory language from Ethiopia. The country case studies demonstrate "good practices" in regulatory language that can be replicated in other sub-Saharan African health settings.

[4] The authors selected Ethiopia, Kenya, and Nigeria because PSP-*One* has extensive in-country presence and could easily gather all the necessary laws, policies and regulations.

Table 1: A Checklist for Evaluating the Effectiveness of the Legal and Regulatory Environment

1 (A) Laws and regulations governing health professional licensing requirements

What to look for in regulations governing medical professionals (general and specialists)	Do the legal/regulatory statutes have the desired impact? What are the positive and negative implications?	Strategies, actions, and incentives to facilitate private sector participation
Professional Licensing/Relicensing: • Clearly defined terms for professional licensing • Periodic license renewal required (5 years or less) **Continuing Medical Education:** • Continuing education requirements are clearly defined for each cadre **Scopes of Practice**: • Statutes permit special accreditation to enable professionals to achieve skill upgrades to offer certain services • Clearly defined scopes for each health professional cadre • Consistency between public and private sectors • Prescribing privileges are clearly defined among the health cadres • Articulate responsibilities for disease reporting **Private Practice:** • Clear and well defined terms of dual practice, or private practice after hours among health professionals employed by the public sector • Clear and well defined terms for health professional entry into private practice. **Patient Rights:** • Non-professionals/consumer representatives sit on licensing boards to serve as patient right's advocate • Patient rights are articulated • Law effectively prohibits advertising and restricts use or terms that may mislead consumers by implying professional licensure (doctor, clinic, etc.)	**Professional Licensing/Relicensing:** **+** Encourages continued quality oversight of the health professional cadres - Strict or cumbersome relicensing procedures could lead to fewer access points for primary care and make task shifting more difficult to achieve **Continuing Medical Education:** + Encourages skill updates and maintains a current list of practicing physicians **Scopes of Practice:** + Reduce conflicts between professionals and among inspectors and facilities - Rigid scopes may unnecessarily restrict provider services without improving patient safeguards +Increases access to low risk and high benefit drugs +/-Creates higher standards for high risk/highly important services **Private Practice:** +Flexible dual practice terms could incentivize retention of health staff and reward public health service. - Onerous requirements to enter the private health sector could limit service access points and encourage outward migration of health staff + Articulates the provider's role and obligation to report infectious diseases, thereby strengthening the country's epidemiological surveillance system. **Patient Rights:** +Limits health professionals' ability to execute self-serving oversight over the public interest +Allows consumers to make more informed choices among different kinds of providers	**Professional Licensing/Relicensing:** • Streamline procedures for licensing and relicensing to encourage market entry and prevent bottlenecks to professional licensing. • Ensure that facility licensing laws and regulations on staffing mirror the professional scopes of practice **Continuing Medical Education:** • Require proof of continuing education in license renewal • Education requirements take into account realistic availability and consider alternative measures to train professionals • Link license to disease reporting requirements in a practical manner (e.g., monthly reports, use of Information technology tools to report diseases, etc.) **Private Practice:** • Utilize dual practice to incentivize retention. • Limit waiting period to enter private practice to no more than 2-3 years**.** **Scopes of Practice:** • Permit requirement for supplemental accreditation of specified services • Delegate authority to the appropriate professional licensing body to define the scope of practice for the profession (just as it defines the training and experience requirements). This will ensure that scopes are consistent with training. • Establish a mechanism, such as an overarching council of allied medical professions, or the Ministry of Health, to resolve conflicts where more than one profession claims the sole right to conduct a particular activity or procedure • Grant clear permission for an individual to be licensed for private practice when working within the agreed scope of practice

		• Providers and inspectors anticipate task delegation to maximize services for consumers • Permit modification of prescribing requirements based on new diagnostic technologies **Patient Rights:** • Cleary articulated as part of the licensure requirement. • Patient grievance procedures are easy and clearly stated and disseminated • Oversight bodies readily respond to such grievances through review, sanctions, remedial action, dismissal, or licensure revocation with public reporting of violations
1 (B) Enforcement of Health Professional Licensing Requirements		
What to look for in licensing requirements for private medical professionals	Do the legal/regulatory statutes have the desired impact? What are the positive and negative implications?	Strategies, action and incentives actions to facilitate private sector participation
Sanctions of professionals • A specific regulatory agency is authorized to regulate and maintain responsibility to sanction medical professionals • The law specifies whether the primary agency either has the authority to remove or limit the license or collect a fine; or a court or the agency ordering the sanction must remove the license • Penalties and sanctions for violating rules are clearly defined for: -Those who hold licenses -Unlicensed non-professionals • Transparent and clear process for sanctioning those who violate rules • Sufficient and dedicated legal staff to pursue enforcement actions • Defined process for evidentiary hearings for allegations and decision making before sanctions • Requirement to keep medical records • Procedures for evidentiary hearings on the allegations are specified; in general the licensee may present evidence, but in less than a full scale trial • Are sanctions overturned on judicial appeal? Do these sanctions reveal anything about the sanctioning process?	**Positive Impacts:** • Enable the licensing board to be independent of the ministry and any one medical society, to encourage the protection of the public interest, rather than self-interest of one professional group • Boards may review sanctions to determine if they are proportionate to the violation, and if they offer corrective measures to restore quality • Sanctions/patient grievance remedies may be simple and responsive • In the event of a public health emergency, procedures for sanctioning licensees could be shortened **Negative Impacts:** • Complex, time-consuming and unresponsive to grievances • If a court order is required to de-license a professional, this may make the process time-consuming and unresponsive • Multiple levels of decision making for sanctions may deter sanctions since the process is so cumbersome	**Strategies to Improve Effectiveness** • Vest authority in professional registration council with government appointing members • Ensure adequate budget for inspectors and travel is allocated • Ensure supervision of inspectors to reduce graft or abuse of authority • Include fines, suspension, and corrective actions as well as de-licensing among sanctions • Permit fact-finding and preliminary determination by administrative hearing officer or small panel consisting of professionals and at least one consumer • Allow de-licensing to occur by administrative action (not a court order) and follow up with an option for appeal (with lawyers assigned to this function). • Acknowledge supplementary peer review or accreditation

2(A) Facility requirements for public and private sector health care providers

What to look for in licensing private medical facilities (e.g. clinics, nursing/maternity homes, hospitals, laboratories)	Do the legal/regulatory statutes have the desired impact? What are the positive and negative implications?	Strategies, action and incentives actions to facilitate private sector participation
Staffing, Equipment and Physical Facility Requirements: • Staffing, equipment, and building levels are commensurate with risk and level of care, and harmonized between public and private sectors • Certificate of Need for high tech equipment/services • Patient rights and grievance protocols are clearly defined and visible within the facility • Disease reporting and maintenance of medical records are required • Some authority to waive specific requirements in underserved rural areas **Inspections:** • Unannounced inspections permitted and recorded • Laboratories have a quality control requirement to check accuracy • Multiple inspection authorities are listed vs. one comprehensive authority • The scheduled vs. actual frequency of routine inspections is similar • The number and location of inspectional staff is articulated in the statute or in related regulations • Inspectional staff have appropriate training requisites • Records are maintained noting the location and characteristics of the licensed entities or individuals • The report includes the number of enforcement actions undertaken and concluded **Restrictions:** • Ownership restrictions such as limits on the number of clinics one person may own; or limits on the types of clinics that the private sector may operate. • Period of government service required prior to private practice	**Positive:** • Quality guarantees may encourage wealthier people to use the private sector, leaving more public sector access for the poor • Statutes apply pressure for quality upgrade in public services • May increase patient access and consumer responsiveness • Reduce unnecessary investments in equipment/infrastructure or staffing that is not relevant to patient needs • Adjust requirements so that facilities may operate with alternatives to optimum staff when areas face shortages of health professional **Negative:** • Higher quality or more costly private sector services may produce less political demand for public sector upgrades • If equipment and staffing levels are not commensurate with risk level of procedure, this may lead to unnecessary increases in facility costs • If facility requirements are highly costly for the private sector, this may stymie market entrance **Multiple inspection authorities:** • May lead to redundant, inefficient oversight **Restrictions:** (Eg. Government service preceding entry into private service): + May recover investments in training, but - Could lead to outward migration of professionals if they cannot find a government post	**Staffing/Equipment and Physical Facility Requirements:** • Clear statement that ALL facilities are subject to regulation. Regulations shall be based on classification of facility, irrespective of public vs. private ownership. • Consider waivers or flexible arrangements for facilities in rural areas. Allow franchising or partnering to be one mechanism in which a rural or low-resource facility can meet licensing requirements. • Adjust facility/staffing requirements to service level; possible special category for rural areas • For certain expensive investments that may have limited public health impact, require approval before licensee can purchase selected list of equipment • Leave room for the requirements to be updated more frequently than the law by delegating standard determination to the regulatory agency. The agency should constantly ask the questions: Does this particular requirement really protect the patient? From what risk? Is there a better (less expensive, or equally expensive and more effective) way to protect the patient from the same risk? • Ensure that facility licensing occurs at least every five years to continually maintain oversight **Inspections:** • Make clear that sanitary and medical inspections should be done by same agency, at a decentralized level (even if facility accreditation is complete at federal level) • Inspections should inquire whether the facility classification is appropriate. Is there patient demand (and provider will) to initiate procedures that have a higher level of risk (eg. surgeries, procedures requiring anesthesia? • Require laboratories to do quality checks at random intervals, contingent for facility licensing **Restrictions:** • State period of required government service before private practice

2 (B) Enforcement of health facility requirements		
What to look for in legislation/regulations of facility licensing and requirements	Do the legal/regulatory statutes have the desired impact? What are the positive and negative implications?	Strategies, action and incentives actions to facilitate private sector participation
• Sufficient number of inspectors with appropriate qualifications, and training • Maintenance of adequate facility inspection records • Procedure to control inspectors to avoid corruption • Ability for inspectors to review medical records • Duplicative inspections (e.g.; one for hygiene, another for licensure) • Clarity vs. confusion regarding licensure of individual professionals	+ Regional and local inspection offices AND a national register of professionals/facilities leads to faster more responsive inspections + Quality assessments must give inspectors authority to review patient records in order to enable thorough and effective oversight + Agencies licensing facilities have a clear understanding of their scope of oversight (responsibility of professional vs. facility licensing agencies is clearly outlined)	• Facility inspectorate confirms license of required professionals - shares data on poor care with professional licensing agency • Sufficient budget for inspection cadre and travel • Combine inspections (hygiene, medical) to reduce time and administrative barriers to licensing and renewal

3 (A) Laws and regulations governing pharmacists and other related professionals		
What to look for in legislation/regulations of pharmacists, pharmacists technologists, drug sellers, other	Do the legal/regulatory statutes have the desired impact? What are the positive and negative implications?	Strategies, action and incentives to facilitate sector participation
Professional Licensing/Relicensing: • Periodic license renewal required (5 years of less) **Continuing Education:** • Continuing education of pharmacist is clearly defined and appropriate to changes in technology and pharmaceutical innovations **Scope of Practice:** • Vague or restrictive scope of practice for pharmacists, pharmacist technician and drug sellers • Requirement for prescribing based on the provider level • Drug lists for different levels of facility and provider **Private Practice:** • Creates clear and well defined terms of dual practice, or private practice after hours among health professionals employed by the public sector • Creates clear and well defined terms for health professional entry into private practice. **Patient Rights:** • Non-professionals/consumer representatives sit on licensing boards to serve as patient rights advocate • Patient rights are articulated with clear grievance procedures established **Restrictions:** • Limits on prescribing • Limits on dispensing	**Professional Licensing/Relicensing:** + Clearly defined terms for professional licensing allow professionals to plan for market entry **Continuing Education:** - Continuing education can encourage adoption of new technologies and pharmaceutical innovations **Scope of Practice:** - Scopes of practice that are too vague or not clearly defined may lead to too much access to essential drugs. Rigid scopes may needlessly restrict essential drugs - If prescribers dispense, drug costs may go up due to conflict of interest - Requiring presence of a pharmacist may mean that many consumers cannot obtain essential drugs	**Scope of Practice:** • Establish drug lists for different levels of provider that are responsive to available staffing cadres • Require prescriptions if the system can enforce the prescription but not where prescribers are unavailable or health risk is low • Allow for franchises where a supervisory pharmacist may oversee a pool of pharmacy shops managed full-time by pharmacy technicians, particularly in rural areas where pharmacists may be scarce **Continuing Education:** • As technologies and improved diagnostic capacity evolve, allow prescribing and dispensing protocols to be flexible to empower task shifting • Medical education and licensing guidelines should be flexible enough to adjust to changes in diagnostic capacity and in available drugs **Patient Rights:** • Law effectively prohibits advertising/restricts use or terms that may mislead consumers by implying professional licensure (pharmacist, pharmacy, etc)
3 (B) Enforcement of pharmacists licensing requirements (see enforcement under medical professions)		

4 (A) Laws and regulations governing facilities supplying pharmaceuticals		
What to look for in legislation/regulations governing facilities supplying pharmaceuticals	Do the legal/regulatory statutes have the desired impact? What are the positive and negative implications?	Strategies, actions and incentives actions to facilitate private sector participation
Staffing, Equipment and Physical Facility Requirements: • Staffing levels are explicitly defined • Physical facility requirements are clearly outlined and are responsive to drug storage and dispensing needs **Ownership Restrictions:** • Requirement of pharmacy ownership by pharmacist • Limitations on multiple sites **Record Keeping**: • Requirements are explicit **Drug Requirements:** • Outdated and unregistered drugs are prohibited	**Staffing, Equipment and Physical Facility Requirements:** - Requirement for pharmacists as managers is a poor use of available pharmacy technical talent **Drug Requirements:** - Without clear drug lists and staffing levels, drugs may be abused or improperly used. - Essential drugs not available	**Staffing, Equipment and Physical Facility Requirements:** • Allow managers to oversee administrative and financial aspects of running the pharmacy to free up pharmaceutical knowledge for relevant dispensing, patient assessment, verification of appropriate storage mechanisms • Permit technical supervision of facility by pharmacist without constant on-site presence • Network of multiple sites overseen by a pharmacist, or permit franchises • Make exceptions to facility or staffing requirements when rural areas cannot meet certain requirements. These exceptions should be reviewed periodically. **Drug Requirements:** • Utilize a tiered drug list according to the level of facility staffing/supervision
4 (B) Enforcement of pharmacy facility requirements		
What to look for in legislation/regulations governing facilities supplying pharmaceuticals	Do the legal/regulatory statutes have the desired impact? What are the positive and negative implications?	Strategies, actions and incentives actions to facilitate private sector participation
Inspection: • Unified facility inspection force (including sanitation, storage and technical oversight) • Adequacy of inspection staff---numbers, training, travel budget, record inspection, protocols • Unannounced inspections • Supervision and control of abuse by inspectors	**Inspection:** - Insufficient frequency or depth of inspection to detect violations - Extortion by inspectors - Unfair competition for compliant providers	**Inspection:** • Use health facility inspectors (with pharmaceutical expertise) to investigate pharmaceutical facilities • Permit administrative actions (sanctions, fines, corrective actions) without court appearance • Use lawyers dedicated to facility/professional licensing to sanction/fine/or impose corrective actions on facilities • Permit fines as well as administrative closure orders (with an appellate procedure)

5 (A) Laws and regulations governing pharmaceutical supply		
What to look for in legislation/regulations governing pharmaceutical supply	Do the legal/regulatory statutes have the desired impact? What are the positive and negative implications?	Strategies, action and incentives actions to facilitate private sector participation
Rx Requirements: • Marketing approval Accept other, reputable (eg. EU, US) jurisdictions' drug registrations in order to save resources on expensive and timely drug registry processes **Penalties for:** • Counterfeit drugs and unapproved products • Parallel imports • Restrict number of wholesalers **Inspections:** • Oversee manufacturing practices with spontaneous inspections	+ Pharmaceutical requirements are designed to limit dangerous or counterfeit drugs - Drug registration procedures (if long) may lead to delays in important drugs not being available and may raise cost of essential drugs - Slack oversight of manufacturing may risk poor quality or adulterated drugs - Distributors may be too small to provide service/quality guarantees	• "**Follow the leader" licensing** (if approved by FDA, EU, etc). This may include a requirement for submission of the summarized data from post market surveillance of drug integrity in the countries where the drug is already licensed. The drug would be approved only for the uses approved in the reference country. • Require evidence of cost/benefit of the registration of a new pharmaceutical. • Require Good Manufacturing Practices (GMP) • Set internal and external quality control requirements • For imports, expedite customs procedures and reduce or waive taxes for essential medicine
5 (B) Enforcement of pharmaceutical supply		
What to look for in legislation/regulations governing pharmaceutical supply	Do the legal/regulatory statutes have the desired impact? What are the positive and negative implications?	Strategies, action and incentives actions to facilitate private sector participation
Inspections: • Adequacy of inspectors---number of inspectors, training • Corruption controls (supervisors of inspectors) • Unannounced inspections **Quality Control:** • Labs to verify contents and integrity of medicines • Periodic/random quality control by government labs and the manufacturer	• Same as other enforcement systems	• Adequate staffing and funding for Government drug lab • Require quality control by ISSO certified labs

6 (A) Laws and regulations protecting consumers		
What to look for in legislation/regulations governing consumer protection	Do the legal/regulatory statutes have the desired impact? What are the positive and negative implications?	Strategies, action and incentives actions to facilitate private sector participation
Patient Complaint Process: • Defined and well publicized **Patient rights:** • Defined and tied to facility and licensure status **Regulatory Agency:** • In place and charged with assessing and responding to consumer complaints	• Consumer protection must be recognized in a credible licensing system for them to have a positive effect • Complaints can augment inspections by helping to identify violations	• Link patient rights to facility and professional licensure • NGO(s) can be designated to help complainants; or • Supporting the patient grievance process could be contracted out to an independent body
6 (B) Enforcement of laws and regulations on consumer protection		
What to look for in legislation/regulations governing consumer protection	Do the legal/regulatory statutes have the desired impact? What are the positive and negative implications?	Strategies, action and incentives actions to facilitate private sector participation
Defined Process and Place to Address Patient Complaints: • Investigation, records of complaint and findings, enforcement of disciplinary measures) • The grievance process is well publicized and can be filed without significant travel, time or other expense to the file **Management of the Complaint:** • There is a written record of the complaint and the findings • Complaints are used to drive sanctions or corrective actions among providers/facilities • A sufficient number of investigators or inspectors (with adequate geographic distribution, transport, and authority) to review complaints and check out those with face validity	+ Link to license enforcement (facility and professional) + Inspections are conducted when a complainant provides credible evidence of a regulatory violation or danger to the public health + Valid complaints lead to disciplinary measures within a reasonable period of time + Builds public trust in system + Creates accountability	**Defined Process and Place to Address Patient Complaints:** • Ensure that patients can easily file complaints by establishing well-publicized contacts for submission of complaints in person or in writing **Management of the Complaint:** • Create a clear system to remedy the patient grievance, either through fines, sanctions, penalties, license revocation, or grievance dismissal as needed • Inspectors have authority to review the medical records of the complainant, and preferably those of others treated at the same site or by the same professional • Fund complaint investigators (working for health professional or facility licensing agency) • Keep clear records of patient grievances and action taken. A formal response should be issued to the complainant on the outcome of the investigation - either: 1) a statement that the facts do not justify pursuit of a case under the licensing law, or 2) a formal report that initiates the apparatus for professional discipline or facility sanctions

6. COMMON REGULATORY PROBLEMS IN AFRICAN COUNTRIES

Several regulatory weaknesses affect both healthcare providers and their patients in Africa. These weaknesses, which include ill-defined or overlapping scopes of work, insufficient accommodation of African realities such as staff scarcities, and overly restrictive regulations, can increase health costs and negatively affect quality of care. A description of common problems and potential solutions appear below.

6.1 VAGUELY DEFINED SCOPES OF PRACTICE

Common problems that may stem from health professionals' scope of practice include: ambiguous or unclear scopes, overlapping scopes between health professionals that trigger turf battles, and policies or practices that create conflicting scopes for health professionals operating in the public vs. private sectors.

In Zambia for example, nurses, who provide most of the primary care in public facilities enjoy a clear scope of practice, which includes a list of medicines they are allowed to prescribe, and the procedures they can perform (some on the completion of additional training). Despite broad acceptance of the scope within the public system, few Zambian nurses in the private practice were able operate under the same scope of practice. The Medical Council responsible for licensing facilities took the position that private health facilities needed a managing physician in order to be issued a license. Pharmacy regulations would not permit pharmacists to fill prescriptions written by a privately practicing nurse, even though the prescription would be filled if ordered by a nurse in the public facility. The ramifications of this dual set of standards meant that a fully trained nurse wishing to start a private practice would be required to hire a supervising physician to legally undertake the same activities she would otherwise perform, without physician supervision in the public sector. In countries like Zambia (and every sub-Saharan nation), where doctors are scarce, this approach can limit the supply of primary care services available, particularly in remote and poorer areas, where physician shortages are even more pronounced.

Comparative analysis of scopes of practice among Zambia's neighbors reveals that this double-standard is outside the norm for sub-Saharan Africa. In Namibia, Uganda, Kenya and Ethiopia, nurses can obtain a license and run private clinics as long as they limit the procedures performed to those for which they are trained. While the facility licensing statute in Ethiopia is quite basic, it clearly anticipates that the lowest level of licensed clinic can be run by a non-physician.

Kenya demonstrates how lack of consensus among the health professions about scopes of practice can lead to conflicts between the professions. Though the scopes of practice between nurses, clinical officers and physicians operating in private practice were clearly defined, hospitals recognized that auxiliary patient support was also needed. Hospitals began training nurse's aides to undertake these non-medical tasks. During inspection, however, the absence of an agreed scope of practice for such support personnel resulted in charges from Nursing Council inspectors that the aides were serving as unlicensed

nurses, which threatened the facility license. To avoid these controversies, all parties must establish and agree on clear dividing lines. For example, medication management clearly is a task for nurses, but such tasks as personal hygiene and clerical work could be undertaken by nurse's aides, enabling nurses to spend more time with patients. In many countries, this division of labor is well established, with the scope for a "nurse's aide," "patient care assistant," or "ward clerk" defined to prevent charges of violating facility licenses or professional licensing.

To minimize conflicts over scope of practice, the ideal regulatory system will:

- Delegate authority to the appropriate professional licensing body to define the scope of practice for the profession (just as it defines the training and experience requirements). This will ensure that scopes are consistent with training.

- Establish a mechanism, such as an overarching council of allied medical professions, or the MOH, to resolve conflicts where more than one profession claims the sole right to conduct a particular activity or procedure.

- Grant clear permission for an individual to be licensed for private practice when working within the agreed scope of practice.

- Ensure that facility licensing laws and regulations on facility staffing mirror the professional scopes of practice.

- Anticipate task delegation to maximize services for consumers.

- Permit modification of prescribing requirements based on new diagnostic technologies.

6.2 FAILURE TO ACCOMMODATE HUMAN RESOURCE SHORTAGES

Quite often, facility regulations require the services of health professionals who are in short supply. This impedes licensed facilities from operating in underserved parts of the country. For example:

- To dispense some essential drugs (such as antibiotics or painkillers), regulations require a fully licensed pharmacy with an on-site pharmacist. There are few pharmacists in the country, and they are all employed in big hospitals or urban pharmacies. Thus, in many rural locations, there is no properly licensed entity to dispense these drugs. Patients go without the drugs or obtain them from unlicensed drug sellers.

- In some countries, only physicians can prescribe and administer ARVs even though trained nurses can prescribe many other essential drugs which also require careful administration (antimalarials, antibiotics). In earlier years, when less was known about ARVs and their appropriate administration, limiting their administration to physicians made sense. Today, however, protocols and specific instructions have been developed to train nurses to safely and competently prescribe and administer ARVs. Also, the volume of patients receiving ART has grown so large that there are too few doctors to manage all enrolled ART patients. Experiments suggest that properly trained nurses obtain results comparable to doctors when managing uncomplicated first-line ART.

Regulations must adapt over time to recognize that evidence-based models and tools for supportive care can enable more plentiful staff, such as nurses, to be trained in the evolving treatment regimes. As

therapies grow in demand, this "task shifting" enables qualified health professionals to meet the needs of this growing patient base, even in areas where physicians are scarce. Regulations need to be flexible to accommodate therapeutic and treatment innovations that prove safe for task-shifting. Several legal strategies enable regulations to be responsive to evolving treatment and diagnostic technologies and protocols. Scopes of practice should be subject to amendment by regulatory action of the licensing body, rather than by change in the statute. The MOH, or a Health Professions Council, should have the authority to encourage and approve such changes to increase public access to new models of care.

Laws should also have special provisions for rural or underserved areas, where different (and potentially less onerous) requirements apply. In the United States, for example, some hospital rules are waived for small and isolated rural hospitals. In the pharmaceutical example, drug sellers can receive extra training and supportive technologies to enable them to dispense the full essential drug list if population density is below a certain level, or if the nearest fully licensed pharmacy is more than a certain distance away.

In areas with shortages of physicians, specialists or pharmacists, facilities are unable to meet licensure requirements mandating full time staffing of these positions. When these market constraints exist, an alternative policy allowing clinics to form networks, sharing experts and offering good supportive supervision, could allow clinics to meet licensing requirements. Such an allowance would still enable licensed facilities to operate in remote areas, but under more limited scopes. To safeguard quality assurance, a pharmacy technician, for example, may receive additional training, job aids, and protocols developed by a pharmacist. This pharmacist will provide periodic supportive supervision (perhaps with a defined frequency) to carry out some "pharmacist tasks." Enhancements to information communication technology now make this type of supportive supervision increasingly feasible, further underscoring the need for flexible regulations that respond to changing health care trends in the developing world.

To execute the strategy in this example, a facility's license to sell essential drugs could be conditioned on the facility's membership in the formal network. Alternatively, nurses operating in these underserved areas could receive training and supportive supervision to dispense essential drugs. Many countries ban prescribing professionals from dispensing drugs to limit the financial incentive to overprescribe. But in underserved or remote areas, the greater danger may be patients' inability to obtain these essential drugs.

- Explicitly recognize and anticipate treatment-specific task shifting. Nurses with defined additional training in ART could be allowed to prescribe first-line ART when the proper supervisory arrangements for physician review and referral are in place. As government clinics permit nurses or clinical officers to assume these responsibilities from physicians, NGO and for-profit clinics obtaining similar training should be allowed to operate at a similar level.

- Consider waivers or flexible arrangements for facilities in rural areas. Allow franchising or partnering to be one mechanism by which a rural or low-resource facility can meet licensing requirements. At the same time, ensure that facility licensing laws and regulations on staffing mirror the professional scopes of practice.

6.3 OVERLY RESTRICTIVE REGULATIONS IN PRIVATE HEALTH FACILITIES

When it comes to physical facilities, there can be too much, or too little, regulation. Highly detailed, prescriptive regulations raise the cost of medical care without providing benefits to patients. But regulations that are silent on truly critical elements do create risks.

Requirements for physical facilities and equipment should be scaled to the type of practice performed in the facility. Consider first the typical consulting room used by a nurse, doctor, or clinical officer in a practice that performs basic diagnosis and prescribes simple treatments. No invasive procedures are done. This practice can be carried out in any office. If lab samples are drawn or vaccinations provided, then a sterilizer or refrigerator may be necessary. Running water for hand washing is desirable. Beyond this, there is little need for minimum facility requirements, and in fact many government primary care facilities would not meet even simple physical facility minimums. In many developed countries, a physician's office is NOT licensed as a health facility unless it performs invasive procedures or has extensive diagnostic equipment.

If a physician is to perform invasive procedures such as examinations or insertions of intrauterine devices (IUDs), additional equipment, sanitation and sterilization requirement may be required, but not more than would be included in the design of typical public facilities performing the same procedures.

A higher level of facility regulation may be required when private health facilities conduct minor operative procedures, have their own laboratories,[5] or use complex diagnostic equipment with potentially dangerous side effects, such as X-rays. This is particularly true if the facility carries out procedure requiring general anesthesia. The facility licensing body may consider a special class of license for such advanced diagnostic clinics or "day surgery" facilities. Some of these requirements will be similar to those in hospitals, but should not duplicate all of the requirements imposed on a facility that houses inpatients.

Without creating multiple license classes, the regulatory agency can draft facility rules that tie required standards to the level of service offered. Thus, the simple consulting room might not require a facility license at all. Requirements for basic sanitation could be subsumed within the physician's basic obligation as a professional, and enforced through the professional license. A second level of facility requirements would apply where minor invasive procedures or diagnostic techniques are performed, a third set for a full-scale outpatient surgery or diagnostic facility.

Such regulations should also recognize that basic outpatient facilities do not require on-site laboratories, but should permit practitioners to take samples for analysis by a qualified lab, rather than requiring the patient to travel across town to have the necessary samples taken. Details regarding facility regulations should be left to agency-developed regulations or guidelines written within a broad statutory framework. For example, rather than creating an unwieldy set of facility license categories, the new Health Professions Act in Zambia permits accreditation of a licensed facility for a special service (presumably of high public concern), without creating unnecessary requirements on the whole class of licensed facilities.

---

[5] However, the use of approved rapid self-analyzing tests should NOT trigger such laboratory licensing requirements.

Flexible approaches to facility licensing include having the regulatory body:

- Update and adjust facility requirements more often than the basic licensing law, to stay abreast of new and innovative technologies, clinical practices and patient demand for services. Each facility should be licensed no less than every 5 years.

- Constantly review whether the particular requirement really protects the patient from certain risks. The regulatory agency should also weigh whether there are less expensive, or equally expensive and more effective, ways to protect patients from the same risk.

- Indicate in the basic statute that ALL facilities are subject to regulations based on classification of facility, irrespective of public versus private ownership.

- Consider waivers or flexible arrangements for facilities in rural areas. Allow franchising or partnering as one mechanism by which a rural or low-resource facility can meet licensing requirements.

- Adjust facility and staffing requirements to service level.

- Have inspections of different types (sanitation and medical) performed by one body to save resources.

6.4 EXCESSIVE REGULATORY ROADBLOCKS THAT DO NOT BENEFIT PATIENTS

A classic example of excessive requirements occurs in the regulation of pharmaceuticals, where a country that offers a relatively small market may require extensive submission of data, perhaps even new clinical trials, before releasing a product in a new jurisdiction. This is particularly wasteful when the product has already been licensed for several years in other jurisdictions. In the light of the small market size, the costs of the filing, or developing the data, may discourage a company from registering the drug. The cost of these filings will increase the drug's price, if it is approved, yet patients will be no safer than in other countries that have already incurred the expense of reviewing and approving the drug.

The simplest answer to such excessive filing requirements would be to accept licensing by another country (US, Japan, EU) as the basis for issuing a new product registration. The drug regulation agency could require the submission of summarized data from post-market surveillance of drug integrity in the countries where the drug is already licensed. The drug would be approved only for the uses approved in the reference country. The same warnings or package inserts would be required, but in a local language. As an alternative, one country with a relatively sophisticated drug agency would conduct the review of new submissions, but the approval would be accepted in nearby countries that have agreed to such cooperation. For example, South Africa might issue drug registrations that would be valid for import and marketing in all countries of the region. The law in Ethiopia specifically provides that the approving drug agency assure the quality of drugs as per its own pharmacopoeia or the pharmacopoeia of other countries that are recognized by it."

Even if a country is unwilling to accept the marketing approval of a new drug in another country, regulations could allow the submission to include the same data as that submitted in one or more countries where the drug is already licensed. This saves the manufacturer the cost of generating new data, which is likely of little patient benefit unless there are scientific reasons to expect a different biological response in the population. It also saves the regulatory agency the cost of reviewing the data, which it may not be staffed to do. Given the ease of electronic communications, questions that arise

during the licensing review can be addressed to a drug approval agency in a large market that has already approved a similar application.

6.5 NO EFFECTIVE AVENUE TO ADDRESS PATIENT COMPLAINTS ABOUT POOR QUALITY

Professionals must participate in the definition of unprofessional or dangerous conduct within their specialty. Nevertheless, many regulatory systems are dominated by the professionals being regulated. The result may be "regulatory capture," where there is little responsiveness to consumer complaints. Where the MOH controls the licensing process, it may be protective of its own employees and institutions, or place a low priority on investigating complaints or levying sanctions.
One protection against regulatory capture is to include individuals other than members of the regulated profession on the board that makes professional licensure decisions. Such individuals need a basic knowledge of health, but can come from a variety of backgrounds. Some may be well-educated members of other professions, but they can ask the difficult questions that the health professionals may avoid. The recently enacted Health Professions Act in Zambia specifically provides for two such members on the Health Professions Council.

It is also important that these non-professionals serve on disciplinary committees that hear complaints of unprofessional or negligent conduct. While professionals would hold the majority of the votes on such a committee, the non-professionals can give their views and address sensitive or difficult issues. They are also more likely to give credence to a patient's testimony when the facts of the case are in dispute. The new Zambia law requires that the Council's Disciplinary Committee include a lay member.

Another way to prevent regulatory capture is to have a neutral hearings officer conduct evidentiary hearings on alleged license violations. The officer narrowly frames questions about professional conduct or good medical practice for review by a committee of regulated professionals. The hearings officer is the fact-finder, but the professional committee makes a technical determination about the particular clinical activity in question.

A regulatory system should provide a clear avenue for submission, investigation, and resolution of complaints including:

- Well-publicized contacts for submission of complaints in person or in writing. Schemes for registering complaints can include use of electronic devices (see Box Eight).
- A sufficient number of investigators or inspectors (with adequate geographic distribution and transport) to review complaints and look into those with face validity.
- Authority for these inspectors to review the complainant's medical records, and preferably those of others treated at the same site or by the same professional.
- A formal determination that the facts do not justify pursuit of a case under the licensing law, OR a formal report that initiates the apparatus for professional discipline or facility sanctions.
- A formal response to the complainant on the outcome of the investigation.

Box Eight: Empowering Consumers Through Technology

The rising penetration of mobile handsets in sub-Saharan Africa offers exciting opportunities for consumer protection. One innovative study supported by www.mpedigree.org in Ghana pilot-tested the feasibility of SMS messaging, enabling consumers to verify their prescription with a national drug registry database prior to purchase of the drug. The real-time confirmation of the prescription drug's integrity has the potential to protect consumer health and combat the growing counterfeit drug industry. Innovations along these lines may strengthen the accountability of the health system by giving consumers an avenue to serve as watchdogs over their own health system.

6.6 POOR ENFORCEMENT MECHANISMS AND PRACTICES

In most of the developing world, the laws are better than the enforcement process. There are a number of reasons for this; the most important are summarized in Box Nine. Any regulatory assessment must look at how the laws are actually enforced. In addition to looking at data from the responsible agencies, the assessment must extend to interviews with licensed providers (professionals and facilities) and their associations. Is there a perception that unlicensed or substandard facilities or individuals continue to operate with impunity? Why is this perceived to be so?

Box Nine: Top Five Reasons Why Regulations Are Not Effectively Enforced

1. **Inadequate budgets.** It is unrealistic to expect license fees paid by regulated professionals or facilities to cover all these costs. Lack of budgets result in few or poorly trained inspectors, lack of vehicles or travel funds, and limited money for lawyers or hearing officers to conduct disciplinary hearings.
2. **Regulatory enforcement is a low priority for the MOH.** The MOH is focused on running its own facilities, not enforcing standards equally across the public and private sector.
3. **Corruption.** The incentives to corrupt inspectors are great, the controls on corruption weak.
4. **Complaints are ignored or inadequately investigated.** Patient complaints may warn of dangerous or negligent practices, but the agency responsible for investigating these claims ignores the complaint.
5. **Cumbersome processes.** There are so many complicated steps to revoke the license of a health facility or professional that disciplinary actions are never completed

Some steps can be taken during statutory reform to improve the enforcement system. This includes streamlining the sanctions process and ensuring transparency by publishing regulatory standards and distribution the standards to licensees. However, most of the actions needed to strengthen enforcement depend on political will, adequate funding, and management skill.

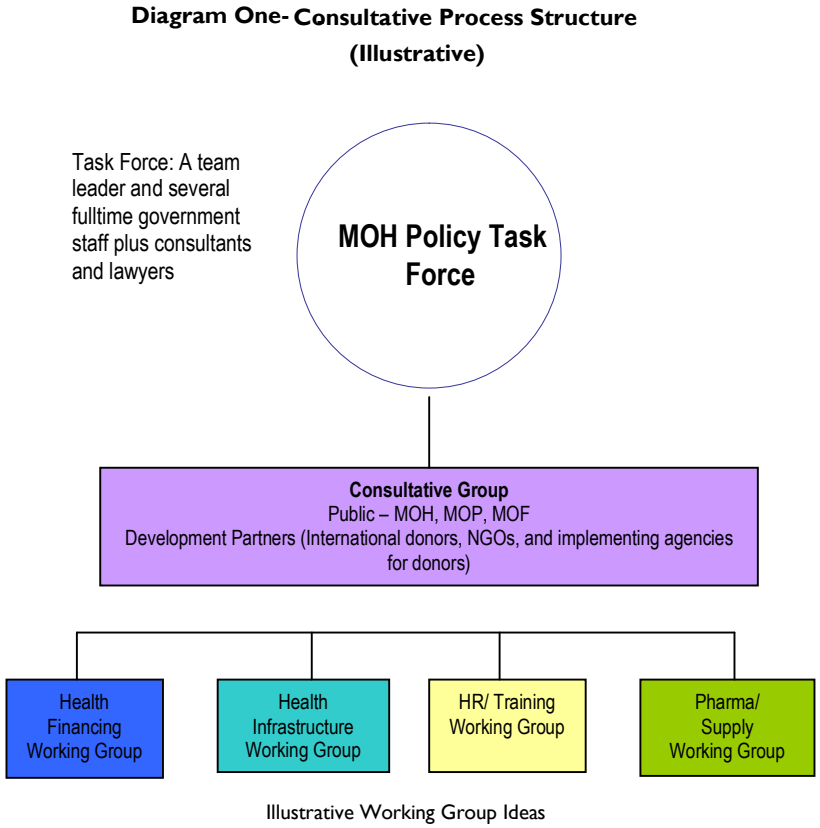
7. SECURING LOCAL OWNERSHIP IN POLICY REFORM

This report focuses on tools to identify potential legal and regulatory issues that affect private sector capacity to deliver basic health services. However, regulatory reform requires the participation or "ownership" of all stakeholders. Building broad support is labor-intensive and challenging, and requires a long-term commitment. This section provides suggestions on how to conduct a participatory process that helps foster political support and stakeholder buy-in. The steps outlined below are designed to guide the team tasked with managing a reform process. The steps include: 1) laying the foundation to build local ownership; 2) preparing to analyze the present legal context; 3) integrating stakeholder perspectives to solidify local ownership; and 4) securing approval and resources for the reform.

Laying the Foundation: Structure to Build Local Ownership

1. Establish health care regulatory reform as a priority for the government and the MOH. This should be done through advocacy at the highest levels to ensure that the reform process has sufficient political backing and support to succeed. Without high-level political support, the reform process is unlikely to sustain the momentum needed for full passage, and resources will be wasted.

FIGURE 2: CONSULTATIVE PROCESS STRUCTURE (ILLUSTRATIVE)



2. *Create a task force (secretariat or coordinating committee) to guide the reform process.* The task force is usually a temporary structure created for the sole purpose of reviewing and drafting the new policies, laws, or regulations depending on the scope of the reform process. Given the MOH leadership role, the task force is staffed with appointed Ministry personnel, often requiring additional expertise such a lawyer(s) and policy analysts. Ministry staff should be fully seconded to work full-time on these issues, and a task leader should be assigned to sustain the process. The Task Force's roles and responsibilities include: 1) organizing and leading the reform process, 2) drafting, revising, and finalizing the laws and regulations, and 3) submitting the draft reform to the appropriate authority for approval. The task force can also be instrumental in latter stages to help disseminate and secure internal buy-in among Ministry staff for implementation of the approved regulatory changes.

3. *Name a consultative group of public and private representatives.* Creating a forum in which multiple stakeholder groups can express their perspective is critical. Including diverse stakeholders from the beginning demonstrates government commitment to a transparent and inclusive process. This representative group can greatly assist the task force by: 1) organizing consultative meetings to discuss proposals and drafts; 2) mobilizing technical expertise to inform policy analysis and design, and 3) contributing in-kind and financial resources to cover expenses associated with participation and consultation. The consultative group should be small but strategic (e.g., key leaders with authority to represent their constituents, and who have political influence and resources).

Getting Ready: Preparing to Analyze the Current Legal Context

1. *Secure resources and staff needed.* The MOH team will need additional resources to carry out the analysis and sustain the participatory process. An outside consultant(s) (perhaps donor funded) can provide examples of statutory language and approaches to desired reforms from other countries. Additionally, the team may need a local lawyer assigned to the Consultative Group to prepare iterative drafts of the proposed reform legislation.

2. *Gather and review data on the current legal environment.* As this report demonstrates, multiple sources of data are necessary to conduct the assessment. The first step is to gather all existing statutes governing healthcare providers, and all regulations issued under these statutes. Secondly, develop a flow chart showing the process of regulatory enforcement for each professional or facility category. Third, obtain data on current procedures for licensing: license applications and renewals, denials, revocations, and sanctions. Finally, map out the policy approval processes, timetables, and key dates.

Sustaining Local Ownership: Mechanisms to Integrate Different Perspectives and Priorities

1. *Informant interviews to identify issues and priorities.* Identify key stakeholders who have a vested interest in the proposed policy reforms. Interview a sample of these stakeholders, including the MOH, Ministry of Finance (MOF), Ministry of Planning (MOP), human resource offices, private and public providers, provider associations, pharmaceutical suppliers, and others. Ask the informants about the regulatory process and how it affects or constrains them. Look for key themes among stakeholder groups to prioritize problems to be redressed.

2. *Working groups to identify agenda for reform.* The interviews will help identify major concerns and create a preliminary list of issues for reform. Based on emerging priorities, establish several Working Groups. The Working Groups review existing laws and regulations to identify gaps, inconsistencies, overlaps, and unnecessary controls. The groups then develop a priorities list - an agenda - of required reforms.

3. *Working Groups to negotiate compromises.* The Ministry Task Force, assisted by lawyers and outside consultants, develops several drafts. The Working Group reviews the drafts and proposes changes in language. The government, through the Task Force, attempts to resolve differences over draft reform legislation.

4. *Coalition to support change.* With the proposed law in hand, politicians, leaders and influential groups needed to secure cabinet or legislative approval should be brought into the process. Building on the base of technical experts, implementing partners who are affected by the proposed policy reforms can expand the base of support through a coalition by reaching out to the target audiences through a variety of channels: policy briefs, meetings, forums, and other means.

Moving Towards Change: Securing Approval and Resources

1. *Finalize the policy for submission.* Once the drafts have been negotiated and the language finalized, government lawyers review proposed language for conflicts with other laws or policies. The government then prepares the final reform bill and submits it for action by the cabinet or parliament.

2. *Build support for government approval.* Inclusion of different stakeholders, broad participation by implementing partners, and advocacy with political leader will facilitate cabinet or legislative support. Although the foundation has been put in place, the Task Force needs to broker the bill through the legislative process. The coalition of "friendly supporters" can help the MOH to actively participate and monitor the process.

3. *Mobilize resources to implement the reforms.* Once the reform is drafted, the second "push" for local ownership of implementation and enforcement begins. First, the government identifies the funding and administrative changes necessary to implement reforms. Changes are incorporated in government budgets and approved by the MOF. Second, reform legislation is enacted. The government names a senior official responsible for implementation of reforms, and new appointments are made (i.e. of councils and administrators) consistent with reform legislation. Responsible licensing bodies seek external input from stakeholders and begin revising regulations. Changes in inspection and enforcement process are then implemented.

4. *Build support among implementing partners.* While the MOH is putting into place the resources and institutional structures needed to implement the reforms, the Ministry also has the responsibility of informing health care providers of the changes. The Task Force, Working Groups and Coalition can be used to help disseminate the new laws within their own constituencies and networks, and also to sponsor forums among different stakeholder groups to review and discuss the reform's implications. Moreover, the government can offer training on the new policy changes to public and private providers.

8. CONCLUSIONS

To improve public health, African governments must marshal all the resources available in the health sector - public and private alike. An increasing body of evidence from the region shows that the private sector can complement public sector resources to expand access to critical services such as FP and RH, MCH, and HIV/AIDS. The government, however, has a unique role as the public steward of health. In this capacity, it is responsible for creating a supportive policy environment that enables public-private collaboration. Policies, laws, and regulations are important instruments that a government can use to facilitate a bigger private sector role in delivering basic health services, including FP.

Using laws and regulations from three Africa countries, this report provides African policymakers and other key stakeholder a road map on what laws to review and interpret. The legal and regulatory checklist (Table 1) highlights what to look for in the regulations and strategies to create an enabling environment for improved private sector participation. Although this paper focuses on policy reforms that will enable greater private sector participation in the overall health system, these changes will also benefit critical health services such as FP/RH, maternal health and HIV/AIDS.

Main lessons that African policymakers, in-country stakeholders and international donors should consider when planning or executing a legal and regulatory reform include:

Policy reform is a balancing act. For policies to be effective, a government must ***balance*** market realities of the private sector with the concerns of the public sector to expand access to quality services to underserved groups. Active stewardship involves soliciting stakeholder input - from public and private health providers as well as consumers - to reach a middle ground between too much and too little regulation.

Time and timing are critical factors in legal reform. Policymakers and donors considering legislative reform must expect to make a long-term commitment to ensure meaningful change. Both time and timing play a role: 1) Reform itself is a long-term process. The parliamentary passage of any new legal reform may take several months, but setting the stage for effective implementation may take years. 2) Rules that have been adopted recently will be harder to change. Older legal codes will likely have a backlog of changes desired by regulated parities, creating an opportunity for general reform which includes multiple changes. 3) Parliamentary and cabinet procedures have timetable with important deadlines. Knowledge of the legislative cycle and key deadlines will inform ones reform strategy.

The majority of regulations affecting private sector participation are grounded in seven areas. Although the legal framework governing health systems is highly complex, there are seven regulatory themes that influence the ability of the private health sector to deliver quality health services. These include the laws and regulations governing 1) health professional licensing; 2) facility licensing requirements; 3) licensing of pharmacists and related professionals; 4) drug facility licensing; 5) the quality of the drug supply; 6) consumer protection, and 7) enforcement mechanisms and capacity. Focusing on these seven areas can maximize existing private sector resources.

Enforcement has been neglected in policy reform. In many developing countries, the laws are better than the enforcement system. Policymakers, health practitioners, and international donors must

bear in mind that regulatory change is just one side of the equation, and that enforcement merits more attention. The processes for regulatory assessment and policy reforms proposed in this report present ideal opportunities to strengthen enforcement policies and practices. However, reforming enforcement systems will require political commitment to ensure that the reforms actually occur, adequate resources to properly staff and fund the regulatory agency's activities, and skilled management and trained staff to fulfill the scope of enforcement policies and implement the changes in policies and procedures.

Local ownership is critical for the long-term success of legal reform. Changing laws or regulations is a long-term commitment, requiring years of investment to yield results. A participatory and inclusive process can help foster political support and stakeholder buy-in. This local ownership is needed to manage political roadblocks and opposition created during any major shifts in legal and regulatory reform, ensure that policy reforms reflect the concerns and perspectives of all actors in the health sector, and increase likelihood for implementation after the policy changes are approved.

Now is the moment to introduce the consumer voice into African legal and regulatory frameworks. Policymakers and professional associations increasingly recognize the importance of integrating patient rights and consumer protection within law and policy. Since significant regulatory changes may occur only once in a generation, it is opportune to include consumer concerns within current initiatives in Kenya, Zambia, and other countries where vital policy and legislative updates are underway.

ANNEX A: EXAMINATION OF NIGERIAN REGULATIONS

NIGERIA	
Topic: Medical professionals (general and specialists)	
What to look for	What is the impact (+/-)
Licensing: • Full Registration: Any person who practices medicine or dentistry in Nigeria without being appropriately registered with the Council contravenes the law (Article 9) • Specialists must register with the council in order to practice their specialty. (Article 15) **Licensing of Nurses and Midwives: The Nursing and Midwifery Decree 1979**): • In accordance with the Nurses Ordinance of 1959 and The Nurses Decree of 1970, persons registered at training hospitals are student nurses. Upon the successful completion of 18 months training student nurses must pass the Nursing and Midwifery Council of Nigeria's examination to register as a professional nurse. Similarly, student midwives have to complete required training and pass the examination to be registered as midwives. • District committees supervise conduct, practice, professional needs and professional training of registered nurses and midwives in their districts. **Limited or temporary registration** is issued to foreigners. • Unlike the full registration, it must be periodically renewed. Any change of employment invalidates the existing registration and requires a new one. • Practitioners on temporary registration: i) cannot set up or run a clinic or hospital on their own; ii) cannot own a private institution iii) can only work in institutions owned by the government, NGOs or a fully registered practitioner. (Article 9) **Continuing Medical Education:** • CME was issued by the Medical and Dental Council of Nigeria in accordance with the provisions of Section 1, subsection 2 c, of the Medical and Dental Practitioners Act [CAP 221] (1990) Source: Code of Medical Ethics in Nigeria **Relicensing:** • Evidence of participating in continuing professional activities is a necessary condition for renewal of practicing licenses. (Article 29) • Any medical practitioner or dental surgeon failing to pay annual licensing fee shall be guilty of an offence. (Article 9) **Scope of Work:** • Other members of health team acting/operating as physicians in the context of health institutions: other members of the health team may perform procedures exclusive to physicians and dentists provided that these procedures are performed at the request or under the supervision of the medical practitioner or dental surgeon. The practitioner is responsible for results obtained under his supervision. (Article 12, Also Article 39.3b)	**Licensing:** (+) appears to be consistent rules for public and private providers **Licensing of Nurses and Midwives: The Nursing and Midwifery Decree 1979**): (+) supports decentralized quality control for nurses **Relicensing:** (+) Explicit periodic renewal regulations for temporary licensing **Scope of Work:** (-) not clear who has responsibility for defining scope of practice (+) permits controlled task-shifting to "health team" by recognizing the need for subsidiary professionals

Topic: Medical professionals (general and specialists) (continued)	
What to look for	What is the impact +/-
Private Practice: **Moonlighting (Articles 49-52)** • Registered full time public practitioners shall not work at private clinics during official duty time • Practitioners with 10 + yrs post-registration experience, who hold consultant status, can run one private clinic which will open for business only during periods when is not on official duty • In-hospital care to private patients can be only provided at public hospitals • Non-consultant public practitioners can engage in private practice outside official hours at institutions owned and run by private practitioners • Non-consultant or practitioners with less than 10 yrs post-registered experience cannot own or run private institutions. • A registered nurse or midwife cannot set up private maternity home unless: 1) he has minimum 5 years post-registration experience as a staff nurse/midwife at a recognized health institution; 2) the maternity home is under the supervision of a gynecologist or obstetrician. **Others:** • Practitioners who engage in fraudulent deals (e.g., issuing fake bills, fee sharing, false certification etc.) shall be deleted from the medical and dental register upon conviction at a court of law. • A practitioner shall not have a commission arrangement with a chemist, optician, laboratory, insurance agent, etc. (Article 37). **Self-Advertisement (Article 54)** • Doctors must refrain from self-advertisement. A practitioner will be deemed to have breached the Code of Ethics if he is proved to have advertised himself for the purpose of obtaining patients, commending or directing attention to his professional skills, knowledge or qualifications.	**Private Practice:** (+) permits and regulates moonlighting: detailed, clear, language prevents abuse (+/-) protects the consumer, but 10 + yrs requirement before allowing private practice is excessive. (-) medical professionals should be able to advertise, with regulatory protection for fraudulent claims (+) prohibition on commission arrangements
Malpractice: • A practitioner who keeps a patient in the hospital as an in-patient when it is not necessary or longer than is necessary, or who undertakes any form of ill-defined/unnecessary procedures for the sole purpose of increasing his earnings from the patient breaches the Code of Ethics and shall be guilty of malpractice. (Article 35) • No practitioner shall permit his services or name to be used in aiding of unauthorized practice of medicine or dentistry. (Article 36) • Nurses and Midwives (The Nursing and Midwifery Decree 1979): Tribunal of the council can make a recommendation for the removal of a nurse from the register in case where a nurse is convicted of an offence involving malpractice, negligence or other misconduct.	**Malpractice:** (-) requirement of a gynecologist or an obstetrician for setting up a maternity home may not be feasible
Topic: Enforcement of Professional Regulations	
• Medical supervisors at public institutions have responsibility to ensure strict compliance with Public Service Regulations. If they fail to report violations, they will be personally liable to disciplinary process. (Article 50) • After due process of investigation and trial of a practitioner, where such trial results in conviction of the practitioner, the Registrar of the Medical and Dental Council of Nigeria (MDCN) shall take the following steps: • In every such case where the guilt of the practitioner is pronounced by the MDPDT, the sentence shall be published in the Gazette of the Federal Republic of Nigeria and as a paid advertisement in each of the four national newspapers. • The name of practitioner will be suspended from the Register for a period of time. • The Registrar will direct the practitioner to complete on a monthly basis, an approved pro forma to the effect that he maintains compliance with the sentence until the period of suspension expires. (Article 69)	(+) clear responsibility on monitoring

Topic: Facility Licensing: Private medical facilities (clinics, nursing/maternity homes, hospitals)	
What to look for	What is the impact +/-
Staffing: • Practitioners who are connected/involved with public, private hospitals, clinics, screening centers, nursing homes, rehabilitation centers, and advisory agencies in any capacity in which their status as a medical practitioner or dental surgeon would be construed to lend support have responsibility to ensure that provisions of the Code of Medical Ethics are complied with. (Article 14.1)	(-) unclear process, time period for facilities to maintain their licensing prior to renewal. **Staffing:** (+) consistency between private and public facilities (+) good language on duty of care (-) need clarity regarding staffing requirements of basic level clinics
Levels of Care: • Primary Health Institutions: (Article 14.2) *Clinics:* o Only consultation and out-patient services provided • *Health Centers:* o Outpatient consultation and a definite program of care involving components of primary care (e.g. health education, family planning, nutrition education, immunization, etc.) o Doctors may include family physicians, primary care doctors, obstetricians, but they all work together irrespective of their areas of specialization, taking emergency duties in turn. (no departmental boundaries) • Tertiary Health Institutions (Article 14.4) o *Teaching Hospitals:* ▪ Accredited for teaching and training of doctors (under/post graduate) ▪ Organized along departmental lines (e.g., anesthesiology, general medicine, psychiatry, primary care, pathology, pediatrics, etc.) ▪ Each dept has any number of consultant units, each with its own out-patient sessions. ▪ Patients are normally referred to such hospitals from a lower order institution o *Specialty Hospitals:* ▪ Dedicated to single condition (e.g., orthopedic, psychiatric, etc.) ▪ Following components are required: emergency unit, diagnostic unit, outpatient consultation unit, wards unit, treatment unit	**Levels of Care:** (+) appropriate level of specificity for levels of care
Equipment/Physical Facility: Primary Health Institutions: (Article 14.2) • *Clinics:* o Specialist Clinics should be clearly indicated as such (e.g. Ophthalmology Clinic); if there is more than one specialty, then must be set up as Polyclinic *Health Centers:* o Few bed spaces may be available on site o Comprehensive Health Centers o Incorporates the facilities of the health center and facilities for simple medical and surgical services o Complemented by up to 30 beds	**Equipment/Physical Facility**

Topic: Facility Licensing: Private medical facilities (continued)	
What to look for	What is the impact +/-
• Secondary Health Institutions (General Hospitals) (Article 14.3) Essential components: o Emergency Unit o At least four basic departments (general medicine, general surgery, obstetrics & gynecology, pediatrics o Those accredited with Internship must have at least **4** consultants (registered practitioners) o Pharmacy unit o X ray, laboratory diagnostic services o Catering, laundry o Outpatient consultation unit • Wards (surgical, medical, pediatric, obstetrics/gynecology, postnatal)	
Ownership Restrictions: • Practitioners are advised to consider seriously the dangers inherent in the establishment of clinics and hospitals as strict business enterprises or limited liability companies, bearing in mind the strict ethical code of conduct in the profession. (Article 14.1) • *Federal Medical Centers* o Owned and funded by the Federal Government o Operate at a higher level than general hospitals o Operate in departments but not associate with medical colleges **Self-advertisement:** Advertisements of such institutions should not promote professional qualities or services of identified practitioners connected with the organization. (Article 14.1) • Such ads should not entice patients with promotional materials or interfere in any way with their rights of referral. (Article 14.1)	**Ownership Restrictions**
Public Health Reporting: • Nothing Listed **Certificate of Need:** • Authors could find nothing listed regarding certificate of need.	**Public Health Reporting:** (+) nothing noted regarding disease surveillance and public health recording. **Certificate of Need:** (-) lacks certificate of need for equipment/services (particularly for high-cost and high-tech)

Topic: Pharmacists and other related professionals	
What to look for	What is the impact +/-
Pharmacist Licensing: Registration as a Pharmacist (Pharmacists Council of Nigeria Procedures for Registration Article 2): • Pharmacist Council of Nigeria Act of 1992 (No 91) authorizes the Council to set standards of education, registration to practice and lay down the code of conduct desirable for the profession. • Graduates of institutions approved by PCN, after taking an oath are qualified for provisional registration *Foreign Pharmacists:* • Graduates of foreign pharmacy schools must successfully complete a 4-week orientation program and a 12-month internship program to be eligible for registration • A foreign national may register if there is a reciprocity agreement between his country and Nigeria, provided that he has been a resident for no less than 12 months and passed the exams required by the council	**Pharmacist Licensing**
Continuing Pharmacist Education (CME): From Code of Ethics for Pharmacists in Nigeria: a) A pharmacist should hold the health and safety of patients to be of first consideration and should provide to each relevant information on drugs and medicinal products; b) Any drug or medicine likely to be abused and which may be detrimental to health should not be supplied to a patient when there is no reason to believe that the drug or medicine is required for such purposes; c) A pharmacist should never condone or assist therein, the manufacture, importation, promotion, distribution, storage, sale or dispensing of drug, poisons and medicinal products which are not of good quality or which do not meet standards required by law. d) A pharmacist should respect the confidential and personal nature of his professional records. Except where the best interest of the patient requires, or the law demands, he should not disclose such information to anyone without proper patient authorization.	**CME:** (+) There is the ethical responsibility for the pharmacist to expand his knowledge. This could be used as a basis for a CPE requirement. (-) Couching the continuing pharmacist education requirement in the code of ethics is vague. It would be better if the pharmacist's board had authority to specifically require CPE and determine the requirements.
Relicensing: • There is an implicit requirement of annual re-licensing even though it is not clearly indicated in the document (Form H requirement)	**Relicensing:** (+) periodic license renewal for pharmacists

Topic: Pharmacists and other related professionals	
What to look for	What is the impact +/-
Private Practice, Dual Practice and Scopes of Work/Pharmacist Subsidiary Professions: The Patent and Proprietary Medicines Vendors License • Under the law, PCN can grant licenses to non-pharmacists to stock, market, and sell simple medicinal remedies. • Missionaries are permitted to mix, compound, prepare or dispense drugs or poisons (1958 Poisons and Pharmacy Act Article 9) A corporate body/firm can carry on the business of dispensing and selling of drugs/poisons provided that: • Activities are carried out under direct personal control of a superintendent pharmacist • Every sale is effected on behalf of body corporate by the selling dispenser • No drug or poison is mixed, prepared or dispensed on behalf of body corporate except by a chemist 1958 Poisons and Pharmacy Act Article 20)	**Private Practice, Dual Practice and Scopes of Work and Regulations about Pharmacist Subsidiary Professions:** (+) good task-shifting language permitting non-pharmacists to dispense meds with supervision
Patient Rights/Malpractice: A pharmacists should not: • have interest in or be associated with the conduct of Patient Medicine Stores • sell to or purchase drugs, poisons and medicinal products from unauthorized or illegal sources; A pharmacist always: • should strive to perfect and enlarge his professional knowledge. He should utilize and make available this knowledge as may be required in accordance with his best professional judgment. • have the duty to observe the law, to upload the dignity and honor of the profession and to accept its ethical principles. He should not engage in any activity that will bring discredit to the profession, and should expose without fear or favor, illegal or unethical conduct that affects the profession. **Labeling, Instructions in Language, etc.:** From Code of Ethics for Pharmacists in Nigeria • The code applies to all registered pharmacists holding licenses, certificates or permits under the Pharmacists Council of Nigeria Decree No. 91 of 1992, the Poison and Pharmacy Act, Cap 535 of 1990 or any other relevant legislation regulating the handling of drugs and poisons. • A pharmacist should not display any material either on the premises, in the press, or elsewhere, in connection with sale to the public of medicines or medical appliances which is undignified in style or which contain: i) Any wording, design or illustration reflecting unfavorably on pharmacists collectively or upon any group of pharmacists; ii) a disparaging reference direct or by implication to other suppliers, products, remedies or treatments; iii) Misleading or exaggerated statements or claims, or an appeal to fear; iv) The word "Cure" in reference to an ailment or symptoms of ill-health or a guarantee of efficacy of any product; v) A price competition or similar scheme designed to attract customers to a particular pharmacy.	**Patient Rights/Malpractice:** (+) good truth in advertising language
Topic: Enforcement of Pharmacists' regulations	
• Pharmacists Council of Nigeria Disciplinary Tribunal (PCNDT) is the main enforcer of the code of conduct desirable for the profession • Pharmaceutical Inspectorate Division (2005) –(PID) operates under the Council, made of registered pharmacist appointed by the council as pharmaceutical inspectors (PIs) • PID can enter any premises where relevant items manufactured, preserved, packaged or sold; examine any article which is used to manufacture, packaging or sale of drugs, and seize/detain drugs, poisons, devices, or wares if they suspect that such items are unwholesome, impure, fake or banned. (Inspection, Location, and Structure of Pharmaceutical Premises Reg. Article 1-2)	

Topic: Facilities Supplying Pharmaceuticals	
What to look for	What is the impact +/-
Staffing: • All hospitals shall employ and maintain a minimum number of registered pharmacists as prescribed by the Council to handle the pharmaceutical needs of the hospital." (Registration of Pharmaceutical Premises Regulations 2005, Article 7). • Retail/Distributors/Importation Premises: A fully registered pharmacist is eligible to apply for the registration of a retail or distribution or importation pharmacy provided that he has completed his National Youth Service Corps (NYSC) primary assignment and presents an NYSC discharge or exemption certificate. (PCNPR Article 3)	**Facilities:** **Note**: the authors could not locate language for staffing requirements beyond hospital pharmacy staffing requirements.
Approval to Enter Market: Licensing Renewal: • Any pharmaceutical premises that remain unregistered by 31st day of January of every year shall pay an extra 50 percent fine. Premises that remain unregistered by the 31st day of March each year, shall be closed. (Registration of Pharmaceutical Premises Regulations, 2005, Article 9)	**Approval to Enter Market:** (+) periodic license renewal for pharmaceutical premises.
Appropriate Facility: Manufacturing Premises: • In addition to above, the following must be included in application: list of products to be manufactured, list of staff qualifications/duties, factory layout, production flow chart, water analysis report, quality control department etc. (PCNPR Article 3) Location of Premises: • Shall not be located in motor parks, market places, etc. • Premises in a shopping center cannot be more than 3, should be separated from each by distance of no less than 200 meters. (Inspection, Location, and Structure of Pharmaceutical Premises Reg. Article 6) Structure of Premises: • Shall not be less than 30 sq. meters, be made of concrete walls not in the form of a kiosk or bull-doff • Contain dispensing area and an office for the superintendent pharmacist • Metric balances, a refrigerator, good water supply, storage shelves, etc.	**Appropriate Facility:** Location of Premises: (+)To prevent oversaturation of tiny pharmacies, no more than three are allowed per shopping center.
Record Keeping: • Manufacturers, importers, wholesalers, retailers of drugs, poisons, and devices shall keep appropriate records of the receipt and disposal of drugs • Facilities must keep proper records of purchases and sales. (Inspection, Location, and Structure of Pharmaceutical Premises Reg. Article 7-10) **Drugs/ Disclosure:** • Any registered practitioner would be liable to disciplinary proceedings if he employs and leaves in charge of any "open shop" or other place where dangerous drugs within the meaning of the Dangerous Drugs Act may be sold to the public, any assistant not legally qualified to use such poisons. (Code of Medical Ethics Article 39.2b) • Any unauthorized disposal shall be penalized by the council. (b154, Article 5)	**Record Keeping:** (+) sound requirements for record keeping

Topic: Enforcement of Facilities Supplying Pharmaceuticals	
What to look for	What is the impact +/-
Pharmacist Council of Nigeria (PCN): • The regulation and control of the practice of the pharmacy profession is the responsibility of the PCN. • PCN sets the standards for good professional practice and conducts in regard to pharmaceutical manufacturing plants, factory layouts, hygienic conditions, quality assurance, staff training, minimum equipments, storage facilities, documentation, labeling, and research and development (R&D). • Similarly PCN also regulates and sets the standards for hospital pharmacies and community pharmacists.	
Topic: Pharmaceutical Supply (drugs)	
Counterfeit Drug/Promotion (Deceptive): Disclosure of Compositions of Medicine • No person shall take a part publication of any advertisement by a method whatsoever, including a notice, circular, label or wrapper or other document, or by canvassing, referring to the sale, supplying, or offering for sale, or offering to supply a medicine or surgical appliances or referring to administration of, or the offering to administer a treatment to the public whether directly or indirectly or by implication as being effective for the purpose of treatment of human beings for any of the following purposes… (1958 Poisons and Pharmacy Act Article 39) • No person shall sell by retail a patent or proprietary medicine or supply an article as sample to induce persons to buy by retail the substance of which it consists or comprises unless active constituents or the ingredients are clearly stated on the container … (1958 Poisons and Pharmacy Act Article 33)	
Topic: Enforcement of Pharmaceutical Supply	
• Food and Drug Administration (FDA) regulates the import/export, manufacture, advertisement, sale, distribution and use of food, drugs, cosmetics, medical devices, chemicals and bottled water. FDA Decree 1993, Article 5 • FDA can investigate premises, inspect food, drugs, cosmetics etc., and set industry standards Applications for registration of drugs, medical devices etc must be made to the Agency Drugs and Related Products Decree 1993, Article 4 • Agency may suspend or cancel the registration of a product if the grounds on which it was originally registered were later found to be false or incomplete, or if the standards of safety, quality are contravened. Drugs and Related Products Decree 1993, Article 7 • Contravention of the provisions of aforesaid decree is deemed an offence. Where an offence is committed every person who was purporting to the act in capacity (director, manager, partner, trustee, secretary, etc.) is guilty of that offence and liable to punishment as if he had himself committed the offence unless he proves that the act occurred without his knowledge.	

Topic: Consumer protection	
What to look for	What is the impact +/-
Legislation/Regulations: Confidentiality: • Information about the patient that comes to the knowledge of the practitioner is secret information which must in no way be divulged by him to a third party. • Disclosure of information can only be made following an informed consent of the patient in writing. (Article 44) Right to Withdraw Services • If the patient insists upon unjust or immoral course during the treatment, of he deliberately disregards an agreement or obligation as to fees or expenses, the doctor may be warranted in withdrawing on due notice to the patient. (Article 45) Professional Fees • A practitioner is permitted to take reasonable steps, which includes instituting a law suit, to recover his fees from a defaulting patient. • A practitioner who deliberately undercuts colleagues by inducing other's patients by charging ridiculous fees shall be deemed liable to appropriate sanction if charged before the disciplinary tribunal. (Article 47)	**Legislation/Regulations:** (-) silent on patient rights, addresses only doctor rights, (-) no defined process to register complaints, (-) no regulatory agency in place and no patient rights defined

ANNEX B: EXAMINATION OF KENYAN REGULATIONS

KENYA[6]	
Topic: Medical professionals (general and specialists)	
What to look for	What is the impact (+/-)
Physicians and Dentists: • A person is eligible to register as medical or dental practitioner if he has a degree/diploma or other qualification recognized by the Medical Practitioners and Dentists Board and completed at least one year internship at a medical institution approved by the Board (The Medical Practitioners and Dentists Act, MPDA Article 11) • If it considers that it is in the public interest, the Board can confer upon any person who is not otherwise eligible to register as a practitioner, a license to render medical and dental services (MPDA Article 13) • Registered practitioners can render medical and dental services only as salaried employees in government and local health schemes or at an institution approved by the Board. **Foreign physicians and dentists:** • No person shall be registered as a medical/dental practitioner unless he has successfully completed a prescribed period of internship. Graduates of foreign institutions are required to pass an internship qualifying examination. (The Medical Practitioners and Dentists Registration, Licensing, Assessment and Internship Rules, Article 15 & 28) **Licensure for Clinical Officers:** • Licenses expire on Dec 31 every year and are renewable in accordance with provisions of the Act (Clinical Officers Training, Registration and Licensing Act Article 11) **Nurses & Midwives:** • Every person who has undergone a prescribed course of instruction and had passed the appropriate examination by the Nursing Council of Kenya is eligible to register as a nurse/midwife upon the payment of the prescribed fee. (The Nurses Act Article 13-15) • A license to practice as a nurse shall be for such a period, not exceeding two years…On expiry, a license can be renewed for such further period not exceeding one year… (The Nurses Act Article 17) **Continuing Medical Education:** Each nurse is required to engage in a minimum of 20 hours of continuing education per year in a relevant professional discipline (Standards of Nursing Education Standard 5 & Standards of Nursing Practice Standard VI)	(-) Board's authority to confer upon any one a license opens the system to possibility of corruption. (+) The internship requirement for graduates of foreign institutions is a positive requirement. (+) Rules for private and public practitioners appear to be similar (+) Detailed professional licensing language, enables enforcement **Continuing Medical Education:** (-) No CME requirements for physicians, dentists or clinical officers (but this was recently addressed by Council)[7] (-) Lack of clear educational attainment for nursing qualifications. (+) there is a well-defined scope of practice.

[6]David I. Muthaka et al. (2004). *A review of the regulatory framework for private health care services in Kenya*, Nairobi: Kenya Institute for Public Policy Research and Analysis

Topic: Medical professionals (continued)	
What to look for	What is the impact (+/-)
Relicensing: **Clinical Officers:** • Licenses expire on Dec 31 every year and are renewable in accordance with provisions of the Act. (Clinical Officers Training, Registration and Licensing Act Article 11) **Nurses and Midwives:** • A license to practice as a nurse shall be for such a period, not exceeding two years…On expiry, a license can be renewed for such further period not exceeding one year… (The Nurses Act Article 17).	**Relicensing:** (-) Licensing language lacks defined license term for physicians and dentists. It does however detail licensing terms for clinical officers and nurses and midwives
Scope of Practice: **Clinical Officers:** ▲ Limitations of the Practice: A clinical officer licensed for private practice can only treat ailments listed in the First Schedule, and prescribed drugs listed in Second Schedule. (Clinical Officers Training, Registration and Licensing Act Article 13) **Nurses and Midwives:** • The Nursing Council of Kenya has adapted the Scope of Nursing Practice in 2007, which specifically describes the expected roles of nurses at various levels of educational qualifications from certificate level nurses to PhD level nurses.	**Scope of Practice:** (+) Well-defined scope of practice. It also appears to be consistent across private and public sectors. (-) Licensing for just one year is a small period of time; three year licensing is commonly used in other countries (-) Private practitioner licenses that are tied to premises may be unduly restrictive (-) There is no statutory definition which specifically allows nurses to delegate personal care tasks to auxiliary health care staff (+) Promotes doctor task-shifting with separate license for sub-physician Clinical Officer (+) Clear and detailed scope of work for nurses
Private practice **Physicians and Dentists:** • Practitioners cannot engage in private practice unless they specifically hold a license enabling them to do so. (MPDA Article 14) • In order to obtain a license from the Board to engage in solo private practice or to be employed full or part time by a private practitioner, a medical practitioner shall have suitable working experience in medicine and dentistry. (MPDA Article 15) • Licenses for private practices are granted for a period of one year and are renewable. (MPDA Article 15) • No person can collect any fees for a medical/dental service he has performed unless he is appropriately licensed under section 15 of the act. • A practitioner is eligible for license to engage private practice if he has continuously worked in Kenya no less than 3 years. If the Board considers in the public interest 3 years requirement can be waived. (Medical Practitioners and Dentists Private Practice Rules Article 3) • Licenses are issued only for a specific premise cannot be applied to other premises without prior approval of the Board. (Medical Practitioners and Dentists Private Practice Rules Art 5). • The board can recognize a practitioner as a specialist if he has a postgraduate degree and has had no less than 5 years of post-registration experience and training. (Medical Practitioners and Dentists Private Practice Rules Article 25)	**Private practice:** (-) Nursing provisions prohibits dual practice (-) requirements for private practice vary greatly by professional level. Physicians require 3 years public practice, clinical officers require 10 years public practices but Nurses are not allowed to engage in dual practice until they retire from public practice. (-) The requirement of 10 + yrs experience to issue private clinical officer license is excessive

[7] January 2009 interviews with the Professional Boards. At the time of this report's print, the CME requirements for physicians were just going into effect.

Topic: Enforcement of Medical professionals licensing	
What to look for	What is the impact (+/-)
Malpractice: **Code of Ethics:** The Council has also issued a detailed code of ethics and conduct for the profession. **Physicians and Dentists** • If a medical/dental practitioner is found to have committed infamous or disgraceful conduct, the Board may remove his name from the register and cancel his license. Once removed from the register a person's name cannot be again entered except by order of the Board. (MPDA Article 20 & 21) **Clinical officers:** • Are also subject to the code of professional conduct and discipline as contained in the Code of Professional Conduct and Discipline issued by the Medical Practitioners and Dentists Board. (Clinical Officers Training, Registration and Licensing Act Article 15). • The Council can cancel registration and license of an officer if he is found guilty of infamous or disgraceful conduct (Clinical Officers Training, Registration and Licensing Act Article 15) **Nurse:** • If a nurse is found guilty of negligence, malpractice, impropriety or misconduct the Council remove his name from the register, suspend his license for period up to 12months. (The Nurses Act Article 25)	**Malpractice:** (+) well-defined code of ethics and conduct for all the professions
Topic: Private medical facilities (clinics, nursing/maternity homes, hospitals)	
What to look for	What is the impact (+/-)
Facility Licensing: • No premises can be used for private practice unless they are authorized by the Board for such use. (MPDA Article 15) • No private practitioner shall operate a private clinic unless the premises where the clinic is situated have been approved by the Board. • A private clinic must conform to the minimum standards set the in act. • It cannot be part of residential building, unless special permission was obtained from the board. **Staffing:** • Nurse: patient Ratio: The management shall ensure to keep the following nurse: patient ratio at clinical areas: • Outpatient department: 1:50 • Inpatient Depts. • General medical wards: 1:6 • General Surgical wards: 1:5 • Labor Ward: 1:1 • I CU: 1:1 • Pediatric Ward: 1:5 (Standards of Nursing Practice Standard V)	**Facility Licensing:** (+) minimum standards are established **Staffing:** (-) even though it is commendable to target a nurse-patient ratio, it may not be feasible considering the current shortage of nurses and other trained medical professionals

Topic: Medical professionals (continued)	
What to look for	What is the impact (+/-)
Equipment: The following equipments must be available at the premises: ✓ Diagnostic instruments, instruments for carrying out certain procedures (e.g., opening abscesses stitching wounds etc.), cabinets for storing patient files, sterilizers, and a facility to examine urine ✓ Premises should also be equipped to store and stock essential drugs. (Medical Practitioners and Dentists Private Practice Rules Article 9) A private clinic may not include: • A radiological laboratory unless there is a licensed practitioner at the premise who is qualified to use ionizing radiation. • A clinical laboratory, unless the examination of specimens are undertaken by the medical practitioner personally or a qualified medical laboratory technician. Such a laboratory may only be used for undertaking the following examinations: hemoglobin, blood slides, urine analysis, stool microscopy, occult blood test, gram stains, special smears (Medical Practitioners and Dentists Private Practice Rules Article 17).	
Physical Facility: • Premises should contain: a consulting room, a waiting room, examination room, treatment room, each room being adequately furnished and maintained. • Private Clinics of Medical Officers: Building must be of permanent standard, or made of wattle and mud as may be approved by the local Medical officer of health. The building must also contain the following facilities: consultation room, waiting area, treatment room, access to road transport, and access to lavatory. (Clinical Officers Training, Registration and Licensing Act Third Schedule)	**Physical Facility:** (-) the laws and regulations covering facilities only apply to the private (not public) facilities (-) the law does not define levels of facilities according to risk of services provided (with tiered standards set accordingly) (-) language regarding the laboratory capacity is overly specific for placement in the regulation, especially as capacities can rapidly change with new technologies (-) there is no certificate of need cited, which prevents facilities from investing limited resources in expensive technologies (-) the MOH is not setting objective staffing standards; instead it is delegating staffing standards to a group of potentially self-interested professional boards can challenge the adequacy of staffing to favor their own health cadre's profession. This represents a lack of oversight by the MoH and exposes staffing standards to conflict of interest by the health professionals.
Ownership Restrictions: • A practitioner cannot be licensed to operate more than 1 clinic at once, unless they are located in a rural area. (Medical Practitioners and Dentists Private Practice Rules Article 11)	**Owner Restriction:** (+) pragmatic rural exemption for ownership restriction
Public Health Reporting (See above)	**Certificate of Need:** (-) lacks certificate of need for equipment/services

Topic: Enforcement of medical facilities regulations	
What to look for	What is the impact (+/-)
• A private clinic must be open to inspection at any reasonable time by an authorized officer of the Board. (Medical Practitioners and Dentists Private Practice Rules Article 9) • A practitioner who uses any words implying that a private clinic is a hospital or nursing home, or advertises a clinic in any manner whatsoever to the general public shall be guilty of an offence. (Medical Practitioners and Dentists Private Practice Rules Article 12) • The minister of health, on the advice of Central Board of Health, may make rules for the conduct and inspection of nursing homes, convalescent homes, private hospitals, private mental hospitals maternity homes, infirmaries, or any other institutions where invalids convalescents or children are treated or received upon payment of fees or charges and no person shall open, or keep open, any such premises unless the premises and the keeper thereof are licensed by the board. The Director of Medical Services may authorize a practitioner to visit and inspect such premises. The Board may cancel any license if premises do not conform to standards or the keeper cannot be deemed trustworthy to conduct premises. (Public Health Act Article153)	(+) good enforcement language (-) this language appears to exempt public facilities from licensing.
Topic: Pharmaceutical supply (pharmacists and other providers)	
What to look for	What is the impact (+/-)
Professionals: **Pharmacist Licensing:** • A Pharmacist shall only be eligible to superintend over registered premises if he/ or she holds a valid practice license. **Pharmacist Subsidiary:** • A pharmaceutical technologist shall only be eligible to superintend over premises registered for a pharmaceutical technologist and only if he or she holds a valid license to practice as a pharmaceutical technologist. **Staffing:** • A pharmaceutical technologist shall only be eligible to superintend over premises registered for a pharmaceutical technologist if he/she has worked under supervision of another qualified superintendent (pharmacist or pharmaceutical technologist) for a period of not less than six years from the time of obtaining the diploma in pharmacy. • One person shall only be eligible to superintend over one registered premise. • A body corporate/ limited liability company may apply to operate more than one premise (as branches). However the requirements stipulated under section 21 of the Pharmacy and Poisons Act must be adhered to including that in each set of premises there shall be a different superintendent pharmacist working under the supervision of the overall responsible company pharmacist.	**Professionals:** **Pharmaceutical Licensing:** (-) no requirement for pharmacist CME (but this was recently addressed by Council) (-) no laws regulating the conditions under which a pharmacist can set up private practice in medicine; **Pharmacist Subsidiary:** (+) good task-shifting, provides for technologists

Topic: Pharmaceutical facilities	
What to look for	What is the impact (+/-)
Facilities: • A reasonable distance shall be maintained between any two registered premises to discourage unfair competitive trade practices. • The Pharmacy and Poisons Board shall be notified in writing at least 30 days prior to any changes affecting the following being implemented: o Change of ownership - includes change in share distribution, change of directors, etc. o Superintendent/ responsible pharmacist/ pharmaceutical technologist o Change in registered premises i.e. change in location, plot number, building, etc. o Nature of business- wholesale/ retail o Change from business of a pharmacist to business of a pharmaceutical technologist and vice versa. (Guidelines for Registration of Premises and issuance of Wholesale Dealer's License Article 3) • Any one premise for a pharmacist shall be registered as either retail or wholesale business but NOT as both. The premises registration automatically expires on 31st day of December in the year it is issued and, if not renewed, the registration shall become void. (Guidelines for Registration of Premises and issuance of Wholesale Dealer's License Article 4). • The minimum requirements for premises and standards of practice are contained in the Pharmacy and Poisons Board guidelines for Good Wholesaling and Retail Practices for Pharmaceuticals which set standards on following areas:	**Physical Facility:** (+) clear rules of renewal and licensing terms (+) establishes reasonable coverage for required standards for pharmacies
Facility Handling of Drugs: (Safeguards Against Counterfeits or Unsafe Drugs) • Sale of unregistered medicines Other: **1.** Stock handling and Stock control **2.** Transport **3.** Building and grounds **4.** Facilities	**Facility Handling of Drugs:** (-) unclear whether Kenya allows proof of registration in developed market to streamline drug registration process (+) drug registration law is comprehensive (+) language on drug handling is quite thorough and covers the bases. (-) unclear whether Kenya allows proof of registration in developed market to streamline drug registration process
Staffing: • Personnel **Record Keeping:** • Documentation and records **Patient Rights** • Complaints	

Topic: Pharmaceutical facility enforcement	
What to look for	What is the impact (+/-)
DRUGS//Registration of a drug requires: • Letter of appointment of a local agent by the manufacturer. The local agent must be a registered whole seller of drugs in Kenya. • Payment of Good Manufacturing Practice (GMP) inspection fee of US$4,000 • $1,000 registration fee for every product application, six copies of a duly completed application dossier and six samples of the product. **Conditions for manufacturer registration:** • Registration • A separate application for each product • Payment of the approved fees • The manufacturer must comply with Good Manufacturing Practices. • The Pharmacy and Poisons Board (PPB) reserves the right to verify the Good Manufacturing Practices Compliance of the manufacturer at the applicant's expense. • Each foreign manufacturer shall have one local agent with blanket power of attorney. • Provision of a free sale certificate from the country of origin or a certificate of a pharmaceutical product. • Certificate issued is valid for a period of five years • In case a manufacturer contracts-out the manufacturing and packaging operations to a third party, it must still have influence over the subject as will enable him to bear full responsibility for the relevant information that is given in the application for registration.	**Drugs:** (-) silent on terms standards and rules of disclosure and promotion.
Imports/Exports: • The Minister for Health in consultation with the Pharmacy and Poisons Board is empowered by section 44(1) of the Pharmacy and Poisons Act, Cap 244 of 2002 to make rules under which medicines may be imported into Kenya, manufactured for sale or sold in Kenya. • To procure a cost-effective or less expensive medicine than the one already registered and available in the Kenyan Market, the Registrar may authorize, through a permit the importation of the same medicine manufactured by, or on behalf of the approved manufacturer from any other country and the restrictions imposed by the patent or registration shall not apply.	(+) the Registrar may authorize Kenya to identify and import cheaper generic versions of pharmaceuticals for public health, since they cannot afford higher prices for patented medicines
Laboratory Testing Capacity (Quality Control): The National Quality Control Laboratory (NQCL): • The NQCL is the quality control arm of the Pharmacy and Poisons Board that supervises all activities aimed at ensuring that consumers and patients receive a product that meets established specifications and standards of quality, safety an efficacy. • The NQCL also carries out drug analysis on request from other parties such as the pharmaceutical industry, medical institutions, NGO's and other governmental institutions. Drug Safety/Adverse Drug Reactions: • The Department of Pharmacovigilance at the Pharmacy and Poisons Board (PPB) is to develop and implement a system for detecting, reporting and monitoring adverse drug reactions (ADRs) and other relevant problems with medicines in Kenya. The department strives to ensure the safety and efficacy of pharmaceutical products in Kenya. The department also carries out routine post market surveillance on all medicines in Kenya. All manufacturers and distributors are expected to submit all findings and reports on adverse events with drugs to PPB.	**Laboratory Testing Capacity (Quality Control):** (+) NQCL to ensure that the quality of drugs available on the Kenyan market, both through responding to adverse reactions, and through post market surveillance through the national laboratory (-) little, however, written in the regulations on enforcement authority

Topic: Consumer protection	
What to look for	What is the impact (+/-)
Complaints against Practitioners: • Whenever the Chairman of the Board receives a complaint of information from a person and it appears to him that a practitioner's conduct may constitute serious professional misconduct, the chairman shall submit the matter to the preliminary inquiry committee. (Medical Practitioners and Dentists Disciplinary Proceedings (Procedure) Rules Article 5) • Malpractice is defined as "careless, illegal or unethical behavior by somebody in a professional or official position that endangers the life of clients, staff, co-workers, self or environment." (Nursing Council's Code of Ethics). • The nursing council may remove the name of a person who has been found guilty of negligence or malpractice (Nurses Act (1985) Article 25).	(-) laws not explicit or proactive in protecting patients against negligent health staff including Doctors (+) there is room for complaint-driven investigations however, as the board is obligated to investigate complaints. (-) the law does not prescribe a complaint mechanism for patients to appeal to, or a mechanism to sanction and de-license the violator.

BIBLIOGRAPHY

Andaleeb, Syed Saad (2000). "Public and private hospitals in Bangladesh: service quality and predictors of hospital choice," Health Policy And Planning15(1): 95–102.

De Costa, Ayesha (2008), "Barriers of mistrust: Public and private health care providers in Madhya Pradesh, India," Ph.D. Thesis, Division of International Health (IHCAR), Department of Public Health Sciences Karolinska Institutet, Stockholm.

Govender, V., D. McIntyre., and R. Loewenson (2008). "Progress towards the Abuja target for government spending on health care in East and Southern Africa," EQUINET Discussion Paper Series 57. Harare: EQUINET.

Hongoro, Charles and Lilani Kumaranayake(2000). "Do they work? Regulating for-profit providers in Zimbabwe," Health Policy and Planning 15(4): 368-377.

Hozumi, Dai et al. (2008). "The role of the private sector in health: A landscape analysis of global players' attitudes toward the private sector in health systems and policy levers that influence these attitudes," Technical Partner Paper 2. PATH and the Rockefeller Institute.

International Finance Corporation (2007). The Business of Health in Africa: Partnering with the Private Sector to Improve People's Lives. Washington, DC: World Bank Group.

Mackintosh, Maureen (2007). "Planning and market regulation: Strengths, weaknesses and interactions in the provision of less inequitable and better quality health care," Paper commissioned by the Health Systems Knowledge Network of the World Health Organization's Commission on the Social Determinants of Health (11/7/09: http://www.who.int/social_determinants/publications/healthsystems/en/index.html]

Muthaka, David I. et al. (2004). A review of the regulatory framework for private healthcare services in Kenya. Nairobi: Kenya Institute for Public Policy Research and Analysis.

Nandraj, S. et al. (2001). Private health sector in India: Review and annotated bibliography. Mumbai/Madras/New Delhi: Centre for Enquiry into Health and Allied Themes, Foundation for Sustainable Development, Indian Institute of Technology, Centre of Social Medicine and Community Health, Jawaharal Nehru University.

O'Hanlon, Barbara, Nelson Gitonga, and Jeff Barnes (2009). Private Health Sector Assessment: PSP-*One* Technical Report, Washington, DC: World Bank.

Peters, D. et al. (2002). Better Health Systems for India's Poor: Findings, Analysis, and Options. New Delhi: The World Bank.

Ruairi, Brugha and Anthony Zwi (1998). "Improving the quality of private sector delivery of public health services, challenges and strategies," Health Policy and Planning 13(2): 107-120.

Sulzbach, Sara, Wenjuan Wang, and Barbara O'Hanlon. 2009. Assessing the Role of the Private Health Sector in HIV/AIDS Service Delivery in Ethiopia. Bethesda, MD: Private Sector Partnerships-*One* project, Abt Associates Inc.

U.S. Agency for International Development (2009). "Briefing Paper: The Status of Family Planning in sub-Saharan Africa," online at http://www.usaid.gov/our_work/global_health/pop/news/issue_briefs/africa_region.pdf (Accessed October 30, 2009).

Vyas R.M., P. M. Small, and K. DeRiemer (2003), "The private-public divide: impact of conflicting perceptions between the private and public health care sectors in India," The International Journal of Tuberculosis and Lung Disease 7(6): 543-549.

World Health Organization (WHO) (2006). The World Health Report 2006: Working Together for Health. Geneva: WHO.