

# **A Review of the Regulatory Framework for Private Healthcare Services in Kenya**

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## **Abstract**

*This paper examines the regulatory issues that govern private healthcare services in Kenya. It identifies the existing gaps which make enforcement of the laws governing private healthcare provision difficult and the laws that need to be amended for proper regulation of private healthcare providers. The major finding is that the legal and regulatory requirements for the practice and provision of private healthcare have serious weaknesses, which need to be addressed by the Ministry of Health and the various regulatory agencies. Unfortunately, some of the regulatory agencies have not been functional. For instance, the Central Board of Health, whose critical role is to advise the Minister for Health on all matters related to health, has never been constituted. Despite the fact that pharmacists and traditional practitioners are a major source of healthcare for many households, these healthcare providers are not regarded as medical practitioners and are therefore not properly regulated. Furthermore, laws to deal with malpractices and negligence in the provision of private healthcare services in Kenya are inadequate. Although the various professional bodies in the health sector are empowered to take disciplinary measures against professional misconduct, very few cases of punishment have been witnessed. Medical boards do not publicize cases of negligence or malpractice for fear of damaging the reputation of the profession. Nevertheless, most existing laws and statutes cover most of the areas of concern in the health sector (licensing of practitioners, premises, and sale of drugs). There is need for a strong monitoring capacity within the government and regulatory agencies in order to improve the operations of private healthcare providers. There is also need for legal restrictions or controls where participants must conform to legislated requirements. However, legal restrictions are only successful in the context of a well-resourced regulatory framework for implementation and monitoring, and a functioning judicial system for enforcement and sanctioning.*

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# 1. Introduction

Private healthcare system in Kenya has grown tremendously over the last two decades due to various reasons, among them lack of adequate and quality public healthcare services and introduction of user fees. This growth can also be associated with the health sector reforms undertaken in the 1980s and 1990s when the government relaxed the licensing and regulation of private healthcare providers and also relaxed the prohibition of public sector personnel from working in private practice (Hursh-Cesar *et al*, 1994). The reform measures implemented by the government called for greater involvement of the private sector in the economy. These reforms were a result of fiscal constraints that compelled the government to reduce overall expenditure, including budgetary allocations to the health sector, and therefore the need to encourage private healthcare providers to expand and play a greater role in healthcare provision.

Although the relaxation of government policies, regulations, and licensing procedures in the health sector seems to have encouraged growth in private healthcare provision, most of these providers are concentrated in urban areas (Hursh-Cesar *et al*, 1994). Also, the laws and regulations in private healthcare provision tend to be weakly enforced and show large gaps in application. Nevertheless, the non-restrictive policy environment towards private provision of healthcare services has, among other factors, contributed to the rapid expansion of the Kenyan health system. According to the Health Management Information Systems (Government of Kenya, 2001a), non-governmental organizations, private, and mission organizations account for 47% of all health facilities in Kenya. Private clinics, pharmacies, nursing homes and traditional practitioners have mushroomed in most urban and rural areas. However, these private facilities thrive in an unregulated environment. This necessitates government intervention as the reliability

of such facilities in terms of quality and ethics is questionable (Gallacchi *et al*, 1998).

Government intervention in regulation is desired in situations where, due to the nature of a good or service, information asymmetry may lead to low quality provision of the service by the private sector. In the case of healthcare, a patient has less information on, for instance, the efficacy of a treatment program but the doctor has all the information on the efficacy and dangers of the treatment. Since this information is not available to the patient, the pricing mechanism is distorted. For example, Kumaranayake (1998) indicates that hospitals respond to the threat of regulation (designed to reduce costs) in ways that lead to a decline in the quality of services. They may respond by reducing staff, eliminating selective services and postponing capital improvements. This results in contravention of the set laws that govern the sector. Therefore, the government should intervene to protect consumers of health services from the dangers arising from malpractices or negligence of the providers of these services. This protection should be provided through regulations and legislation that governs the healthcare practice.

The proliferation of private healthcare providers has been highlighted in the National Development Plan (2002-2008) as a problem that needs to be addressed. The proliferation calls for development and enforcement of guidelines under which private healthcare providers operate. The level and quality of services obtainable from these providers are as varied as the providers themselves. To safeguard the patients, there is need to regulate the activities of these providers (Republic of Kenya, 2002).

Based on the foregoing, the main objective of this study is to review the legal and regulatory environment pertaining to provision of private healthcare services in Kenya. The study examines the trend in growth of private healthcare facilities over time and assesses the nature of



regulations governing the operations of private healthcare providers. It reviews the impact of current healthcare regulations on healthcare provision and recommends legal and regulatory changes to enhance the growth of the private healthcare sector and the safety of the services provided to the population.

This study is premised on the grounds that the private healthcare sector if not adequately regulated poses risks of profiteering in medicine at the expense of the patient's health. This is because of the great asymmetry of information that exists between patients and healthcare providers. The fact that there is also confusion in terminologies used during licensing of the different private healthcare providers complicates the legal, regulatory and policy environment. This study aims to provide information that can be used to design regulations for protecting the health of patients without impeding the growth of the private healthcare sector.

The rest of the paper is organized as follows: section 2 presents an overview of the health sector in Kenya with focus on private healthcare providers. Section 3 outlines the rules and regulations that currently govern private healthcare practice in medicine. This includes registration of private medical practitioners and private healthcare facilities. Section 4 provides conclusions and makes some recommendations aimed at improving the provision of private healthcare services in Kenya.

## **2. The Health Sector in Kenya**

### **2.1 Public Healthcare Sector**

The key players in Kenya's health system are the central government (through the Ministry of Health), non-governmental organizations (NGOs), private for-profit healthcare organizations, and local government authorities. The public healthcare sector is organized into national, provincial, district, and community level, therefore forming a pyramid-like pattern. Health posts, mobile clinics, and dispensaries are at the very bottom of the pyramid with health centers, sub-district, district, and provincial hospitals at the middle of the pyramid. Kenyatta National Hospital in Nairobi and Moi Teaching and Referral Hospital in Eldoret are at the apex of the public healthcare system.

Besides being the main employer, the government controls approximately 53% of all health facilities in the country, while private companies, religious organizations, and the Ministry of Local Government control the rest of health facilities. The public sector has a dominant representation in health centers (79%), sub-health centers (92%), and dispensaries (60%). The NGO sector leads in health clinics, maternity and nursing homes (94%) and medical centers (86%) (IEA/SID, 2001)<sup>1</sup>.

The Kenyan health system has expanded rapidly in the post-independence period. This has been driven by the government's commitment to making healthcare services accessible and affordable to the majority of Kenyan's. To achieve this, the government during the early years of independence, increased budgetary allocations to the health sector, and later adopted a non-restrictive policy environment towards private provision of healthcare services. The physical growth

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<sup>1</sup> IEA (Institute of Economic Affairs) and SID (Society for International Development).

of infrastructure for healthcare services in Kenya is evidenced by the increase in the number of hospitals and other health centers. The number of hospitals grew from 148 in 1963 to about 308 in 1993, while health centers increased from 160 to 569 in the same period. By 2002, the total number of healthcare institutions was 4,499, with hospitals, health centers, and dispensaries being 514, 634, and 3,351, respectively. The Ministry of Health administers about 50% of healthcare institutions while the Local Government administers about 3%. The rest of the institutions are administered by private organizations, religious organizations, and the NGO sector (Government of Kenya, 2001a).

Although the health physical infrastructure has expanded rapidly since independence, maintenance and rehabilitation has been a problem because expansion has not been complemented with a parallel rise in financing. Most equipment essential to effective and efficient provision of quality healthcare is in need of repair, rehabilitation, or replacement. In addition, the Ministry of Health has been unable to enforce standards for the type, quality, and compatibility of a vast array of the equipment, fixtures, and vehicles it requires. Since the public sector has become inefficient in delivery of healthcare services, health clinics have mushroomed in all corners of the country. Entry of unqualified medical practitioners in the provision of healthcare has been blamed on the government bodies that are charged with the role of regulating medical practitioners. These bodies, in addition to the Ministry of Health, include: the Central Board of Health (CBH), Medical Practitioners and Dentists Board (MP&DB), Clinical Officers Council, Nursing Council of Kenya, Pharmacy and Poisons Board, and the Ministry of Local Government. Most of these regulatory bodies are established under various Acts of Parliament for the main purpose of regulating the practice of the medical professions.

## **2.2 Private Healthcare Sector**

The private healthcare sector comprises the activities of agents who are largely outside the control of government. This includes individuals who privately own health facilities and seek to make profit in the healthcare sector, clinics and hospitals owned by private employers and those operated by religious missions and other non-governmental organizations (NGO's). These agents play a significant role in provision of health services in Kenya. The impression in many countries is that private healthcare is expanding and this has made many countries to adopt a pluralistic health system.

Kenya has followed a strategy of pluralism in the health sector for a long time, allowing a large and diverse non-government healthcare sector to develop. The government, on realizing the potential that exists in the non-governmental sector, has tried to create an enabling environment for private investment in healthcare provision. Private healthcare providers are often assumed to be more efficient and provide a higher quality healthcare alternative than public sector providers. Non-governmental healthcare providers include religious organizations, for-profit private healthcare enterprises, pharmacies/chemists, and traditional practitioners.

The growth of private healthcare providers is attributed more to government reforms that took place in the 1980s on the Kenyan health sector. The government was facing a fiscal burden in provision of healthcare, which had to be transferred to private healthcare providers and individuals. The government initiated a cost-sharing program as part of reducing government burden, while it undertook to create a conducive environment for greater private sector involvement in healthcare. This created a two-tier health system in which some people are served by government facilities and others by the private sector.

The private healthcare sector has made a remarkable contribution in delivery of healthcare to the public. The sector is used by almost all socioeconomic groups, and appears to have relatively better distribution in both rural and urban areas. Nevertheless, there has not been proper policy formulation for this sector due to its diversity and nature. As Hanson and Berman (1994) note, failure to consider the diversity of private healthcare providers could lead to faulty policy advice because form, behavior, and importance with respect to both size and range of activities is likely to differ significantly between types of providers.

### **2.2.1 Classification of Private Healthcare Providers**

Many studies on private healthcare providers have cited the existence of confusing arrays of terminologies over their classification (Oduwo *et al*, 2001; Kumaranayake, 1998; Hursh-Cesar *et al*, 1994).<sup>2</sup> For instance, some health facilities identify themselves as hospitals whereas others with similar features identify themselves as clinics or nursing homes, although the law stipulates what should be hospitals, nursing homes, and clinics. Terminologies used to define the facilities are important as they dictate the regulatory mechanism to be applied for a particular type. Therefore, confusion arises when different facilities with similar features are regulated differently.

Doctors, nurse practitioners, or clinical officers operate most private healthcare facilities. However, it is very difficult to know how health clinics, for example, are run by these types of practitioners given the proliferation of the use of the title "Doctor" in Kenya. For example, traditional health practitioners and pharmacists, and even clinical officers have adopted the title of "doctor", particularly in rural areas,

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<sup>2</sup> The classification problem has arisen due to providers changing names, e.g. from hospital to nursing home, so that they can qualify for higher reimbursement from the National Hospital Insurance Fund (NHIF).

ignoring the rules and regulations that govern the profession. This has made the country to have a diverse mix of different types of private healthcare providers, ranging from traditional to modern practitioners and from individual to large hospitals (Hursh-Cesar *et al*, 1994). Various studies have classified private healthcare providers according to a number of criteria, with each criterion emphasizing a specific aspect of the sector (Kumaranayake 1998; Hursh-Cesar *et al* 1994). Commercial orientation, ownership, type of facility, and therapeutic system are used in this paper to classify various types of private healthcare providers.

**(i) Economic orientation**

The first and main component of classification of private healthcare providers is by economic orientation, which includes for-profit or not-for-profit facilities (Kumaranayake, 1998; Hursh-Cesar *et al*, 1994). Health facilities run by churches or various religious faiths constitute the main not-for-profit private healthcare providers. Other non-governmental organizations in this sector include single-purpose organizations such as the Family Planning Association of Kenya (FPAK). Health facilities owned by sole proprietors, partnerships, companies and parastatals, pharmacists and traditional health practitioners form the main for-profit private healthcare providers. Table 1 presents a typology of private health providers, categorised as either for-profit or not-for profit.

**(ii) Ownership**

The second category of classification of private health providers is by ownership. Economic agents of different types own private healthcare facilities. These agents include religious organizations, companies, parastatals, private enterprises, and individuals such as pharmacists and traditional healers who own private healthcare facilities. Community-based health workers, community-based distributors of

**Table 1: Typology of private healthcare providers in Kenya**

Not-for-profit sub-sector		For-profit sub-sector
<b>Religious organizations</b>	<b>Other NGOs (non-profit)</b>	
<i>Church Health Association of Kenya (CHAK)</i> Hospitals, health centers, clinics/ dispensaries	<i>NGOs involved in family planning</i> Family Planning Association of Kenya clinics	<i>Sole/group practices (clinics) and hospitals</i> Doctors, clinical officers, nurses, private hospitals
<i>Kenya Catholic Secretariat</i> Hospitals, cottage hospitals, health centers, sub-centers	<i>Community-based providers</i> Community health workers, community pharmacies	<i>Employers (including parastatals)</i> Industrial clinics, parastatals, pharmacies, chemists
<i>Crescent Medical Association, i.e. Islamic organizations</i> Clinics, dispensaries, pharmacies	<i>Other non-profit organizations</i> e.g. flying doctors, foreign/local non-government organizations, hospitals	<i>Individual pharmacies</i> Registered Pharmacists and chemists; Pharmaceutical Technologists <i>Individual laboratories</i> Radiological laboratories, clinical laboratories <i>Stores and shops</i> Drug stores and market vendors <i>Traditional health practitioners</i> Traditional birth attendants, herbalists, bonesetters, diviners, etc

Source: Berman et al (1995); Hursh-cesar et al (1994)

contraceptives, and community pharmacies also fall under this classification.

**(iii) Type of facility**

The third classification of private healthcare providers is by type of facility. This classification produces three broad categories of health facilities: hospitals, health centers, and sub-health centers. However, the Health Management Information System (HMIS) database lists the following types of private health facilities: hospital, health center, sub-health center, dispensary, health clinic, maternity home, nursing home, medical center, mobile clinic, special health institutions, health programs and community pharmacies (Government of Kenya, 2001a). It is very clear that it is not easy to tell what distinguishes one type of health facility from the other as listed in the database. However, a good guide would be the conditions that the health facilities must meet in order to be licensed by the Medical Practitioners and Dentists Board as a particular type of healthcare facility. The Medical Practitioners and Dentists Act, Cap 253 of the Laws of Kenya has outlined these conditions<sup>3</sup>.

**(iv) Therapeutic system**

Traditional healthcare providers do not seem to fit easily into any of the above classification of private healthcare providers. Therefore, these facilities and other similar facilities may be categorized as therapeutic or healing systems. Nevertheless, traditional healthcare practitioners can also be categorized as owners, and may range from herbalists, herbalists' diviners, and herbalists' bonesetters. In studies by Hursh-Cesar *et al* (1994) and Berman *et al* (1995), healers, charismatics, and

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<sup>3</sup> The requirements are listed in Section 3 of this paper.



birth attendants are indicated as the most accessible and most important source of healthcare in rural areas. They are a “one-stop” source of care – diagnosis, medicine, and treatment.

Traditional medicine includes a diversity of health practices, approaches, knowledge, and beliefs incorporating plant, animal, and/or mineral-based medicines; spiritual therapies; manual techniques and exercises, applied singly or in combination to maintain well-being, and to treat, diagnose, or prevent illness (WHO, 2001)<sup>4</sup>. The comprehensiveness of the term ‘traditional medicine’, and the wide range of practices it encompasses, makes it difficult to define or describe, especially in a global context.

As evidenced above, there is considerable confusion in the terminologies used to classify private healthcare facilities. No classification presents a sufficiently complete framework for analysis of the private healthcare sector. As indicated in IEA/SID (2001), due to the diversity of the private healthcare sector and a wide array of terminology, it is hard to properly classify and account for all its activities. Although all health facilities in Kenya are required to submit annual returns to the Health Management Information Systems (HMIS)<sup>5</sup>, not all of them do this. Furthermore, the HMIS is not clear over the coding and classification of health facilities by ownership (Berman *et al*, 1995). This is complicated by the different numbers of these providers, which has increased especially in recent years.

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<sup>4</sup>World Health Organization (WHO).

<sup>5</sup>The existing licensing and inspection machinery is said to be inadequate as manifested in the disparities between national registers and the local district Ministry of Health register. The Ministry of Health is only aware of those health facilities that submit their monthly returns (Wangombe *et al*, 1998).

### **2.2.2 Growth of Private Healthcare Providers in Kenya**

The private healthcare sector has made a remarkable contribution in the delivery of healthcare services in Kenya. It has filled a resource gap for health development by improving efficiency and quality of care by promoting competition and complementing public sector services. As noted earlier, the growth of the sector in Kenya is partly attributed to the decision by the government in the late 1980s to allow clinical officers, nurses, and pharmaceutical technologists to engage in private provision of healthcare services. The deteriorating conditions in public health facilities, which have forced the public to seek alternatives, are another contributing factor. Leonard *et al* (2000) observe that government health services have failed to provide reliable and good quality healthcare despite the fact that patients exhibit willingness to pay for quality healthcare. Non-governmental healthcare providers seem to be running successful healthcare facilities for which even poor patients are willing to pay. There is therefore a substantial private sector activity in healthcare provision in Kenya.

Kumaranayake (1998) provides three main reasons for the increase in private sector activity within the health sector. First, an explicit deliberate policy choice of health sector reforms were carried out purposely to encourage the development of the private sector as an alternative means of healthcare provision. This has been spurred by increasing resource constraints and the poor performance of the public sector. The second is a response to weak provision of public health services. The public health sector has become inefficient in delivery of health services, accounting for 30% wastage of resources. The poor remuneration of personnel, low morale, lack of ownership of the services by communities, poor logistic support, and little opportunities for continuing education have further degraded the quality of services. Mushrooming of unregistered clinics run by unqualified personnel has slowly taken advantage of the inefficiency in public health services

(Oduwo *et al*, 2001; IEA, 1998; IEA/SID, 2001). Poor remuneration in the public healthcare sector has forced doctors to resort to private clinics or seek employment in other countries (Nyangena, 2000). The poor performance of the public healthcare system could also have contributed to the growth in traditional medicine as an alternative source of healthcare.

The third reason for the increase in private healthcare services arises from the need to respond to increased consumer affluence (e.g. increasing middleclass) and preference for greater quality services. Studies by Berman *et al* (1995) and Hursh-Cesar *et al* (1994) found that in many low and middle-income countries, the demand for private healthcare has been driven by its perception as a higher-quality service.

Kenya, like most African countries, inherited a small health sector at independence. However, private healthcare provision has grown from a few providers at independence to about 1,446 in 1994. This growth is traced in two periods. The first was the 1970s when the government allowed civil servants to engage in private remunerative activities in their free time, on condition that these activities are not prejudicial to their public service. The second was in the early 1980s when the government sought to withdraw this privilege because of abuses (diversion of public supplies and time of professional staff to the private sector; and admission of private patients in public facilities). Many doctors resigned from government services in 1984 after their part-time licenses were withheld. The policy was later modified to allow specialist doctors to engage in part-time private practice while denying junior doctors this opportunity. This change of rules governing private practice of government health officials saw the setting up of different health institutions ranging from clinics to hospitals.

**Table 2a: Hospitals and hospital beds by operating agency (1967)**

Agency	Hospitals	
	Number	%
Central Government	74	37
Local Government	2	1
Catholic Church	58	29
Protestant Church	33	17
Private hospitals	26	13
Company hospitals	6	3
<b>Total</b>	<b>199</b>	<b>100</b>

Source: Kimalu *et al*, 2004

The number of health institutions increased from 861 in 1967 to about 4,557 in 2003.<sup>6</sup> As shown in Table 2a, the government only controlled 37% of the hospitals in 1967 while 46% of hospitals were controlled by religious organizations, 13% by private individuals, and 3% by companies. Today, the government controls about 52% of all health facilities, with private healthcare providers controlling the remaining 48%.

By 1994, private healthcare providers owned and operated about 42% of all health facilities in the country, that is 50% of all hospitals, 21% of all health centers, and about 50% of all other health facilities. The private healthcare facilities are owned by a variety of agencies and individuals. About 47.3% are owned by the mission sector, 51% by the private/company sector and the remaining 1.7% are owned and operated by the Family Planning Association of Kenya (Berman *et al*, 1995). Table 2b shows the distribution of the facilities by type of ownership.

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<sup>6</sup> The annex table provides the growth in numbers of health facilities and also health professionals in Kenya between 1981 and 2003. The statistics are compiled from various issues of the Kenya Economic Survey.

**Table 2b: Distribution of health facilities by controlling agency (1999)**

Type	Gov. of Kenya		NGO/private		Total
	No.	%	No.	%	No.
Hospital	110	49.8	111	50.2	221
Health center	465	80.2	115	19.8	580
Dispensary	1,583	61.5	992	38.5	2,575
Nursing and maternity home	0	0	189	100.0	189
Health clinics and medical centers	94	12.9	635	87.1	729
<b>Total</b>	<b>2,252</b>	<b>52.4</b>	<b>2,042</b>	<b>47.6</b>	<b>4,294</b>

Source: Government of Kenya (2001a)

Non-governmental organizations and the private sector controlled about 48% of all health facilities in 1999 (including 50.2% of hospitals, 87.1% of health clinics and medical centers, 38.5% of dispensaries, and 19.8% of health centers (Government of Kenya, 2001a). The 2001 Economic Survey indicates an increase in health facilities by 7.1%, 1.3%, and 2.5% for hospitals, health centers, and dispensaries, respectively. The increase is attributed to a high number of new private nursing homes, and an expanded investment by the private sector and NGOs (Government of Kenya, 2001b).

In terms of distribution of types of private healthcare facilities by ownership, the mission sector owns more than two-thirds of hospitals, 86.6% of health centers, and 42% of “other” health facilities. The private/company sector owns slightly more than 30% of hospitals, less than 15% of health centers and more than half (55%) of all “other” health facilities. Therefore, religious organizations seem to be the largest non-governmental provider of curative healthcare. These organizations include the Christian Health Association of Kenya (CHAK)<sup>6</sup> and the

<sup>7</sup> CHAK comprises the protestant denominations including Seventh Day Adventist (SDA), Presbyterian Church of East Africa (PCEA), Anglican Church of Kenya (ACK), and the African Inland Church (AIC).

Kenya Catholic Secretariat (KCS). Other religious affiliated healthcare facilities are those provided by the Islamic religion. There were about 12 mosque health facilities in Kenya by 1994 (Berman *et al*, 1995). The Crescent Medical Aid (CMA), unlike CHAK and KCS directly manage the facilities set up by individual mosque owners.

Some employers also provide healthcare facilities mainly as outpatient facilities for their employees. There is no estimate of the number of employer-provided healthcare facilities or the number of Kenyans who benefit from such facilities. The Health Management Information System (HMIS) database is incomplete and lumps employer-owned health facilities together with private-for-profit providers, therefore making it difficult to estimate the number of employer-related healthcare facilities. Employers provide all types of services, but mostly outpatient care through clinics, pharmacies and specialized laboratories. Like the for-profit providers, companies and parastatals tend to concentrate their services in urban areas (Hursh-Cesar *et al*, 1994). Many employers also use the services of Health Management Organizations (HMOs). These are health insurance organizations, which double up as providers of insurance services and health facilities. There has been concern that HMOs are not properly regulated. In the budget speech for the year 2002/2003, the Minister for Finance noted that HMOs continued to transact medical business in Kenya without any form of regulation and supervision. The Minister proposed that all HMOs, medical aid organizations, and similar bodies that are involved in the provision of medical insurance be brought under the ambit of the Insurance Act in order to protect the public from potential fraud, and to improve the quality of service to Kenyans seeking medical care.

Although nursing homes, dispensaries, and medical centers are the formally recognized healthcare providers, there are other facilities and providers operated by private practitioners. These include pharmacies,

traditional birth attendants (TBAs), and community health workers. There were about 290 pharmacies and chemists in Kenya as of July 1994. The number of TBAs in Kenya by 1994 was 7,953 (Berman *et al* (1995). Health policy makers are increasingly recognizing the role of traditional birth attendants (TBAs) as healthcare providers. Although traditional birth attendants and other traditional health practitioners assist in over 20% of total births, majority of TBAs are untrained. In addition, it is not easy to quantify this category of providers in terms of the number of facilities or beds provided or even patients seen (Kumaranayake, 1998; Hursh-Cesar *et al*, 1994) due to the reluctance of Kenyans to reveal their visits to traditional health practitioners. Traditional health practice is often associated with the stigma of witchcraft and sorcery.

Given the diversity of private healthcare providers therefore, there is need to ensure that a conducive environment exists for them and their consumers. Intervention in form of laws and regulations governing private healthcare provision is necessary in order to ensure the safety and health of the consumers of health services. It has been noted that medical practitioners rarely conform to the rules and regulations governing their profession especially if enforcement is weak. Records

**Table 2c: The number of registered private healthcare providers**

	2000	2001	2002
Dispensaries	34	152	206
Health centers	12	70	91
Hospitals	22	67	89
Health clinics	42	35	58
Nursing homes	39	111	131
Medical centers	34	17	31
Maternity homes	9	20	25
Laboratories	5	6	7
<b>Total</b>	<b>197</b>	<b>478</b>	<b>638</b>

Source: Medical Practitioners and Dentists Board newsletter, various issues

from the Medical Practitioners and Dentists Board, for instance, show very few facilities being registered before the year 2001 (Table 2c). Although the number of health facilities under private providers was more than 2000 in the year 1999 (Table 2b), the register of the Board shows that there were only 197 private healthcare facilities in the year 2000, and the number only increased to 638 in the year 2002. This implies that most private healthcare facilities have not been approved by the Board to provide healthcare.

In addition to the problem of non-registered private healthcare providers, some providers do not meet the training and licensing requirements and yet they continue practising as medical professionals. The circumstances that have led to the growth of private healthcare providers, together with the problems associated with private healthcare provision, are reviewed in the next section.

### **2.2.3 Problems in Private Healthcare Provision**

Many problems arise in the financing and delivery of health services. These include: poor physical infrastructure and a shortage of qualified staff; low standards of care; poor equipment or inappropriate technology; misuse of public resources within the private sector; and medical malpractice and negligence<sup>8</sup>. Kumaranayake (1998) gives examples of misuse of privileges, medical malpractice, and medical negligence among licensed private doctors in Bombay where over 60% of health workers prescribed drugs requested by patients, and admitted that they occasionally gave patients drugs not indicated for the disease in order to satisfy the psychological needs of the patient. Some practitioners specialize in the sale of pharmaceuticals but do not carry out any diagnosis of the problem before sale of drug (Leonard and David, 2000; Wangombe *et al*, 1998). Unlicensed groups often sold

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<sup>8</sup> Malpractice is any 'professional misconduct that encompasses an unreasonable lack of skill or faithfulness in carrying out professional duties' (Gabale, 2003).



medicine in shops, drug stores and on streets. Some drugs sold through these outlets are cheaper than those sold in pharmacies, which makes their source suspect.

Arguments in the literature indicate that there is little evidence on the relative quality and efficiency of private healthcare provision in Kenya. However, private healthcare facilities charge fees that are considerably higher than those charged in government facilities. Therefore, Kenyans living in areas predominantly served by the private sector may be paying more for healthcare, other things remaining constant. However, there are limited incentives to encourage those private providers operating in underserved areas, and the laws regulating this sector seem to be a burden to the provider. The upshot of all this has been fragmentation, poor coordination, concentration of health facilities in urban areas and intense competition for staff and patients (IEA, 1998).

The government policy of permitting consultant physicians to work in private practice alongside their government duties, and the laws that permit nurses and clinical officers to operate private practice conditional upon leaving public service have brought some problems. Although consultants working privately are supposed to declare the hours they intend to work in their public sector postings to ensure that they maintain the terms of their contract, this has not been complied with. In the absence of adequate monitoring of contractual obligations, it is likely that the public sector does not get the full output of these consultants. Other consultants admit their own private patients to government facilities and never pay the facility for the services rendered.

Private healthcare providers are too concentrated in urban areas, and mainly serve upper-income consumers<sup>9</sup>; get unfair concessions; use

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<sup>9</sup> Unequal spread of facilities creates pockets of underserved areas in which users are denied easy access to healthcare services.

inappropriate and expensive technology; focus on curative services to the detriment of preventive health; and their motives are commercial and exploitative (Hursh-Cesar *et al*, 1994). The profit motive may cause poor provision of healthcare services by profit-driven health providers without proper regulation. The lack of a clear licensing mechanism system may lead to poor provision of healthcare services.

Other problems that affect the operations of the private healthcare sector include the political system and political ideology, the overall availability of infrastructure, and also the macroeconomic management issues (Berman *et al*, 1995). Some government systems, for example, believe that it is not good to promote private clinics due to the nature of health as a good. Specific problems include financial constraints and lack of administrative and management skills, and lack of places in local medical institutions for training paramedics such as radiographers, laboratory technicians and technologists. Other problems include high taxation, poor infrastructure, lack of access to credit especially in rural areas, and loopholes in the laws regulating this sector, including the Local Government Act and the Foreign Investments Protection Act. Poor enforcement of the existing laws is also a major problem that affects private healthcare provision (IEA/SID, 2001; IEA, 1998). This is in addition to lack of adequate information and guidance from the Ministry of Health on public health activities and providers of medical care.

There are also weak institutional links between the government and private healthcare providers. There is for example little consultation between the Ministry of Health and the private health sector in formulating policy or in coordinating response to health problems. Although there have been attempts to strengthen the relationship, traditional health practitioners appear to have been left out of the new arrangements (IEA/SID, 2001).

Licensing requirements for medical practitioners are also a barrier to engagement of foreign and foreign-trained doctors. Since Kenya does not have enough doctors, hospitals seek permits to employ foreign doctors. In addition, Kenyan doctors trained overseas, even if they have practiced for long periods, face tedious and time consuming registration and licensing requirements. However, there is fear that easing registration and licensing controls may open up the process to abuse and subversion of its purpose. Registration and licensing are part of government regulation procedures to protect the consumers of healthcare, as the problems created/posed by private healthcare providers need to be addressed through all means. As noted earlier, the bodies vested with regulation, registration and licensing of the medical professional include the Ministry of Health, Central Board of Health, the Medical Practitioners and Dentists Board, etc. These and other bodies are reviewed in the next section

### **2.3 Health Sector Regulatory Bodies**

The overall government agency for regulating healthcare provision is the Ministry of Health. The Ministry is the main provider of health services in the country and has the following functions:

- Formulation and implementation of the national health policy;
- Preparation and implementation of national health development plans;
- Organization and administration of central health services;
- Reviewing health-related Acts and regulations;
- Training of health and allied personnel;
- Promotion of medical science and maintenance of medical and health standards;

- Liaison and co-ordination with other government departments and non-governmental agencies;
- Ensuring internal health regulations.

Different statutory bodies under the Ministry of Health assist it in exercising day-to-day oversight. These bodies are autonomous and include:

**(i) Central Board of Health**

This Board is established under the Public Health Act, Cap 242, with the following functions, among others: to advise the Minister for Health on all matters affecting public health; to promote public health; to advise and direct local authorities on matters affecting public health; and to prepare and publish reports or other information related to public health. According to the Public Health Act, Cap 242, the Central Board of Health (which has never been constituted) is established under Section 3 of this Act. The Board members are supposed to be, among others, the Director of Medical Services, a sanitary engineer, a secretary, and such other person or persons not exceeding six (three of whom shall be medical practitioners) as are appointed from time to time by the Minister for Health. The main function of the Board is to advise the Minister on all matters affecting public health. Therefore, given that the Board has never been constituted, it is not clear where the Minister for Health gets advise from on matters relating to public health.

**(ii) Medical Practitioners and Dentists Board**

This Board is established under the Medical Practitioners and Dentists (MP&DB) Act, Cap 253 of the Laws of Kenya. This Act of Parliament enacted in 1978 makes provision for registration of medical practitioners and dentists. The Board is charged with the responsibility of registering and licensing medical practitioners and dentists (including those in

private practice); registering and licensing private health facilities; and inspecting nursing homes and hospitals. It is also supposed to ensure that practitioners maintain internationally-accepted standards of practice. In case of professional misconduct, the Board is empowered to discipline the practitioners, including deregistration and cancellation of licenses. Therefore, this Board has a very strong mandate of ensuring that all medical practitioners offering medical services in both public and private health facilities are qualified. Besides, the Board is empowered to discipline medical practitioners who are involved in professional misconduct.

**(iii) Clinical Officers Council**

This Council is established under the Clinical Officers Act, Cap 260. The main functions of the Council are to assess the qualifications of clinical officers, to register and license clinical officers, and to maintain the register and records of clinical officers registered. The Council is empowered to take necessary disciplinary measures in cases of violations of professional conduct and discipline, and to collaborate with other medical bodies in the furtherance of the functions of the Council and the bodies. The issue of qualification and discipline of clinical officers is therefore well highlighted in this statute. The Council is expected to ensure that consumers of the health products provided by clinical officers are well protected.

**(iv) Nursing Council of Kenya**

This Council is established under the Nurses Act, Cap 257 of the Laws of Kenya. Its functions include, among others: to have regard for the standards of nursing care, qualified staff, facilities, conditions and environment of health institutions; and to take such disciplinary or appropriate measures as may be necessary to maintain proper standards

of nursing care in health institutions. The Council is expected to advise the Minister for Health on all matters concerning all aspects of nursing and, with approval of the Minister for Health, to make provision for the training and instruction for persons seeking registration or enrolment under this Act. The Council is expected to prescribe and conduct examinations for persons seeking registration or enrolment under this Act. The functions of the Council show that nursing as a profession plays a big role in assisting better delivery of health services, and this special role cannot be easily substituted. Therefore, poor delivery of services by the Council translates into poor delivery of health services by nurses.

**(v) Pharmacy and Poisons Board**

The Pharmacy and Poisons Board is established under Cap 244 of the Laws of Kenya. As in the other Boards, it regulates the profession of pharmacy. It is responsible for registration of pharmacists, giving of power to pharmacists to sell poison, and is responsible for remedial measures in cases of violation of professional conduct and discipline. The Board therefore retains the overall duty of regulating the drugs offered in the market. Issues of sub-standard, expired, and poisonous drugs are in the domain of the Pharmacy and Poisons Board.

**(vi) Local Government**

The Public Health Act gives power to municipal councils to provide hospitals. Any municipal council, with the sanction of the Central Board of Health, may provide for the use of the inhabitants of its area hospitals or temporary places for receiving the sick. The municipal council may: build such hospitals or places of reception, contract for the use of any such hospital or part of a hospital or place of reception, or enter into any agreement with any person having the management of any hospital

for the reception of the sick inhabitants of their area. The Public Health Act also empowers a municipal council to supply or contract out supply of medicine on a temporary basis to poorer people in their respective district, but may at their discretion charge for the same. The Minister for Local Government is supposed to obtain an agreement from the Minister for Health before approving any by-law made by a municipal council affecting public health. The Minister for Local Government is empowered to order a municipal council to perform its duties in relation to any complaint made to the Central Board of Health on public health in the locality of the municipal council.

The Public Health Act, Cap 242, is the overall guiding legislation on health issues, whether by public or private healthcare providers. It is well outlined in the Act that whenever there is conflict of Cap 242 with other Acts, its provisions prevail. The Public Health Act also comes out strongly in making provisions for securing and maintaining health. It gives powers to the Minister for Health as regards regulation of nursing homes, private hospitals, private mental hospitals, maternity homes, etc., and no person shall keep open any such premises unless the premises and the keeper thereof are licensed by the Medical Practitioners and Dentists Board (MP&DB). The Act empowers the Director of Medical Services to visit and inspect such premises and report to the Central Board of Health on any matter or thing connected with such premises or the use thereof. Since the Central Board of Health in Kenya is not operational, it is not clear where the Director of Medical Services reports public health matters. Therefore, the Ministry of Health and its agencies are the only regulatory bodies in the healthcare market. The next section presents an overview of other key players in healthcare provision.

### **3. Regulation and Licensing of Healthcare Providers**

#### **3.1 Role of Regulation**

Regulation means to control by means of rules or principles. The rules set out the desired behaviour, while the regulatory administration oversees conformity to the regulation.. Regulation allows a government to formalize and institutionalize its commitments to protect consumers and investors. Governments undertake regulation to, among other things:

- (i) Protect consumers;
- (ii) Promote allocative and productive efficiency;
- (iii) Minimize informational rent (due to information asymmetry between regulator and firm);
- (iv) Avoid regulatory capture; and
- (v) Develop credible commitment.

In most cases, regulation is a response to problems of market failure and is therefore aimed at correcting the failures through either very specific actions, which can include measures of functional integration and separation, control of pricing and possibly investment and quality, or a legal prohibition of the exercise of potential monopoly power (ECLAC<sup>10</sup>, 1996).

Regulatory intervention may also involve legal restrictions or controls, which the players in the industry must conform to. In addition to informal rules, the healthcare sector has formal rules and codes of conduct and guidelines that can lead to punishment when violated. However, the success of legal restrictions rests upon an informed society

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<sup>10</sup> Economic Commission for Latin America and the Caribbean.



and existence of a well-functioning judicial system. Most of the requirements used for regulating the players in the health sector are legislated, although basic legislation is thought of as establishing minimum standards for operation.

Several stakeholders are involved in developing health regulations. In Kenya, the Ministry of Health, local authorities, healthcare professionals, non-governmental organizations, and the community all have key roles in healthcare provision and regulation. These roles have been especially important with increased private sector participation in healthcare provision. As in privatization, regulation has distinct advantages over public ownership in that it allows market forces to operate and government intervention to be directed to areas where market failure is most pronounced. Effective regulation requires that the precise sources of market failure be identified, isolated and targeted. The role that regulation plays in economic activities therefore justifies economic analysis. Application of economic analysis to regulation is based on the premise that economic efficiency is useful in examining legal rules and institutions, and that efficiency is useful in explaining the actual structure of the law, and in suggesting how rules and institutions can be improved or made more efficient.

### **3.1.1 Importance of Regulation**

The traditional economic rationale for regulation is based on the existence of market failures (e.g. monopoly), which lead to inefficient resource allocation. Markets, like other institutions, are not necessarily created to be socially efficient. Their special features make them unsuitable for resource allocation. These features include a wide range of stakeholders, relevant perspectives, asymmetric information, and provider capture. The stakeholders view only those costs (internal or private costs) captured by their perspective's boundary. Externalities and internal costs of other perspectives are not usually taken into

account in decision-making by that group. Where externalities occur, the operation of a free and unregulated market will not result in allocative efficiency. Asymmetric information, moral hazard, cream skimming and cost shifting result in market failure and reduce allocative efficiency (Scott and Hellen, 2002). Governments seek to improve allocative efficiency by imposing regulations or in this case introducing a national health service.

Cream skimming occurs where health insurers and Health Management Organisations (HMOs) in an unregulated free market have an incentive to reduce their costs by selecting low risk clients and declining to cover those likely to fall ill (as in HIV/AIDS cases) and require healthcare. Besides cream skimming, some health practitioners practice cost shifting, a practice that transfers costs from one subset of society to another. For instance, cost shifting may occur where a medical specialist works both in a private clinic and a public hospital. Such a physician may direct low profit margin cases to the public healthcare system and the high profit cases to the private clinic. Costs are also shifted from the private clinic to the public health sector. Such nature of usage of public hospital facilities to treat private customers has been common since the government started allowing medical practitioners to register their own clinics in Kenya in the 1980s.

Asymmetric information in the health sector occurs because providers of healthcare usually have much better information about health and healthcare interventions than consumers. The resultant risk of the providers capturing the market and disadvantaging consumers generates a need for government regulation (Scott *et al*, 2002). The patients' lack of information opens the way for possible abuse, particularly if the physician's income is directly linked to the amount of treatment provided or where salaries are so low that staff are willing to trade their own professional ethics for additional income by inducing unnecessary demand. In such a situation, government intervention

becomes important for protection of the interests of patients. The approaches available for intervention include: regulating the medical profession; providing additional information for patients; and appointing purchasers to negotiate with medical providers on the patient's behalf.

As noted in ECLAC (1996), when a government allows the private sector to provide goods and services, it may also want to influence private sector behavior. With increased liberalization of markets over the last few years, health services have mainly been left in the hands of private sector. This has raised widespread interest in the role of regulation in achieving positive benefits from the private sector. There has been an assumption, for example, that liberalization leads to competition such that prices would tend to drop. However, price competition does not necessarily mean quality competition. As Kumaranayake (1998) notes, quality is a crucial factor in healthcare although quality is in some cases associated with higher investment in technology and equipment. Patients are therefore left to judge hospitals by such indicators as availability of certain equipment or the nature of buildings. Due to imperfect knowledge, patients may view pharmaceuticals and injections as indicators of quality. Therefore, there is a likelihood of providers concentrating their investment on these areas in order to signal to patients the quality of their services, and may lead to irrational prescribing practices. Market failure results from such asymmetry of information, moral hazard, and uncertainty, which sometimes leads to inefficiency and escalation of costs. These problems have been associated with overcharging, use of unnecessary high technology equipment, and over-reliance on laboratory tests. Regulations are required to ensure that quality standards are met, that financial fraud and other abuses do not take place, and that those entitled to healthcare are not denied the services. Whereas this might be possible with regulation, it remains the

physician's duty to reduce information asymmetry for the health market to operate efficiently for the benefit of consumers.

In healthcare markets, consumers often do not know what type of care will generate greatest improvement in their health status and must rely on the providers for advise. The complexity of medical diagnosis and procedures available makes obtaining accurate knowledge difficult and costly. The consequence of lack of information is that most consumers must rely on an informed agent to act as a representative. The agent is usually the physician, although other medical staff such as nurse, pharmacist and dentist also act as agents but are assumed to have insufficient information. The patient's agent is able to influence the amount of healthcare consumed. The physician orders tests, prescribes drugs and courses of treatment, and decides whether and when a patient will be admitted to and discharged from a hospital. However, as Kumaranayake (1998) notes, a doctor is both an economic agent with skills to sell and is a member of a pressure group with interests to defend. However, that latter role should not compromise customers' safety.

### **3.1.2 Regulation in the Health Sector**

The characteristics of health and healthcare mean that there is a strong case for government involvement. A number of features, among them the non-homogeneity of products, characterize the market for healthcare. When products are non-homogenous, customers cannot simply compare prices or assess the appropriateness and quality of intervention. The key roles that regulation can play within the health sector include: control of market entry and exit; control of competitive practices; control of market organization; control of standards/quality; and ensuring safety. Quality of provision is done through the self-regulating function of the medical professionals. Pharmaceutical legislation controls the entry and distribution of drugs. In many countries, regulation of physicians, nurses, and pharmacists takes the

form of a basic regulation with respect to licensing through medical boards and councils (Kumaranayake, 1998).

There is quite substantial self-regulation in the health sector, particularly among healthcare professionals. Medical professionals are often regulated by a group of peers, such as medical boards and councils, who have the authority under existing legislation to license and sanction medical professionals. The advantage of such a process is the relatively small resource required to administer self-regulation. However, there are very real issues of effectiveness and transparency in self-regulation because a close relationship between the regulatory body and the regulatee may jeopardize the implementation of regulation, as the regulator may be sympathetic towards or easily manipulated by the regulators. This phenomenon is referred to as regulatory capture. Being peers, medical practitioners may not be ready to take action, in order to protect the reputation of the profession. This may encourage malpractice and negligence in the medical profession.

According to Wangombe *et al* (1998), regulations and standards such as licensing and inspection, which need to be observed in setting and running healthcare facilities act as safeguards for maintenance of quality care. Licensing prevents unqualified persons from practicing, facilitates recognition by the government, and therefore enhances confidence in the community. Added advantages include prevention of mushrooming of illegal clinics, maintenance of health standards, and provision of security to the provider to practice freely. However, there have been complaints of corruption and inefficiency during the licensing and inspection process, which may result in sub-optimal outcome for society.

### **3.2 Health Sector Regulation in Kenya**

In Kenya, the government has given the role of regulation to the Ministry of Health, which is the overall government watchdog in the health sector.

Regulation of private health providers is entrenched in the country's statutes, which define the conditions and requirements for private healthcare provision. The main objectives of the statutes is control of entry into the medical profession, that is registration and licensing, control of standards and quality of health services provided by the practitioners, and public safety. Some basic regulation with respect to licensing for medical professionals such as physicians, nurses, and pharmacists also exists. To ease regulation, the government has created medical boards and councils of professionals who self-regulate their profession, including registration of medical facilities.

In Kenya, the Medical Practitioners and Dentists Board is responsible for approving registration of private hospitals and clinics and for overall supervision of the practice of medicine by qualified physicians and dentists in the country to ensure high quality service to consumers. However, there have been weaknesses in enforcement, attributed to limited funding available to professional bodies responsible for regulating the profession. Nevertheless, even if professional bodies were adequately resourced, it is argued that they can be reluctant to take disciplinary steps against their own membership and self-interest. In some instances, it has been noted that the Board has not publicized any cases of malpractice for fear of damaging the reputation of the profession.

Kenyan laws governing the private healthcare sector seem weak in regulating the quality of inputs. The laws only establish minimum standards of entry into the sector and the framework of exchange of services in the private health sector market. There are significant gaps in the laws affecting non-government healthcare providers, particularly those laws addressing the development of private practice by non-physicians. The laws are poorly enforced and therefore often do not have the desired effect (Berman *et al*, 1995). Problems associated with the private sector include medical malpractice and negligence;

unregistered persons practicing medicine and dentistry; misuse of the title 'doctor', which deceives the public; rapid increase of unlicensed and unregistered laboratories; unqualified persons working in laboratories; and sale of drugs over the counter in shops and by unlicensed street peddlers, among others. These problems result in poor service and inefficiency and may lead to escalation of costs.

Given the need for regulation of private healthcare providers, the government has left enforcement of the rules and regulations that govern the private healthcare providers to the bodies that monitor the medical profession. The use of formal regulatory mechanisms requires precise rules or incentives established and monitored by a regulatory body. Therefore, medical boards and councils have set up requirements for registration and licensing of these professionals.

### **3.2.1 Registration and Licensing of Medical Practitioners**

Medical practitioners are registered and licensed by the Medical Practitioners and Dentists Board, a legal entity established under Cap 253 of the Laws of Kenya. Registration as a medical practitioner under this Act or license entitles the person registered to practice medicine or dentistry or to render medical or dental services, as the case may be, in a salaried post under a government or local government health scheme or in such salaried posts in such institutions as the Board may approve from time to time. The amendment of Cap 253 in 1993 empowered the Board to oversee the training of doctors and dentists in all Kenyan universities in order to ensure high standards. To regulate the qualifications of those in the medical profession, certain requirements have been set. Kenyans are required to complete six years of university education and a one-year internship<sup>11</sup> in a large hospital.

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<sup>11</sup> Currently, the Medical Practitioners and Dentists Board recognizes about twenty internship-training centers, starting with Kenyatta National Hospital. Over the last five years, the Board has extended internship training from provincial hospitals to both missionary and district hospitals.

The Act outlines other requirements for persons eligible for registration as a medical practitioner. One must be a holder of a degree, diploma or other qualification recognized by the Board. As implied therein, it means that under this Act, pharmacists and traditional practitioners are not recognized as medical practitioners although they serve as sources of medical care. Pharmacists are only provided for under the Pharmacy and Poisons Act, not for private practice as medical practitioners but to engage in stocking and selling of drugs. Only Section 13 of the Medical Practitioners and Dentists Board provides for any other person to be registered as a medical practitioner even without meeting the provisions of this Act, but under the authority of the Director of Medical Services (DMS). Pharmacists and traditional healers are however not covered by this provision.

The Act clearly states the penalty for unregistered and unlicensed persons practicing, including misrepresentation. However, enforcement of some sections has been weak; some people practice under fake titles while some chemists and pharmacies, which offer consulting and dispensing services, misrepresent themselves as doctors with impunity. The Act clearly states that a person who willfully and falsely takes or uses any name, title or addition implying a qualification to practice medicine, surgery, dentistry, or who, not being registered or licensed under this Act, practices or professes to practice or publishes his name as practicing medicine or surgery or...and who, not being licensed under Section 15 of Cap 253, practices as a private practitioner shall be guilty of an offence.

### **3.2.2 Registration of Private Healthcare Practitioners**

A “private practitioner” is a person registered under Cap 253 as either a medical practitioner or a dentist, and who is also licensed to practice medicine or dentistry. Registration as a private practitioner allows doctors, dentists, and clinical officers to set own clinic or nursing home.



Eligibility for license to engage in private practice requires one to have worked in a salaried position under supervision in Kenya on full time basis in government or private hospital or in any non-profit making approved medical institution for a period of not less than three years. Doctors must be registered with their board, in this case the Kenya Medical and Dentists Registration Board (the prerequisite for which is the possession of a medical degree from an accredited institution and completion of a one-year internship program). One must also obtain a private practice license from the Medical Practitioners and Dentists' Board. Locum doctors must satisfy the same minimum private practice eligibility requirements. Private practice licenses are issued only in respect of premises and are not transferable among individuals or facilities. Licenses are issued in the first instance for one year and must be renewed annually. A "one doctor-one clinic" rule is in place, although a doctor can operate two clinics in rural areas. Separate licenses must be obtained for each clinic.

Doctors in private practice are required to keep an adequate stock of essential drugs and good records of all drugs. Their clinics can only include clinical and radiological laboratories if certain eligibility conditions are met; that is a qualified person must be employed to run the laboratory or the doctor himself must be qualified in the secondary discipline. Doctors are required to register their laboratory facilities separately, with minimum qualifications stipulated for those who work in private laboratories. However, poor enforcement of this requirement has contributed to rapid growth of laboratory facilities. Besides, the Medical Board only regulates training for doctors and dentists but not for the lower level cadres of the profession. This complicates regulation of medical services and may compromise the quality of services provided in some of the private facilities.

### **3.2.3 Registration and Licensing of Clinical Officers**

In 1989, the government began to grant clinical officers leave to run and operate own private clinics. The enabling law for this is the Clinical Officers Act, Cap 260 of 1989. This is an Act of Parliament making provision for training, registration and licensing of clinical officers and to regulate their practice and for connected purposes. This Act also stipulates that no clinical officer shall be entitled to render medical or dental services in Kenya as a clinical officer unless registered by the Clinical Officers Council. A person shall be entitled to registration if the Council is satisfied that the person has, among other things, successfully undergone a prescribed course of training at an approved training institution. In order to enter into private practice, clinical officers must have worked for at least 10 years. The effectiveness of enforcement of these requirements is questionable. The Council is empowered to take necessary disciplinary measures in cases of violations of professional conduct and discipline.

The Council issues clinical officers running private clinics with private practice licenses in respect of premises for one year in the first instance. The licenses are subject to annual renewals. The law also provides for regulation of opening and closing hours of the practice. Although there are no legal restrictions on the number of clinics a clinical officer can operate, the requirement that clinics can only be open when the clinical officer is physically present is an indirect restriction on the number of clinics a clinical officer can operate.

The Clinical Officers Act stipulates that a clinical officer licensed to engage in private practice shall only treat the ailments listed in the First Schedule of the Act. This is a list of diseases that a clinical officer in private practice may, where necessary, give initial treatment (as first aid) but shall not undertake to treat the diseases and ailments but refer the cases to the nearest doctor or practitioner. However, it seems that some clinical officers do not adhere to these rules. Some clinical officers

misrepresent themselves as “doctors” by treating most diseases including those not listed in the Schedule of Cap 260. Misrepresentation is an offence under the Medical Practitioners and Dentists Act, Cap 253.

### **3.2.4 Registration and Licensing of Nurses**

The Nurses Act, Cap 257, is the Act of Parliament that makes provisions for the training, registration, enrolment and licensing of nurses, to regulate their conduct and to ensure their maximum participation in the healthcare of the community and for connected purposes. Section 13 of the Act stipulates that any person<sup>12</sup> who satisfies the Nursing Council that he or she is of good character and has paid the prescribed registration fee, and who has undergone a prescribed course of instruction and has passed the appropriate examination conducted or prescribed by the Council be entitled to registration. In addition, the person should have undergone a course of training and passed an examination, elsewhere than in Kenya, which the Council recognizes as equivalent to the training and instruction required in the case of persons trained in Kenya and as equivalent to the qualification by examination required under this Act.

The Act is not categorical on the professional attainments, say a diploma or degree, as in other medical professions. This may give a leeway to registration of unqualified or under-qualified persons, with the consequences being borne by patients who are attended to by such a nurse. This is made worse by the fact that existing training institutions for nurses are not properly regulated. Nurses are expected to assist doctors in their day-to-day work, which implies that if their qualifications are not up to date, quality of services might be compromised. The Nursing Council of Kenya, with approval of the Minister for Health, is allowed to make regulations generally for

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<sup>12</sup> Includes nurses, midwives, community health nurses, psychiatric nurses, and sick children’s nurses.

carrying out of the provisions of this Act. The Council is therefore responsible for implementation of rules and regulations that govern the nursing profession. It is therefore empowered to take disciplinary or appropriate measures as may be necessary to maintain proper standards of nursing care in health institutions.

The Nurses Act, Cap 257, does not have any provisions for private practice by nurses. However, there are informal views that the minimum requirement for private practice by nurses should be at least 10 years of work experience (Berman *et al*, 1995).

### **3.2.5 Registration and Licensing of Pharmacists**

The pharmacy profession is controlled through the Pharmacy and Poisons Act, Cap 244, an Act of Parliament for control of drugs and poisons. Under the Act, “drug” includes medicine, medicinal preparation, or therapeutic substance. This Act provides the conditions for a person who is to qualify as a registered pharmacist. The basic requirement for the practice of pharmacy in Kenya is registration by the Pharmacy and Poisons Board, subject to possession of a degree from a recognized institution. The Board regulates the profession of pharmacy, registers pharmacists, gives power to pharmacists to sell poisons, and is responsible for taking disciplinary measures in cases of violation of professional conduct and discipline.

Cap 244 outlines the general restrictions for unregistered persons. However, there is a controversial section in the Act, which may be misused by other drug dealers. The section says that “nothing shall make it unlawful for any person to sell any non-poisonous drug provided that such drug is sold in its original condition as received by the seller or to require such person to be registered as a pharmacist”. It is not clear from this section whether this allows shops, kiosks and other vendors to sell drugs and medicines. The Act, however, categorically

states that no other person other than those authorized to import, possess, distribute, sell, or purchase Part I Poisons under the Act shall import, possess, distribute, sell, or purchase any drug.

Many types of drugs are usually sold in shops, drug stores and by street peddlers. These groups of providers are not licensed to sell prescription drugs yet it is common to freely purchase antibiotics at street corners and from various kiosks. Selling of some drugs over the counter is normally not allowed. Cap 244 gives power only to a person licensed to deal as a wholesale dealer in poisons to sell Part I poisons. However, some clauses of the Act prohibit such dealing unless a registered pharmacist is in direct control of the premises where the poisons are sold. However, this does not happen in most pharmacies because some of them employ doctors, while others engage clinical officers and nurses in the running of the pharmacy. Some pharmacists also misuse the title “doctor”<sup>13</sup>. Under Cap 260, a clinical officer licensed to engage in private practice is only allowed to handle and issue prescriptions for specific drugs and equipment listed in the Second Schedule of the rules of the Act, and may therefore not provide such services in a pharmacy.

The Minister for Health is empowered under Cap 244, after consulting the Central Board of Health, to prohibit sale by retail of a specified Part I poison and to prohibit, regulate or restrict the sale of Part II poisons. The Minister is also empowered to prohibit, regulate or restrict the manufacture, sale, or advertising of drugs, etc. Therefore, the Minister and the Board have enormous responsibility in regulating the practice of pharmacy and trade in drugs. This is also consistent with the Public Health Act, which the local authority implements in conjunction with the Central Board of Health.

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<sup>13</sup> According to the Medical Practitioners and Dentists Board newsletter of November 2002, the Board is pursuing those pharmacists and others who call themselves “doctor”. According to the publication, the matter has been lodged in the High Court for interpretation and/or determination.

### **3.2.6 Registration and Licensing of Pharmaceutical Technologists**

Pharmaceutical technologists are a new phenomenon in the private practice of the medical profession in Kenya. These are pharmacy equivalent of clinical officers, registered with the Ministry of Health. There are no laws regulating this practice yet, although pharmacists engage these technologists or even run independent pharmacies and chemists. Lack of clear regulations for this profession exposes consumers to risk arising from negligence and malpractices from these healthcare service providers.

### **3.2.7 Registration of Traditional Healers**

Traditional medicine includes a diversity of health practices, approaches, knowledge, and beliefs incorporating plant and animal-based medicines, together with spiritual therapies applied singly or in combination to maintain well being, as well as to treat, diagnose, or prevent illness (WHO, 2001). The comprehensiveness of the term “traditional medicine” and the wide range of practices it encompasses make it difficult to define or describe. Although the Ministry of Health recognizes that traditional healers provide services to a varied group of Kenyans, the Ministry appears to be indifferent towards traditional healers.

Traditional health practitioners appear to have been ignored in health management. There is very little communication between traditional healers and the Ministry of Health, and/or with the “modern sector”. The process of incorporating traditional practitioners into the health system has taken a long time. According to WHO (2001) traditional medicine started being incorporated into Kenya’s national health policy framework in the late 1970s. This continued into the 1980s, with the National Development Plan 1989-1993 recognizing traditional medicine and making a commitment to promote the welfare of traditional medicine practitioners.

A registry of traditional healers was opened in 1994 in the Ministry of Culture and Social Services. To be registered, a traditional healer was expected to pass two examinations administered by the Ministry. This process did not take off because the Ministry of Health did not commit to recognize traditional healers as medical providers after such a process of registration. Traditional healers therefore still operate under conditions and environments that are suspect, yet they continue to play a significant role in health provision, especially to the poor.

The Ministry of Health in May 2003 issued a directive that made it mandatory for all foreign practitioners of traditional, complementary, or alternative medicine in Kenya to register their clinics in conformity with the Public Health Act. This forced some practitioners who were running the mushrooming and lucrative Chinese and Indian herbal clinics to close down. This came after authorities discovered that unscrupulous practitioners were fleecing unsuspecting patients of their money. Currently, foreign practitioners are required to get letters from their local embassies, verifying their credentials and copies of their certificates translated in English and delivered to the Ministry of Health. Traditional and complimentary medical products imported into the country are required to be registered as per the Pharmacy and Poisons Act, Cap 244. A draft traditional healthcare practitioners' Bill by the government prohibits them not to use the prefix "Dr".

### **3.3 Licensing of Health Facilities**

Kenya law distinguishes between private health provision by sole or group practices and private provision by institutions such as hospitals and nursing homes. There are only minimal conditions that must be met before a hospital can be established, but there is no restriction on the number of facilities that any formally-incorporated hospital can operate. The Medical Practitioners and Dentists Act, Cap 253, of the Laws of Kenya defines what constitutes the different health institutions:

- “Hospital” means an institution, which has, in addition to resident medical practitioners or dentists, an operating theatre and a mortuary. Many health institutions do not usually meet this condition, and these can therefore be accused of misusing the name, which is an offence under Cap 253 on misrepresentation.
- “Clinic” is defined as consulting rooms, offices, or an outpatient department without beds used by a practitioner for diagnosis and treatment of disease or giving of medical or dental advice and instructions.
- “Nursing home” is defined as any premises, howsoever named or described, which are used for the reception of, and for provision of medical care and nursing for, persons suffering from any sickness, injury, or infirmity, and having a mortuary and an outpatient department, but does not include premises maintained or directly controlled by the government or a local authority.

The Medical Practitioners and Dentists Board is supposed to approve all the premises used as private clinics. A license for private clinic is issued subject to minimum conditions for the premises. The conditions include well-maintained premises, kept reasonably secure from unauthorized entry, and the premises must not be a residential building except with special permission from the Board. Nevertheless, there are many health clinics situated in residential buildings without clearance from the Board.

### **3.3.1 Licensing of Hospitals**

Private hospitals are responsible for enforcing the provisions of the law as they apply to individual doctors and:

- Must submit the list of all general practitioners and dentists in their employment every six months;



- Are also required to submit another list of all general practitioners to whom they have granted admitting privileges and the location of the primary places of practice of these individuals;
- Private nursing homes and hospitals must also ensure that doctors in their employment do not practice in areas outside their competency (except in cases of emergency).

Unfortunately, diversity of the private health sector due to usage of a confusingly wide array of terminology has made it hard to make them account for all their activities. Not all health facilities submit annual returns to the Health Information System as required. The response rate is low, besides the fact that there is confusion over the coding and classification of health facilities.

### **3.3.2 Licensing of Clinics**

In addition to the definition given in Cap 253 of what a clinic should constitute, the third schedule of the Clinical Officers Act contains the minimum requirements for registering a private clinic. These requirements relate to the physical conditions to be met and include:

- Spacious consultation room;
- Waiting room covered from sun, rain and wind;
- Treatment room;
- Access to road transport;
- Access to lavatory.

A private practitioner cannot be licensed to operate more than one private clinic, although the Medical Practitioners and Dentists Board can allow this if both clinics are situated in a rural area. Nevertheless, the rule does not clearly define what the coverage of the rural area is or how far apart the clinics should be, in case the doctor will be servicing both clinics.

There are also discrepancies in the minimum level of amenities a clinic must possess. Clinics run by physicians are required to have a higher level of facilities than those run by nurses and clinical officers. However, there seems to be no justification for such regulatory requirements, an explanation of how they will be enforced, or the benefits of such regulation.

### **3.3.3 Licensing of Pharmacies**

Practice in pharmacy in Kenya appears to be treated as a non-medical service. Pharmacies are registered and licensed to sell prescription and over-the-counter drugs. Unlike in the cases of doctors and clinical officers, there are no laws regulating the conditions under which pharmacists can set up private practice as medical practitioners. Existing health laws only regulate the activities of medical practitioners. However, experience shows that most patients go directly to pharmacies for consultation. Therefore, pharmacies serve as one-stop providers of healthcare, transforming themselves from mere places where prescription drugs are dispensed to places where drugs are actually prescribed. One important regulation for pharmacies in Kenya is the one that prohibits pharmacists from falsely representing the efficacy of drugs. Since patients visit pharmacies for both diagnosis and prescription of medicine, there seems to be a strong justification to regulate the activities of pharmacists like other medical practitioners to ensure safety of patients and other consumers.

The Medical Practitioners and Dentists Act, Cap 253 of the Laws of Kenya stipulates that no premises may be habitually used for the purposes of private healthcare practice unless the Medical Practitioners and Dentists Board authorizes it for such use. Beside the premises, pharmacists may be guilty of misrepresenting themselves as medical practitioners, an offence also under Cap 253. It might be necessary to put in place some

procedures for regulating pharmacies as healthcare providers, instead of the current regulation where they are treated as private businesses.

### **3.4 Weaknesses in the Regulations**

The laws and regulations governing private healthcare provision in Kenya have gaps that could compromise the quality of services provided in some private facilities. For instance, there has been a rapid increase in the number of private laboratory facilities operated out of doctors' offices. Although doctors are required to register their laboratory facilities separately, and there are minimum qualifications stipulated for those who work in private laboratories, there has been little enforcement of this requirement. In addition, there have been concerns about the ethical and quality implications of the increase in the number of laboratories operated by private doctors. Where these facilities are not separately registered, regular inspection by qualified laboratory personnel and monitoring of the quality of tests performed is difficult.

Other than control of entry and distribution of drugs in Kenya, there are no strong controls on pricing. Healthcare providers are left free to establish their own prices. Further, there seems to be no requirements for in-service training and refresher training in order to update the skills of physicians. The medical board is only empowered to oversee the training of medical practitioners only in Kenya's universities, and this does not include continuous medical education. Medical knowledge of most practitioners may not be up-to-date due to lack of a legal requirement for continuous updating of medical knowledge and skills. With the challenge of emerging new diseases, a practitioner may easily become limited in application of new methods of diagnosis and treatment and continue using outdated medical technology, leading to errors. The medical board therefore needs to come up with legal requirements for evidence of continuous training before renewing the practitioners' licenses each year.

Nyangena (2000) argues that the high quality training that has been producing high-class personnel in Kenya is threatened by the quarter system of intake, which is based on regional considerations rather than merit. The increased commercialization of university education programs, which allows less qualified people to join medical and other professional training, may compromise the quality of medical personnel. Further, lack of legal recognition for the Kenya Medical Association (KMA), which could have served to protect the integrity of the medical profession, may compound the problem of quality. The Association can only enforce rules to its members and not to other medical professionals because registration with the professional board is not mandatory.

Evidence from developed countries shows that quality of health institutions has helped victims of HIV/AIDS acquire the necessary information and prescriptions because health facilities have qualified people who are able to provide guidance on proper prescriptions. This is not happening in developing countries like Kenya, mainly due to unavailability of qualified personnel and lack of enforcement of regulations. Health laws do not seem to be designed to protect the patient from negligent doctors or those whose skills have atrophied. Although malpractices such as caesarean births designed to charge a patient more money, poor surgical operations resulting to complications or death, wrong prescriptions, etc are regularly reported, the Medical Practitioners and Dentists Board has not taken necessary disciplinary measures in most cases.

Practice in pharmacy in Kenya appears to be treated as a non-medical service. However, the role of pharmacies in diagnosing and prescribing treatment appears to be rising rapidly. Pharmacies are providing both health consultations and advice to patients, though it is not legally clear whether they should engage in clinical practices, and go by the title "Doctor". Increasing numbers of Kenyans go to pharmacists for medical

treatment and advice, probably as a substitution effect.<sup>14</sup> The legal gaps on the role and activities of consulting pharmacists should be filled in order to protect patients.

Evidence from low and medium income countries on the impact of drug regulations is quite alarming. Kumaranayake (1998) notes that while deregistered drugs are sometimes successfully withdrawn from the majority of outlets, black-marketing of the products sometimes continues due to lack of inspection and monitoring. Pharmaceutical companies themselves seem to determine the extent and pace of withdrawal of these drugs.<sup>15</sup> Regulatory intervention accompanied by efforts to change the attitudes and prescribing habits of physicians is critical in this area.

Traditional health practitioners have not been catered for in modern health laws. The argument has been that their role has been overshadowed by the advent of modern medicine. However, traditional healthcare practitioners are a source of healthcare for many people, and especially the poor. Herbal systems of medicine are sometimes opted for due to easy accessibility, non-availability of modern medical facilities, low treatment costs, and faith of people in the healing capacity of herbs. Nevertheless, their efficacy and effectiveness remains a controversial issue. Most of them are not reliable, although they provide an alternative in healthcare.

Another controversial issue is the registration of traditional health practitioners by the Ministry of Culture and Social Services. The argument is that traditional practitioners are performing cultural

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<sup>14</sup> With introduction of cost sharing in government facilities, and rising charges in private facilities, many Kenyans are substituting out of visits to formal health facilities in favor of less expensive pharmacies to avoid consultation fee.

<sup>15</sup> Due to this, Wangombe *et al* (1998) argue for the need to design mechanisms to safeguard against misuse of drugs and pharmaceuticals, and dumping of low quality and expired drugs.

practices, which are governed through the African Customary Law. This limits the registration of the traditional practitioners under the Ministry of Health, as their practices are considered cultural. Nevertheless, when it comes to malpractices, the African Customary Law is limited in the application of justice. It is only applicable in civil cases where one or more of the parties are subject to it, so far as it is applicable and is not repugnant to justice and morality or inconsistent with any written law. Therefore, it cannot be a defence for a traditional practitioner to harm a person just because it is a customary practice.

The recognition of traditional health practitioners through the African Customary Law creates conflict with modern law in terms of regulation of their activities. For instance, under modern law, medical doctors are not allowed to advertise their services. However, traditional health practitioners do it with impunity. This impartiality in application of law is not healthy for the patients especially given the misrepresentation<sup>16</sup> of traditional practitioners as 'doctors'. Traditional 'doctors' purport to heal even chronic diseases, which over the years have defied conventional clinical management. The truth about this has not been ascertained and it has always seemed that the claim is used as a marketing tool for their services. Advertisements are sometimes false, fraudulent, deceptive, or misleading. They are likely to create false or unjustified expectations in a prospective patient. Given that they are not regulated by the Ministry of Health, and are also not registered by the Medical Practitioners and Dentists Board, their actions are never seen as a crime under the laws that govern modern medical practice. However, continuation of this behaviour is to the detriment of healthcare consumers.

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<sup>16</sup> Misrepresentation constitutes a fraud, which is an intentional tort. This applies especially to a physician who promises that a procedure will cure a patient when he knows it will not.

### **3.5 Consequences of Poor Regulation**

Laws for self-regulation of healthcare professionals, regulation of health facilities, and tort laws provide the legal framework on the health delivery system. The laws governing medical councils and boards show that these bodies have failed to use the laws to establish their monopoly for regulation of medical care. This has left the consumers of health services unprotected.

According to IEA (1998), the prevailing legal regime on healthcare is largely inadequate and inefficient. On provision of services, there are no laws to protect patients against negligent healthcare staff, including doctors. The physicians are not legally required to update their skills with a view to providing quality services. Weak enforcement and monitoring in the health system is evident from the increase in the number of the following cases:

- (i) Consultants failing to meet their contractual obligations;
- (ii) Offences regarding loss, misuse, or diversion of health funds to other uses;
- (iii) Unlicensed and unregistered laboratories;
- (iv) Uncertified or banned drugs being offered for sale locally; and
- (v) Unrestricted practice of companies providing drug samples to medical practitioners.

Table 3 lists the main laws that regulate the medical practitioners, the enforcement bodies, and the consequences arising due to the weakness in regulation.

**Table 3: Observed consequences of poor regulation**

<b>Act: Public Health Act, Cap 242</b>	
<b>Main enforcement agency:</b>	Central Board of Health (CBH)
<b>Other enforcers:</b>	Ministry of Health; Local Authorities
Observed consequences of poor regulation:	
<ul style="list-style-type: none"> <li>• Mushrooming of unregistered clinics;</li> <li>• Poor physical healthcare infrastructure;</li> <li>• Poor equipment or inappropriate technology;</li> <li>• Medical malpractices and negligence;</li> <li>• Low health standards;</li> <li>• Corruption and poor inspection; and</li> <li>• Use of unapproved premises for provision of medical services.</li> </ul>	
<b>Act: Local Government Act, Cap 265</b>	
<b>Main enforcement agency:</b>	Local Authorities
<b>Other enforcers:</b>	Ministry of Local Government
Observed consequences of poor regulation:	
<ul style="list-style-type: none"> <li>• Lack of strict enforcement of laws governing public health officers;</li> <li>• Poor inspection of health facilities;</li> <li>• Corruption during inspections.</li> </ul>	
<b>Act: Medical Practitioners and Dentists Act, Cap 253</b>	
<b>Main enforcement agency:</b>	Medical Practitioners & Dentists Board
<b>Other enforcers:</b>	Ministry of Health
Observed consequences of poor regulation:	
<ul style="list-style-type: none"> <li>• There seems to be partial enforcement of regulations;</li> <li>• No laws requiring physicians to update their skills;</li> <li>• No clear laws to protect patients against negligent health staff including doctors;</li> <li>• Unregistered clinics run by quacks, which threaten the general well-being of the population;</li> <li>• Unregistered persons practicing medicine and dentistry;</li> <li>• Misuse of the title 'doctor', which may deceive the public;</li> </ul>	



- Rapid increase in unlicensed and unregistered laboratories;
- Unqualified persons working in laboratories;
- Use of a wide range of terminologies;
- Reluctance of disciplining irate practitioners/colleagues;
- Corruption and unreliability during licensing and inspection process;
- Private health facilities operating without meeting all the requirements;
- Doctors operating more than one clinic against the law.

**Act: Pharmacy and Poisons Act, Cap 244**

**Main enforcement agency:** Pharmacy and Poisons Board

**Other enforcers:** Ministry of Health; Central Board of Health; Police; Medical Practitioners and Dentists Board

Observed consequences of poor regulation:

- Pharmacists practicing and going by the title 'doctor';
- No laws regulating the conditions under which a pharmacist can set up private practice in medicine;
- No laws regulating practice by pharmaceutical technologists;
- A market flooded with substandard medicines;
- No price controls for drugs;
- Expired drugs finding their ways to the market;
- Uncertified or banned drugs being offered for sale locally;
- Unrestricted practice of companies providing drug samples to medical practitioners;
- Sale of drugs over the counter in shops and by unlicensed street peddlers;
- Use of unapproved premises for provision of medical services.

**Act: Clinical Officers Act, Cap 260**

**Main enforcement agency:** Clinical Officers Council

**Other enforcers:** Ministry of Health; Central Board of Health; Medical Practitioners and Dentists Board

Observed consequences of poor regulation:

- Slow pace of instilling discipline to officers in the field;
- Clinical officers operating more than one clinic;

<ul style="list-style-type: none"><li>• Clinical officers misrepresenting themselves as doctors; and</li><li>• Treatment of ailments other than those they are supposed to (e.g. tetanus, cancer, diabetes, typhoid fever, etc).</li></ul>	
<b>Act: Nurses Act, Cap 257</b>	
<b>Main enforcement agency:</b>	Nursing Council of Kenya
<b>Other enforcers:</b>	Ministry of Health; Local Authorities; Medical Practitioners & Dentists Board
Observed consequences of poor regulation:	
<ul style="list-style-type: none"><li>• Lack of rules for private practice by nurses; and</li><li>• Lack of clear educational attainment for nursing qualifications.</li></ul>	

*Source: Generated from reviewed literature*

### **3.5.1 Medical Ethics and Malpractices**

Poor enforcement of the laws that govern private healthcare providers is also a result of poor development of tort law in Kenya, which defines the morals and ethics of professions.<sup>17</sup> A tort is a civil wrong which gives rise to an action at common law for unliquidated damages, although in some cases other remedies may be required such as an injunction or specific restitution. The right of action in tort springs from the breach of duty, created either by common law or statute. As Jackson (1988) notes, as a general rule, motive is not relevant in deciding whether a person is liable in tort. When a doctor carries out a surgery that leads to death or leaves a surgical instrument in a patient's stomach that cause harm, the surgeon is liable for negligence even though the motive was well intended.

Medical errors which can amount to negligence include: a surgeon damaging an organ or failing to tie off a blood vessel; a nurse picking a medication and reading it incorrectly, therefore giving the wrong dose or giving a dose to the wrong patient (this can usually happen due to handwriting prescriptions among other things); misreading of an x-ray; or failure to carry out a test on a patient. Various malpractices and medical errors are documented in developed countries. However, in developing countries like Kenya, such cases remain allegations.

Medical ethics is the code that governs the physician's conduct vis-à-vis colleagues and patients. Historically, physicians were the ones who formulated such codes (for example the Hippocratic oath<sup>18</sup>). Medical ethics deal with problems in clinical practice and medical research.

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<sup>17</sup> Tort law in Kenya is not well developed for medical cases. Given that tort law is created through judges (Common law), there are very few precedents in Kenya for medical malpractice and negligence to strengthen our tort laws.

<sup>18</sup> This oath has formed the basis of more recent medical oaths taken by students as they begin the practice of medicine. The chief tenets of this oath are among others: honor instructions in the medical arts; practice for the benefit of patients; give no deadly medicine or substance to produce abortion; abstain from mischief and corruption; doctor-patient confidentiality.

Although medical ethics are supposed to play a very big role in promoting quality healthcare, lack of appropriate malpractice laws may compromise healthcare services. Medical malpractice includes misdiagnosis of or failure to diagnose a medical condition; failure to administer medications properly; failure to properly treat a patient's medical condition; and failure of a nurse or other health personnel to keep a treating physician informed of a patient's condition.

In *Chester versus Afshar*<sup>19</sup>, the motive of the surgeon was not an evil one. However, the surgeon was found guilty of negligence for failing to inform the patient the likely dangers of an operation he was about to undergo. Chester suffered from back pain and consulted Afshar, an eminent neurosurgeon. Chester was keen to avoid surgery but Afshar recommended an operation to remove three discs. The risk associated with the operation was 1-2% of nerve damage even if carried out correctly, with the consequences of nerve damage ranging from minor effects to paralysis. Chester consented but unfortunately suffered nerve damage with very serious consequences. The trial judge and even the appeal judge awarded damages to Chester. The observation made was that Afshar had performed the operation competently, but had negligently failed to warn Chester about the risk of nerve damage. It was also ruled that if Afshar had warned Chester, then she would not have undergone the operation when she did; she might have consented to it at a later date. What makes Afshar to be found guilty of negligence is not negligently creating a risk, but the failure to tell her about it. It was therefore argued that giving such information to patients better protects their autonomy and dignity as human beings.

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<sup>19</sup> This case was downloaded on 3 October 2003 from the site:  
<http://www.cwx.prehnall.com/bookbind/pubbooks>

In India, a group known by the name Medico Friend Circle actively helps victims of medical malpractice. This group has taken the task of articulating people's grievances against what is seen as growing arrogance of medical providers and their refusal to be socially accountable and sensitive. Besides organizing seminars, the group files litigation on the issues arising from the cases. This started after issues were highlighted about suffering, struggles, and frustrations of relatives of victims of medical malpractice. These cases highlighted the domination of private sector in healthcare delivery and virtual absence of regulation over it, lack of strong ethical framework for monitoring doctors' conduct, and lack of understanding of tort laws and consumer protection. These observations show the need for the government to protect the patients' rights and enforce the observance of medical ethics. However, patients' rights and ethics should not be reduced to simple market regulatory phenomenon but should emerge as the basis for empowering people in healthcare provision.

### **3.5.2 Malpractices by Pharmacists**

Competition in the pharmaceutical industry is very stiff due to proliferation of pharmacies and shops selling drugs countrywide. However, salaried personnel who are not qualified to handle prescriptions operate most of these pharmacies, and yet most customers who visit these drugs outlets request for medicine without a prescription. Patients bargain with the attendants for options that match their purchasing power, and the attendants suggest various options such as buying only a few drugs that are necessary, or are within the patient's budget. This is not only unhealthy to the patient but is also illegal and adversely affects those with chronic diseases. Such actions by pharmacies amounts to malpractice and are liable to penalty. Pharmacists are supposed to sell drugs against a prescription from a qualified medical practitioner.

The proliferation of drug outlets has also led to development of a chain of commissions from pharmaceutical companies, to wholesalers and retailers. Pharmaceutical companies give various incentives such as commissions, cash discounts, credits and bonuses to their wholesale buyers and retailers. Pharmacists will most likely enquire for existence of such schemes even before getting to know about the merits of the drugs. Malpractice by pharmacists also takes the form of gift offers to doctors so that they can direct patients with prescriptions to their premises. Other doctors and pharmacists work in partnership with medical representatives to promote pharmaceutical products with no guarantee for quality. Some physicians also own or have interests in some pharmacies, and this is likely to lead to exploitation of patients. Therefore, the retail medicine business has become very lucrative for various players. Lack of enforcement of morals and ethics in the medical profession has made most players in the pharmaceutical business to be more profit oriented, disregarding the legal requirements such as licensing and qualifications required to run the businesses. Marketing and promotion in the pharmaceutical industry needs to be reviewed and regulated as it indirectly promotes malpractices such as irrational prescription of drugs. Mass marketing of products increases the population's exposure to potentially injurious products and substances.

In summary, experiences from developed countries show that the objective of universal healthcare cannot be achieved until the private and public sectors are brought under the purview of law. There is urgent need for legislation aimed at consumer protection against medical malpractices in Kenya. Legislation plays an important role in formalizing the state policy and guaranteeing a certain amount of stability in the health policies of the government.

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## 4. Conclusion and Recommendations

The importance of private healthcare provision has increased due to reduction in allocation of financial resources to the public healthcare sector by the government. However, the legal and regulatory requirements for private healthcare provision in Kenya have not been adequately addressed. For instance, the Central Board of Health, whose critical role is to advise the Minister for Health on all matters related to health has never been constituted, therefore leaving a vacuum in control and monitoring of the activities of the private healthcare sector. The Medical Practitioners and Dentists Board, which is empowered to be the overall regulator of all medical practitioners, has not strongly enforced disciplinary action on those involved in malpractices and negligence. Laws governing healthcare provision in Kenya are not adequately enforced to the extent that pharmacies offer medical consultancy and many people seek medical care in pharmacies for both consultation and prescriptions. Lack of recognition of pharmacies as healthcare providers has left them unregulated, therefore exposing patients to various dangers.

Greater and impartial enforcement of regulations is urgently needed to improve confidence in the private healthcare sector in Kenya. Existing laws and statutes cover most of the areas of concern in the health sector (licensing of practitioners, premises, and sale of drugs). However, lack of enforcement or capacity to enforce the laws by the Central Board of Health, the local government (for Public Health Act), the Medical Practitioners and Dentists Board, the Pharmacy and Poisons Board, the Clinical Officers Council, and the Nursing Council of Kenya is one of the problems facing the development of the health sector. Therefore, the laws need to be reviewed to fit in the modern context of medical care provision, to guarantee the constitutional right to healthcare, and to promote healthcare practice by all providers. There is therefore need for a comprehensive healthcare law that provides clear guidelines to

the sector as required, and encourages proper development of private healthcare practice by physicians.

A comprehensive review of the health sector in Kenya should aim at:

- Reinforcing regular certification of health facilities;
- Ensuring continuous education training and updating of medical skills and knowledge by health practitioners;
- Building government capacity to monitor quality in both the public and private healthcare sectors, improve it overall, and take action to remedy problems; and
- Developing clear laws that outline the boundaries of private healthcare practice by the various practitioners, including clinical officers, nurses and pharmacists;

More specifically, there is need for the Ministry of Health to:

- Improve the regulatory mechanism in order to keep a check on the malpractices in the pharmaceutical industry, and create public awareness on the activities and requirements of the industry; and
- Ensure that shop attendants in pharmacies and the pharmaceutical industry in general are appropriately educated and trained and have appropriate knowledge of the drugs that they dispense.

The existing licensing Acts need to be amended to ensure that all categories of private healthcare practitioners, including traditional practitioners, are licensed through one umbrella body. This will improve efficiency and monitoring of the qualifications of persons seeking registration to ensure safety of the public. Current laws regulating non-governmental health providers offer limited protection for consumers. However, enhancement of the regulatory role of the bodies must be accompanied by a careful analysis of the resources and capabilities required of these bodies. In this regard, it may be useful to:



- Take functional units of the boards/councils to the district level;
- Amend the licensing and registration provisions in the laws related to boards/councils to ensure equitable distribution of healthcare facilities and professionals in all parts of the country;
- Make the boards/councils transparent especially for public scrutiny;
- Develop continuing education and training opportunities for private providers, review and develop input standards, and monitor output facilities; and
- Re-evaluate the certification mechanisms of, and the roles played by traditional healers and practitioners in order to bring them into the public health debate and use their services, where such services complement and extend coverage of the modern healthcare system.

Further, the government should:

- Put in place mechanisms to ensure that laws are enforced by the relevant bodies;
- Build precedents for tort by educating the public about their rights as regards medical malpractice and negligence. The government should be responsible for informing the public about the rights of patients and the actions that can be taken when these rights are violated. This will strengthen the tort law in Kenya;
- Increase the availability of information to the public regarding qualifications of healthcare providers, and restrictions on their clinical practice;
- Provide enough support to the local government for enforcement of the Public Health Act, Cap 242; and
- Explore other ways of enforcing the Public Health Act, Cap 242, given that the local government is a player in healthcare provision. There

may be need to review the legal elements local government should enforce and those to be enforced by other bodies that are not an interested party in the provision of healthcare.

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**Annex: Number of health facilities and health professionals in Kenya (1981-2003)**

	1981	1982	1983	1984	1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003
Hospitals	221	220	216	213	243	249	254	260	264	268	277	301	308	324	346	387	398	420	449	481	500	514	526
Health centers	262	276	288	293	269	276	282	294	294	299	357	477	569	562	522	548	566	579	593	601	611	634	649
Sub-health centers & dispensaries	1130	1135	1213	1273	1173	1424	1535	1553	1555	1564	1712	1859	2267	2868	2925	3058	3105	3146	3193	3273	3310	3351	3382
<b>Total</b>	<b>1613</b>	<b>1631</b>	<b>1717</b>	<b>1779</b>	<b>1685</b>	<b>1949</b>	<b>2071</b>	<b>2107</b>	<b>2113</b>	<b>2131</b>	<b>2346</b>	<b>2637</b>	<b>3144</b>	<b>3802</b>	<b>3993</b>	<b>4069</b>	<b>4145</b>	<b>4235</b>	<b>4355</b>	<b>4466</b>	<b>4499</b>	<b>4557</b>	<b>4557</b>
<b>Doctors</b>	<b>2057</b>	<b>2151</b>	<b>2366</b>	<b>2591</b>	<b>2842</b>	<b>2980</b>	<b>3071</b>	<b>3176</b>	<b>3266</b>	<b>3357</b>	<b>1457</b>	<b>3554</b>	<b>3794</b>	<b>3895</b>	<b>3855</b>	<b>3971</b>	<b>4078</b>	<b>4242</b>	<b>4411</b>	<b>4506</b>	<b>4630</b>	<b>4740</b>	<b>4813</b>
<b>Dentists</b>	<b>197</b>	<b>239</b>	<b>289</b>	<b>331</b>	<b>384</b>	<b>441</b>	<b>492</b>	<b>527</b>	<b>561</b>	<b>596</b>	<b>631</b>	<b>664</b>	<b>664</b>	<b>630</b>	<b>655</b>	<b>685</b>	<b>704</b>	<b>715</b>	<b>734</b>	<b>746</b>	<b>763</b>	<b>761</b>	<b>772</b>
<b>Clinical officers</b>	<b>1723</b>	<b>1821</b>	<b>1921</b>	<b>2001</b>	<b>2107</b>	<b>2224</b>	<b>2355</b>	<b>2464</b>	<b>2534</b>	<b>2630</b>	<b>2675</b>	<b>2786</b>	<b>2913</b>	<b>1644</b>	<b>2950</b>	<b>3085</b>	<b>3232</b>	<b>4007</b>	<b>4277</b>	<b>4492</b>	<b>4610</b>	<b>4778</b>	<b>4804</b>
<b>Pharmacists</b>	<b>84</b>	<b>86</b>	<b>113</b>	<b>131</b>	<b>231</b>	-	<b>362</b>	<b>388</b>	<b>413</b>	<b>443</b>	<b>472</b>	<b>542</b>	<b>605</b>	<b>1260</b>	<b>1357</b>	<b>1447</b>	<b>1539</b>	<b>1629</b>	<b>1650</b>	<b>1682</b>	<b>1758</b>	<b>1866</b>	<b>1881</b>
<b>Registered nurses</b>	<b>6892</b>	<b>7675</b>	<b>8547</b>	<b>9165</b>	<b>9377</b>	<b>9627</b>	<b>9862</b>	<b>10009</b>	<b>10289</b>	<b>5441</b>	<b>10700</b>	<b>5879</b>	<b>6210</b>	<b>6719</b>	<b>6920</b>	<b>7115</b>	<b>8006</b>	<b>8339</b>	<b>8671</b>	<b>9211</b>	<b>9392</b>	<b>9753</b>	<b>9869</b>
<b>Enrolled nurses</b>	<b>9190</b>	<b>9518</b>	<b>10168</b>	<b>10650</b>	<b>11248</b>	<b>12452</b>	<b>13202</b>	<b>14078</b>	<b>15200</b>	<b>17734</b>	<b>18674</b>	<b>19604</b>	<b>20993</b>	<b>21147</b>	<b>22347</b>	<b>23512</b>	<b>24602</b>	<b>25803</b>	<b>22073</b>	<b>27902</b>	<b>28420</b>	<b>29094</b>	<b>30212</b>
<b>Pharmaceutical technologists</b>	<b>326</b>	<b>359</b>	<b>395</b>	<b>427</b>	<b>459</b>	<b>493</b>	<b>494</b>	<b>526</b>	<b>559</b>	<b>604</b>	<b>644</b>	<b>680</b>	<b>720</b>	<b>660</b>	<b>885</b>	<b>957</b>	<b>1047</b>	<b>1137</b>	<b>1167</b>	<b>1232</b>	<b>1321</b>	<b>1399</b>	<b>1405</b>

Source: Kenya Economic Surveys (various issues)