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Strengthening the Regulatory Framework for Private Healthcare Providers in Kenya

Private healthcare provision has grown from a few providers at independence to about 2,640 by 2004. This growth can be 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. Many doctors resigned from government services after their part-time licenses were withheld. The policy was later modified to allow specialist doctors to engage in part-time private practice but junior doctors were denied this opportunity. This change of rules governing private practice of government health officials led to setting up of different health institutions ranging from clinics to hospitals.

The private healthcare sector contributes significantly to delivery of healthcare. Private clinics, pharmacies, nursing homes and traditional practitioners have come up in most urban and rural areas. However, they have operated in an unregulated environment, sometimes with unqualified personnel and in unlicensed facilities. The private facilities have been driven mostly by the profit motive, especially so because after the introduction of structural adjustment programmes, the private facilities became the preferred choice due to the perceived higher quality of services. Lack of resources by the regulatory bodies and the close relationship between members of regulatory bodies and those they are expected to regulate may be blamed on improper regulation.

Due to weaknesses in the legal and regulatory framework for private healthcare provision in Kenya, there have been concerns that unregistered persons are practicing medicine and dentistry, some misusing the title 'doctor' to deceive the public. There has been a rapid increase of unlicensed and unregistered laboratories, unqualified persons working in laboratories, cases of malpractice and negligence, and sale of drugs over the counter in shops and by unlicensed street peddlers. This has been blamed on the lack of capacity to enforce laws by the medical bodies; conflict of interest in the regulatory agents; lack of clarity in the laws; withering skills due to absence of refresher courses, and hence frequent medical errors; and unregulated traditional practitioners.

Weaknesses in the Regulatory Framework

The regulatory bodies in private healthcare provision include the Ministry of Health, Central Board of Health, Medical Practitioners and Dentists Board, Clinical Officers Council, Nursing Council of Kenya, and the Pharmacy and Poisons Board. As these bodies regulate specific but sometimes overlapping areas, the weaknesses relate to both practitioners (medical practitioners, pharmacists, clinical officers, nurses, and traditional healers) and the facilities (hospitals, clinics, and pharmacies). Some of these weaknesses in the laws are highlighted below.

Practitioners

Medical practitioners

A "private practitioner" is legally defined as a person registered under the Medical Practitioners and Dentist Act, Cap 253 of the Laws of Kenya, as a medical practitioner or dentist. Registration as a private practitioner allows doctors, dentists, and clinical officers to set own clinics or nursing homes. To be registered as a medical practitioner, one must be a holder of a degree, diploma or other qualification recognized by the Medical Practitioners and Dentists Board, among other things. Under the Act, pharmacists and traditional healers 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 as medical practitioners, to engage in stocking and selling of drugs. Only Section 13 of Cap 253 provide that any other person may be registered as a medical practitioner even without meeting the provisions of this Act, but under the authority of the Director of Medical Services. Pharmacists and traditional healers are, however, not covered by this provision. The Act, therefore, makes it illegal for such unregistered and unlicensed persons to practice and also to misrepresent themselves as practitioners. However, enforcement of such sections of the Act has been weak.

Clinical officers

The Clinical Officers Act, Cap 260, which establishes the Clinical Officers' Council, regulates clinical officers. The

This policy brief is based on KIPPRA Discussion Paper No.35 on Review of the Regulatory Framework for Private Healthcare Services in Kenya (2004). The study examines the regulatory issues that govern private healthcare services in Kenya, identifies existing gaps that make enforcement of the laws governing healthcare provision difficult, and makes recommendations that would lead to provision and expansion of quality private healthcare.

The private healthcare sector contribute significantly to delivery of healthcare. Private clinics, pharmacies, nursing homes and traditional practitioners have come up in most urban and rural areas. However, they have operated in an unregulated environment, sometimes with unqualified personnel and in unlicensed facilities. The private facilities have been driven mostly by the profit motive, especially so because after the introduction of structural adjustment programmes, the private facilities became the preferred choice due to the perceived higher quality of services.

Council issues clinical officers running private clinics with private practice licenses in respect of premises for one year in the first instance, but renewable annually. The Act stipulates that a clinical officer in private practice shall only treat the ailments listed in the First Schedule of the Act. However, such an officer may, where necessary, give initial treatment but not undertake to treat the diseases and ailments listed in the Fourth Schedule but should refer the cases to the nearest doctor or practitioner. These diseases include Tetanus, some cases of Tuberculosis, Typhoid fever, Diabetes, Cholera, among others. However, it is not a surprise to get clinical officers treating such diseases. Some clinical officers misrepresent themselves as "doctors" (an offence under Cap 253) by treating most diseases, including those not listed in the Schedule under Cap 260.

Nurses

The Nurses Act, Cap 257, makes provisions for the training, registration, enrolment and licensing of nurses. Section 13 of the Act stipulates that any person 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 is entitled to registration.

The Act is not categorical on the professional attainment, as in other medical professions. This may give leeway for registration of unqualified or under-qualified persons. This is made worse by the fact that existing training institutions for nurses are not properly regulated.

Pharmacists

The pharmacy profession is guided by the Pharmacy and Poisons Act, Cap 244, of the Laws of Kenya. Cap 244 outlines the general restrictions for unregistered persons who deal with drugs. However, there is a controversial section in the Act, which may be misused by other drug dealers. The section stipulates 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 whether this allows any vendor to sell drugs. The Act, however, categorically states that no other person other than those authorized to deal with Part I poisons under the Act shall do so. Nevertheless, many types of drugs are sold in shops, drug stores and by street vendors.

Cap 244 also gives power only to a person licensed to deal as a wholesale dealer in poisons to sell Part I poisons. The Act also prohibits such dealing unless a registered pharmacist is in direct control of the premises where the poisons are sold. This may not be happening in some pharmacies that employ pharmaceutical technologists, clinical officers and nurses to run the pharmacy. 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. Some pharmacists also use the title "doctor", and this is an offence of misrepresentation under Cap 253.

Practice in pharmacy in Kenya appears to be treated as a non-medical service. 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.

Traditional healers

According to the definition of the World Health Organization, traditional medicine includes a diversity of health practices and beliefs incorporating plant and animal-based medicines, together with spiritual therapies applied singly or in combination to treat, diagnose, or prevent illness.

Traditional health practitioners are not catered for in modern health laws. They are registered by the Ministry of Culture and Social Services as it is argued that they are performing cultural practices, which are governed through the African Customary Law. Therefore, they cannot be registered under the Ministry of Health.

The recognition of traditional healers under the African Customary Law creates conflict with modern health laws in terms of regulation of their activities. For instance, medical doctors are not allowed to advertise their services. However, traditional healthcare providers do it with impunity because it is not a crime under the African Customary Law. This selective application of law is unhealthy for the patients, especially given the misrepresentation of traditional practitioners as 'doctors', who purport to heal chronic diseases that have defied conventional clinical management.

Facilities

The Medical Practitioners and Dentists Act, Cap 253, defines what constitutes the different health institutions. For instance, "hospital" means an institution that has, in addition to resident doctor or dentists, an operating theatre and a mortuary. Some institutions identified as hospitals do not meet this requirement, and especially the requirement to have a resident doctor and mortuary. Even for theatres, the physical facility may be there but may lack proper equipment. These can, therefore, be accused of misusing the name, which is an offence of misrepresentation under Cap 253.

Clinics

The Medical Practitioners and Dentists Board approves all premises used as private clinics. For a private clinic to be licensed, a premise has to, among other things, not be a residential building except with special permission from the Board. Nevertheless, there are many health clinics situated in residential buildings.

A private practitioner cannot be licensed to operate more than one private clinic, although the Board can allow this if both clinics are situated in a rural area. However, the rule does not clearly define the coverage of the rural area or how far apart the clinics should be, in case the doctor has to serve both clinics.

Pharmacy

The Medical Practitioners and Dentists Act, Cap 253, stipulates that no premises may be habitually used for the purposes of private healthcare practice unless the Board authorizes it for such use. However, experience shows that 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. Pharmacies are never authorized facilities for medical care provision.

Other Areas of Concern

Refresher training

There seems to be no requirements for in-service and refresher training to update the skills of physicians. The Medical Board is empowered to oversee the training of medical practitioners only in Kenya's universities, and this does not include continuous medical education. 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 medical errors.

Malpractice and negligence

There lacks an explicit malpractice and negligence law to protect patients from negligent doctors. 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 Board has not come out publicly to show the number of cases reported and solved.

There has been malpractice by pharmacists in 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 pharmacists also sell drugs without a prescription from a doctor. Legally, pharmacists are supposed to sell some drugs against a prescription from a qualified medical practitioner. Other attendants sell half doses of drugs to patients. This is not only unhealthy to the patient but is also illegal and adversely affects those with chronic diseases. Lack of enforcement of morals and ethics in the profession has made most players in the pharmaceutical business to be more profit oriented, and disregard the danger they expose their customers to.

There has been a rapid increase of unlicensed and unregistered laboratories, unqualified persons working in laboratories, cases of malpractice and negligence, and sale of drugs over the counter in shops and by unlicensed street peddlers. This has been blamed on the lack of capacity to enforce laws by the medical bodies; conflict of interest in the regulatory agents; lack of clarity in the laws; withering skills due to absence of refresher courses, and hence frequent medical errors; and unregulated traditional practitioners.

From the foregoing, there is need to address the weaknesses either through proper regulation, amendments to the Acts, and enforcements of existing laws. The medical councils and boards have failed to use the laws governing them to establish their monopoly in regulation of medical care. The close relationship between the regulatory bodies and the ones being regulated is a possible hindrance to proper implementation of regulation, as the regulator may be sympathetic towards those being regulated.

Past Efforts in Addressing Some of the Weaknesses

Regulation of private healthcare providers is entrenched in the country's statutes, which define the conditions and requirements for private healthcare provision. In the past, the medical boards and councils created through the statutes have tried to address some of the past weaknesses. For instance, in 1993, the Medical Practitioners and Dentists Act, Cap 253, was amended to empower 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 were set. However, the amendment fell short of empowering the Board to initiate or oversee refresher training.

The Board has also been pursuing cases of illegal practicing and misrepresentation. This is documented in past press reports and the annual newsletters of the Board. For instance, in the Board's newsletter of 2002, it was reported that it was pursuing those pharmacists and others who misrepresent themselves as "doctors". The matter had been lodged in the High Court for interpretation and determination but has not been determined yet. This means that pharmacists are yet to be allowed to practice as medical practitioners and their premises are yet to be allowed as medical facilities.

As for clinical officers, the government began to grant them leave in 1989 to run and operate own private clinics. This was through the Clinical Officers Act, Cap 260 of 1989 that made provision for training, registration and licensing of clinical officers.

Efforts to mainstream the traditional medicine started being incorporated into Kenya's national health policy

framework in the late 1970s and continued into the 1980s. 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. However, there have been efforts by the Ministry to formulate a traditional healthcare practitioners bill.

Policy Recommendations

Strengthen enforcement

The Ministry of Health should review the capacities of the medical boards and councils in reference to enforcement of the laws governing the professions. Capacity should be built to improve the effectiveness of the Boards, by providing more resources to the regulatory bodies to establish regional offices (at provincial or district level) for effective supervision as the number of private healthcare practitioners has increased countrywide. Currently, services are rendered from the headquarters in Nairobi. When the bodies are to inspect the providers, they have to travel long distances. This does not happen regularly and hence the likelihood of having practitioners who are not adhering to the legal and Board's/Councils' requirements.

Re-evaluate the role of pharmacists and traditional healers

Given the high poverty levels in Kenya, majority of the population cannot afford the high consultation fees charged in private health facilities. This has promoted pharmacies and traditional healers as healthcare providers. To safeguard the consumers of their services, these providers should be incorporated as mainstream healthcare providers and regulated as such. This can be done by regulating them under Medical Practitioners and Dentists Board, or other clear legal frameworks.

Establish one umbrella body for licensing

Some of the problems and weaknesses highlighted include conflicts in the laws governing specific professions. For instance, the Clinical Officers' Council registers those clinical officers who want to engage in private practice. However, the Medical Practitioners and Dentists' Board have to authorize all premises to be used as medical facilities. Besides, there is need to bring traditional practitioners into the modern health framework. Therefore, 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 ensure monitoring of the qualifications of persons providing healthcare. It will also ensure a one-stop shop for registration of those engaged in private healthcare practice.

Enact a malpractice and negligence law

The government should encourage the development of tort law in Kenya 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. To achieve this, the government may need to introduce a medical malpractice and negligence legislation to assist the aggrieved and also to protect the medical practitioners in malpractice and negligence cases. This would create an explicit law for these sensitive issues.

Introduce refresher training

Medical practitioners should be encouraged to attend refresher training. This would not only reduce medical errors that lead to negligence cases against them but would also improve the quality of healthcare. To make sure they attend such courses regularly, the Kenya Medical Association should be given a legal backing to enforce such a requirement. The Association should also be given mandate to offer such training periodically. However, in its current form, the Association can only enforce rules to its members and not to other medical professionals because registration with the professional board is not mandatory. If the Association is legally entrenched, it could be recommended to offer refresher courses to practitioners. It would, therefore, be upon the recommendation by the Kenya Medical Association that a practitioner's license is renewed.

Enforce Public Health Act

The Public Health Act, Cap 242, is the overall guiding legislation on health issues, whether by public or private healthcare providers. The government should provide enough resources to the Director of Medical Services for enforcement of the Public Health Act. The envisaged Central Board of Health in section 3 of Cap 242 should be constituted. This is because it is supposed to play a very significant role in the implementation of the Act. It defines the roles of the Director of Medical services, the Minister for Health, the Local Government, and defines the restrictions for medical practitioners, including pharmacists.

About KIPPRA Policy Briefs

KIPPRA Policy Briefs are aimed at a wide dissemination of the Institute's policy research findings. The findings are expected to stimulate discussion and also build capacity in the public policy making process in Kenya.

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