Assessing the regulation of the private health sector in the Eastern Mediterranean Region

Egypt

World Health Organization
Regional Office for the Eastern Mediterranean

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Contents

Introduction

The private health sector in most low- and middle-income countries of the Eastern Mediterranean Region of the World Health Organization (WHO) plays a central role in the provision of health care. The governments in the countries of the Region encourage greater involvement of the private sector in the economy and follow a strategy of pluralism in the health sector allowing large and diverse nongovernmental entities to develop *(1,2)*.

Evidence suggests that the private health sector can contribute to the achievement of public health goals if steered constructively *(3)*. While the importance of the private health sector is increasingly acknowledged, several concerns have been raised in the Region regarding low quality of services and high out-of-pocket payments *(3,4,5)*. Regulation is an essential element to ensure that, in addition to access and equity of public sector services, issues of quality of services and patient safety are integrated into private health service delivery. The unique character of health care as both a social and a private good reinforces the importance of active government regulation in the health sector. While most countries in the Region appear to have passed substantial regulations related to the private health sector, little is known about the regulatory process or its comprehensiveness, effectiveness, institutional capacity and regulation enforcement mechanisms.

The countries of the Region have had health care regulation for decades. However, there have been hardly any studies looking at the private health-care regulations and their role in governing service provision. This has triggered the WHO to propose research be conducted to better understand the regulations in which the private health sector thrives, with the focus on the legislative process, institutional arrangements for regulation, and regulatory instruments. It was thus proposed to undertake a study on the private health sector in selected countries of the Region targeting Egypt in the pilot phase. The study originates from WHO work in the Region started in 2005 and completed in 2012 which underlined the problems associated with regulation of the private health sector *(3,6,7)*. The study is further inspired by the need to develop evidence-based strategies for the regulation of the private health sector in countries of the Region.

Study scope and objectives

Based on the WHO terms of reference, the main objectives of this research are to:

- review the national health policies, strategies and plans, and existing legislation/regulations, for the private sector;
- examine institutions and institutional arrangements with regard to the system of regulation;
- assess regulatory instruments;
- evaluate effectiveness and efficiency of regulatory enforcement.

The study was designed to answer the following questions.

- Is there a system of regulation in place and is it effective for the private provider?
- Have any bureaucratic hierarchal control measures been taken for public providers with regard to their commercialized care-giving behaviour?
- What are the policy considerations with regard to informal providers?

The full country reports are available at the WHO Regional Office for the Eastern Mediterranean. This summary report is organized into three chapters. The first chapter presents the research methodology covering the WHO regulatory framework, instruments and research subjects. The second chapter provides the research results. The report ends with the conclusion of this research and makes suggestions for strengthening the contribution of the private sector in health-care service provision.

1. Research methodology

1.1 Regulatory framework

The research was based on the WHO methodology and regulatory framework and used a mixed methods approach: document review, key informant in-depth interviews, focus group discussions and online surveys.

The assessment of the private health sector regulations in Egypt applied the WHO regulatory framework (Fig. 1). The regulations are affected by the macro-legislative and business environment, the national health policy, strategies and plans, the regulatory regime and its capacity, and the targets of regulation. These elements constitute the framework for regulatory analysis in the paradigm of economic efficiency. Distribution equity is dealt with at the policy level in the national health policies, strategies and plans, and is outside this framework.

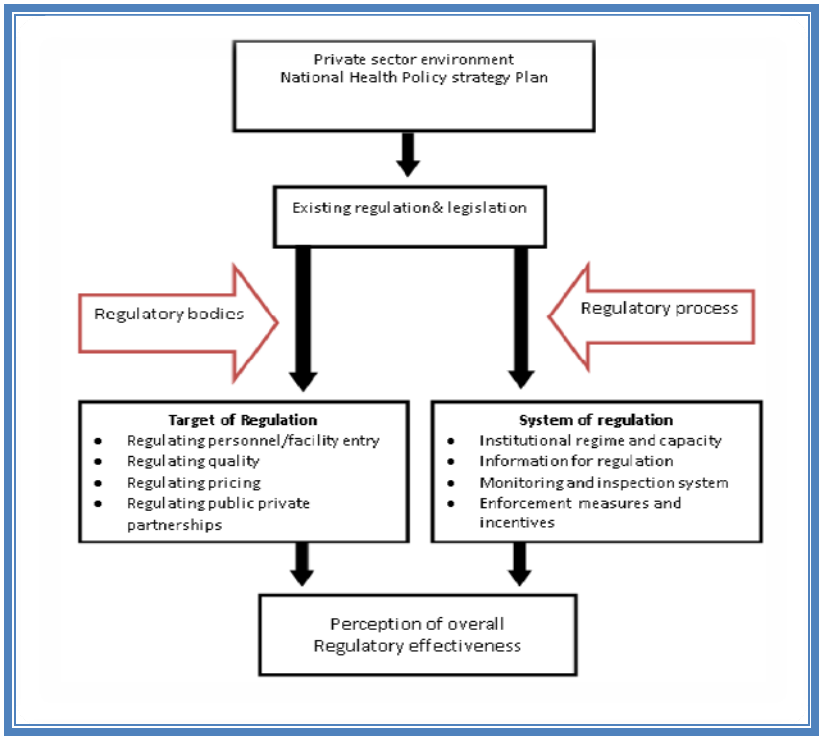

Fig. 1. WHO regulatory framework to assess regulation of the private health sector in the Eastern Mediterranean Region

1.2 Key variables for data collection and instruments

Based on the regulatory framework, WHO has developed a list of key variables for data collection. These are:

- regulatory environment
- law and regulation of general environment for private sector
- documents related to the national health policies, strategies and plans, and transparent policy process
- perception of health care as private good, quasi-public good, or public good
- laws and regulations for private health sector
- documents of existing legislation and regulations for private health sector
- regulatory body
- governing relationship between regulator and policy-making body
- description of regulatory system and regulatory process
- regulatory capacity (quality and quantity of staff and budget)
- regulatory targets
- market entry
- quality (in the sense of locally professionally-accepted practice)
- price
- public–private partnership (purchase, contracting, etc.)
- enforcement measures.

The research used the WHO generic instruments for key informant in-depth interviews and online surveys. The instruments were reviewed for consistency and completeness. An orientation workshop “Assessing the regulation of the private health sector in the Eastern Mediterranean Region: Phase I: Egypt and Yemen” was organized by the Social Research Center, American University in Cairo (AUC), and WHO in Cairo on 19 and 20 December 2012. The workshop was arranged to justify the need for the research, share research experience in other countries/regions and train interviewers/facilitators on the research instruments. This allowed the research team to better acquaint themselves with the importance of the research; to come to an agreement on the appropriateness of the instruments; and to be better prepared for the field work. The Social Research Center used participants’ recommendations to modify the research instruments and guide the field work. The English and Arabic versions of all instruments are available from WHO.

1.3 Data collection methods and research subjects

The research incorporates data collection through document review, key informant in-depth interviews, focus group discussions and online surveys.

Document review

The desk review aimed at understanding the private sector, including the private health sector, as well as identifying the private health sector regulations and regulatory system.

The search used three approaches: first, manual and online searches using key words, e.g. private sector, private health sector, public–private partnership, health sector regulation in various

combinations; second, collecting legislation, regulations and by-laws pertaining to the private health sector directly or influencing the private sector functioning in the country; and third, compiling reports and publications pertaining to the private health sector. All identified documents were filtered for relevance to the study objectives. A list of regulations is given in Annex 1.

In-depth interviews

The key informant in-depth interviews were aimed at better understanding the regulations and the regulatory system as well as the key informants' perceptions of the effectiveness of the system. The WHO proposed a total of 30–42 participants. A total of 33 Egyptians were enrolled in the study.

Focus group discussions

The focus group discussions were conducted to explore participants' perceptions on two themes: dual job-holding and informal health-care providers (defined as traditional health-care providers and non-medical doctors such as pharmacists, nurses, technicians, *dayas*, barbers, etc.). Four focus group discussions were conducted per theme. Groups were set up according to sex, age, education and employment characteristics.

Online survey

The purpose of the online survey was to generate additional quantifiable information and reach informants who might otherwise not be available for interviews. The information was not representative, but served as a useful guideline for evaluation. We received 68 responses. Data analysis was done using the SPSS computer package.

1.4 Ethical considerations

Procedures

Participation of all respondents in the key informant in-depth interviews, focus group discussions and online survey was strictly voluntary. Measures were taken to assure the respect, dignity and freedom of each individual participating in the data collection. During training of interviewers/facilitators, emphasis was placed on the importance of obtaining informed consent and avoiding coercion of any kind. Complete confidentiality for participants was also emphasized.

All completed forms were placed in an envelope that was sealed by each interviewer/facilitator. The outside of the envelope contained the following information: the number of forms, date of collection, name of the interviewer/facilitator, and the name of the field supervisor. The databases that were generated through the online survey did not contain data that could be used to identify any of the participants.

Ethical review

The Social Research Center prepared consent forms for key informant in-depth interviews and focus group discussions in English, and sent them for review by all partners. The documents were then translated into Arabic and these versions were shared with all Arabic-speaking partners. The Social Research Center reviewed and modified the introductory paragraph on the online survey questionnaire to accord with the local and cultural context. The proposal, instruments and consent

forms were sent to the Institutional Review Board of the American University in Cairo for approval. The modifications they requested were made and the documents finalized. English and Arabic versions of consent forms are available at the Social Research Center and WHO.

Informed consent

Each participant was asked to read the prepared informed consent letter explaining the study and the role of the participant and assuring anonymity, privacy and confidentiality before consent was obtained. Every interviewee was informed about the objectives, benefits and risks of the research. The interviewer/facilitator presented the study objectives. If the candidate met the inclusion criteria, the interviewer/facilitator read out the consent letter. The interviewees were informed about the option not to answer any question that they did not want to answer and to withdraw from the study at any time. It was explained that deciding not to take part in the study would not affect them in any way. The forms were signed by the interviewee and a witness from the research team. The consent forms were separated from the instruments to guarantee anonymity. The information from the consent form was not recorded anywhere or entered into the study database. The interviewers gave the supervisor the instruments and the consent forms which were placed in a sealed envelope.

2. Assessing regulation of the private health sector in Egypt

2.1 Context

Egypt has an exceptional geographic location at the north-east corner of Africa, with a total land area of 1 001 450 km^2. Estimated population at 1 January 2012 was 81 395 million, distributed over 27 governorates *(8)*. It has been a republic since 1953. The government has three main branches, executive, legislative, and judicial. The official sources of legislation in the country include the constitution, laws, treaties and international agreements, presidential decrees, prime minister's resolutions, ministerial resolutions, and governors' acts. Since the 1990s, the government policy has been to encourage private-sector development and growth, not only in business but in infrastructure and power as well. Egypt is a middle-income country with a per capita gross domestic product of US$ 2781 in 2012 *(9)*. The Egyptian economy has witnessed robust growth over the years, however the revolution in 2011 led to a slowdown. Over the past two decades, Egypt has seen marked improvements in a number of demographic and health indicators; child malnutrition and hepatitis C viral infection are, however, among the major health challenges.

2.2 The health sector in Egypt

Health sector reform

Until the 1980s, the public sector was the main health-care provider, with limited private sector participation. Realizing the potential in the non-public sector, Egypt has tried to create an enabling environment for mixed public–private health-care provision. In its policies to promote the private sector, the government launched a major health sector reform programme in 1997 (Box 1). The ultimate goal was to improve population health and promote social well-being. The programme was also aimed at introducing a quality basic package of primary health-care services, contributing to the establishment of a decentralized service system and improving the availability and use of the health services. Moreover, this programme aimed at introducing institutional structural reform based on the concept of separating purchasing from provision and strengthening the regulatory functions of the Ministry of Health and Population.

Box 1. Elements of the health sector reform programme in Egypt

- Redefining the role of the Ministry of Health and Population to develop its regulatory functions, notably to establish quality norms and standards and a mechanism of accreditation and licensure to enforce those standards and to consolidate the multiple vertical public health programmes.
- Strengthening the training programme for family health-care providers, with greater emphasis on preventive health-care.
- Decentralizing the management of the government health-care delivery system to the governorate and district level and introducing greater autonomy at the facility level.
- Rationalizing public investment in health infrastructure and the health workforce

Table 1. Trend in Egypt's expenditure on health

Type of health expenditure	1995	2000	2005	2010
Total expenditure on health (% of gross domestic product)	3.9	5.4	5.2	4.7
Per capita expenditure (current, US$)	36.4	75.8	63.4	123.2
Public expenditure (% of government expenditure)	5.3	7.3	6.7	5.7
Public expenditure (% of expenditure on health)	46.5	40.5	40.6	37.4
Private expenditure (% of expenditure on health)	50.8	58.5	58.1	62.0
Out-of-pocket expenditure (% of total expenditure on health)	48.0	58.0	58.4	61.2
Out-of-pocket expenditure (% of private expenditure on health)	89.6	97.4	98.4	97.7
External resources for health (% of total expenditure on health)	2.7	1.0	1.3	0.6

Source: *(9)*.

Health financing and the health workforce

Over recent years the government has been working on cutting its expenditure on health, allowing the opportunity for the growth of the private sector. This reached over two-thirds of total expenditure on health in 2010 (Table 1). However, most of the private expenditure on health is derived from out-of-pocket payments, exposing households to huge financial burdens.

Egypt faces a unique situation of oversupply of health workforce in clinical practice with a simultaneous artificial shortage. The relaxation of controls on market entry and the prolonged working hours, with day and evening times distributed unevenly between public and private offices, is how the workforce compensates for the low wages for health-care professionals. The inadequate government remuneration and low motivation pushes health-care professionals to seek employment opportunities abroad, especially in the member countries of the Gulf Cooperation Council, or to hold multiple jobs in the private sector within Egypt.

Public health sector

The public (governmental) health sector in Egypt (Fig. 2) functions under various entities and is classified into Ministry of Health and Population, other government sectors, and the semi-public (parastatal) sector. The government sector receives funding from the Ministry of Finance and is permitted to generate income through various means including charging user fees in special units or departments known as economic departments, the income of which is classified as self-funding.

Private health sector policy

The Egyptian Constitution declares health as the right for all Egyptians without discrimination. Health care has always been looked on as a public good offered free of charge to all people by the government. However, with the privatization policies, the government started gradually decreasing its contribution in health expenditure, allowing the private health sector to expand (WHO, 2012). Private expenditure on health has reached 62% of total health expenditure (World Bank, 2013). The Ministry of Health and Population, the key health policy-maker, launched a potent health sector reform programme in the mid-1990s to foster public–private partnership in health-care provision. Over the past two decades, private health-care provision has increased enormously and is estimated to provide 50%–70% of health-care services to all social classes, even the poor (Table 3).

However, the private health sector is characterized by its vast diversity and its nature. There is a confusing array of terminologies over its classification. This has led to a varied mix of different types of private health-care providers, ranging from traditional to modern practitioners and from individuals to large hospitals. The terminologies used to define private health care provision are important as they dictate the regulatory mechanism applied. Box 2 classifies the private health-care providers in Egypt according to the various terminologies.

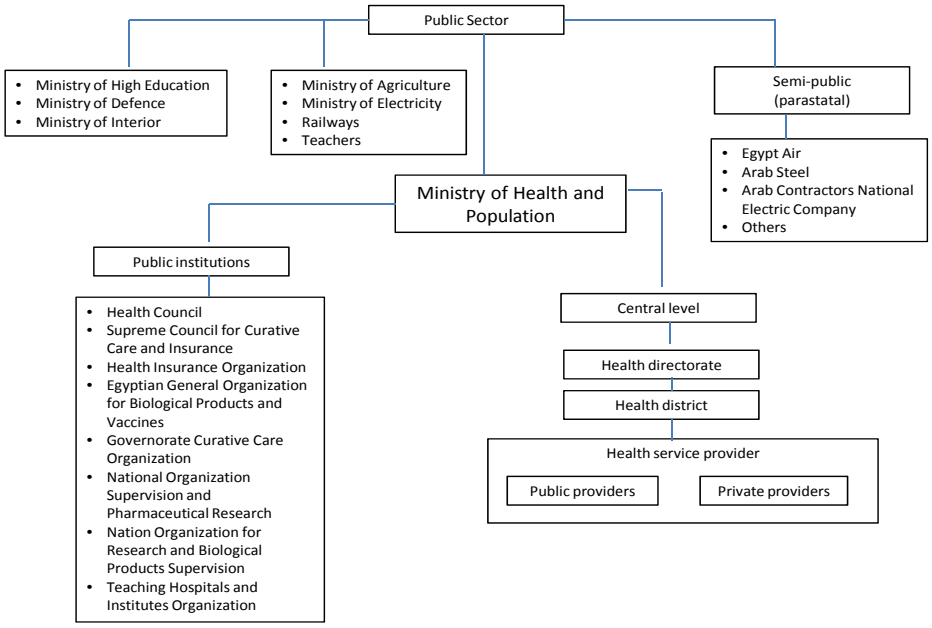

Fig 2. Public health sector in Egypt

Table 2. Public–private health-care provision in Egypt

Type of provision	2000	2005	2010
Health facilities with beds			
Total (number)	2 319	2 683	1 587
Public sector (%)	53.6	50.5	41.6
Private sector (%)	46.4	49.5	58.4
Beds			
Total (number)	140 148	152 172	125 123
Public sector (%)	84.5	82.8	79.3
Private sector (%)	15.5	17.2	20.7

Source: *(8)*.

2.3 Private health sector regulation in Egypt

Table 3 provides a framework for assessing the private health sector environment, policy, regulation and regulatory bodies in Egypt.

Private sector environment

Since the 1990s, the general environment has been directed towards promoting the private sector in Egypt. The government is drawing up a set of horizontal measures to encourage private investment and regulate the market. The Companies Corporate Law (159/1981) and the Investment Guarantees and Incentives Law (8/1997) (amended by Law 13/2004) govern the for-profit private investment, while the Civil Foundations and Associations Law (84/2002) govern the not-for-profit activities. The laws offer direct incentives to encourage private investment not only in business but in infrastructure, including the health sector. The Labour Market Law (12/2003) organizes the relationship between employees and employers in the formal private sector in general, including the private health sector. Law 12/2003 aims at encouraging private sector involvement and achieving greater balance between the rights of employees and those of employers. Law 3/2005 prohibits anticompetitive practices and conflict of interest. Law 67/2010 organizes public–private partnership through contracting for infrastructure establishment and providing services, as well as the establishment of a supervising committee to ensure quality of services. Law 48/1941 and its amendments (Law 106/1980 and Law 281/1994) set out a rigorous disciplinary system in cases of suppression, deception and fraud in regard to the manufacture, import or distribution of goods which may cause harm to the public.

Despite the sustained efforts of the government to encourage the private sector, the country still faces several perceived challenges. The bureaucracy, weak governance and limited resources inherited in the system eclipse the government efforts; the situation is further compounded by what happened following the security disorders after the 2011 revolution. Despite the horizontal regulations providing several incentives (tax holidays, reduced customs duties, and guarantees against expropriation for exchange repatriation of capital and profit), these are often perceived as being insufficient.

Private health sector policy

The Egyptian Constitution declares health as the right for all Egyptians without discrimination. Health care has always been looked on as a public good offered free of charge to all people by the government. However, with the privatization policies, the government started gradually decreasing its contribution in health expenditure, allowing the private health sector to expand. Private expenditure on health has reached 62% of total health expenditure *(9)*. The Ministry of Health and Population, the key health policy-maker, launched a potent health sector reform programme in the mid-1990s to foster public–private partnership in health-care provision. Over the past two decades, private health-care provision has increased enormously and is estimated to provide 50%–70% of health-care services to all social classes, even the poor (Table 3).

Box 2. Classification of private health-care providers in Egypt

Ownership: economic agents of different types own private health-care facilities such as mosques, churches, companies, private enterprises, and individuals such as physicians, pharmacists, nurses and traditional healers.

Economic orientation: including for-profit and not-for-profit health-care providers. Health facilities run by mosques, churches, nongovernmental organizations and civil society constitute the main not-for-profit private health-care providers. Health facilities owned by sole owners, partnerships and companies who seek to make profit form the main for-profit private health-care providers.

Registration: there are five types of registration: private hospitals generally register as investment entities or companies; religious health-care providers in mosques or churches register as charitable societies; and nongovernmental organizations register as national societies, while individual and enterprise-owned facilities register as national societies or private entities.

Type of facility: Law 51/1981 defines five broad categories of health-care facility: private medical clinic (including laboratories and radiology clinics), specialized clinic, specialized medical centre, private hospital and convalescence home.

Therapeutic system

- Formal health-care providers, notably medical doctors who provide one of the following services:
- examination, diagnosis and treatment using traditional health care;
- examination, diagnosis and treatment using modern health care (alternative health care) such as Chinese acupuncture, ozone therapy, oxygen therapy and herbal therapy (such practices are usually unauthorized in the country, however, medical doctors work under license to practise the medical profession to provide such services).
- Informal health-care providers, including:
- non-medical doctors such as pharmacists, nurses, technicians, *dayas* (traditional midwives) and barbers;
- traditional health-care providers, which covers a diversity of practices, approaches, knowledge, and beliefs incorporating herbal, Quran, spiritual and cupping (*al-hegama*) applied separately or in combination to maintain well-being and to treat, diagnose, or prevent illness.
-

However, given the unique character of health care as both a public and a private good, the task of regulating health services is challenging. The Ministry of Health and Population faces a wide range of problems in guiding private sector activities in a mixed delivery system. The Ministry is still swaying between the outdated mindset which believes health is a public good and the current government direction treating health as a mix of public and private good. This controversy has led to policies and strategies that are sometimes perceived as being irrelevant and haphazard. Despite the numerous stakeholders, networking and working jointly is still in its infancy for the Ministry of Health and Population and other potential actors. Moreover, given the limited resources and the incomplete health insurance law, the Ministry is unable to overcome the increasing out-of-pocket expenditure on health, which is estimated to be 97.7% of private expenditure on health, putting serious financial burdens on households. Consequently, informal influences have become entrenched in the system to overcome weakness and bureaucracy.

Existing regulations and legislation

Regulation of private health-care providers is embedded in the legislation and is governed by a number of horizontal and vertical measures. Annex 1 provides a list of health sector regulations in

Egypt. The horizontal laws are new or have been renewed in the past decade to reflect government efforts towards promoting the private sector. Most of the vertical laws date from the 1950s—there are hardly any new laws or amendments to promote private sector involvement in health-care service provision. Despite many of the regulations being nearly analogous, each health-care profession falls under separate laws governing the profession and the syndicates. There is much overlap, but there are sometimes discrepancies between the regulations governing the health-care professionals and facilities. For example, Law 51/1981 states that the director of a health-care facility can own more than one private clinic but cannot be the director of more than one medical facility in addition to his/her private medical clinics; this contradicts Law 415/1954, which does not allow a private doctor to have more than one private clinic.

Ministerial resolutions are executive in nature; they are mainly issued by the Ministry of Health and Population, either alone or jointly with the local administration. The resolutions are piece-meal, fragmented, rapidly dispersed, changing measures; as a result, they are often inaccessible or unknown to most people (Table 3).

The laws and resolutions generally focus on the formal private sector and implicitly allow the private sector to provide all the health services that the public sector provides. The Ministry of Health and Population has established committees to review requests for introducing alternative therapies (MOHP Resolutions 292/2002 and 403/2006). Chinese acupuncture, ozone therapy and oxygen therapy have not been approved; despite this, they are available and are currently offered by licensed medical professionals and are used by many people.

The existing laws and regulations do not explicitly allow or forbid dual job-holding. Recently the Ministry of Health and Population made use of this gap in the regulations to allow medical doctors working in the public sector to use primary health care units and centres for their private practice after working hours (Resolution 674/2010) as a means to compensate for the low salaries in the public sector. Consequently dual job-holding has become the custom and is widely practised in the country without any controls. It is believed that the practice provides financial and professional benefits to health-care providers but threatens the quality of services, notably in the public sector, and encourages patient drain to the for-profit private sector.

The regulations ignore the informal sector, which is considered illegal. There are, however, a few clauses referring to informal health-care provision, for example prohibiting pharmacists from practising medicine, fixing the official list of herbs for herbal medicine shops (Law 127/1955), and prohibiting female genital mutilation (Ministry of Health and Population Resolution 271/2007), implicitly including the informal sector. In general, society does not approve of informal health-care providers but they still exist as the services are believed to be cheap, easily accessible, responsive, affordable and safe.

Regulatory bodies

There are numerous regulatory bodies involved in setting the regulations for health. They include the state executive branch and legislative branch, the Ministry of Health and Population, the Medical Syndicate, other professional syndicates and a number of ministries (Fig. 3). The Ministry of Health and Population is perceived as the key regulatory body as it is responsible for the preparation of bills for vertical laws, issuing executive resolutions and inspection. The Ministry of Health and Population has no role in shaping the horizontal measures which govern the private health sector environment, the government budget for health or the labour market (Table 3).

Table 3. Assessment of the private health sector environment, health policy, regulation and regulatory bodies in Egypt

Document review	In-depth interviews	Focus group discussions	Online survey
Private sector environment			
• Horizontal measures for private sector growth • Environment promotes private investment • Laws provide incentives to encourage private investment	• Environment somewhat encouraging • Insufficient incentives • Bureaucracy, weak governance • Repercussions of revolution, notably insecurity		• Private sector role is important • Environment somewhat encouraging • Insufficient incentives
Private health sector policy			
• Gradual decrease in government expenditure on health • Private expenditure on health is estimated to be 62% of total health expenditure, 97.7% are out-of-pocket • Ministry of Health and Population is key health policy-maker • Health sector reform in mid 1990s to promote public–private partnerships	• Ministry is key health policy-maker • Private health sector expansion (50–75% of service provision) • Controversy in perceiving health (public and/or private good) • Controversy in perceiving health policies (relevant, well planned/irrelevant, haphazard) • Limited resources and unfinished health insurance law • Weak governance, bureaucracy • Informal influences somewhat important	• Significant private health sector contribution • Out-of-pocket is the prevailing payment method	• Private health sector role important • Ministry is key health policy-maker • Controversy in perceiving health (public/private good) • Controversy in perceiving health policies (irrelevant, well planned, haphazard) • Informal influences somewhat important
Private health sector regulation			
• Horizontal measures are recent while vertical measures date since the 1950s • Targets formal providers • Similar private and public services • Flood of executive	• Laws exist but are hardly known • Policy-makers believe that private sector does not offer prevention services but other sectors confirm similar private and public	• No regulatory measures for dual job-holding • No regulations for informal providers	• Regulations not easily accessible • Dual job-holding not controlled • Informal sector not

Document review	In-depth interviews	Focus group discussions	Online survey
measures dispersed by Ministry of Health and Population • Ignores informal providers • No control over dual job-holding •	services • Dual job-holding is approved/accepted • Informal providers are illegal		controlled
Regulatory bodies			
• Ministry of Health and Population, Medical Syndicate, other ministries, state executive branch, legislative branch, • Ministry of Health and Population role confined to vertical measures • Self-regulation enacted through professional syndicates	• Ministry of Health and Population, Medical Syndicate, other ministries • Self-regulation discouraged by policy-makers and encouraged by other sectors of the population		• Ministry of Health and Population, Medical Syndicate, other ministries, civil society • Self-regulation not encouraged

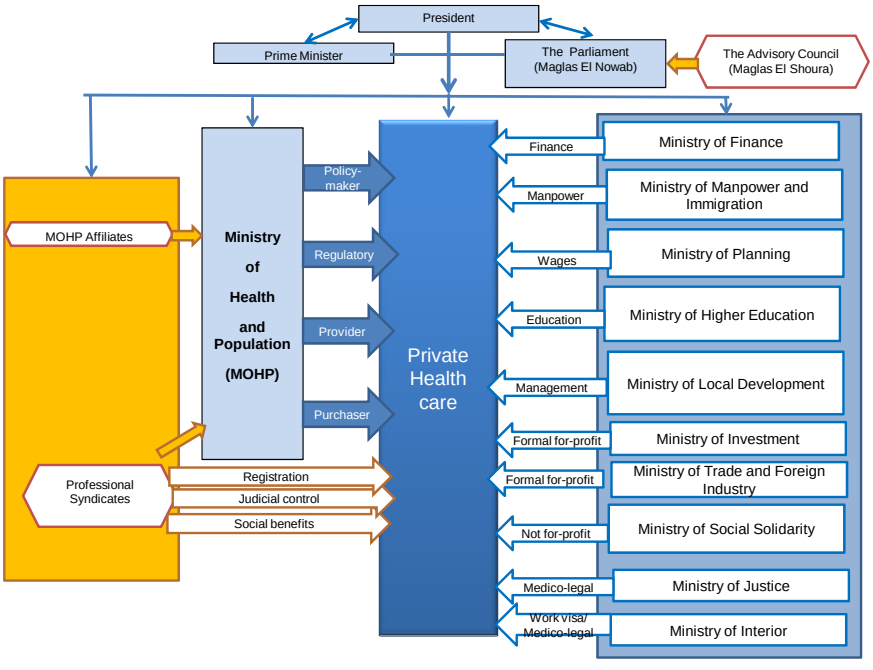

Fig. 3 Regulatory bodies for private health-care service delivery

Self-regulation is enacted through the laws of the professional syndicates (medicine, dentistry, pharmacy, nursing and physiotherapy). They share their policy-making and regulatory powers with the Ministry of Health and Population as they have the right to organize professional education and practice on a national level. All health care professionals must be registered in the relevant syndicate. Health-care facilities must gain approval and be registered with the Medical Syndicate as a step in the Ministry of Health and Population licensing process. Moreover, the syndicates execute judicial power when they rectify the behaviour of their members through a code of ethics and a disciplinary system that preserves the dignity of the profession and respects the values of society. It is apparent that policy-makers discourage self-regulation as they believe that good governance lies in government control and availability of resources. However, the other sectors of the population believe that self-regulation may be beneficial, especially since the regulatory system in individual private hospitals is very effective.

Target of regulations

Table 4 provides an assessment of the private health sector regulation targets in Egypt.

Regulating market entry

Market entry for health-care professionals is governed by horizontal and vertical measures. The Labour Market Law (12/2003) regulates the registration and contracting conditions of the formal staff working in private institutions. The vertical measures regulating the practice of health professionals are governed by several laws and Ministry of Health and Population resolutions specific to 16 specializations (including: physicians; dentists; nurses; physiotherapists and medical massage; biochemistry; specialists in bacteriology and pathology; pharmacists, assistant pharmacists and medicine brokers; midwives and assistant midwives; psychologists; dental manufacturers; and opticians). Market entry is organized through mandatory licensing and registration to practise the profession from the Ministry of Health and Population. The laws establish five syndicates (medical doctors, dentists, pharmacists, nurses and physiotherapists) and stipulate mandatory syndicate registration to practise the profession. The laws do not address relicensing or reregistration for any of the professions. The process appears to be supported and of acceptable duration.

The private for-profit health-care facilities in Egypt register with the Ministry of Trade and Foreign Industry under the Companies Law (159/1981) or with the Ministry of Investment under the Investment Guarantees and Incentive Law (8/1997) and its amendments. Law 84/2002 mandates registration of the private not-for-profit health facilities with the Ministry of Social Solidarity. The vertical measures pertain only to formal, for-profit, health-care facilities and are governed by a plethora of fragmented laws and resolutions. All formal private medical facilities require licensing from the governorate after registration in the Medical Syndicate records. The governorate notifies the Ministry of Health and Population for registration with the Central Registry. Licensing is only provided by the Ministry of Health and Population to facilities which: meet standards; have an approved, clear price list; whose director is an Egyptian medical doctor/dentist (according to type of facility) licensed to practise the profession from the Ministry of Health and Population and registered with the Medical/Dentistry Syndicate; and all health-care staff are licensed to practise the profession by the Ministry of Health and Population and are registered with their syndicates.
To facilitate the process, the Ministry of Health and Population established a standing committee (Resolution 60/2001) to consider requests for the establishment of medical facilities and for issuing

initial approval until licensing is released. However, it seems that this effort has not facilitated the process, which is still perceived as being slow, bureaucratic and allowing for informal influences.

The multiplicity of market entry regulations and controls hinder the Ministry of Health and Population's mission. It has allowed an upsurge in unplanned private health-care providers and has opened the door for numerous street-level health brokers who contrive to smooth the procedures for obtaining a license. The lack of controls over the practice of dual job-holding and the existence of the informal sector have brought about deteriorating quality, increasing costs and conflicts of interest. Moreover, poverty, tradition and deficient health awareness have forced people to look for a provider by reputation rather than a licensed one. This has opened the gate to numerous malpractices and misconduct.

Table 4. Assessment of the private health sector regulation targets in Egypt

Document review	In-depth interviews	Focus group discussions	Online survey
Market entry			
• Ministry licensing and syndicate registration for health-care professionals • Health-care facilities register in ministries other than Ministry of Health and Population, gain authorization from local administration, register in Medical Syndicate and are licensed by Ministry of Health and Population • Private-private contracting with no restriction on dual job-holding • Ministry disapproves of informal sector	• Policy-makers/regulatory bodies: licensing is easy and rapid • Health-care managers and social groups: licensing is bureaucratic and protracted • Informal influences are important • Informal health-care services are restricted	• Dual job-holding is common and encouraged by government • Informal health-care providers exist • Beneficiaries seek reputation rather than license	• Licensing duration moderate for health-care professionals • Licensing duration slow for health-care facilities • Informal influences important • Dual job practice widely accepted • Informal health-care providers not properly integrated/supported
Quality			
• Standards for accrediting health-care facilities • Syndicate	• Accreditation for health-care facilities and certification	• Dual job-holding improves quality in private sector but affects quality in	• Dual job-holding according to individual

Document review	In-depth interviews	Focus group discussions	Online survey
certification for obtaining postgraduate degrees • Code of ethics • Incentives • Accountability and disciplinary system • Standards for practising the medical profession	courses for professionals are optional • Private sector may be better quality, but specialized public institutes offer high quality services • Preventive services lacking in private health sector • Professionals lack skills, are not interested in learning, are interested in money making • Incentives are insufficient	public sector • Private health services superior to public services • Beneficiaries initially seek care in public sector then follow-up in private sector • Private health-care services accessible and responsive • Reputation vs accreditation	interest • Informal sector is supported/integrated
Pricing			
• Weak regulations • Supply and demand	• Supply and demand • Private health-care services expensive • Fee schedule prepared by institution • Pricing not standard and sometimes not transparent	• Expensive down payments • Investigations and medicines are unaffordable • Informal sector is cheap	• Fee schedule is not always perceived and if exists is not transparent • Expensive private health-care services
Public–private partnership			
• Contracting left to hospital director/board estimations • Few benefits to private practitioners	• Services not clear • Interest in making profit		• Not encouraged

Regulating quality

There has been a rapid increase in the number of laws and resolutions governing quality of health-care services, to the extent that they are barely known even to policy-makers and regulatory bodies. The main quality measures are listed below.

- Defining standards for accreditation of health-care facilities: accreditation is, however, optional and is regarded as unimportant by the public, who search for reputable health-care providers.
- Professional and training certification: the syndicates provide members with a specialist certificate for obtaining a master's degree and a consultant's certificate for obtaining a doctorate from an approved university/institute. Training and skills-building certification from the individual or the contracting institution is optional. It is apparent that those working in health-care provision seek certification as a means of attracting clients rather than developing skills.
- Code of ethics for working in the formal private sector and health-care provision: this includes respecting job duties, punctuality, respecting managers and respecting confidentiality of documents. However, the regulations do not address the effectiveness of services, beneficiaries' rights, satisfaction and the responsiveness of the institutions to beneficiaries' needs.
- Incentives: including bonuses (to be determined by the employer), free first-aid care, free health-care services in public and faith-based institutes, employees' right to 21 days paid holiday, maternity leave (for mothers) and paid medical leave. In addition, the Labour Market Law 12/2003 obliges private institutions employing at least 100 women to set up daytime childcare facilities. These are all in addition to the pension and health insurance schemes offered by the syndicates. The for-profit private hospitals and medical centres established under the Investment Guarantees and Incentives Law (8/1997) benefit from a 10-year period of tax exemption on corporate profits on condition that they provide 10% of hospital bed capacity free of charge. However, these incentives are perceived by key informants as being insufficient.
- Accountability and disciplinary system: this covers misconduct, with a mixture of penalties such as warning, notification, censuring, fines, suspension from work, dismissal and imprisonment if found guilty.
- Standards for practising the medical profession: there are numerous fragmented regulations including proving emergency care free in medical-care facilities for 24 hours; prohibiting the practice of major operations in private and specialized medical clinics; standards for conducting operations in medical facilities; standards for conducting surgical and endoscopic procedures; rules for handling radiation in hospitals; providing medical reports to patients upon discharge from hospital; prohibiting female genital cutting by formal and informal health-care providers; allowing the sale of blood bags only in licensed hospitals; prohibiting the circulation and use of renal dialysis filters; laying down infection control measures in cardiac catheterization units; mandating that taking specimens from human subjects should be done by a medical doctor; forbidding the sale of specific types of eye drops and unregistered medicines in pharmacies; prohibiting the sale of eye glasses in optician's shops without a medical prescription; and prohibiting advertisement of any kind for unlicensed health-care providers, medical care, medicines and pharmaceutical products. The actual enforcement of such measures is, however, a matter of debate.

Regulating pricing

There appear to be very few regulations for pricing private health-care services; it is mainly left to supply and demand. According to Law 12/2003, wages in the formal private sector are determined by labour supply and demand, ensuring equal wages and employment opportunities regardless of sex, religion or belief. Wages are set mostly on an individual level according to personal skills and degree of specialization. The law sets the minimum wage, an annual increase of 7% of basic salary and cost of living allowances. The syndicate laws request the syndicates to set a schedule of maximum fees for the activities performed by its members (to be approved by the Ministry of Health and Population). There are, however, no clear estimates for the private health services provided nor for an acceptable profit limit; these are still influenced by supply and demand, depending on the quality of services and geographic location.

Resolution 674/2010, based on the joint Minister of Local Administration and Minister of Health Resolution 239/1997, allows the Ministry of Health and Population local administration facilities to provide economic commercialized health-care services. Accordingly, hospitals and health-care units and health centres may charge economic health-care fees directed at improving the services provided. The resolution provides a price list for economic health care, with an annual increase of 10%. However, each health-care facility is allowed to adjust the cost of services according to the social status of patients, but this should not exceed the approved price list.

The lack of pricing regulation allows each provider to set their own price list. Consequently, pricing varies from one provider to another and health-care services have become very expensive, notably investigations and medicines.

Regulating public–private partnerships

The government initiative reflected in Law 67/2010 encourages public–private partnership through contracting for the establishment of infrastructure and the provision of services. The Ministry of Health and Population (Resolutions 428/2010 and 674/2010) allows public health-care facilities to contract individuals, however, their qualifications, selection and salaries are estimated by the hospital director and board. The public–private partnership is challenged by the low benefits offered to private providers, which creates a window for patient drain to private practice.

The legislative process

The President, the Prime Minister, the ministries and members of parliament all have the right to propose a bill (Fig. 4). It is mainly the role of the Ministry of Health and Population to prepare bills for vertical health sector laws, while the horizontal laws are prepared by other ministries. Once proposed, the bill is sent to Parliament for examination. Parliament has established various specialized committees, including a Health Committee, which may seek the advice of counterparts in the Advisory Council and then submit bills to become laws via an internal vote. When a majority of parliamentarians are present, a quorum is established for voting and a vote on each article of the bill proceeds.

The President has the right to return the bill to Parliament within thirty days if he disagrees with its content. In the event that a bill is returned, Parliament may endorse if supported by a two-thirds majority vote. If Parliament approves the bill at this second reading, it automatically becomes law.

The Ministry of Health and Population then starts the process of issuing executive resolutions to enact the health related laws.

System of regulation

Table 5 provides an assessment of the private health sector system of regulation in Egypt.

Institutional regime and capacity

The Ministry of Health and Population is the key leader of the regulatory system. It is responsible for the whole process through preparing bills for laws, issuing resolutions for executing the laws, inspection, having judicial control status, and applying the disciplinary system, as well as having the power to withdraw licenses form health-care professionals and to close facilities. The Ministry of Health and Population affiliates and the professional syndicates participate in the regulatory process, playing an advisory role to the Ministry of Health and Population. The professional syndicates provide social incentives in the form of pension and health insurance schemes for their members, and execute judicial powers when they rectify the behaviour of their members through a code of ethics and a disciplinary system.

The Ministry of Health and Population's Department of Nongovernmental Curative Care is the only official body responsible for licensing health-care professionals. The law stipulates that health-care professionals register in the governorate professional syndicate; those who have no governmental position register as private professionals.

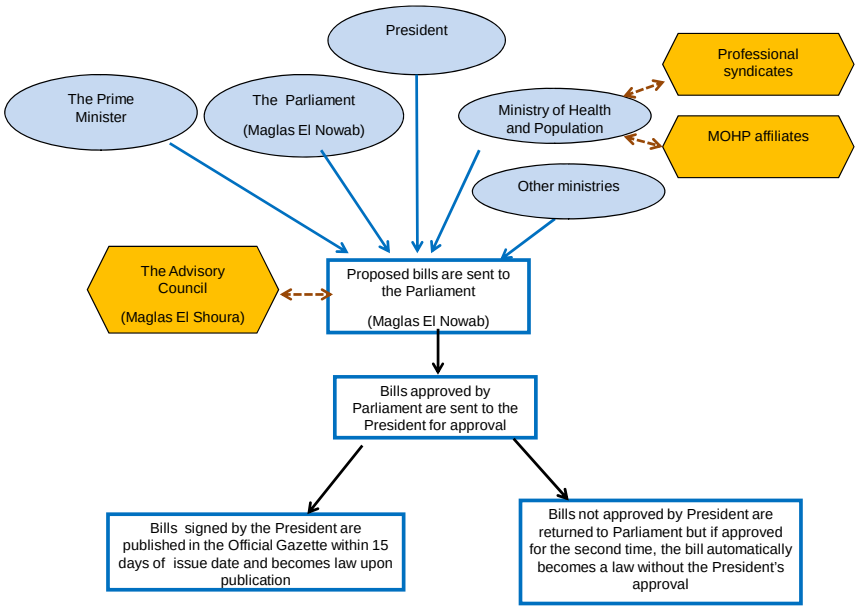

Fig. 4. Legislative process for health-care service delivery

Establishing private health-care facilities requires approval from the governor and registration in the local administration records and the local administration informs the Ministry of Health and Population's Department of Nongovernmental Curative. The Ministry of Health and Population has judicial control and inspects health-care facilities at least once a year for compliance with standards, which are mainly structural in nature. The department keeps records of the name and geographic location of facilities to provide counts and estimate size.

The Ministry of Health and Population's General Department of Quality is the only official body responsible for providing accreditation for private health-care facilities through a standard accreditation process. Through its four sections (accreditation, performance improvement, training and research) the department, aims at: improving the quality of health-care services; improving the efficiency of health-care programmes; and achieving universal coverage. It keeps records of accredited facilities and helps in providing guidelines for accreditation.

The Egyptian Drug Authority is the pharmaceutical policy-maker, regulatory body and supervising agent within the Ministry. It has three sub-organizations, listed below.

- The Central Administration of Pharmaceutical Affairs, through its four departments (registration; licensing and pharmacists' services; inspection and control; and importation and exportation), carries out a range of assessment and monitoring activities for human and veterinary medicines, food supplements, insecticides, medical devices, and cosmetics to ensure that they are of an acceptable standard with the aim of ensuring that the community has access to safe, effective, affordable, secure products.
- The National Organization for Drug Control and Research represents the National Quality Control Authority for locally manufactured and imported pharmaceutical products.
- The National Organization for Research and Control of Biologicals is responsible for ensuring the safety, quality and efficacy of all imported and domestic biological products in compliance with WHO requirements and the International Organization for Standardization.

Information for regulation

The current system produces counts to monitor the size of health-care providers. The Ministry of Health and Population and the professional syndicates keep records on name, sex, specialization and residence of providers. There is no system in place for recording progress, quality of work or place of practice of private health-care providers. A national health information system is in place but is perceived as incomplete and not easily accessed. Moreover, there are no regulations linking the production of information to its use in producing evidenced-based policies.

Monitoring and inspection system

The existing system of inspection focuses on the formal for-profit health-care providers and is mainly structural in nature. The system is not perceived by non-policy-makers, and appears to be weak and unorganized. There is a system in place for connecting beneficiaries' complaints, however, it is considered weak and slow. Beneficiaries usually proceed directly to the medical syndicate to report their complaints. However, the syndicate is perceived as being predisposed towards protecting the health-care professionals and the profession.

Enforcement measures and incentives

The Ministry of Health and Population uses a control-based system and has judicial control status. Policy-makers perceive the role of the Ministry of Health and Population as effective but rank it as average, while the other sectors find it weak and rank it as low. The general public calls for government intervention to control quality and pricing, which indicates that the current system needs strengthening. The role of the Ministry of Health and Population in judicial control gives it the appearance of an enemy trying to dismiss health-care providers from the market rather than a friend trying to help them strengthen their position.

2.4 Outcome of focus group discussions with health-care beneficiaries

During the focus group discussions, health-care beneficiaries proposed actions for consideration by the Ministry of Health and Population. They called for social protection in the form of improving coverage and ensuring affordability of services as well as improving quality, pricing, the health workforce environment, and financing for both the public and the private sectors. Box 3 provides a summary of their recommendations to the Ministry of Health and Population.

Box 3. Action points proposed by health-care beneficiaries for consideration by the health Ministry of Health and Population

Dual job-holding

Social protection

- Improving service coverage in public hospitals
- Providing medication at affordable prices and strengthening supervision over the private/public medication providers
- Standardizing the pricing of services provided at public health-care facilities
- Monitoring the pricing or setting a maximum price for services provided in the private sector to end the exploitation of patients

Quality

- Regular monitoring and evaluation of facilities
- Improving the management system in hospitals to improve the quality of the services provided
- Improving emergency services and regular maintenance of emergency rooms
- Strengthening the role of government in supervising and monitoring the private health sector

Responsiveness

- Doctors, nurses, health care technicians should receive regular training/workshops to improve their skills, especially non-medical skills, to learn how to communicate with patients
- Setting up a responsive, effective grievance mechanism to channel complaints

Informal health-care providers

Social protection

- Providing more services in the public sector and offering them free of charge
- Setting a pricing list for the public and the private sector.
- Reducing the prices of medications and supervising the market regularly

Quality

- Regular supervision over the facilities especially for hygiene/sterilization
- Regular supervision of pharmacies
- Putting the informal sector under the supervision of the Ministry of Health and Population

Financing

- Mobilizing resources to reduce out-of-pocket expenditure on health

Table 5. Assessment of the private health sector system of regulation in Egypt

Document review	In-depth interviews	Focus group discussions	Online survey
Institutional regime and capacity			
• Ministry of Health and Population is the key player, its affiliates and medical syndicates play an advisory role • Medical syndicate provides social incentives and execute a judicial power • Department of Curative Care is responsible for licensing, General Department of Quality is responsible for accreditation, Egyptian Drug Authority is responsible for pharmaceuticals • Registration in the professional syndicates is mandatory for health-care professionals • Governor provides authorization for establishment of health-care facilities; • Registration in the Medical Syndicate and Ministry of Health and Population licensing are mandatory	• Department of Curative Care is responsible for licensing, General Department of Quality is responsible for accreditation, Egyptian Drug Authority is responsible for pharmaceuticals • Registration in the professional syndicates is mandatory • Registration in the medical syndicate is mandatory for health-care facilities • The governor provides authorization for establishment of health-care facilities		
Information			
• No specific regulation linking production to use for guiding the health system • Health system information is inaccessible	• System allows for producing counts to monitor size of health-care providers • Policy-makers/regulatory bodies database exists, but sometimes incomplete • Health-care mangers/social group: information is insufficient, incomplete, inaccurate and inaccessible		• Inaccessible information

Document review	In-depth interviews	Focus group discussions	Online survey
Monitoring/inspection			
• Ministry of Health and Population, professional syndicates • Inspection is mandatory	• Ministry of Health and Population, Medical Syndicate are key players • System focuses on formal-for-profit providers • System not perceived by non-policy-makers • External oversight may exist • System for connecting complaints weak and protects the profession	• No inspection on private health-care services • No inspection of informal providers	
Enforcement			
• Ministry is the key player • Control-based	• Ministry is the key player • Policy-makers/regulatory bodies/social group: system is effective and ranked as average level • Health-care providers: system is ineffective and ranked as low level	• No system perceived	• Control-based

2.5 Outcome of in-depth interviews with key informants

During the in-depth interviews, the key informants suggested strengthening collaboration with WHO. They believed that the WHO contribution should be country-specific, focusing on health priorities, notably hepatitis C viral infection. They identified the WHO role in defining standard international regulations for health-care provision that are applied worldwide. They thought the WHO contribution could also be achieved through capacity-building programmes, knowledge transfer and raising public health awareness. Box 4 provides a summary of the key informants' suggestions for WHO collaboration.

Box 4. Summary of key informants' suggestions for WHO collaboration

Policy-makers	Regulatory bodies	Health-care managers	Social groups
Help in strengthening the health system		Help in strengthening the health system	Help in strengthening the health system
Help in shaping the health insurance law	Help in shaping the health insurance law		
Focus on national health priorities	Focus on national health priorities	Focus on national health priorities	Help in fighting hepatitis C virus and other health priorities
	Develop international regulation system to be respected by all countries		Share experience in health system legislations
Set regulations for facilitating the licensing process			
Set quality standards	Set quality standards	Help in developing an evaluation system	
Knowledge transfer		Knowledge transfer	Knowledge transfer
	Capacity-building	Capacity-building and providing opportunities to study abroad	
			Raising health awareness

3. Conclusions and proposed actions

3.1 Conclusions

The Government of Egypt is supportive of the growth of private investment in all sectors including the provision of health-care services. Over the past few decades health policies have been aimed at expanding the role of the private health sector. The government has gradually decreased their expenditure on health, giving the opportunity for greater expenditure in the private health sector. However, in the absence of an effective health insurance law, out-of-pocket expenditure on health has become the prevailing payment method. The huge out-of pocket expenditure on health, notably in low- and middle-income countries, puts a huge financial burden on households, limits private health-care utilization, and hinders the universal coverage of care, a main target of governments in both groups of countries.

Regulations for governing the private health sector have existed for many years, however they are out of date and are not able to cope with the advancements in health practice nor with government reform policy to encourage public–private mix. The private health sector plays a significant role in service provision and is governed by both horizontal and vertical measures. The laws are outdated and the numerous resolutions/bylaws are fragmented and rapidly changing. The measures target the formal health-care providers with no mention of the widely practised informal health-care provision. Market entry for the formal health-care sector is controlled through licensing, registration and private–private contracting. Quality is governed by a number of imprecise and non-conceptualized measures. Pricing is left to supply and demand, with individual estimations and an interest in making maximum profit. The regulations to standardize pricing and ensure affordability

are weak. Informal influences have become routine in the system as a means towards overcoming weakness and bureaucracy.

The Ministry of Health and Population has four roles, but they are deficient. It is a policy-maker, but makes no contribution in shaping the policies for health. It is a regulatory body, but has no control over the horizontal measures governing market entry for not-for-profit providers, for-profit investors or the workforce; it has no control over commercialized or informal health-care providers and its judicial control role is not accepted by the providers or the beneficiaries. It is a provider of health, but the quality of its services is questionable.

In addition, there are several entities which are entitled to regulate the private health sector without having developed a mechanism for communication to coordinate the activities. None of the regulations provide a basis for a common forum that allows for effective communication between the regulatory bodies. This is further complicated by the overlapping and unclear responsibilities—a situation which has led to the establishment of numerous small health-care facilities that do not comply with the regulations. Similarly, regulatory capacities are a matter of concern but there are no supporting procedural guides.

There is a huge gap between government policies to promote the private health sector on the one hand and health care managers and society at large on the other. Policy-makers believe the system is potent and effective, while health-care managers and beneficiaries perceive it as weak, ineffective and unaffordable.

The government's initiatives encourage commercialized health care, yet it has no control over such practice; this is left to the institutions' own estimation of services and costs. This has resulted in patient drain to the private sector or privatization of public services.

The government's initiatives include public–private partnership through contracting, which is challenged by the willingness of both sectors to collaborate and build trust. Moreover, public institutions offer low benefits to private providers, which again creates a window for patient drain to private practice.

Given the low salaries in the public sector, the government made use of the regulation gap to allow dual job-holding in all sectors, including the health sector. Practitioners operate in several facilities, self-refer cases, and have less energy and interest, notably in public practice, undermining the quality of care in both sectors and in turn users' trust in the system.

Despite the laws prohibiting informal health providers, the government has still found it to be a solution to serving the poor, who cannot afford to pay for private health-care services and have no standing in the public service. There are no control measures in place governing informal providers. This has given rise to numerous instances of malpractice and misconduct.

In addition, bureaucracy and weak regulations have established a fertile environment for the development of street-level health brokers manoeuvring towards facilitating their entry into the market.

3.2 Proposed actions for Ministry of Health and Population

Long-term measures

Moving from "health regulations" to "regulations for health"

A comprehensive strategic package to strengthen the health system is needed to enhance progress on the private health sector front. The country should move from the narrow "health regulation" focus to a broader "regulation for health" vision. This would entail employing an integrated, double-armed, comprehensive strategy allowing the health system to operate more effectively and efficiently. One arm would operate outside the health system level to strengthen horizontal regulations for health, building a strong foundation for the health system. The second arm would focus on strengthening health system governance, building a conceptualized system of health regulations.

Redefining the role of the Ministry of Health and Population

The vision for the Ministry of Health and Population should be focused on policy-making. The regulatory role should be assigned to an independent body. The payer role should be assigned to a national payer.

Establishing an independent regulatory body

Strengthening the regulatory system for health is best achieved by separating the Ministry of Health and Population's role as policy-maker from its regulatory role. Efforts should be directed towards identifying a model regulatory body for health-care provision. The model should be context-specific and relevant to the national situation. The inclusion of an accreditation unit to fit into this independent entity should be studied.

Building a social health insurance system

Support for national expenditure on health is best achieved through expanding risk-pooling and promoting health equity. Efforts should be directed towards harnessing the potential for social health insurance through enhancing planning progress, guiding implementation, separating service provision from financial function, and making it actuarially sound.

Strengthening the public–private partnership

Enforcing public–private partnership requires setting standard regulations for providing comparable health-care services in both the public and the private sectors which are of same quality, responsiveness and pricing. The state should be freed from the obligation of offering health care free of charge and losing revenues. Government subsidies could be removed gradually and replaced by self-funding. This will enable the public sector to secure an income for providing quality services and improving the remuneration for health-care providers.

Short-term measures

Strengthening health regulations

Health regulations need a comprehensive framework to secure the necessary rules targeting all health-care providers and regulation targets on the ground. There is a need to control bureaucratic measures and facilitate the process. The inspection system should be friendly, aiming at improving services, and the enforcement measures should build on incentives rather than revolve around punishments.

Strengthening the capacity to generate strategic evidence for guiding policies
Improving the country's capacity to produce evidence can be achieved by feeding the data sources with health information. This is best achieved by removing restrictions on data collection and sharing as well as enhancing the use of evidence in policy decision-making. In addition, there is a need to strengthen the mechanisms for releasing information to the public. This requires engaging diverse groups (policy-makers, researchers, academia and civil society) in a dialogue to identify research questions that are relevant to needs.

Building capacities of the workforce for health
Building capacity among the public health workforce would involve supporting public health education in academic settings as well as adding health systems, health policy, economics and management to the curriculum. This also includes building clinical capacity by supporting academic education as well as enhancing clinical and non-clinical training.

Enforcing health seeking awareness in the population
There is a need to promote health-seeking behaviour by mounting a nationwide, context-specific, comprehensive, health awareness programme targeting all population subgroups and tackling all health aspects in an integrated standard package. This can be achieved through developing health education capacities and engaging policy-makers, academic institutions, religious leaders, the mass media, nongovernmental organizations and civil society in developing standard, accepted, health education materials and strategies.

3.3 Proposed actions for WHO

Promoting efforts in strengthening the health system

WHO may help in catalysing national efforts to revitalize primary health care into a comprehensive intersectoral package. It could also organize expert advice on social health insurance models, mechanisms to improve spending on health, and efficient use of resources as tools to support the national reform efforts to expand the private health sector. The WHO may help ministries of health to advocate for "regulations for health" rather than "health regulations" through strengthening their role as partners in the horizontal measures influencing the private health sector.

Enhancing efforts in regulating the private health sector

WHO may continue to transfer global norms, standards and guidance on a standard basic set of regulations, regulatory processes and evaluation systems as the means to develop a standard regulatory model for the private health sector.

Building national capacities for private health sector regulations

WHO may help by developing training guides, conducting training, and providing technical assistance to countries to help them improve the capacities of their health workforce.

Enhancing national abilities to build a monitoring and evaluation system

WHO may provide models for a private sector monitoring and evaluation system using standard indicators, frameworks for analysis and regulatory processes.

Strengthening capacity to generate and use strategic evidence for health

WHO may help towards improving the capacity to produce evidence that is used for guiding policy decision-making through knowledge transfer, technical assistance and training and providing opportunities for international contact as a means for better identifying priority health conditions, assessing needs, and evaluating the impact of interventions.

Raising health-seeking awareness

WHO may help in promoting health-seeking behaviours by helping countries mount nationwide, context-specific, comprehensive health awareness programmes targeting all population subgroups and tackling all health aspects in an integrated standard package through developing health education capacities and engaging policy-makers, academic institutions, religious leaders, mass media, nongovernmental organizations, and civil society in developing standard accepted health education materials and strategies.

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Annex 1. Private health sector regulations in Egypt

a) Presidential decrees

1213/1964	Establishment of Alexandria Governorate Curative Care Organization
1212/1964	Establishment of Cairo Governorate Curative Care Organization
1581/1967	Reorganization of Curative Care Organization
94/1972	Establishment of the Egyptian General Organization for Biological Products and Vaccines
1002/1975	Establishment of the Teaching Hospitals and Institutes Organization
382/1976	Establishment of the National Organization for Supervision and Pharmaceutical Research
81/1978	Establishment of the Health Council
242/1996	Organization of the Ministry of Health

b) Laws

48/1941 (amended by Law 106/1980, Law 281/1994)	Suppression of deception and fraud
95/1948	Supply affairs
163/1950	Forced pricing and profits
367/1954 (amended by Laws 70/1955, 76/1957)	Licensing and registration for practising chemistry, bacteriology, and pathology and organization of diagnostic laboratories, scientific research laboratories and vital pharmaceutical laboratories. Cultures for vaccines of bacterial/viral origin should be selected scientifically and infertile if taken from killed microbes and uncontaminated if taken from living microbes and the origin, nature, type of microbe and number (volume/mass per cm3 of dry substance) of the culture should be registered. Sera from human or animal origin should comply with the set standards and the original source should be free from infection. Respect technical and health standards, inspection
415/1954 (Amended by Law 491/1955, Law 29/1965, Ministry of Health and Population Resolution 46/1965)	Licensing and registration of approved practitioners to practise the medical profession Licence restricted to Egyptian nationals and nationals from countries with reciprocal treatment in which Egyptians are allowed by law to practise medicine Licensed physicians have no right to run more than one clinic. Advertisement is not allowed
481/1954 (Amended by Law 140/1981)	Registration and licensing for practising the profession of obstetrics
537/1954 (Amended by Law 301/1956, Law 136/1988	Practising the professions of medicine and dental surgery. License restricted to Egyptian nationals and nationals from countries with reciprocal treatment in which Egyptians are allowed by law to practise medicine. Medico-legal cases and withholding action
127/1955 (Amended by Law 253/1955, Law 7/1956, Law 360/1956, Law 61/1959, Law	Registration and licensing to practise the profession of pharmacy. Forbids working as pharmacists and practising medical profession even if s/he is a qualified medical doctor. Disciplinary system. List of medicinal plants that can be sold according to ministry standards. Pharmacies and drugstores cannot be established except after licensing from ministry. License is for the owner of the pharmacy, who should be a licensed registered pharmacist and managed by a pharmacist with at least one year

44/1982, Law 14/1984, Law 81/1997, Law 167/1998)	post-graduate experience. Health standards set by the ministry, annual inspection. Licensing and registration for local and imported medical products. It is forbidden to sell samples. Standards for packing (sealed containers, production and expiry dates, place of selling in pharmacies, drug stores, pharmaceutical factories and scientific institutions). Standards for importing drugs. Drugs should not be provided/sold without medical prescription. List of narcotics that should be stored separately and tagged as narcotics. List of flammable products and storage procedures. List of drugs that cannot be sold. List of plants that can be sold in traditional medicine herb shops. Pharmacist cannot practise another job (medicine, dentistry or veterinary) even if licensed. Disciplinary system in the form of punishments, fines and jail
499/1955	Trade of any product used in industry is under control of Ministry of Trade, which is responsible for importing, distribution and trade
198/1956	Ministry of Health and Population license for practising the profession of psychology
165/1957 (Amended by Law 3/1995)	Practising the profession of dental manufacturing. Ministry of Health and Population registration and licensing for Egyptian nationals or nationals of countries with reciprocal treatment
21/1958	Organization of industry
9/1959	Importing and exporting
193/1959	Practising the profession of optician. Ministry of Health and Population license. Selling medical glasses upon medical prescription, cannot examine patients, should keep records for patients, inspection, disciplinary system and judicial control
182/1960	Drug control and organization of narcotic use
212/1960	Trade organization nominating the Supreme Council for Drugs to be responsible for importing drugs and chemicals. Distribution of national or imported products should be through General Institute for Drug Trade and Distribution
1253/1960	Establishment of Supreme Council for Trade and Distribution of Drugs and Pharmaceuticals
Resolution 858/1961	List of products that can be sold in optician shops
113/1962	The Supreme Council for Drugs is responsible for importing and manufacturing drugs and medical chemicals. The council is responsible for inspection and juridical control of importing medical products, manufacturing and information offices
13/1964	It is prohibited for pharmacies to prepare drugs and pharmaceuticals under commercial names or for trade in pharmacies. Pharmacies are only allowed to prepare drugs prescribed in medical prescription.
135/1964	Organization of Curative Care Organization
1209/1964	Establishment of the Health Insurance Organization and its branches for workers in the government, local administration units, public bodies and institutions
45/1969	Establishment of the medical syndicates. Obligatory registration for the practice of medicine
46/1969	Establishment of Dentists' Syndicate and cancellation of Law 62/1949 concerning the establishment of the syndicates and unions of the medical profession. Obligatory registration of dentists in Dentists' Syndicate
47/1969	Establishment of pharmacist syndicate. Registration in Pharmacists' Syndicate
448/1969	Establishment of scientific offices for advertisement which respects standards for storage and distribution of samples
118/1975	Importing and exporting
115/1976 (Amended by Law 28/1978, Law 403/1978, Law 16/1982, Law 226/1982, Law 28/1989,	Establishment of the nursing profession syndicate. Registration in Nursing Syndicate

Law 217/1994)	
28/1978	Amending some provisions of Law 115/1976 concerning the establishment of the nursing profession syndicate
403/1978	Issuing the internal organization of the nursing profession syndicate
106/1980	Food supplements. Disciplinary system in the form of punishments, fines and jail for violation of law
51/1981 (Amended by Law 153/2004)	Organization of health facilities. Authorization from governor after registration in the Medical Syndicate and notification to the health ministry of facilities managed by licensed Egyptian medical professionals. A committee is established to set a price list for accommodation and service fees, to be approved by the governor. Facilities to establish a price list, hang it in a visible site and notify the Medical Syndicate and Health Directorate to register it. Types, management by a licensed physician for medical facilities and licensed dentist for dentistry facilities. A medical doctor can own more than one private clinic but cannot be the director of more than one medical facility in addition to his/her private medical clinics. Number of resident physicians and nursing and technical staff proportional to number of beds and decided by the Ministry of Health and Population and they must be all licensed to practise the profession. Must abide by code of medical ethics and ministry standards including equipment and medical care performance. Abiding by standards in operation theatres and organization of handling radiation. Inspection at least once a year. Ministry of Health and Population judicial control. No advertisement should be done before being licensed and should not include diagnostic and treatment methods and the physician should gain approval from the Medical Syndicate. In case of violating the law, person responsible is liable to punishments, fines, closure, cancelation of license and imprisonment
126/1981	Establishment of the Supreme Council for Curative Care and Insurance
133/1981	Consumption Taxation Law
159/1981 (Amended by Laws 212/1994, 3/1998, 159/1998, 98/2009)	Company Law. Registration as simple partnership, joint stock company, general partnership companies, limited liability company in the Ministry of Trade and Foreign Industry. Conditions for formation, financing and management
16/1982	Amending some provisions of Law 115/1976 concerning the establishment of the nursing profession syndicate
226/1982	Amending some provisions of Law 115/1976 concerning the establishment of the nursing profession syndicate
15/1984	Registration of dental manufacturers in Ministry of Health and Population records. Ministry registration and licensing for those employed in a job for over 5 years but not registered in records
3/1985	Organization of the profession of physiotherapy; ministry registration
28/1989	Amending some provisions of Law 115/1976 concerning the establishment of the nursing profession syndicate
11/1991	Sales General Taxation
217/1994	Amending some provisions of Law 115/1976 concerning the establishment of the nursing profession syndicate
209/1994	Establishment of general syndicate for physiotherapy. Registration in the Physiotherapists' Syndicate
281/1994	Medical products. Disciplinary system through punishments, fines and/or jail
193/1995	Optician shops Ministry of Health and Population licensing
8/1997 (amended by Laws 162/2000, 13/2002,	Investment and incentive law. Registration as domestic investment project in the Ministry of Investment. Conditions for formation, financing and management as an investment entity. 10-year tax exemption period on corporate profits on condition of providing 10% of hospital bed capacity free of charge

13/2004, 94/2005, 19/2007)	
90/1999	Prohibiting foreigners practising the profession of medicine or surgery through agents or brokers
84/2002	Registration of nongovernmental and civil society organizations in the Ministry of Social Solidarity. Conditions for formation, financing and management as not-for-profit entity. Internal regulations, inspection at least once a year to verify the availability of planned requirements
12/2003	Labour Market Law. Regulates the registration and contracting of formal private employees working in private employers or institutions whether Egyptians or foreign through advertisement in various types of media. Foreign employees should not exceed 10% of the workforce within an institution and their wages should not exceed 20% of wages within the institution. Regulates participation of children in formal workforce. Wages in private sector are determined by demand and supply ensuring equal wages and employment opportunities regardless of sex, religion or belief. The law sets a minimum wage for the private sector labour market, an annual wage increase of 7% of basic salary and living cost allowances, yet gives the right to employers to fully or partial close the institutions or downsize them and dismiss the employees with a 2 months' notice. The law provides women paid maternity leave of 45 days after delivery in addition to two years thereafter. Contracting only healthy and competent individuals. The law cites the ethics of working in the formal private sector, including respecting job duties, be punctual and respect managers, respect confidentiality of documents. The law covers formal private sector employees with social insurance, gives them right to 21 days paid holidays. The law calls for capacity-building and skills development. Private institutions employing at least 100 women must set up childcare facilities. Provides first-aid care and health care in public or faith-based institutions
3/2005	Protection of competition and forbidding conflict of interests
71/2009	Issuance of the Law for psychiatric patient care and amendment of Penalization Law 58/1937 and Criminal Procedure Law 150/1950 respecting the rights of mental health patients and defining the ethics of mental health care
67/2010	Public–private partnership in infrastructure through contracting for establishment and service provision

c) Resolutions

December 3/1952 Amended by (Resolutions 4/1953, 7/1953, 2/1954, 9/1954, 248/1961, 250/1966, 541/1971, 332/1971, 425/1972, 380/1973, 93/1974, 194/1975, 103/1987, 312/1977, 383/1977,	The practice of the profession of nursing Ministry of Health and Population licenses

436/1979, 218/1982, 353/1983	
5/1955	Assistant pharmacists. Health restrictions required in workers and in those who distribute medicines in pharmaceutical enterprises
14/1955	Standards for adding natural and artificial beta-carotene in colouring food
143/1955	Discipline of assistant pharmacists
14/1956	Pharmacists. Assigning some employees as judicial control officers
463/1963	Drug factories and medical chemicals. Establishment of a committee for setting quality standards for drug factories
397/1966	Inspection of optician shops
38/1969	Assistant pharmacists must be registered in the Ministry of Health and Population records
69/1973	Pharmacies. It is forbidden to sell some types of eye drops
88/1973	Reorganization of the punishment trials for those licensed to practise the profession of processing and selling medical glasses
234/1974	Charter of medical ethics sets the rules for the ethics of medical profession
160/1978	Optician's shops. Prescriptions and fitting of contact lenses are only done by ophthalmologists. Optician's shops are only allowed to produce them
216/1982	Ministry of Health and Population requirements for licensing medical facilities: structural standards, licensing process and price list
480/1982	Midwives and assistant midwives. Conditions for Ministry of Health and Population licensing and registration
487/1985	Organizing the marketing for products affecting mental health
554/1985	Egyptian company for drug trade is responsible for importing vaccines which should be registered in Ministry of Health and Population
150/1986	Execution of Law 3/1985 for the organization of the profession of physiotherapy. Ministry of Health and Population licensing and registration
379/1986	It is prohibited to export drugs and pharmaceuticals that are not registered and their certificates approved in Ministry of Health and Population
210/1987	All blood and blood products imported/received as gifts must be tested by Ministry of Health and Population for viral hepatitis and HIV/AIDS
313/1991	Reformation of the importing and pricing committee for drugs, chemicals and medical product. Set standards and rules for pricing. Pricing for two years under stable conditions
331/1991	It is forbidden to provide non-steroidal anti-inflammatory drugs without a medical prescription that should be signed by the pharmacy except those for external use
191/1992	It is forbidden to provide drugs containing glaphenine without a medical prescription that should be signed by the pharmacy
2/1993	Price list for laboratory investigations in central laboratories of the health ministry
268/1993	National Institute for Drug Monitoring and Research is responsible for examining all industrial phases for pharmaceuticals in place of production through technical committees
129/1994	Formation of the pricing committee for drugs and chemicals. Conduct studies for pricing in vision with economic costing
178/1994	Formation of the importing committee for drugs, chemicals and raw materials. Reviewing importing strategies for the private sector, national company for drug trade, importers and exporters
321/1994	Setting the list of subsidized drugs
326/1994 (Amended by Resolution 386/1994)	Laboratories. Formation of a national committee to confirm quality and control
342/1994	Laboratories. Owned by licensed specialized medical doctor

	Specimens from human subjects should only be withdrawn by a specialized licensed medical doctor
410/1994	Exemption of drug samples from general sales taxation and they are added to the approved list of goods for importing
161/1995	Medical facilities licensed as private or investment establishments must provide emergency care free of charge for 24 hours
412/1995	Prohibiting the circulation of or use of all filters and kidney dialysis equipment except under control certificates issued by the National Organization for Drug Monitoring and Research and control to ensure their compliance with adopted Egyptian standard specifications. Regular inspection from Central Pharmaceutical Unit and National Institute for Drug Monitoring and Research
70/1996	It is prohibited for hospitals or curative institutions to contract foreign medical doctors without ministry permission. Foreign medical doctors should hold a distinguished professional technical record in his/her specialization and that no such experts are available locally.
106/1996	Cosmetics. Registration in Ministry of Health and Population and are only produced locally in licensed factories. Advertisement should abide to description in Ministry of Health and Population records
144/1996	Licensing local drug factories, drug stores and establishment of a record of importers in Ministry of Health and Population Central Pharmaceutical Unit. Implementing health standards for selling drugs and regular inspection
148/1996	Formation of the pricing committee for drugs and chemicals. Conduct studies for pricing
348/1996	List if insecticides that cannot be used or imported
16/1997	Working according to the rules of the roster concerning the ethics of the profession of physiotherapy
113/1997	Child formula and food products. Registration in Ministry of Health and Population Central Department for Pharmaceutical Affairs
242/1997	Banning importing all products produced by genetic engineering
213/1998	Ministry of Health and Population registration for drugs, medical products and disposables
60/1998	It is forbidden to sell medicines that are not registered
326/1998	Food supplements. Registration and inspection by Ministry of Health and Population
90/1999	Foreign medical doctors cannot work through brokers, only through authorized institutions
91/1999	Advertisement for any type or treatment, medicines and pharmaceutical products are prohibited in any mass media communication and requires approval from the Ministry of Health and Population committee
174/1999	It is prohibited to import pharmaceutical products, medical supplies, cosmetics, insecticides, diagnostic products, food supplements and vaccines unless they and their manufacturer are registered in Ministry of Health and Population
34/2000	Private and specialized medical clinics are not allowed to conduct major operations. They are only licensed to practise minor and moderate operations on condition of abiding to structural requirements
76/2000	Registration of drugs, pharmaceutical products, food supplements. Organizing advertisement for drugs, pharmaceutical products, food supplements
172/2000	Stop importing and production of pharmaceuticals which contain codeine and hydrocodeine
240/2000	Quantity of patches containing pfentanyl cannot exceed five patches regardless of the concentration
288/2000	All products containing tramadol, nefopam and nalbuphine are considered narcotics and included as class 2 drugs
300/2000	Ministry of Health and Population authorization for establishment of hospitals or drug factories based on quality standards

60/2001	A standing committee is established to consider requests for the establishment of medical facilities, including hospitals, laboratories, X-ray centres, physiotherapy centres and health clubs) or newly established pharmaceutical factories. The committee is responsible for examining the requests to create, sell, or change activity, change management and the completion of equipment and staffing to ensure comprehensive quality and issues initial approval until licensing is issued
75/2001	Health clubs. Registration in Department of Non-public Curative Care. For health clubs to provide services, they must hire qualified employees capable of providing services
186/2001	Licensed private or investment medical facilities under Law 51/1981 must provide free medical care in cases of emergency for 24 hours only; afterwards the patient has the right to stay in the hospital at his own expense or be transferred to the nearest public hospital. In addition, the hospital director must inform the patients in advance of the costs of surgery and of any possible consequent complications. The patient or a guardian must sign a document declaring his knowledge of the full cost. Health-care facilities are forbidden to hold the patient's body or to exploit a death for financial benefit or force the family to sign checks
187/2001	Rules for the preparation of medical reports in hospitals
192/2001	List of hazardous materials that need licensing for use
244/2001	Private clinics and hospitals. Conditions for conducting operations
254/2001	Medical facilities should provide the patient with a comprehensive medical report immediately after discharge. Physicians entitled to conduct surgical and endoscopic procedures or and procedures necessitating special skills in clinics or private hospitals should have a degree in the specialization and holder of training certificate for at least 2 rounds of approved training and the facility is prepared to cope with any consequent emergency requiring surgical interference or emergency care. The names of these physicians are registered in a special record in the Ministry of Health and Population
271/2001	Female genital mutilation is prohibited by doctors, nurses and others
25/2002	Physicians who commit a serious professional mistake are liable to suspension from work. The physician must receive approved training from an authorized scientific council and prove his/her skill to be authorized to work
206/2002	Pharmacies, drug stores. Health structural requirements
136/2003	Foreign employees in the private sector should receive licensing from the authorized ministry (Ministry of Health and Population in case of private health-care facilities) and work visa for residence and work in Egypt
38/2004	Pharmaceutical factories. Registration in Ministry of Health and Population, registration in factory records in investment journal of ministry of investment. Temporary registration for one year until obtaining quality certificate from national authorities for quality
42/2004	Ministry of Health and Population authorization for importing potassium permanganate, acetone
113/2004	Approval for marketing national and imported pharmaceutical products
153/2004 (amended by 518/2012)	Organization of work in medical facilities
236/2004	Medical facilities. Forbidding the conduction of surgical operations except in places that are equipped and licensed in accordance with the provisions of Law 153/2004
191/2005	Re-registration of pharmaceuticals every 10 years
197/2006	Egypt medicine constitution 2005 is the source for registering drugs and pharmaceuticals in Egypt
229/2006	Registration of local and imported cosmetics. Inspection and testing for efficacy
403/2006	New methods of health care (alternative medicine) should gain approval from the Ministry of Health and Population Committee for New Medical Care before

	implementation
427/2006	Biological products and vaccine factories inspection of vaccines and biological products by Central Department of Pharmaceutical Affairs and National Institute for Research and Monitoring Biological Products
435/2006	Adopting WHO Constitution for good production practices for biological products as Egypt Constitution for production methods for vaccines and biological products. The constitution to be updated according to WHO
436/2006	Adoption of the Egyptian constitution for assessment of clinical trials for biological products. The constitution is to be regularly updated according to WHO instructions
52/2007	Reformation of scientific committee for assessment of products that have no similar products in the market or those whose use is warned by WHO for efficacy, safety and reliability and assessment of all studies done. Assessment of the market need and its efficiency.
271/2007	It is prohibited that doctors, nurses and others cut or modify any natural part of the female reproductive system (FGM) in governmental or nongovernmental hospitals or any other place
537/2007	Adopting WHO Constitution for good laboratory practices for biological products as Egypt Constitution for laboratory practices, vaccines and biological products. The constitution to be updated according to WHO
539/2007	Adopting WHO Constitution for good manufacturing practices for pharmaceutical products. All companies producing pharmaceutical products should comply with the rules and are liable for inspection.
540/2007	Banning products that do not comply with standards
19/2008	List of drugs banned in Egypt
78/2008	Preparation of list of drugs registered in Ministry of Health and Population and electronic publication www.mohp.gov.eg. Preparation of list of imported non-registered drugs allowed for trade in Egypt and considered “in process of registration” for importers to complete registration within 90 days. Updating the list of drugs that are prohibited in Egypt
153/2008	It is forbidden to sell blood bags whether empty or filled as these products are only sold by hospitals authorized and licensed to have blood banks
141/2009	Technical specifications for licensing in government hospitals, private medical centres and others
25/2009	Distribution companies and drug stores. Ministry of Health and Population licensing
26/2009	Registration fees for pharmaceutical products
296/2009	Medical products. Re-organization of registration procedures in Ministry of Health and Population
377/2009	Inspection of health clubs
380/2009	Pharmacies. Inspection and quality standards notably structural
430/2009	Drug, cosmetic and pharmaceutical factories. Establishment of committee for inspection for licensing estimating technical and health requirements set by Ministry of Health and Population
482/2009	Laboratories. Licensing requirements to conduct polymerase chain reaction for diagnostic analysis for influenza A/H1N1
492/2009	Laboratories. Pricing H1N1 analysis (LE 450)
297/2009	Biological products, vaccines, sera and blood products. Rules for registration and re-registration with the health ministry
128/2010	The issuance of the executive regulation of psychiatric patient care Law 71/2009
399/2010	Assessment of clinical trials for biological products and vaccines by national institute for monitoring and research on pharmaceutical products according to standards
428/2010	Price list for economic commercialized public health-care services. Public teaching hospitals and institutions affiliated to the Teaching Hospitals and Institutes Organization may contract individuals or institutions, according to the estimates of the director and board of directors

576/2010	Central committee for inspection of safe disposal of medical waste
622/2010	Reformation of scientific committees for assessment food supplements, general surgery, antiseptics, pain treatment, orthopaedics, drug alertness, insecticides and biological products
674/2010	Price list for economic, commercialized, public health-care services. The hospital director may contract physicians, companies or organizations if needed and the wages are set according to the director's proposition and approval of the board of directors. Family health and primary health-care units and centres may contract pharmacies to prescribe drugs at an economic reduced price with a minimum of 10% for beneficiaries.
131/2011	Assessing the quantity of pharmaceuticals which contain hydromorphine and which the doctor can prescribe in a medical prescription with a maximum of 28 tablets according to concentrations registered in Ministry of Health and Population
172/2011	List of narcotics that affect mental health. Importing of these substances needs approval from Ministry of Health and Population. They cannot be distributed except through the Egyptian Company for Drug Trade and its branches. Inspection on pharmacies and distributed to public upon prescription
560/2011	Cardiovascular catheterization units. Licensing on condition that it is contracted with a licensed hospital. Organizing the work in the departments of cardiovascular catheterization. Structural, equipment and infection control standards
842/2011	Reformation of pricing committee for drugs and food supplements
351/2012	Mental health facilities. Registration fees (LE 500 per bed; maximum LE 10 000) in the records of the Regional Council for Mental |Health). Patient fees LE 100 per case if admission exceeds one week
391/2012	Establishment of clinical pharmacology unit and pharmacology information unit in hospitals
495/2012	Establishment of drug information centre within the central department for pharmaceutical affaires to respond to all technical queries through scientific library compiling all information sources and using the internet
498/2012	Standards for registration and inspection of cosmetics manufactured in the country
499/2012	Pricing pharmaceutical products and profit share for pharmacists
762/2012	The use of any pharmaceutical product containing cyproheptadine with vitamins as a syrup is prohibited; no registration is accepted
575/2012	Registration of pharmaceutical products

The private health care sector plays an increasingly important role in the health systems of many low and middle-income countries. While most countries in the WHO Eastern Mediterranean Region have passed regulations related to the private health sector, little is known about the regulatory process or its comprehensiveness, effectiveness, institutional capacity and enforcement mechanisms.

This report contains the findings of an assessment of the regulation of the private health sector in Egypt. It examines the existing regulatory policy and legislative framework, institutional arrangements, instruments and level of enforcement for private health care within the country. It aims to support the development of evidence-based strategies for the regulation of the private health sector in the countries of the Region.

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