

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

Yemen



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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 triggered WHO to propose that 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 Yemen 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 was 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 were 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 hierarchical 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 a briefing of the country report. The 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 the research and proposes recommendations for strengthening the contribution of the private sector in health-care service provision.

1. Research methodology

1.1 Regulatory framework

This 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 Yemen applied the WHO regulatory framework (Fig.1). The regulations are affected by the macro-legislative and business environment, national health policies, 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.

1.2 Key variables for data collection and instruments

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

- regulatory environment
- law and regulation of general environment for the private sector
- documents related to the national health policies, strategies and plans, and transparent policy process
- perception of health care as a private good, quasi-public good, or public good
- laws and regulations for the 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. English and Arabic versions of all instruments are available from WHO Regional Office for the Eastern Mediterranean.



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

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 36 Yemenis 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 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 that might otherwise not be available for interviews. The information was not representative, but served as a useful guideline for evaluation. We received 39 responses. Data analysis was done using the SPSS computer software 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 the 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 the consent forms are available at the Social Research Centre and WHO Regional Office for the Eastern Mediterranean.

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 the regulation of the private health sector in Yemen

2.1 Context

Yemen lies in the south of the Arabian peninsula. It has a surface area of 460 000 km² and an estimated population of 24 million distributed over 334 districts in 21 governorates. Yemen is one of the least-developed countries, with a human development index ranking of 154 (out of 184) and a per capita gross domestic product of US\$ 1160 (9). The economy is oil-dependent, fluctuating with the global market. The repercussions of a series of armed conflicts in the north, separatist movements in the south and natural emergencies in the east, as well as the 2011

uprising have resulted in acute deterioration of the already poor economic, financial, and monetary indicators and worsening of the livelihood and humanitarian situation. As a response to this situation, the country embarked on political transition over a two-year period ending in February 2014. The country faces numerous challenges, including rapid population growth, poverty, illiteracy, and unemployment (8,9). Yemen has made significant progress in improving the health of the population since 1979 when the primary health care programmes were adopted. However, health indicators show that the situation is still below optimum (9).

2.2 Health system

National health strategy

The National Health Strategy 2010–2025 was developed to set out future directions and outline the vision, mission and actions for the Ministry of Public Health and Population. Among the major axes of intervention were redefining the role of the health ministry, applying proper standards in health services consistent with approved national guidelines, and developing the organizational and legislative framework as a priority area for strengthening Ministry of Public Health and Population leadership and health system performance (Box 1). It should be noted that the private sector was represented during the development of the National Health Strategy and was included in almost all the recommended interventions, along with a call for more specific mechanisms of coordination for public and private partnership.

However, the implementation of the National Health Strategy 2010–2025 was halted by the events of 2011 and it was replaced by the Transitional Programme for Stabilization and Development. Partnership with the private sector was given priority during the transitional period (Box 2).

Health financing and health workforce

Health sector funding is not really adequate to health needs in comparison with other sectors of government. According to the 2007 national accounts, 4.13% of the government budget was allocated to health; per capita government health expenditure was US\$ 16.92 (regional average US\$ 97.8) and government health expenditure was 1.47% of gross domestic product (regional average 2.13%). The government is gradually reducing its contribution to health expenditure. In 2010, private sector expenditure on health was estimated at 79.0% of total health expenditure, and out-of-pocket expenditure was 94.5% of private health expenditure (2). Funding allocation and utilization are not efficient and do not meet the needs at the different levels of care.

Allocation for central operational costs is very limited, weakening the planning, monitoring and supervisory role of the Ministry of Public Health and Population. The majority of health-care users pay directly out-of-pocket for curative care and a large proportion of the preventive health services. This exposes them to falling below the poverty line since there are no adequate mechanisms to protect the poor from catastrophic payments.

There is not yet a national database/map nor a comprehensive plan on human resources development. There is no coordination with academic and training institutes, whether public or private. The Ministry of the Civil Service dominates the identification and approval of the health system's allocation of human resources and their categorization. The health system has

tremendous difficulties in optimizing the performance of health professionals. Wages are low among the different categories of health professional leading to a drop-out of qualified staff from the public sector to the private sector and to outside the country.

Human and financial resources are not balanced within the Ministry of Public Health and Population; this has led to variations in the performance of the directorates without any administrative or objective justification. Both medium- and long-term strategic plans are unrelated to daily practices.

Box 1. The main axes of intervention in the health system, Yemen National Health Strategy (2010–2025)

Governance and leadership

- Develop medium and long term strategies for the health system with clear priorities agreed upon by all partners to ensure harmonization, ownership and sustainability.
- Improve the organizational structure of the Ministry of Public Health and Population with clear definition of rules and responsibilities of the different managerial levels in harmony with the local authority law.

Health services

- Develop an integral framework to provide affordable, accessible and acceptable health care services according to recognized criteria of quality of the care.
- Human resources.
- Improve, manage and organize the health human resources to increase performance levels and job satisfaction and to create a motivating work atmosphere.

Health planning

- Develop and implement a methodology for planning and health investment in services, labour force, technology and infrastructure through the provision of an evidence-based development health plan.

Health information system

- Develop a unified user-friendly system to ensure availability, flow and utilization of correct health information.

Infrastructure

- Develop a health map of health facilities to rehabilitate and operate the present health facilities based on equitable and explicit national criteria.

Medicine and health technology

- Regulate the procedures of procurement, registration, quality control, monitoring and inspection over the production sites of medicines, distribution, storage, pricing, and rational use of medicine and products with improvement of procurement, storage, distribution and maintenance systems.

Health funding and health insurance

- Increase investment in health with a focus on human resources, health information and medicine and health technology. Encourage development partners towards implementing the overall sector approach in funding. Balance allocation of resources among the various levels of health system, the rural and urban areas and the preventive and treatment services in order to further approach regional standards in government health expenditure.

Box 2. Government actions to enhance the role of the private sector in Yemen

- Continue improving the legislative and institutional framework by enacting and implementing new laws, the most important of which is the law on public–private partnership in the field of infrastructure. Develop the information systems and automate the procedures for registration and implementation of investment programmes.
- Enact and enforce the law on public–private partnership.
- Enhance private sector competitiveness, accountability, transparency and free entry.
- Improve cooperation between civil society organizations, the private sector and the local authority.

Public health sector

The Ministry of Public Health and Population has an overall responsibility for public health, mandated by Public Health Law No. 4 of 2009. Public health services are provided by the Ministry of Public Health and Population, Ministry of Interior, the Republican Guard and the Ministry of Defence, and the Aden Refinery Company. The Ministry of Public Health and Population facilities are arranged in a four-tier system starting from baseline primary health care through the secondary and tertiary levels to specialized care. Care at the primary level is maldistributed and malfunctioning. The building and operating of health facilities, especially at the primary level, are influenced by interventions from local leaders' towards politically-visible achievements, leading to a variation in coverage. The functioning of public health facilities is confounded by the scarcity of staff qualified in health administration, weak community involvement, health workers' preference for working in the cities, and a lack of medicines and medical equipment.

The current Ministry of Public Health and Population structure, role and functions are not compatible with the decentralized administrative system. When introduced, decentralization was aimed to give governorate health offices partial control of the capital and operational costs. The absence of clear-cut tasks, and overlapping responsibilities at the central and local levels, along with unclear administrative responsibilities between health offices and local councils, and the lack of clarity in roles, has led to interference from many parties in the leadership of health districts, complicating the existing situation. Similarly, there is no general reference to guide each office in the organizational set-up in governorate health offices. There are major weaknesses in the management and provision of integrated services in health districts.

Private health sector

The private health sector has expanded since the early 1990s, encouraged by the government. Table 1 shows that the number of private hospitals and infirmaries is double that in the public sector and the number of health centres is almost equal. Information is limited on the number of private beds. The private health sector is concentrated in the urban areas; in the capital alone there are approximately 1593 facilities and there are 581 in Aden. This is further aggravated by the geographical diversity and population dispersion.

The role of the not-for-profit private sector is still limited in health. Around 25 local and international nongovernmental organizations offer specific health services in various governorates. The health care provided by charitable institutions and nongovernmental organizations is restricted to the provision of curative services and is largely concentrated in the major cities, the urban areas and their surroundings.

Table 1. Coverage with health services and health personnel

Type of service/personnel	Number/10 000 population	
	Public sector	Private sector
Number of hospitals	0.1	0.20*
Number of beds	7.0	NA
Health centres and units	2.0	0.18
Doctors	3.0	0.95
Dentists	0.2	0.20**
Pharmacists	1.0	2.10***
Nurses and midwives	7.3	NA
Assistant technical workers	10.2	NA

*Includes hospitals and infirmaries; **dental clinics; ***pharmacies and drug stores.

NA = data not available.

Source: Fourth National Health Plan 2010–2025.

Coordination and regulation of the private health facilities is delegated to the district health management teams and governorate health offices. The Ministry of Public Health and Population recognizes the existence and limitations of the activity of the private sector in health, limitations that call for remodelling its role. In the Ministry's assessment, weak organization and supervision of the private sector has limited the quality of health services. However, it is difficult to separate the two sectors as many employees in the public sector work in the private sector as well.

2.3 Private health sector regulation

Private sector environment

Overall, the environment in Yemen promotes private investment, including in the health sector. The investment law provides what is seen as ample incentives in terms of tax and customs waiving and concessions. However, several concerns have been raised about the current security situation and political unrest, which limit the investment potential in the country. Corruption and poor enforcement are also major limitations to private investment in different sectors, including the health sector. Table 2 provides an assessment of the private health sector environment, policy, regulation and regulatory bodies in Yemen.

Private health sector policy

The government is redressing its contribution in health expenditure, giving space to the private health sector, which is estimated at 79.0% of total health expenditure. However, out-of-pocket expenditure on health has markedly increased, reaching 74.5% of private health expenditure (10).

The Ministry of Public Health and Population considers the private health sector an integral part of the health system and encourages its growth. Laws do not set limitations on the type of health services provided by the private sector. In addition to the encouraging investment laws, there is a shortage of public health services in the country, giving much scope for the expansion

of private health care. The plans of the Ministry indicate a readiness for establishing partnerships with the private health sector and civil society in both short-term (Development and Transitional Plan) and long-term (National Health Strategy 2010–2025) policies. According to the key informants, the private health sector is less complicated, more flexible and more able to respond to market needs compared with the public sector (Table 2).

Table 2. Assessment of the private health sector environment, policy, regulation and regulatory bodies in Yemen

Document review	In-depth interviews	Focus group discussions	Online survey
Private sector environment			
<ul style="list-style-type: none"> Government policies promote private sector Investment laws provide incentive to private sector 	<ul style="list-style-type: none"> Environment encourages the private sector Laws provide sufficient incentives Insecurity, political instability, corruption and poor enforcement are major challenges to private investment 		<ul style="list-style-type: none"> Significant private sector contribution Environment is sometimes perceived as discouraging to the private sector
Private health sector policy			
<ul style="list-style-type: none"> Government expenditure on health is declining Private sector expenditure on health is 79% of total health expenditure, 94.5% are out-of-pocket Ministry of Public Health and Population encourages private health sector growth 	<ul style="list-style-type: none"> Significant private health sector contribution Shortage of public health services gives room for expansion of private health care There is controversy in perceiving health (public good/public–private good) Limited financial and human resources, poverty and absence of health insurance limit private health sector utilization Informal sector is not approved and dual job-holding is not governed 	<ul style="list-style-type: none"> Significant private health sector contribution Out-of-pocket payment is the prevailing method 	<ul style="list-style-type: none"> Significant private health sector contribution Environment is somewhat discouraging to private health sector Policies for private health sector differ from those for the public sector There is controversy in perceiving health (public good/public–private good) Informal influences are important
Private health sector regulation			
<ul style="list-style-type: none"> Horizontal and vertical measures Laws do not limit private health 	<ul style="list-style-type: none"> Regulations focus on private sector more than public sector Non-policy-makers 	<ul style="list-style-type: none"> No regulations are perceived 	<ul style="list-style-type: none"> Many are unfamiliar with existing regulations Regulations are not

Document review	In-depth interviews	Focus group discussions	Online survey
<p>services</p> <ul style="list-style-type: none"> No regulation on dual job-holding and informal sector 	<p>are unfamiliar with existing regulations</p> <ul style="list-style-type: none"> Lack of specification on oversight role of the Ministry of Public Health and Population Private sector is competitive rather than complementary 	<p>and even if they exist are not respected</p> <ul style="list-style-type: none"> Doctors are exhausted from working in more than one place The informal sector is easily accessible 	<p>easily accessible</p> <ul style="list-style-type: none"> Regulations are mainly in form of government purchasing services and tax exemptions Dual job-holding is common Informal sector is not controlled
Regulatory bodies			
<ul style="list-style-type: none"> State executive branch, legislative branch, Ministry of Public Health and Population, General Medical Council, Higher Authority for Drugs and Medical Supplies, General Authority for Investment, professional syndicates and other ministries Self-regulation is enacted by professional syndicates 	<ul style="list-style-type: none"> Ministry of Public Health and Population, General Medical Council, General Directorate of Control and Inspection, Higher Authority for Drugs and Medical Supplies, professional syndicates, Union of Private Hospitals Health system is still not ready for self-regulation Role of syndicates in self-regulation is weak 		<ul style="list-style-type: none"> Ministry of Public Health and Population, local councils, professional syndicates, medical associations, patients' organizations, consumer boards, health committees in parliament Self-regulation is not encouraged

Despite the government's efforts and the acknowledged private health sector contribution, some people in Yemen feel that their country discourages the role of the private health sector. This belief is supported by the insecurity, political unrest and corruption. The country is still in the process of converting the vision of health from a public good to a mix of public and private benefit. In addition, inadequate resources and poverty limit people's utilization of private health services and reduce the profitability of private investment, notably because of the absence of a health insurance scheme. In addition, the system appears to provide the opportunity for informal influences such as lobbying, payments and personal communication to influence health sector policies.

Existing regulation and legislation

There is a wide range of entities, laws and regulations focused on governing the health sector. Annex 1. provides a list of private health sector regulations. Health-care professionals are affected by a greater number of the laws. The profession is regulated by the Law on Practice for the Medical and Pharmacy Professions, the Public Health Law and the bylaws of the Ministry of

Public Health and Population. The laws cover all aspects of professional practice, e.g. licensure, rights, numbers and distribution, performance, and advertising. There are, however, no explanatory notes or procedural clauses. An example is the General Medical Council, which still lacks an executive bill. This allows for different interpretations and subjective implementation of the regulations.

Most of the regulations regarding health institutions focus on the private sector. Accordingly, and despite the weak regulatory system, the private health sector is thought to be better at conforming with health standards compared with the public sector. The main regulating law is that on Private Health and Medical Institutions. The clauses are very precise on the requirement and procedures of the licensing process and its renewal, with a general referral to quality of care, number and distribution, and advertising. Problems in Ministry of Public Health and Population oversight arise because of lack of specifications in the law on these aspects.

It is worth noting that many of the non-policy-makers were not familiar with the available regulations and were not aware of an accessible system or database for private health sector legislation and regulatory documents.

It appears that there are no regulations or control of the government on dual job-holding and the informal health sector. This is aggravated by the post-2011 political and security unrest. During the transitional period, 2012–2014, stabilization and regaining security are the top government priorities overtaking system strengthening and governance. This has caused a sense of helplessness and a great deal of frustration towards the government role in regulating the private health sector.

Regulatory bodies

The regulatory bodies include public and independent entities each having diverse levels of involvement and authority. The Ministry of Public Health and Population is the main regulatory body, mandated by the Public Health Law to be in charge of development of health policies, strategic planning and resource allocation, financial management, monitoring and evaluation, and health information systems. Despite this strategic direction, flowing from the redefinition of the role of the Ministry (National Health Strategy 2010–2025), it retains its role in the provision of health services. Other regulatory bodies include the General Medical Council, the professional syndicates, the Higher Authority for Drugs and Medical Supplies, the General Authority for Investment, the Ministry of Local Administration, and the interior and justice ministries. Table 3 presents a brief description of the functions of the main regulating authorities.

Self-regulation is enacted through the professional syndicates, yet they have not played an important role mainly because of internal divisions over political stances and personal interests. In addition, the syndicates do not consider the private sector to be part of their mandate. The syndicates are not able to take actions against their members; the medical syndicate, for example, is faced with the argument that doctors with dual jobs are seeking to improve their income, a situation resulting from the failure of the syndicate in its primary role of protecting the members' financial and professional rights.

The owners of the private health facilities have established the Union of Private Hospitals to protect the rights of investors and coordinate their work in terms of referral among the major

hospitals and continuing medical education. The Union's scientific and other activities are at an early stage. On the other hand, other participants criticized the role of the Union of Private Hospitals for being centred around the benefits of the owners. But overall, the Ministry of Public Health and Population has welcomed this initiative and has gone as far as involving the Union in the implementation of the regulations. Despite these efforts, self-regulation is discouraged. It is thought that the health system lacks a conducive culture for it and is still not ready for self-regulation.

Table 3. The main regulatory bodies and their functions in Yemen

Regulatory body	Functions
Ministry of Public Health and Population	<p>The General Department of Private Health Institutions is responsible for licensing and inspection of the private health facilities.</p> <p>The General Department of Pharmacy and Medical Supply contributes to categorization of pharmacy-related jobs and keeping records and information on private pharmacies.</p> <p>The General Department of Planning works on encouraging investment in health and provides support and information to (potential) investors.</p> <p>The General Department of Architecture Affairs sets the construction standards for the public and private sector facilities.</p>
The General Medical Council	<p>A public entity that follows the Prime Minister's Office. The council is given the authority to enforce all laws regulating the medical and pharmaceutical profession, contributes to updating medical curricula and quality assurance of medical education, appraises certificates, and issues licenses for medical doctors, dentists and pharmacists. The council was established by presidential law (on Establishing the Medical Council, No. 28, 2000) and reactivated in 2009. The role of the Council was further emphasized in another presidential law (Practicing the Medical and Pharmacy Professions, No 22, 2002).</p>
Professional syndicates	<p>Independent professional organizations that are aimed at promoting the professional and personal rights of members. Syndicates issue licenses/work permits and receive complaints about misconduct to be reviewed. There is a great overlap of functions with the General Medical Council. They are overseen by the Ministry of Social Affairs and Labour.</p> <p>The Medical Syndicate is the most visible syndicate. It protects the rights of professionals, patient safety and community health. It issues work permits and encourages professional conduct but has no supervisory role over professionals.</p>
The Higher Authority for Drugs and Medical Supplies	<p>The Authority is responsible for implementing the national health policy on drugs, and medical supplies, and cosmetic, chemical and laboratory substances that have a medical effect. The Authority draws up the drug policy in consultation with the stakeholders, establishes standards for local manufacturing of these products, oversees quality control (running laboratory tests), and gives a technical opinion for import permits.</p> <p>It keeps technical records and databases for the importers, agents and wholesale vendors for local and imported products.</p> <p>It is also responsible for establishing and issuing drug prices and control over implementation, devising a control system for these products and encouraging competition among importers.</p>
The General Authority for Investment	<p>The Authority provides timely and accurate information on the local investment climate, laws and regulations, and supports local and foreign project concept development. The Authority also facilitates the application process for health facility licensure.</p>

Regulation targets

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

Regulating market entry

As clearly outlined in the law on practicing the medical and pharmaceutical professions, health-care professionals initially register at the General Medical Council and the appropriate professional syndicate and then apply for complete registration on condition they have completed an internship and mandatory rural service of 6 months–2 years. Doctors are issued a temporary work permit for rural service. In reality there is an overlap between the syndicates and the General Medical Council because laws governing the syndicates were not modified following the establishment of the General Medical Council in early 2000.

For health-care facilities, the legislators, with the aim of encouraging investors, allow licenses to be issued from more than one public entity, such as the Higher Investment Authority and district/governorate health offices. These entities do not necessarily have the technical capacity to ensure that licensing requirements are applied, leading to the mushrooming of small, substandard hospitals. In addition, health-care facilities must be licensed from the Ministry of Public Health and Population or health offices, according to the capacity of the hospital/facility. An application for a health facility license should take around six weeks from the initial application to the initial license issuance, but in practice may take 6–12 months for hospitals. The facility can be opened under the initial license, which lasts for one year, to allow the investor to complete the furnishing and equipment of the facility. However, the administrative procedures are not controlled and are dependent on the individual employees, which makes the duration of the application unpredictable. Despite this, the administrative fees are nominal, even for the licensing of major health facilities. Informal payments constitute a serious problem at all levels.

Dual job-holding exists and reflects a professional need to compensate for low salaries; it is protected by the associations and the state. This problem is prevalent not only in the health sector but in all government institutions. It is acknowledged that practitioners take additional jobs to supplement their income from public posts. However, holding dual jobs has a negative effect on the practitioner's performance because of overwork and exhaustion. In addition, a number of practitioners will make profits in the public health facilities or direct patients to a private health facility to increase their income. No action is taken against this type of practice mainly because there is no law or regulation banning or governing the practice. In addition, the government and the syndicates accept dual job practice as a matter of fact. This is because of the inability of the syndicates to defend the practitioners' rights to decent wages. The government is assumed to avoid the problem: preventing dual job practice would entail wide-scale intervention and allocation of resources from the government.

Informal health care represents an important portion of the health-care sector. Users seek help from informal health-care providers not only because of community beliefs but mainly because of the poor perception of the availability, quality, prices and administrative procedures of the formal health-care services. These informal services are not licensed and have no oversight from the Ministry of Public Health and Population. The passive position of the government towards the informal sector can be interpreted as indirect encouragement. In comparison, the Medical Syndicate and the General Medical Council, who largely represent the public and

independent medical professions, strongly reject the informal health sector. Although they cannot take action against informal health-care providers, they blame the Ministry's lack of action for its expansion.

Table 4. Assessment of private health sector regulation targets in Yemen

Document review	In-depth interviews	Focus group discussions	Online survey
Market entry			
<ul style="list-style-type: none"> Health-care professionals register at General Medical Council and Medical Syndicate Health-care facilities are licensed from multiple public entities No regulations banning/governing dual job-holding and the informal sector 	<ul style="list-style-type: none"> Health care professionals register at General Medical Council and Medical Syndicate Health care facilities are licensed from multiple public entities Administrative procedures are insufficiently controlled Dual job-holding is a common practice Informal health care is rejected 	<ul style="list-style-type: none"> Dual job-holding is allowed by government Dual job-holding leads to patient drain to private practice Informal health care is sought mainly because of poor perception of availability, quality, affordability and responsiveness of formal health-care services 	<ul style="list-style-type: none"> Licensing clinics is relatively fast while health-care facilities may take a long time Informal influences are important Dual job-holding is common Informal health care is sufficiently supported/integrated in health system
Quality			
<ul style="list-style-type: none"> Quality measures are outlined in laws with several guides for practicing the profession, code of ethics and disciplinary system 	<ul style="list-style-type: none"> No accreditation or quality certification programmes No quality incentives Oversight by several public entities which is mainly structural in nature Lack of culture for implementing quality improvement programmes Neither public nor private sector is of satisfactory quality Private sector conform better to standards than public sector 	<ul style="list-style-type: none"> Dual job-holding affects quality in the public and private sectors because health-care professionals are exhausted by overload Informal health-care services are of good quality and responsive to beneficiaries' needs 	<ul style="list-style-type: none"> Oversight by several public entities Dual job-holding operates according to individual interests
Pricing			
<ul style="list-style-type: none"> Supply and demand 	<ul style="list-style-type: none"> No standard pricing mechanism Pricing is set by facility director/owner Difficult to fix pricing because of high and changing inflation rate 	<ul style="list-style-type: none"> Both sectors are expensive, however the private sector is much more expensive than the public sector Costs of services are not standard 	<ul style="list-style-type: none"> No fee schedule is available, and if available is inaccessible and not transparent

Document review	In-depth interviews	Focus group discussions	Online survey
	<ul style="list-style-type: none"> Few insurance schemes, health insurance law is on way 	<ul style="list-style-type: none"> Consultation fees are affordable but surgery and laboratory investigations are unaffordable 	
Public-private partnership			
<ul style="list-style-type: none"> No clear strategy 	<ul style="list-style-type: none"> Public-private partnership is just on paper Concept is not clear Attempts to share Turkish experience Concerns about willingness; suspicion of corruption and mistrust 	<ul style="list-style-type: none"> 	<ul style="list-style-type: none"> There are few or no initiatives

Regulating quality

Regulating the quality of care is a major weakness in the system. There are no incentives to improve quality, and there are no accreditation or quality certification programmes. There are many entities supervising different aspects of the private health sector such as the construction office (building) and the municipality (cleanliness and waste disposal). The Ministry of Public Health and Population oversees the quality of health-care services through various departments which are represented at central level and through representing health offices at the governorate and district levels.

Quality was outlined in the law on regulating practicing the medical and pharmacy professions. Examples of the quality control measures are listed below.

- A practitioner should keep up-to-date in terms of professional knowledge and skills.
- Private health facilities should be appropriately equipped and prepared.
- Pharmacists should not dispense medication without prescriptions except for over-the-counter drugs.
- Forgery and plagiarism are prohibited among professionals.
- The law prohibits practitioners from posting advertisements about their business, technical expertise or skills if not conforming with professional ethics and manners or for products that mislead the population or are inappropriate for public ethics.
- The health or medical facility is held responsible for the conduct of its staff. While verdicts are decided by the General Medical Council, a court of law should deliver the sentences.

Regulating pricing

The pricing of health services is not determined or unified in either the public or the private sector. Pricing is seen as part of a general problem affecting all trades and other aspects of life. There have been attempts to set the pricing in the public sector with the introduction of community participation but these failed. Currently, prices are fixed within each public hospital but are not standardized across the sector. Pricing is less regulated in the private sector. Fee

schedules are available but they are either not transparent or accessible. The ability of the Ministry of Public Health and Population to regulate pricing in the private sector is limited by the lack of explicit provisions or laws; it is largely thought that pricing is market driven. This is despite reports that the private providers base their fees on cost recovery with a margin of profit. Accordingly, pricing varies widely and changes because of the high inflation rate. Considering the prevailing poverty with Yemen, the unpredictable and widely varying pricing of health-care services poses a barrier to the public and reduces the universal coverage of care, a main target of the government.

Regulating public–private partnerships

Despite efforts to promote private sector growth, the government is not proactive in enhancing public–private partnerships. There are intentions and discussions to share the Turkish experience, but this remains on paper. There are several limitations envisaged to public–private partnerships, such as the unwillingness of the public and private sectors to go into partnership. Concerns about corruption make decision-makers in the public sector reluctant to take steps towards dealing with the private sector. Furthermore, there is mistrust between the public and private sectors.

The legislative process

As shown in Table 3 and Fig. 2, the Prime Minister's Office is the final line for reporting on public authorities. A great number of departments are involved in regulating the health sector. The Ministry of Local Administration has a regulatory role for private health facilities at the subnational level. Governors also have authority over governorate health offices, including on the distribution of health professionals within the governorate.

Departments are ranked in the hierarchy according to their assigned role and responsibilities. For example, the General Medical Council was established in 2000 (Law on Establishing the General Medical Council) to take over all regulatory functions over health professionals. Accordingly, the General Medical Council reports directly to the Minister of Health. The General Medical Council is mandated with enforcing all laws regulating the medical and pharmaceutical professions; it contributes to updating medical curricula and quality assurance of medical education, standardizes certificates, and issues licences for medical doctors, dentists and pharmacists. The structure and work of the General Medical Council is in need of revision; there is not yet a by-law and it is thought to duplicate the work of the Syndicate. The situation regarding the Policy Unit is similar. It was hoped it would participate in drawing up health policy across the different sectors of the Ministry of Public Health and Population.

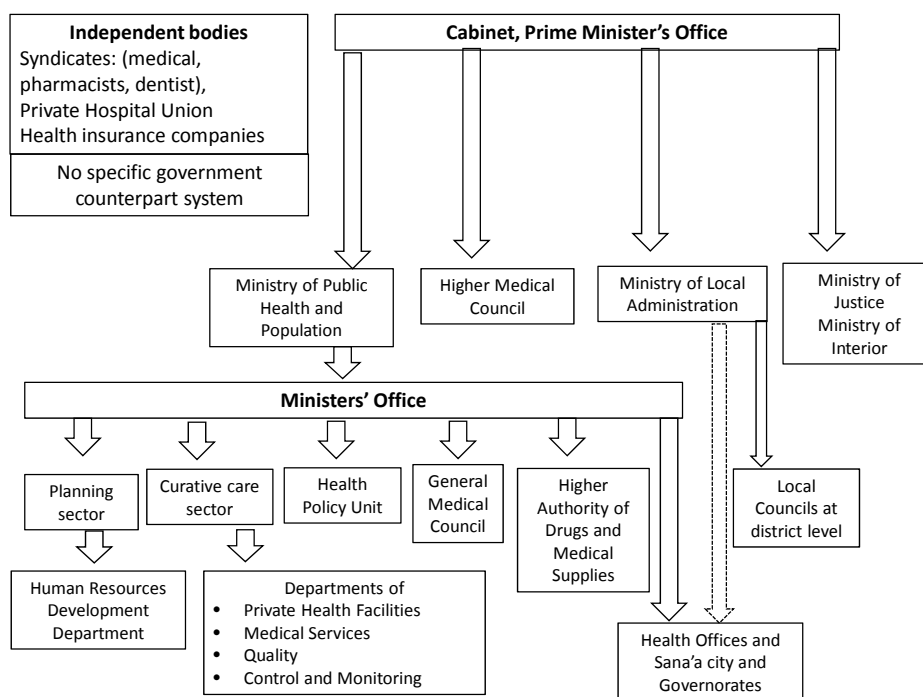


Fig. 2. Regulatory bodies and their relation to the Ministry of Public Health and Population

The entity with the greatest influence is the Ministry of Public Health and Population, in terms of developing legislation which will be endorsed by the Prime Minister's Office and Parliament and issued by a presidential decree or law. The Ministry's by-laws are intended to enact the laws.

System of regulation

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

Institutional regime and capacity

The review of the relevant legislation and documents shows that the regulatory functions are divided among different public and independent entities. The Ministry of Public Health and Population is the key regulatory body. It is responsible for the whole regulatory process (the regulatory bodies and their functions have already been listed in Table 3).

The Yemeni administrative system is decentralized in line with the decentralization policy introduced in 1998. Most of the executive functions are delegated to the governorate and district levels. Accordingly, many of the functions of the regulatory bodies are delegated to similar structures at the government and district levels whenever these structures are complete at the subnational level. Some of the laws contradict each other, such as the local administration law, which decentralized functions of the Ministry of Public Health and Population without a clear division of responsibilities. Moreover, there are no coordinating mechanisms between the different authorities, whether within the public sector or between public and independent

entities. None of the legislation or documents provides a basis for a common forum that allows regular, effective communication among the regulatory bodies at central or subnational levels.

While the local administration should mirror the role of the Ministry of Public Health and Population at the local level, the system is limited by the organizational set-up and processes. It was reported in the health sector review of 2007 that the current structure, role and functions of the Ministry of Public Health and Population had not been amended to correspond with the decentralized administrative system. This causes confusion in enforcing health regulations. This is further complicated by the absence of clear-cut tasks, and overlapping responsibilities, at the central and local levels, as well as by the unclear responsibilities of the administrative entities in the health offices and local councils. There is also interference from many parties in the leadership of health districts, complicating the situation. Similarly, managerial capacities are weak with no supporting procedural guidelines in the health governorates and districts offices.

There have been serious concerns raised about the selection of staff in the regulatory departments within the Ministry of Public Health and Population in terms of their capacity, qualifications and conduct. The inspection committees are made up of staff who are not qualified or trained to conduct the tasks; this may lead to weak cooperation and even a sense of resentment among private sector practitioners. There have been efforts to improve the selection of staff but these are hindered by budgetary shortages.

Information for regulation

Regulatory bodies do not have standard channels to exchange information or to disclose information to the public and relevant sectors. There is also a scarcity of information about the private health sector on its capacity, the range of diseases covered and the services provided. Limited data are collected during inspection visits, such as the number of beds, number of professionals and procedures. The limited range, quantity and quality of data further weaken the regulatory system and its effectiveness. In fact, information is a weak area in the health system as a whole; the data available to inform planning or draw up evidence-based policies are inaccurate and incomplete.

The poor exchange of information may reflect the poor trust of the private sector in the public sector as the data may be shared with the regulatory authorities such as the General Medical Council and tax authorities. The Ministry of Public Health and Population shares part of the blame for this: it does not demand regular information, but rather requests reports and invites representatives from the private health sector on an ad hoc basis, such as for national campaigns or epidemic threats.

Monitoring and inspection system

The private health sector is overseen by a number of public entities such as the Ministry of Public Health and Population, the General Medical Council, the constituencies, local councils, the Central Organization for Control and Accountability, and the Ministry of Construction. Oversight lies with the Department of Private Health Facilities at the Ministry in addition to the Department of Quality Control and Inspection.

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

Document review	In-depth interviews	Focus group discussions	Online survey
Institutional regime and capacity			
<ul style="list-style-type: none"> Ministry of Public Health and Population is key player Several public and independent entities Under the decentralization policies, functions are delegated to governorate and district levels 	<ul style="list-style-type: none"> No regulations to coordinate communication between various entities Limited capacities and resources Staff often lack qualifications and training 		
Information			
<ul style="list-style-type: none"> No regulations to govern production and use of information No regulation for disclosure of information to public 	<ul style="list-style-type: none"> Scarcity of information on private health sector Information is often incomplete, inaccessible and inaccurate Ministry of Public Health and Population does not demand regular information 		<ul style="list-style-type: none"> Information is inaccessible
Monitoring/inspection			
<ul style="list-style-type: none"> Private sector is overseen by several public entities 	<ul style="list-style-type: none"> Policy-makers: regular inspection visits and judicial control status Non-policy makers: irregular visits No national protocols and no precise indicators No standard system to collect complaints 	<ul style="list-style-type: none"> No inspection of formal health-care providers No inspection on informal health-care providers 	
Enforcement			
<ul style="list-style-type: none"> Control-based 	<ul style="list-style-type: none"> Control-based Fines of increasing amounts, imprisonment of the guilty staff, and temporary or complete closure of a health facility Weak implementation 	<ul style="list-style-type: none"> No system perceived 	<ul style="list-style-type: none"> Fines, loss of license, criminal prosecution, education and persuasion and naming and shaming

Regular visits are conducted by specially established inspection and control committees at the governorate level. The members of the inspecting committee are nominated by the Private Health Facilities Department. The names are referred to the Minister of Justice in order to grant them judicial control status. There are no standard national protocols and no mention of assessment indicators or criteria to establish supervisory visits or the content of the supervision. There are no standardized instruments for supervision although some teams may use special

forms. Inspection visits to health facilities are perceived as irregular and sporadic; they are usually conditional on the management and availability of resources, with little or no coordination between the different supervising entities. This burdens both the regulating agencies and the institution itself and further weakens the trust of the private sector in the regulatory system.

A report should be prepared by the inspectors including all remarks and findings and this should be passed on to the Private Health Facilities Department at the governorate level. Reports will be then communicated to the same department at the Ministry of Public Health and Population. A member of this department, along with doctors from the relevant specialization, will review any reported misconduct or deviation from standards. Having judicial control status is supposed to allow the inspectors to take measures against private health providers or facilities breaching the laws or regulations.

It is widely recognized that government oversight is weak over medical practice in general and over private hospitals in particular. The oversight activity is not consistent; it varies between departments and across time periods. The budget in turn is usually unpredictable in amount and in the time of transfer.

Despite this, the National Health Strategy (2010–2025) is aimed, along with other objectives, at improving quality of care and elevating user satisfaction. There is, however, no standardized system to collect public opinion or to deal with complaints. Complaint boxes are placed in the Ministry of Public Health and Population and a number of health facilities for the public but it is not clear how they are dealt with. In comparison, the major private hospitals are more likely to deal with complaints as part of their client-focused care. In fact, a number of hospitals have established technical committees to investigate complaints and medical errors and review patient complaints. The disputes are usually resolved within the hospitals unless the users of the care or their families opt to raise it at a higher level. The General Medical Council is responsible for reviewing the complaints for a technical verdict and referring cases to the court of law. Complaints are submitted directly to the General Medical Council or referred from the Ministry of Public Health and Population. Mistrust in the complaints system among families of patients has sometimes led to violence: there have been cases where health professionals have been attacked and even murdered in cases of patient death due to perceived medical errors. Most of the complaint mechanisms are centralized at the Ministry of Public Health and Population. It is not clear how accessible and responsive these mechanisms are to less-affluent people in rural areas, i.e. the vast majority of the population.

Enforcement measures and incentives

The existing legislation is mostly control-based. There are different measures for the enforcement of laws, such as fines of increasing amounts, imprisonment of those found guilty, and temporary or complete closure of a health facility. But the implementation of the laws is not consistent. Many disputes are settled by reconciliation in the court of law or beforehand through tribal rules. The penalty can be shared by the facility and the provider of the care or paid by the provider alone.

Enforcement of regulations is subjective, widely contingent on the personal views of employees and the prevalence of informal payments to bypass the health standards. The political will to

impose health system regulations as a priority is weak. Improper, or nonexistent, oversight has caused chaos and great variations in the private health market. One example is the ease with which first-aid surgeries, that are widespread in the country, were opened without any real supervision from the Ministry of Public Health and Population. Weak regulation enforcement is a major and prevailing feature of the whole state, not only the health sector.

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 Public Health and Population. They called for social protection measures and financing for both the public and the private sector. Box 3 provides a summary of the outcomes of the discussions.

Box 3. Action points proposed by health-care beneficiaries consideration by the Ministry of Public Health and Population	
Dual job-holding	Informal health-care providers
<p>Social protection</p> <ul style="list-style-type: none"> • Improve coverage and quality of health services in rural areas, not only in the cities. • Provide the emergency services with ambulances and all necessary equipment. • Provide medication free or at affordable prices. • Improve primary health care centres in regard to staff, medication and supplies, not just buildings. Because of lower costs, the less-affluent, i.e. the majority of the population, attend primary health care centres. • Expand health insurance scheme to include whole population rather than the employed only. <p>Pricing</p> <ul style="list-style-type: none"> • Reduce and standardize the costs of services at public health facilities. • Set a ceiling for the pricing for each service in the private health sector. <p>Quality</p> <ul style="list-style-type: none"> • Strengthen government supervision over public and private health services. • Focus on management of hospitals and health facilities in order to improve the quality of care. • Set up a responsive and effective complaint system to deal with malpractice. <p>Health workforce</p> <ul style="list-style-type: none"> • Oversee health professionals and inspect their certificates, especially those coming from abroad. • Set licensing exams to be renewed on a regular basis. • Staff should be supported financially and through continuing education and career development. • Ban duplication of jobs; provide competitive salaries for health-care providers and workers. 	<p>Social protection</p> <ul style="list-style-type: none"> • Participants with a lower economic status demanded that services in public hospitals should be free of charge while the slightly better-off participants demanded that at least medication should be dispensed free of charge in public health facilities. <p>Pricing</p> <ul style="list-style-type: none"> • Prices should be standardized and price lists made available to the public. <p>Quality</p> <ul style="list-style-type: none"> • The government should activate its control mechanisms over public and private hospitals. • Dual job practice should be banned by the state. • Informal health care can be integrated into the health system to standardize care and improve the health services provided by this sector. <p>Health workforce</p> <ul style="list-style-type: none"> • The state should retain doctors in the public health sector through improving their working environment, financial situation, education and career development. • Doctors should keep up to date with the changing medical and scientific developments. <p>Financing</p> <ul style="list-style-type: none"> • Allocate an adequate budget to the health sector.

2.5 Outcome of in-depth interviews with key informants

Key informants suggested specific areas of collaboration between WHO and the institutions in regard to strengthening health sector regulations. Box 4 provides a summary of the outcome of the interviews.

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

- Update and review the existing health legislation and review the structure and functions of legislative and executive entities.
- Develop effective coordination mechanisms among the different entities involved in legislation and regulation of the private health sector such as the Ministry of Public Health and Population, parliament, the Higher Investment Authority and other ministries, the syndicates and the Union of Private Hospitals.
- Support training and developing capacities through health legislation because of the limited number of professionals in this field. Provide experts and examples of draft legislation from other countries.
- Support the establishment and maintenance of a database of private health facilities.
- Strengthen the mechanisms of collaboration in the country.
- Being the leading technical agency, WHO should advise the Ministry of Public Health and Population leadership on setting the public health agenda and directing it towards the most important priorities and cost-effective interventions.
- Extend partners beyond the Ministry of Public Health and Population (government). The private and non-governmental health sectors should be included within the WHO communications network (information exchange) and as future partners (developing and implementing legislation).
- Review the current partners and implementation in the Ministry of Public Health and Population and other institutions to ensure effective utilization of resources.

3. Conclusions and proposed actions

3.1 Conclusions

The Government of Yemen 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, but are out of date and are not able to cope with advancements in health practice and 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 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 of overcoming weakness and bureaucracy.

The Ministry of Public Health and Population has four roles, but they are deficient. It is a policy-maker but has 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, several entities are entitled to regulate the private health sector without having developed a mechanism for communication to coordinate their activities. None of the regulations provides a basis for a common forum that allows for effective communication among the regulatory bodies. This is further complicated by 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 the perceptions of health-care managers and society 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 encourages commercialized health care, yet has no control over such practice, which 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 initiatives include public–private partnership through contracting, which is challenged by the unwillingness 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 has 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 found it to be a solution to serving the poor, who cannot afford to pay for private health-care services and have no standing with public services. 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 regulation 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 the Ministry of Public 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 Public Health and Population

The vision for the Ministry of Public 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 Public 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 public–private partnerships

Enforcing public–private partnerships requires setting standard regulations for providing comparable health-care services in both the public and the private sectors which are of the 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

The 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 the capacity 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, 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 national reform efforts to expand the private health sector. 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 global standard private health sector regulatory model.

Building national capacities for private health sector regulation

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 regulation in Yemen

No.	Regulation	Description
1.	Law on practice for the medical and pharmacy professions	<p>Sets the legal basis for medical and pharmaceutical practice in order to ensure good quality services for the public and maintain the scientific, moral and financial status of the professionals.</p> <p>The law details the licensing process and the requirements, duties and rights of the practitioners, the conditions for performing surgical procedures, taking pathological samples and organ transplants, and the reprimands and penalties for misconduct.</p>
2.	Law on private health and medical institutions	<p>Regulates private health and the medical institutions following updated scientific and technical criteria and controls to reduce misconduct. The aim is to encourage private sector investment in health and to expand the private sector contribution in the provision of primary health services and health education in cities and rural areas. The law aims to contribute to universal coverage: good quality health services that are geographically and financially accessible.</p>
3.	Decree: Amended Executive Bill of the Private Health and Medical Institutions Law	<p>Replaces the Decree: Executive Bill of the Private Health and Medical Institutions Law.</p> <p>Lists the types of private health facilities and their definition. Describes issuing and renewing the entry permit (technical, human resources requirements, processes and responsible bodies), and the bodies responsible for licensing, inspection, complaints management, and the reprimand process.</p>
4.	Law: Establishing the Medical Council	<p>Sets up the General Medical Council with the following objectives: regulation and inspection of the performance of health professionals, maintenance of health-care standards and protection of patients' rights. The law itemizes the composition and functions of the board members, the frequency of meetings, the financial system and accountability and reprimands.</p>
5.	Law: The Executive Bill (structure and functions) of the Ministry of Public Health and Population	<p>The presidential law sets out the structure of the Ministry of Public Health and Population and describes its functions from the Minister to the General Department level. The General Department of Private Health Institutions is responsible for licensing and inspection of the private health facilities.</p> <p>The General Department of Pharmacy and Medical Supply contributes to the categorization of pharmacy-related jobs and keeping records and information on private pharmacies.</p> <p>The General Department of Planning works at encouraging investment in health and provides support and information to the (potential) investors</p> <p>The General Department of Architecture Affairs sets the construction standards for public and private sector facilities.</p>

No.	Regulation	Description
6.	Public Health Law	The law sets out the rights of patients to preventive and curative aspects of public health, e.g. medical services, drugs, water and sanitation, and waste disposal. It covers universal access and quality of services.
7.	Bill regulating the manufacturing and trade in drug and medical supplies and similar products	<p>The regulating body is the Higher Authority for Drugs and Medical Supplies. This aims to offer high quality, safe and effective drugs and medical supplies at an accessible price; coordinate efforts among relevant parties to regulate manufacturing and trading through devising common mechanisms to implement the national health, industrial and trade policies; establish regulating measures to control the drug services; and encourage competition within an open trade environment.</p> <p>It covers drugs, vaccines, artificial infant milk and feeding substitutes, medicinal herbs and alternative medicine products, and cosmetic products. It also regulates the import and export of these products (who imports, the exporter, procedures, storage); manufacturing (establishing a drug factory, quality and standards of manufacturing, distribution, documentation); registration of drug companies and their factories (required documents and procedures); registration of pharmaceutical products (documents, procedures and information required to be available to the public); registration of medical products; distribution and sale of drugs and medical supplies (who, where). It is also responsible for compiling a detailed list of possible deviations from regulations and corresponding reprimand action.</p>
8.	Decree: Review of the Higher Authority for Drugs and Medical Supplies Regulations	The authority is responsible for drawing up and implementing the national health policy on drugs, medical supplies, and cosmetic, chemical and laboratory substances that have a medical effect.
9.	Decree: Regulating the Private Health Institutes	Regulates the requirements and time frame for applications to set up a private institute. The specializations and curricula replicate those at the public institutes although the specializations taught and number of students are left to the owner. The Ministry of Public Health and Population coordinates with the Ministry of Higher Education to endorse the curricula and specializations. The Ministry does the supervision although the costs of supervision are paid by the private institute. Diplomas are certified by the Minister of Public Health and Population. Specializations include midwifery/nursing, medical assistant, dental assistant, technician (laboratory, public health, physiotherapy, pharmacy, medical biostatistics, anaesthesia, operating room).
10.	Decree: Executive Bill of the Educational Regulations for the Private Health Institutes	Details the internal educational process in terms of student registration, academic year and exams.
11.	Decree: Bill regulating the work of the private health institutes	Details the permit application process and general and administrative aspects of private institute work.

No.	Regulation	Description
12.	Bill regulating the work of the in-service health training centres	The bill regulates the centres which provide in-service training for health workers. Courses should not exceed three months. Although not explicitly mentioned, training can include management and biostatistics courses. The General Department of Human Resources Development at the Ministry of Public Health and Population is responsible for reviewing permit applications from the administrative and educational aspects. The Department also supervises the centres. Supervision costs are paid by the centres.
13.	Law: Health and Social Insurance	The law regulates the various aspects of insurance in terms of eligibility, insurers, services and providers of care. The law also establishes the Health and Social Insurance Fund, and lays out its role, management and regulation. The fund is under the supervision of the Authority for Health and Social Insurance.
14.	Law establishing the General Authority for Health and Social Insurance	The authority is an independent body under the supervision of the Ministry of Public Health and Population. It has the mandate to supervise, control and assess the performance of the National Insurance System and to recommend measures to maintain the financial balance of the insurance system. The authority is managed by a board which includes representation from the Commerce and Trade Chamber.
15.	Decree: The Executive Bill for Health and Social Insurance	The bill details the health insurance fund and draws up the medical and diagnostic services covered by the insurance system. It sets out the accreditation standards, requirements and processes as well as the contracting process for service providers. The rights and duties of service providers and users are also detailed.
16.	Decree: Establishing the Drug Fund	The Drug Fund is an independent entity under the supervision of the Ministry of Public Health and Population. The fund purchases drugs at nominal prices, then stores, distributes and sells them through its outlets around the governorates. The selling price includes an additional 15% which revolves to cover the operational costs of the fund.
17.	Law of Investment (replaces Law 22, 2002)	This sets out the conditions and incentives to encourage national and international investment in different sectors in Yemen. It includes establishing the Higher Authority for Investment. The Yemeni law states that foreign investment is treated equally to the Yemeni private sector for tax deductions and customs waiving. It forbids nationalization of private capital and ensures fair compensation in the case of any mishaps. The foreign investor is allowed property and land ownership.
18.	Establishing the Centre for Blood Transfusion and Research	This outlines the functions and responsibilities of the centre, which is the only entity responsible for all procedures done on blood and blood products or derivatives.
19.	Establishing the National Centre for Public Health Laboratories	The National Centre replaces the former Central Laboratory. The decree gives the centre a mandate to supervise all medical laboratories (the private sector is not explicitly mentioned).

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 Yemen. 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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