This document contains links to websites where you can find national legislation and health laws. We link to official government legal sources wherever possible. Where we link to unofficial sources this is noted and users should take this into account before relying on these materials. We recommend checking with the relevant national government if you have questions about the currency or validity of any unofficial source of law.

Legal system

Civil law

National law database

<table>
<thead>
<tr>
<th>Language:</th>
<th>Portuguese</th>
</tr>
</thead>
<tbody>
<tr>
<td>Link:</td>
<td><a href="http://www.dre.pt">www.dre.pt</a></td>
</tr>
<tr>
<td>Nature:</td>
<td>Official journal of Portugal</td>
</tr>
<tr>
<td>Organisation responsible for the website:</td>
<td>Documentation and comparative law office</td>
</tr>
</tbody>
</table>

Legal UHC start date

1979

Source:


The health system and policy monitor: regulation (PDF)

As part of its Health Systems in Transition (HiT) series the European Observatory on Health Systems and Policies systematically describes the functioning of health systems in countries as well as reform and policy initiatives in progress or under development. The HiT health system reviews cover the countries of the WHO European Region as well as some additional OECD countries. This PDF includes information about the country’s regulation. To see the complete HiT report of this country go to:

Search list of contents:

Regulation

Overview and publication details .................................................. 2
Regulation Portugal ........................................................................ 3
Regulation

Portugal
HSPM Members: Universidade Nova de Lisboa, NOVA School of Business and Economics
HSPM Contributors: Barros P, Machado S, Simões J, Cylus J
Portugal: Regulation

2.8 Regulation

The Portuguese Constitution stipulates that the economic and social organization of the country must be guided, coordinated and disciplined by a national plan. The national plan must ensure, for example, the harmonious development of the different sectors and regions, the efficient use of productive resources, and the equitable allocation of resources among the population and between regions. As the NHS does not have its own central independent administration, the Ministry of Health carries out most of the planning, regulation and management functions. The main aspects of the NHS are centralized in the ACSS. There are central, regional and sector planning bodies. Central planning for health is mainly carried out by the DGH, based on plans submitted by the RHA boards. The High Commissioner for Health (GPEARI) has authority over the RHAs. Consequently, a general framework within the National Health Plan has been created to avoid regions pursuing national policies at their own pace, as has happened in the past.

A formal national health strategy and health care policy with quantified objectives and targets were defined for the first time in 1998, for the period 1998–2002. A revised version of this policy document was produced in 1999 involving a broader range of social partners and stakeholders. It was made public by the Ministry of Health under the title Health: a commitment. In fact, this structuring tool was a true commitment of the administration to the citizens. In 2002, the GPEARI produced a national report on health gains revising the achievements and pitfalls of the strategy for the period 1998–2002 (DGH, 2002).

A new National Health Plan has been designed and implemented throughout the country since 2004 (DGH, 2004). The National Health Plan 2004–2010 is in its final stage; a thorough evaluation is under way, coordinated by the GPEARI. It comprised strategic guidelines and objectives with relation to a minimum set of health system activities to be put into effect by the Ministry of Health. In 2004, the Plan set three main strategic goals:

- to improve health status at every stage of the life-cycle, reducing the burden of disease;
- to ensure that citizens are at the centre of the changes to be implemented, reorganizing health care provision; and
- to ensure that the Plan has sufficient human and physical resources for it to be implemented, as well as defining appropriate assessment and auditing mechanisms.

The DGH has been responsible for the Plan's design and execution (see section 2.3 and section 5.1).

With respect to regulatory management mechanisms, the Portuguese system might be viewed as highly normative, with extensive legislative provisions. There are, for example, numerous and sometimes very restrictive controls over pharmaceutical goods, high-technology equipment, and the education, training and registration of health personnel (see section 4.2.3 Training of health care personnel). The defined rules and procedures, however, are not always adhered to or enforced, leading to what might be called a "management regulation deficit" of the statutory health system. Recognition that entrepreneurial initiatives require adequate measures to control what may otherwise be decisions made purely in the interests of the managers, rather than in the interests of the Ministry, is making the issue of management regulation a matter for discussion.

INFARMED, established in 1993, was reorganized in 1999 to meet the new and reinforced EU regulations in the area of pharmaceuticals. It is responsible for the regulation of pharmaceuticals and medical equipment, and supported by the Pharmaceutical Inspection Service, the Pharmacosurveillance Service and the Official Laboratory for Pharmaceutical Quality Control. A full description of their respective functions is given in section 5.6.

The Court of Auditors, an independent body that conducts periodic external auditing of NHS performance, has in recent years produced some critical reports. These reports have looked at the overall public health expenditure as well as giving a comparison across three hospitals. Since the year 2000, a few major auditing reports have been drawn up. In 2003, the financial status of the NHS was audited (Court of
Portugal - Regulation

Auditors, 2003). By 2005, it was the turn of the Internal Control System of the NHS to be examined (Court of Auditors, 2005). A 2006 report (Court of Auditors, 2006) evaluated the management scheme of the *Sector empresarial do Estado* (state-owned companies), with relation to the period 2001–2004. In 2007, the Regional Health Service of the Madeira Archipelago was audited (Court of Auditors, 2007). These analyses have highlighted major organizational and financial problems and have made recommendations.

The HRA was created in 2003 to regulate and supervise health care providers’ activity. Its aims were to guarantee enough competition between providers and to protect the citizens’ rights to universal health care coverage. Its competences included the regulation and supervision of all activity and health care delivery of all providers, with respect to access, quality and safety, as well as patients’ rights. In 2009, the organizational structure of the HRA was reformed. The main changes included the nomination of an Advisory Board; the redefinition of the attributes of the HRA, which now include economic regulation; and a more precise definition of the sanctions to be applied by the HRA.

A recent example of the HRA’s work is the study conducted on emergency room health care provision. The report concludes that most of the private provision of emergency health care is not suitable to patients needs; moreover, many of these departments do not conform to basic legal requirements (ERS, 2010). In 2009, the HRA received more complaints from consumers than in the previous year. This is possibly due to the online system that is now available on the official web site. Other reports include studies on the licensing of providers (ERS, 2007) and on the conventions regime of the NHS (see section 2.7.1 *Regulation and governance of third-party payers*).

### Human resources policy

It was just published the inventory of human resources in the health sector.

#### 2.8.1 Regulation and governance of third-party payers

RHAs play an essential role in the contracting of health care providers to work with the NHS. They are responsible for setting up (and paying for) conventions (‘conventions’ refers to the contracting of private sector providers to provide NHS patients with specific health care services) and *contratos programa* (contracts) with the hospitals (based on cost history, utilization and complexity variables; see section 3.7.1 *Paying for health services*). RHAs are also in charge of negotiating and signing public–private partnership contracts. These follow the procedure used in the contract that established the first public hospital under private management, signed between the private operators and an RHA.

The HRA conducted an assessment of the conventions contracted by the NHS (through RHAs). This is a way of making use of the HRA’s powers. These conventions are responsible for almost 10% of the total costs of the NHS, which makes it a key issue with respect to cost-containment. The law regulating conventions was changed in 1998. The law specifies that there should be a known set of general contractual clauses (following an approach known as “any willing provider”) for each type of convention. These changes have not entered into force; such general contractual clauses have only been drawn up for surgery, dialysis and a system for the management of (waiting list) patients waiting for surgery (SIGIC, *Sistema de Gestão dos Utentes Inscritos para Cirurgia*). This raises several problems, such as lack of competition, market foreclosure, higher costs and prices, and lower service quality for patients.

Health subsystems manage the provision of their own contracted health care providers among NHS and private sector services. The opting-out option can be put into effect by an agreement between the subsystem and the RHA.

Several insurance companies provide VHI. Médis and Multicare are the companies with the largest market shares (see section 3.5 for further information). Private insurers are free to choose their providers. In fact, providers have to apply in order to be accepted as an “official provider” of a specific system. The way they work is different from both NHS and health subsystems health care provision. There are quite a few rules to conform to in order to be accepted as a client of the insurer. Insurance companies are under the jurisdiction of the Portuguese Insurance Institute, the Portuguese Competition Authority and the HRA, but are not directly under the Ministry of Health supervision.
2.8.2 Regulation and governance of providers

All hospitals belonging to the NHS are in the public sector, under the Ministry of Health jurisdiction, as described in section 3.7.1 Paying for health services. Private sector hospitals, both non-profit-making and profit-making, have their own management arrangements.

Since 2003, the majority of NHS hospitals have been given status similar to those of a public-interest company (in what may be termed “autonomous public hospitals”, whereby the government retains ultimate ownership but gives some autonomy to hospital management – “Hospitais EPE”). This represents an attempt to introduce a more corporate structure into hospital management, with the expected effects on efficiency and cost-containment. The hospitals not yet transformed are now under pressure to provide better services to their patients, as their performance can be compared to that of the hospitals that have already been converted.

All hospitals are financed through contracts (contratos programa), but “Hospitais EPE” have many decision-making powers with relation to capital, staff and negotiation of input prices, which are not present in the traditional NHS-run hospitals. Among the new management rules, “Hospitais EPE” may hire staff under individual labour contracts (instead of collective agreements) and may set the performance-related payment schedules of professionals. The use of incentive schemes is seen as a way to counteract the existing rule of “equal pay/least possible effort”. This change generated competitive pressures in the labour market, more precisely in the demand for physicians in the most sought-after specialties, leading to wage escalation. Several hospitals are also getting together to block-purchase pharmaceutical products and other clinical consumables, taking advantage of the bargaining power resulting from larger acquisition volumes.

In 2007, the HRA published recommendations based on a study about the licensing of private health care providers (ERS, 2007). Many licensing laws exist, one for each kind of practice. For example, rehabilitation and physical medicine have completely separate licensing arrangements from clinical pathological laboratories. Since it was found that the present group of laws concerning the licensing of private hospitals and health care facilities is very broad and enables the coexistence of licensed and unlicensed health care providers, it was recommended this issue be subject to a legislative review that should specify the general rules for all facilities of this kind and define the technical specifications for each specialty.

With relation to the organization of services, there is usually a strict gatekeeping process performed by primary care physicians. Access to laboratory tests and screening tests (MRI, CT scans, etc.) is limited if it falls outside of routine procedures.

The main responsibility for regulation of policy objectives and national quality standards lies at the central level with the DGH. Under this body, a functionally separate institute for quality was created in 1999. Its scope covered the development of policies, strategies and procedures that support professionals and provider organizations in the continuous improvement of quality for the delivery of health care. It also promoted methods of health institution certification and the continuous education of professionals. Progress in this area has been achieved with the MoniQuor organizational quality model applied to primary care centres and use of the King’s Fund Certification Process (a partnership of the Institute for Quality (IQS, Instituto da Qualidade em Saúde) and the King’s Fund in London, United Kingdom), now under way in more than one-third of NHS hospitals.¹

The MoniQuor model, which aims to monitor the quality of organization at the primary care centre level, was put into action in 1998, but has evolved into a cross-analysis process: each primary care centre supervises another one, and is supervised by a third one. The IQS was integrated into the DGH after the restructuring of the Ministry of Health associated with the general reform in civil service organization.

The HRA plays an important role in the assessment of quality of care. It is able to monitor and audit quality of providers, and adherence to legislation.

In 2009, the Ministry published the National Strategy for Quality in Health, an initiative in line with the objectives of the National Health Plan 2004–2010, with a five-year timeline. The strategy defines seven priorities:
Portugal - Regulation

- organizational and clinical practice quality
- information to the patient
- patients’ safety
- quality and accreditation of health care providers
- disease management and innovation
- international patient mobility management
- evaluation and follow-up of patients’ complaints and suggestions.

The DGH also created a voluntary National Accreditation Programme for Quality in Health.

Medical negligence is overseen by the Medical Association (see section 2.8.4 Complaints procedures).

---

1 The Health Quality Service is a health accreditation service in the United Kingdom and the rest of Europe. It works together with international health care organizations to improve the quality of patient care through consultancy services and the development of health care standards and assessment processes. See http://www.chks.co.uk/index.php?primarycare for details on the accreditation in primary care, as an example of its activity.

**New statutory law reinforces the role of the Health Regulatory Authority**

By César Carneiro, Jorge Simões
Additional Credits: Pedro Pita Barros, Sara R Machado

The new statutory law of the Health Regulatory Authority (HRA) was published in August 2014, giving the HRA new powers (Law Decree 126/2014). The new statutes give the HRA exclusive jurisdiction for assessment and monitoring of all complaints by users of all health services, not just private providers. The HRA will also supervise the process of licensing private health care providers, including issuing, maintaining and revoking licenses, as well as inspecting facilities. These changes strengthen regulation in areas that directly contribute to safeguarding the rights of health care users and to the quality and safety of services.

---

**New legal framework for NHS to contract with private providers**

By Pedro Pita Barros
Additional Credits: Pedro Pita Barros

The delivery of diagnostic and therapeutic services by private providers to the NHS is an area that for several years has been of concern for Portuguese authorities. As studies have pointed out, the public procurement framework of such contracting by the NHS has been in place since the late 1980’s was responsible for a lack of competition within this subsector and for the substantial cost to the NHS for such services (an extensive review on this subject is given in [1]).

To tackle this problem the government approved a long-awaited new legal framework for private services contracting by the NHS (Decree-Law no. 139/2013, of 9 October). According to this new framework, NHS authorities will choose whether they contract by adhesion contracts or public tenders, and this choice must be based on the potential competition in each relevant market. The rationale for this measure is to make public procurement more sensitive to market competition and as a result, to achieve lower prices. Public tenders should be the option for relevant markets with a substantial number of potential competitors for contracts with the NHS, with providers having to compete for lower prices. On the other hand, in markets with few competitors, contracting should be done by adhering to pre-determined conditions, particularly prices for services.
This reform was triggered by the commitment made by Portuguese authorities in the Memorandum of Understanding with the EU and the IMF to increase competition among private healthcare providers and to reduce public spending with private services by 10% in 2011 and another 10% in 2012. There is no publicly available data on the overall spending by the NHS with contracted services. However, a recent report from the Portuguese health regulation authority (ERS) shows that the total expenditure for services of Clinical Pathology, Dialysis, Physical Medicine and Rehabilitation and Radiology, decreased 9% in 2011 and 14% in 2012 [2].


2.8.3 Registration/licensing and planning of health care personnel

Most NHS staff are civil servants and all new posts have to be approved by the Ministry of Finance. An increasing number of workers are under individual contracts, which do not confer upon them the same rights as those workers with civil servant status. In addition, it is clear that rules for civil servants are becoming closer to those of private labour relations. A numerus clausus was introduced in 1977, limiting the number of places available in medical schools in response to the excess of doctors created after the revolution in 1974. These restrictions on medical education and other health professional careers, namely nursing, have made it necessary to recruit professionals from other countries. However, this has been reversed in recent years both with the creation of new medical schools and large increases in the existing school intakes.

The striking lack of nursing personnel, the scarcity of doctors in some regions and specialties (e.g. GPs), and the imbalance in numbers of primary care clinicians versus hospital specialists are some of the visible signs of the weakness of public health policy in the field of human resources. Moreover, the retirement in the near future of many physicians will create a shortage, as the numerus clausus policy applied in the past did not ensure a sufficient intake to replace them.

A Resolution of the Council of Ministers in December 1998 pointed out some solutions to this human resource problem:

- the founding of health sciences departments in existing universities;
- the creation of new graduate programmes in medicine in the northern region of the country;
- the improvement of existing conditions for current graduates in medicine and dentistry;
- the reorganization of the nursing and technological public schools network;
- a gradual increase in the number of student admissions; and
- the creation of various partnerships between the Ministry of Health and the Ministry of Science and Graduate Education.

As part of this process, two more universities (Universidade do Minho and Universidade da Beira Interior) started to offer degrees in medicine in 2001, increasing the number of medical doctors trained. There is also a new medical school within the Universidade do Algarve (since 2008) and the Universidade de Aveiro Medical School was established in 2010. Simultaneously, several private schools have started to offer degrees in nursing and paramedic training.

A strategic plan for health personnel education and training was another relevant output of the 1998 Resolution. A working document was presented in December 2001, with a detailed needs assessment considering the average European staffing levels. In general terms, the document drew attention to regional asymmetries in the distribution of doctors (the absolute numbers are within the European averages, however) and the need to increase the number permitted by the numerus clausus. The chronic understaffing of nurses in primary and long-term care is also addressed, setting the European average as
the target for NHS nurse staffing by 2010.

In 2010, the Ministry of Health gave incentives for recently retired physicians to come back to the NHS to overcome the shortage in physician supply. Although in the current situation the main problem is more associated with distribution (geographic and by specialty) and productivity than with supply, absolute numbers will become an issue in the future if current trends of retirement prevail.

Although there is a shortage of GPs (and physicians in general), there are strict limitations in terms of internship places, which depend on the reported capacity of national health care facilities (NHS primary care centres and hospitals). In fact, from 2004 to 2008 there was an increase in the number of physicians working for the Portuguese NHS (4.2%). The NHS has been recruiting health professionals from abroad, mainly from Spain, although a specific census to analyse this has not been conducted. Despite the existence of an active constraint on the number of training places, during that same period there was an increase of 49% in intern admissions and an increase of 42% in the number of interns in training programmes for GPs and family medicine, which shows the effort that is being made to address the limitations in primary care. From a global point of view, intern admissions increased by 111% and the actual number of interns in training increased by 57%. It is widely recognized that a shortage of GPs exists and that this situation is likely to worsen in the future, as current GPs start to enter retirement. Recent decisions of the Ministry of Health regarding training vacancies indicate a willingness to deal with this issue. Section 4.2.3 describes the training of health care personnel.

The Law-Decree no. 279/2009 establishes the new juridical regime of private health care units. The new model aims to guarantee high quality standards in private health care delivery, as well as to simplify the process of licensing new units. The HRA is responsible for ensuring that providers follow all the regulations and procedures regarding quality certification.

2.8.4 Regulation and governance of pharmaceutical care

A series of changes in recent years have modified, and in many cases, relaxed, the regulation of pharmaceuticals in Portugal. These are described in more detail in section 5.6, but can be summarized as follows: the ownership of pharmacies is no longer restricted to pharmacists (since 2007); the price of OTC medications is no longer fixed and they can be sold outside pharmacies (since 2005); and retail pharmacies can operate in hospitals (since 2006). Since 2007 there has been no change to the strong regulation of pharmacy locations and the maximum number of pharmacists that are permitted in each community (Portaria 1430/2007). Administrative prices of pharmaceutical products are now maximum prices, with pharmacies being able to provide discounts on prices to patients.

Since 1990, several legislative changes have resulted from the implementation of European Commission Directives, such as that to guarantee the quality and safety of pharmaceuticals. In addition, public information and education programmes on the rational use of pharmaceuticals were developed and cost-containment policies were adopted. INFARMED was established in 1993. Since 1994, its remit has been widened to cover not only pharmaceuticals but also medical equipment and other medical products. INFARMED is responsible for approving all pharmaceuticals to be reimbursed by the NHS and for suggesting co-payment levels to the Secretary of State. It has introduced some cost–effectiveness measures into the pharmaceutical assessment procedures, and it can request cost–effectiveness studies to justify the reimbursement of new pharmaceuticals. In 1999, the government issued official guidelines about how best to carry out cost–effectiveness studies. This initiative decisively increased the utilization of efficiency criteria in reimbursement decisions concerning pharmaceuticals.

The guarantee system for the quality and safety of pharmaceuticals is a complex one and is not limited to the industrial process. Owing to the unique features of the pharmaceutical market, decisions are not made under normal market conditions. Pharmaceutical production is controlled by a strong system of regulation. INFARMED’s responsibilities include:

- to contribute to the national health policy, namely in the definition and use of pharmaceuticals, medical devices and cosmetics;
- to regulate, evaluate, authorize, discipline, audit and verify as the National Reference Laboratory, and to ensure the surveillance and control of R&D, production, distribution, sales and consumption of pharmaceuticals, devices and cosmetics;
to ensure the fulfilment of the regulations on clinical trials on pharmaceuticals, as well as good clinical practice;

- to guarantee the quality, efficacy and cost–effectiveness of pharmaceuticals, devices and cosmetics;

- to screen consumption and use of pharmaceuticals; and

- to ensure the adequate integration and participation in the Network of Pharmaceuticals, Devices and Cosmetics Authorities in the EU and in the official Quality Laboratories network.

In recent years there have been a number of regulatory reforms directed towards improving the cost-effective consumption of pharmaceuticals (these are described in detail in section 5.6). To promote the use of generic drugs, the price of generic drugs was lowered and pharmacists were permitted to substitute generic equivalents for brand name drugs. Reference pricing for pharmaceutical reimbursement was also introduced in 2003. Moreover, as of March 2007, the government enacted new rulings related to the way prices of new pharmaceutical products are determined and established maximum (not fixed) prices.

### 2.8.5 Regulation and governance of medical devices

Medical devices are regulated by Law-Decree no. 145/2009, which determines that the INFARMED is the entity responsible for the surveillance of all medical devices. The document adopts the EU Directive no. 2007/47/CE to Portuguese legislation.

### 2.8.6 Regulation of capital investment

Capital investments in health are determined at the central level by the Ministry of Health, namely by the ACSS. The geographical distribution of health care facilities is often a point of contention, although it is unclear to the external observer how considerations of an equitable geographical distribution are balanced with the demands from local representatives of the population. One of the mechanisms that the government has used to improve NHS capacity and value for money has been through an increased use of private entities to build, maintain and operate health facilities, under the so-called PPPs. More information on capital investments, along with details on the use of PPPs for investment, can be found in section 4.1.2. *Capital stock and investments.*