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**

*Language:* Hungarian  
*Link:* [http://www.njt.hu](http://www.njt.hu)  
*Nature:* National legislative database  
*Organisation responsible for the website:* The publications office for Hungary

**Legal UHC start date**

1945


**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: [http://www.euro.who.int/en/about-us/partners/observatory/publications/health-system-reviews-hits](http://www.euro.who.int/en/about-us/partners/observatory/publications/health-system-reviews-hits)
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HSPM Members: Semmelweis University
HSPM Contributors: Gaál P, Szigeti S, Panteli D
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2.8 Regulation

The chief regulatory role in the Hungarian health system is played by the government and relevant ministries, but other actors, such as the professional chambers, National Institutes of Health and the NPHMOS, are also involved. All aspects of the service production process are regulated. With regard to health care inputs, there is extensive regulation of human resources, medical devices and medical facilities.

<table>
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<th>Changes in the top management of public hospitals</th>
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<td>On July 4th the Ministry of Human Resources (which is the ministry responsible for health) announced that applications for the position of hospital director at state-owned healthcare providers filed by individuals aged 62 or older would not be considered. This is in line with the Government's intention that public servants retire upon reaching the age of 62. The overall policy aims to decrease the number of public sector employees, incurring considerable savings in public expenditure. The State Minister for Health, however, has repeatedly declared that obligatory retirement is not feasible in the health sector, where there already is a substantial shortage of professionals and the average age is almost 50</td>
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<th>Important step in the institutionalization of health system performance assessment in Hungary</th>
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<td>By Szabolcs Szigel</td>
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<td>On 20 June 2012, the Parliament approved the plan of the Ministry of Human Resources to institutionalize the Health System Performance Assessment Framework in a special ministerial decree, partly in collaboration with the WHO.</td>
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2.8.1 Regulation and governance of third-party payers

Although the head of the NHIFA is appointed by the prime minister, the NHIFA is directly supervised by the State Secretariat for Healthcare (2006/16). For its part, the NHIFA plays an important role in preparing the policy decisions of the State Secretariat for Healthcare, and it also makes proposals for improving existing regulations.

The package of benefits covered by the HIF is defined in Act CLIV of 1997 on Health (1997/20) and Act LXXXIII of 1997 on the Services of Compulsory Health Insurance (1997/9). The HIF scheme provides nearly universal coverage and a comprehensive benefits package with few exclusions and little or no co-payment except for pharmaceuticals, medical aids and prostheses and some additional services. There is still no regular mechanism for reviewing the benefits package to exclude services that are not cost-effective (see section 3.3.1).

Strategic health planning and systematic needs assessment are not applied in purchasing decisions. Similarly, a framework for systematic performance measurement is also lacking. As a result, mechanisms for ensuring accountability are restricted mainly to audits conducted by the State Audit Office, which focuses for the most part on financial and legal aspects of providers’ business operations. On an annual basis, the State Audit Office also publishes a global report on any changes made to the regulatory framework of the health system.
The establishing and functioning of private insurers, including the rules of competition, are regulated by the National Assembly and supervised by the government (1995/12).

Cross-border care and care for non-resident citizens of other EU Member States are described in section 2.9.6.

2.8.2 Regulation and governance of providers

According to the primary division of tasks between counties and municipalities, only the former are responsible for the provision of secondary and tertiary care to the local population. In practice, however, municipalities also provide specialist care on the basis of the principle of subsidiarity. In general, county governments own large multi-specialty hospitals, which provide secondary and tertiary inpatient and outpatient care to the acutely and chronically ill, whereas larger municipalities own a range of institutions, including polyclinics (independent, multi-specialty institutions providing outpatient specialist care), dispensaries (single-specialty institutions providing outpatient care to the chronically ill), and multi-specialty municipal hospitals (which provide secondary acute and chronic inpatient and outpatient care). Outpatient care is provided in hospitals or in independent polyclinics. Since 2004, the outsourcing of hospital management has become more common (see section 2.4).

The central government also owns hospitals, which provide acute and chronic inpatient and outpatient care. These are divided among the Ministry of Interior, the Ministry for Economic Development, the Ministry of Defence, the Ministry of Justice and the Ministry of National Resources (see section 2.3.3). The Ministry of National Resources owns university hospitals. The single-specialty clinical departments of the medical faculties provide both secondary and tertiary care. The Ministry of National Resources also manages single-specialty providers known as the National Institutes of Health, which for the most part deliver highly specialized tertiary care only, as well as state hospitals, which are mainly sanatoria that provide medical rehabilitation.

The territorial supply obligation applies to all public providers, but the size of the catchment area is determined by the NPHMOS and depends on the type of care provided and on the estimated number of people in need (see sections 5.3 and 5.4). The same health care institution can have different catchment areas for different types of care. In general, secondary outpatient care services have been assigned the smallest catchment area, which are, however, still larger than primary care districts. Tertiary care is offered at least on a regional basis. Highly specialized tertiary care services, which are provided to patients suffering from rare diseases, have the largest catchment area, namely the whole country (1990/3, 1997/20).

Health care providers must obtain a licence to practice from the NPHMOS, which maintains a registration database (1989/5, 1996/5, 1997/11). Before issuing a licence, medical officers from the NPHMOS inspect the facilities and ascertain whether minimum standards for infrastructure, hygiene, personnel and material supplies have been fulfilled. Special rules apply to a number of services, such as primary care (2000/3), home care (1996/7), patient transfer (1998/6), emergency ambulance services (1998/7), human fertility treatment (1998/13), sterilization procedures (1998/10) and organ transplantation (1998/23). The provision of complementary and alternative medical treatment is also regulated in terms of related educational, infrastructure and administrative requirements (1997/1).

In 2000, the government introduced a complex quota system based on practice permits for family doctors. Each family doctor working in a primary care district with a territorial supply obligation in 2000 was granted such a permit (known as a “practice right”, or praxisjog; see section 5.3).

Family doctors currently have four employment options.

1. The municipality can employ family doctors on the basis of a monthly salary.
2. Family doctors can contract with the municipality as private providers for a primary care district, but they work in a surgery owned by the local government and use equipment owned by the local government. The family doctor is paid an adjusted capitation fee directly from the HIF to cover recurrent expenses, according to the number of registered inhabitants, while the municipality remains responsible for capital costs according to the principle of maintenance obligation. This scheme is known as “functional privatization”.
3. Family doctors can work as independent private providers with no municipal contract and no
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territorial supply obligation, if patients choose them, but they are only entitled to capitation payment from the HIF if they have a minimum of 200 registered patients. It is worth noting that the system of “practice rights” established in 2000, does not apply to this group of practitioners.

4. Employment options were widened in 2001 and 2003 through the introduction of the so-called freelance medical doctor status (2001/12 and 2003/19), which removes doctors from public employee regulations, but does not make them self-employed private entrepreneurs. Physicians who opt for a freelance status contract with the health care provider and are free to negotiate fees; they are also allowed to form group practices.

Health service provision is supervised by the NPHMOS. Monitoring of providers is regular and includes checking personnel and material minimum standards, and the quality of services delivered. The system consists of supervisory chief medical doctors at the municipal, county and in some cases regional level for various medical specialties, and there is one national supervisory chief medical doctor for 54 specialty areas. The National Centre for Healthcare Audit and Inspection is responsible for appointing these supervisory chief medical doctors upon the approval of the national and regional chief medical officers and in collaboration with the professional colleges and the National Institutes of Health.

Reimbursement prices and utilization, including the scope of benefits, referrals and waiting lists are also regulated within the health insurance system.

To ensure the quality of training and minimum standards of service provision, all health workers are expected to improve their professional knowledge, and medical doctors must achieve a minimum of 250 credit points on accredited courses in a five-year continuing education cycle.

To ensure the quality of care provided, the government decided to develop a national accreditation system and create a system of quality assurance in 1994 (1994/7), requiring the professional colleges to take part in elaborating the standards of the quality assurance system (1995/4). In 1996 the government established the National Quality Award, for which the providers can apply based on the European Foundation for Quality Management model. But it was only in 1997 that the National Assembly regulated the mechanism to ensure quality in health care by setting up internal and external mechanisms (1997/20), including the controlling and accreditation of the system. In this context, every institution is required to maintain internal quality system in order to develop services continuously and to prevent possible mistakes. At the same time, the external system ensures the proper licensing of the providers, which includes determining, maintaining and publishing standards, as well as the supervision of providers in this respect. The latter task is the responsibility of the NPHMOS. On a voluntary basis, the providers can seek additional assessment of the quality of their business operations by professional companies to obtain different certificates or they can participate in peer reviews.

Earlier, the requirements of the internal quality assurance systems were clarified in a guideline published by the Ministry of Health; however, the guideline was not updated after its expiry in 2005, although the Ministry of Health should have reviewed it every two years. Also, an overall quality monitoring system has yet to be introduced. For its part, the NPHMOS is charged with checking the existence of the internal quality assurance system of the providers and also other related activities regarding quality policies; these tasks are carried out via the National Centre for Healthcare Audit and Inspection. Based on its findings, it proposes only recommendations to refine the national standards published by the Ministry of Health (Ministry of Health, 2007).

In 2007 more than half of all Hungarian hospitals had some kind of certified quality assurance system, while most of these apply the International Organization for Standardization (ISO) 9000 quality system and other operational standards (Legido-Quigley et al., 2008). However, there is still no overall consolidated strategic plan for developing quality in health care (Gödény & Csath, 2008).

There is elaborate legislation regarding medical negligence; the necessary procedures are carried out by the National Ethics Council and its county branches (1997/20), as well as the professional chambers in cases related to their members (2006/7) since 2006. For its part, the NPHMOS ensures the administrative support for the councils. In certain cases, the provider institutions have to apply Labour Code provisions regarding discipline. A professional-ethical procedure follows, during which councils or the chambers examine negligence cases and apply disciplinary measures. In many cases, the councils and chambers can start ethical/professional procedures when they are informed about a certain negligence of the
professional staff (1997/20, 2006/7). All health care providers are obliged to take out liability insurance to enable them to compensate patients appropriately in justified malpractice claims, which have to be checked by the NPHMOS (2003/7).

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**Nationalization of specialist health care providers owned by local governments stops at polyclinics**

By Peter Gaal

As part of the overall government policy, the Ministry responsible for health implemented the nationalization of virtually all hospitals owned by local governments in 2011 and 2012. The central government assumed full responsibility for the provision of secondary and tertiary care in the social health insurance financed system. According to the regulations passed in 2012, the next step would have been the takeover of local government owned polyclinics. These so-called “independent” polyclinics are outpatient specialist providers, which are not integrated organizationally with hospitals. In this case, however, the legislation did not force local governments to give up ownership of these facilities, but allowed them to decide whether they would keep their outpatient specialist providers, or offer them to the central government to take over. According to preliminary data, the vast majority of local governments have opted for keeping their health care facilities, which suggests that the nationalization process started by this government will most probably stop at the doorstep of polyclinics.

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**2.8.3 Registration and planning of human resources**

Regulatory measures related to the registration, licensing and training of health professionals include:

- control of the number of health personnel to be trained by determining the number of students financed from the government budget (1998/4);
- control of recognition of foreign diplomas (1972/2, 1993/8, 1997/20);
- compulsory registration and licensing of health workers through the Office of Health Authorization and Administrative Procedures (OHAAP) (1998/12, 1999/6, 2007/5);
- regulation of the number of primary care practices with the introduction of the “practice right” (see section 2.8.2) (2000/1, 2000/2);
- determination of the minimum salary of public employee health workers (1992/5).

Medical professionals can proceed with their activities if they have the proper professional training, have completed their obligations regarding continuing education and are registered with the OHAAP. The EU standards for mutual recognition are applied in Hungary (1997/20). In 1998 the then Minister of Health established the Health Care Professional Training and Continuing Education Council to evaluate the professional and educational needs of the health system and to formulate proposals for developing the level of education, including for the accreditation of institutions offering education for specialists (1998/21, 2010/1).

**2.8.4 Regulation and governance of pharmaceuticals**

In Hungary, the pharmaceutical industry is comprehensively regulated, from production to marketing and distribution (1998/3). Pharmaceutical companies were previously owned by the state and not only supplied most of the domestic market but also exported to countries of the former socialist bloc. In the early period of the economic transition, the market was liberalized and all but one of the Hungarian pharmaceutical companies were privatized. The majority of the wholesale and retail industries have also been privatized and, by the end of 1997, all of the previously state-owned pharmacies serving the general public were private (HCSO, 2002).

Because the National Assembly decided in 1990 not to use statutory pricing for pharmaceuticals, there is a
system of free pricing at the manufacturer level for all pharmaceuticals in Hungary, whether these are prescription-only or over the counter (1990/4). Thus, pharmaceutical companies are free to set the prices of non-reimbursable pharmaceuticals as they wish, and there is no separate price-setting procedure. The retail and wholesale margins, however, are regulated by the State Secretariat for Healthcare, with the former being a combination of a proportional regressive and fixed mark-up, and the latter being a proportional regressive mark-up (2001/2, 2007/1). The retail margin is based on the wholesale price, and the wholesale margin is calculated based on the ex-factory or import price. The average mark-up of pharmacies was 19.5% in 2006 (PPRI, 2007).

In 1992 Hungary signed the European Free Trade Area agreement and the Pharmaceutical Inspection Convention, and now follows EU registration conventions and inter-country notification practices, and enforces mandatory standards of good laboratory, manufacturing and clinical practices. All pharmaceuticals must pass a registration and licensing procedure administered by the National Institute of Pharmacy (1982/1, 1998/3) before they can enter into trade.

Within the framework of reimbursement decisions, price negotiations for the outpatient sector used to take place between the producers and a governmental committee. Representatives of the Ministry of Health, the Ministry of Finance and the NHIFA took part in the annual negotiations, formalized as the Social Insurance Price and Subsidy Committee (2000/6). Currently, however, there is no overall price negotiation with the producers, and they have to apply for reimbursement to the NHIFA. The proposed price is evaluated by the NHIFA based on either external or internal reference pricing, as well as the use of HTA for new substances.

In the case of innovative pharmaceuticals, companies have to indicate external prices in their reimbursement application. The manufacturer price of a new preparation containing active ingredients cannot be higher than the lowest existing manufacturer price in the reference countries selected by the State Secretariat for Healthcare (2004/4). The companies must indicate external prices in their reimbursement application. Thus, the manufacturer price of the substances cannot be higher than the lowest existing manufacturer price in the countries listed in the application form.

Since payment of hospitals includes all the costs that can occur during acute hospital care, including pharmaceuticals, every hospital has the autonomy to purchase the necessary medical products by tendering or public procurement. Pharmaceutical companies usually offer rebates (discounts) to hospitals. With regard to the reimbursement of these medicines, the NHIFA applies the same procedure as that used for medicines delivered in outpatient care and includes them in the positive list in the 0% reimbursement category.

The State Secretariat for Healthcare also determines the rules of prescription, which can have an effect on the amount of subsidy for which the patient is eligible (1995/2, 2004/5). Concerning the level of reimbursement, the subsidy in the normal positive list can be 0%, 25%, 55% or 80% of the agreed consumer price (including VAT as of 2009), while for expensive pharmaceuticals with approved special indications, such as insulin for diabetic patients, the reimbursement can be 50%, 70%, 90% or 100% of the consumer price if prescribed by a specialist or through the written recommendation of a specialist, otherwise they fall under the lower reimbursement levels of normal reimbursement as of 2006 (2004/4). The list of diseases is defined by the State Secretariat for Healthcare along with the Ministry for National Economy. In addition, there is special reimbursement for people with low incomes within the pharmaceutical co-payment exemption system, and pharmaceuticals can also be reimbursed through individual applications. In addition, certain very expensive drugs are purchased centrally by the NHIFA. In 2007 the reimbursement of the normal list accounted for 41.9% of the pharmaceutical expenditure of the NHIFA (PPRI, 2007).

Regarding generics, there are some specific regulations that determine the maximum reimbursement prices. Within the framework of internal reference pricing, a generic is eligible for reimbursement when its price is equal to or lower than the daily cost of therapy of the reference product that has the same active ingredient and the same strength. If its price is higher, then the product is eligible for fixed-amount reimbursement, classified either by substance or in certain cases by therapies. Through the mechanism of step pricing for generics, additional conditions for the inclusion of generics were laid down, namely that the manufacturer price of the product should be at least 30% below the manufacturer price of the original preparation as long as the first reference product or reference price is set (2004/4). Similarly, the next
generic included in the positive list in this substance group has to apply a 10% lower price compared with the first product, then the third product has to be priced 10% lower than the second one. Other competitors must simply apply a lower price for reimbursement than the previous ones from 2006 (2004/4, 2006/20).

Besides the clawback scheme for the pharmaceutical industry, there have been individual price–volume agreements with manufacturers for certain pharmaceuticals since 2003 (2002/21). Trader or manufacturer repayments are based on the annual sales volume. Overspending in the pharmaceutical budget caused by sales exceeding the contracted volume is covered by both the government and the industry. The higher the overspend, the higher the share covered by the industry. Monthly repayment can also be agreed in the individual contracts.

Since 2004, when Hungary joined the EU, it has been necessary to adopt the Transparency Directive of the European Commission (89/105/EEC). As a result of the introduction of the Transparency Directive, the government has to decide on reimbursement applications of traders and manufacturers with a maximum time of 90 days.

In the case of new substances, companies are required to submit their applications to the NHIFA together with a comprehensive study in order to demonstrate the cost–effectiveness of their products and to obtain reimbursement status for their pharmaceuticals, that is, to be accepted onto the positive list. The Pharmaceutical Department of the NHIFA transfers the complete documentation to the Office of Health Technology Assessment of the NISHR in order to carry out a critical appraisal of the documents. Further evaluation takes place by the Technology Appraisal Committee within the NHIFA, involving the experts of the professional colleges, to evaluate the merits and shortcomings of the application. The final reimbursement decision on new substances for outpatient care is made by the Head of the Pharmaceutical Department of the NHIFA, while in the case of hospital-only medicines, it is done by the Head of Department for Financing (formerly Curative-Preventive Provisions).

Effective 2007, the government focused increasingly on fostering more competition by refining the internal reference pricing system through laying down more rigorous rules for excluding the expensive products of competitive substance groups; liberalizing the ownership of the retail market, such as pharmacies; and increasing the accountability of physicians by setting standards and requiring more rational prescription of pharmaceuticals through centrally accredited IT programs (2006/8).

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9 As of 2010 called the State Secretariat for Healthcare within the Ministry of National Resources.

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**Reshaping reference pricing of pharmaceuticals**

By Gergely Németh, Balázs Hankó, Szabolcs Szigeti

In July 2011, the National Assembly accepted several important changes in the regulation of price-setting in the pharmaceutical sector in order to increase competition in the pharmaceutical market.

First, the stepped pricing system for generics was changed: the first generic has to have a 40% lower price than the originator products followed by 20-10-5-5-5% cheaper prices for the next generics.

Second, reference prices are recalculated twice per year (instead of the previously applied quarterly frequency) with the exception of new reference groups, where the stepped pricing system is expected to bring down the prices more than the semi-annual reference status.

Third, the so-called “blind bidding” for reference prices was introduced. Competitor companies cannot see the bids of others while submitting the prices of their product to the NHIFA. At the same time, products which were hidden at a 5% higher price than the reference product, could be reimbursed by 15% less than the reference product. In the meantime, this percentage has been modified to 10% (Act LXXIX of 2012, Article 66, effective of 1 July 2012).

Fourth, in the case of innovative pharmaceuticals, companies will have to indicate at least three external prices in their reimbursement application, and prices reimbursed by the NHIFA cannot be higher than the lowest of these external prices.
2.8.5 Regulation of medical devices and aids

The trading, distribution, prescription and use of medical aids and prostheses (such as hearing aids and wheelchairs) are regulated in a similar way to the pharmaceutical system. Registration and licensing have recently been reorganized according to EU regulations (1999/8). The system is run by the OHAAP of the State Secretariat for Healthcare (2000/4). Compared to pharmaceuticals, medical aids and prostheses have been less subject to cost-containment policies, for example, margins for wholesale and retail prices have not yet been regulated.

Medical devices, including medical aids and prostheses, fall under a registration and licensing system administered by the Authority for Medical Devices of the Ministry of Health\(^\text{10}\) (2000/4). In 2009, the government proposed the system for reimbursing medical aids, which follows a similar logic to that governing the reimbursement of pharmaceuticals. Therefore, since 2010, medical aids have also been reimbursed by the NHIFA through various financial techniques, such as by a proportional or a fixed amount (2010/9). In the case of proportional reimbursement, the categories are defined as 98%, 90%, 80%, 70%, 50% or 0%. Likewise, internal reference pricing is also used to determine the reimbursement of certain medical aids classified in reimbursement groups (see also section 2.7.2) (2010/13).

\(^{10}\) As of 2010 called the State Secretariat for Healthcare within the Ministry of National Resources.

2.8.6 Regulation of capital investment

In 1990, the budget of the health service was transferred to the newly established Social Insurance Fund. Since the Social Insurance Fund was meant to cover the recurrent costs of services, funds for capital costs remained in the central government budget. In 1989, full private health care entrepreneurship was legalized and private providers were permitted (1989/5).

The owners of health care facilities are responsible for financing capital costs. Such investment costs are usually beyond the financial capabilities of local governments, which have owned the majority of health care providers since 1990 (1990/3). The central government provides subsidies via conditional and matching grants. Given that most capital investment comes from these funds, this system allows the central government to control health care investment (1992/9).