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:* Lithuanian, English, French, Russian and German

*Link:* [http://www3.lrs.lt](http://www3.lrs.lt)

*Nature:* Official website of the parliament of Lithuania

*Organisation responsible for the website:* The parliament of Lithuania

**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: Lithuanian University of Health Sciences, Academy of Medicine, Faculty of Public Health, Health Research Institute
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2.8 Regulation

Traditionally, the Ministry of Health has been a major player in health system regulation through setting standards and requirements, licensing and approving capital investments. Outside the ministry, the number of regulatory agencies has declined in the period from 2008 to 2012 through a government policy to reduce bureaucracy and related costs. At present, the SMCA is the single pharmaceutical regulatory agency (after the Pharmacy Department under the Ministry of Health became a division within the ministry). In public health, the SPHS carried out regulatory functions until it was abolished in 2012, with some functions transferred to the Ministry of Health. The NHIF regulates financial flows and purchasing. The State Medical Audit, responsible for quality assurance and licensing, has been merged with the SHCAA, which is also in charge of licensing health professionals (with the exception of pharmacists, who are licensed by the SMCA, and dentists, who are licensed by the Dental Chamber). The Lithuanian Bioethics Committee continues to control and oversee patient rights and safeguard professional conduct.

Implementation of accreditation of primary care institutions

By Liuba Murauskiene
Additional Credits: Marina Karanikolos

In March 2013 the project on accreditation of primary care co-financed by the European Social Fund was launched in Lithuania. In addition to obligatory licencing of health care services, the framework for external voluntary accreditation in family medicine was created to strengthen patient-centered. A special working group developed a manual for accreditation covering five sets of standards in the following domains: patient rights and needs, provider services, management of health data, safety and quality improvement, and provider resources. A pilot using these standards in 6 primary healthcare facilities was launched. Among the main challenges, experts discuss an overall acceptance of accreditation as precondition for its implementation, scope and costs of standardization, as well as lack of motivation for team working and limited development of E-Health system.


2.8.1 Regulation and governance of third-party payers

In 2002, the NHIF was brought under the control of the Ministry of Health. Territorial NHIF branches purchase health-care services and reimburse medicine costs according to contracts with providers. The Ministry of Health determines services paid by the NHIF according to the Health Insurance Law, and their payment mechanisms set the rules of health-care provision, set reference prices for health-care services and for reimbursement of pharmaceuticals, establish the rules for provider contracts, and make budgeting and financial management decisions. The NHIF is accountable to the Ministry of Health and the Ministry of Finance (see Fig2.1). In purchasing policy, the NHIF follows the priorities set by the Ministry of Health. It funds many programmes through allocations outside of common contractual agreements, which is a more explicit way of supporting policy implementation. The NHIF is also responsible for payment for health-care services provided to insured citizens while visiting or temporarily staying in other countries of the EU or the European Economic Area (EEA). On the international level, the NHIF is involved in negotiations on and assures implementation of the relevant EU directives, for example the EU Directive 2011/24/EU on application of patient rights in cross-border health care (see section 2.9.6).

In the parallel health-care systems, integrated health provision models are employed. The Ministries of Defence, Interior and Justice decide on health-care service provision and allocations for health-care providers from their budgets.
Regulation of private insurers falls under the overall national financial regulatory framework (see section 3.5). Since 2012, the Bank of Lithuania is in charge of private insurance matters due to the abolition of the Lithuanian Insurance Supervision Commission.

**2.8.2 Regulation and governance of providers**

The vast majority of health-care providers (except for parallel health systems of the Ministries of Defence, Interior and Justice) are not budgetary institutions but public non-profit-making enterprises. This legal status for health-care facilities was introduced by the Law on Health Care Institutions in 1996. Currently, the Ministry of Health and municipalities are owners of the public health-care facilities (see Fig2.1). The owners have the power to reorganize and abolish their facilities, employ an administrator through public tender, make decisions on asset management, determine salaries and medicine costs (as a share of total expenditure) and define volumes of obligatory services. The last function is particularly difficult to implement in practice because of the dominance of the NHIF in contracting and paying for services. In reality, the owners use fewer governance instruments than they are legally equipped with, mainly using those concerning assets management and using hardly anything to influence health-care provision and performance directly. Besides the rights gained as an owner of health-care facilities, the Ministry of Health licenses providers, sets requirements for health-care provision (both generic and specific) and controls compliance with the standards. Together with the Ministry of Finance, the Ministry of Health proposes to the government on budget allocations for providers, and together with the NHIF it decides on the minimum requirements for provider networks.
The Health Care Institutions Law states that the public health service provider must have an administration (Parliament of the Republic of Lithuania, 1996a). Appointing a head of administration is one of the few real tools of influence for owners over the providers’ governance. Related provisions have been reviewed many times, and at the end of 2011 the parliament decided that appointment of the head of administration should be based on a public tender, and the duration of the appointment should be limited to five years. Other managerial structures obligatory for the public health-care provider (e.g. the steering board, the physicians’ board and the nursing board) perform advisory roles.

In parallel health-care systems, health-care providers are budgetary institutions directly subordinated to the corresponding ministries. They function according to the overall regulatory framework of budgetary institutions, defined by the Ministry of Finance, as well as in line with the relevant provisions of the Health Care Institutions Law. For example, the Ministry of Health, together with a ministry running a parallel system, sets the rules for service provision and controls compliance. At the same time, general rules for licensing of facilities and professionals apply to health-care institutions as well as to any other organizations delivering health care (i.e. private clinics and social care institutions).

The SHCAA performs many regulatory functions on licensing, registering and inspecting providers. It can also accredit health-care providers at their request, provided they have been functioning longer than three years. At present, the SHCAA is implementing an accreditation framework and five accreditation standards, financed from the EU structural funds. However, providers lack incentives to seek accreditation, as the purchasing arrangements do not regard the quality of the services delivered.

Health-care institutions and professionals are mainly concerned with meeting the minimum requirements (e.g. the minimum number of hours of professional training for retaining their licence). There have been many attempts to improve quality assurance but few initiatives have received proper funding. Currently, the system is mostly based on inspection. A whole chapter of the Health Care Institutions Law describes inspection rules in relation to all health-care providers. Control functions are granted to the Ministry of Health, the NHIF, the SHCAA and the Bioethics Committee, and the inspection authorities can, among other measures, stop service provision and introduce forced temporary administration. There is also a legal requirement for municipalities as owners, as well as for the administration of health-care institutions, to make internal audit arrangements seeking to assure safety and quality of care.

The quality of standards and guidelines developed by the Ministry of Health have been criticized for lacking an evidence-based approach and proper pathway structure, and for having a one-sided focus on only medical aspects of treatment (Justickis & Saladis, 2011).
2.8.3 Regulation and planning of human resources

Obligatory licensing of health-care professionals has four major categories: physicians, nurses, dentists and pharmacists. The SHCAA licenses and registers health-care professionals. The Centre for Quality Assessment of Higher Education is an independent public institution, established by the Ministry of Education and Science, that implements external quality assurance policy in higher education in Lithuania and assesses qualifications to assist free movement of the workforce. The Ministry of Education and Science and the Ministry of Health are jointly responsible for indicative planning of the health-care workforce, with limited possibilities for directly influencing autonomous educational institutions (see more on human resources in section 4.2).

2.8.4 Regulation and governance of pharmaceuticals

The introduction of a new Pharmacy Law in 2006 required revision of the entire legislation in the area and incorporated all relevant EU legislation. One of the main changes was shifting the licensing of pharmaceuticals from the Ministry of Health to the SMCA. The SMCA, the Ministry of Health and the NHIF are currently the main actors in the regulation of pharmaceuticals in Lithuania. The Ministry of Health has the most important role as it decides both on strategic planning and on whether a product will be reimbursed and at what price. The Pharmaceuticals Reimbursement Committee, consisting of representatives from the Ministry of Health, the SMCA and the NHIF, advises the Minister of Health on reimbursement decisions.
According to the Health Systems Law of 1994, the SMCA carries out regulatory and control functions by granting marketing authorization, classifying prescription status (prescription-only versus over-the-counter drug), conducting pharmacovigilance, inspecting the pharmaceutical industry and pharmaceutical product distribution companies (including pharmacies), controlling the quality and advertising of pharmaceuticals and supervising clinical trials. The SMCA registers pharmaceuticals and keeps a list of licences of pharmaceutical companies, pharmacies and pharmacists. The activities of the SMCA only concern human medicines. The control of veterinary medicine and related activities is carried out by the State Food and Veterinary Service.

The NHIF is in charge of contracting pharmacies and reimbursing medicine costs, as well as for procuring high-cost pharmaceuticals via public tenders.

New evaluation criteria for reimbursed pharmaceuticals were introduced in 2007. The main criteria for reimbursement are medical benefit provided by the pharmaceutical (effectiveness, safety and severity of the disease treated, taking into account data from published clinical trials), results of pharmaco-economic evaluation and the impact of reimbursement of that pharmaceutical on the budget of the NHIF (an estimation is made for each indication submitted for reimbursement). Most of this information is provided by the applicant company, and usually no additional analysis is carried out. The final decision is made by the Minister of Health, supported by the technical evaluations from the Pharmaceuticals Reimbursement Commission and the NHIF.

In 2007, price negotiations on pharmaceuticals were introduced. Prices of reimbursed pharmaceuticals are regulated only through a reference pricing system. Since 2010, the reference manufacturing price should not exceed 95% of the average manufacturer's price in the eight reference EU countries (Bulgaria, Czech Republic, Estonia, Hungary, Latvia, Poland, Romania and Slovakia). Pharmaceuticals are grouped on the basis of the International Nonproprietary Name (INN), method of use, form, purpose and length of action. The reference price for the group is the cheapest priced product in the group. The wholesale and pharmacy retail prices of reimbursed pharmaceuticals are regulated by adding a mark-up approved by the Ministry of Health. When the pharmaceutical price is higher than the reference price, the patient pays the difference as a co-payment. In addition, the patient has to pay a user fee for every pharmaceutical except for insulin (Krukiene & Alonderis, 2008).

Responding to the growing expenditure on reimbursed pharmaceuticals and the economic crisis, the Plan for the Improvement of Pharmaceutical Accessibility and Price Reductions was approved by the Minister of Health in 2009. In accordance with the Plan, new requirements were introduced on generic pricing (30% below the originator for the first generic and at least 10% below for the second and third); prescribing by INN, with some exceptions; and the obligation for pharmacies to provide data on prices to patients and have the cheapest product in stock. In addition, since 2008 there have been price volume agreements for new pharmaceuticals (Garuoliene, Alonderis & Marcinkevicius, 2011).

The prices of all non-reimbursed prescription pharmaceuticals and over-the-counter pharmaceuticals are regulated by adding maximum retail and wholesale mark-ups set by Governmental Decree. In addition, marketing authorization holders and parallel importers, or their representatives, have to declare to the Ministry of Health the price at which a non-reimbursed medicinal product will be distributed in Lithuania and submit the prices of this product in eight reference countries (see above). The declared prices of non-reimbursed medicinal products and the maximum retail prices, which pharmacies should not exceed, are published on the web site of the Ministry of Health.

Pharmaceutical information included in patient information leaflets has to be officially authorized by the SMCA. Advertising for prescription-only medicines is prohibited. Transparency International survey in Lithuania (Transparency International Lithuania, 2007) and media reports (Simaite, 2009; Vysniauskiene, 2011) on ties between physicians and pharmaceutical companies have led to the introduction of control measures over promotional activities, including restrictions on payments for physicians’ participation in promotional events, as well as annual reports on promotional expenditure to the SMCA.

There is a legal requirement that medicinal products ordered by phone and online shall only be dispensed on pharmacy premises with obligatory clear information about the product in Lithuanian, as required for all medicines.

Prescribing guidelines were introduced in 2002, and by 2009 included 27 conditions. The guidelines are
recommendations that are typically produced by universities and physicians associations and approved by the Ministry of Health.

### 2.8.5 Medical devices and aids

Public facilities have to adhere to procurement rules for purchasing any supplies, including medical devices. The Public Procurement Office is in charge of compliance with legal requirements, with more transparency increasingly being introduced for tendering procedures through the use of a publicly available web site.

The registration of and control over the use of medical equipment is regulated according to the relevant national and EU legislation. The SHCAA registers suppliers of medical equipment and companies licensed to perform technical service of medical equipment. The SHCAA also collects data on expensive medical devices, costing over €29 000 (100 000 litas), or those bringing an annual revenue from the NHIF to providers of more than €290 000 (1 million litas). The information collected includes financial and usage intensity indicators for public providers; private providers not contracted by the NHIF only report starting and final dates of the usage of the equipment. A parliamentary commission dealing with corruption (Parliament of the Republic of Lithuania Anticorruption Commission, 2011) called for more thorough collection of detailed information on existing medical equipment across providers in order to ensure more rational spending and effective use of the equipment.

### 2.8.6 Regulation of capital investment

A major part of the long-term assets of public health-care facilities (land, buildings, etc.) is in state or municipal ownership. An owner has to approve important managerial decisions regarding the long-term assets. However, currently there is no clarity on responsibilities for management of the state assets and for maintenance of the infrastructure. In practice, capital investments are financed through the state investment programmes. The rules for allocating state capital investments are defined by the Ministry of Finance, which develops three-year state and local budgets, while the Ministry of Health approves the proposed investment projects. There is no systematic assessment of the investment strategy, and investment decisions often lack transparency. Since 2004, capital investments in the health sector have been mostly paid from the EU structural funds, and these investment decisions have been more transparent given the accountability obligations and open access to information. Even so, on the operational level, most of the funding is allocated not in a competitive way but according to the decisions of the public authorities.