THE HEALTHCARE LAW REVIEW

Editor
Sarah Ellson

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LITHUANIA

Rūta Pumputienė[1]

I OVERVIEW

The structure and the main principles of the Lithuanian health system are set in the Law on the Health System. According to this Law, the health system consists of governance institutions (the government, ministries and municipalities, as well as other control bodies), providers of healthcare services, health system resources and services. The health system in Lithuania is predominantly funded by the National Health Insurance Fund (which consists of contributions from employers and employees and from revenue created through state and social insurance activity), and supplemented by state contributions on behalf of those who are economically incapable of contributing. Accordingly, Lithuania provides free state-funded healthcare to all citizens and registered long-term residents. Providers of such healthcare (both state or municipal entities and private ones) shall conclude a contract with the National or Territorial Health Insurance Fund and become a part of Lithuanian National Health System. Purely private healthcare (i.e., based on private medical insurance or payments for the services) is also available in the country.

The Ministry of Health directly controls the national healthcare institutions, as well as being responsible for implementing government policy, licensing healthcare personnel, and keeping the register of medical professionals. The Ministry of Health also establishes the prices for services provided by institutions that are a part of the Lithuanian National Health System. The prices for services provided by institutions that do not belong to the Lithuanian National Health System are established by their management bodies or owners in accordance with the procedure established by the laws of these institutions.

In order to provide healthcare services, institutions and healthcare professionals must obtain healthcare licences from the State Healthcare Accreditation Agency, which are of indeterminate duration.

Healthcare in Lithuania is divided into three levels: (1) primary (healthcare provided by family doctors or their assistants, nurses, obstetricians, or midwives, etc.); (2) secondary; and (3) tertiary. Primary and secondary healthcare services are organised by municipalities, while the Ministry of Health organises the tertiary level of healthcare. Secondary and tertiary level healthcare institutions provide specialised care of two types – outpatient and inpatient care. Unless it is a case of emergency, both secondary and tertiary level healthcare services require that the patient had been issued with a referral by a family practitioner or specialist.

If the healthcare institution is not a part of the Lithuanian National Health System, it is less restricted to the state control as the national inspectorate bodies are able to control

1 Rūta Pumputienė is the founder of and a partner at Rūta Pumputienė Law Firm.

healthcare institutions that have received funding from the national or municipal budgets. However, not being a part of the National Health System may mean restrictions to the activities that can be performed by such institutions.

II THE HEALTHCARE ECONOMY

i General

Health expenditure as share of GDP fell between 2010 and 2013 from 6.82 per cent to 6.14 per cent, and grew to 6.52 per cent between 2014 and 2015.[2] Just as in the two other Baltic countries – Latvia and Estonia – the healthcare financing system in Lithuania is focused on curative health, which receives 49 per cent of all health spending. In 2015, there were 5.1 hospitals per 100,000 people in Lithuania, compared with 3.4 hospitals in Latvia and 4.2 hospitals in Estonia per 100,000 people.[3] In 2015, there were 430 healthcare institutions of primary level in the National Health System, 260 of which were private institutions and 168 public. The total number of hospital beds per 10,000 of the population in 2015 was 87.9, compared with 55.6 Latvia and 55.6 in Estonia.[4] Compared with 2005, in 2015, the number of physicians' visits per person increased in Lithuania by almost 30 per cent.

ii The role of health insurance

In Lithuania, like in many other European countries, health insurance is compulsory, which means that residents of Lithuania are obliged to pay compulsory health insurance contributions. The Compulsory Health Insurance Fund (CHIF) is regulated by the Law on Health Insurance and is an autonomous fund separated from the state and municipalities funds. The Ministry of Health implements the state's health insurance policy and the Compulsory Health Commission (an advisory Ministry of Health body), National Health Insurance Fund and territorial health insurance funds administer the compulsory health insurance.

Those healthcare institutions that have entered into a contract with the National Health Insurance Fund are compensated from the CHIF for the provided healthcare services to insured people. The CHIF also covers expenses of pharmacies for the reimbursed medicinal products, medicinal devices, preventive medicinal programmes, rehabilitation, care and social services, etc. The health insurance system is based on two principles of solidarity and universality. The latter principle means that every citizen of Lithuania and foreign nationals permanently residing in Lithuania, also foreign nationals temporarily residing and legally employed in Lithuania must pay compulsory health insurance contributions and, therefore, are entitled to receive healthcare services that are compensated from the budget of the CHIF. The principle of solidarity means that the insurance contribution ranges depending on the practical abilities of the payer, while the CHIF will guarantee that the healthcare services will be provided regardless of the paid contribution. Therefore, persons who are insured may be divided into two groups: (1) persons who pay compulsory health insurance contributions (by themselves or by their employer), and (2) persons who are insured with state funds (retired

2 According to data in Health Studies Lithuania 2016: Importance of Health for Sustainable Growth of Economy, Vilnius, 2017, by Cerniauskas, G, Buivydas, R.

3 According to data in Health in Baltic Countries 2015.

4 Ibid.

persons, disabled persons, mothers on maternity leave, registered unemployed, minors, etc.). The Law on Health Insurance states that the supplementary health insurance is also possible to cover expenses for the healthcare services that are not covered by the CHIF.

iii Funding and payment for specific services

Lithuanian regulations ensure that all persons who are insured with compulsory health insurance are provided with free-of-charge healthcare services. The CHIF covers individual healthcare services provided on the primary, secondary and tertiary levels of healthcare institutions; covers medical rehabilitation, nursing care and social services; and reimburses expenses related to medicinal products and medical devices, etc. If the patient is entitled to free healthcare services, healthcare institutions are not allowed to introduce co-payments for reimbursed healthcare services, except in cases when a patient personally chooses more expensive services, materials, or procedures, or if the patient asks for additional services and agrees to them in writing. In this case, these services will not be reimbursed by the state or municipal authorities, but rather paid by the patient himself or herself, by a particular legal person (i.e., employer) or by the supplementary health insurance.

Emergency medical services are provided free of charge to all patients, including non-residents. The Ministry of Health approves a list of paid healthcare services and prices for such services. As the public healthcare institutions are non-profit organisations, they are not allowed to include a profit margin in their pricing.

The institutions that provide primary healthcare services are paid depending on the number of residents that are registered to the institution – this is the main funding source, which is also called the base payment. Moreover, these institutions receive extra payments for the registered residents of rural areas, good healthcare results, and for special services (there are 13 groups of special services, e.g., low-risk pregnancy care, healthcare for disabled people, early diagnosis of malignant tumours and child immunoprophylaxis). Since 1 January 2012, the diagnosis-related groups (DRG)-based reimbursement of healthcare services system has been used in Lithuania at hospital level. Clinically and economically similar services are classified into groups. Different reference prices are approved for each group. After assessment of the patient's diagnosis, interventions carried out during the treatment episode and any complications, the healthcare service is assigned to a DRG group. The price paid to hospitals depends on the DRG group to which the particular service has been assigned. The costs of expensive examinations and procedures performed during the episode of the active inpatient treatment are included in the total cost of healthcare service and are not reimbursed separately. The actual cost of the service increases if expensive blood components, medical aids or chemotherapy pharmaceuticals are used.

Those healthcare institutions that do not belong the Lithuanian National Health System provide healthcare services that are paid for by citizens personally. Offices of obstetricians and gynaecologists are not usually a part of the National Health System.

Furthermore, there are paid healthcare services that are not reimbursed by the CHIF, even though they are provided by healthcare institutions that belong to the system. The Minister of Health approves a list of such paid healthcare services and it includes preventive health examination for those who are going abroad, cosmetic surgeries, and dental prosthetics and implants.

III PRIMARY / FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

As mentioned above, healthcare is divided into three levels: (1) primary, (2) secondary and (3) tertiary. The primary level is healthcare services provided by family doctors and other qualified specialists that provide personal, comprehensive care for individuals and provide referral to specialised institutions (secondary and tertiary level healthcare) when needed. The referral from the primary healthcare specialists is a prerequisite for patient to receive free-of-charge healthcare. Without the referral, unless it is an emergency case, the healthcare services would be paid by the patient himself or herself, or a supplementary insurance fund. The patient is free to choose primary healthcare institutions or specialists according to his or her preference, and this also applies to both private and public institutions, although healthcare will be paid only for those services that were provided in an institution that had entered into a contract with the National Health Insurance Fund or territory health insurance funds.

As stated in the Law on the Health System, Lithuania supports the use of an e-health system, which has the following priorities: (1) general access to e-health services for patients and health professionals; (2) cooperation between the healthcare sector participants; (3) general access to the healthcare sector information resources – the Electronic Health Record (EHR), registers and classifications; (4) general access to public administration information resources and e-government services; and (5) the creation of conditions for more efficient, more qualitative and accessible health services via continuous information gathering, data exchange, interoperability and information security. However, the progress of the e-health system coming into use has not been promising. Since the end of 2015, the obligation has been imposed on only 170 of 500 state healthcare institutions who took part in e-health projects to start using certain information systems; for those that did not take part in these projects, the mandatory obligation will begin from 2018.

IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

i Regulators

The obligation for the institutions that are planning to provide healthcare to obtain a licence for healthcare services is set in the Law on Health Institutions. This law also sets rules on establishing institutions that provide healthcare, both those institutions that belong to the National Health System and those that do not, both private and public. Moreover, this law indicates rights and obligations of the healthcare-providing institutions as well as sets the monitoring body for such institutions. The key body for licensing healthcare institutions and individual professionals is the State Healthcare Accreditation Agency (SHAA). The SHAA is mainly engaged in licensing healthcare providers and professionals (i.e., medical doctors, nurses, midwives and public healthcare specialists, except for dental services) and public health institutions, laboratories and pathology services; it also has a role in the assessment and control of medical devices. Only after receiving a licence from the SHAA can an institution provide healthcare. The rules of the licensing process are set in the Order of the Health Minister No. V-156. (the Licensing Rules). The SHAA also supervises whether the healthcare institutions are providing healthcare services according to the national legislation and whether the terms and conditions of the licence are being complied with.

ii Institutional healthcare providers

As mentioned above, the SHAA is responsible for issuing licences for healthcare institutions in line with the Law on Healthcare Institutions and the Licensing Rules. Under the Licensing Rules, the SHAA can not only issue licences, but also revoke licences (or parts of licences), withhold licences and refuse to issue licences. A licence is issued after 30 calendar days from the submission date. The submission for the licence can also be made via e-registration. When a healthcare institution is applying for the healthcare services licence, it must comply with the requirement of the institutions that are set in the national legislation (such as civil liability insurance for damage to patients, the institutions are in line with hygiene requirements, etc.) and have enough specialists, as well as equipment to provide the healthcare services.

iii Healthcare professionals

Healthcare professionals are also required to obtain a licence from the SHAA to provide healthcare services and be named on the practitioners' list. After receiving a licence, they can enter into contracts with healthcare institutions that have licences to provide the particular healthcare service that the professional holds the licence for. There are few licence categories for healthcare professionals issued by the SHAA: medical doctors, nurses, midwives and public health specialists. Licences for dentists aand oral care specialists are not issued by the SHAA, but by the Lithuanian Dental Chamber.

According to the Law on medical practice regarding the licence of medical doctors, medical doctors are allowed to provide healthcare services only in institutions that also have a licence for healthcare service provision. Therefore, it is illegal for a medical doctor to practise in any other institution, regardless of its legal form, if the institution is not licensed by the SHAA. This principle applies to all healthcare professionals as it is set in the Law on the Health System. According to the Code of Administrative Offences of the Republic of Lithuania, persons illegally engaged in healthcare activities are to receive a fine of between €600 and €1140. Also, there is a provision in the Penal Code that imposes criminal liability on a medical doctor who has the right to perform the abortion procedure, but carries out the procedure outside of a healthcare institution.

V NEGLIGENCE LIABILITY

As mentioned above, institutions willing to provide healthcare services and obtain a licence must be insured with civil liability insurance for the damage caused to patients (both pecuniary and non-pecuniary damage). The law on the Rights of Patients and Compensation for the Damage to their Health sets the mechanism of the health damage compensation. Under this law, a mandatory pre-litigation procedure exists, as the patient who suffered damage due to the fault of the healthcare institution or staff of this institution must firstly refer to the Commission for the establishment of the damage caused to the patients under the Ministry of Health. If the patient does not agree with the decisions made by these institutions, it possible to seek compensation through legal proceedings.

i Overview

As the mandatory pre-litigation procedure exists, not so many cases reach the national courts. The current model of damage compensation means that the patient must prove that he or she suffered damage as a result of fault by the healthcare institution or its staff, therefore, the patient must prove that there are all four mandatory conditions for the responsibility to arise:

negligence or malpractice, damage (pecuniary, non-pecuniary), the fault of the person who has caused the damage and causality between the damage and wrongful actions. The case law in Lithuanian national courts shows that fault of the healthcare professional is presumed and the injured person must prove the other mentioned conditions. According to the case law, the healthcare professional's mistake when diagnosing an illness or patient's condition will not be viewed as a negligence if he or she did his or her utmost and what was necessary under particular circumstances. Thus, the burden of proof will be on the patient to prove that the doctor had not done everything he or she could and should have done.

The process of compensation is difficult and it is often criticised by patients and healthcare professionals. The compensations for the injured persons are usually very little and sometimes regarded as inadequate.

ii Notable cases

One of the most famous cases regarding compensation for damage to a patient's health in Lithuania was in regard to seriously injured newborn twins. Although not so recent, this case is famous for the non-pecuniary damages awarded from the healthcare institution for both parents and twins, which was 500,000 litai (around €145,000), and is still the highest amount of compensation awarded for damage to patients' health since 2005. The healthcare professionals whose negligence resulted in injuring the newborn twins were included in the case as a third party. The Supreme Court of Lithuania rejected the arguments that as a result of the amount of the compensation the hospital would go bankrupt, as there was no real evidence to indicate this, also the financial state of the subject that caused the damage for the patients cannot be the decisive criterion for the damages awarded. The main criteria for non-pecuniary damages are negligence and the consequences for health and sufferance as a result of such negligence.

VI OWNERSHIP OF HEALTHCARE BUSINESSES

According to the Law on Healthcare Institutions, there may be few legal forms of the public healthcare institution. The public healthcare institution may be: (1) a budgetary institution, (2) an enclosed budgetary institution, or (3) a public non-profit institution. Budgetary institutions include sports medicine centres, addiction centres, centres for infants with developmental delays and the national transplant bureau. Budgetary institutions are owned either by municipalities or the state. Enclosed budgetary institutions are special budget institutions also owned by the state or municipalities, and are used for convicted imprisoned persons, persons with mental illnesses, and officers and cadets. The Ministry of Health establishes enclosed budget institutions. Finally, the public institutions are non-profit healthcare institutions established by the Ministry of Health, municipalities, higher education institutions or educational and scientific institutions altogether with Ministry of Health with the consent of the government. The great majority of healthcare providers are not budgetary institutions but public non-profit institutions.

There are no restrictions on foreigners owning companies. Also, for private healthcare institutions, the same regulation applies as to any other private legal body, in addition to obtaining a licence from the SHAA.

VII COMMISSIONING AND PROCUREMENT

As mentioned above, emergency medical services are provided free of charge to all residents. Secondary and tertiary healthcare services are provided to the insured by compulsory health insurance. To receive healthcare services, a patient should turn to his or her family practitioner first. If the family practitioner decides that it is necessary, then he or she will give a referral to a specialist and that consultation will be covered by CHIF. The admission to the hospital takes place with the referral issued by a family practitioner or specialist. Only in the case of an emergency can a patient go directly to the hospital.

Healthcare services payment procedure is regulated by Personal Healthcare Services' Payment Order No. V-1113, approved by the Minister of Health. Healthcare institutions that have entered into a contract with the National Health Insurance Fund are paid for providing healthcare services according to approved basic prices of services, which is reimbursed from the CHIF budget.

Since 1 January 2012, the DRG-based reimbursement of healthcare services in the hospital level of the system has been used in Lithuania. Clinically and economically similar services are classified into groups. Different reference prices are approved for each group. After assessment of the patient's diagnosis, interventions carried out during the treatment episode and any complications, the healthcare service is assigned to a DRG group. The price paid to hospitals depends on the DRG group to which the particular service has been assigned. The costs of expensive examinations and procedures performed during the episode of the active inpatient treatment are included in the total cost of healthcare service and are not reimbursed separately. The actual cost of the service increases if expensive blood components, medical aids or chemotherapy pharmaceuticals are used. As far as medicinal products are concerned in the outpatient sector, the Ministry of Health approves a list of conditions for which medical treatment would be reimbursed by the CHIF. In order for a medicinal product to be reimbursed, it must meet the legal criteria (i.e., requirements for medicinal benefits, pharmaeconomic value, reimbursement impact to the budget). Only then are medicinal products included on the List of Diseases and Reimbursable Medicinal Preparations for their Treatment (the 'A-list') and with the approval of the Ministry of Health included on the Price List of Reimbursable Medicinal Products. The National Health Insurance Fund reimburses the price by paying pharmacies according to the prescriptions. Only a certain compensation level of the base price of the medicinal product is reimbursed (either 100 per cent, 90 per cent, 80 per cent or 50 per cent). With regard to the inpatient sector, there are two possible ways of commissioning medicinal products: (1) the National Health Insurance Fund procures medicinal products through the Central Procurement Organisation (nevertheless, medicinal products still need to be included into the A-list); or (2) the healthcare institutions (hospitals) procure medicinal products through hospital tenders. Inpatient services are fully reimbursed and no co-payments from insured patients are needed. The situation with medical devices is similar, as medical devices are also reimbursed only if they are included on the List of Diseases and Reimbursable Medical Devices for their Treatment (the 'C-List') and the Price List.

VIII MARKETING AND PROMOTION OF SERVICES

There is only one particular restriction regarding the advertisement of healthcare services, which is set in the Law on Advertising. It prohibits using a patient's first name, surname, image, and relying on recommendations of healthcare institutions or professionals. Moreover,

the general rules on advertisement also apply, which prohibit degrading a person's dignity and honour, inciting hatred and discrimination and promoting behaviour that poses a threat to health, as well as prohibiting misleading advertising.

IX FUTURE OUTLOOK AND NEW OPPORTUNITIES

One of the major unresolved issues in Lithuanian healthcare is the implementation and use of e-health. The Lithuanian National Electronic Health System was only launched in 2015. If it becomes fully operational, it may improve the efficiency and quality of healthcare, and make it easier for different institutions to exchange data. The introduction of electronic methods to make the funding process more transparent is also expected.

Lithuania is working to strengthen long-term care. As society ages, and employment rates rise, there will be an increasing demand for long-term care services. With the help of EU funds, Lithuania is putting in place and modernising its long-term care infrastructure (such as day-care centres), establishing new community-based care homes for the elderly and developing the provision of social and nursing care at home. The establishment of an efficient and effective long-term care system will require close coordination between the Ministry of Health and the Ministry of Social Affairs.[5]

While there are no fiscal sustainability problems in the Lithuanian health system in the medium or long term, Lithuania could support future sustainability by linking expenditure increases to improvements in cost-effectiveness.

However, limited progress has been made in the recent past on improving the performance of the healthcare system. Several challenges remain. The primary care system needs strengthening so that more patients are treated instead of being referred to a specialist, which will also require a change in attitude by patients. Transparency and accountability need to be increased in resource allocation, including financing of capital investment and in the payer–provider relationship. In addition, out-of-pocket payments remain high (in particular, for pharmaceuticals) and could threaten health access for vulnerable groups. Finally, population health, albeit improving, remains a concern, and major progress can be achieved by reducing the burden of amenable and preventable mortality.[6]

X CONCLUSIONS

Lithuania has a modern state healthcare system, funded by the government through a national health insurance scheme. Like many other European states, Lithuania has put in place the compulsory health insurance system, which means that residents of Lithuania are obliged to obtain health insurance coverage (i.e., pay compulsory health insurance contributions). With respect to the insured, the state guarantees healthcare services compensated by the CHIF. In other words, all employers must register employees to the scheme, and they will then automatically be covered. Disadvantaged groups, such as the elderly and the long-term sick, do not have to contribute, but are still covered by the scheme.

5 Country Report Lithuania 2016. Commission Staff Working Document. Brussels, 26 February 2016 SWD(2016) 83 final.

6 Lithuania: health system review, by L Murauskienie, R Janoniene, M Veniute, E Van Ginneken and M Karanikolos, World Health Organization 2013.

Healthcare, including emergency treatment, is free at the point of delivery, with the standard system of family doctors (GPs) providing referrals for non-urgent cases.

The standard of some local hospitals may still be poor; however, the city hospitals tend to be far better, and the general standard of healthcare facilities in Lithuania is improving as the government prioritises funding for health. Naturally, the private healthcare facilities, especially those aimed at the medical tourist market, are even better.

Public financing of the health sector has gradually increased since 2013 to 6.14 per cent, and grew in 2014–2015 to 6.51 per cent; however, this number is still one of the lowest in the EU, and the future government's plans in public health spending is a cause for concern.

Many challenges remain ahead.

Appendix 1

ABOUT THE AUTHORS

RŪTA PUMPUTIENĖ

Rūta Pumputienė Law Firm

Mrs Rūta Pumputienė is an attorney-at-law and the founder and managing partner of Ruta Pumputiene Law Firm, with over 12 years' legal experience, mainly in the life sciences sector. Rūta continues her practice after working for 10 years as an associate partner in the biggest business law firm in the Baltics. She works with leading international life science companies in Lithuania within the pharmaceutical, food and other regulated industries sectors. She is widely considered one of the most experienced life sciences law and intellectual property experts in the Baltic States. Mrs Pumputienė graduated from Vilnius University Faculty of Law in 2004. In 2010, she obtained a master of law (LLM) degree in international intellectual property law from the University of London. Since 2013, Mrs Pumputienė has been the head of the Local American Working Group (LAWG), a standing committee established by the American Chamber in Commerce in Lithuania to tackle issues concerning the healthcare system and pharmaceutical industry in Lithuania. Recently, Rūta Pumputienė was announced as one of the top lawyers in Lithuania in biotechnology law, information technology law and intellectual property law in the seventh edition of *Best Lawyers*.

Mrs Pumputienė is also a frequent speaker in national and international conferences on medical law, intellectual property, and EU and domestic trade law spheres, and has authored and co-authored dozens of publications on medical law, pharmaceutical law, intellectual property and related law matters.

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