Healthcare Quality and Safety

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Safety and quality standards in healthcare in Latvia are strictly regulated, the requirements are established in the Law on Medical Treatment and in other regulatory acts. The regulatory acts applicable to healthcare are harmonised with the EU regulatory acts and are regularly updated and supplemented.

Healthcare services may be provided exclusively by the medical institutions which are listed in the Registry of Medical Institutions (part of the national information system which includes information about all medical institutions in the state) and comply with the established mandatory requirements.

Mandatory Fundamental Requirements for Medical Institutions

Mandatory fundamental requirements are applicable to various medical institutions in Latvia, such as healthcare centres, day-time in-patient facilities, dental practices. The mandatory requirements establish what structural units, premises and equipment the medical facility of the respective profile shall have; in an out-patient medical facility, information shall be available about the healthcare professionals and medical support staff who provide out-patient healthcare services to patients (name, surname, profession, speciality, opening hours, and location) and about the available healthcare services.

To assure control over the quality of the provided healthcare services, the healthcare institution shall develop, approve, and implement a quality management system that ensures continuous control over the quality of the provided healthcare services, processing of patient claims and suggestions, analysis of the treatment results (outcomes), improvement of the healthcare service quality.

The following shall be entitled to provide healthcare services in the respective profession independently:

- Registered healthcare professionals.
- Persons listed in the Registry of HealthCare Professionals and Medical Support Staff.

After entry into the Registry, the healthcare professional or medical support staff is entitled to provide healthcare services in the respective profession for five years. Certified healthcare professionals listed in the Registry of Healthcare Professionals and Medical Support Staff shall be entitled to provide healthcare services in the particular speciality independently. The obligations, authorisations and liability of the employees of healthcare institutions are established in external and internal regulatory acts and orders issued by the head of the medical institution.

For the medical institution to be able to provide the necessary healthcare services to its patients, the head of the medical institution shall assure that the medical institution can be accessed conveniently by the disabled.

Individuals with impaired sight or hearing shall be able to receive the necessary audio or visual information.

Access can be provided in various manners. For instance, if the building of the medical institution has the status of a historical building, then access to it can be provided by alternative technical solutions.

*More information about the types of access can be received by contacting the respective medical institution.

Use of medical technologies

The head of the medical institution is responsible that the institution uses the medical technologies (treatment methods and medical devices) which are duly approved.

The healthcare professional is responsible for the use of the chosen medical technology and the consequences of such use. In Latvia, medical technologies are evaluated and approved by the National Health Service.

Information about these technologies is available on the Database of Medical Technologies for Therapeutic Use.

Application of Clinical Guidelines

To assure better treatment outcomes, treatment shall be performed in accordance with the clinical guidelines which establish the most appropriate disease prevention, diagnostic, treatment, rehabilitation and care tactics as well as facilitate professional education of healthcare professionals, patient training, and cooperation between patients and healthcare professionals.

The clinical guidelines shall be followed in treatment, medical education training programmes, and in control over and supervision of the quality of the provision of healthcare services. Draft guidelines may be developed and submitted for entry into the database of guidelines applicable to medical treatment by the professional organisations of healthcare professionals, medical institutions, and institutions of tertiary education. A procedure for the development, registration and implementation of clinical guidelines is established in Latvia.

The listing of the approved Clinical guidelines is entered into the Database of Clinical Guidelines.

Use of Medical Devices

Medical institutions providing medical radiological treatments or medical radiation exposure services shall have a special permit (licence) or a permit for manipulations with sources of ionising irradiation. The state has an established procedure for registration, conformity assessment of medical devices as well as for their distribution, operation, and maintenance.

Medical institutions shall assure the following:

- a permanent location for the medical device;
- verification of electrical safety of medical devices, their main functions and indicators;
- proper technical servicing (maintenance) of the medical device;
- appointment of a duly qualified person responsible for medical devices.

A system for control over safe operation of medical devices has been established in Latvia. The system is a set of measures which envisages reporting and evaluation of the reports on all actual or potential incidents/accidents related to operation/use of medical devices which have caused or might cause damage to human health or danger to human life.

The State Agency of Medicines maintains the LATMED electronic database of medical devices which contains information about devices, their manufacturers, distributors, incidents/accidents related to the operation/use of medical devices as well as other information.

Hygiene Requirements and Compliance with Them

To avoid spreading of virulent diseases whose cause is related to patient healthcare, hygiene requirements have been established in the hygiene assurance plan of the medical institution.

The plan includes requirements for:

- cleaning of premises and equipment;
- cleaning, disinfection, sterilisation of medical devices;
- treatment of hands of the employees; use of gloves and other means of protection;

use and laundry of bed linen; management of waste.

Employees shall comply with this plan of the institution. To assure implementation of the plan, the head of the medical institution shall appoint a person responsible for the implementation of the plan and the internal control, or shall establish an infection control commission. The medical institution shall organise training in prevention of infections for the employees before hiring them and at least once every three years.

Purchase and storage of medicinal products

The state has a regulated procedure for purchase, storage, and use of medicinal products by medical and social care institutions. A procedure for the provision of first aid, approved by the head) shall be available in all medical institutions. All medical institutions (except for dental technical laboratories and clinical diagnostics laboratories) shall have the medicinal products and medical products necessary to provide emergency medical assistance.

In order to better assure public health protection with regard to safe use of medicinal products and to obtain information regarding the potential risks from medicinal products, a pharmacovigilance system has been established for use to pool and scientifically evaluate information about side effects of medicinal products caused by approved or unapproved use of medicinal products. It also enables to consider risk mitigation and preventive measures as well as measures with regard to authorisation of medicinal products.

Obligations of healthcare professionals, pharmacists and patients and their rights to become involved in the reporting of possible side effects of medicinal products have been established in Latvia. The pharmacovigilance system is supervised by the State Agency of Medicines.

Supervision of Healthcare Providers

The Health Inspectorate performs the surveillance and monitoring functions in the healthcare sector in the entire territory of Latvia by exercising control over the following:

- compliance with the requirements established in the regulatory acts for medical institutions (hygiene and anti-epidemic requirements; turnover of medicinal products, including narcotic and psychotropic medicinal products and alcohol, in medical institutions; medical documentation; procedure for registration and issue of sickness certificates; requirements for operation of medical devices, etc.);
- availability of the state funded healthcare services to the patients, justification of the provision of the services, and payment for the services;
- quality of healthcare professional and working ability expert examinations in healthcare institutions.

Inspections conducted by the Health Inspectorate may be scheduled or unscheduled: Scheduled inspections or case evaluations are performed in medical institutions in case an application or information about possible non-compliance is received from an inhabitant. Simultaneously, the data provided by the healthcare institutions are analysed continuously in the electronic payment system operated by the National Health Service.

Scheduled inspections are conducted according to the plan approved by the Health Inspectorate for the specific year.

Unscheduled inspections are conducted with regard to an application or information about possible violations in a medical institution.

The Health Inspectorate may conduct inspections and control any facility at no advance notice, any special permit, payment or any other restrictions in the entire territory of Latvia, except for places of imprisonment and other restricted access institutions and territories which are established in the regulatory acts and can be visited only if an approval is received from the management of the institution or the administration of the territory.

During healthcare institution inspections and upon identification of non-compliance, the Health Inspectorate provides recommendations and requires that the medical institution should eliminate the non-compliances.

- If non-compliance has been found during the inspection which presents risks to successful treatment process, a written warning is issued to the medical institution.
- If the non-compliances specified in the warning are not corrected within the fixed timeline, the Health Inspectorate may decide to suspend the operation of the medical institution or any of its structural units.
- If the Health Inspectorate detects a non-compliance which presents risks to the health or life of patients, the operation of the medical institution shall be suspended at no advance notice.

The responsible medical institution shall report on the corrective action with regard to the identified cases of non-compliance to the Health Inspectorate in writing, and the Health Inspectorate, in its turn, shall verify after the receipt of the report if the detected non-compliances have been corrected. If all the non-compliances mentioned in the decision on suspension of the operation have been corrected, the Health Inspectorate shall issue a written permission for recommencement of the operation after a successful additional inspection.

Supervision of the State Funded Healthcare

The Health Inspectorate shall monitor the availability of the state funded healthcare to the patients, justification of the provided services, and payment for the services in accordance with the applicable requirements and the agreements signed with the medical institutions for the provision of the state-paid healthcare services.

In case it is detected that the reported work does not correspond to the actual situation, the established requirements and the terms and conditions of the agreement, the Health Inspectorate shall require that the medical institution should correct the identified non-compliances, e.g., assure that the working hours of the healthcare professional correspond to the agreement, provide understandable and updated public information to patients, 24/7 availability of diagnostic and laboratory examinations, etc.

In case the violation has caused financial losses in the state budget or to the patient, the Health Inspectorate shall calculate the unjustified payment and decide on return of the amount into the state budget or to the patient.

The Health Inspectorate shall exercise control over the quality of healthcare professional and working ability expert examinations in medical institutions:

- perform expert examinations and issue reports regarding the quality of professional and working ability expert examinations in the medical institution;
- perform expert examinations and issue reports regarding the quality of medical services if the healthcare professional has provided healthcare services outside the medical institution or the quality of treatment in cases when such has been provided by a person without medical education;
- expert examinations shall be performed based on reviews of the applications received from patients, legal entities, law enforcement bodies, non-governmental organisations regarding the quality of healthcare and the quality of working ability in healthcare institutions.

Depending on the identified non-compliances, the Health Inspectorate may issue a warning or decide to impose an administrative pecuniary penalty, impose fine on the healthcare professional or the head of the medical institution, and to request that the Latvian Medical Society should evaluate the compliance of the doctor with the provisions of their certificate. If the Health Inspectorate identifies possible signs of criminal offence, the case materials shall be forwarded to law enforcement bodies.

https://www.vmnvd.gov.lv/en/healthcare-quality-and-safety