

# Establishment and registration of private healthcare institutions



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## **Establishment and registration of private healthcare institutions**

The establishment of private healthcare institutions in the Republic of Srpska is regulated with the Law on Health Protection in the Republic of Srpska, and bylaws – the Rulebook on the conditions for the commencement of health institutions and Rulebook on certification procedure of healthcare institutions and content of the registry of certified health care institutions.

There is a certain type of healthcare institutions, which have to be established in accordance with the Law on Health Protection, i.e. the Law on the amendments to the same, but there are still no special Rulebooks that would more closely regulate the establishment of the same.

The registration of a private healthcare institution, as well as other business entities, shall be implemented with application of the Law on Registration of Business Entities in the Republic of Srpska.

The Law on Health Protection, in principle, regulates issues of ensuring healthcare, then healthcare principles, rights and obligations of citizens and patients, healthcare levels, establishment and termination, bodies of healthcare institutions, work organisation of healthcare institutions, working hours, strike of employees, defining the healthcare worker or associate, certification and accreditation of healthcare institutions, supervision, financing of healthcare institutions, as well as all other issues relevant to the organisation and implementation of health protection.

According to the legal provisions regulating this area in the Republic of Srpska, the health protection shall be realized through the work of healthcare institutions, and the same can be established either as a public or a private institution. However, regardless which healthcare institution is concerned, the public or the private, the same shall be established on equal terms in accordance with the law.

The Law ensures establishment of the following institutions: out-patients clinic for treatment, care and rehabilitation; specialist clinic for family medicine; specialist clinic; dental clinic; medical centre; pharmacy; specialist centre; hospital; special hospital; clinical centre; institute; public health institute; centre for healthcare; laboratory; bank of biological materials and stem cell bank.

The Law makes a clear distinction between a private and a public healthcare institution, and stipulates who can establish a private or public healthcare institution, and differentiate types of healthcare institutions which may be established depending on whether it is a public or private healthcare institution i.e. depending on the fact who is the founder of the same.

Therefore, a public healthcare institution may be established only by the Republic of Srpska and local governments. There is no possibility that an individual may establish a public

healthcare institution. Depending on who is the founder of the public healthcare institution, the same shall be established in the form of hospital; special hospital; clinical centre; institute; institute of public health; stem cell bank and a bank of biological material **if the founder is the Republic of Srpska**, and then in the form of a medical centre, out-patients clinic for treatment, care and rehabilitation; specialist clinic of family medicine; specialist clinic; dental clinic; pharmacy and centre for healthcare **if the founder is a local government unit.**

## 1. ESTABLISHMENT OF A PRIVATE HEALTHCARE INSTITUTION

A private healthcare institution may be established by an individual or by a legal entity. If a legal entity is the founder, i.e. a company establish a healthcare institution, then the same may also provide healthcare services, only if the Ministry of Health and Social Protection with its decision determines that the entity/individual meets the requirements to carry out medical activity. In this connection, a private healthcare institution can be organized in the following forms:

- Out-patients clinic for treatment, care and rehabilitation
- Specialist Clinic of Family Medicine
- Specialist out-patients Clinic
- Dental Clinic
- Pharmacy
- Specialist Clinic
- Hospital
- Specialist hospital
- Centre for Health Care
- Laboratory
- Steam cell bank

*Out-patients clinic for treatment, care and rehabilitation* understands a healthcare institution which promotes health, medical treatments, care and rehabilitation and provides health protection. The same must employ one medical doctor and a nurse - technician. If the founder of a healthcare institution is a legal entity, the same in addition to the doctor and nurse may engage healthcare associates.

*Specialist Clinic of Family Medicine* is a healthcare institution, which provides primary health protection and hires a team for family medicine. The team is consisted of specialists in family medicine and at least two nurses - technicians with additional training for family medicine.

*Specialist Clinics* under the Law on health care represent a health facility that through one or more specialists in one branch of medicine or dentistry performs promotional, preventive, diagnostic, therapeutic, rehabilitative or other activities in the field of medicine or

dentistry, except for hospital treatment. The said Rulebook specifies general and special conditions for the establishment of some forms of specialist clinics. In this regard, it is allowed to establish the following specialized clinics:

- Specialist Clinic of Occupational Medicine
- Specialist Pulmonary Clinic
- Specialist Clinic for classical-conventional X-ray diagnostics
- Specialized clinic for a mammogram
- Specialist Clinic for angiography
- Specialist Clinic for computed tomography
- Specialist Clinic MRI
- Specialist Clinic for ultrasound diagnostics
- Specialist radiology clinic
- Specialist paediatric clinic
- Gynaecological clinic
- Specialist Clinic of General Surgery
- Specialist Clinic of Plastic and Reconstructive Surgery
- Specialist orthopaedic clinic
- Specialist urological clinic
- Specialist otorhinolaryngology clinic
- Specialist Ophthalmic clinic
- Specialized Psychiatric clinic
- Specialist Neurological clinic
- Specialist Psychotherapy clinic
- Specialist Dermatology clinic
- Specialist Infection clinic
- Specialist Clinic of physical medicine and rehabilitation
- Specialist clinic of internal medicine
- Specialist Clinic of Nuclear Medicine
- Specialist Clinic dental disease
- Specialist Clinic for oral diseases
- Specialist Clinic for Oral Surgery
- Specialist Clinic preventive and children's dentistry
- Specialist Clinic dental prosthetics
- Specialist Clinic orthodontics
- Clinic of maxillofacial surgery.

*Dental Clinic* is a healthcare institution that conducts promotion of health, prevention, suppression, early detection and treatment of dental diseases.

*Pharmacy* is a medical institution that supplies citizens with medicines products and medical devices, provides instructions for their proper use and information about medicines and medical devices. Pharmaceutical service is carried out in accordance with the specific laws and regulations governing this activity.

*Specialist Clinic* is a healthcare institution which, through more specialist branches of medicine or dentistry, performs promotional, preventive, diagnostic, therapeutic, rehabilitative or other activities in the field of medicine or dentistry, except for hospital treatment.

*Hospital* is a healthcare institution of the first, second, third or fourth level in the categorization of hospitals which performs the activity of primary, secondary and tertiary prevention of diseases and conditions, diagnosis, treatment, medical rehabilitation and medical care, and provides accommodation and food for patients. The same performs specialist, consultative and hospital treatment of all population and nosology groups. Categorization of hospitals shall be done on the basis of a decision on the categorization issued by the Minister of Health and Social Welfare of the Republic of Srpska and on the basis of special Regulations governing the process of categorization.

*Specialist Hospital* is a healthcare institution that provides health care to persons of certain populations and/or nosology groups, primary, secondary and tertiary prevention of diseases and conditions; diagnostics; treatments; medical rehabilitation; nursing of patients and provides accommodation and food for the patients. Same as hospital, the specialist hospital performs specialist, consultative and hospital treatment of all population and nosology groups and has possibility of organizing supply of drugs and medical products in accordance with special regulations governing the pharmacy industry. Within the specialist hospital are also departments, centres, divisions or other organizational units which are established depending on the needs of hospitals.

*Centre for Health Care* is a healthcare institution that conducts continuous health and palliative care in stationary conditions.

*Laboratory* is a healthcare institution that performs specialized diagnostic services in the field of haematology, biochemistry, immunology, pathohistology and dentistry in accordance with the applicable 180 standards.

*Stem Cell Bank* is a medical institution, which engages in processing, testing, preservation, quarantine, storage and distribution of stem cells, which is regulated by a special law.

#### 1.1. REQUIREMENTS FOR ESTABLISHMENT OF A HEALTHCARE INSTITUTION

When we talk about conditions that must be met to establish a private (or public) healthcare institution, the law emphasizes creation of conditions for providing high quality,

safe, efficient and effective health care, as well as conditions for performance of health services in accordance with the medical doctrine and use of medical technology.

The procedure for establishing a private healthcare institution, if taken formally, could be divided into several steps, including:

- Fulfilment of pre-conditions in terms of space, staff and equipment,
- Obtaining the ruling of the Ministry of Health and Social Welfare of the Republic of Srpska on previously fulfilled conditions,
- Registration of a private healthcare institution with the relevant registration court,
- Registration of a healthcare institution in the Register of health institutions with the Ministry of Health and Social Welfare of the Republic of Srpska,
- The process of certification and accreditation of a private healthcare institution with the Agency for certification, accreditation and quality improvement of healthcare in the Republic of Srpska.

When we talk about pre-conditions that must be met in order to establish a private healthcare institution, these are mainly conditions related to the space, staff and equipment. These conditions are prescribed by the Rulebook on the conditions for the commencement of the healthcare institution.

The Rulebook on the conditions for the commencement of healthcare institutions makes a distinction between general and specific conditions that must be met to apply for determining the fulfilment of pre-conditions.

General terms and conditions are related to technical characteristics of the building in which will be placed the healthcare institution. In this connection, the building structure meets the general requirements for the performance of health services if the same possess the following characteristics and documents:

- ✓ That the facility possess the use permit
- ✓ that the facility is built with a purpose and fully adapted for performing healthcare activities
- ✓ that the facility is built of building materials in accordance with the design and construction standards
- ✓ that there is a separate business area from residential area or other business units if the building structure is intended for a multi-use, but the entrance to the building structure can be shared for both residential and business units
- ✓ that there is a direct communication between the operating rooms
- ✓ that the facility is located in an accessible place, with built access road and parking and an access for unhindered movement of persons with reduced physical abilities and persons with disabilities

- ✓ that there is a copy of the building layout for performing health activities which is properly marked
- ✓ that the area has unique functional and technological unit for performing health activities
- ✓ that the area has resolved the issue of heating source which is in accordance with the technical and environmental standards
- ✓ that the facility is secured with the fire extinguisher or other systems for fire fighting
- ✓ that the facility has rooms for performance of administrative tasks.

In terms of general conditions relating to the interior of the facility it is requested that the same possess the air conditioning system, in the case there is not no central system in the institution (if the healthcare institution is composed of surgery rooms, delivery rooms, rooms for intensive care), as well as reserve devices for electricity production which will be used in case of power failure from the public power grid.

Rooms in a healthcare institution shall be at least 260 cm of height, while there should be the lighting, either from natural or artificial light source. Floors must be made of materials that are easily cleaned and disinfected, and the same must be from anti-static material for some health institutions (institutions that own the surgery room, the room for radiological activities and rooms for intensive care).

Doors, walls and ceilings must be with smooth and flat surfaces, while door openings must not have thresholds. Entire surface of walls (of height 160 cm to 180 cm) of sanitary rooms and laboratories must be coated with paint that allows easy cleaning and disinfection or must be covered with wall tiles. All working and sanitary rooms must be provided with hot and cold water from a sink, unless the entrance to the sanitary rooms is from the same hall then one sink would be enough. Entire surface of the wall starting (of height 160-180 cm) of working areas must also be coated with paint that allows easy cleaning and disinfection or must be covered with wall tiles.

Access to sanitary rooms for patients must be enabled from the waiting room or hallway. Furniture must be suitable for cleaning and disinfecting.

In terms of waste generated during provision of health services, the law obliges each healthcare institution to establish a system of medical waste management in accordance with the legislation governing this area.

In terms of staff there is a general requirement that all healthcare workers and associates must be employed for full-time.

In relation to the special conditions specified in the Rulebook on the conditions for the commencement of healthcare institutions there are also closely specified requirements that every healthcare institution (depending on the form of the establishment) must fulfil. The same

includes the technical requirement related to the construction of the facility, then related to the equipment which the institution must have depending on the level of health protection that provides (primary, secondary or tertiary). In this paper, we will not closer refer to the specific conditions required for each healthcare institution due to the fact that the same are already listed in the aforementioned Rulebook so there is no need to explain it further.

However, still worth of mentioning is that the law restricts private healthcare institutions in the performance of certain medical services. So, private healthcare institutions cannot perform the following medical services:

- Transplantation
- Transfusion medicine
- Forensic
- Social Medicine
- Hygiene
- Epidemiology
- Medical emergency
- Autopsy and determining causes of death
- Forensic psychiatrist
- Cytogenetic, except for sampling
- Microbiology, except sampling.

After meeting all of the above conditions it is necessary to submit an application to determine conditions in terms of premises, staff and equipment for the commencement of the healthcare institution. The same is to be filed with the Ministry of Health and Social Welfare for the purpose of rendering a decision on fulfilment of conditions. After filing a proper application the minister shall appoint the Commission on the basis of whose statements shall be issued a decision on fulfilment of conditions.

## 1.2. REGISTRATION OF A PRIVATE HEALTHCARE INSTITUTION WITH THE REGISTRATION COURT

Obtaining a certificate on fulfilment of conditions for the commencement of the healthcare institution is a condition that needs to be fulfilled prior to the registration of the healthcare institution in the Court Register and the Register of Healthcare Institutions kept by the Ministry of Health and Social Welfare of the Republic of Srpska. The procedure of registration of the healthcare institution has to be implemented in accordance with the provisions of the Law on Registration of Business Entities of the Republic of Srpska. The registration procedure of healthcare institutions is mandatory i.e. a healthcare institution before the commencement of its activity must be registered with the relevant Court Register.

The registration procedure shall be initiated by filing an application of the Agency for Intermediary, IT and financial services (hereinafter: APIF) of the Republic of Srpska. The same shall, with no delay, submit the application to the competent registration court to decide.

When deciding on the submitted application, the registration court examines the application with its formal and material side and pass decision within 2 (two) days from the filing date, of course if the application includes all necessary documents.

If the registration court finds that the application for registration is grounded, the court issues a decision on registration of a business entity and the same grants entry of the business entity in the register. The decision on registration, as well as all other decisions issued by the Court in the registration process, shall be published on the website of APIF, and in the Official Gazette of the Republic of Srpska.

Entry into the register of business entities enables healthcare institution to start performing its activities.

### **1.3 PROCEDURE FOR REGISTRATION OF A HEALTH INSTITUTION IN THE REGISTER OF HEALTH INSTITUTIONS**

After registration of a healthcare institution with the competent court, it is necessary that the Ministry of Health and Social Welfare of the Republic of Srpska submit an application for registration in the Register of Health Institutions. The procedure of registration in the Register of Health Institutions is regulated by the Rulebook on the content and manner of keeping the register of medical institutions.

An application for registration of a healthcare institution (on a prescribed form) must be filed within fifteen (15) days of receiving the decision on the registration, and the same should contain the following:

- Type of healthcare institution
- Name and seat of healthcare institution
- Name and surname of the Director
- Telephone/Fax number, internet address of healthcare institution,
- Number and date of the Decision on fulfilment of all requirements for commencement of work,
- Number and date of the Decision on the registration issued by the competent court,
- Name and surname of employed health workers and associates with university degree or secondary education,
- Working hours of healthcare institution.

Any change in the organization of healthcare institutions shall, within eight (8) days from the date of the change, be reported to the Ministry, for entry in the Register. The Register of Health Institutions shall be kept in electronic form.

## 1.4 PROCEDURE FOR CERTIFICATION OF A PRIVATE HEALTHCARE INSTITUTION

After registering a private healthcare institution with the relevant registration court and obtaining a decision on registration, the healthcare institution shall, within one (1) year from the date of the decision, apply for certification of the healthcare institution.

The application for certification shall be submitted to the Agency for certification, accreditation and quality improvement of health care of the Republic of Srpska (hereinafter: the Agency). Upon receiving the application, the Agency shall deliver the questionnaire to the healthcare institution for the preparation of a plan for the implementation of certification, self-evaluation questionnaire and the list of certification services. On the basis of the information provided, the Agency shall prepare a plan of certification and submit it to the health institution, together with the pricelist of the certification procedure.

If a healthcare institution is certified, the same shall submit the following documents to the Agency:

- Decision on the registration of the healthcare institution with the competent court,
- Rulebook on the internal organisation and systematization of working places,
- Documents regulating procedure of provision of health services
- Proof of payment of a fee for the certification.

Following the submission of the abovementioned documents, the Agency shall appoint an assessor who shall prepare and perform pre-assessment visit in order to inspect the healthcare institution and prepare a pre-assessment report.

Assessment of a healthcare institution shall be performed by assessors who meet the prescribed legal requirements to act as assessors. The Agency selects the members of the team of assessors, while a healthcare institution has the right to file a complaint (objection) to the composition of the team of assessors and it is on the Agency Director to make the final decision following the complaint.

After completing the assessment process the team of assessors shall define findings and team leader shall prepare the report. In the report the team may propose:

- to award certification
- to postpone the award of certification with recommendations related to corrective measures to be taken and determine the deadline for implementation of the same, or
- refuse certification

The final decision shall be passed by the Minister of Health and Social Welfare of the Republic of Srpska, who on the basis of the report on the procedure of certification with a recommendation on certification and the explanation submitted by the Director of the Agency, shall confirm the certification of the healthcare institution, if the same:

- meet the requirements of standards for certification,
- meet the criteria and rules prescribed by the Agency,
- pay the fee for certification.

After the certification of the healthcare institution the same is obliged to inform its customers and the public about the certification, and to seek professional opinion of the Agency, if necessary.

The Agency conducts periodic monitoring of healthcare institutions in accordance with the annual plan adopted by the Management Board of the Agency, in order to determine the manner in which institutions hold their status of certification standards. Healthcare institutions are obliged to inform the Agency of the following:

- Change in organizations,
- Change in activities,
- Change of the location, work area and / or spatial capacity,
- Change of the structure of necessary staff, and
- Change in the processes that affect the security of the services that are defined in the scope of certification.

The assessment of healthcare institutions in the process of certification shall be performed according to the applicable certification standards, which are consisted of sets of criteria and which are assessed through indicators that allow an accurate assessment of meeting the criteria. In the assessment procedure also includes:

- Interview with healthcare workers and associates,
- Review of selected medical documents and documentation of the healthcare institution, and
- Tour of the institution and inspection of medical equipment, as well as insight in the way of development of the work process.

After the certification of the healthcare institution the same shall be entered in the Registry of certified healthcare institutions, which is to be updated on monthly basis, depending on changes in the status of certified healthcare institutions.

## **CONCLUSION**

Nowadays in the Republic of Srpska exists and works 297 of public and private healthcare institutions. The procedure of establishing a private healthcare institution in the Republic of Srpska is complex and requires fulfilment of large number of pre-conditions. The

fact that the health system in the Republic of Srpska is a sector with quite high degree of state regulation it further complicates the process of fulfilling the conditions for the commencement of performance of health activities.

Every healthcare institution should strive for continuous improvement in the provision of health care quality in line with the development trends of this sector in the countries of Europe and America. In this sense, there is a need to improve the health care quality as well as introduction of quality systems in health care i.e. the development of private health sector.

The private health sector in many countries has reached such a level that its existence and quality of health services provided is without prejudice. However, the establishment of such sector requires continuous professional training and development, good organization of the management of healthcare institutions which will be aware of the local needs, then the legislation and regulations in this field and familiarity with the area of the financial system.

On the other hand, it is necessary to ensure satisfaction of patients, which should be the main motive and goal of healthcare institutions. If healthcare institutions, or managers of the same, manage to harmonize all this then good results and successful operation could be expected.

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