## **HEALTHCARE ACT**

(Consolidated version, Official Gazette 150/08, 71/10, 139/10, 22/11, 84/11, 154/11, 12/12, 35/12 - OUSRH, 70/12, 144/12, 82/13, 159/13, 22/14 - O and RUSRH, 154/14 and **70/16**)

## I GENERAL PROVISIONS

#### Article 1

This Act regulates the healthcare principles and measures, the rights and obligations of healthcare beneficiaries, the authorities competent for public healthcare, the content and organisational forms of the provision of healthcare and the supervision of its provision.

The provisions of this Act and the ensuing subordinate legislation shall also apply to healthcare provided in the Ministry of Defence and the Armed Forces of the Republic of Croatia and in the Ministry of Justice, unless provided otherwise by a separate law.

Definitions used in this Act and the ensuing regulations, which are gender-specific, regardless of whether they are used in masculine or feminine gender shall include equally both masculine and feminine gender.

# Article 1.a

This Act transposes the following directives into the legal system of the Republic of Croatia: – Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (OJ L 255, 4.4.2008), – Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011), – Council Directive 2010/32/EU of 10 May 2010 implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU (SL L 134, 1.6.2010).

#### II HEALTHCARE

#### Article 2

For the purposes of this Act, healthcare shall include a system of social, group and individual measures, services and activities for health maintenance and improvement, disease prevention, early disease detection, timely treatment and medical care and rehabilitation.

## Article 3

Everyone shall be entitled to healthcare and to the possibility of the achievement of optimal health level in accordance with the provisions of this Act and the Mandatory Health Insurance Act.

Everyone shall take care of their health.

No one shall endanger the health of others.

Everyone shall provide first aid in emergencies to an injured or ill person and enable such a person an access to emergency medical assistance.

#### PUBLIC HEALTHCARE

## Article 4

The Republic of Croatia shall adopt economic and social policies to create conditions for the implementation of healthcare, and conditions for the protection, maintenance and improvement of the population's health and co-ordinate activities and development in all healthcare areas in order to provide healthcare to the population.

In accordance with the established rules and obligations, local and regional self-government units shall ensure conditions for the protection, maintenance and improvement of the population's health, and organise and ensure the provision of healthcare in their areas of responsibility.

#### Article 5

The Republic of Croatia shall exercise its rights, obligations, duties and objectives in the field of healthcare by:

- planning healthcare and determining the healthcare development strategy,
- ensuring the legislative basis for the achievement of healthcare objectives,
- encouraging the development of healthy lifestyles through tax and economic policies,
- ensuring conditions for raising the health awareness of the population,
- ensuring the development of a health-information system in the Republic of Croatia,
- ensuring the development of the system of telemedicine in the Republic of Croatia,
- ensuring the development of scientific research in the field of healthcare,
- ensuring conditions for the education of healthcare professionals.

The Republic of Croatia shall also provide public healthcare to its inhabitants through healthcare measures against harmful environmental factors, which ensure to the population healthy foodstuffs and drinking water, water for recreation and other waters, general use items, protection against noise, air quality, and measures for safe waste disposal, health protective measures against the harmful effect of chemicals and for protection against the sources of ionising and non-ionising radiation.

The measures referred to in paragraph 2 of this Article shall be implemented in accordance with the programme of health protection measures against harmful environmental factors, which is passed by the minister competent for health (hereinafter: the Minister) at the proposal of the Croatian National Institute of Public Health and subject to prior approval by the minister competent for environmental protection.

The conditions, organisation and the modes of conducting telemedicine shall be laid down by the Minister in an ordinance.

#### Article 6

Subject to prior opinion of the Croatian National Institute of Public Health and the competent chambers and on the basis of an analysis of the population's health status and requirements, the Minister shall pass the healthcare plan of the Republic of Croatia (hereinafter: the Healthcare Plan) ensuring a purposeful division of labour and taking into consideration the availability of funds and human and other resources.

#### Article 7

The Healthcare Plan shall include:

- duties and objectives of healthcare,
- priority development areas,
- health requirements of the population of special interest for the Republic of Croatia,
- specific needs and possibilities for the provision of healthcare in specific areas,
- implementing bodies and deadlines for achieving the Healthcare Plan,
- bases for the development of healthcare by level, including the education and training of human resources, and the bases for the development of the healthcare system,
- criteria for determining the network of the public health service, taking into account the availability of healthcare by area.

# Article 8

From the state budget, the Republic of Croatia shall allocate funds for the following:

- programming, adjustment, implementation and monitoring of public awareness and education of the population about health, and promotion of health in accordance with the Healthcare Plan,
- research and monitoring of health of the population,
- implementation of the programme for the improvement of the health of all citizens,

- epidemiological monitoring, prevention and elimination of infectious diseases and chronic mass diseases, including alcoholism, smoking, drug addiction and other addictions,
- urgent medical assistance on state roads,
- healthcare statistical and other social and healthcare activities important for the Republic as a whole,
- financing of scientific research in the field of healthcare,
- blood drives and the transplantation of organs, tissue and cells,
- emergency healthcare to persons with permanent residence in the Republic of Croatia who do not have health insurance and who do not have means to pay the costs of healthcare,
- implementation of health ecology measures of interest to the Republic of Croatia, in accordance with the programme of measures referred to in Article 5, paragraph 3 of this Act,
- ensuring and monitoring the implementation, protection and promotion of the rights of patients,
- other tasks within its competence laid down in this Act and the Mandatory Health Insurance Act,
- healthcare costs in line with special regulations.

The Republic of Croatia shall ensure funds for capital investments and investment and current maintenance of healthcare institutions – facilities, medical and non-medical equipment and means of transport, and the computerisation of healthcare, in accordance with the plan and programme of healthcare measures in the public health network for healthcare institutions founded by the Republic of Croatia and for the coverage of losses of healthcare institutions founded by the Republic of Croatia.

By way of derogation from the provision of paragraph 2 of this Article, the Republic of Croatia shall ensure funds for investments in hospitals and investments in all healthcare institutions founded by counties and towns, which are located in the areas of special state concern.

The Republic of Croatia shall also ensure funds for capital investments in healthcare institutions founded by counties and towns if it is necessary to remedy the consequences of natural disasters or other catastrophes.

#### Article 9

A unit of regional self-government shall exercise its rights, obligations, duties and objectives in the field of healthcare by:

- ensuring the replenishment of the network of the public health service in its area of responsibility,

- organising the work of the institutions that it has founded,
- coordinating the work of all legal and natural persons performing the healthcare activity in the territory of the unit of regional self-government,
- in line with the network of the public health service or the network of occupational medicine contractors, granting concessions for the performance of the healthcare activity in its area of responsibility,
- in accordance with the Healthcare Plan of the Republic of Croatia, adopting the healthcare plan for the area of responsibility of the unit of regional self-government,
- for the area of responsibility of the unit of regional self-government, adopting annual and tri-annual plans for the promotion of health, prevention and early detection of diseases,
- organising and implementing public health measures in accordance with the plans referred to in sub-paragraphs 5 and 6 of this paragraph,
- organising the implementation of integrated public procurement procedures for the healthcare institutions founded by the unit of regional self-government,
- in cooperation with the ministry competent for health (hereinafter: the Ministry) and the Croatian Health Insurance Institute (hereinafter: the Institute), ensuring the implementation of specific measures and the providing of healthcare on the islands and in scarcely populated and underdeveloped areas.

In the implementation of its rights, obligations, duties and objectives in the field of healthcare, the unit of regional self-government shall ensure funds for:

- the implementation of public health, epidemiological and environmental-health activities and the prevention of diseases in its area of responsibility,
- the implementation of measures of health ecology, specifically: the testing of foodstuffs and general use items, testing of drinking water, testing of the harmful influence of air pollution on human health, testing of noise and testing of soil pollution and waters intended for swimming and recreation, of interest to the unit of regional self-government, in accordance with the programme of measures referred to in Article 5, paragraph 3 of this Act,
- emergency medical assistance in its area of responsibility, unless provided by the Republic of Croatia,
- the organisation and operation of the coroner's office.

Counties and towns shall ensure funds for capital investments and for investment and current maintenance of healthcare institutions – facilities, medical and non-medical equipment and means of transport, and for the computerisation of healthcare, in accordance with the plan and programme of healthcare measures and the network of public health service, and for the coverage of the losses of healthcare institutions founded by such counties and towns.

Once a year, the Government of the Republic of Croatia shall issue a decision on criteria for ensuring the level of capital investments and investments and current maintenance and the computerisation of healthcare referred to in paragraph 3 of this Article, which is to be the basis for planning support from the state budget.

A unit of regional self-government and a unit of local self-government may ensure funds for the provision of healthcare to citizens in their area above the standards provided for by mandatory health insurance.

The organisation and financing of the implementation of healthcare measures in the event of an increased number of healthcare beneficiaries during the tourist season shall be regulated by means of a contract between the unit of regional self-government or the unit of local self-government, tourist board and healthcare institution, a company providing healthcare services or a private practice healthcare professional.

The organisation and financing of healthcare services provided to tourists shall be regulated by means of a contract between a legal or natural person engaged in the tourist activity and a healthcare institution, a company providing healthcare activities or a private practice healthcare professional.

## Article 10

With a view to realising the rights, obligations, duties and objectives in the field of healthcare in its area of responsibility, the unit of regional self-government shall establish the Health Counselling Service.

The number of members of the Health Counselling Service shall be regulated in the statute of the unit of regional self-government.

The Health Counselling Service shall ensure the participation of the representatives of local self-government, health chambers, professional associations, associations for the protection of the rights of patients and health trade unions and employers in the planning and evaluation of healthcare in the area of the unit of regional self-government.

With a view to realising the duties referred to in paragraph 3 of this Article, the Health Counselling Service shall issue an opinion on the proposal of the healthcare plan for the area of the unit of regional self-government and propose measures for ensuring the availability and quality of healthcare in the unit of regional self-government.

## HEALTHCARE PRINCIPLES

# Article 11

Healthcare of the population of the Republic of Croatia shall be provided on the basis of principles of comprehensiveness, continuity, availability and an integral approach in primary healthcare, and a specialised approach in specialist-consultation and hospital healthcare.

#### Article 12

The comprehensiveness of healthcare includes the entire population of the Republic of Croatia in the implementation of adequate healthcare measures in accordance with law.

#### Article 13

The continuity of healthcare is achieved by the overall organisation of healthcare, particularly at the level of primary healthcare, which provides continuous healthcare to the population of all ages. In ensuring continuity, the healthcare system in the Republic of Croatia must be mutually and functionally connected and co-ordinated.

## Article 14

The availability of healthcare shall be ensured through such a distribution of healthcare institutions, companies engaged in the provision of healthcare and healthcare professionals in the territory of the Republic of Croatia that will ensure the provision of healthcare services to the population under equal conditions, in particular at the primary healthcare level.

The availability of healthcare in the area of the unit of regional self-government shall be ensured through the provision of healthcare in the institutions founded by such a unit, the award of concessions for the provision of public health services, the coordination of their work and participation in ensuring the funds for the performance of healthcare in its area.

## Article 15

The integrated approach principle in primary healthcare is ensured through the implementation of uniform measures aimed at improving health and preventing diseases, and treatment and rehabilitation.

## Article 16

The specialised approach principle shall be ensured through the organisation and development of specialised clinical and public health achievements and knowledge, and through their practical application.

#### HEALTHCARE MEASURES

#### Article 17

Healthcare measures shall include the following:

- 1. protection against environmental factors adversely affecting health, including all measures aimed at preserving, upgrading, monitoring and improving health and hygienic conditions for the life and work.
- 2. health education, training and promotion with the aim of improving the mental and physical abilities.

- 3. detecting and removing the causes of diseases, that is, the prevention and elimination of diseases and injuries and their consequences,
- 4. measures and activities for the prevention, timely detection and elimination of infectious and chronic mass diseases,
- 5. healthcare measures related to the work and the working environment (specific healthcare of workers),
- 6. treatment and rehabilitation of the sick, physically and mentally impaired and injured persons, and persons with disabilities,
- 7. special healthcare measures for the population older than 65 years of age,
- 8. palliative care for the terminally ill or dying,
- 9. ensuring overall (preventive, curative and rehabilitative) healthcare for children and young people,
- 10. ensuring the overall healthcare for the protection of women, especially relating to family planning, pregnancy, birth and maternity,
- 11. supply with medicinal products and medical devices for healthcare,
- 12. post-mortem examinations.

## Article 18

Healthcare measures shall be performed on the basis of the plan and programme of healthcare measures, which are adopted at the proposal of state health institutes by the Minister, subject to prior opinion of the competent chambers.

The way of ensuring a medically acceptable time for the implementation of healthcare measures shall be laid down by the Minister in an ordinance.

## Article 19

Healthcare measures regarding work and the working environment (specific healthcare of workers) which must be ensured by the employer shall be as follows:

- 1. measures aimed at preventing and detecting occupational diseases, preventing injuries at work and providing appropriate first aid,
- 2. measures aimed at protecting the health of workers exposed to special health hazards at work,
- 3. healthcare measures prescribed by special regulations,

4. measures taken to prevent injuries from sharps for healthcare professionals who directly provide healthcare as part of their profession and for non-healthcare professionals who may get injured by sharps.

The method for their implementation and the measures taken to prevent the injuries from sharps from paragraph 1, item 4 hereof shall be laid down by the Minister in an ordinance.

#### Article 20

Specific healthcare of workers shall include:

- 1. medical examinations and diagnostic procedures aimed at determining their working capacity,
- 2. monitoring the health status of workers,
- 3. check-up examinations of workers in view of their gender, age and working conditions, as well as in view of an outbreak of occupational diseases and injuries at work,
- 4. counselling on health, safety, work organisation and personal protective equipment,
- 5. organisation and provision of first aid and emergency medical interventions at the work place,
- 6. monitoring and analysis of morbidity related to work-related injuries and occupational diseases.
- 7. ongoing care to adapt working conditions to better suit workers, including working hours, manner and conditions of work.
- 8. co-operation in information-sharing, professional training and education in the field of occupational safety and health and organisation of work,
- 9. assessment of working conditions at workplace to protect workers against injuries at work and occupational diseases,
- 10. promotion of health and healthcare education of workers,
- 11. participation in occupational rehabilitation measures,
- 12. performance of diagnostic procedures to identify occupational diseases.

The content of measures of specific healthcare of workers and the method of implementing them shall be laid down by the Minister in an ordinance at the proposal of the Croatian Institute for Health Protection and Safety at Work, subject to prior approval by the minister competent for labour.

The measures of specific healthcare of police officials of the Ministry of the Interior and the members of the Ministry of Defence and the Armed Forces of the Republic of Croatia shall be

laid down by the minister competent for the interior and the minister competent for defence, respectively, in an ordinance, subject to prior approval by the Minister.

#### Article 21

Workers exercise their right to specific healthcare in accordance with the Mandatory Health Insurance Act.

# RIGHTS AND DUTIES OF PERSONS IN EXERCISING THEIR RIGHT TO HEALTHCARE

## Article 22

In the exercise of the right to healthcare in accordance with the provisions of this Act and the regulations pertaining to mandatory health insurance, every person has the right to:

- 1. equal treatment in the exercise of the right to healthcare.
- 2. free selection of the doctor of medicine or doctor of dental medicine,
- 3. health service of a standardised quality and the same content,
- 4. first aid and emergency medical assistance whenever necessary,
- 5. refuse treatment by students and to refuse all other interventions that would be performed independently by healthcare professionals before having passed the state examination and obtained the licence for independent work,
- 6. refuse examination and treatment, except in the case where this would jeopardise the health of others, including the right to request another doctor of medicine or doctor of dental medicine in writing during treatment, the reasons for which do not have to be elaborated extensively,
- 7. diet in accordance with one's beliefs during the stay in the healthcare institution,
- 8. performance of religious rites during the stay in the healthcare institution in an area anticipated for such purposes,
- 9. the right to death care in the morgue in the case of death, in compliance with religious or other customs connected to the expression of dignity towards the deceased person.

In the exercise of the right to healthcare, every person shall also exercise their rights under the legislation on the protection of the rights of patients.

#### Article 23

Every person shall exercise their right to healthcare in accordance with the provisions of this Act and the instructions on treatment provided by the doctor of medicine and doctor of dental

medicine and he or she shall be personally responsible in the case of failure to abide by the instructions.

Every person with legal capacity shall also be obligated to take actions to maintain and improve their health and to avoid any risk factors that might jeopardise their life and health (such as the use of narcotics, alcohol, tobacco products, risky sexual behaviour and other medically recognised risk factors).

In the exercise of his or her right to healthcare, every person shall be obligated to abide by the house rules of the healthcare institution, company performing healthcare activities or private practice healthcare professionals.

Every person shall be entitled to request, either directly or in writing, from the head of the healthcare institution, management board or persons authorised to operate the business of the company performing healthcare activities or a private practice healthcare professional, the protection of his rights in view of quality, content and type of healthcare service being provided.

The head of the healthcare institution, management board or persons authorised to operate the business of the company performing healthcare activities or the private practice healthcare professional shall react without any delay to the objection and inform the person in writing about measures taken at the latest within eight days.

If the person is not satisfied with the measures taken, he/she may request the protection of his/her rights from the Minister, the competent chamber or the competent court.

# III THE HEALTHCARE ACTIVITY

#### Article 24

The healthcare activity is an activity of interest for the Republic of Croatia performed as a public service by healthcare professionals in providing healthcare in accordance with the professional medical doctrine and with the use of medical technology, according to the requirements and in the manner prescribed by this Act.

By way of derogation from paragraph 1 of this Article, the healthcare activity in the field of the promotion of health, prevention of diseases and protection of mental health may be performed by persons who are not healthcare professionals according to the requirements and in the manner laid down by the Minister in an ordinance, subject to prveviosly obtained opinion of the competent chambers.

THE LEVELS OF THE HEALTHCARE ACTIVITY

Article 25

Healthcare activity shall be provided at primary, secondary and tertiary levels and at the level of healthcare institutes.

## Article 26

Healthcare at the primary level shall include:

- monitoring the health of the population and proposing measures for protecting and improving the health of the population,
- preventing and detecting diseases, as well as treatment and rehabilitation of patients,
- specific preventive healthcare for children and young people, especially in primary and secondary schools and universities in its area,
- healthcare for persons over the age of 65,
- healthcare for women,
- healthcare for persons with disabilities,
- preventive healthcare for risk-exposed groups and other inhabitants in accordance with preventive healthcare programmes and the organisation of mandatory preventive check-up examinations.
- advice, healthcare education and promotion of health with the aim of its maintenance and improvement,
- hygienic-epidemiological protection,
- preventing, detecting and treating diseases of the teeth and mouth with rehabilitation,
- medical rehabilitation of children and young people with disorders in physical and mental development,
- house calls, medical care and assistance in the home,
- occupational medicine,
- emergency medical assistance,
- palliative care,
- protection of mental health,
- supply with and the manufacture of medicinal products and supply with medical devices,
- medical transport,
- telemedicine.

Healthcare at the primary level shall be provided through the following activities:

- general/family medicine,
- healthcare of pre-school children,
- preventive-educational measures for the healthcare of school children and students,
- public health,
- healthcare of women,
- dental healthcare,
- hygienic-epidemiological healthcare,
- occupational medicine,
- protection of mental health, prevention and outpatient treatment of addiction,
- house calls,
- medical care in the patient's home,
- emergency medical assistance,
- medical transport,
- palliative care,
- pharmacy,
- laboratory diagnostics
- telemedicine.

## Article 27

The healthcare activity at the primary level shall be conducted and organised as teamwork, including at least one healthcare professional holding a degree in healthcare-oriented undergraduate and graduate university studies or integrated undergraduate and graduate university studies and a healthcare professional holding a bachelor's degree or a healthcare professional with secondary school qualifications.

At the primary level, healthcare activities are performed by doctors of medicine, specialists in family medicine, paediatricians, gynaecologists, specialists in occupational medicine, specialists in occupational medicine and sports and specialists in school medicine in a team with a nurse, specialists in emergency medicine in a team with at least one nurse, nurse with additional specialised training in emergency medicine in a team with at least one nurse, doctors of dental medicine in a team work with a dental assistant or nurse, specialists in

epidemiology, health ecology and public health, specialists in medical biochemistry or persons holding a graduate degree in medical biochemistry in a team with a person holding a degree in university undergraduate or professional studies in laboratory diagnostics or a laboratory technician, pharmacists in a team with a pharmaceutical assistant, midwives in a team with a midwife-assistant and house-call nurses, while the activities of protecting mental health and prevention and outpatient treatment of addictions shall be performed by specialists in psychiatry.

Psychologists, speech therapists, social workers, and other experts in specific fields of healthcare shall participate in the performance of individual measures of healthcare at the primary level, and especially in the healthcare of workers, pre-school and schoolchildren, persons over the age of 65 and in the protection of mental health.

Healthcare professionals at the primary level shall co-operate as a team with healthcare professionals specialised in other fields in providing specialist-consultation and hospital healthcare.

## Article 28

Healthcare at the secondary level includes specialist-consultation and hospital healthcare.

By way of derogation from Article 26, paragraph 2, subparagraph 14 of this Act, palliative care can be also performed on a secondary level.

## Article 29

The specialist-consultation activity in comparison to healthcare at the primary level includes more complex measures and procedures regarding prevention, diagnostics and treatment of diseases and injuries, outpatient rehabilitation and medical rehabilitation in the home of the beneficiary or wards in social welfare institutions.

The specialist-consultation activity must have laboratory and other diagnostic activity ensured for its needs.

# Article 30

Hospital activity shall include diagnostics, treatment and medical rehabilitation, medical care and the stay and nutrition of patients in hospitals.

## Article 31

The healthcare activity at the tertiary level in addition to the performance of the healthcare activities referred to in Article 28 of this Act shall cover the provision of the most complex forms of specialist-consultation and hospital activities, scientific research and the teaching of classes contracted out for the needs of medical teaching establishments.

The classes referred to in paragraph 1 of this Article may be performed at both primary and secondary levels of healthcare activity, as well as at the level of healthcare institutes.

#### Article 32

The healthcare activity at the tertiary level shall include the activity of clinics, clinical hospitals and clinical hospital centres.

#### Article 33

The activity of healthcare institutes shall be a part of the healthcare activity performed at the primary, secondary and tertiary healthcare levels, and shall include public healthcare, transfusion medicine, occupational medicine, mental health protection, toxicology and antidoping, emergency medicine and telemedicine.

The healthcare activity at the level of state healthcare institutes shall include public healthcare, transfusion medicine, occupational medicine, mental health protection, toxicology and antidoping, emergency medicine and telemedicine.

The healthcare activity at the level of healthcare institutes of the units of regional self-government shall include public healthcare and emergency medicine.

In accordance with the decision of the founder of the institute of emergency medicine of units of (regional) local self-government, the healthcare activities on the level of these healthcare institutions may also cover medical transport.

## Article 34

Pharmaceutical activity shall be a part of the healthcare activity performed at the primary, secondary and tertiary level of healthcare, and it shall include the supply of the population with medicinal products and medical devices in accordance with a separate law.

Pharmaceutical activity shall be performed only within the framework of the public healthcare service network.

By way of derogation from the provision of paragraph 2 of this Article, a part of the pharmaceutical activity relating to galenic laboratories and laboratories for quality control of galenic compounds and identification of therapeutic substances is outside the public healthcare service network.

## Article 34.a

Telemedicine activities are carried out via the network of telemedicine centres.

The network of telemedicine centres shall determine the necessary number of healthcare institutions, companies engaged in the provision of healthcare and private practice healthcare professionals with a licence for work of the telemedicine centre issued by the Croatian Institute of Telemedicine.

The conditions for the issuance of the licence for work of the telemedicine centre from paragraph 2 of this Article shall be prescribed by the Minister in an ordinance.

The network of telemedicine centres shall be set up by the Minister at the proposal of the Croatian Institute of Telemedicine.

The network of telemedicine centres shall consist of the basic network of telemedicine centres and the expanded network of telemedicine centres.

# IV THE CONTENT AND ORGANISATIONAL FORMS OF THE HEALTHCARE ACTIVITY

## Article 35

Healthcare shall be performed by healthcare institutions, companies and private practice healthcare professionals under the conditions and in the manner prescribed by this Act, the Act on Mandatory Health Insurance, the Institutions Act, the Companies Act and the Concessions Act.

By way of derogation from the provision of paragraph 1 of this Article, healthcare may be performed by other legal and natural persons in accordance with a separate law.

Healthcare shall also be performed by the organisational units of the Ministry of Defence and the Armed Forces of the Republic of Croatia and of the Ministry of Justice in accordance with special regulations.

## Article 36

The healthcare activity as a public service shall be performed within the framework of the public healthcare service network and outside the public healthcare service network.

The criteria for determining the public healthcare service network shall be laid down in the healthcare plan, taking into account the following:

- health status, number, age and social structure of the population,
- equal conditions or availability of healthcare services,
- the necessary scope of an individual activity referred to in Article 25 of this Act,
- the degree of urbanisation of the area, transport connections, specific population density and availability on demographically endangered areas, especially the islands,
- impact of the environment on the health of the population, and
- economic capabilities.

## Article 37

The public healthcare service network shall set out the required number of healthcare institutions and private practice healthcare professionals with which the Institute is to

conclude a contract on healthcare services for the area of the Republic of Croatia or the unit of regional self-government.

The public healthcare service network, subject to prior opinion of the Institute, the Croatian National Institute of Public Health, the competent chambers and the representative authorities of the units of regional self-government, shall be established by the Minister.

If a body referred to in paragraph 2 of this Article fails to deliver an opinion on the public healthcare service network to the Minister within 30 days of the date of the request, it shall be considered as having given a positive opinion .

#### Article 38

The network of contractual subjects of occupational medicine shall set out the required number of healthcare institutions and private practice specialists in occupational medicine which the Institute is to conclude a contract on healthcare services.

The network of contractual subjects of occupational medicine shall be established by the Minister, Insurance, subject to prior approval by the Croatian Institute for Occupational Health and Safety and the competent chambers.

If a body from paragraph 2 of this Article fails to submit the opinion on the network of occupational medicine contractors to the Minister within 30 days days of the date of the request, it shall be considered as having given a positive opinion.

#### Article 39

Public healthcare service must be organised in a way to ensure that emergency medical assistance is always ensured and available to the population of the Republic of Croatia.

# V CONCESSIONS FOR PERFORMING THE PUBLIC HEALTHCARE SERVICE

### Article 40

The public healthcare service at the primary level of the healthcare activity may be performed under a concession by natural persons and healthcare institutions, other than institutions founded by the Republic of Croatia, counties or the city of Zagreb, if they satisfy the requirements laid down in this Act.

Concessions may serve as grounds for performing the healthcare activity of family (general) medicine, dental healthcare, the healthcare of pre-school children, the healthcare of women, laboratory diagnostics, occupational medicine and medical care in the home of the patient.

Private healthcare professionals must satisfy the requirement referred to in Article 145, paragraph 1, item 6 of this Act at the beginning of using the concession.

## Article 41

Where the tenderer is a natural person, tender documents in the procedure of concession award shall include, along with the documents laid down in the Concessions Act, the approval issued to the healthcare professional to work independently, proof of disposing with premises, and the employment contract or declaration concerning work in the team of a member/members of the team legalised by a notary public, and where the applicant is a healthcare institution, the decision on entry in the court register and the decision on commencement of work issued by the Minister.

The documentation from paragraph 1 of this Article shall be approved by the Minister.

Concessions for the performance of the public healthcare service in the public healthcare service network shall be granted by the county prefect or mayor at the proposal of the head of the administrative office competent for health, subject to prior approval by the Minister.

A county prefect, or the mayor of the City of Zagreb, shall publish a notification on the intention to grant concessions in a number determined by the public health services network or by the network of occupational medicine contractors, reduced by the number of primary healthcare teams for which the health centre has concluded an agreement on the provision of healthcare with the Institute.

By way of derogation from paragraph 4 of this Article and following the notification submitted by the workers of the health centres – i.e. holders of primary healthcare teams of the health centre - to the county prefect, or to the mayor of the City of Zagreb, on the intention to place an offer for the provision of healthcare services on the basis of the concession, the county prefect, or the mayor of the City of Zagreb, subject to prior approval by the management board of the health centre, shall publish the notification on the intention to grant concessions for a number of concessions stipulated by paragraph 4 of this Article, augmented by the number of primary healthcare teams for whom the approval of the management board of the health centre has been procured.

In the case of the written statements of the Institute's contractors from Article 43.a of this Act submitted to the county prefect, or to the mayor of the City of Zagreb, stating that they will not place an offer for the provision of healthcare services on the basis of concession, the number of concessions for which a notification on the intention to grant concessions stipulated in accordance with paragraphs 4 and 5 of this Article is given shall be diminished by the number which corresponds to that of the Institute's contractors who gave those statements.

In granting the concession referred to in paragraph 3 of this Article, the current status of the tenderer as an Institute's contractor shall have priority over all other selection criteria.

In granting the concession that follows the concession referred to in paragraph 3 of this Article, the current status of the concessionaire in accordance with this Act shall have priority over all other selection criteria.

The highest amount of the concession fee shall be laid down by the Minister.

If the premises for performing the activity are leased to the concessionaire by the health centre, the rent is paid by the concession grantor.

The concession award procedure that is not regulated by this Act shall be governed by the provisions of the Concessions Act.

## Article 41.a

By way of derogation from the provision of Article 41, paragraph 3 of this Act, the concession for occupational medicine activities in accordance with the network of occupational medicine contractors and at the proposal of the head of the administrative body office competent for health shall be granted by the county prefect or the mayor, subject to prior approval by the Minister.

## Article 42

In the concession contract, the concession grantor and the concessionaire regulate their mutual rights and obligations connected with the granting of the concession.

The concession contract concluded with a natural person must include the following information:

- provision on the type of healthcare activity to be performed on the basis of the concession,
- provision on the scope of performance of the public service,
- provision on the commencement of the concession,
- provision on the granting of the concession for a ten-year term,
- provision on the concession fee,
- information on the person or persons with whom the concessionaire will work in a team laid down by the standard of mandatory health insurance,
- provision on the premises and equipment in which the healthcare activity will be performed,
- provision concerning the obligation of the concessionaire to continue his employment with the healthcare professional with whom he worked until the commencement of the concession,
- provision concerning the obligation of the concessionaire stating that at the time of setting the salary of the healthcare professional in his team he/she is to align the salary calculation with the provisions of the collective agreement for the activity of health and health insurance,

- provision on the obligation of the concessionare to procure the concession grantor approval in the event of change of the premises for performance of the activities under concession,
- provision concerning the obligation of the concessionaire to notify the concession grantor of any changes relating to the content of the concession contract.

Concession contracts concluded with a healthcare institution shall include the provisions referred to in paragraph 2 of this Article, except for the provisions referred to in subparagraphs 6 and 8 of the same paragraph.

Issues included in the concession contract which are not regulated in this Act shall be governed by the provisions of the Concessions Act.

#### Article 43

If it is established that a concessionaire does not provide the public healthcare service in accordance with the regulations, the decision granting the concession or the concession contract, the concession grantor shall set a term to remedy the defects.

If the concessionaire fails to remedy the defects within the fixed term, the concession shall be repealed.

If the concession is repealed, the concession grantor must ensure that the patients are accepted for care under the same conditions by a healthcare institution or a private practice healthcare professional providing the public service.

## Article 43.a

Healthcare professionals who were granted the Minister's authorisation for work in the leased units of health centres on the basis of the Ordinance on the conditions for leasing primary healthcare institutions and health resorts (Official Gazette 6/96, 29/97, 1/98, 45/99, 121/99, 112/00, 87/02, 150/02 and 7/03) and the Ordinance on the conditions and procedure for leasing parts of health centres and pharmaceutical healthcare institutions (Official Gazette 80/07), and who fail to place an offer following the published notification on the intention to grant concessions shall be given priority in the process of recruitment in health centres following the expiry of the deadline for the submission of offers if they satisfy the requirements given in the vacancy announcement.

The health centre shall open the vacancy announcement from paragraph 1 of this Article within 30 days of the expiry of the deadline for the placement of offers for healthcare services on the basis of the concession.

#### Article 43.b

The Minister shall issue the ordinance on the conditions and the procedure for authorising the healthcare professional to continue to work in a private practice in the event of termination of the concession.

VI ESTABLISHMENT AND ORGANISATION OF HEALTHCARE INSTITUTIONS

#### Article 44

The national health institute, a clinic as an independent institution, a clinical hospital and a clinical hospital centre may be founded by the Republic of Croatia.

A general hospital may be founded by a unit of regional self-government.

A special hospital may be founded by a unit of regional self-government, town and other legal persons.

A health centre, an institution for emergency medical assistance and a public health institute may be founded by a unit of regional self-government.

A polyclinic, a medical resort, an institution for medical care, an institution for palliative care and a pharmaceutical institution may be founded by a unit of regional self-government and other legal and natural persons.

An institution for healthcare may be founded by natural persons holding a university graduate degree in healthcare.

## Article 45

A healthcare institution founded by a legal person and a healthcare institution founded by a natural person may not perform the activities of state healthcare institutes.

A healthcare institution founded by a legal person, except for a unit of regional self-government, and a healthcare institution founded by a natural person may not perform the comprehensive activity of healthcare institutes and health centres.

#### Article 46

The founder of a healthcare institution shall pass the deed of incorporation, which shall in particular include:

- the company name or name, and the seat or permanent residence of the founder,
- the name and the seat of the healthcare institution,
- the activity of the healthcare institution,
- the conditions and the manner of securing the premises and equipment,
- provisions on the funds required to establish and commence operation and the manner of procuring or ensuring such funds,
- the rights and obligations of the founder with respect to the performance of activities for which the healthcare institution is established,
- the bodies of the healthcare institution and provisions on the management of the healthcare institution and the running of its business,

– the deadline for the adoption of the articles of association.

## Article 47

The founder of the healthcare institution shall request the Ministry to evaluate the conformity of the deed of incorporation with the Institutions Act and this Act.

#### Article 48

With the request for the evaluation of conformity of the deed of incorporation, the founder of the healthcare institution shall enclose the evidence of disposing with premises and an opinion on the justifiability of incorporation of the healthcare institution in the public healthcare service network, which is issued by the Institute and the competent chamber, and an opinion on the justifiability of incorporation of the healthcare institution outside the public healthcare service network, which is issued by the competent chamber.

#### Article 49

The Ministry shall establish in a decision whether the deed of incorporation of a healthcare institution is in accordance with this Act.

The appeal against the decision referred to in paragraph 1 of this Article shall not be admitted, but an administrative dispute may be initiated.

The healthcare institution shall be entered in the court register before it commences its operation.

On entry in the court register, the healthcare institution shall acquire the capacity of a legal person.

# Article 50

The Ministry shall establish in a decision whether the healthcare institution meets the conditions in terms of the premises, workers and medical-technical equipment.

The appeal against the decision referred to in paragraph 1 of this Article shall not be admitted, but an administrative dispute may be initiated.

The founder shall submit the request for the decision referred to in paragraph 1 of this Article within six months of the date of issuing of the decision referred to in Article 49, paragraph 1 of this Act.

The conditions in terms of the premises, workers and medical-technical equipment shall be laid down by the Minister in an ordinance, subject to prior opinion of the competent chambers.

## Article 51

The Ordinance on the categorisation of medical-technical equipment of healthcare institutions shall be issued by the Minister.

#### Article 52

The provisions of Articles 47 through 50 of this Act shall also apply in the event of expansion or change of activities.

#### Article 53

The activities of a healthcare institution founded by the Republic of Croatia may not be changed without the approval by the Ministry.

## Article 54

The healthcare institution shall cease with its operations if:

- the founder adopts a decision on termination of operation,
- the need for the performance of the activity for which the healthcare institution was established no longer exists, and it is not possible to re-organise the healthcare institution for the performance of some other healthcare activity,
- the healthcare institution does not meet the conditions prescribed by law for the performance of the activity.

The proposal for the termination of operation of the healthcare institution may be submitted by the founder, the competent chamber, the health inspection based on the results of the inspection supervision and the Institute for health care institutions in the public healthcare service network.

The decision on the termination of operation of the healthcare institution shall be passed by the Ministry.

The appeal against the decision referred to in paragraph 3 of this Article shall not be admitted, but an administrative dispute may be initiated.

The healthcare institution shall lose the capacity of a legal person following the entry of its deletion from the court register of institutions.

## Article 55

The healthcare institution in the public healthcare service network may generate means for work in the following ways:

- through a contract with the Institute,
- through a contract with the Ministry or other bodies of the state authorities for the activities funded from the state budget under law,
- through a contract with faculties and other medical institutions of higher education,
- from the means of the founder in accordance with the deed of incorporation,

- through a contract with the unit of regional self-government,
- through a contract with the unit of local self-government,
- through a contract with voluntary insurers,
- through a contract with a legal person on the higher standard of accommodation during one's stay in the healthcare institution in relation to the standard laid down in the regulations on mandatory health insurance,
- through a contract with companies and other legal persons for the implementation of special projects,
- through the participation of healthcare beneficiaries in the coverage of a part or the total expenses of healthcare,
- from other sources in the manner and under the conditions prescribed by law, the deed of incorporation and the articles of association of the healthcare institution.

The healthcare institution outside the public healthcare service network may generate means for work on grounds referred to in paragraph 1 of this Article, except for the grounds referred to in sub-paragraph 1 of that paragraph, and in accordance with the deed of incorporation and the articles of association of the healthcare institution.

# Article 56

Should there be losses resulting from the performance of the activities of the healthcare institution, such losses shall be covered by the founder in accordance with the Institutions Act.

## BODIES OF THE HEALTHCARE INSTITUTION

Management Board

#### Article 57

The management board shall manage the healthcare institution.

The management board of the healthcare institution founded by the Republic of Croatia shall be comprised of five members, consisting of the representatives of:

- the founder (chairman and two members),
- the employees of the institution (two members).

The management board of the healthcare institution founded by a unit of regional self-government and a town shall have five members and consist of the representatives of:

- the founder (chairman and two members),

- the employees of the institution (two members).

Members of the management board referred to in paragraph 2, sub-paragraph 1 of this Article shall be appointed by the founder at the proposal of the Minister, and members of the management board referred to in paragraph 3, sub-paragraph 1 of this Article shall be appointed by the founder at the proposal of the head of the office of the administrative body of the unit of regional self-government or the town competent for health.

One member of the management board referred to in sub-paragraph 2, paragraphs 2 and 3 of this Article shall be appointed by the workers' council of the healthcare institution, and one member by the expert council of the healthcare institution from amongst the workers of the institution with higher education professional qualifications.

Members of the management board shall have higher education professional qualifications.

The condition referred to in paragraph 8 of this Article shall not apply to the member of the management board appointed by the workers' council of the healthcare institution.

The term of office of the members of the management board shall be four years.

The amount of remuneration of the members of the management board shall be determined by the Minister and paid from the funds of the healthcare institution.

## Business Recovery Committee

## Article 57.a

In the business recovery procedure, the business recovery committee shall take over the management of the healthcare institution during business recovery and two years following a decision on its completion.

The business recovery committee of the healthcare institution from paragraph 1 of this Article shall comprise of three members, i.e. the representatives of:

- the ministry competent for health (chairman),
- the ministry competent for finance (one member),
- an employee of the healthcare institution (one member).

The members of the business recovery committee from paragraph 2 of this Article shall be appointed by the Government of the Republic of Croatia at the proposal of the minister competent for health (a representative of the ministry of health and an employee of the healthcare institution) and the minister competent for finance (a representative of the ministry of finance).

By virtue of the entry into force of the decision on the appointment of the business recovery committee of the healthcare institution, the term of office of all members of the Management Board of the healthcare institution shall expire.

The members of the business recovery committee shall hold an undergraduate and graduate university degree or an integrated undergraduate and graduate university degree.

The term of office of the members of the business recovery committee shall commence on the day of the entry into force of the decision on their appointment and shall last two years

following the entry into force of the decision on the completion of the business recovery procedure.

The remuneration fee for members of the business recovery committee shall be established by the minister competent for health, and it shall be paid from the budget of the ministry competent for health.

## Article 58

The management board of the healthcare institution shall:

- adopt the articles of association with the approval of the founder,
- adopt other general acts,
- adopt the operating and development plan,
- supervise the execution of the operating and development plan of the healthcare institution,
- adopt the financial plan and the closing statement,
- analyse the financial operations of the healthcare institution at least once a month,
- in the case of operating losses of the healthcare institution, shall notify its founder without any delay,
- propose changes or expansion of the scope of activities to the founder,
- issue second-instance decisions in the cases relating to the individual rights of workers,
- discuss and decide on the manager's reports at least every three months,
- carry out other activities laid down by the articles of association.

By way of derogation from the provision of paragraph 1, subparagraph 1 of this Article, the articles of association of the healthcare institution founded by the Republic of Croatia shall be adopted by the management board, subject to prior approval by the Minister.

The management board shall adopt decisions by a majority vote of the total number of members.

## Article 58.a

The business recovery committee of the healthcare institution shall:

- adopt its articles of association subject to prior approval by the Minister,
- adopt other general acts,
- adopt its operating and development plan,
- adopt a draft business rescue plan for the healthcare institution,
- supervise the execution of the operating plan and of the development plan of the healthcare institution,
- adopt a financial plan and the closing statement,
- analyse financial operations of the healthcare institution on a monthly basis as a minimum,

- in the event of an operating loss of the healthcare institution, shall inform its founder without any delay,
- propose a change or expansion of the scope of activities to the founder,
- pass second-instance decisions in the cases related to the individual rights of employees,
- discuss and make decisions on the reports of the business rescue manager at least every three months,
- carry out other activities laid down by the articles of association.

The business recovery committee shall pass its decisions unanimously.

## Manager

#### Article 59

The manager shall organise and run business operations, represent the healthcare institution and be responsible for the legality of its operations.

The manager of the healthcare institution shall have a deputy, and in hospital healthcare institutions and health centres a nursing assistant, i.e. the head nurse of the healthcare institution, while in clinical healthcare institutions he shall also have an assistant for financial operations.

The manager of the healthcare institution shall be appointed on the basis of a competition.

The manager of the healthcare institution shall be appointed and relieved of duty by the management board.

The manager of the healthcare institution shall hold an undergraduate and graduate university degree or an integrated undergraduate and graduate university degree and have and at least five years' working experience in the profession and meet other conditions prescribed by the deed of incorporation or the articles of association.

If the manager of the healthcare institution does not hold an undergraduate and graduate university degree or an integrated undergraduate and graduate university degree in the field of healthcare, his deputy shall hold an undergraduate and graduate university degree or an integrated undergraduate and graduate university degree in healthcare and have at least five years' working experience.

The deputy manager shall be appointed and relieved of duty by the management board of the healthcare institution at the manager's proposal

The manager's term of office shall be four years. Following its expiration, the same person may be re-appointed on the basis of a competition.

Business Rescue Manager

Article 59.a

A business rescue manager shall organise and manage operations, represent the healthcare institution and assume responsibility for the legality of its operations.

The business rescue manager of the healthcare institution shall have his deputy, an assistant for legal affairs, an assistant for financial operations and an assistant for nursing – the head nurse of the healthcare institution.

The business rescue manager of the healthcare institution shall be appointed and relieved of duty by the Government of the Republic of Croatia at the proposal of the minister competent for health.

By virtue of the entry into force of the decision on the appointment of the business rescue manager of the healthcare institution, the term of office of the healthcare institution manager shall expire.

The business rescue manager shall hold an undegraduate and graduate university degree or an integrated undergraduate and graduate university degree and have at least five years of professional work experience and satisfy other requirements stipulated by the deed of incorporation or articles of association.

If the business rescue manager of the healthcare institution does not hold an undergraduate and graduate university degree or an integrated undergraduate and graduate university degree in the field of healthcare, his deputy shall hold an undergraduate and graduate university degree or an integrated undergraduate and graduate university degree in the field of healthcare and have at least five years of work experience.

The deputy and the assistants of the business rescue manager of the healthcare institution shall be appointed and relieved of duty by the business rescue committee of the healthcare institution at the proposal of the business rescue manager of the healthcare institution. By virtue of the entry into force of the decision of the business rescue committee of the healthcare institution on the appointment of the deputy and assistants of the business rescue manager of the healthcare institution, the term of office of the deputy and assistants of the healthcare institution manager shall expire.

The salary of the business rescue manager, his deputy and his assistants shall be established in the way and in the amount of the salary of the manager, deputy manager and assistant manager of the healthcare institution.

The term of office of the business rescue manager of the healthcare institution, his deputy and his assistants shall be in force as of the day of the entry into force of the decision on their appointment and two years following the entry into force of the decision on the completion of the business rescue procedure of the healthcare institution.

## Article 60

By way of derogation from the provision of Article 59, paragraph 4 of this Act, the manager of the healthcare institution founded by the Republic of Croatia shall be appointed and relieved of duty by the management board subject to prior approval by the Minister.

#### Article 61

The manager shall submit a written report to the management board on the overall business operations of the healthcare institution once every three months.

The manager shall participate in the work of the management board, but shall not have the right to participate in a decision-making process.

Article 61.a

The business rescue manager shall submit a written report on the overall business operations of the healthcare institution to the business rescue committee once every three months. The business rescue manager shall participate in the work of the business rescue committee without any right to pass decisions.

#### Article 62

The manager may be relieved of duty before the expiration of the term for which he was appointed.

The management board shall relieve the manager of duty before the end of his term of office:

- at the manager's request,
- in the event of any of the reasons anticipated by special regulations or regulations governing labour relations leading to termination of the employment contract,
- if the manager does not perform the contractual obligations towards the Institute,
- if the manager does not implement the operating and development plan of the healthcare institution adopted by the management board,
- if in the performance of the activities of the healthcare institution there are losses to be covered by the founder in accordance with Article 56 of this Act, unless the losses are due to delays in generating the planned revenues,
- if in his work the manager violates the regulations and general acts of the healthcare institution or unjustifiably fails to execute the decisions of the management board or acts contrary to them,
- if by his unconscientious or irregular work he causes significant damage to the healthcare institution, neglects or negligently performs his duties, which results or might result in serious disturbances in the performance of the activities of the institution,
- if the healthcare inspection detects violations of the regulations and general acts of the healthcare institution or irregularities in the work of the manager.

If the management board does not relieve the manager of his duty for the reasons referred to in paragraph 2 of this Article within 30 days from the date of learning about any of the reasons, the decision to relieve the manager of duty shall be made by the Minister.

The appeal against the decision referred to in paragraph 3 of this Article shall not be admitted, but an administrative dispute may be initiated.

The management board shall inform the manager about the reasons for relief of duty and provide an opportunity to the manager to give a written statement.

Article 62.a

The business rescue manager may be relieved of duty before the expiry of the term of office to which he was appointed.

The business rescue committee shall inform the minister competent for health about the prerequisites for the relief of duty of the business rescue manager before the expiry of his term of office:

- if the business rescue manager himself requests to be relieved of duty,
- in the event of any reasons which lead to the termination of his contract of employment in accordance with special regulations or the regulations governing labour relations,
- if he fails to fulfil his obligations in regard of the Institute,
- if he fails to execute the operating and development plan of the healthcare institution adopted by the management board or by the business rescue committee,
- if he fails to execute the business rescue plan adopted by the ministry competent for health,
- in the event of a loss generated by the healthcare institution to be covered by the founder in accordance with Article 56 hereof, except in the case of a loss due to a delay in generating the planned revenues,
- if he breaches the regulations and general acts of the healthcare institution or fails to execute the decisions of the management board or of the business rescue committee without any justification or acts contrary to them,
- if his unconscientious or irregular actions cause a major damage to the healthcare institution, if he neglects or negligently performs his duties in a way which led or may lead to the major disturbances in the performance of the activities of the institution,
- if the healthcare inspection has established the occurrence of a breach of regulations or general acts of the healthcare institution or regularities in the work of the business rescue manager.

Within 30 days of knowledge of any of the reasons from paragraph 2 of this Article, the minister competent for health shall submit a proposal to the Government of the Republic of Croatia to relieve the business rescue manager of duty.

## Article 63

The manager shall submit quarterly written reports to the Minister about the number of persons who died in the healthcare institution and about the number of post-mortem examinations performed.

In extraordinary circumstances, if the process of the provision of healthcare is threatened or if there is an immediate danger to the life and health of persons, the manager shall inform the Ministry and the Croatian National Institute of Public Health without any delay about such circumstances.

## Article 63.a

The business rescue manager shall submit quarterly written reports to the Minister about the number of persons who died in the healthcare institution and about the number of postmortem examinations performed.

In extraordinary circumstances, if the process of the provision of healthcare services is threatened or if there is an immediate danger to life and health of persons, the business rescue manager shall inform the Ministry and the Croatian National Public Health Institute without any delay about such circumstances.

#### Article 64

The expert council shall be appointed by the manager and it shall consist of at least the heads of the organisational units of the institution referred to in Articles 74 and 75 of this Act.

Healthcare associates may also participate in the work of the expert council.

The manager of the health centre shall appoint to the expert council healthcare professionals – concessionaires who concluded a contract on the provision of healthcare with the health centre, and at least one healthcare professional who is a concessionaire who concluded a contract on the provision of healthcare with the health centre and who was elected by a majority vote of the concessionaires of that health centre.

#### Article 64.a

The expert council of the healthcare institution may be appointed by the business rescue manager in the business rescue procedure and it shall comprise of at least the heads of the institution's organisational units in accordance with Articles 74 and 75 hereof. Healthcare associates may also participate in the work of the expert council. The business rescue manager of the healthcare centre shall appoint healthcare professionals – concessionaries who have signed contracts on the provision of healthcare services with the health centre and at least one healthcare professional – concessionaire who has signed a contract on the provision of healthcare with the health centre elected by the majority vote of concessionaries of that particular health centre.

## Article 65

The manager of the healthcare institution may not be the chairman or a member of the expert council.

The expert council shall meet at least once in 30 days.

#### Article 65.a

The business rescue manager of the healthcare institution may not be the chairman or a member of the expert council.

The expert council shall meet at least once in 30 days.

#### Article 66

The expert council of the healthcare institution shall:

- discuss and decide on issues from the scope of the professional activities of the institution,
- propose expert solutions relating to the activities of the healthcare institution,
- propose expert foundations for the operating and development plan of the healthcare institution,

- propose measures for the improvement of the quality of work in the healthcare institution,
- give opinions and proposals to the management board and the manager regarding the organisation of work and conditions for the development of the healthcare activity,
- propose the adjustment of the professional work of the healthcare institution to its financial resources to the manager and the management board,
- propose specialist training of healthcare professionals and subspecialty training of healthcare professionals for the needs of the healthcare institution,
- propose to the management board the performance of duties by healthcare professionals outside full working hours if that would be in the special interest of citizens and the work of the healthcare institution,
- take care about the implementation of the internal audit of the expert work of healthcare professionals at the institution,
- perform other activities laid down by the articles of association.

## Article 66.a

In the business rescue procedure, the expert council of the healthcare institution shall:

- discuss and decide on issues from the scope of the professional activities of the institution,
- propose expert solutions relating to the activities of the healthcare institution,
- propose expert foundations for the operating and development plan of the healthcare institution,
- propose measures for the improvement of the quality of work in the healthcare institution,
- give opinions and proposals to the business rescue committee and the business rescue manager regarding the organisation of work and conditions for the development of the healthcare activity.
- propose the adjustment of the professional work of the healthcare institution to its financial resources to the business rescue manager and the business rescue committee,
- propose specialist training of healthcare professionals and subspecialty training of healthcare professionals for the needs of the healthcare institution,
- propose to the business rescue committee the performance of duties by healthcare professionals outside full working hours if that would be in the special interest of citizens and the work of the healthcare institution,
- take care about the implementation of the internal audit of the expert work of healthcare professionals at the institution,
- perform other activities laid down by the articles of association.

Expert Board

Article 67

The expert board is a body that with respect to each of the healthcare activities of the healthcare institution reviews issues pertaining to that activity.

The composition and the manner of work of the expert board are regulated by the articles of association of the healthcare institution.

#### Ethics Committee

#### Article 68

The ethics committee of the healthcare institution is a body that ensures the performance of the activities of the institution in accordance with the principles of medical ethics and deontology.

The ethics committee shall be appointed by the management board and shall consist of at least five members, of whom at least 40% of the members shall be of the opposite gender, where at least one member of the ethics committee shall be a representative of non-medical professions, and at least one member shall not be an employee of the healthcare institution.

The management board shall also appoint deputy members of the ethics committee.

The number of members and the composition of the ethics committee shall be regulated by the articles of association of the healthcare institution in accordance with the provisions of paragraphs 2 and 3 of this Article.

For the performance of the activities referred to in paragraph 1 of this Article, the healthcare institution founded by a legal or a natural person may authorise the ethics committee of another healthcare institution.

The ethics committee shall adopt its rules of procedure.

## Article 68.a

The ethics committee of the healthcare institution is a body that ensures the performance of the activities of the institution in accordance with the principles of medical ethics and deontology.

The ethics committee of the healthcare institution may be appointed by the business rescue committee in the business rescue procedure and it shall consist of at least five members, of whom at least 40% of the underrepresented sex, whereas at least one member of the ethics committee shall be a representative of non-medical professions, and at least one member shall not be an employee of the healthcare institution.

The business rescue committee shall also appoint deputy members of the ethics committee. The number of members and composition of the ethic committee shall be regulated by the articles of association of the healthcare institution in accordance with the provisions of paragraphs 2 and 3 of this Article.

For the performance of the activities referred to in paragraph 1 of this Article, the healthcare institution founded by a legal or a natural person may authorise the ethics committee of another healthcare institution.

The ethics committee shall adopt its rules of procedure.

#### Article 69

The ethics committee of the healthcare institution shall:

- monitor the application of ethical and deontological principles of the healthcare profession in the performance of the activities of the healthcare institution,
- approve scientific research in the healthcare institution,
- supervise taking of the parts of the human body after post-mortem examinations for medical and scientific-teaching purposes,
- resolve other ethical issues in the performance of the activities of the healthcare institution.

## Committee for Medicinal Products

#### Article 70

The committee for medicinal products of a healthcare institution is a body that ensures the implementation of all activities related to the use of medicinal products and medical devices in the healthcare institution.

The committee for medicinal products shall be appointed by the management board and shall include at least five members who are appointed from amongst the specialists in medicine, dental medicine or pharmacy.

The composition and the number of members of the committee for medicinal products referred to in paragraph 2 of this Article shall be regulated by the articles of association of the healthcare institution.

The committee for medicinal products shall adopt its rules of procedure.

The committee for medicinal products of a healthcare institution shall:

- supervise the testing of medicinal products and medical devices in the healthcare institution,
- submit to the management board and the manager of the healthcare institution a trimonthly financial statement on the clinical trials of medicinal products being conducted in the healthcare institution,
- coordinate activities regarding reported side-effects of medicinal products and medical devices to the competent authority,
- evaluate the justifiability of the use of medicinal products from the special lists of medicinal products of the Institute and approve the use of medicinal products from the special list of medicinal products at the proposal of the doctor of medicine,

– monitor the consumption of medicinal products and medical devices and propose measures for the rational use of medicinal products and medical devices in the healthcare institution.

#### Article 70.a

The committee for medicinal products of a healthcare institution is a body that ensures the implementation of all activities related to the use of medicinal products and medical devices in the healthcare institution.

In the business rescue procedure, the committee for medicinal products of a healthcare institution may be appointed by the business rescue committee and it shall include at least five members who are appointed from amongst the specialists in medicine, dental medicine or pharmacy.

The composition and the number of members of the committee for medicinal products referred to in paragraph 2 of this Article shall be regulated by the articles of association of the healthcare institution.

The committee for medicinal products shall adopt its rules of procedure.

The committee for medicinal products of a healthcare institution shall:

- supervise the testing of medicinal products and medical devices in the healthcare institution,
- submit to the business rescue committee and the business rescue manager of the healthcare institution a trimonthly financial statement on the clinical trials of medicinal products being conducted in the healthcare institution,
- coordinate activities regarding reporting side-effects of medicinal products and medical devices to the competent authority,
- evaluate the justifiability of the use of medicinal products from the special lists of medicinal products of the Institute and approve the use of medicinal products from the special list of medicinal products at proposal of the doctor of medicine,
- monitor the consumption of medicinal products and medical devices and propose measures for the rational use of medicinal products and medical devices in the healthcare institution.

# Committee for Quality

#### Article 71

The committee for quality of a healthcare institution shall be a body that ensures the quality control of healthcare and the implementation of regulations in the field of quality of healthcare.

The committee for quality shall be appointed by the management board and shall include at least five members.

The committee for quality shall include the representatives of all activities.

The composition and the number of members of the committee for quality referred to in paragraph 2 of this Article shall be regulated by the articles of association of the healthcare institution.

The committee for quality shall adopt its rules of procedure.

The committee for quality of a healthcare institution shall:

- maintain the register of the healthcare institution on deceased patients,
- maintain the register of the healthcare institution on unwanted outcomes of treatment in accordance with the general acts of the Agency for Quality and Accreditation in Healthcare,
- perform quality control of medical documentation of the healthcare institution.

## Article 71.a

The Committee for Quality of the healthcare institution shall be a body ensuring the quality control of healthcare and the implementation of regulations in the field of quality of healthcare.

In the business rescue procedure, the committee for quality of the healthcare institution may be appointed by the business rescue committee and shall include at least five members.

The committee for quality shall include the representatives of all activities.

The composition and the number of members of the committee for quality of the healthcare institution referred to in paragraph 2 of this Article shall be regulated by the articles of association of the healthcare institution.

The committee for quality of the healthcare institution shall adopt its rules of procedure.

The committee for quality of a healthcare institution shall:

- maintain the register of the healthcare institution on deceased patients,
- maintain the register of the healthcare institution on unwanted outcomes of treatment in accordance with the general acts of the Agency for Quality and Accreditation in Healthcare,
- perform quality control of medical documentation of the healthcare institution.

# ACTS OF THE HEALTHCARE INSTITUTION

## Article 72

Acts of the healthcare institutions shall be the articles of association and other general acts.

The articles of association shall be the basic general act of the healthcare institution that shall regulate in particular:

- the organisation of the healthcare institution,
- the manner of decision-making by the manager and the management board according to which the manager passes all decisions regarding the operation of the healthcare institution, except the decisions prescribed in Article 58 of this Act,
- other rights and obligations of the manager and the management board,
- the manner of electing and the composition and work of the expert board,
- other issues important for the performance of the healthcare activity and for the work and operations of the healthcare institution.

Article 72.a

Acts of the healthcare institutions in the business rescue procedure shall be the articles of association and other general acts.

The articles of association shall be the basic general act of the healthcare institution that shall regulate in particular:

- the organisation of the healthcare institution,
- the manner of decision-making by the business rescue manager and the business rescue committee according to which the business rescue manager passes all decisions regarding the the operation of the healthcare institution, except the decisions prescribed in Article 58.a of this Act.
- other rights and obligations of the business rescue manager and the business rescue committee,
- the manner of electing and the composition and work of the expert board,
- other issues important for the performance of the healthcare activity and for the work and operations of the healthcare institution.

#### Article 73

The management and acts of healthcare institutions founded by a legal person, except for healthcare institutions founded by a unit of local self-government and by a unit of regional self-government and healthcare institutions founded by a natural person, shall be regulated by the deed of incorporation or by the articles of association of the healthcare institution in accordance with the Institutions Act.

# THE INTERNAL ORGANISATIONAL STRUCTURE OF CLINICAL AND HOSPITAL HEALTHCARE INSTITUTIONS

### Article 74

Clinics and clinical institutes shall be formed in clinical hospital centres and clinical hospitals.

Institutes or departments shall be formed in clinics.

Departments shall be established in clinical institutes.

Conditions for the organisation of institutes and departments in clinical hospital centres and clinical hospitals shall be regulated by the Minister in an ordinance.

# Article 75

In general and special hospitals, departments are formed.

Conditions for the organisation of departments in general and special hospitals shall be regulated by the Minister in an ordinance.

VII HEALTHCARE INSTITUTIONS AT PRIMARY HEALTHCARE LEVEL

Health Centre

Article 76

A health centre shall be a healthcare institution providing healthcare services for the population of a specific area at the primary healthcare level.

There shall be at least one health centre per county, and in the territory of the City of Zagreb, there shall be at least three health centres.

A county may establish a health centre on an island in view of the specific nature of providing healthcare services.

### Article 77

Health centres shall be the principal providers of healthcare at the primary healthcare level, which shall ensure the realisation of the principle of a comprehensive and overall approach of primary healthcare and the principle of availability and continuing nature of provision of healthcare in their respective areas of responsibility.

Health centres shall organise and take care of the system of improvement of health and prevention of diseases in their respective areas of responsibility.

In their respective areas of responsibility, health centres shall also coordinate and agree on the implementation of some of the healthcare measures which are conducted by the holders of the healthcare activity, including group private practices and private practice healthcare professionals providing the public health service on the basis of a concession.

In the implementation of the activities referred to in paragraph 3 of this Article, health centres shall also coordinate the work of the home healthcare service, medical care and palliative care with the teams of family (general) medicine.

# Article 78

Health centres shall include family (general) medicine, dental healthcare, healthcare for women, healthcare for pre-school children, occupational medicine, laboratory, radiological and other types of diagnostics, medical transport, the pharmacist activity, home healthcare, medical care and palliative care.

In line with the founder's decision, health centre shall ensure that there is at least 30% of doctor's offices in each approved activity from paragraph 1 of this Article following the expiry of concession and private practice.

Health centres shall provide for the implementation of activities referred to in paragraph 1 of this Article, unless the performance of such activities is organised in some other way according to the public healthcare service network.

Health centres may form out-patient departments in line with the needs of the population in the area of responsibility of the health centre.

The activity of the out-patient departments referred to in paragraph 3 of this Article shall include comprehensive healthcare measures in the community, which include prevention,

treatment, social medical care and care for specific health needs of the population in a particular area.

Health centres may organise working units for the performance of the activities referred to in paragraphs 1 and 3 of this Article in accordance with the public healthcare service network.

Health centres may organise, in accordance with the public healthcare service network, work units for the performance of individual specialised activities if they are needed in view of the health of the population and if the provision of healthcare in a polyclinic or hospital would render such care more difficult.

Health centres shall organise house calls.

By way of derogation from paragraph 1 of this Article, in areas with specific needs relating to the health of the population, in accordance with the public healthcare service network, the health centre may form a maternity ward in the health centre, and a ward for diagnostics and treatment of acute patients.

#### Article 78.a

By way of derogation from the provision of Article 78, paragraph 1 of this Act, medical transport may be performed by other healthcare institutions under the conditions laid down by the ordinance referred to in Article 79 hereof.

### Article 79

Conditions, organisation and performance of the activity of medical transport shall be regulated by the Minister in an ordinance, subject to prior opinion of the Croatian Institute of Emergency Medicine.

### Article 80

Health centres may lease the business premises to legal and natural persons for the performance of the healthcare activity in the public healthcare service network pursuant to a decision of the management board, and to legal and natural persons for the performance of the healthcare activity outside the public healthcare service network pursuant to a decision of the management board and subject to prior approval by the founder.

Health centres may lease the business premises to legal and natural persons for the performance of the non-healthcare activity pursuant to a decision of the management board and subject to prior approval by the founder and the Minister.

Military Health Centre of the Ministry of Defence and Armed Forces of the Republic of Croatia

#### Article 80.a

The Military Health Centre of the Ministry of Defence and Armed Forces of the Republic of Croatia is a military health institution for the provision of healthcare services to the

employees of the Ministry of Defence and the members of the Armed Forces of the Republic of Croatia. Its activities comprise general (family) medicine, dental medicine, specific healthcare services, hygienic-epidemiologic healthcare services and pharmacy services. The conditions related to the premises, equipment and employees from paragraph 1 of this Article shall be stipulated by the minister competent for health in an ordinance, subject to approval by the minister competent for defence.

#### Article 80.b

The healthcare institution from Article 44, paragraph 9 of this Act shall provide healthcare services to the persons deprived of freedom and shall be engaged in the activities of general (family) medicine, dental medicine, specific healthcare, hygienic-epidemiologic healthcare services, pharmacy services and hospital treatment.

The conditions related to the premises, equipment and employees from paragraph 1 of this Article shall be stipulated by the minister competent for health in an ordinance, subject to prior approval by the minister competent for justice.

# Healthcare Facility

# Article 81

A healthcare facility is a healthcare institution providing healthcare as part of the healthcare activity at the primary level.

# Institution for Medical Care

# Article 82

An institution for medical care shall be a healthcare institution providing medical care and rehabilitation to patients according to the instructions of doctors of medicine.

The institution from paragraph 1 of this Article may perform physical therapy at home.

The institution referred to in paragraph 1 of this Article may temporarily accommodate patients who need medical care and rehabilitation as in-patients in accordance with the report of a house-call nurse and according to the instructions of doctors of medicine.

# Institution for Palliative Care

#### Article 83

An institution for palliative care shall be a healthcare institution that has a palliative interdisciplinary team for house calls (doctor, nurse, physical therapist, and social worker with special training for communication with terminal patients), a clinic for pain relief and palliative care, and day care and in-patient clinic.

VIII HEALTHCARE INSTITUTIONS AT THE SECONDARY HEALTHCARE LEVEL

## **Polyclinics**

### Article 84

A polyclinic shall be a healthcare institution that performs specialist-consultation healthcare, diagnostics and medical rehabilitation, other than hospital treatment.

Polyclinics, depending on the activities for which they are formed, may ensure conditions for a daytime hospital.

Polyclinics shall perform the activity in at least two offices that have different or similar specialised or narrowly specialised activities or in one office that has a specialised or narrowly specialised activity and a laboratory.

For each of its activities, polyclinics shall conclude an employment contract for an indefinite term with at least one doctor of medicine or dental medicine who is a specialist in the relevant branch, depending on the activities of the polyclinic.

If a polyclinic has a medical-biochemical laboratory, the polyclinic shall conclude an employment contract for an indefinite term with at least one doctor of medicine and one specialist graduate engineer of medical biochemistry.

# Hospitals

# Article 85

A hospital shall be a healthcare institution performing the activity of diagnostics, treatment, medical rehabilitation and medical care of patients and ensuring accommodation and meals for its patients.

The activity referred to in paragraph 1 of this Article shall be performed in general and specialised hospitals.

#### Article 86

A general hospital shall be a healthcare institution performing at least the activities of surgery, internal medicine, paediatrics, gynaecology and obstetrics, and emergency medicine, and having the accommodation, diagnostic and other possibilities adapted to its purpose.

If in a town with a general hospital there is also a specialised hospital for children's diseases or for gynaecology and obstetrics, it is not necessary for the general hospital to have a work unit for paediatrics and gynaecology and obstetrics, respectively.

### Article 87

A specialised hospital shall be a healthcare institution for specialist-consultation and hospital treatment of specific diseases or certain age groups, which, apart from the conditions referred to in Article 88 of this Act, also offers accommodation, diagnostic and other possibilities adapted to its purpose.

#### Article 88

The hospital shall have units for:

- specialist-consultation treatment,
- radiological, laboratory and other medical-laboratory diagnostics,
- the supply of medicinal products and medical devices.

The hospital shall provide for the following:

- medical rehabilitation,
- pathology,
- cytological and microbiological diagnostics,
- supply with blood and blood products,
- anaesthesiology, reanimation and intensive care, if required by the nature of its work.

## Article 89

The Minister shall determine in the form of an ordinance the categories of hospitals in view of the scope of their work, capacity, organisation of work and number of expert units, human resources, space and equipment for the classification of hospitals into categories.

At the proposal of the Agency for Quality and Accreditation in Healthcare, the Minister shall determine the procedure and manner of accreditation of hospitals for classification according to the quality of work.

#### Article 90

By way of derogation from Article 87 of this Act, specialised hospitals may provide for social welfare measures in accordance with the regulations in the field of social welfare.

The costs of the measures referred to in paragraph 1 of this Article shall be paid from the funds of social welfare.

Specialised hospitals may provide healthcare services in tourism in accordance with special regulations.

#### Health Resorts

## Article 91

Health resorts shall be healthcare institutions in which natural therapeutical sources are used to provide preventive healthcare, specialised and hospital rehabilitation.

Health resorts may provide healthcare services in tourism in accordance with special regulations.

### IX HEALTHCARE INSTITUTIONS AT THE TERTIARY HEALTHCARE LEVEL

#### Clinical Institutions

#### Article 92

Clinical institutions shall be a clinic, clinical hospital and clinical hospital centre.

A clinic shall be a healthcare institution or a part of a healthcare institution which in addition to the performance of the healthcare activities referred to in Article 28 of this Act performs the most complex forms of healthcare pertaining to a specialist-consulting activity and in which universities have classes and in which scientific research is performed for the activity for which the clinic was formed.

A clinical institute shall be a part of a healthcare institution meeting the conditions referred to in paragraph 2 of this Article, which performs the activity of diagnostics.

A clinical hospital shall be a general hospital in which at least two of the mentioned activities (internal medicine, surgery, paediatrics, gynaecology and obstetrics) have the title of clinic, and at least two other activities of other specialisations or diagnostics.

A clinical hospital centre shall be a general hospital in which apart from the title of clinic for the activities of internal medicine, surgery, paediatrics, gynaecology and obstetrics, more than half of the other specialised fields have the title of clinic and in which more than half of the curriculum of the faculties of medicine, dental medicine or pharmacy-biochemistry is conducted.

#### Article 93

Clinical institutions shall organise classes for higher education students and for graduate and postgraduate studies.

Clinical institutions shall be authorised and obligated to organise and conduct specialised training and development in the fields of sub-specialisation of healthcare professionals.

#### Article 94

The Minister shall lay down in an ordinance, subject to prior approval by the minister competent for science, the conditions that must be met by clinics, clinical hospitals and clinical hospital centres to receive the title of a clinical institution.

The Minister shall grant the title of a clinical institution referred to in paragraph 1 of this Article after first having obtained the opinion of the competent higher education institution.

The rights of the founder over the healthcare institution shall not be transferred upon acquisition or loss of the requirements for the title of clinic, clinical hospital and clinical

hospital centre, and on the granting of the appropriate title to the healthcare institution or a part of it.

#### Article 95

Exceptionally, a healthcare-oriented higher education institution may entrust the conducting of part of classes to a healthcare institution which does not meet the conditions referred to in Article 94 of this Act, subject to prior approval by the Minister.

The Minister shall award the title of an associate institution of a clinical hospital centre, clinical hospital or clinic to the institution referred to in paragraph 1 of this Article.

Conditions for the award of the title of an associate institution referred to in paragraph 2 of this Article shall be laid down by the Minister in an ordinance.

The Minister may approve classes and especially the parts including practical work at the primary level of heath care, provided that there is a contract in place with the healthcare-oriented higher education institution.

# Article 96

Lecturers and persons holding associate professions – healthcare professionals holding classes in healthcare institutions for the needs of healthcare-oriented higher education institutions may simultaneously establish employment with one healthcare institution and with one or at most two healthcare-oriented higher education institutions in a way that in the healthcare institution or higher education institution they work less than full working hours, so that their full working time is at most 40 hours per week.

By way of derogation from paragraph 1 of this Article, lecturers and persons in associate professions – healthcare professionals having a contract with the Institute may at the same time establish employment with one higher education institution in a way that their full working time is at most 40 hours per week.

Healthcare institutions and healthcare-oriented higher education institutions shall regulate issues arising from employment in conducting classes through a contract.

# Article 97

Healthcare-oriented faculties may, in accordance with a special law, form internal organisational units in which healthcare is provided for teaching purposes at the faculty.

Internal organisational units referred to in paragraph 1 of this Article shall be established and their work regulated subject to prior approval by the Minister.

For the performance of the healthcare activity referred to in paragraph 1 of this Article, healthcare-oriented faculties shall generate funds through a contract with the Institute.

#### Article 98

Healthcare institutes shall include state healthcare institutes, public health institutes of regional self-government and institutes for emergency medicine of regional self-government units.

State healthcare institutes shall be healthcare institutions for the performance of professional and scientific activities within the framework of the rights and duties of the Republic of Croatia in the field of the public health activity, transfusion medicine, occupational medicine, mental health, toxicology and antidoping, emergency medicine and telemedicine.

State healthcare institutes include the Croatian National Institute of Public Health, the Croatian National Institute of Transfusion Medicine, the Croatian National Institute for Protection of Health and Safety at Work, the Croatian National Institute for Telemedicine, the Croatian National Institute for Toxicology and Antidoping and the Croatian National Institute for Emergency Medicine.

As part of the activities referred to in paragraph 2 of this Article, the state healthcare institutes shall perform other activities within their scope of work at the request of the Ministry.

Public health institutes of regional self-government units are healthcare institutions for the performance of professional and scientific activities within the framework of the rights and duties of regional self-government in the field of the public healthcare activity.

Public health institutes of regional self-government units in which teaching activities shall be conducted in the field of public health activities, that is, which form the teaching base for faculties of medicine, have the right to an addition to their name – teaching public health institutes.

Institutes for emergency medicine of regional self-government units shall be healthcare institutions for the performance of activities within the framework of the rights and obligations of regional self-government units in the field of emergency medicine.

Institutes for emergency medicine of regional self-government units in which teaching activities are conducted in the field of emergency medicine, that is, which form the teaching base for faculties of medicine, have the right to an addition to their name – teaching institutes for emergency medicine.

Croatian National Institute of Public Health

## Article 99

The Croatian National Institute of Public Health shall be a healthcare institution for the performance of activities relating to the epidemiology of quarantine and other infectious diseases and chronic mass non-infectious diseases, public health, education about health and health promotion and disease prevention, health ecology, microbiology, school medicine, mental health and prevention of addictions.

Article 100

The Croatian National Institute of Public Health shall perform the following activities:

- proposing and conducting research in the field of healthcare for the purpose of monitoring, analysing and assessing the health of the population, and in the field of organisation and work of healthcare services,
- planning, proposing and implementing measures for the maintenance and improvement of the health of the population,
- through educational and other activities and through health promotion, maintaining and improving the health of the population,
- planning, proposing, coordinating and monitoring the specific healthcare protection of children and young people, especially in primary and secondary schools and higher education institutions,
- monitoring and analysing the epidemiological situation, proposing, organising and conducting preventive and anti-epidemic measures,
- planning, supervising and evaluating the implementation of mandatory immunisation,
- planning and supervising the measures of disinfection, pest control and rodent control and performing preventive and anti-epidemic procedures of disinfection, pest control and rodent control,
- performing microbiological activities of interest for the Republic of Croatia, including participation in the implementation and organisation of inter-laboratory comparative tests at national and international levels and performing confirmatory analyses,
- monitoring, analysing, observing and evaluating the safety of drinking water, water for dialysis, water for recreation and physical therapy, ground waters and effluents, the condition of the water supply in the area, the safety of foodstuffs and general use items, as well as those intended for international trade,
- monitoring and evaluating the dietary condition of the population and proposes public health measures for improving the diet,
- testing, monitoring, analysing and evaluating the effect of environmental factors on the health of people and proposing and participating in the performance of measures for the prevention of their harmful effects,
- proposing the programme of healthcare measures and participating in the preparation of the nomenclature of services and tasks,
- supervising and evaluating the implementation of preventive programmes and other measures of healthcare,
- performing part of the activities of preventive healthcare for the Croatian Army,

- monitoring, studying and reporting on the health of the veterans of the Croatian Homeland War,
- planning, proposing and implementing activities on the establishment, development and operation of the health information system,
- participating in the education of healthcare professionals, conducting expert and scientific research in the field of public health,
- keeping state public health registers and supervising the gathering of data and co-ordinating the work of other registers in healthcare,
- educating the population about health and about addictive diseases,
- collecting data and records in the field of addictive diseases (including tobacco, alcohol and psychoactive drugs),
- creating the doctrine in the treatment of addictive diseases and supervise its application,
- giving a prior opinion to the Minister on special programmes of measures for the control and prevention of addictive diseases,
- participating in the organisation and implementation of permanent education of healthcare and other workers in the field of control of addictive diseases,
- planning, proposing and implementing measures for the preservation and improvement of mental health of the population,
- planning and proposing development strategy and action programmes for the improved protection of mental health and psychiatric care at primary, secondary and tertiary level of healthcare.
- proposing the programme of healthcare measures from its scope of work,
- monitoring, studying and reporting on mental health of the veterans of Croatian Homeland War.
- designing and proposing programmes and conduct research in the area of mental health protection and psychiatric care in order to monitor, analyse and assess the mental health of the population,
- maintaining and improving the mental health of the population through health education, promotional and other activities,
- planning and proposing programmes and coordinating and supervising the implementation of specific protection and improvement of mental health of children and adolescents, especially in primary and secondary schools and higher education institutions,
- collecting and analysing epidemiologic data on mental diseases and disorders in the territory of the Republic of Croatia,

- keeping the state register of persons suffering from mental diseases and disorders,
- continuously supervising and evaluating the quality of measures for the prevention, diagnostics and treatment in the area of mental health protection and psychiatric care,
- participating in the education of healthcare professionals,
- may perform professional assignments in the area of environmental protection in line with special regulations related to environmental and air protection.

The Croatian National Institute of Public Health shall coordinate, provide professional guidance and supervise the work of county institutes of public health.

### Article 101

Public health institutes of regional self-government units shall be a healthcare institution for the performance of the public health activity in the field of regional self-government units.

A public health institute must organise health promotion, epidemiology, microbiology, public health, health ecology, school medicine, protection of mental health and prevention of addiction in the area of the unit of regional self-government concerned.

Public health institutes of regional self-government units shall perform the following activities:

- specific preventive healthcare of children and young people, especially in primary and secondary schools and faculties in its area,
- monitoring, examining, evaluating and reporting on the health requirements and functional problems of the elderly and propose health measures for its area,
- collecting, controlling and analysing statistical reports in the field of healthcare, including addictive diseases, at the level of the units of regional self-government for the purposes of the Croatian National Institute of Public Health,
- at the request of the county prefect or mayor, monitoring and evaluating the health of the population in its area,
- continuously conducting measures of hygienic-epidemiological protection with an epidemiological analysis of the situation in the area of the unit of regional self-government and if necessary conducts anti-epidemic measures and supervises the implementation of mandatory immunisation,
- conducting measures of gerontological healthcare,
- analysing the epidemiological situation, planning, proposing and participating in the implementation of measures and activities for the prevention, early detection and elimination of addictive diseases,

- co-operating with healthcare and other institutions and healthcare professionals in the implementation of diagnostics and treatment of addictive diseases and rehabilitation and social integration of addicts,
- supervising the implementation of measures of disinfection, pest control and rodent control and implementing preventive and anti-epidemic procedures of disinfection, pest control and rodent control in the area of the unit of regional self-government,
- performing microbiological activity of interest for the unit of regional self-government,
- monitoring, analysing, observing and evaluating the safety of drinking water, water for recreation and physical therapy, ground waters and effluents, the condition of the water supply in the area, the safety of foodstuffs and general use items in the area of the unit of regional self-government,
- participating in the preparation and implementation of programmes of health protection in extraordinary circumstances,
- monitoring, analysing and evaluating the impact of the environment and food on the health of the population of the unit of regional self-government,
- participating in the planning, proposing and implementation of measures for the prevention, early detection and elimination of chronic mass diseases, including addictive diseases,
- distributing mandatory vaccination to the doctors' offices at the primary healthcare level in the area of the unit of regional self-government,
- may perform professional assignments in the area of environmental protection in line with special regulations related to environmental and air protection,
- performing other activities for the purposes of public health in accordance with special regulations.

# Croatian National Institute of Transfusion Medicine

#### Article 102

The Croatian National Institute of Transfusion Medicine shall be a healthcare institution performing the activities of transfusion.

The activities of transfusion shall include the promotion and organisation of blood drives and the collecting of blood and plasma for processing, the processing of plasma, blood testing, satisfying the requirements for products made from blood and blood-based medicaments, ensuring the quality of blood products, the distribution of products, diagnostic research, therapeutic procedures, control and supervision of transfusion treatment, collecting of stem cells, tissue typing and consultation in clinical medicine.

Along with the Croatian Institute of Transfusion Medicine, the activities of medical transfusion shall also be performed by the units of transfusion medicine in hospitals.

#### Article 103

The Croatian National Institute of Transfusion Medicine and the Croatian Red Cross shall promote blood drives, plan the requirements for blood-based medicaments and organise blood drives on the basis of special contracts.

#### Article 104

The Croatian National Institute of Transfusion Medicine shall do the following:

- performing the activities of transfusion in accordance with Article 102 of this Act,
- co-ordinating the application of standards in blood drives, laboratory tests, preparation, preservation, issuance, and transportation of blood products and blood-based medicaments and their clinical usage,
- proposing the programme of healthcare measures in the field of its work,
- co-ordinating the promotion and organisation of blood drives with the Croatian Red Cross,
- gathering data for the annual analysis of the activities of transfusion, analyse them and forward them to the Ministry,
- making infusion solutions and disposable medical products.

Croatian National Institute for the Protection of Health and Safety at Work

# Article 105

The Croatian National Institute for the Protection of Health and Safety at Work shall be a healthcare institution for the performance of activities pertaining to occupational medicine, for monitoring the situation and improving safety at work.

The activities of occupational medicine shall include the protection and maintenance of the health of workers in a safe and healthy working environment.

In the field of specific health protection of workers, the Croatian National Institute for the Protection of Health and Safety at Work shall carry out the following:

- conducting statistical research in the field of occupational medicine,
- planning, proposing and implementing measures for the maintenance and improvement of the health of workers and organising specific healthcare with the aim of prevention,
- forming the doctrine, standards and methods of work for the evaluation of health capacity and for monitoring the health of workers,
- issuing opinions on the measures proposed for maintaining and improving the health of sportsmen and the sporting population,

- keeping the register of professional diseases and monitoring and researching the causes of injuries at work,
- participating in the proposing of the programme of healthcare measures and the nomenclature of diagnostic and therapeutic procedures, regarding the specific healthcare of workers,
- participating in the additional professional training of workers in the field of occupational medicine,
- conducting expertise in the event of professional diseases and evaluating working capacity,
- conducting the second-instance procedure under special regulations,
- performing other activities in the field of occupational medicine in accordance with special regulations.

In the field of monitoring the situation and improving safety at work, the Croatian National Institute for the Protection of Health and Safety at Work shall:

- monitor the situation concerning safety at work, studies the risk of injuries at work and professional diseases and conducts statistical research,
- set out the standards and procedures concerning the organisation of work which is worker friendly,
- maintain the registers of workers exposed to harmful impact, danger and strain in cases where that is laid down by the regulations in the field of safety at work,
- plan, propose and conduct measures for the preservation and improvement of worker safety,
- develop the doctrine, standards and methods of work in assessing working conditions,
- draw up evaluation methods and models for resolving problems concerning safety at work on the basis of data obtained by monitoring health and safety at work,
- draw up expert opinions in the field of safety at work,
- provide expert assistance to employers' associations, trade unions, institutions, companies
  and natural persons authorised to perform activities of protecting the health and safety at
  work, and to administration bodies regarding data from within its scope of work, and conducts
  expertise from within its scope of work,
- conduct preventive actions and counselling in the field of safety at work,
- participate in further professional training of experts in safety at work,
- perform other activities in the activity of safety at work in accordance with special regulations.

Along with the activities referred to in paragraph 3 of this Article, the Croatian National Institute for the Protection of Health and Safety at Work shall coordinate and supervise all offices of occupational medicine engaged in the specific healthcare of workers in the territory of the Republic of Croatia.

The supervision referred to in paragraph 5 of this Article shall be conducted in accordance with an ordinance to be adopted by the Minister at the proposal of the Croatian National Institute for the Protection of Health and Safety at Work, subject to prior opinion of the competent chamber.

# The Croatian Institute of Telemedicine

## Article 106

The Croatian Institute of Telemedicine is a healthcare institution for the introduction and promotion of techniques and technologies in the distance diagnostics and treatment in the Republic of Croatia.

# Article 107

The Croatian Institute of Telemedicine shall perform the following activities:

- organising the use of information and telecommunication technologies in remote data exchange with the aim of facilitating the provision of healthcare,
- organising the introduction of telemedicine services in the health system of the Republic of Croatia,
- issuing licences to practice to telemedicine centres,
- proposing to the Minister the conditions for granting licences to practice to telemedicine centres and healthcare professionals who perform telemedicine activity,
- conducting supervision over the work of telemedicine centres and the work of healthcare professionals who perform telemedicine activity,
- proposing to the Minister the network of telemedicine centres,
- organising the basic network of telemedicine centres in order to ensure the availability of health services in the entire territory of the Republic of Croatia,
- developping, building and maintaining the computer and communication infrastructure and a system for providing telemedicine services,
- conducting second-instance proceedings according to special regulations,
- participating in proposing the healthcare measures programme and the nomenclature of diagnostic and therapeutic procedures connected with telemedicine,
- defining standards and methods of work in telemedicine,
- giving opinions for granting and renewing the title of a Ministry reference centre for those medical fields where telemedicine services are delivered while providing healthcare.
- encouraging civilian and military cooperation in the telemedicine field,
- coordinating activities connected with the technical and technological development of the telemedicine infrastructure.

- comprehensively and systematically monitoring and applying developmental directives and technologies in telemedicine,
- establishing measures of success and the system of control, correction and elaboration of instruments of system excellence which will be implemented and further developed by telemedicine in the Republic of Croatia,
- organising scientific, professional and promotional activities related to the application of telemedicine,
- giving proposals and expert opinions when regulations are prepared that will affect the development of telemedicine in the Republic of Croatia,
- cooperating with the Central State Office for e-Croatia in interdepartmental activity in telemedicine,
- performing other activities through which it achieves its founding goals, in line with the law.

Croatian Institute for Toxicology and Antidoping

### Article 108

The Croatian Institute for Toxicology shall be a healthcare institution engaged in:

- -testing of chemicals in the air, water, soil, rivers, the sea, the flora and fauna, food and feed, under regular conditions, in the case of an extraordinary event or whenever an extraordinary event is suspected to have occurred, and proposing protection measures,
- planning and supervising the implementation of measures for the protection of human and animal life against the harmful impact of chemicals in their regular use or in the case of an extraordinary event or whenever an extraordinary event is suspected to have occurred,
- monitoring and maintaining records on chemicals produced, imported, acquired, transported, used, in transit, deposited or removed, exported, on persons working with such chemicals and taking and performing other adequate measures within its scope of work,
- further professional training for work with chemicals and examining such further professional training,
- monitoring and implementing international conventions against doping in sports in the Republic of Croatia,
- systematic monitoring and coordinating actions of governmental and non-governmental organisations in the fight against doping in sports,
- proposing and implementing measures in the fight against doping in sports,
- implementation of the World Anti-Doping Agency Code and the rules of the Croatian Olympic Committee, the World Anti-Doping Agency and international sports associations.

The Croatian Institute for Toxicology shall, in addition to the activities referred to in paragraph 1 of this Article, propose the programme of healthcare measures in the field of its work and perform other activities in accordance with a separate law.

# Croatian Institute of Emergency Medicine

#### Article 109

The Croatian Institute for Emergency Medicine shall be a healthcare institution engaged in the activities of emergency medicine.

The activity of emergency medicine shall include the implementation of measures of emergency healthcare, the emergency transport of ill and injured persons to an adequate healthcare institution and medical care during such transport.

The conditions, organisation and the method of performing emergency medicine shall be laid down by the Minister in an ordinance, at the proposal of the Croatian Institute for Emergency Medicine.

The conditions for the implementation of the programme of the publicly available early defibrillation shall be laid done by the Minister in an ordinance, at the proposal of the Croatian Institute for Emergency Medicine.

# Article 110

The Croatian Institute for Emergency Medicine, along with the activities referred to in Article 109 of this Act, shall also be engaged in the following activities:

- proposing, planning, monitoring and analysing the measures of emergency medicine in the Republic of Croatia,
- proposing the network of emergency medicine to the Minister,
- establishing the standards for equipment, vehicles and visual identity of vehicles and healthcare professionals in accordance with the standards of modern emergency medicine,
- setting binding standards for operating procedures, work protocols and action algorhythms, for all forms of emergency medicine and coordinates their application,
- establishing the standards of emergency medicine for emergency medical transport by road, air and water,
- monitoring, analysing and supervising uniform implementation of the standards of quality of work and equipment quality in all county institutes for emergency medicine,
- proposing and developing curricula for lifelong learning and ongoing training, participating
  in the implementation and supervising the education and professional training of healthcare
  professionals in emergency medicine,
- participating in the training of healthcare professionals,

- developing the doctrine in the activity of emergency medicine,
- proposing the programme of healthcare measures in the field of work of emergency medicine,
- planning and implementing activities with a view to setting up the IT system for emergency medicine which would be compatible with the IT system of the Institute,
- raising public awareness from within its scope of work,
- cooperating with other healthcare institutions and healthcare professionals with a view to promoting treatment and diagnostics in the field of emergency medicine,
- monitoring and conducting professional and scientific research in emergency medicine,
- collecting data for the annual analysis of work of emergency medicine, analysing them and forwarding them to the Ministry, the Croatian National Institute of Public Health and the Institute,
- collecting data and maintaining registers in the field of emergency medicine,
- planning and participating in the development and implementation of individual healthcare projects in extraordinary circumstances, in coordination with the Crisis Headquarters of the Ministry, the National Protection and Rescue Directorate, the Ministry of the Interior, the Ministry of Defence, the Croatian Red Cross, the Croatian Mountain Rescue Service and other rescue services.
- coordinating, providing professional guidance and supervising the work of county institutes for emergency medicine.

# Article 111

Institutes for emergency medicine of units of regional self-government shall carry out the following activities:

- conducting measures of emergency medicine in the area of the unit of regional self-government,
- ensuring cooperation in providing emergency medicine with the neighbouring units of regional self-government,
- organising and providing for the recruitment of staff for the network of teams in the area of the unit of regional self-government,
- ensuring the implementation of the standards for equipment, vehicles and visual identity of vehicles and healthcare professionals,
- implementing the standards of emergency medicine for urgent medical transport by road, and the standards for emergency transport by air and water in cooperation with the Croatian National Institute for Emergency Medicine,

- ensuring the implementation of quality of work standards and proposing to the Croatian National Institute for Emergency Medicine the measures needed to improve the existing standards of the quality of work and equipment,
- participating in the planning and implementation of training of healthcare professionals,
   conducting professional and scientific research in the field of emergency medicine in
   cooperation with the Croatian National Institute for Emergency Medicine,
- undertaking activities with a view to establishing an IT system for emergency medicine,
- collecting data and maintaining registers in the field of emergency medicine for the unit of regional self-government and forwarding them to the Croatian National Institute for Emergency Medicine,
- in line with the founder's decision, they may engage in the activity of medical transport,
- planning, organising and participating in the raising of public awareness in the field of emergency medicine in its area of responsibility,
- cooperating with other healthcare institutions and healthcare professionals in the implementation of treatment and diagnostics od diseases,
- planning and participating in the drawing-up and implementation of healthcare projects in extraordinary circumstances in coordination with the Croatian National Institute for Emergency Medicine,
- undertaking other activities in the field of emergency medicine for the needs of the unit of regional self-government.
- in extraordinary circumstances and hardly accessible areas, cooperating with the National Protection and Rescue Directorate, the Croatian Mountain Rescue Service, the Ministry of the Interior, fire-fighting units, the Croatian Red Cross, Harbour Master's offices and other rescue services.

## Article 111.a

Healthcare institutions may provide social welfare measures in line with the regulations from the field of social welfare.

#### Article 111.b

Healthcare professionals in private practices, healthcare institutions and companies engaged in the provision of healthcare may provide healthcare services in tourism in accordance with special regulations for activities for which they are authorised.

XI A REFERENCE CENTRE OF THE MINISTRY

## Article 112

A reference centre of the Ministry (hereinafter: the reference centre) may be a healthcare institution or a part of a healthcare institution or some other legal person or a part of a legal person that provides healthcare in accordance with a special law and that meets the norms and standards for the provision of the most complex forms of healthcare.

At the proposal of the National Health Council and subject to prior opinion of the expert society of the Croatian Medical Association or other relevant societies, the Minister shall pass a decision on appointment of the reference centre.

Once it obtains the decision, the healthcare institution or a part of the healthcare institution or some other legal person or a part of such legal person providing healthcare in accordance with a special law shall acquire the right to use and present its logo and its title of the reference centre. The decision on the appointment of the reference centre shall be published in the Official Gazette.

The title of the reference centre shall be awarded for a period of five years.

The criteria for the award and renewal of the title of the reference centre shall be laid down by the Minister in an ordinance.

# Article 113

In addition to its basic activities, the reference centre shall perform the activities related to the application and monitoring of the uniform doctrine and methodology in the prevention, diagnostics, therapy and rehabilitation of diseases in the field for which it was established.

# Article 114

The reference centre shall, in particular:

- monitor, research and improve the situation in the field for which it was established,
- provide expert-methodological assistance through education and other forms of dissemination of knowledge in the field for which it was established,
- establish doctrinary criteria for the prevention, diagnostics, treatment and rehabilitation of diseases in the field for which it was established,
- provide assessments and opinions on methods, procedures and work programmes in the field of healthcare for which it was established.
- participate in planning, monitoring and evaluating research and promoting the use of research results in the field for which it was established,
- follow the professional development of healthcare professionals.

For the performance of the activities referred to in paragraph 1 of this Article, the reference centre shall not receive any additional funds.

Expert opinions of the reference centre shall become mandatory once adopted by the Minister in the form of instructions, subject to prior opinion of the National Health Council.

Only one reference centre per field of medicine may be appointed.

The National Health Council shall determine the fields of medicine that may be awarded the title of the reference centre due to their importance for the Republic of Croatia.

#### XII THE NATIONAL HEALTH COUNCIL

#### Article 115

The National Health Council shall have nine members, of whom at least 40% of the underrepresented gender. They shall be appointed and relieved of duty by the Croatian Parliament, at the proposal of the Minister, from among the prominent experts in the specific fields of medicine to monitor all fields of healthcare and to issue and propose expert opinions related to planning, programming, development and other health matters important for the Republic of Croatia. The National Health Council shall give its opinion related to the change of sex. In the performance of its activities from paragraph 1 of this Article, the National Health Council may request the opinion of other experts from certain fields of medicine that is required to solve certain issues.

Members of the National Health Council shall be appointed for a term of four years.

An appointed member of the National Health Council may be relieved of duty before the end of his term in office if he:

- requests to be relieved of duty,
- does not perform the obligations of a member,
- loses the capacity to perform his duties,
- by his conduct, damages the reputation of the duties he performs.

The procedure for establishing the conditions to relieve a particular member of duty may be initiated by the chairman of the National Health Council or by at least five members of the Council, by submitting a request to the Council.

Following the receipt of the request referred to in paragraph 4 of this Article, the National Health Council shall appoint a commission from amongst its members, and on the basis of their report it shall decide whether to propose to the Croatian Parliament that a member of the National Health Council be relieved of duty or whether to reject the request by which the procedure was initiated.

The remuneration for work of the members of the National Health Council shall be laid down by the Minister and paid from the state budget.

### XIII COMPANIES ENGAGED IN THE PROVISION OF HEALTHCARE

#### Article 116

A company may be established for the provision of healthcare. A company established for the provision of healthcare shall be established outside the public health service network. The companies the provision of healthcare need not employ healthcare professionals on a permanent basis.

#### Article 117

The companies referred to in Article 116 of this Act may not perform pharmaceutical or comprehensive activities of healthcare institutions, namely clinical hospital centres, clinical hospitals, clinics, general hospitals, healthcare institutes and health centres.

#### Article 118

The act of incorporation of a company referred to in Article 116 of this Act shall regulate the rights and obligations of the members of the company.

The incorporation, termination, responsibility or other issues relating to the company referred to in Article 116 of this Act, which are not regulated by the provisions of this Act, shall be governed by the provisions of the Companies Act.

## Article 119

Founders of the company shall request the Ministry to perform the assessment of the conformity of the act or deed of incorporation with this Act.

### Article 120

With the request for conformity assessment of the act or deed of incorporation of the company for the provision of healthcare, the founders shall enclose a proof that it disposes of the premises and an opinion of the competent chamber concerning the justifiability of its incorporation.

#### Article 121

The Ministry shall issue a decision establishing that the act or deed of incorporation of a company for the provision of healthcare is in accordance with this Act.

The appeal against the decision referred to in paragraph 1 of this Article shall not be admitted, but an administrative dispute may be initiated.

The company shall be entered in the commercial register before the commencement of its operations.

The company may not commence the provision of healthcare until the Minister issues a decision establishing that the conditions for the provision of healthcare laid down in Article 50, paragraph 1 of this Act are satisfied.

By way of derogation from paragraph 4 of this Article, the company for the provision of healthcare in tourism shall not be obliged to dispose of the premises for the provision of healthcare when submitting the request for the decision from paragraph 4 of this Article.

During the provision of healthcare in tourism, the company referred to in paragraph 5 of this Article shall make sure that the healthcare in tourism is provided by a healthcare professional having the appropriate qualifications and the valid licence for independent work and that the healthcare service in tourism is provided at the premises and with medical and technical equipment which meets minimum requirements with regard to premises, equipment and workers for the provision of healthcare.

The founder shall submit the request for issuance of the decision from paragraph 4 of this Article within six months of the date of issuance of the decision referred to in paragraph 1 of this Article.

## Article 122

The provisions of Articles 119 to 121 of this Act shall also apply in the event of expansion or change of activities of the company engaged in the provision of healthcare.

#### Article 123

The grounds for termination of the company engaged in the provision of healthcare shall be, in particular:

- actions of the company that are contrary to the law and other regulations,
- failure to meet legally prescribed conditions for the performance of activities for which the company was established,
- failure to abide by the code of medical ethics and deontology.

The Ministry shall issue a decision determining the onset of the grounds for termination of the company's operations referred to in paragraph 1 of this Article.

The appeal against the decision referred to in paragraph 2 of this Article shall not be admitted, but an administrative dispute may be initiated.

XIV HEALTHCARE PROFESSIONALS

Article 124

Healthcare professionals shall be the persons with healthcare education who provide healthcare services directly to the population as part of their job, while respecting moral and ethical principles of the healthcare profession.

Healthcare professionals shall receive education at the faculties of medicine, dental medicine or pharmacy and biochemistry and speech therapy and other higher education institutions in the field of healthcare and in high schools for healthcare, or in colleges or high schools authorised for healthcare curricula.

Healthcare professionals shall abide by the rules of the healthcare profession while providing healthcare services by not jeopardising the life and health of people with their actions.

The employer shall make sure that all healthcare professionals who provide healthcare services directly as part of their job have a liability insurance for the damages they may cause in the provision of healthcare.

#### Article 125

Healthcare professionals may contract, for their account, the activities pertaining to the scope of their employer's scope of healthcare activities subject to prior approval by the employer.

The approval from paragraph 1 of this Article shall be granted for a period of one year.

The condition for granting of the approval from paragraph 1 of this Article is the previous contract on rights and obligations between the employer and the healthcare institution, the company engaged in the provision of healthcare and a private practice where a healthcare professional will provide for his own account services from the employer's scope of activities.

# Article 125.a

The employer shall grant the approval from Article 125, paragraph 1 of this Act in line with the criteria laid down by the Minister in an ordinance.

By way of derogation from Article 125, paragraph 1 of this Act, the manger, the deputy manager or the assistant manager of the healthcare institution shall not contract activities from the employer's scope of activities.

#### Article 125.b

Subject to employer's approval from Article 125, paragraph 1 of this Act, a healthcare professional may sign a contract for the provision of healthcare for his own account only with a healthcare institution or with a private practice that has no contract on the provision of healthcare with the Institute and only in a healthcare institution, a company engaged in the provision of healthcare and a private practice that has no unsettled obligations relating to taxes, surtax and contributions or any other due obligations with regard to the Republic of Croatia.

The provision of paragraph 1 of this Article shall not apply to the performance of activities for the account of the healthcare professional who has the employer's approval from Article 125, paragraph 1 of this Act for the provision of healthcare in a healthcare institution whose founder is the Republic of Croatia, a regional self-government unit or a town.

#### Article 125.c

The contract on rights and obligations concluded between the employer and the healthcare institution, the company engaged in the provision of healthcare or a private practice where a healthcare professional will perform the activities from the employer's scope of activities for his own account shall contain:

- the provision on the content of activities from the employer's scope of activities that the healthcare professional will carry out for his account,
- the provision on the work time during which the healthcare professional will carry out the activities for his account in the healthcare institution, the company engaged in the provision of healthcare or the private practice where the healthcare professional is not employed,
- the provision on the remuneration for the healthcare professional who carries out the activities for his account, and which shall not be lower per work hour than the gross amount of the hourly wage of the average monthly salary paid to the healthcare professional over the last six months prior to conclusion of the contract.

Upon worker's request, the employer shall issue a certificate of the gross amount of the hourly wage of the average monthly salary paid to the employee over the last six months prior to conclusion of the contract from paragraph 1 of this Article.

#### Article 125.d

The employer shall revoke the authorisation from Article 125, paragraph 1 hereof to the healthcare professional who carries out the activities for his account contrary to the contract from Article 125.c hereof.

## Article 125.e

The employer shall not be held responsible for any damage that his employee, i.e. the healthcare professional who carries out the activities for his account on the basis of the authorisation from Article 125, paragraph 1 hereof, may cause by the performance of such activities to any third person.

#### Article 126

Healthcare professionals shall keep as a professional secret everything they know about the patient's health status. All other staff engaged in healthcare and students and pupils of healthcare schools shall also keep any professional secrets they learn in the performance of their duties.

All other persons who in the performance of their duties find out information about the health of a patient shall also keep such information as a professional secret.

#### Article 127

The violation of the duty to keep a professional secret shall represent a serious violation of the obligations arising from employment.

By way of derogation from the provision of paragraph 1 of this Article, the persons referred to in Article 126, paragraphs 1 and 2, shall communicate the data about the health of a patient at the request of the Ministry, other bodies of state administration in accordance with special regulations, the competent chamber or the judicial authorities.

The manner of maintaining, keeping, collecting and using the medical documentation shall be laid down by the Minister in an ordinance.

### Article 128

The rights and obligations of healthcare professionals and other issues regarding the performance of activities of healthcare professionals not regulated by this Act shall be governed by the provisions of separate laws on professions in healthcare.

# Article 129

Healthcare associates shall be the persons who have not completed healthcare education and who work in healthcare institutions and participate in a particular segment of healthcare (diagnostic and therapeutic procedures).

The Minister shall issue an ordinance laying down the content and the manner of professional training of healthcare associates, subject to prior opinion of the competent chambers.

#### Article 130

The healthcare professionals shall undergo traineeship after finishing their education.

Traineeship shall be work under supervision by which the healthcare professional is trained to work independently.

#### Article 131

Traineeship for healthcare professionals shall last up to one year.

By way of derogation from paragraph 1 of this Article, the traineeship of doctors of medicine who finished a five-year study of medicine shall last two years.

#### Article 132

After completing their traineeship, healthcare professionals shall sit for the state examination before a commission of the Ministry.

#### Article 133

The provisions of Articles 130 to 132 of this Act shall not apply to the nationals of the European Economic Area (hereinafter: EEA) or to the nationals of the Republic of Croatia who have finished integrated studies of medicine, dental medicine or pharmacy or high school for general care nurses or midwifes which are harmonised with the Act on Regulated Professions and the Recognition of Foreign Professional Qualifications.

#### Article 134

The licence for independent work shall be a public document that is issued by the competent chamber in accordance with a special law after the healthcare professional obtains a certificate of the passed state examination.

The certificate of professional examination shall not be submitted by the healthcare professional from Article 133 of this Act.

A healthcare professional who is a national of EEA shall submit a certificate of professional examination if professional examination is prescribed by the laws and regulations of that EEA country.

With the licence for independent work referred to in paragraph 1 of this Article, the healthcare professional shall acquire the right to independently perform activities in his profession.

# Article 135

The issuance, renewal and revocation of the licence for independent work of healthcare professionals shall be carried out in accordance with a special law.

## Article 136

Subject to prior positive opinion of the competent chamber, the Minister shall issue an ordinance laying down:

- the content and the manner of conducting a traineeship,
- the conditions to be met by healthcare institutions, companies engaged in the provision of healthcare and private practices where healthcare professionals do their traineeship,
- the content, programme and the manner of sitting for the state examination,
- the content and form of the certificate of the passed state examination.

# Article 137

Traineeship shall be served in healthcare institutions and companies engaged in the provision of healthcare.

Healthcare institutions and companies engaged in the provision of healthcare shall accept healthcare professionals for traineeship in accordance with the criteria which shall be laid down by the Minister in an ordinance.

Healthcare professionals may serve a part of their traineeship with a healthcare professional holding a university graduate degree and having a private practice and having at least five years of working experience in the profession and with a legal person in which healthcare activities are performed in accordance with a separate law, according to the criteria which shall be determined by the Minister in an ordinance.

#### Article 138

Healthcare professionals shall have the right and obligation to undergo professional advancement in order to maintain and improve the quality of healthcare.

The general act of the competent chamber shall prescribe the content, deadlines and the procedure of examining the expertise, other than specialisation and sub-specialisation.

### Article 138.a

The procedure and the definition of requirements for the recognition of foreign professional qualifications, issuance of the certificate of recognition of foreign professional qualifications, provision of the information on the procedure and conditions for the recognition of foreign professional qualifications and other activities shall be carried out by the competent chamber in accordance with the Act on Regulated Professions and Recognition of Foreign Professional Qualifications.

The competent chamber shall carry out the recognition of foreign professional qualifications (automatic recognition) acquired exclusively by the nationals of EEA countries who have the evidence of formal qualifications issued by an EEA country, which recognises the equal value of that evidence with the value of the evidence of formal qualifications issued in the Republic of Croatia.

The competent chamber shall carry out the general procedure for the recognition of foreign professional qualifications acquired by third country nationals with the evidence of formal qualifications issued in an EEA country and by the nationals of the Republic of Croatia, EEA countries and third countries who acquired their professional qualifications outside the EEA. The competent chamber shall examine the professional knowledge of the candidate in order to assess his qualifications for the performance of the regulated profession.

The criteria for the recognition of foreign professional qualifications shall be laid down by the Minister in an ordinance, subject to prior opinion of the competent chambers.

The pricelist of services from paragraph 1 of this Article shall be issued by the competent chamber subject to prior approval by the Minister.

The Ministry of Health is competent in the procedure of appeal against a first-instance decision.

## Article 138.b

A healthcare professional who is a national of the Republic of Croatia and who legally performs a healthcare activity in the territory of the Republic of Croatia shall be issued by the competent chamber a certificate of actual and legal performance of that activity in an

uninterrupted period of three years over the last five years.

Competent chambers shall issue certificates for the nationals of the Republic of Croatia whose evidence of formal education for a medical doctor, nurse in the field of general care, dental medicine doctor, pharmacist and midwife is not compatible with the profession (title) registered for the Republic of Croatia in accordance with the Act on Regulated Professions and Recognition of Foreign Professional Qualifications.

The certificate from paragraph 2 of this Article shall determine that the formal qualifications have been issued on the basis of the successful completion of education in accordance with the Act on Regulated Professions and Recognition of Foreign Professional Qualifications.

### Article 139

Healthcare professionals may undergo specialisation in a specific branch of healthcare and specific branches of sub-specialisation.

The branches of specialisation, duration and programme of specialisation and subspecialisation shall be laid down by the Minister in an ordinance at the proposal of the competent chamber and professional associations.

#### Article 140

Specialisation may be granted to a healthcare professional who received s licence for independent work and who is employed by a healthcare institution or a company engaged in the provision of healthcare or who has a private practice or works for a private practice healthcare professional holding a university graduate degree.

The specialisation may be granted by the Minister to the healthcare professional referred to in paragraph 1 of this Article who is not employed in a healthcare institution or a company engaged in provision of healthcare or who does not have a private practice or does not work for a private practice healthcare professional holding a university graduate degree, for one's own purposes, for the purposes of the Ministry, the ministry competent for defence, the ministry competent for justice, the ministry competent for the interior, the ministry competent for the family and veterans' affairs, the ministry competent for science and education, the ministry competent for the environment, the State Institute for Radiologica and Nuclear Safety, the Agency for Medicinal Products and Medical Devices, the Agency for Quality and Accreditation in Healthcare, healthcare-oriented faculties, scientific legal persons, legal persons engaged in the production and trade of medicinal products and medical devices, legal persons engaged in the activities of health insurance and administrative bodies of the units of regional self-government competent for healthcare.

The approval for specialisation (and sub-specialisation) shall be given by the Ministry on the basis of the annual plan of required specialisations and sub-specialisations. This plan shall be adopted at the proposal of scientific institutions, the Institute and the competent chamber.

The approval referred to in paragraph 3 of this Article shall be given by a decision against which no appeal is admitted, but against which an administrative dispute may be initiated.

The specialisation and sub-specialisation may be performed only in authorised healthcare institutions and companies, as well as with authorised private practice healthcare professionals.

The Minister shall lay down, in an ordinance, criteria for admitting specialisation interns and the manner of taking the specialisation examination or the examination of sub-specialisation, and designate authorised healthcare institutions, companies and private practice healthcare professionals authorised to organise the implementation of specialisation internship.

For the purposes of the pharmaceutical activity, a part of the specialisation may be performed with legal persons who are engaged in the production or control of medicinal products.

#### Article 141

The time spent on postgraduate studies shall be recognised as a period of specialisation for a specific specialisation or sub-specialisation either fully or partially, provided that the programme of postgraduate studies corresponds to the specialisation programme or sub-specialisation programme.

A part of the internship of doctors of medicine who have completed a five-year study of medicine served through the second year of internship in the duration of at least six months shall count into their specialisation service.

The Ministry shall issue a decision recognising the period referred to in paragraph 2 of this Article.

The appeal against the decision referred to in paragraph 3 of this Article shall not be admitted, but an administrative dispute may be initiated.

## Article 142

After a successfully completed specialisation internship, the candidate shall take a specialisation examination before the commission and acquire the right to the title of a specialist of a specialisation.

After a successfully completed programme of sub-specialisation, the candidate shall take an examination before the commission and acquire the right to the title from the field of his sub-specialisation.

Members of the commission referred to in paragraphs 1 and 2 of this Article shall be appointed by the Minister from amongst the recognised experts of specific specialisations, primarily from amongst the teachers in the scientific-academic profession of full-time professor, part-time professor or assistant professor.

# Article 143

The Ministy may recognise internship served abroad either fully or partially if the programme of internship served abroad does not substantially differ from the programmes valid in the territory of the Republic of Croatia.

The provisions of paragraph 1 of this Article shall not apply to citizens of the Member States of the European Union.

The Ministry may either fully or partially recognise specialisation or sub-specialisation served abroad, subject to prior opinion of the competent chamber, if the programme of specialisation internship served abroad does not substantially differ from the programme valid in the territory of the Republic of Croatia.

#### Article 144

Doctors of medicine - specialists and doctors of dental medicine - specialist who have ten years of working experience in the capacity of specialists, who have published scientific and professional papers and who have had successful results in the professional development of healthcare professionals may receive the title of a primarius.

The decision on the recognition of the title of a head doctor shall be made by the commission appointed by the Minister from amongst the teachers at the faculties of medicine and dental medicine and prominent medical and dental medicine experts.

The Minister shall lay down in an ordinance the criteria for the recognition of the title of a primarius.

# XV PRIVATE PRACTICE

# Article 145

Any healthcare professional holding a university graduate degree may carry on private practice independently subject to the fulfilment of the following requirements:

- 1. he possesses the relevant healthcare education, has passed the state examination, and in the case of a specialist doctor's offices, the relevant specialist examination and licence for independent work,
- 2. he is a citizen of the Republic of Croatia,
- 3. he possesses working capacity for engaging in private practice,
- 4. he possesses full legal capacity,
- 5. no security measure or protective measure of prohibition to provide healthcare or a protective measure of removal was issued against him pursuant to a final court decision, for the duration of the measures,
- 6. he is not employed, i.e. he does not perform other independent activities,
- 7. he has the appropriate premises,
- 8. he has the appropriate medical-technical equipment,

9. he has obtained the opinion of the Institute and the competent chamber on the justifiability of establishment of his private practice in the public healthcare service network or the opinion of the competent chamber on the justifiability of establishment of his private practice outside the public healthcare service network.

The requirement of having passed the state examination referred to in paragraph 1 of this Article shall not apply to citizens of the Member States of the European Union.

Citizens of the Member States of the European Union shall be proficient in the Croatian language at least at the level needed to ensure unhindered and essential communication with the patient.

Aliens may engage in private practice according to the regulations which govern the work of aliens in the Republic of Croatia, subject to the requirements referred to in paragraph 1 of this Article, save for the requirements referred to in item 2 of the same paragraph, provided that they satisfy the requirement of proficiency in the Croatian language.

#### Article 146

Doctors of medicine and doctors of dental medicine shall have their private practice in private doctor's offices, pharmacists in private pharmacies, and graduate engineers of medical biochemistry in private medical-biochemical laboratories.

By way of derogation from paragraph 1 of this Article, apart from their private office, doctors of dental medicine may also establish a dental technical laboratory for the purpose of engaging in approved private practice.

Doctors of dental medicine shall employ an appropriate number of dental technicians in the dental technical laboratory referred to in paragraph 2 of this Article in accordance with the ordinance referred to in Article 148, paragraph 5 of this Act.

#### Article 147

Healthcare professionals holding a bachelor's degree and healthcare professionals with secondary school qualifications may engage in private practice in the field of their qualifications, specifically:

- nurses.
- senior dentists, dental technicians,
- physical therapists.

Physical therapists may engage in private practice in the field of their qualifications independently, in accordance with the instructions of a specialist in physical medicine and rehabilitation.

Nurses referred to in paragraph 1 of this Article shall engage in the activities of caring for patients independently, in accordance with the instructions of doctors of medicine.

The healthcare professionals referred to in paragraph 1 of this Article shall have the relevant healthcare education, hold the state examination certificate and satisfy the requirements referred to in Article 145, paragraph 1, items 2 through 9 of this Act.

The requirement of having passed the state examination referred to in paragraph 4 of this Article shall not include citizens of the Member States of the European Union.

Citizens of the Member States of the European Union shall be proficient in the Croatian language at least at the level needed to ensure unhindered and essential communication with the patient.

Healthcare professionals holding a bachelor's degree and healthcare professionals holding secondary school qualifications who are aliens may engage in private practice according to the regulations which govern the work of aliens in the Republic of Croatia, subject to the requirements referred to in Article 145, paragraph 1, item 1 and items 3 through 9 of this Act, provided that they satisfy the requirement of proficiency in the Croatian language.

#### Article 148

The application for engaging in private practice shall be submitted to the Ministry which establishes in a decision whether the conditions for engaging in private practice referred to in Articles 145 and 147 of this Act are satisfied.

To the application for engaging in private practice, healthcare professionals shall enclose the evidence on being in possession of the premises and an opinion on the justifiability of establishing the private practice concerned in the public healthcare service network, which are issued by the Institute and the competent chamber, and an opinion on the justifiability of establishing a private practice which is outside the public healthcare service network which is issued by the competent chamber.

The decision referred to in paragraph 1 of this Article shall stipulate fulfilment of the requirements for the commencement of work in view of space, workers and medical-technical equipment.

The appeal against the decision referred to in paragraph 1 of this Article shall not be admitted, but an administrative dispute may be initiated.

Requirements for engaging in private practice in terms of premises, workers and medical-technical equipment, subject to prior opinion of the competent chambers, shall be laid down by the Minister in an ordinance.

#### Article 149

Private practice healthcare professionals shall state in their name their first and last name, address of the private practice, indication of the activity and working hours.

Article 150

Healthcare professionals referred to in Article 145 of this Act may have only one office, pharmacy or medical-biochemical laboratory, and healthcare professionals referred to in Article 147 of this Act may have only one private practice related to their profession.

Healthcare professionals referred to in paragraph 1 of this Article shall engage in their private practice in person.

In the same practice, pharmacy or medical-biochemical laboratory, two teams of healthcare professionals of the same profession may engage in private practice in shift work.

Healthcare professionals referred to in Article 145 of this Act may engage in private practice in a team with one or more healthcare professionals with secondary school qualifications or a bachelor's degree.

By way of derogation from paragraph 2 of this Article, healthcare professionals from Articles 145 and 147 of this Act engaged in provision of healthcare services both in and outside the public healthcare service network, and who provide healthcare services in tourism in accordance with special regulations, may employ one more person of the same profession for the provision of healthcare services in tourism.

Healthcare professionals from Articles 145 and 147 of this Act engaged in provision of healthcare services in the public healthcare service network and who provide healthcare services in tourism, may provide healthcare services in tourism only out of the full working time agreed with the Institute.

# Article 151

Private practice healthcare professionals holding a concession to provide public healthcare services may generate funds:

- pursuant to a contract with the Institute on the provision of healthcare,
- pursuant to a contract with a health centre for providing healthcare in a specific area or over a specific time period of providing healthcare, for implementing the programme of health improvement, prevention and early detection of diseases, for house calls and for cooperation with the out-patient service and work in the out-patient activity,
- pursuant to a contract with a regional self-government unit,
- pursuant to a contract with voluntary insurers,
- pursuant to a contract with faculties and other colleges in the field of healthcare,
- for work outside the agreed full working hours with the Institute, for the performance of activities for which they were granted licence for independent work,
- from the participation of healthcare beneficiaries in the coverage of a part or total healthcare costs.

The price of healthcare services for the activities of private practice in which there is no contractual healthcare professional shall be fixed by the competent chamber.

The price of healthcare services from the scope of private health insurance shall be fixed by the insurance company, subject to prior approval by the competent chamber.

#### Article 152

Several healthcare professionals, who are engaged in private practice in person, may join into a group private practice.

The conditions for the establishment of a group private practice referred to in paragraph 1 of this Article shall be laid down by the Minister in an ordinance, subject to prior opinion of the competent chambers.

The decision on the establishment of a group private practice shall be adopted by the Minister.

The appeal against the decision referred to in paragraph 3 of this Article shall not be admitted, but an administrative dispute may be initiated.

# Article 153

A group private practice engaged in the public healthcare service under a concession may generate funds for work:

- pursuant to a contract with the Institute on the provision of healthcare,
- pursuant to a contract with a health centre for providing healthcare in a specific area or over a specific time period of providing healthcare, for implementing the programme of health improvement, prevention and early detection of diseases, for house calls and for cooperation with the out-patient service and work in the out-patient activity,
- pursuant to a contract with a unit of regional self-government,
- pursuant to a contract with voluntary insurers,
- pursuant to a contract with faculties and colleges in the field of healthcare,
- for work outside the agreed full working hours with the Institute, for the performance of activities for which the healthcare professionals in the group private practice received the licence for independent work,
- from the participation of healthcare beneficiaries in the coverage of a part of or total healthcare costs.

#### Article 154

Healthcare professionals who have complete university graduate studies and who are engaged in private practices may perform the activities pertaining to their profession in healthcare

institutions and companies engaged in the provision of healthcare pursuant to a special contract with the healthcare institution or the company.

The conditions for the performance of the activities referred to in paragraph 1 of this Article shall be laid down by the Minister in an ordinance, subject to prior approval by the competent chamber.

#### Article 155

In the event of absence or suspension of work, any private practice healthcare professional who engaged in the provision of healthcare as the doctor of choice shall provide for a replacement for the insured persons who selected him through a contract with another private practice healthcare professional of the same profession and specialisation or with a healthcare institution of primary healthcare or a company engaged in the provison of healthcare who shall provide healthcare services to such persons during his absence.

#### Article 156

Private practice healthcare professionals shall:

- 1. provide emergency medical assistance which falls within their professional qualifications,
- 2. participate, upon the request of the competent body, in work on the prevention and suppression of infectious diseases and in the protection and rescue of the population in the case of disasters,
- 3. maintain medical records and other records on persons to whom they provide healthcare services and submit reports to the competent healthcare institution in accordance with the regulations on records in healthcare,
- 4. provide information concerning their work upon the request of the competent body.

## Article 157

Private practice healthcare professionals may suspend their work on a temporary basis.

The work may be suspended on a temporary basis on the grounds of illness, military service, if the healthcare professional is elected or appointed to a permanent duty in certain bodies of state authorities or unit of local and regional self-government, if he receives a salary for such work or if he finds employment in a consular post or diplomatic mission, or for other justified reasons. If he should be absent from work for more than 30 working days in a row in the course of one year, the healthcare professional shall notify the Minister accordingly.

A healthcare professional shall submit a request for a temporary suspension of work at least eight days following the expiry of the deadline from paragraph 2 of this Article or three days after the termination of the grounds that prevented him from doing that.

Suspension may last four years at the most.

The decision on suspension of work shall be issued by the Minister.

The appeal against the decision referred to in paragraph 5 of this Article shall not be admitted, but an administrative dispute may be initiated.

#### Article 158

The right to perform private practice terminates:

- 1. by de-registration,
- 2. by force of law,
- 3. pursuant to the decision of the Minister.

#### Article 159

The right to perform private practice by force of law terminates if the person holding the approval for work:

- 1. dies,
- 2. permanently loses his working capacity to perform the activities concerned,
- 3. loses his legal capacity either fully or partly,
- 4. loses the licence for independent work,
- 5. becomes employed or begins to perform another independent activity, except in the case of the suspension of work referred to in Article 157 of this Act, if the person is elected or appointed to a permanent duty in certain bodies of state authorities or units of local and regional self-government, if he receives a salary for such work, or if he finds employment in a consular post or a diplomatic mission,
- 6. loses the right to use the premises or the medical-technical equipment,
- 7. is sentenced to imprisonment by a court judgment with final force and effect for a term longer than six months or if a protective measure of security or a protective measure of prohibition to perform healthcare activity is issued against him.

The right of healthcare professionals to be engaged in private practice in the public healthcare service network shall terminate by force of law when they turn 65 years of age and generate 20 years of insured working service. Without prejudice to the foregoing, where the provision of healthcare is jeopardised, the Minister may approve extension of the performance of private practice to such healthcare professionals up to and including 70 years of age.

The decision on termination of the right to perform private practice by force of law shall be issued by the Minister.

The appeal against the decision referred to in paragraph 3 of this Article shall not be admitted, but an administrative dispute may be initiated.

#### Article 160

The Minister shall issue the decision terminating the approval for the performance of private practice if the defects identified in the performance of activities are not remedied within the time limit fixed in the decision of the competent body.

The Minister may issue the decision terminating the approval for the performance of private practice against a healthcare professional if:

- 1. he fails to comply with Articles 155, 156 and 157 of this Act,
- 2. he ceases to work without the approval by the Minister,
- 3. he does not perform the activities personally or if he takes advantage of the work of other persons contrary to the approval and law,
- 4. he has more than one office, pharmacy or medical-biochemical laboratory or more than one private practice in his profession,
- 5. he advertises his work and his office, pharmacy or medical-biochemical laboratory contrary to the act passed by the competent chamber,
- 6. at the proposal of the competent chamber,
- 7. at the proposal of the Institute for private healthcare professionals in the public healthcare service network.

The appeal against the decision referred to in paragraphs 1 and 2 of this Article shall not be admitted, but an administrative dispute may be initiated.

#### Article 161

Private practice may not be performed for the following activities:

- 1. taking, keeping, transporting and transplanting cells, tissue and organs with the aim of treatment,
- 2. collecting blood and plasma for the processing and supply of blood and blood products,
- 3. public health, epidemiology, school medicine, protection of mental health, prevention and out-patient treatment of addiction and house calls,
- 4. emergency medicine.

XVI ORGANISATION OF WORK AND WORKING HOURS IN THE PUBLIC HEALTHCARE SERVICE NETWORK

Healthcare institutions and companies engaged in the provision of healthcare in the public healthcare service network shall provide healthcare on a continuing basis by working in one, two or several shifts, by re-arranging working hours, by being on alert or on duty based on the needs of the population and the forms of providing healthcare services.

Being on duty is a form of work where the worker must be present in the healthcare institution after the regular working hours. Duty begins after the first or the second shift and ends when the first shift begins.

Being on alert is a form of work where the worker does not have to be present in the healthcare institution, but has to be available to provide emergency medical assistance.

The time spent on duty and on alert is considered as working hours.

The maximum duration of working hours per week, including work on duty and on alert, may not exceed 48 hours.

Exceptionally, if this is necessary in view of the needs of work, the maximum duration of the working hours per week, including work on duty and on alert, may exceed 48 hours, provided that the worker agrees in writing in advance.

Remuneration for work on duty and remuneration for work on alert shall form part of the salary.

Work on call is a form of work where the worker does not have to be available to his employer, but must respond to a call to perform the activity if he is physically able to do so.

Healthcare professionals may not leave their place of work until they have a replacement, although their working hours might have ended, if that would jeopardise the safety of providing healthcare.

The beginning, the end and the schedule of working hours of healthcare institutions and private practice healthcare professionals in the public healthcare service network shall be laid down by the Minister in an ordinance, subject to prior opinion of the competent chamber.

#### Article 162.a

Until the amount of the payment on the basis of the work on duty and work on alert, i.e. the compension for preparedness, is regulated by a collective agreement, the amount of that payment and the compensation shall be laid down by the Minister in a decision, subject to prior opinion of the trade unions.

The prior approval by the trade union shall be required for the first and each next amendment to the decision from paragraph 1 of this Article.

If trade unions fail to submit their opinion within 15 days of the request to submit an opinion from paragraph 1 of this Article or the approval from paragraph 2 of this Article, it shall be considered that they have given a positive opinion.

The trade unions with the majority of members from among the employees in healthcare and health insurance, determined in line with a special regulation, or, should there be no such information or regulation, by the trade unions signatories to the Collective Agreement for healthcare and health insurance (Official Gazette 9/05, 20/06, 156/09, 52/10 and 7/11), shall issue the opinion from paragraph 1 of this Article or the approval from paragraph 2 of this Article.

#### Article 163

Healthcare institutions shall establish the manner of providing healthcare in their general acts, specifically:

- in the activity of emergency medicine, continuously 24 hours a day, and work on alert and duty in line with the needs of the population,
- in the primary healthcare activity, by organising work in one or two shifts, by re-arranging working hours, by continuous being on alert and on duty in line with the needs of the population,
- in specialist-consultation healthcare, by organising work in one or two shifts and by rearranging the working hours in line with the needs of the population,
- in the hospital healthcare activity, in one or several shifts, by being on alert and on duty in line with the needs of the population and specific forms of hospital treatment and the capacity of the healthcare institution.

## Article 164

With a view to managing and coordinating the work of healthcare institutions and private practice healthcare professionals in major incidents/crisis situations, the crisis headquarters of the Ministry (hereinafter: the crisis headquarters) shall be formed.

A major incident/crisis situation is any event which is a serious threat to human health in a particular community and which causes or might cause such a number or type of victims which could not be treated by regular organisation of work in healthcare institutions and private practices healthcare professionals.

Members of the crisis headquarters shall be appointed by the Minister.

The organisational structure and the method of work of the crisis headquarters shall be laid down by the Minister in an ordinance.

#### Article 165

In the event of extraordinary circumstances, catastrophes and epidemics of larger proportions, the Minister is authorised to take measures and activities which are not laid down in this Act, including measures involving mobilisation, the organisation and schedule of work and working hours, changes in the place and conditions of work of individual healthcare institutions and healthcare professionals, for the duration of such circumstances.

#### Article 166

No strikes shall be permitted in the Croatian Institute of Emergency Medicine, institutes for emergency medicine in the units of regional self-government and in contracted emergency medicine services in healthcare institutions.

A strike in other activities of healthcare institutions may not begin before the finalisation of the procedure of conciliation according to the general regulations on strikes.

With respect to the healthcare activities of healthcare institutions, other than the activity of emergency medicine, the Ministry shall determine, within three days of the announcement of a strike and subject to prior opinion of the trade union, activities which are vital and which must be performed on an ongoing basis in order to prevent the endangerment of human life or the onset of patients' disability.

If the trade union does not accept the decision of the Ministry referred to in paragraph 3 of this Article, it may file a complaint with the special arbitration within 48 hours of the receipt of the decision.

The arbitration referred to in paragraph 4 of this Article shall have five members, two of whom are appointed by the Ministry and the trade union, while the chairman of the arbitration is appointed by the president of the Supreme Court of the Republic of Croatia.

The arbitration shall issue an award on the complaint of the trade union within three days from the day of receipt of the complaint. The arbitration award is final.

The remaining part of the procedure in conducting a strike shall proceed in accordance with the general regulations on strikes.

Healthcare professionals performing the activities which must be performed during a strike in accordance with paragraph 3 of this Article shall execute orders issued by the Ministry during the strike.

The employment of any healthcare professional who fails to execute an order of the Ministry shall terminate.

## XVII SUPERVISION

#### Article 167

The supervision of work of healthcare institutions, companies engaged in the provision of healthcare, healthcare professionals in healthcare institutions and private practice healthcare professionals shall include:

- internal supervision,
- professional supervision by the chamber,
- health-inspection supervision.

### **Internal Supervision**

#### Article 168

The healthcare institution and the company engaged in the provison of healthcare shall perform internal supervision of the work of their organisational units and healthcare professionals.

The manager, the management board or the person authorised to run the operations of the company are responsible for the professional work of the healthcare institution or the company engaged in the provision of healthcare.

#### Article 169

The internal supervision shall be performed on the basis of the general act of the healthcare institution or the company engaged in the provision of healthcare and the annual plan and programme of implementation of internal supervision.

The general act referred to in paragraph 1 of this Article establishes the manner of performance of internal supervision.

The healthcare institution and the company engaged in the provision of healthcare shall forward the annual plan and programme of implementation of internal supervision to the Ministry at the latest by 31 December of the current year for the following year.

Professional Supervision by the Chamber

## Article 170

Professional supervision over the quality and type of healthcare services provided by healthcare institutions, companies engaged in the provision of healthcare and private practice healthcare professionals in rendering immediate healthcare to citizens is performed by the competent chamber.

The professional supervision referred to in paragraph 1 of this Article shall be performed in accordance with the general acts of the chamber, to which the Minister provides his consent.

In the event of a professional failure by the healthcare professional or in the event of a violation of the principle of medical ethics and deontology, measures shall be issued in accordance with the acts of the competent chamber.

#### Health Inspection

#### Article 171

Health-inspection supervision over the application and enforcement of laws, other regulations and general acts in the activity of healthcare, as well as the supervision over the professional work of healthcare institutions, companies engaged in the provision of healthcare, healthcare professionals and private practice healthcare professionals shall be conducted by the Ministry – health inspection.

The tasks of health-inspection supervision referred to in paragraph 1 of this Article shall be performed by senior health inspectors, health inspectors and other state officials authorised to perform the supervision.

In the event of a professional failure by the healthcare professional or in the event of a violation of the principles of medical ethics and deontology, senior health inspector or health inspector shall refer the matter to the competent chamber for further proceedings.

#### Article 172

Any person holding a university graduate degree in medicine or law and with at least four years of working experience in the profession, who passed the state examination, may be appointed as senior health inspector.

Any person holding a university graduate degree in medicine or law and with at least three years of working experience in the profession, who passed the state examination, may be appointed as health inspector.

#### Article 173

The Minister shall authorise the appropriate healthcare professionals, healthcare associates and other experts or healthcare institutions to perform specific actions regarding health-inspection activities if special expertise is required for their performance.

## Article 174

The senior health inspector and the health inspector (hereinafter: the inspector) shall have an official identity card to prove their official capacity, identity and powers.

The form and the content of the official card and the manner of issuing and keeping the register of issued official cards shall be laid down by the Minister in an ordinance.

## Article 175

In the performance of inspection, the inspector is independent and conducts the procedure, issues decisions and takes measures within the rights, duties and powers laid down in this Act or other regulations.

The Minister shall determine the annual programme of work of the health inspection.

Health-inspection over the work of healthcare institutions shall be conducted at least once a year.

#### Article 176

Healthcare institutions, companies and private practice healthcare professionals subject to inspection shall enable the inspector to perform the inspection and provide him with the needed information and notifications.

In the performance of inspection, the inspector reviews business premises, facilities, machines and equipment, and the records and acts of the healthcare institution, the company or the healthcare professional.

During the inspection, in order to prevent the concealing of evidence, the inspector is entitled to temporarily seize items and the original documents, provided that he issues the relevant receipt.

#### Article 177

During the inspection, the inspector shall act in such a way that he does not jeopardise the keeping of a state, military, official or professional secret.

Healthcare institutions, companies and healthcare professionals shall notify the inspector of the data which are regarded as a secret in accordance with their general acts.

#### Article 178

The healthcare inspection shall in particular:

- 1. follow and observe the performance of the healthcare activity and take measures for its quality performance,
- 2. supervise the legality of work of healthcare institutions, companies and healthcare professionals in the performance of the healthcare activity,
- 3. review submissions of legal and natural persons regarding supervision within its competence and inform the submitter in writing about the measures and actions taken.

#### Article 179

In the performance of inspection, the inspector shall in particular supervise:

- 1. admission, treatment and discharge of patients,
- 2. the use of the means and methods for prevention, diagnostics, therapy and rehabilitation,
- 3. the way of prescribing medicinal products and medical devices,
- 4. the use of the means and methods of performing laboratory analysis and other diagnostic methods, their conformity to the relevant standards,
- 5. the way of keeping and using the relevant medical documents and records,
- 6. the organisation and performance of internship and specialised internship of healthcare professionals,
- 7. other issues important for establishing and evaluating the quality of work and the way of providing healthcare.

#### Article 180

In the performance of inspection referred to in Article 179 of this Act, the inspector shall have the right and obligation to:

- 1. temporary prohibit work in order to remedy the established irregularities and defects,
- 2. prohibit the implementation of measures and actions contrary to law or other regulations,
- 3. prohibit the work of a healthcare institution, company and private practice healthcare professional who no longer satisfies conditions with respect to its premises, workers and medical-technical equipment,
- 4. prohibit independent work of a healthcare professional who does not have the licence for independent work,
- 5. prohibit the work of a healthcare institution, company and a healthcare professional who does not ensure the quality and content of healthcare services,
- 6. propose to the competent chamber the implementation of a procedure with the aim of establishing the need for additional professional training of a healthcare professional or the need to repeat the verification of his professional competence.
- 7. prohibit the work and propose to the chamber the revocation of the licence for independent work of a healthcare professional,
- 8. prohibit the performance of the healthcare activity if it is performed without the prescribed approval,
- 9. order the healthcare professional or healthcare associate to undergo an examination to determine his health capacity if it is suspected that he is no longer capable of performing the healthcare activity,
- 10. order the implementation of other measures authorised by this Act and other regulations.

If the established defects are not remedied within the fixed term, the inspector shall prohibit the performance of healthcare activities to the healthcare institution, a part of the healthcare institution, the company engaged in the provision of healthcare or the private practice healthcare professional.

If during inspection the inspector observes irregularities or violations of regulations, and if he is not authorised to act directly, he shall notify the competent state administrative authority of the observed irregularities or violations of regulations and request the initiation of a procedure and the implementation of the prescribed measures.

#### Article 181

The inspector shall draw up the report on the performed inspection.

The inspector shall forward a copy of the report to the manager of the healthcare institution, the management board or the person authorised to conduct the activities of the company and to the healthcare professional whose work was the subject of the supervision.

#### Article 182

In the performance of inspection activities, the inspector may also issue a verbal decision for the performance of specific security measures:

- 1. when danger to the health or life of people requires that a certain measure of security is taken immediately, without any delay,
- 2. when there is danger of concealing, replacement or destruction of evidence if the security measure is not taken immediately.

The inspector may order immediate enforcement of the verbal decision. The verbal decision must be entered in the report on supervision.

The inspector shall issue a written copy of the decision within eight days of the date of the entry of the measure in the report on supervision.

#### Article 183

The procedure conducted by the inspector is governed by the provisions of the General Administrative Procedure Act, unless certain issues are otherwise provided by this Act.

## Article 184

The appeal against the decision adopted by the inspector shall not be admitted, but an administrative dispute may be initiated.

#### Article 185

If the inspector justifiably suspects that by a violation of the regulation a minor offence or criminal offence was committed, he shall submit without any delay and at the latest within 15 days of the supervision which established the facts critical for the implementation of measures, in addition to the decision he is authorised to issue, a motion to indict for the initiation of a minor offence procedure or a crime report for the initiation of a criminal procedure.

The authority to which the motion to indict or a crime report referred to in paragraph 1 is submitted shall notify the Ministry about the outcome of the procedure.

#### Article 186

The inspector shall keep a register of the inspections and measures taken, the content, form and manner of keeping of which shall be laid down by the Minister in an ordinance.

If in performing inspection the health inspector encounters physical resistance, the health inspector is authorised to request assistance from an officer of the interior.

#### Article 188

The inspector shall be held accountable:

- 1. if during supervision he fails to take or order measures which he was obligated to take or order under law,
- 2. if he exceeds his legal powers,
- 3. if he does not file the report or fails to notify the competent authorities of the established irregularities or defects.

## XVIII DETERMINING THE CAUSE OF DEATH AND POST-MORTEM EXAMINATION

## Article 189

The time and cause of death shall be determined for each deceased person.

The time and cause of death shall be determined by a doctor of medicine.

Without prejudice to the foregoing, the time and cause of death may be determined by another competent healthcare professional in accordance with the method laid down by the Minister in an ordinance.

# Article 190

The representative body of the unit of regional self-government, at the proposal of municipal or town councils, shall appoint the required number of doctors of medicine or other healthcare professionals who are to be in charge of pronouncing death, and the time and cause of death of persons who died outside healthcare institutions.

The time and cause of death of persons who died in a healthcare institution shall be determined by the doctor of medicine of the healthcare institution concerned.

#### Article 191

Death must be reported without any delay by persons who lived together with the deceased person, by relatives or neighbours, and if there are no such persons, by any person who learns about such death.

The notification referred to in paragraph 1 of this Article shall be submitted to the doctor of medicine or the healthcare professional who is to determine the time and cause of death.

Whenever a person who pronounces death establishes that the death resulted from an infectious disease or as the result of violence, he shall immediately notify the state administration body competent for health or the police.

#### Article 192

The deceased may be buried only after pronouncement of death within the time period from 24 to 48 hours of the onset of death.

By way of derogation from paragraph 1 of this Article, subject to a special approval by the sanitary inspector, the burial may be performed even before the expiration of the 24-hour period or after the expiration of the 48-hour period from the onset of death.

Following the expiration of the 48-hour period from the onset of death, the remains of a deceased adult who gave his consent in life that his body could be used for scientific or teaching purposes after death may be buried.

The Minister shall issue an ordinance laying down the procedure and the manner of issuing the approval referred to in paragraph 3 of this Article.

By way of derogation from paragraph 3 of this Article, following the 48-hour period from the onset of death, the burial of a deceased person may be performed if in life he did not object in writing to taking of his body parts after death under the Act on Explantation and Transplantation of Parts of the Human Body for Therapeutic Purposes, and whose body was used for teaching purposes based on the approval of the ethics committee of a healthcare college, as there is no person who is obligated under law or contract to support and bury the deceased person or if the person does not have the right to be buried under special regulations or in another manner.

The healthcare college shall perform and bear the cost of the burial of the deceased person referred to in paragraphs 3 and 5 of this Article, in full respect of the dignity of the deceased, in conformity with local and religious customs.

### Article 193

Post-mortem examinations of the deceased shall be performed to determine the cause of death.

Post-mortem examinations shall be performed:

- 1. whenever there is suspicion or whenever it is obvious that the death resulted from a criminal offence or is related to a criminal offence,
- 2. whenever necessary to protect human health or when required by epidemiological, sanitary and other professional medical reasons,
- 3. whenever the family of the deceased requests such an examination,
- 4. if the person died in a healthcare institution.

Funds for the post-mortem examination referred to in paragraph 2, items 1 and 2 of this Article shall be provided from the state budget.

The post-mortem examination referred to in paragraph 2, item 4 of this Article shall be performed at the cost of the person obligated to pay the costs of treatment of the deceased, and the post-mortem examination referred to in paragraph 2, item 3 of this Article at the request and cost of the family of the deceased if the death occurred outside the healthcare institution.

By way of derogation from paragraph 4 of this Article, if a person dies in a healthcare institution and he participated in the clinical trial of a particular medicinal product or medical device or in some other scientific research in a healthcare institution, the post-mortem examination shall be performed at the cost of the holder of the authority to conduct the clinical trial or scientific research under a separate law.

#### Article 194

If a person dies in a healthcare institution, the manager may decide at the request of the immediate family of the deceased, in agreement with the head of the organisational unit and the pathologist, that the post-mortem examination need not be performed.

By way of derogation from paragraph 1 of this Article, the post-mortem examination shall be performed:

- 1. in the event of unnatural death or death by unknown causes,
- 2. if death occurs during diagnostic or therapeutic treatment,
- 3. if death whose cause cannot be clearly determined from the existing medical records occurs within 24 hours of admission of the person to the healthcare institution,
- 4. if the person participated in the clinical trial of a medicinal product or a medical device or other scientific research in a healthcare institution,
- 5. in the event of death of a person whose body parts may be used for transplantation for therapeutic purposes under a separate law.

#### Article 195

The Minister shall issue an ordinance laying down the method of examining the deceased and determining the time and cause of death.

## Article 196

The death of any person who dies in a healthcare institution shall be reviewed on an individual basis by the expert board pertaining to the activity of the healthcare institution in which the person died. Medical records concerning the deceased, the opinion of the expert board and the report of the pathologist, if a post-mortem examination was performed, shall be

submitted to the committee for internal supervision of the healthcare institution at the latest within seven days from the onset of death.

The committee for quality of the healthcare institution shall review all the received medical documents, opinions and reports referred to in paragraph 1 of this Article on a monthly basis. The committee shall submit its final opinion concerning the death of each person to the Ministry at the latest by the end of the month which follows the month in which the death occurred.

The content of the form of the final opinion referred to in paragraph 2 of this Article shall be laid down by the Minister in an ordinance.

#### XIX THE CHAMBERS

#### Article 197

The Croatian Medical Chamber, the Croatian Dental Chamber, the Croatian Chamber of Pharmacists, the Croatian Chamber of Medical Biochemists, the Croatian Nursing Council, the Croatian Chamber of Midwives, the Croatian Council of Physiotherapists and other healthcare chambers (hereinafter: the chambers) are occupational organisations of healthcare professionals with the status of a legal person.

#### Article 198

Healthcare professionals holding a university graduate degree, those holding a bachelor's degree, and healthcare professionals with secondary school qualifications engaged in the healthcare activity in the territory of the Republic of Croatia shall have the duty to become members of the chambers referred to in Article 197 of this Act, unless provided otherwise by a separate law.

#### Article 199

The organisational structure, competence and operation of the chambers referred to in Article 197 of this Act shall be regulated in a separate law.

## XX PENAL PROVISIONS

## Article 200

A healthcare institution shall be fined for a minor offence in an amount from HRK 10,000.00 to HRK 50,000.00 in the following cases:

- 1. if it denies persons the rights referred to in Article 22 of this Act,
- 2. if it fails to ensure emergency medical assistance (Article 39),

- 3. if it begins to work before it is established in a decision that the requirements concerning the premises, workers and medical-technical equipment are satisfied (Article 50),
- 4. if it ceases to be engaged in the healthcare activity, contrary to the provision of Article 54 of this Act,
- 5. if it does not admit healthcare professionals for internship (Article 137, paragraph 2),
- 6. if it prevents a healthcare professional from receiving professional training (Article 138, paragraph 1),
- 7. if it concludes a contract with a healthcare professional holding university qualifications who is engaged in private practice contrary to the provision of Article 154 of this Act.
- 8. if it does not provide for the continuity of healthcare or permits healthcare professionals to leave their work posts even if there is no replacement, if that endangers the safety of providing healthcare (Article 162, paragraphs 1 and 9),
- 10. if it fails to conduct internal supervision of the work of its organisational units and healthcare professionals (Article 168, paragraph 1),
- 11. if it prevents an inspector from conducting inspection and refuses to provide the information and notifications required (Article 176, paragraph 1),
- 12. if it does not perform the ordered measures referred to in Article 180 of this Act,
- 13. if it does not perform the required post-mortem examination (Article 194, paragraph 2).

For minor offences referred to in paragraph 1 of this Article, the responsible person in the healthcare institution shall be also fined in an amount from HRK 5,000.00 to HRK 10,000.00.

Private practice healthcare professional shall be fined for a minor offence referred to in paragraph 1, items 1, 2, 5, 11 and 12 of this Article in an amount from HRK 5,000.00 to HRK 10,000.00.

#### Article 201

The manager of a healthcare institution shall be fined for a minor offence in an amount from HRK 5,000.00 to HRK 10,000.00 if:

- 1. he does not act further to the objection of a person who requested the protection of his rights in view of the quality, content and type of healthcare services and fails to notify the person having filed the objection of the measures taken at the latest within eight days (Article 23, paragraphs 4 and 5),
- 2. he fails to submit a written report to the Minister on a quarterly basis on the number of persons who died in the healthcare institution and on the number of post-mortem examinations performed (Article 63, paragraph 1).

The manager of a healthcare institution shall be fined for a minor offence in an amount from HRK 5,000.00 to HRK 10,000.00 if in extraordinary circumstances when the process of healthcare is endangered or if there is immediate danger to the life and health of people he fails to notify the Ministry and the Croatian National Institute of Public Health of the circumstances without any delay (Article 63, paragraph 2).

#### Article 203

A company engaged in the provision of healthcare shall be fined for a minor offence in an amount from HRK 10,000.00 to HRK 50,000.00 in the following cases:

- 1. if it denies persons the rights referred to in Article 22 of this Act,
- 2. if it fails to ensure emergency medical assistance (Article 39),
- 3. if it engages in the healthcare activity contrary to Article 117 of this Act,
- 4. if it begins to work before it is established in a decision that the requirements concerning the premises, workers and medical-technical equipment are satisfied (Article 121, paragraph 4),
- 5. if it engages in healthcare activity contray to the provison of Article 121, paragraph 6,
- 6. if it ceases to be engaged in the healthcare activity, contrary to the provision of Article 123 of this Act,
- 7. if it does not admit healthcare professionals for internship (Article 137, paragraph 2),
- 8. if it prevents a healthcare professional from receiving professional training (Article 138, paragraph 1),
- 9. if it concludes a contract with a healthcare professional holding university qualifications who is engaged in private practice contrary to Article 154 of this Act,
- 10. if it fails to conduct internal supervision of the work of its organisational units and healthcare professionals (Article 168, paragraph 1),
- 11. if it prevents an inspector from conducting inspection and refuses to provide the information and notifications required (Article 176, paragraph 1),
- 12. if it does not perform the ordered measures referred to in Article 180 of this Act.

For minor offences referred to in paragraph 1 of this Article, the responsible person in the company shall also be fined in an amount from HRK 5,000.00 to HRK 10,000.00.

#### Article 204

A private practice healthcare professional shall be fined for a minor offence in an amount from HRK 5,000.00 to HRK 10,000.00 in the following cases:

- 1. if he does not act further to the objection of a person who requested the protection of his rights in view of the quality, content and type of healthcare services and fails to notify the person having filed the objection of the measures taken at the latest within eight days (Article 23, paragraphs 4 and 5),
- 2. he engages in private practice, although he does not meet the requirements referred to in Articles 145 and 147 of this Act,
- 3. he begins to work before it is established in a decision that the requirements concerning the premises, workers and medical-technical equipment are satisfied (Article 148, paragraph 3),
- 4. he carries out activities contrary to the provision of Article 150 of this Act,
- 5. he does not provide for a substitute for the insured persons who selected him through a contract with another private practice healthcare professional in the same profession or with a healthcare institution or company engaged in the provision of healthcare (Article 155),
- 6. he acts contrary to the provisions of Article 156 of this Act,
- 7. he suspends his work without a decision of the Minister (Article 157),
- 8. he fails to comply with the decision of the Minister on termination of the approval to perform private practice work (Article 160),
- 9. he performs private practice work in an activity in which private practice is not permitted (Article 161).

## Article 205

Healthcare professionals shall be fined for a minor offence in an amount from HRK 5,000.00 to HRK 10,000.00 if they engage in work outside full working hours contrary to Article 96, paragraphs 1 and 2 of this Act.

#### Article 206

Any employer who fails to ensure healthcare measures in terms of safety at work and the working environment (Article 19) shall be fined for a minor offence in an amount from HRK 10,000.00 to HRK 40,000.00.

## Article 206.a

A heathcare worker who carries out the activities for his account from the scope of the employer's healthcare activities without the authorisation from Article 125, paragraph 1 of this Act shall be fined for a minor offence in an amount from HRK 10,000.00 to HRK 50,000.00.

Article 206.b

A heathcare worker who carries out the activities for his account from the scope of the employer's healthcare activities without the authorisation from Article 125.c of this Act shall be fined for a minor offence in an amount from HRK 10,000.00 to HRK 50,000.00.

For a minor offence from paragraph 1 of this Article committed for the second time in the period of two years following the legality of the decision on minor offence, the fine shall be accompanied with the protective measure of prohibition to carry out the activity for one's own account from the scope of employer's activities in the period of six months.

For a minor offence from paragraph 1 of this Article committed for the third time in the period of two years following the legality of the decision on minor offence, the fine shall be accompanied with the protective measure of prohibition to carry out the activity for one's own account from the scope of employer's activities in the period of one year.

#### Article 206.c

A healthcare institution or a company engaged in the provision of healthcare where the healthcare professional carries out his activities for his own account on the basis of the authorisation from Article 125, paragraph 1 of this Act, which acts contrary to the contract referred to in Article 125.c of this Act, shall be fined for a minor offence in an amount of HRK 50,000.00 to HRK 100,000.00.

For a minor offence from paragraph 1 of this Article, a fine in the amount of HRK 10,000.00 to 50,000.00 shall be also imposed on a private healthcare provider and a responsible person in the healthcare institution or the company engaged in the provision of healthcare.

For a minor offence from paragraph 1 of this Article committed for the second time in the period of two years following the legality of the decision on a minor offence, the fine shall be accompanied with the protective measure of prohibition to carry out the activity in the period of six months.

For a minor offence from paragraph 1 of this Article committed for the third time following in the period of two years following the legality of the second decision on a minor offence, the fine shall be accompanied with the prohibition to carry out the activity in which the minor offence was committed in a period of one year.

#### Article 206.d

A responsible person of the employer shall be fined for a minor offence in an amount from HRK 10,000.00 to HRK 50,000.00 if:

- he has issued the authorisation to a healthcare professional for the performance of activities for his own account from the scope of the employer's healthcare activities contrary to the criteria from Article 125.c of this Act,
- does not revoke the authorisation in the case referred to in Article 125.d of this Act.

XXI TRANSITIONAL AND FINAL PROVISIONS

Within a period of three months from the day of the entry into force of this Act, the Government of the Republic of Croatia shall establish the Croatian Institute of Emergency Medicine and appoint an interim manager who is to have the powers referred to in Article 15, paragraph 1 of the Institutions Act until the appointment of the manager.

The management board of the Croatian Institute of Emergency Medicine shall adopt its Articles of Association within 60 days from the day of registration of the Institute in the court register.

#### Article 208

Within a period of three months from the day of the entry into force of this Act, the Minister shall issue the Health Protection Plan for the Republic of Croatia.

#### Article 209

Within a period of three months from the day of the entry into force of this Act, the Minister shall set up the public healthcare service network.

## Article 210

Units of regional self-government shall issue a decision establishing the institute of emergency medicine within a period of three years from the day of the entry into force of this Act.

Institutions for emergency medical assistance founded under the Healthcare Act (Official Gazette 75/93, 55/96, 111/97, 95/00 and 129/00) shall change their activities and name into the institute of emergency medicine at the latest within a period of one year from the day of the entry into force of this Act.

As with the day they start their operations, the institutions for emergency medical assistance of the units of regional self-government shall take over the employees who carry out the emergency medical assistance or perform other assignments in order to carry out this activity in health centres in the territory of the units of regional self-government.

The institutes of emergency medicine of units of regional self-government and health centres of units of regional self-government, subject to approval by the competent body of the regional self-government unit shall determine the conditions, the methods of use and the use of the premises and the equipment used for the provision of emergency medical assistance and other rights and obligations arising from the provision of emergency medical assistance in health centres in the territory of regional self-government units.

The institutes of emergency medicine of the units of regional self-government shall begin with the work on 30 June 2012 at the latest.

The units of regional self-government shall conduct the procedure of granting the concession for the performance of the public healthcare service in accordance with the public healthcare service network by 30 June 2010 at the latest.

If the units of regional self-government fail to conduct the procedure of granting the concession within the time limit referred to in paragraph 1 of this Article, the procedure shall be conducted by the Ministry within six months of the expiration of the time limit referred to in paragraph 1 of this Article.

#### Article 212

The Minister shall pass the regulations within his authority under this Act within six months from the day of the entry into force of this Act.

#### Article 213

The units of regional self-government shall found the Health Counselling Service within six months from the day of the entry into force of this Act.

#### Article 214

Until the entry into force of the implementing regulations referred to in Article 212 of this Act, the following shall remain in force:

- 1. Ordinance on internship of healthcare professionals (Official Gazette 18/94, 20/94, 21/95, 47/95, 39/96, 62/96, 58/99, 130/99 and 11/03),
- 2. Ordinance on the criteria for admission of healthcare professionals for internship (Official Gazette 7/07),
- 3. Ordinance on specialised training of pharmacists (Official Gazette 73/08),
- 4. Ordinance on specialised training of doctors of medicine (Official Gazette 73/08),
- 5. Ordinance on specialised training of medical biochemists (Official Gazette 73/08),
- 6. Ordinance on specialised training of doctors of dental medicine (Official Gazette 115/07),
- 7. Ordinance on the acquisition of the status of a specialist of sub-specialisation (Official Gazette 128/06 and 26/07),
- 8. Ordinance on the standards for the recognition of the title od primarius (Official Gazette 66/05),
- 9. Ordinance on the control of expertise in work in healthcare (Official Gazette 40/94),
- 10. Ordinance on the content, form and method of keeping the records on inspections conducted by the healthcare inspector (Official Gazette 46/07),
- 11. Ordinance on the state examination for the healthcare inspector (Official Gazette 35/94),

- 12. Ordinance on the healthcare inspector official card (Official Gazette 76/05),
- 13. Ordinance on the criteria for the award and renewal of the title of reference centre of the ministry competent for health (Official Gazette 77/05 and 125/08),
- 14. Ordinance on the conditions to be met by healthcare institutions or parts of healthcare institutions for the award of the title of clinic or clinical institution (Official Gazette 119/03 and 11/04),
- 15. Ordinance on the conditions for the formation of institutes and departments in clinical hospital centres and clinical hospitals (Official Gazette 106/07),
- 16. Ordinance on the conditions for the formation of departments in general and specialised hospitals (Official Gazette 106/07),
- 17. Ordinance on working hours in healthcare institutions having a contract on the performance of healthcare services with the Croatian Institute for Health Insurance (Official Gazette 87/02 and 9/03),
- 18. Ordinance on the categorisation of medical-technical equipment of healthcare institutions (Official Gazette 55/07),
- 19. Ordinance on the professional title in the activity of occupational medicine (Official Gazette 106/04),
- 20. Order on mandatory notification of the beginning and end of working hours of healthcare institutions and private practice healthcare professionals (Official Gazette 19/99),
- 21. Ordinance on the manner of examining the deceased and determining the time and cause of death (Official Gazette 121/99, 133/99 and 112/00),
- 22. Ordinance on the conditions, organisation and method of engaging in telemedicine (Official Gazette 121/07).
- 23. Order on the conditions of procuring certain medical-technical equipment (Official Gazette 26/97 and 51/97),
- 24. Ordinance on the minimum requirements in terms of space, workers and medical-technical equipment for the performance of the healthcare activity (Official Gazette 90/04 and 38/08),
- 25. Instruction for the suppression and prevention of tuberculosis (Official Gazette 70/98 and 95/98),
- 26. Instruction for the implementation of the Programme for Explantation of Organs (Official Gazette 75/98),
- 27. Ordinance on the criteria for the admission of residents (Official Gazette 133/07),

28. Ordinance on the conditions, organisation and method of work of out-of-hospital emergency medical assistance (Official Gazette 146/03).

#### Article 215

Healthcare professionals who were issued the approval of the Minister for work in the units of health centres leased under the Ordinance on the conditions for leasing primary healthcare institutions and health resorts (Official Gazette 6/96, 29/97, 1/98, 45/99, 121/99, 112/00, 87/02, 150/02 and 7/03) and the Ordinance on the conditions and procedure for leasing parts of health centres and pharmaceutical healthcare institutions (Official Gazette 80/07) until the entry into force of this Act, shall terminate their work in private practices in lease on the day preceding the day of the Minister's approval for work of that healthcare professional in private practice on the basis of concession and on 31 December 2010 at the latest.

#### Article 216

Healthcare professionals who were issued the approval of the Minister for work in the units of health centres leased under the Ordinance on the conditions for leasing primary healthcare institutions and health resorts (Official Gazette 6/96, 29/97, 1/98, 45/99, 121/99, 112/00, 87/02, 150/02 and 7/03) and the Ordinance on the conditions and procedure for leasing parts of health centres and pharmaceutical healthcare institutions (Official Gazette 80/07) until the entry into force of this Act, specifically for the performance of activities which are not subject to the granting of a concession under Article 40, paragraph 2 of this Act, shall terminate the performance of such activities under the contract on the provision of healthcare with the Institute on expiration of the time limit referred to in Article 215 of this Act.

## Article 216.a

Healthcare professionals from Article 216 of this Act may, within 60 days of the entry into force of this Act, file a written statement to the manager of the health centre on their intention of employment in the health centre.

The health centre shall announce vacancies at the proposal of the manager of the health centre from paragraph 1 of this Article within 30 days following the expiry of the period from paragraph 1 of this Article.

Healthcare professionals referred to in Article 216 of this Act shall be given priority of employment in the health centre if they satisfy the requirements from the vacancy announcement referred to in paragraph 2 of this Article.

#### Article 216.b

Healthcare professionals from Article 216 of this Act who do not get employed in the health centre in accordance with Article 216.a of this Act may carry out healthcare activities in a private practice at the premises of the health centre where they carried out that activity until the entry into force of this Act and in accordance with the provisions of the general regulations on the lease of business premises.

The Ordinance on the conditions and procedure for leasing parts of health centres and pharmaceutical healthcare institutions (Official Gazette 80/07) shall cease to have effect on the date of expiration of a period of one year from the day of entry into force of this Act.

#### Article 218

The employment contracts of healthcare professionals who work on the team of the lessee of a leased unit in a health centre shall be transferred to the health centre as the employer who preceded the lessee as the employer in the event that the lessee does not continue to engage in the activity under a concessionin the leased unit in accordance with this Act, within 31 December 2010 at the latest.

#### Article 218.a

In accordance with the concession agreement, the employment contract of a health worker in the concessionaire's team shall be transferred to the health centre if the concessionaire's concession is terminated.

#### Article 219

Healthcare institutions shall align their articles of association with Article 59, paragraph 2, and Article 71 of this Act within six months from the day of the entry into force of this Act.

The management boards of healthcare institutions shall appoint the Quality Committee within six months from the day of the entry into force of this Act.

#### Article 220

Health centres shall align their articles of association with Article 78 of this Act within six months from the day of the entry into force of this Act.

#### Article 221

Doctors of medicine and nurses, who are engaged in the activity of emergency medical assistance on the day of entry into force of this Act, shall continue to engage in the activity of emergency medicine without the required specialisation at most up to the expiration of a period of ten years from the day of the entry into force of this Act.

### Article 222

Healthcare professionals who acquired the relevant professional qualifications or who acquired professional training in the relevant healthcare educational institutions until the entry into force of this Act may continue to engage in the activities of healthcare in accordance with the regulations valid until the entry into force of this Act.

## Article 223

Doctors of dental medicine who on the date of entry into force of this Act work in a team with a dental assistant shall continue to engage in the activities of dental medicine at the primary level in the same team.

#### Article 224

On the day of the entry into force of this Act, all provisions of the Healthcare Act (Official Gazette 121/03, 44/05, 48/05, 85/06 and 117/08), with the exception of Articles 70, 71, 72, 73, 74 and 75, and of the Ordinance on the method of announcing the work of private practice doctors and private practice healthcare institutions (Official Gazette 83/97) shall cease to have effect.

The Act referred to in paragraph 1 of this Article shall cease to have effect on 31 December 2009.

## Article 225

This Act shall be published in the Official Gazette and shall enter into force on 1 January 2009, with the exception of the provisions of Article 162, paragraphs 4, 5 and 6, which shall enter into force on 3 August 2011, and the provisions of Articles 133, 134, paragraph 2, Article 143, paragraph 2, Article 145, paragraphs 2 and 3, and Article 147, paragraphs 5 and 6 of this Act, which shall enter into force on the day of the accession of the Republic of Croatia to the European Union.

# THE TEXT THAT HAS NOT BEEN INCORPORATED IN THE CONSOLIDATED VERSION

## ACT ON AMENDMENTS TO THE HEALTHCARE ACT

(Official Gazette 71/10 of 10 June 2010)

## Article 27

Within three months of the day of the entry into force of this Act, the Minister shall set up the network of occupational medicine contractors and the network of telemedicine centres.

## Article 28

The Minister shall issue the ordinance as authorised under this Act within six months of the day of the entry into force of this Act.

## Article 29

Healthcare professionals who have been granted the Minister's approval for work in the leased units of health centres in the period from 1 January 2009 to 31 December 2009 in accordance with Articles 70, 71, 72, 73, 74 and 75 of the Healthcare Act (Official Gazette 121/03, 44/05, 48/05, 85/06 and 117/08) and the Ordinance on the conditions and the methods for leasing parts of health centres and pharmaceutical health institutions (Official Gazette 80/07) shall cease to work in leased private practices on the day preceding the day of the Minister's approval for their work in private practices on the basis of concession, and on 31 December 2010 at the latest.

Regional self-government units shall carry out the procedure for granting concession for the performance of occupational medicine in accordance with the network of occupational medicine contractors on 30 June 2011 at the latest.

If regional self-government units fail to carry out the procedure for granting concession within the deadline from paragraph 1 of this Article, the Ministry shall carry out this procedure within six months after the expiry of the deadline from paragraph 1 of this Article.

#### Article 31

Healthcare professionals who have been granted the Minister's approval for work in the leased units of health centres on the basis of the Ordinance on the conditions for the lease of primary healthcare institutions and resorts (Official Gazette 6/96, 29/97, 1/98, 45/99, 121/99, 112/00, 87/02, 150/02 and 7/03) and the Ordinance on the conditions and the methods for leasing parts of health centres and pharmaceutical health institutions (Official Gazette 80/07) until 31 December 2009 shall cease to work in leased private practices on the day preceding the day of the Minister's approval for their work in private practices on the basis of concession, and on 31 December 2011 at the latest.

#### Article 32

Healthcare institutions, healthcare professionals, companies engaged in provision of healthcare and private practice healthcare professionals involved in telemedicine shall harmonise their work with the provisions of this Act within two years of the day of the entry into force of this Act.

#### Article 34

The merger of the Croatian Institute of Mental Health and the Croatian Public Health Institute shall be carried out within 60 days of the day of the entry into force of this Act.

The employees of the Croatian Institute of Mental Health shall be taken over by the Croatian Public Health Institute on the day of registration of the expansion of its activities in the court register.

On the day of registration in the court register from paragraph 2 of this Article, the Croatian Public Health Institute shall take over the funds for salaries of transferred employees, equipment and obligations of the Croatian Institute of Mental Health.

### Article 35

On the day of the entry into force of this Act, the Croatian Institute of Telemedicine, established by the Regulation on the establishment of the Telemedicine Institute (Official Gazette 120/05 and 11/10) shall continue to operate in accordance with the provisions of this Act.

#### Article 36

On the day of the entry into force of this Act, the Regulation on amendments to the Healthcare Act (Official Gazette 155/09) and the Regulation on the establishment of the Telemedicine Institute (Official Gazette 120/05 and 11/10) shall cease to have effect.

#### Article 37

This Act shall enter into force on the eighth day after the day of its publication in the Official Gazette, except for Article 19 and Article 20 in a part where Articles 125.b, 125.c, 125.d and 125.e are added, which shall apply as of 1 February 2011.

## THE TEXT THAT HAS NOT BEEN INCORPORATED IN THE CONSOLIDATED VERSION

## ACT ON AMENDMENTS TO THE HEALTHCARE ACT

(Official Gazette 139/10 of 10 December 2010)

#### Article 12

If all healthcare professionals who performed pharmaceutical activities in leased units of health centres on the basis of the Ordinance on the conditions for lease of primary healthcare institutions and resorts (Official Gazette 6/96, 29/97, 1/98, 45/99, 121/99, 112/00, 87/02, 150/02 and 7/03) and the Ordinance on the conditions and the procedure for leasing parts of health centres and pharmaceutical health institutions (Official Gazette 80/07) cease to work, the pharmaceutical activities shall continue to be performed by health centres.

## Article 13

This Act shall enter into force on the eighth day after the day of its publication in the Official Gazette, except for Articles 1, 3, 4, 5 and 10 of this Act which shall apply as of 1 January 2011.

# THE TEXT THAT HAS NOT BEEN INCORPORATED IN THE CONSOLIDATED VERSION

## ACT ON AMENDMENTS TO THE HEALTHCARE ACT

(Official Gazette 22/11 of 18.12.2011)

#### Article 3

The deadlines stipulated by the provisions of Article 211, paragraph 1 and Articles 215 and 218 of the Healthcare Act (Official Gazette 150/08, 71/10 and 139/10) and Article 29 of the Act on Amendments to the Healthcare Act (Official Gazette 71/10) shall be extended so as to expire:

– on 30 June 2011 for conducting the procedure of granting of the concession for the performance of public healthcare services in line with the network of public healthcare services referred to in Article 211, paragraph 1 of the Healthcare Act (Official Gazette 150/08, 71/10 and 139/10),

- at the latest on 31 December 2011 for the cessation of work of a healthcare professional in private practice on the basis of lease from Article 215 of the Healthcare Act (Official Gazette 150/08, 71/10 and 139/10) and Article 29 of the Act on Amendments to the Healthcare Act (Official Gazette 71/10),
- at the latest on 31 December 2011 for the transfer of employment contracts of healthcare professionals in the team of the lessee of the leased unit in the health centre from Article 218 of the Healthcare Act (Official Gazette 150/08, 71/10 and 139/10),

The legal consequences laid down by Articles 211, 215 and 218 of the Healthcare Act (Official Gazette 150/08, 71/10 and 139/10) and Article 29 of the Act on Amendments to the Healthcare Act (Official Gazette 71/10) shall set in with the expiry of deadlines from paragraph 1 of this Article.

#### Article 4

The Minister shall issue the Ordinance from Article 2 of this Act within three months of the day of entry into force of this Act.

#### Article 5

This Act shall enter into force on the day of its publication in the Official Gazette.

# THE TEXT THAT HAS NOT BEEN INCORPORATED IN THE CONSOLIDATED VERSION

## ACT ON AMENDMENTS TO THE HEALTHCARE ACT

(Official Gazette 84/11 of 20 July 2011)

Article 6

The Minister shall adopt the decision from Article 3 of this Act within 30 days of the day of entry into force of this Act.

## Article 7

This Act shall enter into force on the eighth day after the day of its publication in the Official Gazette.

# THE TEXT THAT HAS NOT BEEN INCORPORATED IN THE CONSOLIDATED VERSION

#### REGULATION ON AMENDMENTS TO THE HEALTHCARE ACT

(Official Gazette 154/11 of 29 December 2011)

The deadlines stipulated by the provisions of Article 3 of the Act on Amendments to the Healthcare Act (Official Gazette 22/11) shall be extended so as to expire:

- on 30 June 2012 for conducting the procedure for granting of the concession for the performance of public healthcare services in line with the network of public healthcare services referred to in Article 211, paragraph 1 of the Healthcare Act (Official Gazette 150/08, 71/10, 139/10, 22/11 and 84/11), or in line with the network of occupational medicine contractors from Article 30, paragraph 1 of the Act on Amendments to the Healthcare Act (Official Gazette 71/10),
- at the latest on 31 December 2011 for the cessation of work of a healthcare professional in private practice on the basis of lease from Article 215 of the Healthcare Act (Official Gazette 150/08, 71/10, 139/10, 22/11 and 84/11) and Article 29 of the Act on Amendments to the Healthcare Act (Official Gazette 71/10),
- at the latest on 31 December 2011 for the transfer of employment contracts of healthcare professionals in the team of the lessee of the leased unit in the health centre from Article 218 of the Healthcare Act (Official Gazette 150/08, 71/10, 139/10, 22/11 and 84/11).

The legal consequences stipulated by Articles 211, 215 and 218 of the Healthcare Act (Official Gazette 150/08, 71/10, 139/10, 22/11 and 84/11), and Articles 29 and 30 of the Act on Amendments to the Healthcare Act (Official Gazette 71/10) shall set in with the expiry of deadlines from paragraph 1 of this Article.

#### Article 6

This Regulation shall enter into force on the day of its publication in the Official Gazette.

# THE TEXT THAT HAS NOT BEEN INCORPORATED IN THE CONSOLIDATED <u>VERSION</u>

## ACT ON AMENDMENTS TO THE HEALTHCARE ACT

(Official Gazette 12/12 of 26 January 2012)

#### Article 5

The deadlines stipulated by the provisions of Article 3 of the Act on Amendments to the Healthcare Act (Official Gazette 22/11) shall be extended so as to expire:

– on 30 June 2012 for conducting the procedure of granting of the concession for the performance of public healthcare services in line with the network of public healthcare services referred to in Article 211, paragraph 1 of the Healthcare Act (Official Gazette 150/08, 71/10, 139/10, 22/11 and 84/11), or in line with the network of occupational medicine contractors from Article 30, paragraph 1 of the Act on Amendments to the Healthcare Act (Official Gazette 71/10),

- at the latest on 31 December 2011 for the cessation of work of a healthcare professional in private practice on the basis of lease from Article 215 of the Healthcare Act (Official Gazette 150/08, 71/10, 139/10, 22/11 and 84/11) and Article 29 of the Act on Amendments to the Healthcare Act (Official Gazette 71/10),
- at the latest on 31 December 2011 for the transfer of employment contracts of healthcare professionals in the team of the lessee of the leased unit in the health centre from Article 218 of the Healthcare Act (Official Gazette 150/08, 71/10, 139/10, 22/11 and 84/11).

The legal consequences stipulated by Articles 211, 215 and 218 of the Healthcare Act (Official Gazette 150/08, 71/10, 139/10, 22/11 and 84/11), and Articles 29 and 30 of the Act on Amendments to the Healthcare Act (Official Gazette 71/10) shall set in with the expiry of deadlines from paragraph 1 of this Article.

#### Article 6

On the day of the entry into force of this Act, the Regulation on amendments to the Healthcare Act (Official Gazette 154/11) shall cease to have effect.

#### Article 7

This Act shall enter into force on the eighth day after the day of its publication in the Official Gazette.

# THE TEXT THAT HAS NOT BEEN INCORPORATED IN THE CONSOLIDATED VERSION

## ACT ON AMENDMENTS TO THE HEALTHCARE ACT

(Official Gazette 70/12 of 28 June 2012)

## Article 3

The Minister shall pass the regulations as authorised under this Act within two months of the day of entry into force of this Act.

#### Article 4

This Act shall enter into force on the eighth day after the day of its publication in the Official Gazette.

## THE TEXT THAT HAS NOT BEEN INCORPORATED IN THE CONSOLIDATED VERSION

REGULATION ON AMENDMENTS TO THE HEALTHCARE ACT

### (Official Gazette 144/12 of 21 December 2012)

#### Article 2

This Regulation shall enter into force on the day of its publication in the Official Gazette.

# THE TEXT THAT HAS NOT BEEN INCORPORATED IN THE CONSOLIDATED VERSION

## ACT ON AMENDMENTS TO THE HEALTHCARE ACT

(Official Gazette 82/13 of 30 June 2013)

#### Article 48

Healthcare professionals who finished the studies in medicine, dental medicine or pharmacy or those who completed education for a nurse or a midwife-assistant, which are not harmonised with the Act on Regulated Professions and Recognition of Foreign Professional Qualifications, and other healthcare professionals, shall do their internship and pass the vocational exam in accordance with Articles 130 to 132 of the Healthcare Act (Official Gazette 150/08, 71/10, 139/10, 22/11, 84/11, 12/12, 35/12 – Decision of the Constitutional Court of the Republic of Croatia, 70/12 and 144/12).

By way of derogation from paragraph 1 of this Article, healthcare professionals who finished the studies in medicine, dental medicine or pharmacy or those who completed education for a nurse or a midwife-assistant, which are harmonised with the Act on Regulated Professions and Recognition of Foreign Professional Qualifications, shall not be obliged to do their internship and pass their vocational exam in accordance with Articles 130 to 132 of the Healthcare Act (Official Gazette 150/08, 71/10, 139/10, 22/11, 84/11, 12/12, 35/12 – Decision of the Constitutional Court of the Republic of Croatia, 70/12 and 144/12).

#### Article 49

Healthcare professionals working in a private practice on the basis of the lease agreement from Article 215 of the Healthcare Act (Official Gazette 150/08, 71/10, 139/10, 22/11 and 84/11) and Article 29 of the Act on Amendments to the Healthcare Act (Official Gazette 71/10) may continue to carry out their healthcare activities in a private practice in a health centre or a pharmaceutical healthcare institution where they performed such activities until the day of the entry into force of this Act, in accordance with the provisions of the bylaws on lease of business premises.

Healthcare professionals working in a private practice on the basis of the lease agreement from Article 215 of the Healthcare Act (Official Gazette 150/08, 71/10, 139/10, 22/11 and 84/11) and Article 29 of the Act on Amendments to the Healthcare Act (Official Gazette 71/10) may continue to perform their healthcare activities in a private practice, in business premises which are not in the ownership of the health centre or the pharmaceutical healthcare institution where they performed such activities until the day of the entry into force of this Act, in accordance with the provisions of the bylaws on lease of business premises and on the basis of the proof of use of the mentioned premises.

Healthcare professionals working in a private practice on the basis of the lease agreement from Article 215 of the Healthcare Act (Official Gazette 150/08, 71/10, 139/10, 22/11 and 84/11) and Article 29 of the Act on Amendments to the Healthcare Act (Official Gazette 71/10) shall cease to work in a private practice on the basis of the lease agreement on **31 December 2017** at the latest.

Healthcare professionals working in a private practice on the basis of the lease agreement from Article 215 of the Healthcare Act (Official Gazette 150/08, 71/10, 139/10, 22/11 and 84/11) and Article 29 of the Act on Amendments to the Healthcare Act (Official Gazette 71/10) shall cease to work in a private practice on the basis of the lease agreement on **31 December 2017** at the latest.

By way of derogation from paragraph 1 of this Article, healthcare professionals from paragraph 1 of this Article who perform their activities outside the public healthcare service network, and who do not continue to perform their healthcare activities in a private practice in accordance with the bylaws on lease of business premises until **31 December 2017**, shall be given priority during the employment process in the health centre if there is a need for them to continue their activities in the health centre.

If healthcare professionals from paragraph 1 of this Article do not continue to perform their healthcare activity in a private practice in accordance with the bylaws on lease of business premises, until 31 December 2015, a doctor's office from the public healthcare service network or a pharmacy shall reenter the healthcare centre or the pharmaceutical healthcare institution.

If the right to perform the private practice granted to the lessee from paragraph 1 of this Article who performs a private practice on the basis of the lease agreement until 31 December 2015 is terminated in accordance with Article 158 of the Healthcare Act, employment contracts of healthcare professionals who are members of the lessee's team shall be transferred to the health centre as an employer preceding the lessee as an employer.

The Ordinance on the conditions for granting a healthcare professional from paragraphs 1 and 2 of this Article the approval to continue to work in a private practice shall be issued by the Minister.

#### Article 50

The ministry competent for health shall issue the Instructions on the methods for drafting and implementation of the business rescue programme of a healthcare institution within 10 days of the day of entry into force of the decision on the appointment of the members of the business rescue committee and the business rescue manager of the healthcare institution.

#### Article 51

The business rescue committee shall issue the draft business rescue programme for a healthcare institution at the proposal of the business rescue manager within 30 days of the day of the issuance of the Instructions on the methods for drafting and implementation of the business rescue programme of that healthcare institution.

The Government of the Republic of Croatia shall issue a decision appointing the members of the Coordination Body on Business Rescue Monitoring and shall determine its scope of work and decision-making procedures, as well as the duration of the term of office of the Coordination Body on Business Rescue Monitoring.

#### Article 53

The ministry competent for health shall issue the business rescue programme for a healthcare institution within 60 days of the day of receiving a positive opinion of the Coordination Body on Business Rescue Monitoring on the draft business rescue programme for the healthcare institution.

#### Article 54

During the business rescue procedure, the healthcare institution may submit the draft amendments to the business rescue programme to the Coordination Body on Business Rescue Monitoring.

The Ministry of Health shall issue the amendments to the business rescue programme within 30 days of receiving a positive opinion of the Coordination Body on Business Rescue Monitoring on the draft amendments to the business rescue programme for the healthcare institution.

## Article 55

Within 60 days of the entry into force of this Act, the Minister shall propose to the Croatian Parliament the appointment of the new National Health Council.

## Article 56

The Minister shall issue the ordinances referred to in Articles 4 and 39 of this Act within 14 days of the day of the entry into force of this Act.

The Minister shall issue other ordinances as authorised under this Act within three months of the day of the entry into force of this Act.

### Article 57

On the day of the entry into force of this Act, the Regulation on amendments to the Healthcare Act (Official Gazette 144/12) shall cease to have effect.

#### Article 58

This Act shall enter into force on the first day after the day of its publication in the Official Gazette, with the exception of the provision of Article 35, paragraph 2 thereof, which shall apply as of 25 October 2013.

## THE TEXT THAT HAS NOT BEEN INCORPORATED IN THE CONSOLIDATED VERSION

## REGULATION ON AMENDMENTS TO THE HEALTHCARE ACT

(Official Gazette 159/13 of 30 December 2013)

#### Article 2

This Regulation shall be published in the Official Gazette and shall enter into force on 1 January 2014.

# THE TEXT THAT HAS NOT BEEN INCORPORATED IN THE CONSOLIDATED VERSION

## REGULATION ON AMENDMENTS TO THE HEALTHCARE ACT

(Official Gazette 154/14 of 24 December 2014)

#### Article 3

On the day of the entry into force of this Regulation, the Ordinance on the acquisition of the status of a specialist in sub-specialisation (Official Gazette 128/06 and 26/07) and the Ordinance on the acquisition of the status of a specialist in sub-specialisation (Official Gazette 128/14) shall cease to have effect.

## Article 4

The applications that medical doctors who are specialists have submitted for issuance of a positive opinion on their work in the field of sub-specialisation with the Croatian Medical Chamber until the day of the entry into force of this Regulation shall be solved in accordance with the provisions of the Ordinance on the acquisition of the status of a specialist in subspecialisation (Official Gazette 128/14).

#### Article 5

This Regulation shall be published in the Official Gazette and shall enter into force on 1 January 2015.

# THE TEXT THAT HAS NOT BEEN INCORPORATED IN THE CONSOLIDATED <u>VERSION</u>

## REGULATION ON AMENDMENTS TO THE HEALTHCARE ACT

(Official Gazette 70/16 of 30 July 2016)

#### Article 1

According to the Healthcare Act (Official Gazette 150/08, 71/10, 139/10, 22/11, 84/11, 12/12, 35/12 – Decision of the Constitutional Court of the Republic of Croatia, 70/12, 82/13 and 22/14 – Decision of the Constitutional Court of the Republic of Croatia), the work of healthcare professionals in private practice on lease referred to in Article 215 of the Healthcare Act (Official Gazette 150/08, 71/10, 139/10, 22/11 and 84/11) and Article

29 of the Act on Amendments to the Healthcare Act (Official Gazette 71/10) shall cease at the latest on 31 December 2017.

## **Article 3**

This Regulation shall enter into force on the first day after the day of its publication in the Official Gazette.

