

## **28 Annex - Consumer and health protection**

### **208. THE LAW ON HEALTH CARE**

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## **THE LAW ON HEALTH CARE**

### **I. GENERAL PROVISIONS**

#### **Article 1**

Health care represents a set of measures and activities for preservation, protection, and promotion of health, prevention and fighting illnesses and injuries, early detection of illnesses, and timely medical treatment and rehabilitation.

#### **Article 2**

The aim of this Law is to create conditions for:

- 1) preservation and improvement of health of citizens of the Republic of Montenegro (hereinafter: the Republic) and improvement of health condition of the population;
- 2) the improvement of the quality of life in relation to health;
- 3) accessibility, under equal conditions, to health care for all citizens of the Republic, with particular care of health and socially vulnerable population categories;
- 4) sustainability of the health system;
- 5) improvement of the functioning, efficiency and quality of health services, along with the defining of special programs in the area of human resources, facility network, technology, and medical supplies;
- 6) better functional linking and harmonization among health system institutions of the Republic, as well as the harmonization of private and public interest in this area;
- 7) incentives for performing health activities in accordance with national and international standards.

#### **Article 3**

The citizen shall be entitled to health care in line with the law.

The citizen shall be obliged to take care of his/her own health.

No one may put in danger health of other people.

Everyone shall be obliged, within his/her best knowledge and possibilities, to administer first aid to an injured or ill person and to facilitate his/her access to urgent medical assistance.

#### **Article 4**

In implementation of entitlements to health care, all citizens shall be equal regardless to nationality, race, gender, age, language, religion, education, social background, income status, and any other personal characteristic.

#### **Article 5**

Health activity is the activity of public interest.

#### **Article 6**

Health care shall be implemented on principles of comprehensiveness, continuity, accessibility and integral approach in the primary health care, and specialized approach in the specialist-consulting and hospital health care.

### Article 7

Health care service shall be liable to the quality control of its expert functioning and to the administrative supervision, in line with this Law.

### Article 8

Means for the implementation of health care and for the functioning and development of health services shall be provided in accordance with this Law.

### Article 9

In terms of this Law, specific terms and expressions have the following meanings:

1. **Priority health care measures** - health care measures that are accessible to all citizens in the Republic;
2. **The health system** – comprehensive activity and participation of all entities in the Republic (including health sector and all sectors related to health, educational and other institutions, economic entities and citizens) in providing health care for the population;
3. **Health service** – health institutions, including health workers and associates, employed by them;
4. **Public health** – the scientific-research approach to the development of health system and health policy, as well as the organized activity for health promotion, illness prevention, and creation of conditions for equal accessibility to health care among different social categories, as well as for alignment of the population health condition within sustainable development on the Republic level;
5. **Health activity** – health institutions' activities and other forms of health services in providing health services aimed at health protection of citizens;
6. **Pharmaceutical health activity** – provision of medicinal products and medical devices for citizens, in line with the law;
7. **The health institution** – the legal entity registered for performing health activities, which has a relevant approval in accordance with this Law;
8. **The health institutions network** – the legal act on establishing and planning the type, the number, and distribution of public and private health institutions on the territory of the Republic;
9. **Health** – apart from absence of illnesses and disability, it means the state of complete physical, mental, and social welfare;
10. **Promotion of health** – incentives for certain way of life and identification of social, economic, mental, personal, and other factors that contribute to health, including factors of environment as well;
11. **Health worker** – a person with medical education who meets other conditions for performing health activities, in line with this Law;
12. **Health associate** - a person without medical education who can perform certain duties within health activities, in line with this Law;
13. **The college specialized in health** – the medical college, the dentistry college, and the pharmaceutical college;
14. **Quality of health care** – the level of fulfillment of needs of citizens in terms of the condition of means and equipment and conditions for health care, staff capacity, expertise and skills and their application, improvement of health status, removal of causes and diminishing harmful influence of certain behavior and of the environmental factor, and quality of life;

15. **Accreditation** – evaluation of a health institution in terms of fulfillment of established standards within certain health care area or branch of medicine;
16. **Health technology** – interventions and applied expertise used in health care, including medicinal products, equipment, medical and surgical procedures, and organizational, administrative, and logistic systems within which health care of population is provided.

## **HEALTH CARE**

### **1. Priority Health Care Measures**

#### **Article 10**

Priority health care measures shall include:

- 1) activities in promoting health and upgrading health status of population in the Republic;
- 2) health education in relation to the most common health problems of population in the Republic and methods for their identification, prevention, and control;
- 3) activities in improving systematic provision of food and drinking water to the population, in line with the specific law;
- 4) prevention and protection from ecological factors harmful to health, including all measures and activities in protecting, improving, and promoting health conditions of living and working environment and hygienic conditions for life and work of citizens;
- 5) detection, prevention, and fighting illnesses, injuries, and their consequences on the Republic level;
- 6) prevention, timely detection, medical treatment, and fighting contagious, chronic non-contagious, and malign illnesses and immunization against main infectious illnesses, as well as prevention and control of local endemic diseases;
- 7) health care of children and young people until the end of legally prescribed regular education, protection of women in relation to the family planning, pregnancy, giving birth, and maternity;
- 8) health care (preventive and curative) of citizens over 65 years of age;
- 9) health care of war veterans, military invalids, civil war invalids, their family members, and beneficiaries of veterans' allowance, as well as beneficiaries of social protection, in line with specific regulations;
- 10) upgrading the level of mental health of citizens, medical treatment and rehabilitation of mentally ill persons who are not otherwise insured, as well as hospitalization and medical treatment of mentally ill persons who may do harm to themselves or to their surroundings, in line with the law;
- 11) health care of physically and mentally handicapped persons;
- 12) medical treatment of persons on chronic dialysis program;
- 13) provision of necessary medicinal products and medical devices – essential medicines, in particular;
- 14) urgent hospitalization and medical treatment of persons whose life is threatened due to an illness or an injury; and
- 15) establishing cause of death.

### **2. Public Interest in the Area of Health Care**

#### **Article 11**

Public interest in the area of health care encompasses measures and activities, which contribute to the improvement of living conditions, health, and work of citizens, as well as to the functioning and development of health service.

Public interest in the area of health care shall be provided and implemented on the Republic level and on the level of local self-government units.

### **Article 12**

The Republic shall create conditions for the implementation of health care and conditions for improvement, protection, and preservation of citizens' health, and it shall harmonize the functioning and development of health services throughout the territory of the Republic.

The Republic shall establish health policy that defines and harmonizes functioning and development of the health system on the territory of the Republic.

Implementing the policy referred to in paragraph 2 of this article, the Republic shall:

- 1) establish the development strategy of health in the Republic that includes measures for the implementation of health policy tasks and objectives, priorities in specific areas of health care, measures for improved efficiency of health care provision, and other measures and activities of strategic relevance for the development and promotion of health care;
- 2) give incentive to the developing of healthy living habits through tax and economic policy measures;
- 3) facilitate cooperation with other entities in the health system development and the implementation of priority health care measures through the integrated health system;
- 4) establish measures in the area of living and working environment that may have an impact on citizens' health, in line with the specific law;
- 5) establish standards and norms in the area of health in accordance with scientific achievements, economic possibilities, and general and specific needs of health care beneficiaries;
- 6) establish health institutions network on the territory of the Republic;
- 7) develop a program of integration of private and public sector;
- 8) develop a plan of the human resources development in the area of health care;
- 9) provide funds, in line with the law.

The Government of the Republic of Montenegro (hereinafter: the Government) shall establish the health policy referred to in Par, 2 of this article and shall carry out duties referred to in paragraph 3. Items 1,2,4,6,7 and 9 of this article.

The Ministry competent for health affairs (hereinafter: the Ministry) shall carry out duties referred to in Paragraph 3, items 3,5 and 8 of this article.

### **Article 16**

In the area of health care, the Republic shall provide funds from the Budget for:

- 1) monitoring of the health status of population and identification of health problems in the Republic, as well as for other duties in the area of public health;
- 2) implementation of priority health care measures referred to in Article 10, items 1,2,3,4,10, and 15 of this Law;
- 3) the implementation of health care measures ordered by the competent state administration authority in emergency situations (epidemics, contagious diseases, physical and chemical accidents, natural disasters and other large disasters, bio-terrorism, and others);
- 4) illness prevention, health promotion, investigating health problems and risks, and other social-medical activities relevant to the Republic;

- 5) implementation of promotional programs for the improvement of health of specific most vulnerable population groups, population categories, age groups, and types of diseases that are not included in compulsory health insurance;
- 6) the planning, organizing, and implementation of activities in fighting alcoholism, smoking, use of drugs, and dependence (addiction) illnesses;
- 7) the control of health soundness of the air, drinking water, soil, as well as the control of health soundness of food-stuffs and general purpose items and the noise control, as well as protection of ionizing and non-ionizing radiation, if the funds for this purpose are not allocated otherwise, in line with specific regulations;
- 8) participation in the funding of scientific-research projects in the area of health care;
- 9) urgent medical assistance to the citizens who are not covered by health insurance;
- 10) health care of individuals sentenced to imprisonment, as well of individuals to whom the measure of compulsory custody and medical treatment of alcoholics and drug addicts has been pronounced;
- 11) health care of individuals who are registered as unemployed if the funds for health insurance of these persons is not otherwise provided, in line with the specific law;
- 12) health care of beneficiaries of social-protection rights, military invalids, civil war invalids, their family members, and veteran allowance beneficiaries if they are not otherwise insured;
- 13) health care of foreigners and staff of diplomat-consular representative offices, who are provided with health care on the basis of international agreements if such agreements do not regulate differently, as well as of foreigners who stay in the Republic upon invitation of the state authorities, during their stay in the Republic;
- 14) health care of foreigners with recognized status of refugees and displaced persons, in line with specific regulations and international agreements;
- 15) health care of foreigners ill with plague, cholera, viral hemorrhagic fever, or yellow fever, as well as of foreigners – crew members of foreign vessels ill with VD or other illnesses hazardous to health;
- 16) construction and maintenance of facilities and procurement of medical equipment of high technological value for health institutions founded by the Republic.

Construction of facilities and procurement of equipment referred to in item 16 of this article shall be carried out in accordance with health policy priorities as per method and procedures envisaged by this Law.

#### **Article 14**

The local self-government unit, within its rights and obligations, shall participate in providing conditions for implementation of primary health care on its territory through:

- 1) proposing and initiating measures in the area of primary health care;
- 2) participating in the planning and implementing of primary health care development, which is of direct interest for the local population, in line with this Law and other legal acts developed on the basis of this Law;
- 3) participation in the management of health institutions founded by the Republic on its territory;
- 4) undertaking other activities in order to improve primary health care, in line with the law.

### **3. Health Care Measures in Relation to Work and Working Environment**

#### **Article 15**

When planning and performing their activities, legal and private entities shall be obliged to provide conditions for the implementation of health care through the development and application of appropriate technologies that are not health and environment hazardous, as well as for the implementation of measures for health protection and promotion of the employed.

Health care measures in relation to work and working environment, with the aim at providing specific health care of the employed, which shall be provided by the employer, in line with labor legislation, are:

- 1) prevention and detection of occupational diseases, prevention of injuries at work and administering appropriate first aid;
- 2) protection of health of the employed who are exposed to specific health hazards at work; and
- 3) health care measures established by specific regulations.

#### **Article 16**

Specific health care of the employed shall include:

- 1) medical examinations for the establishment of capability for work;
- 2) monitoring of health condition of the employed;
- 3) identification and assessment of health risks at work;
- 4) general medical check-ups, previous, periodical, and control medical examinations of the employed in regard to their gender, age, and working conditions, incidence of occupational diseases, injuries at work, and chronic diseases;
- 5) counselling on health, safety, hygiene at work, organization, and protection devices;
- 6) medical examinations of the employed that are mandatory conducted for the protection from hazardous factors of the living and working environment, protection of consumers or service users and other mandatory medical examinations;
- 7) organizing and administrating first aid and urgent interventions on the spot and in the working process;
- 8) assessment of working conditions of particular jobs for the protection from occupational diseases;
- 9) assessing needs and referring workers who are exposed to health hazards at work and those chronically overtired and physically exhausted workers to health-preventive active rest and early rehabilitation and monitoring results of such rest and rehabilitation;
- 10) health education of the employed.

The Ministry shall closely establish the scope of measures of specific health care of the employed, with an approval of the ministry competent for labor affairs.

#### **Article 17**

Specific health care of the employed by the employer shall be implemented on the basis of an agreement between the employer and the health institution.

### **4. Rights and Obligations of Citizens in the Implementation of Health Care**

#### **Article 18**

Implementing health care, each citizen shall be entitled to:

- 1) equality in overall treatment when implementing health care;

- 2) free choice of a medical doctor or dentist, in line with the law;
- 3) health care of standard quality and equal scope, as well as entitlement to possible demurrages for the damage that has been caused by inappropriate health care;
- 4) urgent medical assistance when necessary, in line with the specific law;
- 5) free choice among multiple types of medical interventions offered by a MD or a dentist, in line with this Law;
- 6) correct information on all issues concerning his/her health;
- 7) refusal to be used as an object of scientific research without his/her consent or any other examination or medical treatment that is not for the purpose of his/her medical treatment;
- 8) confidentiality of all data related to his/her health;
- 9) refusal of examination or treatment, including his/her right that, in the course of treatment, requests in a writing to change the MD or dentist following his/her statement that he/she has lost confidence in the doctor who has been treating him/her;
- 10) refusal of surgical or any other intervention, in accordance with this Law.

The right of choice, acceptance/refusal of specific diagnostic and therapeutic procedures quoted in Paragraph 1, items 5,7,9, and 10 of this article shall be expressed by citizen's signature of his/her consent when admitted to the health institution unless he/she is under age or incapable for such act.

If the citizen is not capable to make up his/her decision on choice of medical intervention among offered possibilities and there is an non-postponable intervention at issue, whose non-performing may endanger life and health of the citizen or may cause durable damages, his/her immediate family members or other close relatives shall be authorized to bring such decision.

The consent shall not be mandatory if the obtaining of the consent referred to in the previous paragraph would call for longer period of time, which might endanger the citizen's life.

The citizen can refuse a surgical intervention if he/she is conscious and oriented in time and space and if he/she is capable to make clear judgments.

For the person who is unconscious or incapable to make clear judgments, his/her immediate family members or other close relatives shall give the consent unless an emergency is at issue. In such a case, the consent shall not be mandatory.

The consent referred to in Paragraph 2 and 3 of this article also is not mandatory in cases of rendering health care referred to in items 9 and 10 of Paragraph 1 of this article to contagious and mentally ill persons.

The Ministry shall closely establish the method of implementing entitlements referred to in this article, in accordance with relevant international conventions and declarations and this Law.

### **Article 19**

Citizens shall implement primary health care through a selected MD team or selected MD or selected dentist (hereinafter: selected team or selected doctor).

The selected team referred to in Paragraph 1 of this article shall be, as a rule, consisted of:

- primary health care specialist, i.e. general practitioner, general or urgent medicine specialist, internist, pediatrician, or occupational medicine specialist who is educated for primary health care; and
- other health workers with secondary school and higher education (junior college) who are educated for primary health care.

In places where there are no conditions to implement health care as per Paragraph 1 of this article, citizens shall implement health insurance through the doctor who is appointed in line with this Law.



The selection of the doctor shall be made for the minimum of one year.

The Ministry shall establish closer conditions in regard to standards, norms, and quality of the implementation of health care through the selected doctor or selected team, as well as the implementation of health care referred to in Paragraph 1 of this article.

#### **Article 20**

When implementing health care, the relationship between health workers and citizens shall be based on mutual respect, confidence, and personal dignity.

When implementing health care, citizens' personal beliefs shall be respected in regard to their religious, cultural, moral, and other determination.

The citizen shall be obliged to use his/her right to health care in accordance with this Law and instructions for medical treatment issued by the health worker.

Priorities in rendering health care shall be based exclusively on medical indications taking into consideration the degree of disability, seriousness of the illness or injury, and other circumstances related to the citizens' health condition.

#### **Article 21**

The citizen who is deprived of his/her right to health care or if he/she is not satisfied with the administered health service, or with the procedure rendered by a health worker or some other worker from the health institution, can submit a complaint to the health worker in charge of managing the working process or to other authorized person at the health institution (hereinafter: the authorized person).

The complaint shall be submitted verbally or in writing.

The authorized person shall deal with the complaint referred to in Paragraph 1 of this article immediately and shall inform the complainant on the outcome right away or within 5 days from the day when the complaint was submitted.

The citizen, who is not satisfied with the decision referred to in Paragraph 3 of this article, may address the health inspection.

The authorized person shall report monthly to the head of the health institution on submitted complaints.

#### **Article 22**

While receiving health care at the health institution, the citizen shall be obliged to adhere to general legal acts of the health institution on conditions of staying and behavior in such institution.

In the case that the hospitalized citizen requests to interrupt his/her medical treatment, in spite of MD's warning on possible consequences of such a decision, he/she shall be obliged to give a written statement accordingly.

In the case that the citizen refuses to give a written statement referred to in Paragraph 2 of this article, a written note for the file shall be drafted, in the presence of a witness, which is to be kept in his/her medical file.

#### **Article 23**

The medical doctor shall be obliged to apply adequate diagnostic and therapeutic procedures if he/she suspects that the person who is under the treatment is ill with a contagious disease and that such person may be dangerous for other people's health, in accordance with the specific law.

If the medical doctor assesses that the nature of patient's mental illness is such that he/she may put in danger his/her own life or other people's lives or property, the MD may refer such patient to the hospital treatment. The competent MD in such health institution shall be obliged to admit such patient for the hospital treatment without patient's prior consent or consent of his/her family member who is of age.

The MD who refers such patient (from Paragraph 1 of this article) to the psychiatric institution may request assistance from the police if he/she assesses that the patient is in such condition that he/she may be dangerous for the safety of people and surroundings.

Medical doctor shall undertake the measures quoted in Paragraph 2 and 3 of this article in accordance with the specific law.

#### **Article 24**

Health workers shall be obliged to keep as a professional secret all facts that they know about health status of the citizen.

Other health employees shall be obliged to keep professional secret if they learn about it while carrying out their duties, as well as students of medical schools.

Exceptionally, individuals referred to in Paragraph 1 of this article may be released from keeping the professional secret if the person whose health condition is at issue agrees on that or if it is necessary for public interest or in the interest of another person.

In terms of Paragraph 3 of this article, public interest or the interest of another person is:

- revealing or trying the heaviest crimes if it would be significantly slowed down or made impossible without the disclosure of health condition data of a citizen;
- protection of public health and security; and
- preventing that another person's health or life be directly and seriously endangered.

#### **Article 25**

The health institution founded by the Republic or by local self-government may offer to the citizens, within established standards, special conditions of rendering health care regarding staff, accommodation, and time –under the conditions defined by the Ministry.

The health institution referred to in Paragraph 1 of this article shall be obliged to have an approval of the Ministry to render health care as per Paragraph 1 of this article.

The citizen who opts for health care as per Paragraph 1 of this article shall cover in full the cost of such health care by himself/herself.

### **5. Health Care Implementation**

#### **Article 26**

In the implementation of health care, the health institution shall be obliged to apply only scientifically proved medical methods and procedures in prevention, diagnostics, treatment, and rehabilitation of the ill.

The Ministry shall closely establish criteria, standards, and guidelines for assessing medical technologies, as well as the conditions and procedures for introducing new medical methods and procedures.

In the implementation of health care measures, also expertly proven traditional and alternative methods of treatment can be applied that are not harmful to the health of citizens.

Medical treatment methods referred to in Paragraph 3 of this article shall be applied in line with the regulation of the Ministry.

The Ministry shall issue an approval for particular treatment methods referred to in Paragraph 3 of this article.

#### **Article 27**

The testing and introducing of new methods for detecting and fighting diseases, treatment and rehabilitation of the ill and injured, as well as conducting biomedical researches, shall be allowed only with the approval of the ministry competent for health affairs and with written consent of parents or guardians.

The Ministry shall issue its approval for the application of methods and procedures referred to in Paragraph 1 of this article with the prior opinion of the competent association and the relevant medical college.

#### **Article 28**

The advertising of health care methods and procedures in media shall be forbidden, as well as such advertising by individuals who are not health workers.

Health institutions may advertise in media only the following - the name of health institution, its activity, the address and telephone number, and working hours.

The results of expert-medical methods and procedures of health care may be communicated only at expert gatherings and published in expert magazines and publications, on which citizens can be informed through media.

### **6. Maintaining of Medical Documentation and Records**

#### **Article 29**

All individuals rendering health care shall be obliged to maintain medical documentation, reports, and records in accordance with the law. They shall submit, within envisaged deadlines, individual, collective, and periodical reports to the Institute for Public Health (IPH).

### **7. Health Care of Foreigners**

#### **Article 30**

Individuals with the approved refugee status in the Republic shall be entitled to health care in line with provisions of this Law, unless the international agreement otherwise regulates.

#### **Article 31**

Health institutions and health workers shall be obliged to administer urgent medical assistance to the foreigner.

Foreigners shall bear themselves the cost of administered urgent medical assistance or other type of health care, unless the international agreement otherwise regulates.

For the use of health care referred to in Paragraph 1 of this article, the foreigner shall be charged as per price list of the health institution.

## **THE HEALTH ACTIVITY AND HEALTH INSTITUTIONS**

### **1. Levels of Health Activities**

**Article 32**

Health activities shall be organized on primary, secondary, and tertiary levels.

Primary health care is the basis of the health care system and the first level on which a citizen implements health care or where he/she enters the process of the implementation of health care on other levels, apart from emergency cases.

**Article 33**

The health activity performed on the primary level of health care shall usually include:

- 1) activities for health improvement;
- 2) the health education related to most common health problems in certain area and to methods of their identification, prevention and control;
- 3) promoting healthy way of life, including health food of the population;
- 4) cooperation with other authorities, organizations, and entities in order to support protection, improvement and promotion of the living and working environment and hygienic conditions for the life and work of individuals and local community units;
- 5) health care of mothers and children and family planning;
- 6) detection, prevention, and control of malign diseases;
- 7) detection, prevention, and control of endemic diseases;
- 8) detection, fighting, and treating mouth and teeth diseases;
- 9) health care of the employed;
- 10) protection and improvement of mental health;
- 11) immunization against main contagious diseases;
- 12) patronage medical visits (house calls), medical treatment and rehabilitation at home;
- 13) prevention and medical treatment of common diseases and injuries;
- 14) urgent medical assistance;
- 15) health rehabilitation of children and young people with disorders in physical development and health;
- 16) provision of appropriate medicinal products.

**Article 34**

Urgent medical aid shall be organized in line with the specialized law in order to undertake necessary and emergency medical interventions that otherwise might endanger life and health of citizens or cause permanent damages, if they are not undertaken immediately.

**Article 35**

On the secondary and tertiary levels of health care, citizens shall be provided with specialized and highly specialized health care, which cannot be provided on the primary health care level.

Specialized and highly specialized health care referred to in Paragraph 1 of this article shall include more complex measures and procedures regarding diagnostics, medical treatment, and the implementation of outpatient rehabilitation with the aim at solving out more complex health problems.

Secondary and tertiary levels of health care shall be organized in such way to supplement primary health care and provide it with organized and continuous assistance and support. Among other

things, the support shall be in education and offering expert instructions, advice, recommendations, and expert information to the staff working on the primary health care level on practical issues and problems appearing in administering primary health care.

#### **Article 36**

Tertiary health care level shall provide highly specialized care by performing the most complex types of specialist care, organize expert lab analysis, and offers logistic support to other levels of health care.

The scientific-research and scientific activity shall be organized and conducted on the tertiary health care level.

Teaching activities for needs of medical schools shall be conducted on all levels of health activities in the Republic.

#### **Article 37**

Health institutions on all levels of health care shall establish a uniformed system of referring citizens from one level of health care to the other.

In the case when a citizen cannot be provided with adequate and timely health care on the primary level health care, the health institution or selected team or selected medical doctor shall refer the citizen to the appropriate institution or to the appropriate specialist on the secondary, or exceptionally on the tertiary, health care level for examination, treatment, and obtaining an opinion and instructions for further medical treatment on the primary health care level.

Hospitals and other types of inpatient health institutions or a doctor-specialist to whom a citizen is referred from the primary level may refer such citizen to the next level of health care where highly specialized health care shall be provided through the top-level health technology.

#### **Article 38**

The system of referring citizens from one to other levels of health care shall include the exchange of information from the primary level on the citizen's health condition with data on the illness or health problems for which he has addressed the selected team or selected doctor and on undertaken measures. From the secondary or tertiary level – information on performed examinations, findings, and undertaken treatment measures and with detailed instructions for further treatment.

## **2. Types of Health Institutions**

#### **Article 39**

Health institutions are: the public health center - PHC ("*Dom Zdravlja*"), the local clinic ("*Ambulanta*"), laboratory, pharmacy, hospital, institute ("*Zavod*"), health resort (sanatorium), clinic, clinical center, special institute, and the Institute for Public Health (IPH).

The scope of activities of health institutions referred to in Paragraph 1 of this article, their organization, conditions and method of work, as well as conditions they have to meet regarding premises, staff, and medical-technical equipment shall be regulated by the Ministry in accordance with the standards and norms.

#### **Article 40**

**The Public Health Center - PHC ("*Dom Zdravlja*")** is a referral center of primary health care that provides support to the selected team or selected medical doctor referred to in Article 19 of this Law in the following areas: 1) immunization against main contagious diseases; 2) detection and

fighting factors that have an impact on incidence and spread of contagious and non-contagious diseases; 3) health care of women and family planning; 4) home care and care through patronage visits.

PHC can also provide support to the selected team or selected medical doctor in the following areas: 1) the implementation of health training and education on common health problems and methods for their identification, prevention, and control; 2) hygienic-epidemiological protection; 3) mental health care; 4) treatment of lung diseases and TB; and 5) lab, x-ray and other types of diagnostics; and other areas that the Ministry shall define.

The selected team or selected medical doctor referred to in Paragraph 1 of this article may be organized individually or within the PHC.

#### **Article 41**

The local clinic ("Ambulanta") and the Laboratory are health institutions that can perform health activities on all levels of health care.

#### **Article 42**

**The Pharmacy** is a health institution on the primary health care level that performs pharmaceutical health activity.

The pharmacy shall keep financial and material records, in line with the law.

#### **Article 43**

**The Hospital** is a health institution that performs hospital activities.

The hospital activity includes - diagnostics, medical treatment, and medical rehabilitation. During hospital treatment, citizens shall be provided with accommodation, food, and appropriate health care.

Beside hospital activity, the hospital shall perform the following - specialist-consultative and the medical treatment by a panel of doctors; urgent medical assistance; lab, x-ray and other diagnostics; outpatient medical rehabilitation, if the nature of its work requires it; provision of blood and plasma; anesthesiology activity; pathology activity; morgue; as well as provision of drugs and medical means through the hospital's pharmacy.

Hospitals can be general and special. Particular forms of specialist health care can be performed in the day-hospital, too.

The general hospital is a health institution on the secondary level of health care that, beside activities quoted in Paragraph 1,2,3 of this article, performs at least activities in surgery, intern medicine, pediatrics, gynecology and OB.

The general hospital shall establish wards/departments for implementing activities referred to in Paragraph 5 of this article.

The general hospital shall be obliged to create conditions for taking care of acute contagious diseases and acute psychiatric condition.

Special hospital is a health institution on secondary health care level that performs specialist-consultative and highly specialized health activity through a panel of doctors and hospital treatment for certain types of diseases and adequate medical rehabilitation.

The special hospital shall be obliged to have the adequate number of beds according to its purpose, diagnostic and other specific conditions for performing activities in a specific branch of health care that it administers.

The day-hospital shall render specialist health care through treatment during the day, without overnight stay.

#### **Article 44**

**The Institute** is a health institution, which is founded for a certain area of health care or for health care of certain population category or population group.

#### **Article 45**

**The Health Resort** (sanatorium) is a health institution that performs medical treatment and medical rehabilitation using natural factors in treatment (water, mud, sand, sea, and other).

#### **Article 46**

**The Clinic** is a health institution or the health institution's organizational unit that performs highly specialized specialist-consultative and hospital health activities within certain branch of medicine or dentistry.

#### **Article 47**

**The Clinical Center** is a highly specialized health institution on the tertiary health care level that uses the most complex methods of diagnostics and medical treatment and performs specialist-consultative and sub-specialist hospital health activities within multiple areas of health care, i.e. branches of medicine.

The clinical center shall be the teaching facility of the college of medicine and it shall perform the teaching and scientific-research activity within clinical branches of medicine, in accordance with the law.

The clinical center shall be responsible for expert-methodology education and coordination in all areas of health care on the secondary level.

The clinical center shall organize and implement undergraduate and postgraduate studies for University students at the college of medicine, on the basis of an agreement with the college, in line with the college's curriculum.

The clinical center shall organize and implement specialization courses in the area of health workers' specialties within clinical branches of medicine, according to Paragraph 4 of this article.

#### **Article 48**

**The Special Institute** is a health institution on the tertiary health care level or the health institution's organizational unit that performs highly specialized specialist-consultative and hospital activities or only specialist-consultative activity.

The special institute can be founded to perform activities within one or more areas of health care or branches of medicine or dentistry.

The special institute shall perform also the teaching and scientific-research activity, in line with the law.

#### **Article 49**

**The Institute for Public Health (IPH)** is a highly specialized health institution on the tertiary health care level and its activity shall be oriented towards preservation and improvement of health of all citizens.

In carrying out the activities referred to in Paragraph 1 of this article, the IPH shall:

- monitor and assess health status of the population and create data base for planning, monitoring, and evaluation of all public health activities and health care activities in the Republic;
- identify risk factors to health from contagious and chronic mass non-contagious diseases, including biological, ecological, and social-economic factors and life styles and undertake measures for diminishing their impact or for eliminating them;
- prevent and control contagious diseases;
- propose and undertake measures for protection and promotion of health, especially in regard to soundness of food stuffs, items of general purpose, drinking water, solid and waste materials, noise, and air pollution;
- make analysis and report to the competent state authorities on infrastructure, human resources, activities, utilization and quality of health care provided by all health care institutions in the Republic;
- perform the function of a reference laboratory for certain analysis that the IPH is accredited for;
- research and develop activities within public health area, health policy, and create public health programs;
- organize undergraduate and postgraduate education in public health disciplines, as well as the activities of continuous education in other areas of health care;
- take part in preventive supervision over the design and construction of buildings and other structures and in the development of space and urban planning in view of protection and promotion of the living and working environment and health of citizens;
- propose necessary measures in case of extraordinary circumstances, natural disasters and epidemics of larger scale and participate in their implementation;
- maintain records in the area of health care and health activity, in line with specific regulations;

The IPH may carry out microbiological and biochemical trials for health institutions on the primary and secondary level of health care, as well as for other legal and private entities if these activities do not jeopardize the principal IPH activity.

The IPH shall perform activities referred to in Paragraph 3 of this article on the basis of an agreement with the institution or other legal or private entity.

### **3. The Founding of Health Institutions**

#### **Article 50**

Health institutions shall be founded in accordance with the health institutions' network that is based on standards, norms, planned development of the health system and priority measures of health care.

#### **Article 51**

The founder of a health institution can be the Republic, the local self-government unit, the national and the international legal and private entity.

As an exception from Paragraph 1 of this article, the Republic shall found health institutions involved in public health activities, blood transfusion, human body parts transplantation, urgent medical assistance, clinical centers and the IPH.

#### **Article 52**



If the founder of a health institution is the Republic or the local self-government unit, then the Government or the competent authority of the local self-government unit shall issue the legal act on foundation.

### **Article 53**

The legal act on foundation of a health institution shall include, in particular:

- 1) the name and headquarters or domicile of the founder;
- 2) the name and headquarters of the health institution;
- 3) activity of the health institution;
- 4) conditions and methods of obtaining premises and medical-technical equipment;
- 5) means necessary for the founding and commencement of the health institution's functioning and methods for their provision;
- 6) the founder's rights and obligations in regard to the activity for which the institution is to be founded;
- 7) health institution's governing bodies; and
- 8) other issues relevant to the founding of such institution.

### **Article 54**

The health institution may commence with its activities under conditions prescribed by this Law and regulations of the Ministry.

The Ministry shall issue a formal decision on fulfillment of conditions referred to in Paragraph 1 of this article within 30 days from the day of the submitting of application.

### **Article 55**

Upon receiving the formal decision referred to in Article 54 of this Law, the health institution shall be entered into the central registry of the Commercial Court.

By being entered into the registry referred to in Paragraph 1 of this article, the health institution shall acquire status of a legal entity.

The health institution referred to in Paragraph 2 of this article shall be obliged to inform the Ministry on any change of conditions for performing health activities, which are prescribed by this Law.

### **Article 56**

The cost incurred in the procedure of applying for the foundation and commencement of work of the health institution shall be borne by the founder.

The Ministry shall regulate the method of establishing costs and the amount of costs referred to in Paragraph 1 of this article.

### **Article 57**

Provisions of articles 54-56 of this Law shall be applied also in the case of expansion and change of activities of the health institution.

### **Article 58**

The health institution shall cease its activities when there is no more need for the activity for which it has been founded or if it does not meet conditions for performing such activity as prescribed by the law.

The founder shall issue the decision on cessation of activities of the health institution.

#### **4. The Health Institution Governing Bodies**

##### **Article 59**

The health institution's governing bodies are the Board of Directors and the Director.

The Board of Directors is a managing body and the Director is an executive body of the health institution.

The Board of Directors shall not be a mandatory health institution body unless the founder is the Republic or the local self-government unit.

If the health institution does not have the Board of Directors, the Director shall perform Board's functions.

If the founder is a private person, he/she may perform Director's duties or appoint other person.

##### **Article 60**

The number of members of the health institution's Board of Directors shall be defined by the Statute depending on the type and volume of activities performed.

The number of members of the Board of Directors of the health institution whose founder is the Republic or the local self-government unit cannot be smaller than 5 not bigger than 9 members.

The Board of Directors referred to Paragraph 2 of this article shall be consisted of representatives of the founder and the employed in the health institution.

Representatives of the founder shall make more than a half of members of the Board of Directors.

Representatives of NGOs whose principal aim is to protect handicapped, disabled, and ill persons can be also appointed to the Board of Directors.

##### **Article 61**

Upon proposal of the Ministry, the Government shall appoint the Board of Directors in the health institution founded by the Republic.

It is mandatory that one or more representatives of the local self-government unit shall be appointed to the Board of Directors of the health institution referred to in Paragraph 1 of this article, which is founded for the territory of the local self-government unit, i.e. it performs its activities on that territory.

The competent body of the local self-government unit shall propose, in line with its Statute, members of the Board of Directors referred to in Paragraph 2 of this article.

The competent authority of the local self-government unit shall appoint the Board of Directors in the health institution founded by the local self-government unit.

Term in the office of the Board of Directors members of the health institution founded by the Republic shall be 4 years.

##### **Article 62**

The Board of Directors of the health institution shall:

- 1) develop the Statute and other general legal acts;
- 2) develop the plan and program of activities and development of the institution, the program for staff education and shall supervise its implementation;
- 3) develop the financial plan and adopt financial statements and reports;
- 4) propose to the founder the change or expansion of activities;
- 5) decide in the second instance on specific rights of the employed, in line with regulations in the area of labor;
- 6) set up charges of health services administered to the third party, upon approval of the Ministry;
- 7) set up charges for health services that are administered above standards which are established by the specific law, as well as charges for services administered under special conditions, with an approval of the Ministry, in terms of Article 25 of this Law; and
- 8) perform other duties as per Statute of the health institution.

The Board of Directors shall bring its decisions by majority of votes of the total number of members unless the health institution's Statute envisages other qualified majority for deciding on particular issues.

#### **Article 63**

The Director of the health institution founded by the Republic or the local self-government unit shall be elected on the basis of a competition and submitted program.

The Board of Directors shall elect and relieve of duties the Director of the health institution founded by the Republic or the local self-government unit.

As an exception of Paragraph 2 of this article, the Government shall elect and relieve of duties the Director of the clinical center and the IPH, upon the proposal of the Ministry.

Term in the office of the Director referred to in Paragraph1 of this article shall be 4 years.

#### **Article 64**

The Director shall organize and manage business activities, represent and act for the health institution and shall be responsible for the legality of work and financial activity of the institution, as well as for the application of relevant technologies when providing health care.

The Director shall report at least once a year to the Board of Directors on business activities of the institution.

The Director shall take part in the work of the Board of Directors, with no right of decision.

#### **Article 65**

The Director may be relieved of duties even before the end of his term in the office to which he has been elected, in the following cases:

- 1) upon personal request;
- 2) due to any reason which, based on specific regulations or labor law regulations, may be basis for the termination of employment, i.e. cancellation of the employment agreement;
- 3) if the health institution does not fulfill contractual obligations towards the Republic Insurance Fund (hereinafter the HIF);
- 4) if he/she does not adhere to regulations, general legal acts, plans and programs of the health institution or does not, without justification, implement decisions of the Board;
- 5) if he/she causes damage to the health institution by his/her incorrect or unconscientious work;

6) if he/she contributes to deterioration of expert performance of health activities of the health institution by negligently performing his/her duties.

Prior to the decision on relieve of duties referred to in Paragraph 2-6 of this article, the Director shall be provided with a possibility to submit his/her comments on reasons for relieve of duties.

#### **Article 66**

Health institutions on the tertiary health level shall establish the Medical Committee.

The Medical Committee is an expert-advisory body, which follows scientific and expert activities and scientific projects in the area of clinical medicine. It implements the cooperation in the area of scientific-research activities with the medical college and other scientific institutions in the country and abroad.

The Statute of the health institution shall closely regulate the composition and the number of members of the Medical Committee, the method of their election, and scope of committee's work.

#### **Article 67**

Health institutions on the tertiary health level may establish the Ethical Committee.

The Board of Directors shall appoint the Ethical Committee as its advisory body with the aim of conducting activities of the institution on principles of ethics and deontology.

As a rule, the Ethical Committee shall have 5 members: 3 representatives of the health institution and 2 representatives coming from judiciary, scientific and other expert authorities or organizations.

The Ethical Committee members shall elect the Ethical Committee President among themselves, by majority of votes.

#### **Article 68**

The Ethical Committee of the health institution shall:

- 1) monitor application of ethical principles of health profession in the performing of principal activity of the health institution;
- 2) give an opinion on ethical aspects of scientific testing and research in the health institution;
- 3) give an opinion on using of body organs of the deceased, following the autopsy, for scientific-teaching purposes;
- 4) give an opinion on other ethical issues in performing activities of the health institution.

### **5. The Statute and Internal Organization of Health Institutions**

#### **Article 69**

The health institution shall develop the Statute and other general legal acts.

The Statute shall regulate in particular: the activity of the health institution; the organization and method of functioning of the health institution; conditions for election of the Director; mandate and method of work of the Director; the method of bringing decisions and other issues relevant for the health institution functioning.

#### **Article 70**

The Ministry or competent authority of local self-government unit shall approve the Statute and legal act on internal organization and system of staff positions of other health organizations that are founded by the Republic or the local self-government unit.

## **6. Organization of Work and Working Hours**

### **Article 71**

Working hours' schedule in the health institution shall be established depending on the type of health institution, i.e. on the type of health care administered by such health institution, in accordance with needs of citizens.

The health institution shall organize its activities and define its working hours, in terms of Paragraph 1 of this article, in accordance with the legal act of the Ministry.

The health institution shall be obliged to administrate health care continuously within established working hours either by working in shifts or in split shifts or with on-call or duty service.

On-call service is a special form of work when the health worker is not obliged to be present in the health institution but has to be available to administrate urgent medical assistance.

The duty service shall be introduced and organized in line with labor regulations.

Health workers cannot leave their duty before they are replaced even if their hours are up if that could jeopardize health care administering.

Health institutions shall be obliged to place the working hours schedule on a visible place.

### **Article 72**

In case of extraordinary situations, natural disasters, and large scale epidemics, the Ministry may undertake the following measures and activities regarding: the organization of work and working hours, change of location and working conditions for specific health institutions, health workers, and health associates.

### **Article 73**

Health workers who are appointed as teachers and associates at the college of medicine perform health, scientific-research, and teaching activities within the unique working process.

An agreement shall regulate mutual rights and obligations between the health institution and the medical college.

### **Article 74**

The health worker who is employed with one health institution may enter an agreement on additional employment with another health institution upon an approval issued by the health institution Director, in line with labor regulations.

## **6. Leasing**

### **Article 75**

The health institution founded by the Republic or by the local self-government unit may lease its premises, medical-technical equipment, and other means necessary for performing health care activity or any other equipment and means that are in the function of performing health care activity in health institutions.

The Ministry shall prescribe conditions for leasing premises, equipment, and other means referred to in Paragraph 1 of this article.

The health institution referred to in Paragraph 1 of this article shall be obliged to obtain the approval from the Ministry for leasing premises, equipment, and other means in terms with Paragraph 1 of this article.

## **7. Funds for Work of Health Institutions**

### **Article 76**

The health institution shall acquire funds for work from:

- 1) the founder, in accordance with the legal act on foundation;
- 2) the Fund (HIF);
- 3) the Republic Budget or the budget of local self-government unit;
- 4) legal and private entities under conditions established by the law, the legal act on foundation, and the health institution's Statute;
- 5) the funds of voluntary insurance; and
- 6) other sources.

### **Article 77**

Public and private health institutions shall be entitled to obtain funds provided by the HIF, in accordance with this Law and the law regulating health insurance.

## **8. Other Entities that Can Perform Health Activities**

### **Article 78**

Institutions of social care and childcare, penitentiary institutions and other institutions aimed at accommodating people, as well as state authorities with specific needs in the area of health care and enterprises may perform health activities on the primary level of health care, under conditions established by this Law for corresponding health institution.

Hotels may perform health care activities for the persons accommodated in them, under the conditions referred to in Paragraph 1 of this article.

The Ministry shall closely regulate conditions for performing health activities in regard to premises, staff, and medical-technical equipment, depending on the type of health institution in terms of Paragraph 1 of this article.

### **Article 79**

The obligation of health institutions established by this Law in regard to the maintaining of medical documentation, records and submitting of relevant reports shall be accordingly applied to the institutions, state authorities, and other entities quoted in Article 78 of this Law.

## **HEALTH WORKERS AND HEALTH ASSOCIATES**

### **1. Common Provisions**

#### **Article 80**

Health workers and associates shall perform expert-medical activities and measures and procedures related to health activities, under the conditions established by this Law.

Any individual who is not considered to be a health worker or associate, in terms of this Law, shall be forbidden to perform health activities.

#### **Article 81**

Depending on the level of qualification and health activity they perform, health workers are:

- 1) Medical doctor, dentistry doctor, and graduated pharmacist – medical biochemist (hereinafter: pharmacist);
- 2) Senior reg. nurse, senior reg. medical technician and senior health technician, and senior dentist, in line with the specific law; and
- 3) Nurse/technician, lab technician, pharmaceutical technician, dentistry technician, in line with the specific law.

#### **Article 82**

Health workers acquire their education at medical colleges, junior medical colleges and secondary medical schools.

#### **Article 83**

Health workers and associates shall be obliged, after completing their education, to serve apprenticeship at health institutions and pass the licensing exam.

Health institutions shall be obliged to enable health workers and associates to serve their apprenticeship.

The apprenticeship shall be implemented according to the established program, through practical work at health institutions under direct supervision of an authorized health worker with at least two years of experience in independent work and with the same level of education as the apprentice, at least.

Data on length of time of apprenticeship and on apprentice's work shall be entered in apprentice's records and verified by the health institution where apprenticeship has been conducted.

The Ministry shall closely regulate conditions, duration, and the method of implementation of apprenticeship and obligations of health institutions to the apprentice during his/her apprenticeship.

#### **Article 84**

The Ministry shall develop regulations on the apprenticeship program for health workers and associates, conditions of conducting apprenticeship and the method of its recording, the plan and program of practical work and training for apprentices, health workers and associates, the method of organizing licensing exams, of composition and the functioning of the examining board. It shall also regulate the scope of licensing exams, the format of records of the licensing exam, the format of the licensing exam certificate, the format and method of entering data into apprentice's records and method of taking the licensing exam.

The Ministry shall organize licensing exams for health workers and associates with University education and with junior college and secondary school education.

The licensing exam shall be taken before the examining board whose members are appointed by the Ministry.

#### **Article 85**

For health workers and associates who have completed apprenticeship, or part of it, abroad, the Ministry may issue approval of their apprenticeship, or part of it, upon their request, given that the apprenticeship program completed abroad is not essentially different from the apprenticeship program developed on the basis of this Law.

### **2. Skill Training and Capacity Building of Health Workers**

#### **Article 86**

Health workers and associates shall have the right and obligation of capacity building in order to maintain and improve the quality of health care they administer.

The health institution shall be obliged to provide expert and scientific capacity building of health workers and associates, in accordance with this Law.

#### **Article 87**

Specialization or sub-specialization, as a special form of capacity building, shall provide expertise and skills for specialist and sub-specialist practical work within certain area of health care.

Specialization or sub-specialization shall be implemented according to the program that includes both theoretical and practical part. The theoretical part of specialization or sub-specialization shall be conducted at the relevant medical college, and the practical part – at the health institution, which meets prescribed conditions.

Health workers and associates who are assigned to specialization or sub-specialization shall commence the specialist training on the day of their enrolment into the medical college.

The Ministry, upon proposal of the medical college, shall establish: types, programs and duration of specialization or sub-specialization, the method of internship and exams taking, conditions that health institutions should meet to conduct such training, detailed conditions and methods for the recognition of specialist training.

#### **Article 88**

Specialization can be approved to a health worker and associate with university degree who has passed the licensing exam and who is employed by a health institution.

Exceptionally, the Ministry may approve specialization to a health worker referred to in Paragraph 1 of this article, who is not employed by the health institution, for the needs of the Ministry and the relevant Republic administration authorities, the college of medicine, scientific-research institutions, and legal entities involved in production and trade of medical means.

After completing specialization, the health worker with university degree can continue sub-specialization.

#### **Article 89**

The Ministry shall develop the annual plan of specialization and sub-specialization in accordance with standards on the number of staff for specific areas and levels of health care and the staff development plan in the area of health care.



The annual plan referred to in Paragraph 1 of this article shall establish the number of specialization or sub-specialization courses across areas of health care or branches of medicine, dentistry, and pharmacy that can be approved.

Selection of health workers and associates who receive approval for specialization or sub-specialization, in line with provisions of Paragraph 2 of this article, shall be carried out through a public advert published by the health institution or other institution performing health activity, with prior approval of the Ministry.

The Director of the health institution referred to in Paragraph 3 of this article shall bring decision on approving specialization or sub-specialization.

The health worker or associate may appeal to the Board of Directors against the Director's decision referred to in Paragraph 4 of this article, within 15 days from the day of receipt of such decision.

#### **Article 90**

The general legal act of the Ministry shall closely regulate conditions and criteria for conducting specialization or sub-specialization, the procedure for selecting applied candidates and regulating rights and obligations of selected candidates towards health institution related to the approved specialization or sub-specialization.

Mutual rights and obligations between the health institution and the health worker or associate who is awarded with specialization or sub-specialization shall be regulated by an agreement.

#### **Article 91**

The health worker or associate who has completed specialization or sub-specialization shall take a specialist exam not later than 6 months following the completion of the specialist training.

The specialist exam shall be taken before the board appointed by the medical college.

The medical college shall issue the certificate (diploma) on the specialist exam that was passed.

#### **Article 92**

The health worker or associate who has completed the relevant school or college abroad, as well as the health worker or associate who is a foreign citizen can perform health activities if they validate their degree.

The diploma validation referred to in Paragraph 1 of this article shall be carried out in accordance with the law.

The Ministry may recognize, with prior opinion of the medical college, specialization completed abroad, in full or partially, if the program of the specialist training does not essentially differ from the program developed on the basis of this Law.

#### **Article 93**

Medical doctors, dentistry doctors, and pharmacists who have 10 years of experience as specialists, who have published scientific and expert papers, have license, and achieved good results in capacity building and development of health care may be granted with the title of "*Primarius*" (head doctor) as a form of expert and social recognition.

The request for obtaining the title of Primarius shall be submitted by the health institution where the candidate is employed as defined by the general legal act.

A special board established by the Ministry shall grant the title of Primarius. The board members shall be elected among medical college professors and prominent health care experts.

The Ministry shall closely prescribe methods of functioning of the board referred to in Paragraph 3 of this article.

#### **Article 94**

Expert and scientific capacity building of health workers and associates shall include health workers' and associates' participation in training courses, seminars, symposia, conventions, and other expert and scientific gatherings in the field of their work and specialization.

Submitting expert and scientific papers and other types of written contributions at gatherings referred to in Paragraph 2 of this article is one of conditions for issuing license referred to in Article 99 of this Law and professional promotion of health workers and associates.

#### **Article 95**

In order to receive training and acquire expertise, health workers and associates shall be obliged to spend certain period of time in expert seminars, training courses, and other type of professional capacity building, in line with this Law. They will be also obliged to continuously follow up and acknowledge modern expertise.

The health institution shall be obliged to provide to health workers capacity building referred to in Paragraph 1 of this article in accordance with the staff education program, which shall be based on human resources development plan referred to in Article 12, Paragraph 3 Item 8 of this Law.

In the case that the health institution refuses to provide health worker to implement rights referred to in Paragraph 2 of this article, the health worker may appeal to the Ministry and inform the competent association on it.

Administrative proceedings can be initiated before the court of justice against the decision referred to in Paragraph 3 of this article.

The Ministry shall issue close instructions for capacity building of health workers and associates in terms of Paragraph 1 of this article.

#### **Article 96.**

The competent association shall value and implement expert and scientific papers of health workers and their capacity building referred to in Article 94 and 95 of this Law of health workers in terms of Paragraph 3 of this article.

### **3. Licenses**

#### **Article 97**

Health workers can perform health care activity if they, beside appropriate education, pass the licensing exam.

#### **Article 98**

The Ministry shall issue a general license to health workers who acquired higher education and passed licensing exam and it shall maintain records of issued licenses.

Health worker referred to in Paragraph 1 of this article shall submit an application for the issuing of a general license.

The procedure of issuing or taking away the license referred to in Paragraph 1 of this article shall be conducted according to provision of the law regulating general administrative procedures.

The Ministry shall regulate the method of maintaining records of general licenses.

#### **Article 99**

Health workers referred to in Article 98, Paragraph 1 of this Law can also obtain the license based on their practice, under the conditions established by this Law.

The license based on practice shall be issued to MD or dentist given that such doctor has:

- 1) general license;
- 2) additional expertise and skills, in line with Article 94 and 95 of this Law;
- 3) evidence on prior experience in the field of medicine or dentistry (expert references); and
- 4) appropriate specialization or sub-specialization if he/she performs health activity in particular area of specialist or sub-specialist medicine or dentistry.

Pharmacists can obtain the license based on their practice if they have:

- 1) general license;
- 2) evidence on prior experience in the field of pharmacy (expert references);
- 3) appropriate specialization or sub-specialization if it is necessary for the particular area of work.

The license based on practice shall represent grounds for promotion of health workers and awarding them.

The license based on practice referred to in Paragraph 2 and 3 of this article shall be issued by the competent association.

The license based on practice shall be valid for the period of 7 years and it shall be renewed according to the specific legal act of the competent association.

The procedure of issuing, revoking, and renewing the license referred to in Paragraph 2 and 3 of this article shall be regulated by provisions of the law regulating the general administrative procedure.

Health workers may appeal against the formal decision of the competent association referred to in Paragraph 5 of this article.

The appeal shall be addressed to the Ministry.

The competent association shall regulate the method of maintaining records of licenses based on practice, with prior approval of the Ministry.

#### **Article 100**

The license referred to in Article 98 and 99 of this article may be taken away from the health worker, temporarily or permanently.

#### **Article 101**

The Ministry shall temporarily revoke general license if:

- 1) the health worker is sentenced to imprisonment for a criminal act against people's health, except for crimes quoted in Article 102, Paragraph 1 of this Law;
- 2) the measure of banning to perform health activities is pronounced to the health worker;
- 3) the health worker carries out activities that are out of the area for which the license is valid; and
- 4) the health worker breaches the health ethics codex.

The competent association shall revoke the license based on practice if the health worker does not acquire expertise and skills in accordance with this Law.

Period of time for which the license referred to in Paragraph 1 and 2 of this article is revoked cannot be longer than 5 years.

#### **Article 102**

Permanent taking away of the license shall be applied when the health worker is sentenced to imprisonment for committing a heavy crime against people's health or for crimes against humanity or other goods protected by international law.

The Ministry shall issue a formal decision on permanent taking away of general license.

#### **Article 103**

Health workers may appeal against formal decisions issued by the Ministry, referred to in Article 101, Paragraph 2 of this Law.

The appeal shall be addressed to the Ministry as the second instance authority.

#### **Article 104**

An administrative lawsuit can be initiated against the formal decision of the Ministry referred to in Article 98, Paragraph 1, Article 99, Paragraph 9, Article 102, Paragraph 2, and Article 103, Paragraph 2 of this Law.

### **4. The Association of Doctors, Dentists, or Pharmacists**

#### **Article 105**

The Doctors' Association of Montenegro, the Dentists' Association of Montenegro, and the Pharmaceutical Association of Montenegro shall be established in order to improve conditions for carrying out MDs', dentists' and pharmacists' profession, protection of their professional interests, and taking part in the improvement of health care quality.

Members of the Doctors' Association of Montenegro are MDs carrying out health care activities in the area of medicine.

Members of the Dentists' Association of Montenegro are dentists carrying out health care activities in the area of dentistry.

Members of the Pharmacists' Association of Montenegro are pharmacists carrying out health care activities in the area of pharmacy (pharmaceutical activity).

#### **Article 106**

The Doctors' Association of Montenegro, the Dentists' Association of Montenegro, or the Pharmaceutical Association of Montenegro (hereinafter: the Association) shall have the status of a legal entity.

The Association shall develop the Statute, which shall define: objectives and tasks of their founding, the work and functioning of the Association, Association's governing bodies and the method of their election and their mandate, the method of passing and implementing decisions, the method of financing Association, rights and obligations of the Association members, and other issues relevant to the Association functioning.

The Ministry shall approve of the Statute of the Association.

The Ministry shall supervise legality of the Association's activities, in accordance with the law.

**Article 107**

The funding for the Association functioning shall be provided from:

- 1) membership fees;
- 2) the Republic Budget – for covering real cost;
- 3) donations and other sources.

**Article 108**

The Association shall perform the following activities:

- 1) develops the plan and program of the Association activities;
- 2) defines ethical standards for the Association's members in performing health activities (Health Ethics Codex) and ensures its implementation;
- 3) maintains the Registry of licenses based on practice and issues certificates on facts on which records are kept;
- 4) issues, renews, and revokes licenses based on practice;
- 5) monitors and studies the activity and working conditions of its members in performing health activities;
- 6) develops the act on valorization in terms of Article 96 of this Law;
- 7) undertakes measures to upgrade quality of professional work of its members;
- 8) offers opinions in the procedure of the development and application of laws, plans, and other regulations in the field of health, in accordance with the law;
- 9) performs other activities established by this Law and the Association's Statute.

The Association shall perform activities referred to in Paragraph 1, items 1,3,4 and 6 of this article as assigned duties that are funded from the Republic Budget.

**THE QUALITY OF HEALTH CARE AND CONTROL OF THE QUALITY OF PROFESSIONAL PERFORMANCE**

**1. The Upgrading of the Quality of Health Care**

**Article 109**

Health institutions shall be obliged to work on the improvement of health care quality.

Each health worker and associate shall be responsible for the improvement of health care quality, within his/her authorization.

**Article 110**

The health care quality shall be established in relation to conditions and means of health care, human resources, expertise and skills and their application, the improvement of health conditions, removal of causes and reduction of damaging impacts of risky actions and environmental factors, as well as the quality of life.

### **Article 111**

The improvement of health care quality means the introduction of the monitoring and evaluation process into all levels of health care, as an integral part of the health care system management and management of health activities in the Republic.

Health institutions shall be obliged to establish monitoring and evaluation processes as an integral part of their regular and expert activities in administering health care to the population.

The Ministry shall issue detailed instruction for performing monitoring and establishing evaluation process, with indicators and criteria as means of monitoring or evaluation.

## **2. Control of the Quality of Professional Performance**

### **Article 112**

Control of the quality of professional performance shall be conducted internally and externally.

The quality control shall encompass the assessment and measuring of:

- Fulfillment of prescribed working conditions of health institutions,
- Application of adopted health standards,
- Reduction of non-desirable, unnecessary, and inappropriate processes,
- Undertaken measures for professional capacity building and education of health workers.

### **Article 113**

Internal control of professional performance shall be conducted in continuum, with methods and under conditions established by the health institution's Statute.

Heads of organizational units and directors of health institutions shall have particular obligation and responsibility for the quality of professional performance.

### **Article 114**

The Ministry shall organize and implement external control of professional performance.

External control of professional performance can be regular or extraordinary.

Regular control shall be conducted in continuum and extraordinary control shall be undertaken upon submitted request and in other extraordinary cases.

### **Article 115**

Control of the quality of professional performance shall be conducted by a commission.

The commission members, appointed by the Ministry, shall be prominent health workers, representatives of the competent association and the college of medicine.

The Chairman of the commission should have at least the same level of education or scientific title as the head of the organizational unit and health worker whose performance quality is being controlled.

### **Article 116**

Any legal or private entity can submit the request for the professional performance quality control.

The request shall be submitted to the Ministry.

The Ministry shall inform the applicant on found facts and undertaken measures against the request referred to in Paragraph 1 of this article.

#### **Article 117**

The Ministry, on the basis of the report on completed control of the quality of professional performance, may ban the health institution or its part to perform certain activities if found inadequacies are of such nature that they may have serious impact on citizens' health.

#### **Article 118**

The Ministry shall regulate the method, procedure, and organization of internal and external quality control of professional performance, measures that can be undertaken for removal of found inadequacies, and other issues relevant for the professional performance quality control.

### **3. Health Institution Accreditation**

#### **Article 119**

The committee for accreditation of health institutions (hereinafter: the committee), with rights and obligations established by this Law, shall carry out evaluation of the health institution in terms of meeting the optimum level of established standards within certain area of health care or branch of medicine and the quality of administered health services.

The committee referred to in Paragraph 1 of this article shall issue certificates on the health institution accreditation.

The Committee shall regulate the evaluation method and issuing or revoking certificates for health institution accreditation.

#### **Article 120**

The Ministry shall determine composition of the committee for certain areas of health care or branch of medicine – the committee members shall be elected from the established reference list of accreditation experts.

The Ministry shall establish the reference list upon proposal of the Doctors' or Pharmaceutical Association and medical college.

The list referred to in Paragraph 2 of this article shall be published in the Official Gazette of the Republic of Montenegro.

The Ministry shall closely regulate composition, the method of functioning, decision making, and other issues relevant for the work of the committee.

#### **Article 121**

The accreditation shall be voluntary.

The health institution, which wants to be accredited, shall submit its application for accreditation to the committee.

The accreditation shall be granted to the health institution for which the committee finds that it meets established standards for certain area of health care or branch of medicine.

#### **Article 122**

The committee shall issue the certificate on accreditation to the health institution after it has established that the applicant met established accreditation standards.

The certificate referred to in Paragraph 1 of this article may refer to a specific area of health care or branch of medicine or to the overall activity of the health institution and it shall be issued for a definite period of time – maximum to the period of 7 years.

The committee's report shall be incorporated into the certificate referred to in Paragraph 2 of this article.

Exceptionally, the committee may issue a temporary certificate to the health institution that does not fully meet accreditation conditions.

The temporary certificate referred to in Paragraph 4 of this article shall define the deadline within which the health institution is obliged to meet established standards.

The Committee shall be obliged to make the certificate on accreditation of the health institution, including temporary certificate, accessible and public.

#### **Article 123**

The health institution, which has acquired accreditation, shall be obliged to report to the committee any change related to accreditation.

#### **Article 124**

The accreditation certificate acquired in accordance with this Law or certificate recognized by the European Agency competent for health institutions accreditation shall represent evidence on health institution's reference.

#### **Article 125**

The accreditation cost shall be borne by the health institution that has applied for accreditation.

The Ministry shall establish the cost amount referred to in Paragraph 1 of this article.

### **ESTABLISHMENT OF THE CAUSE OF DEATH**

#### **Article 126**

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

For persons who die at the health institution, the time of death shall be established by the medical doctor employed by that institution.

For persons who die out of the health institution, the time of death shall be established by MD who is assigned by the competent authority of the local self-government unit, from coroners' list that is established by the Ministry.

Means for establishing time of death for persons who die out of the health institution shall be provided in accordance with the law.

#### **Article 127**

In the case that MD, when establishing the cause of death, finds or suspects that cause of death is a contagious disease, which is liable to mandatory reporting, he/she shall be obliged to report it to the health inspector or to the competent police authority in case of suspicion that the death has been caused by applied force, suicide, or an accident

#### **Article 128**



The autopsy shall be performed as a special measure for establishing the cause of death.

The dead body shall be mandatory exposed to autopsy in the following cases:

- 1) of the person who has died at the health institution if the exact cause of death has not been established;
- 2) upon request of MD who has medically treated the dead person;
- 3) of the person brought to the health institution with unknown cause of death;
- 4) upon request of MD assigned to establish the cause of death;
- 5) upon request of the family member of the deceased;
- 6) if requested by the investigation authority on the basis of a suspicion that the death was caused by a criminal offence or related to the criminal offence;
- 7) when it is of a special relevance for the protection of health of citizens or when epidemiological and sanitary reasons call for it.

Forensic autopsy shall be performed by one or more specialists of forensic medicine.

Pathological-anatomical (clinical) autopsy shall be performed by one or more pathology specialists.

In exceptionally complex and boundary cases, an expert team, with at least one forensic specialist and one pathologist, shall perform autopsy.

#### **Article 129**

The cost of autopsy of dead person referred to in Article 128 of this Law shall be born by:

- 1) for dead person referred to in items 1-4 and item 7 – the Republic;
- 2) for dead person referred to in items 5 and 6 – the person who has requested autopsy.

#### **Article 130**

The dead person shall be buried after the cause of death has been established, within 24-48 hours after the death has occurred, as a rule.

Exceptionally, upon the request of the administrative authority competent for sanitary inspection, burial can be performed before 24 hours have elapsed or after 48 hours have elapsed from the occurrence of death.

#### **Article 131**

The Ministry shall closely regulate conditions for the establishment of time and cause of death of dead persons and for autopsy of dead bodies.

#### **Article 132**

The procedure for handling human body parts that have been removed surgically, or in some other manner, shall be regulated by the Ministry, with an approval of the ministry competent for the housing and communal affairs.

Each human body part that has been surgically removed shall be patho-morphologically and histologically processed.

### **SUPERVISION**

### **Article 133**

The Ministry shall perform, in line with the law, supervision over the application of provisions of this Law and regulations and other general legal acts developed on the basis of this Law, as well as over the implementation of prescribed measures of health care.

Health inspectors shall carry out, in line with the law, the inspecting supervision within the Ministry's competence.

## **PENAL PROVISIONS**

### **Article 134**

The health institution shall be fined for an offence with twenty-fold to three hundred-fold the amount of the minimum wages (the lowest labor price) in the Republic if it:

- 1) deprives a citizen of rights quoted in Article 18 of this Law;
- 2) does not admit a mentally ill patient for temporary in-patient medical treatment if such patient may endanger his/her own life or lives of other persons, in line with the provision of Article 23, Paragraph 2 of this Law;
- 3) provides health care under special conditions, which is in collision with the provision of Article 25 of this Law;
- 4) in implementation of health care, does not apply recognized and scientifically proved medical methods and procedures prescribed by Article 26, Paragraph 1 and Article 27 of this Law;
- 5) advertises medical methods and procedures of health care in media, thus acting against provisions of Article 28 of this Law;
- 6) performs activities before the Ministry has established that conditions for performing health activity are met according to the provision of Article 54 of this Law;
- 7) does not inform the Ministry on the change of conditions for performing health activity in terms of the provision of Article 55, Paragraph 3 of this Law;
- 8) does not provide continuity of health care and working hours schedule, in line with the provision of Article 71 of this Law;
- 9) leases premises, medical-technical equipment, and other means necessary for performing health care activity or other equipment and means that serve for the provision of health care, which is in collision with the provision of Article 75 of this Law;
- 10) prevents the health worker or associate from his/her professional capacity building aimed at maintaining and improving of the health care quality, in line with the provision of Article 86 of this Law;
- 11) does not conduct internal control of the professional performance quality in terms of articles 112 and 113 of this Law;
- 12) does not perform autopsy of a dead body in terms of Article 128 of this Law.

Also, the responsible person of the health institution shall be fined for an offence referred to in Paragraph 1 of this article with five-fold to twenty-fold the amount of the minimum wage in the Republic.

### **Article 135**

A private person, who is not a health worker or a health associate in terms of Article 81 of this Law and performs health activity, shall be fined with twenty-fold amount of the minimum wage in the Republic.

### **Article 136**

The health worker shall be fined for an offence with the five-fold to twenty-fold the amount of the minimum wage in the Republic for performing health activity if he/she:

- 1) does not administer urgent medical assistance when needed in terms of the provision of Article 18, paragraph 1, Item 4 of this Law;
- 2) does not point to the citizen consequences that may occur on the basis of refusal of medical intervention, in terms of the provision of Article 22 of this Law;
- 3) does not implement appropriate diagnostic and therapeutic procedures if he/she suspects the person is dangerous for the health of others due to contagious disease, in terms of the provision of Article 23, Paragraph 1 of this Law;
- 4) breaches the obligation of keeping professional secret established by Article 24, Paragraph 1 of this Law;
- 5) advertises medical methods and procedures of health care in media, thus acting against provisions of Article 28 of this Law;
- 6) performs health activities before it has been established by a formal decision that conditions for performing health activity are met, which is in opposition to Article 28 of this Law;
- 7) abandons working place, which is in opposition to Article 71, Paragraph 6 of this Law.

### **Article 137**

Private person shall be fined for an offence with five-fold to ten-fold the amount of the minimum wage in the Republic if he/she:

- 1) in emergency situation, does not administer urgent medical assistance to the injured or ill person or does not provide such person with an access to the emergency facility, in line with the provision of Article 3, Paragraph 4 of this Law;
- 2) advertises medical methods and procedures of health care in media, and he/she is not a health worker in line with Article 81 of this Law;
- 3) buries a dead person after deadlines prescribed by Article 130 of this Law.

### **Article 138**

Legal entity shall be fined for an offence with the twenty-fold to three hundred-fold the amount of the minimum wage in the Republic if it enables advertising medical methods and procedures of health care in media, thus acting against provisions of Article 24 of this Law.

The responsible person of the legal entity shall be fined for the offence referred to in Paragraph 1 of this article with five-fold to twenty-fold the amount of the minimum wage in the Republic.

### **Article 139**

Employer shall be fined for an offence with the twenty-fold to three hundred-fold the amount of the minimum wage in the Republic if it does not provide specific health care of the employed, in line with Article 15 of this Law.

The responsible person of the employer shall be fined for the offence referred to in Paragraph 1 of this article with one half to twenty-fold the amount of the minimum wage in the Republic.

## **TRANSITIONAL AND FINAL PROVISIONS**

**Article 140**

By-laws for the implementation of this Law shall be developed within one year from the date of enactment of this Law.

Existing legal acts shall be applied until by-laws referred to in Paragraph 1 of this article are developed, if they are not in collision with this Law.

The legal act quoted in Article 19, Paragraph 5 of this law shall be developed within 6 months from the date of enactment of this Law.

**Article 141**

Primary health care, which is implemented through selected team or selected doctor in terms of Article 19 of this Law, shall be introduced gradually commencing from the date of enactment of the legal act referred to in Article 140, Paragraph 3 of this Law.

Professional capacity building and education of health workers for work in primary health care in line with Article 19 of this Law shall be implemented gradually, according to the plan, which will be developed by the Ministry within three months from the date of enactment of this Law.

**Article 142**

The health institution network shall be developed within one year from the day of enactment of this Law.

Until the network referred to in Paragraph 1 of this article is developed, health institutions that were founded, i.e. organized by the Decision on Organizing Public Institutions in the Area of Health Care in SR Montenegro (Official Gazette of Socialist Republic of Montenegro 21/91 and the Official Gazette of the Republic of Montenegro 34/91) and by the Decision on Organizing the Public Health Institution "The Clinical Center of Montenegro" (Official Gazette of the Republic of Montenegro 19/2000 and 63/2002), shall continue their activities.

The public health institution the Institute for Public Health of Montenegro, founded by the Decision on Organizing the Public health Institution "The Institute for Public Health of Montenegro" (Official Gazette of the Republic of Montenegro 3/2002 and 63/2002), shall continue its activities as the Institute for Public Health and shall harmonize its organization and functioning with provisions of this Law within three months from the date of enactment of this Law.

**Article 143**

The program for integration of private and public sector, in terms of Article 12 of this Law, shall be developed within one year from the date of enactment of this Law.

**Article 144**

Health institutions and other legal acts performing health activity shall harmonize their organization, functioning, and legal acts with provisions of this Law within one year from the date of enactment of this Law.

Existing legal acts shall be applied until general legal acts referred to in Paragraph 1 of this article are developed, if they are not in collision with this Law.

**Article 145**

The Doctors' Association of Montenegro or the Dentists' Association of Montenegro shall be organized, in line with provisions of this Law, within six months from the date of enactment of this Law.

The existing Doctors' Association of Montenegro shall carry out preparations for organizing associations referred to in Paragraph 1 of this article.

**Article 146**

The Doctors' Association of Montenegro or the Pharmaceutical Association of Montenegro shall harmonize their organization, functioning, and legal acts, in line with provisions of this Law, within six months from the date of enactment of this Law, and The Dentists' Association shall do that within one year from the date of enactment of this Law.

**Article 147**

The Ministry shall issue general license referred to in Article 98 of this Law to those health workers who have already acquired the license according to the existing regulations.

Health workers who meet the conditions for acquiring the license based on practice may submit their applications for this license within 30 days from the date of enactment of the legal act quoted in Article 99, Paragraph 10 of this Law.

**Article 148**

The procedure of approving and implementing specialization, which has commenced before the enactment of this Law, shall be finalized according to the regulations that were in force until enactment of this Law.

**Article 149**

On the day of enactment of this Law, provisions of the Law on Health Care and Health Insurance (Official Gazette of the Socialist Republic of Montenegro 39/90, 21/91, and the Official Gazette of the Republic of Montenegro 30/92, 58/92, 6/94, 27/94, 16/95, 20/95, and 23/96) related to health care shall become invalid.

**Article 150**

This Law shall come into force on the eight day after being published in the Official Gazette of the Republic of Montenegro.