

L A W
ON HEALTH CARE

I. BASIC PROVISIONS

Article 1

This Law governs the health care system, organization of the health service, social care for the health of the population, general interest in health care, the rights and obligations of patients, health care of foreigners, setting up of the Agency for Accreditation of Health Care Facilities of Serbia, supervision over the enforcement of this Law, as well as other issues of importance for the organization and implementation of health care.

Health Care

Article 2

Health care, in the sense of this Law, is the organized and comprehensive activity of the society with the underlying goal to achieve the highest possible level of preservation of the health of citizens and families.

Health care, in the sense of this Law, includes implementation of measures for preservation and improvement of the health of citizens, prevention, control, and early detection of diseases, injuries, and other health disorders and timely and efficient treatment and rehabilitation.

The Right to Health Care

Article 3

A citizen of the Republic of Serbia (hereinafter referred to as: the Republic), same as any other person who has permanent or temporary residence in the Republic, is entitled to health care, in accordance with the law, and it is his/her duty to preserve and improve his/her health and the health of other citizens, as well as the conditions of living and working environment.

Participants in Health Care

Article 4

Citizens, family, employers, educational and other facilities, humanitarian, religious, sports and other organizations, associations, health service, the health insurance organization, as well as municipalities, cities, autonomous provinces, and the Republic shall participate in the provision and implementation of health care in the Republic.

Health Care Activity

Article 5

Health care activity is the activity by which health care of the citizens is provided, which includes implementation of measures and activities of health care, which are, in accordance with the health care doctrine and using health care technologies, used for preservation and improvement of the health of people, and which is provided by the health service.

The measures and activities of health care must be based on scientific evidence, i.e. they must be safe, reliable and efficient and in compliance with the principles of professional ethics.

Health Service

Article 6

The health service in the Republic is made up of the health care facilities and other forms of health service (hereinafter referred to as: private practice), which are set up for the purpose of implementation and providing of health care, as well as of medical workers, and/or medical associates, who engage in health care activity, in accordance with this Law.

Financing of Health Care

Article 7

The resources for the implementation of health care, as well as for the work and development of health service, shall be provided in accordance with the law.

II. SOCIAL CARE FOR THE HEALTH OF THE POPULATION

Article 8

Social care for the health of the population is realized on the level of the Republic, autonomous province, municipality, or city, employer, and individual.

Within the social care for health referred to in paragraph 1 of this Article health care is provided, which includes:

- 1) Preservation and improvement of health, detection, and control of risk factors influencing onset of diseases, acquiring of the knowledge and habits concerning healthy lifestyle;
- 2) Prevention, control, and early detection of diseases;
- 3) Early diagnostics, timely treatment, rehabilitation of the diseased and injured;
- 4) Information needed by the population or individual for responsible actions and for exercising of the right to health.

Social Care for Health on the Republic Level

Article 9

Social care for health on the Republic level consists of the measures of economic and social policies by which conditions are created for implementation of health care for the purpose of preservation and improvement of the health of people, as well as the measures by which the activity and development of the health care system are harmonized.

Article 10

Social care for health on the Republic level, in the sense of Article 9 of this Law, includes:

- 1) Establishing of the priorities, planning, adoption of special programs for implementation of health care, as well as passing of regulations in this area;
- 2) Implementation of measures of taxation and economic policies stimulating the development of healthy lifestyle habits;
- 3) Providing of the conditions for education concerning the health of the population;
- 4) Providing of the conditions for development of an integrated health care information system in the Republic;
- 5) Development of scientific R&D activity in the field of health care;
- 6) Providing of the conditions for professional advancement of medical workers and medical associates.

Social care for health on the Republic level also includes adoption of the Republic Program in the area of protection of health from polluted environment, which is caused by noxious and hazardous matters in air, water and soil, disposal of waste matters, noxious chemicals, sources of ionizing and non-ionizing radiations, noise and vibrations, as well as carrying out of systematic tests of victuals, items of general use, mineral drinking waters, drinking water and other waters used for the production and processing of foodstuffs and for sanitary and hygienic and recreational requirements, for the purpose of establishing their sanitary and hygienic condition and the specified quality (monitoring).

The Program referred to in paragraph 2 of this Article shall jointly adopt the minister in charge of health affairs (hereinafter referred to as: the minister) and the minister in charge of the affairs of environment protection.

The resources for the implementation of the social care for health on the Republic level shall be provided in accordance with the law.

Article 11

Social care for health, under equal conditions, shall be exercised in the territory of the Republic by providing health care to the groups of population that are exposed to an increased risk of contracting diseases, health care of persons related to prevention, control, early detection, and treatment of diseases of major

social and medical importance, as well as by health care of the socially vulnerable population.

Health care referred to in paragraph 1 of this Article includes:

1) Children up to turning 15 years of age, school children and students until the end of statutory schooling, and maximum up to 26 years of age, in compliance with the law;

2) Women related to family planning, as well as during pregnancy, childbirth and maternity up to 12 months after childbirth;

3) Persons over 65 years of age;

4) Persons with a disability and mentally insufficiently developed persons;

5) Persons who have contracted HIV infection or other communicable diseases that are specified by a separate law governing the area of protection of the population from communicable diseases, malignant diseases, hemophilia, diabetes mellitus, psychosis, epilepsy, multiple sclerosis, persons in the terminal stage of chronic kidney insufficiency, cystic fibrosis, systemic autoimmune disease, rheumatic fever, addiction diseases, diseased and/or injured persons related to providing emergency medical care, as well as health care related to donation and receiving of tissues and organs;

6) Monks and nuns;

7) Materially unprovided persons who receive relief according to the regulations on social welfare and protection of veterans, military and civilian invalids of war, as well as members of their families if they are not health insured;

8) Beneficiaries of permanent pecuniary aid according to the regulations on social welfare as well as of benefit for placement in institutions of social protection or in other families;

9) Unemployed persons and other categories of socially vulnerable persons whose monthly income earnings are below income earnings established in compliance with the law governing health insurance;

10) Beneficiaries of cash benefit for the family members whose breadwinner is doing his military service;

11) Persons of the Roma nationality who, due to their traditional lifestyle do not have permanent or temporary residence in the Republic.

12) Domestic violence victims;

13) People trafficking victims;

14) Persons to whom mandatory immunization is provided pursuant to the provisions regulating public health protection from infectious diseases;

15) Persons to whom targeted preventive examinations, or screening, are provided pursuant to the relevant government programs;

16) Single parents of children up to seven years of age, with monthly income below that established by law regulating health insurance.

The Government of the Republic of Serbia (hereinafter referred to as: the Government) shall regulate the contents and scope, the method and procedure,

as well as the conditions for exercising of health care of the persons referred to in paragraph 2 of this Article, unless otherwise laid down by the legislation.

Article 12

Health care for the persons referred to in Article 11 of this Law who are covered by compulsory health insurance shall be provided from the funds of compulsory health insurance in compliance with the law governing the area of compulsory health insurance.

Unless otherwise laid down by the legislation, the funds for exercising of health care referred to in Article 11, paragraph 3 of this Law for the persons who are not covered by compulsory health insurance shall be provided in the budget of the Republic and shall be transferred to the organization in charge of compulsory health insurance.

Social Care for Health on the Level of the Autonomous Province, Municipality, or City

Article 13

Social care for health on the level of an autonomous province, municipality, or city, includes the measures for providing and implementation of health care of interest for the citizens in the territory of autonomous province, municipality, or city, as follows:

1) Monitoring of the state of health of the population and the operation of the health service in their respective territories, as well as looking after the implementation of the established priorities in health care;

2) Creating of conditions for accessibility and equal use of the primary health care in their respective territories;

3) Coordination, encouraging, organization, and targeting of the implementation of health care, which is exercised by the activity of the authorities of the local self-government units, citizens, enterprises, social, educational, and other facilities and other organizations;

4) Planning and implementation of own program/s for preservation and protection of health from polluted environment, which is caused by noxious and hazardous matters in air, water, and soil, disposal of waste matters, hazardous chemicals, sources of ionizing and non-ionizing radiation, noise and vibrations in their respective territories, as well as by carrying out systematic tests of victuals, items of general use, mineral drinking waters, drinking water, and other waters used for production and processing of foodstuffs, and sanitary and hygienic and recreational requirements, for the purpose of establishing their sanitary and hygienic condition and the specified quality;

5) Providing of the funds for assuming of the foundation rights to the health care facilities it is the founder of in compliance with the law and with the Plan of the network of health care facilities, and which includes construction, maintenance, and equipping of health care facilities, and/or capital investment, capital-current maintenance of premises, medical and non-medical equipment and means of transport, equipment in the area of integrated health care information system, as well as for other liabilities specified by the law and by the articles of association;

6) Cooperation with humanitarian and professional organizations, unions and associations, in the affairs of health care development;

7) Provision of conditions for better staffing of its health care institution along with norms, or standards established pursuant to this Law and bylaws adopted for the enforcement of this Law, for which, due to lack of resources of the mandatory health insurance, the required resources cannot be provided based on the contract concluded with the mandatory health insurance organization, or due to lack of resources of the health care institution, until the conditions are provided for funding the staffing by mandatory health insurance, or from the income of the health care institution itself;

8) Provision of resources for emergency medical aid pursuant to Article 162. paragraphs 1 and 2 of this Law.

A municipality or city shall ensure the operation of coroner's service in their respective territories.

An autonomous province, municipality, or city shall provide the funds for realization of social care for health referred to in paragraph 1 of this Article in the of the autonomous province, municipality, or city, in accordance with the law.

An autonomous province, municipality, or city may adopt special health care programs for certain categories of the population, and/or kinds of diseases that are specific for the autonomous province, municipality, or city, for which no special health care program has been adopted on the Republic level, in accordance with their respective capabilities, and shall set prices of such individual services, or programs.

Article 13

(1) Social care for health at the level of autonomous province, municipality, or city can also include measures for the provision of health care of interest to the citizens in the territory of such autonomous province, municipality or city, which provide the conditions for better accessibility to the use of health care in their territories in health care institutions founded it and which are of higher priority than the norms, or standards set out by this Law and bylaws adopted for the enforcement of this Law in terms of space, equipment, staff, medicines and medical devices that are not provided pursuant to the provisions of the law governing mandatory health insurance, including other necessary costs of operation of the said health care institution contributing to higher standards in the provision of health care.

(2) The provision of staff set out in Article 13, paragraph 1, item 7) of this Law, and paragraph 1 of this Law involves the provision of resources for employee salaries, bonuses and other compensations according to law, or the collective agreement, and the mandatory health care fees.

(3) An autonomous province, municipality or city can provide the resources also for the execution of founder's rights over a health care institution in order to perform the obligations of the health care institutions, for obligations not funded from the mandatory health insurance or in any other way pursuant to law for which a health care institution cannot provide the resources in the financial plan.

(4) An autonomous province, municipality or city can provide the resources also for security of the facilities and equipment of the health care institution of which it is founder, pursuant to law.

(5) An autonomous province, municipality or city shall provide the resources for providing social care of health set out in paragraphs 1-4 of this Article in the budget of such autonomous province, municipality or city pursuant to law.

Social Care for Health on the Employer Level

Article 14

Employer shall organize and provide, from his/her own funds, health care of the employees for the purpose of creating conditions for health-responsible behavior and protection of health at the workplace of the employee, which includes as a minimum:

1) Physical examinations for the purpose of establishing the capacity for work against the order of the employer;

2) Implementation of measures for prevention and early detection of occupational diseases, diseases related to work, and prevention of accidents at work;

3) Preventive physical examinations of the employees (preliminary, periodic, control and targeted examinations) depending on the sex, age, and working conditions, as well as incidence of occupational diseases, accidents at work, and chronic diseases;

4) Physical examinations of employees that are compulsorily conducted for the protection of the living and working environment, for the purpose of protection of the employees from communicable diseases in accordance with the regulations governing the area of protection of the population from communicable diseases, protection of consumers, or users and other compulsory physical examinations, in compliance with the law;

5) Familiarization of employees with the health care measures of safety at work and their education related to the specific conditions, as well as to the use of personal and collective protective devices;

6) Provision of sanitary, technical, and hygienic conditions (sanitary conditions) in the facilities under sanitary supervision and in other facilities in which an activity of public interest takes place in compliance with the law governing the area of sanitary supervision, as well as provision and implementation of general measures for protection of the population from communicable diseases in compliance with the law governing the area of protection of the population from communicable diseases;

7) Other preventive measures (non-mandatory vaccinations, non-mandatory periodic medical periodic checkups), in accordance with the bylaw of the employer;

8) Monitoring of the working conditions and safety at work, as well as assessments of occupational hazards for the purpose of improvement of the working conditions and ergonomic measures, by adjustment of work to the psycho-physiological abilities of the employees;

9) Monitoring of incidences of diseases, injuries, absentees, and mortality rate, particularly from occupational diseases, diseases related to work, accidents at work, and other health damages that affect temporary or permanent change of capacity for work;

10) Participation in the organization of the work and vacation schedules of employees, as well as in the assessment of new equipment and new technologies from the health and ergonomic aspects;

11) Implementation of measures for improvement of health of the workers exposed to health risks during the process of work, including assessment and referral of the workers working on particularly difficult and risky jobs to health care and preventive activities and vacation;

12) Administering of first aid in case of injury at workplace and providing of conditions for emergency medical interventions.

Social care for health on the employer level, in the sense of paragraph 1 of this Article, includes both preliminary and periodic physical examinations of the workers working at workplaces with increased hazard, in the manner and according to the procedure established by the regulations governing the area of safety and health at work.

In providing social care for health on the employer level, the employer shall also provide to the employees other measures of safety and health at work, in accordance with the regulations governing the area of safety and health at work.

Social Care for Health on Individual Level

Article 15

An individual shall, within the limits of his/her knowledge and abilities join in the social care for health, as well as administer first aid to an injured or diseased person in an emergency case and enable him/her access to the emergency medical service.

An individual shall look after his/her own health, the health of other people, as well as the living and working environment.

An individual shall be subjected to compulsory vaccination in international circulation against certain communicable diseases specified by the law governing the area of protection of the population from communicable diseases, as well as bear the expenses of vaccination incurred in the procedure of implementation of that measure.

Health Care Development Plan

Article 16

For the purpose of providing and implementation of the social care for health on the Republic level, the National Parliament of the Republic of Serbia shall adopt the Health Care Development Plan (hereinafter referred to as: the Development Plan).

For the purpose of implementation of the Development Plan, the Government shall adopt health care programs.

Article 17

The Development Plan is based on the analysis of the state of health of the population, needs of the population for health care, available staff, financial and other capabilities.

The Development Plan shall contain:

- 1) The priorities in the development of health care;
- 2) Goals, measures, and activates of health care;
- 3) Health needs of the groups of the population that are exposed to particular risk of contracting diseases of the interest for the Republic;
- 4) Specific needs of the population for health care and possibility of their meeting in certain areas;
- 5) Indicators for monitoring of achievements in the implementation of goals;
- 6) Agents of measures and activities and timeframes for attaining the objective of health care;
- 7) Criteria for setting up of the network of health care facilities in the Republic the founder of which is the Republic, autonomous province, municipality, or city, as well as the bases for the development of health service on the primary, secondary, and tertiary levels;
- 8) Elements for planning, education, and improvement of the employees within the health care system, as well as the elements for planning of construction of new and restructuring of the existing capacities with respect to the premises and equipment;
- 9) Sources for financing of health care and development of the health insurance system;
- 10) Other data of importance for the development of the health care system.

III. ACCOMPLISHING OF GENERAL INTEREST IN HEALTH CARE

Article 18

The Republic shall provide, as the general interest in health care, the following:

- 1) Monitoring and studying of the living and working conditions and the state of health of the population, and/or individual groups of the population, causes of onset, spreading, and methods of prevention and control of diseases and injuries of major social and medical importance;
- 2) Health promotion in compliance with the health care programs and providing of the conditions for implementation of special programs for preservation and improvement of health;
- 3) Implementation of epidemiological supervision and organizing and implementation of special measures for the protection of the population from communicable diseases, implementation of emergency measures established in compliance with the law governing the area of protection of the population from communicable diseases, as well as implementation of the programs for prevention, control, elimination, and eradication of communicable diseases, in compliance with the law;
- 4) Prevention, control, and eradication of epidemics of communicable diseases;

5) Monitoring and prevention of chronic mass non-communicable diseases and addition diseases;

6) Systematic epidemiological and systematic hygienic monitoring, as well as systematic monitoring and testing of the effects of environment pollution on the health of people, as well as systematic testing of sanitary quality of foodstuffs, items of general use, and drinking water;

7) Emergency medical care to persons of unknown residence;

8) Health care of persons serving a prison sentence, which is provided to them outside the penitentiary institution, implementation of security measures of compulsory psychiatric treatment and placement in a health care facility, compulsory psychiatric outpatient treatment, compulsory treatment of alcoholics and drug addicts;

9) Prevention and elimination of consequences to health caused by natural and other disasters and emergency situations;

10) Organization and development of an integrated health care information system by acquisition, processing, and analysis of health and statistical and other data and information on the state of health and health needs of the population, as well as monitoring of the data on the functioning of the health service with respect to the provided premises, staff, equipment, and drugs, as well as monitoring of the performance indicators;

11) Monitoring and continuous improvement of the quality of health care and implementation and control of the quality of health care;

12) Organization and implementation of quality assurance of professional work;

13) Extraordinary control of the quality of drugs, as well as control of random samples of drugs that are used in humane medicine, according to the program of the ministry in charge of the affairs of health (hereinafter referred to as: the Ministry);

14) Encouraging the activities to improve rational pharmacotherapy in the treatment of the diseased and injured;

15) Encouraging the activities on popularization of voluntary blood donation and implementation of programs of collection of blood, as well as of donation and receiving of organs and tissues for transplantation;

16) Providing of conditions for the work of the Republic professional commissions, as well as of the commission for evaluation of health care technologies;

17) Encouraging the activities of the humanitarian and professional organizations, unions and associations on the operations that are, as a priority, envisaged by the Development Plan, and/or by special health care programs;

18) Participation in providing funds for equalization of the conditions for uniform providing of health care in the entire territory of the Republic, and in particular on the primary health care level in the municipalities having unfavorable demographic characteristics and underdeveloped municipalities, in accordance with the priorities;

19) Providing the funds for construction and equipping of state owned health care facilities the founder of which is the Republic, which includes: capital investment, capital - current maintenance of premises, medical and non-medical equipment and means of transport, equipping in the area of integrated health care

information system, as well as providing of funds for other liabilities specified by the law and by the articles of association;

20) Financing of applied research works in the area of health care;

21) Implementation of the Government measures in natural and other major disasters and emergency situations.

22) Provision of resources for conducting the activities set out in Article 124, paragraph 2, items 1)-7) of this Law, and for conducting the procedure for the establishment of the level of ionizing and non-ionizing radiation in the field of health care by the Occupational Health Institute established for the territory of the Republic of Serbia.

The funds for realization of the general interest in health care referred to in paragraph 1 of this Article shall be provided from/in the budget of the Republic.

(3) The Commission for proposing the priorities set out in paragraph 1, item 19) of this Article shall be established by the Minister.

IV. PRINCIPLES OF HEALTH CARE

The Principle of Accessibility to Health Care

Article 19

The principle of accessibility to health care shall be realized by providing of adequate health care to the citizens of the Republic, which is physically, geographically, and economically accessible, and/or culturally acceptable, and in particular of the health care on the primary level.

The Principle of Equity of Health Care

Article 20

The principle of equity of health care shall be realized by the ban on discrimination while providing health care on the grounds of race, sex, age, national affiliation, social origin, religious beliefs, political or other affiliations, income scale, culture, language, kind of disease, mental or bodily disability.

The Principle of Comprehensiveness of Health Care

Article 21

The principle of comprehensiveness of health care shall be realized by inclusion of all citizens of the Republic in the health care system, with the implementation of uniform measures and procedures of health care, which include health promotion, prevention of diseases at all levels, early diagnostics, treatment, and rehabilitation.

The Principle of Continuity of Health Care

Article 22

The principle of continuity of health care shall be realized by the overall organization of the health care system, which must be functionally interconnected and harmonized by levels, from the primary through the secondary to the tertiary level of health care and which shall provide continuous health care to the citizens of the Republic at any age of life.

The Principle of Continuous Improvement of the Quality of Health Care

Article 23

The principle of continuous enhancing of the quality of health care shall be realized by the measures and activities by which, in line with the modern achievements of the medical science and practice, the possibilities of favorable outcome are increased and the risks and other unwanted consequences for the health and the state of health of individuals and the community as a whole are reduced.

The Principle of Efficiency of Health Care

Article 24

The principle of efficiency of health care shall be realized by achieving the best possible results with respect to the available financial resources, and/or by achieving the highest level of health care at the lowest expenditure of funds.

V. HUMAN RIGHTS AND VALUES IN HEALTH CARE AND THE RIGHTS OF PATIENTS

1. Human Rights and Values in Health Care

Article 25

Every citizen has the right to be provided health care while respecting the highest possible standard of human rights and values, i.e. he/she has the right to physical and mental integrity and to the security of his/her personality, as well as to the respect of his/her moral, cultural, religious, and philosophical affiliations.

Every child up to turning 18 years of age shall have the right to the highest possible standard of health and health care.

2. Rights of Patients

The Right to Availability of Health Care

Article 26

Deleted (Official Journal of the RS No.45/13)

The Right to Information

Article 27

Deleted (Official Journal of the RS No.45/13)

The Right to Be Informed

Article 28

Deleted (Official Journal of the RS No.45/13)

The Right to Free Choice

Article 29

Deleted (Official Journal of the RS No.45/13)

The Right to Privacy and Confidential Information

Article 30

Deleted (Official Journal of the RS No.45/13)

The Right to Independent Decision and Consent

Article 31

Deleted (Official Journal of the RS No.45/13)

Article 32

Deleted (Official Journal of the RS No.45/13)

Article 33

Deleted (Official Journal of the RS No.45/13)

Article 34

Deleted (Official Journal of the RS No.45/13)

Article 35

Deleted (Official Journal of the RS No.45/13)

The Right to Insight in Medical Documentation

Article 36

Deleted (Official Journal of the RS No.45/13)

The Right to Confidential Data

Article 37

Deleted (Official Journal of the RS No.45/13)

The Right of Patient on Whom Medical Experiment is Conducted

Article 38

Deleted (Official Journal of the RS No.45/13)

The Right to Complaint

Article 39

The patient who has been denied the right to health care, and/or a patient who is not satisfied with the provided health service, or with the act of a health or other worker in a health care facility, may file a complaint to the health care practitioner who manages the process of work or to a person employed in the health care facility who administers the affairs of protection of patients' rights (hereinafter referred to as: the advocate of patients' rights).

health care facility shall organize the work of the advocate of patients' rights.

The director of a health care facility shall nominate the advocate of patients' rights.

The contest shall be filed orally when the minutes are made or in writing.

Further to the complaint referred to in paragraph 4 of this Article, the advocate of patients' rights, promptly and not later than within five days from the date of filing of the complaint, shall establish all the important circumstances and facts related to the allegations presented in the contest.

Promptly and not later than within three days, the advocate of patients' rights shall inform superior of the organizational unit, the director of the health care facility, as well as the party filing the complaint about his/her findings.

The patient who is dissatisfied with the finding further to the complaint may, in compliance with the law, apply to the health inspectorate, or to the competent authority of the health insurance organization with which the patient is health insured.

The advocate of patients' rights shall submit a monthly report about the filed complaints to the director of the health care facility, and a six-monthly and annual report to the management board of the health care facility and to the Ministry.

The advocate of patients' rights shall be independent in his/her work and the director of the health care facility, or any other health care practitioner may not influence his/her work and decision making.

The Right to Damage Compensation

Article 40

Deleted (Official Journal of the RS No. 45/13)

The Right to Respect for Patients Time

Article 40

Deleted (Official Journal of the RS No. 45/13)

3. Informing the Public

Article 41

The citizens of the Republic have the right to information that are needed for preservation of health and acquiring of healthy lifestyle habits, as well as to information on the harmful factors of the living and working environment, which may have negative consequences for health.

The citizens of the Republic have the right to be informed about the protection of their respective health in case of break out of epidemics and other major disasters and accidents (threat from ionizing radiation, poisoning, etc.).

The competent health care facility and private practice shall timely and truthfully submit the data about break out of epidemics and disasters referred to in paragraph 2 of this Article to the competent authorities of the municipality, city, autonomous province, and the Republic, which shall inform the public thereon.

VI. DUTIES OF PATIENTS

Article 42

Deleted (Official Journal of the RS No. 45/13)

Article 43

Deleted (Official Journal of the RS No. 45/13)

VII. MANDATORY REFERRAL TO A PSYCHIATRIC INSTITUTION

Article 44

Should a doctor of medicine, or a specialist psychiatrist, or a specialist neuropsychiatrist assess that the nature of mental illness of a patient is such that it may threaten the life of the patient or the life of other persons or property, he/she may refer him/her to hospital treatment, and the relevant doctor of medicine of the relevant inpatient health care facility in charge admit him/her for hospital treatment without the personal consent of the patient in compliance with the law, provided that the day following the admittance, the collegiate body of the inpatient health care facility should decide whether the patient will be withheld for hospital treatment.

The inpatient health care facility shall, within 48 hours from the date of admittance of the patient, notify the competent court about the admittance of the patient referred to in paragraph 1 of this Article.

The method and procedure, as well as organization and the conditions of treatment of mentally ill persons, and/or placement of such persons in an inpatient health care facility, shall be regulated by a separate law.

VIII. HEALTH SERVICE

Article 45

Health service comprises of:

- 1) Health care facilities and private practice;
- 2) Health care practitioners and medical associates who engage in a health care activity in health care facilities and in private practice.

health care facility is engaged in a health care activity, and private practice – in certain types of practice within the health care activity.

. HEALTH CARE FACILITIES AND PRIVATE PRACTICE

1. Types, Requirements for Setting up and Termination of Work of Health Care Facilities

Article 46

health care facility may be founded by the Republic, autonomous province, local self-government, legal or natural person, under the conditions laid down by this Law.

Health care facilities may be founded with the funds in state ownership or private ownership, unless otherwise regulated by this Law.

health care facility may be founded as:

- 1) Outpatient department;

- 2) Pharmacy;
- 3) Hospital (general and specialty);
- 4) Institute;
- 5) Public health institute;
- 6) Clinic;
- 7) Institute – center of excellence;
- 8) Clinical hospital;
- 9) Clinical center.

Article 47

Health care facilities that are founded with the funds in state ownership (hereinafter referred to as: state owned health care facility) are founded in accordance with the Plan of the network of health care facilities (hereinafter referred to as: Plan of the network), which shall be adopted by the Government.

The Plan of the network for the territory of autonomous province shall be established at the proposal of the autonomous province.

The Plan of the network shall be established on the basis of:

- 1) Development Plan;
- 2) State of health of the population;
- 3) Number and age structure of the population;
- 4) The existing number, capacities, and distribution of the health care facilities;
- 5) The degree of urbanization, development, and communications of certain areas;
- 6) Equal access to health care;
- 7) Required scope of certain levels of health care activity;
- 8) Economic capabilities of the Republic.

The Plan of the Network specifies: the number, structure, capacities, and spatial distribution of health care facilities and their organizational units by levels of health care, organization of the service of emergency medical care, as well as other issues of importance for the organization of health service in the Republic.

Article 48

State owned health care facilities referred to in Article 46 of this Law, depending on their type, are founded by the Republic, autonomous province, municipality, or city, in compliance with this Law and the Plan of the network.

Health care facilities referred to in paragraph 1 of this Article shall be founded as follows:

- 1) Outpatient department and pharmacy – shall be founded by the municipality, or city;

2) Institute on the primary level of engaging in a health care activity and clinical hospital – shall be founded by a city;

3) A general hospital, specialty hospital, clinic, institute and clinical center – shall be founded by the Republic, and in the territory of the autonomous province – by the autonomous province;

4) Health care facilities engaged in the activity on several levels of health care, as follows: public health institute, blood transfusion institute, occupational medicine institute, forensic medicine institute, virology, vaccines, and serums institute, rabies prophylaxis institute, psycho-physiological disorders and speech pathology institute, and disinfection, pest control and pest extermination institute – shall be founded in compliance with this Law.

Health care facilities that provide emergency medical care, supply of blood and blood derivative products, taking, keeping, and transplantation of organs and parts of human body, production of serums and vaccines and pathoanatomical and autopsy activity, as well as the health care activity in the area of public health, shall be founded exclusively in state ownership.

Article 49

A health care facility may engage in a health care activity if it meets the requirements laid down by this Law, as follows:

1) If it has certain profile and number of health care practitioners of adequate professional qualifications, who have passed intern's exit exam, and for engaging in certain practices with the relevant specialization, or scientific, and/or academic title;

2) If it has diagnostic, therapeutic and other equipment for safe and modern providing of health care in the activity for which it has been founded;

3) If it has adequate premises for admitting of patients, or healthy persons, for carrying out diagnostic and therapeutical procedures of treatment and placement of patients, as well as for keeping of drugs and Medical devices.

4) If it has adequate kinds and quantities of drugs and Medical devices that are required for engaging in certain health care activities for which the health care facility is founded.

Two or more health care facilities may organize joint medical services for laboratory, x-ray and other diagnostics, as well as joint non-medical services for legal, economic and financial, technical and other affairs.

Detailed requirements with respect to the staff, equipment, premises, and drugs for setting up and engaging in a health care activity by health care facilities referred to in paragraph 1 of this Article shall be specified by the minister.

A health care facility using the sources of ionizing radiation must, apart from the requirements referred to in paragraphs 1 and 3 of this Article, also meet other requirements laid down by the law regulating protection from ionizing radiation.

Article 50

The founder of a health care facility shall adopt articles of association, which shall contain:

- 1) Name and seat, or name and address of the founder;
- 2) Name and seat of the health care facility;
- 3) Activity of the health care facility;
- 4) The amount of funds for setting up and commencement of work of the health care facility and the method of providing the funds;
- 5) The rights and obligations of the founder with respect to engaging in the activity for which the health care facility is founded;
- 6) Mutual right and obligations of the health care facility and the founder;
- 7) Management bodies of the health care facility that is being founded and their authorizations;
- 8) The person who will, up to the appointment of the director of the health care facility, administer the affairs and exercise the authorities of the director;
- 9) The deadline for adoption of the articles of association, appointment of the director and management bodies.

The articles of Association of the health care facility, engaged in the health care activity on the primary level of health care, and founded for the territory of several municipalities, shall regulate mutual rights and obligations of the founder of the health care facility and of other municipalities from the territory of which that health care facility has been founded.

Article 51

A health care facility may engage in a health care activity should the Ministry by its decision establish that the requirements laid down by the law for engaging in health care activities have been met.

A health care facility may only engage in the health care activity that is specified by the decision of the Ministry concerning fulfillment of the requirements for engaging in a health care activity.

The decision referred to in paragraph 1 of this Article shall be handed down by health inspector, in compliance with this Law and the law regulating general administrative procedure.

Against the decision referred to in paragraph 3 of this Article a complaint may be filed to the minister, within 15 days from the date of receipt of the decision of the health inspector.

The decision of the Minister referred to in paragraph 4 of this Article shall be final in the administrative procedure and an administrative suit may be instituted against it.

On the basis of the decision concerning fulfillment of the requirements for engaging in a health care activity, the health care facility shall be registered in the register with the competent court, in compliance with the law.

A health care facility shall start working on the date of registration in the register referred to in paragraph 6 of this Article.

Article 52

A health care facility may be closed down, merge with another health care facility or divided into several health care facilities, in compliance with the law.

The Government shall decide about closing down, merger and division of state owned health care facilities, in accordance with the Plan of the Network, upon the consultation with the founder.

The founder shall decide about closing down, merger and division of the health care facilities in private ownership.

Article 53

The Ministry shall hand down the decision on temporary ban on work, or on temporary ban on engaging in certain types of practice within the health care activity, if:

1) A health care facility does not meet the requirements laid down by the law with respect to the staff, equipment, premises, and drugs;

2) Engages in a health care activity that is not specified by the decision on commencement of engaging in a health care activity;

3) In the procedure of quality assessment of professional work, or exercising supervision over the work of the health care facility, one of the measures specified by this Law is handed down;

4) Puts up the name, or marks the health care facility contrary to the decision on commencement of engaging in a health care activity;

5) Advertises practicing of professional medical procedures and methods of health care, as well as other health services that are provided in the health care facility, contrary to the provisions of Article 71 of this Law;

6) For other reasons specified by the law.

A health inspector, upon establishing the facts referred to in paragraph 1 of this Article shall hand down the decision on the temporary ban on work, or engaging in a health care activity or in certain types of practice within the health care activity.

Against the decision referred to in paragraph 2 of this Article, which is handed down by health inspector, a complaint may be filed to the minister, within 15 days from the date of receipt of the decision.

The decision of the Minister referred to in paragraph 3 of this Article shall be final in the administrative procedure and an administrative suit may be instituted against it.

A health care facility may, on the basis of the decision of the Ministry, resume its work if it, within the time period laid down by the law, or by the decision of the Ministry, eliminates the reasons that gave rise to the temporary ban on work of health care facility or the temporary ban on engaging in certain types of practice within the health care activity.

Article 54

The medical faculties may engage in a health care activity through their organizational units should the Ministry establish that those organizational units meet the requirements laid down by this Law concerning certain type of a health care facility.

Institutions of social protection, penitentiary institutions, as well as other legal persons which are, by a separate law, designated to engage in certain types of practice within the health care activity, may engage in a health care activity should the Ministry establish that they meet the requirements concerning certain type of health care facility, or the requirements concerning certain type of private practice.

2. Types, Requirements for Setting up, and Termination of Work of Private Practice

Article 55

Private practice may be set up by:

- 1) An unemployed health care practitioner who has passed intern's exit exam;
- 2) A health care practitioner beneficiary of old age pension, with the approval of the association of health care practitioners.

Article 56

A private practice may be set up as:

- 1) Outpatient unit of a physician, or dentist (general and specialty);
- 2) Polyclinic;
- 3) Laboratory (for medical, and/or clinical biochemistry, microbiology, pathohystology);
- 4) Pharmacy;
- 5) Outpatient unit (for health care and for rehabilitation);
- 6) Dental laboratory.

Private practice referred to in paragraph 1, Items 5) and 6) of this Article may be set up by a health care practitioner having adequate medical two-year post-secondary school qualifications, or secondary school qualifications, in compliance with this Law and the regulations adopted for enforcement of this Law.

Private practice referred to in paragraph 1, Item 2) of this Article may be set up by several health care practitioners having medical university qualifications, in compliance with this Law and the regulations adopted for enforcement of this Law.

The founder of private practice referred to in paragraph 1 of this Article shall independently engage in an activity as an entrepreneur.

A health care practitioner may set up only one form of private practice referred to in paragraph 1 of this Article.

Private practice may not engage in a health care activity in the area of emergency medical care, supply of blood and blood derivative products, taking, keeping and transplantation of organs and parts of human body, production of serums and vaccines, pathoanatomical – autopsy activity, or a health care activity in the area of public health.

Article 57

The health care practitioner referred to in Article 55 of this Law may set up private practice under the condition that he/she:

- 1) Is generally physically fit;
- 2) Has graduated from a university, or relevant medical school and passed intern's exit exam, and for specialists, the relevant certification exam;
- 3) Has been registered in the directory of the competent association;
- 4) Has been issued, or renewed the license for independent practice, in compliance with the law;
- 5) Meets the requirements laid down by this Law concerning the setting up and commencement of work of private practice with respect to the staff, equipment, premises, and drugs;
- 6) By judgment absolute, he/she has not been handed down a criminal sanction – security measure banning engagement in the health care activity, or by a decision of the competent body of the association, he/she has not been handed down one of the disciplinary actions banning independent practice, in compliance with the law regulating the work of the associations of health care practitioners;
- 7) Meets other requirements laid down by the law.

Article 58

Private practice may engage in certain types of practice within the health care activity if it meets the requirements laid down by this Law, as follows:

- 1) If it has certain profile and number of health care practitioners of adequate professional qualifications, who have passed intern's exist exam, and for engaging in certain types of practice, with the relevant specialization as well;
- 2) If it has diagnostic, therapeutic, and other equipment for safe and modern providing of health care for the activity for which it has been set up;
- 3) If it has adequate premises to engage in a health care activity, or certain types of practice within the health care activity for which it has been set up;
- 4) If it has adequate kinds and quantities of drugs and Medical devices that are required for engaging in certain types of practice with the health care activity for which the private practice is set up.

Detailed requirements with respect to the staff, equipment, premises, and drugs for setting up and engaging in certain types of practice within the health care activity of private practice referred to in paragraph 1 of this Article shall be specified by the minister.

Private practice using the sources of ionizing radiation must, apart from the requirements referred to in paragraphs 1 and 2 of this Article, also meet other requirements laid down by the law regulating the protection from ionizing radiation.

Article 59

Private practice may engage in certain types of practice within the health care activity should the Ministry by its decision establish that the requirements laid down by the law concerning engaging in certain types of practice within the health care activity have been met.

The decision referred to in paragraph 1 of this Article shall be handed down by the health inspector, in compliance with this Law and the law regulating general administrative procedure.

Against the decision referred to in paragraph 2 of this Article a complaint may be filed to the minister, within 15 days from the date receipt of the decision of the health inspector.

The decision of the minister referred to in paragraph 3 of this Article shall be final in the administrative procedure and an administrative suit may be instituted against it.

On the basis of the decision concerning fulfillment of the requirements for engaging in certain types of practice within the health care activity, private practice shall register in the register with the competent authority, in compliance with the law.

Private practice shall start working on the date of registration in the register referred to in paragraph 5 of this Article.

Article 60

Private practice may engage only in certain types of practice within the health care activity that are specified by the decision of the Ministry concerning fulfillment of the requirements for engaging in certain types of practice within the health care activity.

The decision of the Ministry referred to in paragraph 1 of this Article shall also specify the work of private practice in one or in two shifts.

Article 61

Private practice may temporarily terminate engagement in certain types of practice within the health care activity should it inform the Ministry about the reasons for temporary termination of engagement in those type of practice.

The Ministry shall hand down the decision on temporary termination of engagement in certain types of practice within the health care activity of the private practice referred to in paragraph 1 of this Article.

The temporary termination may last maximum 12 months.

The private practice referred to in paragraph 2 of this Article shall notify the Ministry, municipal, or city administration in the territory of which is the seat of private practice, as well as the competent association about its resuming engagement in certain types of practice within the health care activity.

Article 62

Private practice shall:

- 1) Provide emergency medical care to all the citizens;
- 2) Participate at the invitation of the competent government authority in the work on prevention and control of communicable diseases, as well as on protection and rescue of the population in case of natural and other major disasters and emergency situations;
- 3) Carry out continuous quality assurance of its professional work in compliance with the law;
- 4) Put up the work schedule and adhere to that schedule;
- 5) Put up the pricelist of health services and issue the bill for the provided health services;
- 6) Regularly submit to the competent institute, or public health institute, the medical and statistical reports and other records in the field of health care, in compliance with the law;
- 7) Organize, and/or provide measures for collection and/or disposal of medical waste, in compliance with the law.

Article 63

Private practice referred to in Article 56, paragraph 1, Items 1) and 2) of this Law, apart from the requirements laid down by the law and the regulations adopted for enforcements of this Law, in accordance with activity it is engaged in, must also provide constantly available ambulance transport, by concluding the agreement with the closest health care facility that can secure ambulance transport.

Private practice referred to in paragraph 1 of this Article may provide the laboratory and other additional diagnostics that is required to make the diagnosis for its own patient, exclusively in the areas of medicine, or dentistry, which represent the basic activity of the private practice specified in the decision of the Ministry concerning fulfillment of the requirements for engagement in certain types of practice within the health care activity of private practice, by concluding the agreement with the closest health care facility or private practice.

A health care facility, or private practice, with which the founder of private practice has concluded the agreement referred to in paragraphs 1 and 2 of this Article, shall admit the patient with the referral sheet from private practice, or the referral sheet issued by a health care practitioner employed in that private practice.

The expenses of providing health care referred to in paragraphs 1 and 2 of this Article shall be borne by the patient.

For the expenses incurred by providing emergency medical care in private practice, the funds will be provided in compliance with the law.

Article 64

Private practice shall be stricken off the register in case of:

- 1) Being stricken off;
- 2) Death of the founder of private practice;
- 3) Should the founder of private practice permanently lose the capacity for work concerning engaging in a health care activity, upon the decision of the competent authority;
- 4) Should the founder of private practice lose legal/business capacity, fully or partially, upon the decision of the competent court;
- 5) Should the founder of private practice sign an employment contract, or start engaging in any other independent activity as the main occupation, or should he/she be elected, nominated or appointed to a certain function in a government authority, or an authority of the territorial autonomy or a unit of local self-government, for which he/she receives salary;
- 6) Fail to start engaging in certain types of practice within the health care activity within 12 months from the date of registration in the register with the competent authority, in compliance with the law;
- 7) Should he/she set up more than one form of private practice;
- 8) Should he/she engage in the activity at the time of temporary termination of practice upon the decision of the competent authority;
- 9) Being sentenced, more than three times, for engaging in the activity for which it does not fulfill the statutory requirements;
- 10) Should the measure of the ban on engaging in an activity be brought against it because of failing to fulfill the requirement for engaging in that activity, and within the time period specified in the measure handed down, fail to fulfill those requirements, or fail to harmonize the activity;
- 11) For other reasons laid down by the law.

Article 65

The Ministry shall hand down the decision on temporary ban on the work of private practice, if:

- 1) Private practice does not fulfill the statutory requirements with respect to the staff, equipment, premises, and drugs;
- 2) It engages in practicing of a health care activity contrary to the decision of the Ministry by which it has been established that the requirements for engaging in certain types of practice within the health care activity have been fulfilled;
- 3) In the procedure of quality assessment of professional work, or exercising of supervision over the work of private practice, one of the measures/actions specified by this Law is handed down;
- 4) It fails to renew the license for independent practice, or if the license for its independent work is revoked, in compliance with this Law;
- 5) By the decision of the competent body of the association one of the disciplinary actions concerning the ban on independent practice is brought against the founder of private practice;

6) Puts up the business name, or marks private practice contrary to the decision of the Ministry concerning fulfillment of the requirements for engaging in certain types of practice within the health care activity;

7) Advertises practicing of professional medical procedures and methods of health care, as well as other health services that are provided in private practice, contrary to the provisions of Article 71 of this Law;

8) For other reasons laid down by the law.

The health inspector shall, upon establishing the facts referred to in paragraph 1 of this Article, hand down the decision on the temporary ban on work of private practice.

Against the decision referred to in paragraph 2 of this Article a complaint may be filed the minister, within 15 days from the date of receipt of the decision.

The decision of the minister referred to in paragraph 3 of this Article shall be final in the administrative procedure and an administrative suit may be instituted against it.

Private practice may, on the basis of the decision of the Ministry, resume engaging in certain types of practice within the health care activity if it, within the time period laid down by the law, or specified by the decision of the Ministry, eliminates the reasons that gave rise to temporary ban on work of private practice.

Article 66

The regulations governing the area of private entrepreneurship shall apply to the work of private practice, unless otherwise regulated by this Law.

3. Evaluation of Health care Technologies

Article 67

In the implementation of health care, a health care facility and private practice shall apply scientifically verified, tested, and safe health care technologies in prevention, diagnostics, treatment, and rehabilitation.

The health care technologies, in the sense of this Law, imply all health care methods and procedures that can be used for the purpose of improvement of the health of people, in prevention, diagnostics, and treatment of diseases, injuries, and in rehabilitation, which include safe, quality, and efficient drugs and Medical devices, medical procedures, as well as the conditions for providing of health care.

Evaluation of the health care technologies referred to in paragraph 2 of this Article shall be done by the Ministry, on the basis of analysis of medical, ethical, social, and economic consequences and effects of development, spreading or use of health care technologies in providing health care.

For the purpose of assessment of health care technologies, the minister shall form the Commission for Assessment of health care technologies, as a professional body.

The members of the Commission for Evaluation of health care technologies shall be prominent health care practitioners who have made a considerable contribution to the development of certain areas of medicine, dentistry, or pharmacy, application and development of health care technologies, and/or in engaging in a health care activity.

The tenure of the members of the Commission for Evaluation of health care technologies shall be five years.

The Commission for Evaluation of health care technologies shall adopt its rules of procedure.

(8) Detailed requirements, and the method for the assessment of health care technologies and provision of opinion pursuant to this Law, and other issues regulating functioning of the Commission for Evaluation of Health care Technologies shall be prescribed by the Minister.

Article 68

The Commission for Evaluation of health care technologies shall:

- 1) Monitor and coordinate the development of health care technologies in the Republic;
- 2) Harmonize the development of health care technologies with the goals specified in the Development Plan;
- 3) Harmonize the development of health care technologies in the Republic with the international standards and experiences;
- 4) Make assessment of the existing and establish the requirements for introduction of new health care technologies required for providing health care that is based on the evidence of the quality, safety, and efficiency of the methods and procedures of health care;
- 5) Participate in the elaboration of national guidelines of best practice for certain areas of health care;
- 6) Deleted (Official Journal of the RS No.57/11)
- 7) Administer other affairs in compliance with the document on setting up of this Commission.

The Commission for Evaluation of health care technologies in the process of evaluation of health care technologies that are based on application of medical equipment containing the sources of ionizing radiation shall seek opinion from the ministry in charge of the affairs of environmental protection.

The funds for the work of the Commission for Evaluation of health care technologies shall be provided in the budget of the Republic.

(3) In order to provide evaluation and opinion pursuant to this Law, the Commission for Evaluation of Health care Technologies can request the professional position of the competent Government professional commission, competent health care institutions, relevant university departments, scientific and research institutions, public agencies and other bodies, or organizations, and of recognized experts on issues pertaining to the Commission authorities.

Article 69

A health care facility or private practice shall submit the application to the Ministry for issuing of the permit to use new health care technologies.

The new health care technologies, in the sense of this Law, imply the health care technologies that are for the first time introduced in use in the health care facilities in the Republic, or at certain levels of health care, as well as health care technologies that are for the first time used by a certain health care facility or private practice.

The Commission for Evaluation of health care technologies shall hand down the opinion based on new technologies from the area of medicine that are applied in other highly developed countries, the scientific acceptability of which has been confirmed in medical practice of those countries, and they can be applied in the implementation of health care with us.

On the basis of the opinion of the Commission for Evaluation of health care technologies, the Ministry by its decision issues the permit for use of new health care technologies in a health care facility or in private practice.

The decision referred to in paragraph 4 of this Article shall be final in the administrative procedure and an administrative suit may be instituted against it.

(6) The decision referred to in paragraph 4 of this Article shall be submitted to the Agency for licensing Serbian health care institutions, the Public Health Institute established for the territory of the Republic, and the Public Health Institute established for the territory of the Autonomous province of Vojvodina for health care institutions established in the territory of the Autonomous province of Vojvodina.

Article 70

A health care facility or private practice may not use new health care technologies without the permit for use of new health care technologies issued by the Ministry in compliance with this Law.

Should a health care facility or private practice use new health care technologies without the permit for use of new health care technologies, the Ministry shall hand down the decision on the ban on the use of new health care technologies.

The decision referred to in paragraph 2 of this Article shall be final in the administrative procedure and an administrative suit may be instituted against it.

4. Prohibition of Advertising

Article 71

It is prohibited to advertise, and/or publicize health care services, professional medical procedures and methods of health care, including health services, methods and procedures of the traditional medicine (alternative, homeopathic, and other complementary medicine), practiced in health care facility, private practice or in other legal person engaged in a health care activity, in the media and on other carriers of advertising messages that are regulated by the law governing the area of advertising (publicizing).

It shall be permitted to advertise the name of a health care facility, or the business name of private practice, seat, activity that is specified by the decision concerning fulfillment of the requirements for engaging in a health care activity, as well as the working hours.

The results of the implementation of professional medical methods and procedures of health care may be presented only at professional and scientific gatherings and published in professional and scientific journals and publications.

5. Marking of Health Care Facility and Private Practice

Article 72

A health care facility and private practice shall put up the name, or the business name with the data on the activity that is specified by the decision concerning fulfillment of the requirements for engaging in a health care activity, working hours, the founder and the seat of a health care facility or private practice, in compliance with the law.

The name of a health care facility or the business name of private practice must not have the traits to which the character of advertising or publicizing could be attributed.

The minister shall specify the method of interior and exterior marking of a health care facility and private practice.

6. Keeping the Medical Documentation and Records

Article 73

A health care facility, private practice, institutions of social protection, penitentiary institutions, medical faculties that are engaged in certain type of practice within the health care activity, as well as other legal persons that are engaged in certain types of practice within the health care activity in compliance with the law, shall keep medical documentation and records and in the specified timeframes submit individual, summary, and periodic reports to the competent institute of public health, as well as to other organizations in the manner laid down by a separate law.

Confidentiality shall be guaranteed concerning the data from the medical documentation of patients that is processed and submitted for individual, summary, and periodic reports referred to in paragraph 1 of this Article, and/or that are processed for the medical documentation and records.

A health care facility, private practice, as well as other legal persons referred to in paragraph 1 of this Article shall safeguard the medical documentation of patients from unauthorized access, copying, and abuse, irrespective of the form in which the data from the medical documentation are kept (paper, microfilm, optical and laser disks, magnetic media, etc.), in compliance with the law.

Keeping of medical documentation and entry of data in the medical documentation shall be exclusively performed by authorized persons, in compliance with the law.

The kinds and contents of medical documentation and records, the manner and the procedure of their keeping, the persons authorized to keep the medical documentation and to enter data, the timeframes for submitting and processing of data, the manner of disposing of the data from the medical documentation of patients that is used for data processing, as well as other issues of importance for keeping of medical documentation and records, shall be regulated by a separate law.

7. Integrated Health Care Information System

Article 74

For the purpose of planning and efficient management of the health care system, as well as of acquisition and processing of data related to the state of health of the population and functioning of the health service, or acquisition and processing of health care information, the integrated health care information system in the Republic shall be organized and developed.

The program of work, development and organization of the integrated health care information system, as well as the content of health care information referred to in paragraph 1 of this Article, shall be adopted by the Government.

8. Work Schedule, Working Hours and Health Care during Strike

Article 75

Weekly work schedule, time of opening and closing in a health care facility and private practice, shall be established depending on the type of the health care facility or private practice, as well as on the kind of the health care activity they are engaged in, in accordance with the needs of the citizens and the organization of work of other health care facilities and private practice in a certain territory.

Weekly work schedule, time of opening and closing in a health care facility, or private practice, shall be specified by the founder, and in case of the health care facilities founded by the Republic – by the Ministry.

A health care facility that has been founded in private ownership, same as private practice, shall inform the municipality, or the city in the territory of which it has its seat, about the weekly work schedule, time of opening and closing.

Weekly work schedule, time of opening and closing of health care facility and private practice at the time of epidemics and elimination of the consequences caused by natural and other major disasters and emergency situations shall be specified by the minister, and for the health care facilities and private practice situated in the territory of autonomous province, at the proposal of the government authority of the province in charge of health affairs.

During a strike, a health care facility shall, depending on the activity, ensure the minimum work process, which shall include: continuous and unhindered carrying out of regular vaccinations according to the established schedules; implementation of hygienic and epidemiological measures in case of a threat from break out, or in the course of an epidemic of a communicable disease; diagnostics and therapy including the transport of patients, emergency and acute diseases, states and injuries; taking, treatment, processing and giving of blood and products

produced from blood supply of the essential drugs and Medical devices; health care of and providing meals to hospitalized patients, and other forms of necessary medical care.

It is prohibited to organize a strike in the health care facilities that provide emergency medical care.

The minimum work process during the strike referred to in paragraph 5 of this Article according to the types of state owned health care facilities shall be specified in detail by the Government.

9. Organization of Work of Health Care Facility and Private Practice

Article 76

A health care facility shall, within the established weekly work schedule and working hours, provide health care by working in one, two or more shifts, in accordance with the activity of the health care facility, on which the decision will be handed down by the director of the health care facility.

Private practice shall, within the established weekly work schedule and working hours, provide health care in one or in two shifts, in accordance with the decision of the Ministry referred to in Article 60, paragraph 2 of this Law.

10. Overtime Work in a Health Care Facility

Duty Hours

Article 77

A health care facility may introduce duty hours as overtime work, if by organization of work in shifts referred to in Article 76 of this Law or by rescheduling of working hours it is not in a position to provide health care.

During the duty hours, a health care practitioner must be present in the health care facility.

The duty hours referred to in paragraph 1 of this Article may be introduced during night, on national holidays, and on Sundays.

The duty hours that are introduced during night shall start after the second shift and end at the beginning of the work of the first shift.

The decision on the introduction and number of duty hours on the level of a health care facility, as well as per health care practitioner, shall be handed down by the director of the health care facility.

Duty hours of a health care practitioner may not last longer than ten hours per week.

Exceptionally from paragraph 6 of this Article, the director of the health care facility may hand down the decision that for a certain health care practitioner duty hours last even longer, maximum up to 20 hours a week, depending on the

activity of the health care facility, available staff, as well as on the organization of health service in the territory covered by the health care facility.

The Ministry shall approve the decision referred to in paragraph 7 of this Article, with the previously obtained opinion from the competent public health institute.

The health care practitioner for whom duty hours have been introduced by the decision of the director of the health care facility shall be entitled to increased income earnings for duty hours as overtime work, in compliance with the law and the regulations regulating labor.

Standby Hours and On-Call Hours in a Health Care Facility

Article 78

The duty hours, in the sense of this Law, shall also imply both standby hours and on-call hours.

A health care facility may introduce both standby hours and on-call hours.

Standby hours is a special form of overtime work whereby a health care practitioner does not have to be present in the health care facility, but must be constantly available for the purpose of providing emergency medical care in the health care facility.

On-call hours is a special form of overtime work whereby a health care practitioner does not have to be present in the health care facility, but must respond to the call for the purpose of providing health care.

The decision on the introduction and the scope of standby hours and on-call hours shall be handed down by the director of the health care facility.

Health care practitioners who are engaged in the types of practice referred to in paragraphs 3 and 4 of this Article shall be entitled to increased income earnings in compliance with the law and the regulations regulating labor.

B. ACTIVITY AND ORGANIZATION OF HEALTH CARE FACILITIES

1. Common Provisions

Article 79

Health care activity shall be provided on the primary, secondary, and tertiary levels.

Article 80

A health care facility shall:

- 1) Monitor the state of health of the population in the territory for which it has been founded and undertake and propose measures for its improvement;
- 2) Monitor and implement methods and procedures of prevention, diagnostics, treatment, and rehabilitation based on evidence, and in particular the established professional, methodological, and doctrinaire protocols;
- 3) Organize and provide health care given by nurses, medical technicians and midwives;
- 4) Provide conditions for continuous professional advancement of its employees;
- 5) Implement the programs of health care;
- 6) Implement measures for the purpose of prevention of undesired complications and consequences while providing health care, as well as the measures of overall safety during the stay of the citizens in health care facilities and ensure continuous control of such measures;
- 7) Organize and implement the measures of continuous improvement of the quality of professional work;
- 8) Organize and implement the measures in case of natural and other major disasters and emergency situations;
- 9) Organize, and/or provide measures for collection and/or disposal of medical waste, in compliance with the law;
- 10) Administer other affairs, in compliance with the law.

Article 81

An institute, public health institute, clinic, institute, clinical hospital, and clinical center, apart from practices referred to in Article 80 of this Law, shall:

- 1) Examine and discover causes, onset and spreading of diseases, and/or injuries, as well as the method and measures for their prevention, control, early detection, and efficient and timely treatment and rehabilitation;
- 2) Test and propose introduction of new methods of prevention, diagnostics, treatment, and rehabilitation;
- 3) Participate in establishing of professional medical and doctrinaire positions and provide professional and methodological assistance in their implementation;
- 4) Organize and implement practical training in the course of education and professional advancement of health care practitioners and medical associates;
- 5) Participate in the implementation of external quality assurance of professional work in other health care facilities and private practice;
- 6) Organize and implement other measures, in compliance with the law.

A clinic, which is an organizational part of a clinical hospital or clinical center, same as an institute, which is an organizational part of the clinical center, shall engage in the practices referred to in paragraph 1 of this Article and must meet the requirements laid down by this Law concerning a clinic, or an institute.

Referential Health Care Facilities

Article 82

For the purpose of engaging in the practices of health care, implementation, monitoring, and improvement of uniform doctrine and methodology in prevention, diagnostics, treatment, and rehabilitation of diseases in certain areas of health care, the Minister shall by the decision designate the referential health care facilities for certain areas of the health care activity that meet the requirements laid down by this Law.

The referential health care facilities, apart from the requirements referred to in Article 49 of this Law, must also meet the following requirements:

- 1) To have organized service, and/or adequate staff to monitor and propose new health care technologies, studying and evaluation of health care and health service in the territory for which they have been founded;
- 2) To apply the latest achievements of medical science and practice;
- 3) To have recognized results in fundamental and applied scientific and research work;
- 4) To have recognized results in the area of professional advancement, postgraduate improvement, specialization and super-specialization in the area of health care activity for which they the referential ones.

Pharmaceutical Health care Activity

Article 83

Health care facilities engaged in the health care activity on the primary, secondary, and tertiary level shall also engage in the practices of the pharmaceutical health care activity, under the conditions laid down by this Law.

The pharmaceutical health care activity, in the sense of this Law, shall imply responsible supply with drugs and certain types of Medical devices to the population, health care facilities and private practice, by providing rational pharmacotherapy for the purpose of treatment, improvement, and maintaining the quality of life of the patients, which graduate pharmacist, or graduate pharmacist having relevant specialization, shall practice in cooperation with other health care practitioners, as well as a continuous process of improvement of the use of drugs and certain types of Medical devices, and/or monitoring of undesired reactions to drugs and Medical devices.

(3) The pharmaceutical health care activity shall be conducted as set out by this Law, the Law regulating the filed of pharmaceuticals and medical devices, the Law governing health insurance, and in compliance with the Good Pharmacy Practice.

(4) The Good Pharmacy Practice set out in paragraph 3 of this Article shall comply with this Law, and the Law regulating the filed of pharmaceuticals and medical devices, the Law governing health insurance, and in compliance with current developments of the pharmaceutical profession.

(5) The Good Pharmacy Practice shall be generated by the

Pharmaceutical Chamber of Serbia which activity shall be approved by the Minister.

Detailed requirements with respect to the staff, equipment, premises, and drugs, as well as the method of engaging in the pharmaceutical health care activity shall be specified by the minister.

Article 84

The pharmaceutical health care activity shall include:

- 1) Implementation of preventive measures for preservation and care for the health of the population, and/or health promotion;
- 2) Improvement of pharmacotherapeutic measures and procedures in rational use of drugs and certain types of Medical devices;
- 3) Rationalization of expenses incurred due to implementation of established therapeutic protocols of treatment;
- 4) Monitoring of undesired reactions to drugs and Medical devices, as well as avoidance or diminishing of such reactions;
- 5) Avoidance of interactions in therapeutic duplication in administering drugs;
- 6) Other affairs of the pharmaceutical health care activity, in compliance with the law.

The pharmaceutical health care activity shall also include making of galenic remedies, and/or magistral preparations, in compliance with the law.

Article 85

The pharmaceutical health care activity shall be practiced in a pharmacy as an independent health care facility, in an organizational part of an inpatient health care facility (hereinafter referred to as: the hospital pharmacy), or in another organizational part of the health care facility, which provides supply with drugs and certain types of Medical devices.

Certain types of practice of the pharmaceutical health care activity shall also be practiced in a pharmacy set up as a private practice, under the conditions laid down by this Law and by the regulations adopted for enforcement of this Law.

The pharmaceutical health care activity shall be practiced by a graduate pharmacist, or a graduate pharmacist having relevant specialization (hereinafter referred to as: the pharmacist) and by a pharmaceutical technician who has graduated from the relevant medical school.

Article 86

While being engaged in the pharmaceutical health care activity, the pharmacist is prohibited to:

- 1) Engage in retail trade in drugs and Medical devices for which the permit for putting into circulation of drugs and Medical devices has not been issued, in compliance with the law;

2) Issue, or sell a medicine without prescription, and/or other medical documentation prescribed in compliance with the law, and which are issued against prescription;

3) Engage in retail trade in drugs and Medical devices produced by a legal person who does not have the license for production, and/or making of drugs in a licensed pharmacy, as well as those/ procured from a legal person who does not have the permit for wholesale trade in drugs and Medical devices;

4) Engage in retail trade in drugs and Medical devices that are not labeled in compliance with the law;

5) Engage in retail trade in drugs and Medical devices that do not have relevant documentation on their quality;

6) Engage in retail trade in drugs and Medical devices, the expiry date of which, indicated on the packaging, has expired or deficiency with respect to their specified quality has been established;

7) Engage in retail trade in drugs and Medical devices via Internet.

Retail trade in drugs and Medical devices, in the sense of this Law, shall include ordering, keeping, issuing against prescription or without prescription, or against the order, as well as sale of drugs and Medical devices, and/or making of galenic and magistral preparations.

Article 87

While engaging in the pharmaceutical health care activity, a pharmaceutical technician is prohibited to:

1) Engage in the pharmaceutical health care activity without the presence of a pharmacist;

2) Issue, and/or retail sell prescription drugs as well as the drugs that contain narcotics, or relevant Medical devices;

3) Make galenic, and/or magistral preparations on his/her own.

Primary, Secondary, and Tertiary Health Care Activity

Article 88

The health care activity on the primary level shall include:

1) Protection and improvement of health, prevention and early detection of diseases, treatment, rehabilitation of the diseased and injured;

2) Preventive health care of groups of the population exposed to increased risk of contracting diseases and of other inhabitants, in accordance with special program of preventive health care;

3) Health education and counseling for preservation and improvement of health;

4) Prevention, early detection, and control of malignant diseases;

5) Prevention, detection, and treatment of diseases of mouth and teeth;

- 6) Domiciliary care, treatment, and rehabilitation in patient's home;
- 7) Prevention and early detection of diseases, health care and rehabilitation for/of persons placed in institutions of social protection;
- 8) Emergency medical care and ambulance transport;
- 9) Pharmaceutical health care;
- 10) Rehabilitation of children and young adults with bodily and mental disorders;
- 11) Protection of mental health;
- 12) Palliative care;
- 13) Other affairs specified by the law.

In engaging in the health care activity on the primary level, health care facilities shall maintain cooperation with other health care, social welfare, educational, and other facilities and organizations in preparing and implementing programs for preservation and improvement of health.

Article 89

The specialist and consulting activity may be practiced in a outpatient department and other health care facility on the primary level.

The specialist and consulting activity taking place on the primary level must have adequate laboratory and other diagnostics for its own requirements.

A outpatient department, same as other health care facilities on the primary level, in its engaging in the specialist and consulting activity shall be interconnected, in the professional or organizational sense, with the relevant health care facility that is engaged in the secondary health care activity.

Article 90

Health care activity on the secondary level shall include specialist and consulting and hospital health care activities.

Specialist and consulting activity on the secondary level, with respect to the health care activity on the primary level, shall include more complex measures and procedures of detection of diseases and injuries as well as treatment and rehabilitation of the diseased and injured.

Hospital health care activity shall include diagnostics, treatment, and rehabilitation, health care, and placement in hospitals, as well as the pharmaceutical health care activity in the hospital pharmacy.

Article 91

The health care activity on the tertiary level shall include providing of the most complex forms of health care and specialist and consulting and hospital health care activity as well as scientific and research and educational activities, in compliance with the law governing the scientific and research activity, and/or educational activity.

The health care activity on the tertiary level shall also include engaging in the pharmaceutical health care activity in the hospital pharmacy.

Article 92

The minister shall by his/her decision designate the health care facility on the tertiary level that will administer the affairs of the Republic poison control center.

The poison control center referred to in paragraph 1. of this Article shall collect and process the data on the effect of toxic chemicals and natural poisons; keep the register of incidents of poisoning; participate in the formation and supervision over the central stocks of antidotes in the Republic; provide information and advice related to acute poisonings to the health care facilities, private practice, health care practitioners, as well as to other legal and natural persons; perform testing and apply new methods of prevention of poisoning; establish professional medical and doctrinaire positions related to the protection from poisoning, as well as providing medical assistance and elimination of the consequences of poisoning.

The poison control center must have the information center for acquisition and processing of data from its sphere of competence.

The poison control center must also have a toxicological laboratory and the inpatient health care service.

A health care facility and private practice shall submit the data on cases of poisoning to the poison control center, in compliance with the law.

The poison control center shall, by March 31 of the current year, submit the acquired data on poisoning with chemicals for the previous year to the Ministry, as well as to the ministry in charge of the affairs of chemicals management.

The method of acquisition, processing, and storage of data on poisoning and effects of toxins/poisons, as well as the scope and contents of the data submitted to the competent ministries referred to in paragraph 6 of this Article, shall be jointly specified by the minister and the minister in charge of the affairs of chemicals management.

Article 92

(1) The tertiary health care institutions operating as centers for specific types of rare diseases (hereinafter: Center for Rare Diseases) shall be appointed by the ministerial decision.

(2) The Center for Rare Diseases shall involve the diagnostic procedures for patients with rare diseases, prenatal, and neonatal screening, genetic consulting, management of patients with rare diseases, keeping the registry of patients suffering from rare diseases in the territory of the Republic of Serbia pursuant to law, professional relationship with international reference centers for diagnosing and treatment of rare diseases, and with the network of European and global organizations for rare diseases, continual education in rare diseases, and other activities for improving diagnosis and treatment of patients suffering from rare diseases.

(3) Based on the Decision of the Minister, The Center for Rare

Diseases can conduct other activities in order to improve diagnosis and treatment of patients suffering from rare diseases..

(4) The in-house organization, activities and other issues of importance for the operation of the Center for rare Diseases are specified in more details by the articles of association of health care institutions set out in paragraph 1 of this Article.

(5) Health care facilities, or private practice, or other legal entities dealing with health care set out by this Law shall, pursuant to law, submit to the Center for Rare Diseases the data on number, type, diagnosed, or treated patients suffering from rare diseases, and other data necessary for keeping the register of patients with rare diseases set out in paragraph 2 of this Article.

Article 93

Apart from the health care facilities that are engaged in the health care activity on the tertiary level, educational activity may also be practiced in the facilities of the primary and secondary levels of health care.

A health care facility may engage in educational activity should it conclude an agreement with the relevant school, or faculty.

The requirements that a health care facility must meet in order to provide practical training of medical pupils and students shall be jointly specified by the minister and the minister in charge of the affairs of education.

2. Health Care Activity on the Primary Level

Outpatient department

Article 94

A outpatient department is a health care facility that is engaged in a health care activity on the primary level.

A state owned outpatient department shall be founded for the territory of one or several municipalities, or city, in accordance with the Plan of the Network.

A state owned outpatient department shall be founded by a municipality or city.

The founder of a state owned outpatient department that has been founded for the territory of several municipalities shall be the municipality in which the seat of the outpatient department is situated.

Article 95

A outpatient department is a health care facility that provides minimum preventive health care to all categories of the population, emergency medical care, general medicine, health care of women and children, domiciliary care service, as well as laboratory and other diagnostics.

A outpatient department shall also provide prevention and treatment in the area dental health care, health care of employees, or occupational medicine and

physical medicine and rehabilitation, if practicing of this health care activity is not organized in another health care facility in the territory for which the outpatient department has been founded.

A outpatient department shall also provide ambulance transport if that service is not organized in a hospital or in other health care facility in the territory for which the outpatient department has been founded.

A outpatient department shall also engage in the pharmaceutical health care activity, in compliance with this Law.

If a municipality has a outpatient department and a general hospital that are state owned, the laboratory, radiological, and other diagnostics may be organized only within one health care facility.

Article 96

A outpatient department, depending on the number of citizens in a municipality as well as on their health needs, distance to the nearest general hospital, and/or existence of other health care facilities in the municipality, may also engage in some other specialist and consulting activity, which is not related hospital treatment, in accordance with the Plan of the Network.

Exceptionally, in the territories with specific needs concerning providing of health care to the population, where transport and geographic conditions justify that, in accordance with the Plan of the Network, maternity hospital and inpatient clinic for diagnostics and treatment of acute and chronic diseases may be organized in a outpatient department.

Article 97

For the purpose of providing access to health care outpatient units and local clinics may be organized in a outpatient department, in accordance with the Plan of the Network.

As a minimum, a local clinic provides emergency medical care, the activity of general medicine, and health care of children.

As a minimum, health care outpatient unit provide the activity of general medicine.

Article 98

The citizens shall be provided primary health care in a outpatient department through the chosen physician.

The chosen physician shall be:

- 1) A doctor of medicine or a doctor of medicine specialist in general medicine, or specialist in occupational medicine;
- 2) A doctor of medicine specialist in pediatrics;
- 3) A doctor of medicine specialist in gynecology;
- 4) A doctor of dental medicine.

The chosen physician shall exercise health care in a team with a health care practitioner of adequate medical qualifications.

Exceptionally from paragraph 2 of this Article, the chosen physician may also be a doctor of medicine of some other specialty, under the conditions specified by the minister.

Article 99

The chosen physician shall:

- 1) Organize and implement measures for preservation and improvement of the health of individuals and families;
- 2) Work on detection and control of the factors of risk for onset of diseases;
- 3) Administer diagnostics and timely treatment of patients;
- 4) Provide emergency medical care;
- 5) Refer patients to relevant health care facility subject to medical indications or to a doctor specialist and shall harmonize the opinions and proposals for continuation of treatment of the patient;
- 6) Provide home treatment, health care, and palliative care, as well as treatment of patients who do not require hospital treatment;
- 7) Prescribe drugs and Medical devices;
- 8) Provide health care in the area of mental health;
- 9) Administer other affairs, in compliance with the law.

In the process of exercising health care, the chosen physician shall refer the patient to the secondary and tertiary levels.

The chosen physician, on the basis of the opinion of the doctor of medicine specialist of the relevant branch of medicine, shall refer the patient to the tertiary level.

The chosen physician shall keep full medical documentation about the state of health of a patient.

Health care through the chosen physician shall be provided in compliance with the law governing the area of health insurance.

Pharmacy

Article 100

A pharmacy is a health care facility in which the pharmaceutical health care activity is practiced on the primary level.

A state owned pharmacy shall be founded for the territory of one or several municipalities, or city, in accordance with the Plan of the Network.

A state owned pharmacy shall be founded shall be founded by a municipality or city.

The founder of a state owned pharmacy, which has been founded for the territory of several municipalities, shall be the municipality in which the seat of the pharmacy is situated.

The pharmaceutical health care activity shall be practiced in a pharmacy, which includes:

- 1) Health promotion, and/or health education and counseling for preservation and improvement of health by proper use of drug and certain types of Medical devices;
- 2) Retail trade in drugs and certain types of Medical devices, on the basis of plans for procurement of drugs and Medical devices for regular and emergency requirements;
- 3) Monitoring of advanced professional and scientific achievements in the area of pharmacotherapy and providing to the citizens, health care practitioners, other health care facilities and private practice, as well as to other interested subjects, information on drugs and types of Medical devices;
- 4) Giving advice to patients concerning proper use of drugs and certain types of Medical devices, and/or instructions for their proper use;
- 5) Making magistral preparations;
- 6) Other affairs, in compliance with the law.

Article 101

The pharmacy referred to in Article 100 of this Law may have within its complement a galenic laboratory for making of galenic remedies (hereinafter referred to as: the licensed pharmacy), in accordance with the regulations governing the area of drugs and Medical devices.

A galenic remedy prepared in a licensed pharmacy may be in retail trade in that pharmacy, as well as in another pharmacy that does not have a galenic laboratory within its complement, and with which the licensed pharmacy has concluded the agreement on retail trade in galenic remedies.

A pharmacy may organize branches of the pharmacy or a unit for issuing of officinal drugs.

The pharmaceutical health care activity shall be practiced in a pharmacy in accordance with the Best Pharmaceutical Practice, and/or in accordance with the guidelines for Best Laboratory Practice, Best Distribution Practice, Best Manufacturing Practice for making of galenic remedies, which has the elements of industrial production, in compliance with the law governing the area of drugs and Medical devices.

The Best Pharmaceutical Practice referred to in paragraph 4 of this Article shall be specified by the Minister.

A pharmacy shall put out on a prominent place the name of licensed pharmacist, who shall be responsible for the entire handling of drugs, and/or making of galenic remedies and magistral preparations, in compliance with the law governing the area of drugs and Medical devices.

Apart from retail trade in drugs and Medical devices, a pharmacy may also supply the citizens with baby food, dietary products, certain kinds of toiletries and other items for health care, in accordance with the enactment adopted by the competent association.

Institute

Article 102

An institute is a health care facility that is engaged in the health care activity on the primary level and provides health care to certain groups of the population, or health care activity in certain areas of health care.

An institute shall be founded as:

- 1) Students' Health-Care Institute;
- 2) Employees' Health-Care Institute;
- 3) Emergency Medical Care Institute;
- 4) Gerontology Institute;
- 5) Dentistry Institute;
- 6) Lung Diseases and Tuberculosis Institute;
- 7) Skin And Venereal Diseases Institute.

The institute referred to in paragraph 2 of this Article may also engage in the specialist and consulting activity.

The state owned institute referred to in paragraph 2 of this Article may be founded only in the territory in which is the seat of a university, which within its complement has a medical faculty, in accordance with the Plan of the Network.

The institute referred to in paragraph 4 of this Article shall be founded by a city, except for the Health Care of Employees Institute of the Ministry of Interior Affairs, which shall be founded by the Republic.

Article 103

The students' health care institute is a health care facility that provides health care of students and which organizes preventive and curative health care in the area of general medicine, dentistry, gynecology, laboratory and other diagnostics and therapy for the requirements of students.

The students' health care institute may also engage in specialist and consulting activity, as well as inpatient health care activity.

Health care of students may also be provided in a outpatient department, in compliance with the law.

Article 104

The employees health care institute is a health care facility that provides health care and preservation of health of employees in a safe and healthy working environment, by engaging in the activity of occupational medicine.

The employees health care institute may also engage in preventive and curative health care activities in the areas of general medicine, dentistry, gynecology, as well as in specialist and consulting activity.

An employer may, for the requirements of his/her employees, set up an outpatient unit for occupational medicine, which shall engage in the practices of the preventive health care activity in the area of occupational medicine.

The Minister shall specify the requirements for setting up and commencement of the work and engaging in the activity of an outpatient unit for occupational medicine referred to in paragraph 3 of this Article.

Article 105

The emergency medical care institute is a health care facility that provides emergency medical care and ambulance transport of the acute diseased and injured to other relevant health care facilities, transport of patients on dialysis, as well as supply of with drugs administered in emergency cases.

Article 106

The gerontology institute is a health care facility that provides health care to elderly persons and implements measures for preservation and improvement of health and prevention of diseases among this group of the population, and which is also engaged in the activity of domiciliary treatment and care, palliative care and rehabilitation of elderly persons.

Article 107

The dentistry institute is a health care facility that is engaged in the health care activity in the area of dental health care, which includes preventive, diagnostic, therapeutical, and rehabilitation health services.

The dentistry institute may also engage in specialist and consulting activity in the area of dentistry.

Article 108

The lung diseases and tuberculosis institute is a health care facility that is engaged in specialist and consulting activity and which provides preventive, diagnostic, therapeutic, and rehabilitation health services in the area of health care of patients who have contracted tuberculosis and other lung diseases that may be treated in outpatient units.

The lung diseases and tuberculosis institute within preventive health care shall organize and implement the measures for prevention, control, early detection, and monitoring of tuberculosis and other lung diseases.

Article 109

The skin and venereal diseases institute is a health care facility that is engaged in specialist and consulting activity and which provides preventive, diagnostic, therapeutic, and rehabilitation health services in the area of dermatovenerology and microbiology including parasitology.

The skin and venereal diseases institute, within the preventive health care activity, shall organize and implement the measures for prevention, control, early detection, and monitoring of sexually transmitted infections.

3. Health Care Activity on the Secondary Level

Hospital (General and Specialty)

Article 110

A hospital is a health care facility that is engaged in health care activity on the secondary level.

As a rule, a hospital is engaged in health care activity as a continuation of diagnostics, treatment and rehabilitation in a outpatient department, i.e. when, due to complexity and seriousness of a disease, special conditions are required with respect to the staff, equipment, accommodation, and drugs.

A hospital shall cooperate with a outpatient department and provide it with professional assistance in the implementation of measures of the primary health care.

The inpatient and specialist and consulting activity of the hospital shall make single functional and organizational unity.

A hospital shall organize its work in such a way that the majority of patients is tested and treated in polyclinical service, and provide inpatient treatment to the diseased and injured persons only when necessary.

A hospital may have, or organize special organizational units for extended hospital care (geriatrics), palliative care of the diseased in the terminal stage of a disease, as well as for treatment of the diseased in the course of day work (day hospital).

A hospital may be general and specialty hospital.

Article 111

A general hospital shall provide health care to the persons of all ages suffering from different kinds of diseases.

A state owned general hospital shall be founded for the territory of one or more municipalities.

As a minimum, a general hospital must have organized services for:

- 1) Admittance and management of emergency states;

2) Engaging in the specialist and consulting and inpatient health care activity in internal medicine, pediatrics, gynecology and obstetrics, and general surgery;

3) Laboratory, x-ray, and other diagnostics in accordance with its activity;

4) Anesthesiology with resuscitation;

5) Outpatient unit for rehabilitation;

6) Pharmaceutical health care activity through the hospital pharmacy.

A general hospital must also provide either on its own or through another health care facility:

1) Ambulance transport for patients' referral to the tertiary level;

2) Supply with blood and products produced from blood;

3) Service for pathological anatomy.

A general hospital may also engage in specialist and consulting activities from other branches of medicine.

A general hospital that has been founded for the territory of several municipalities, as well as a hospital in the seat of a county, apart from the services specified in paragraph 3 of this Article, may also engage in the hospital health care activity from other branches of medicine.

Article 112

A specialty hospital shall provide health care to the persons of certain age groups, or to those suffering from certain diseases.

A specialty hospital shall engage in the specialistic, consulting, and inpatient health care activity in the field for which it has been founded, laboratory and other diagnostics, as well as the pharmaceutical health care activity through the hospital pharmacy.

A specialty hospital, in accordance with the activity it is engaged in, must also provide either on its own or through another health care facility:

1) Ambulance transport for patients' referral to the tertiary level;

2) Supply of blood and products produced from blood;

3) Service for pathological anatomy.

Article 113

A specialty hospital that, in engaging in the health care activity, uses a natural factor of treatment (gas, mineral water, peloid, etc.) shall, in the course of use of the natural factor monitor its therapeutic properties and, at least once in three years, repeat testing of its therapeutic qualities in the relevant health care facility.

The specialty hospital referred to in paragraph 1 of this Article may also provide the services in tourism, in accordance with the regulations governing the area of tourism.

Article 114

A hospital the founder of which is the Republic or autonomous province shall be liaised and cooperate with the facilities on the primary level from the territory for which it has been founded, with the aim to establish and maintain appropriate referral a patients to the secondary level of health care and exchange of professional knowledge and experience.

4. Health Care Activity on the Tertiary Level

Clinic

Article 115

A clinic is a health care facility that is engaged in highly specialized specialist and consulting and inpatient health care activity from a certain branch of medicine, or dentistry.

A clinic shall also engage in educational and scientific and research activity, in compliance with the law.

A clinic, in accordance with the activity it is engaged in, must also meet the requirements referred to in Article 111, paragraphs 3 and 4 of this Law.

A clinic may be founded only at the seat of a university, which has within its complement a medical faculty.

A state owned clinic, in the seat of which there is no general hospital, shall also engage in the relevant activity of a general hospital for the territory for which it has been founded.

Institute – Center of Excellence

Article 116

An institute – center of excellence is a health care facility that is engaged in a highly specialized specialist and consulting and inpatient health care activity, or only a highly specialized specialist and consulting health care activity in one of several branches of medicine or dentistry.

An institute – center of excellence is engaged in educational and scientific and research activity, in compliance with the law.

Apart from the requirements laid down by this Law concerning engaging in health care activity, an institute – center of excellence must also meet the requirements that are laid down by the law governing the area of scientific and research activity.

An institute – center of excellence, in accordance with the activity it is engaged in, must also meet the requirements referred to in Article 111, paragraphs 3 and 4 of this Law.

An institute – center of excellence may be founded only in the seat of a university, which within its complement has a medical faculty.

A state owned institute – center of excellence, in the seat of which there is no general hospital, shall also engage in the relevant activity of a general hospital for the citizens from that territory.

Clinical Hospital

Article 117

A clinical hospital is a health care facility that is engaged in a highly specialized specialist and consulting and inpatient health care activity on the tertiary level in one or several branches of medicine.

Apart from the requirements specified by this Law concerning general hospital, a clinical hospital in the branches of medicine in which it is engaged in a highly specialized health care activity must also meet the requirements specified by this Law concerning a clinic.

A clinical hospital may only be founded in the seat of a university, which within its complement has a medical faculty.

A state owned clinical hospital, in the seat of which there is no general hospital, shall also engage in the relevant activity of a general hospital for the territory for which it has been founded.

Clinical Center

Article 118

A clinical center is a health care facility that unifies the activities of three or several clinics, in such a way that it makes a functional unity, organized and capable to successfully administer the affairs and carry out tasks related to:

- 1) Engaging in a highly specialized specialist and consulting and inpatient health care activity;
- 2) Educational and teaching activities;
- 3) Scientific and research activity.

A clinical center is engaged in a specialized polyclinical and hospital health care activity in several branches of medicine, and/or areas of health care.

A clinical center may be founded only in the seat of the university, which within its complement has a medical faculty.

A state owned clinical center, in the seat of which there is no general hospital, shall also engage in the activity of a general hospital for the territory for which it has been founded.

5. Health Care Activity Taking Place on Several Levels

Public Health Institute

Article 119

A public health institute shall be founded by the Republic and, in the territory of an autonomous province – by the autonomous province.

The public health institute is a health care facility that is founded for the territory of several municipalities, or a city, as well as for the territory of the Republic, in accordance with the Plan of the Network.

Public health, in the sense of this Law, implies realizing of public interest by creating conditions for preservation of the health of the population through organized comprehensive activities of the society targeted to the preservation of physical and mental health, and/or preservation of the environment, as well as prevention of the appearance of the factors of risk for onset of diseases and injuries, which is realized by applying health care technologies and measures intended to health promotion, prevention of diseases, and improvement of the quality of life.

Article 120

The public health institute shall:

- 1) Monitor, assess, and analyze the state of health of the population and report to the competent authorities and the public;
- 2) Monitor and study health problems and risks for the health of the population;
- 3) Propose elements of health care policy, plans, and programs with the measures and activities intended to preserve and improve health of the population;
- 4) Disseminate information, provide education, and training of the population to look after their own health;
- 5) Make assessment of efficiency, accessibility to and quality of health care;
- 6) Plan the development of professional advancement of health care practitioners and medical associates;
- 7) Encourage development of integrated health care information system;
- 8) Carry out applied research works in the area of public health;
- 9) Cooperate and develop partnerships in the social community in identification and dealing with health problems of the population;
- 10) Administer other affairs, in compliance with the law.

Article 121

The public health institute is a health care facility that is engaged in social medical, hygienic and ecological, epidemiological, and microbiological health care activities.

The public health institute makes bacteriological, serological, virological, chemical, and toxicological examinations and tests related to the production of and trade in foodstuffs, water, air, items of general use, as well as related to diagnostics of communicable and non-communicable diseases.

The public health institute shall coordinate, harmonize, and professionally correlate the work of health care facilities from the Plan of the Network, for the territory for which it has been founded.

The public health institute shall cooperate with other health care facilities in the territory for which it has been founded, as well as with the competent authorities of the local self-government and other institutes and organizations of importance for improvement of public health.

The founder may organize the public health institute as an institute – center of excellence if the requirements laid down by Article 116 of this Law have been met.

The public health institute may engage in the practice of disinfection, pest control, and pest extermination if in the territory for which it has been founded there is no other health care facility engaged in such types of practice.

Article 122

The public health institute founded for the territory of the Republic, apart from the practices referred to in Articles 120 and 121 of this Law shall also engage in the following types of practice:

- 1) Coordinate and monitor professional work of the public health institute and other health care facilities engaged in hygienic and epidemiological and social and medical activities in the Republic;
- 2) Study and in cooperation with other health care facilities propose long-term strategy of health care with priorities and methodologically manages its implementation, in cooperation with the medical faculties;
- 3) Establish the necessary measures in natural and other major disasters and emergencies and implement them in cooperation with other institutes.

The method and procedure, as well as the conditions for organization and implementation of public health shall be regulated by a separate law.

Blood Transfusion Institute

Article 123

A blood transfusion institute is founded by the Republic and, in the territory of the autonomous province – by the autonomous province.

A blood transfusion institute is a health care facility that is engaged in the practice of collecting of blood and blood plasma for processing, blood tests, satisfying of the requirements for blood derivative products and drugs produced from blood, distribution of blood derivative products, diagnostic tests, therapeutical procedures, control and supervision of the transfusiological treatment, collection of

stem cells, typification of tissues, consultations in clinical medicine, as well as promotion and organization of voluntary blood donation.

A blood transfusion institute may be founded only in the seat of the university, which within its complement has a medical faculty.

A blood transfusion institute shall establish a uniform doctrine, ensure its implementation and professional liaison with the blood transfusion services in inpatient health care facilities.

Supply of blood and blood derivative products shall be provided by blood transfusion institutes and blood transfusion services in inpatient health care facilities.

The blood transfusion institute, in cooperation with the Red Cross of Serbia, shall stimulate and organize activities on popularization of voluntary blood donation, implementation of programs of collection of blood, as well as planning of the requirements for drugs produced from blood.

The blood transfusion institute founded for the territory of the Republic, apart from the affairs referred to in paragraph 2, 4, 5, and 6 of this Article, shall also administer other affairs in compliance with the law governing the area of blood transfusion.

The founder may organize a blood transfusion institute as an institute – center of excellence if the requirements laid down by Article 116 of this Law are met.

The method and procedure, as well as the conditions and organization of transfusiological activities, shall be regulated by a separate law.

Occupational Medicine Institute

Article 124

The occupational medicine institute for the territory of the Republic – shall be founded by the Republic.

The occupational medicine institute referred to in paragraph 1 of this Article is a health care facility that is engaged in the activity in the area of occupational medicine, and/or protection of health at work, as follows:

1) Monitors and studies conditions of work, organization and implementation of the information system for data acquisition and monitoring of epidemiological situation in the territory of the Republic in the field of occupational diseases, diseases related to work, and accidents at work and proposes measures for their prevention and containment;

2) Plans, organizes, implements, and evaluates measures, activities, and procedures in the area of protection of health at work, establishes professional and medical and doctrinaire positions in the area of occupational medicine, promotion of health at work, and provides professional and methodological assistance in their implementation;

3) Improves organization and work of health care facilities in the area of protection of health at work and coordinates their work;

4) Establishes uniform methodology and procedures in programming, planning, and implementation of measures of preventive care of workers;

5) Introduces and tests new health care technologies, as well as implementation of new methods of prevention, diagnostics, treatment, and rehabilitation in the area of occupational medicine;

6) Monitors modern achievements in the area of organization of occupational medicine and proposes health care standards for improvement and development;

7) Studies all the factors of occupational hazards and their identification, qualification, and assessment;

8) Conducts physical and other examinations and measurements related to ionizing and non-ionizing radiation in health care, and/or radiological health care;

9) Implements professional medical procedures and activities related to job specifications, jobs with increased hazards, and/or jobs for which contribution period is calculated with increased duration;

10) Proposes and implements preventive checkups of workers working at workplaces with increased hazard;

11) Proposes and implements criteria for assessment of fitness for driving motor vehicles;

12) Assesses the capacity for work of those suffering from occupational diseases, diseases related to work, consequences of accidents at work and outside work, assesses the capacity for work and overall vitality, assesses bodily damage and performs other expert evaluations related to capacity for work of employees;

12) Provides the diagnosis and treatment of occupational diseases, subacute and chronic poisoning, work-associated diseases, and consequences of injuries at work;

13) Administers other affairs in the area of protection of health at work, in compliance with the law.

The occupational medicine institute shall also engage in educational activity in the area of protection of health at work.

The founder may organize the occupational medicine institute as an institute – center of excellence if the requirements laid down by Article 116 of this Law have been met.

Forensic Medicine Institute

Article 125

A state owned forensic medicine institute shall be founded by the Republic.

The forensic medicine institute is a health care facility that is engaged in the activity in the area of forensic medicine, i.e. forensic diagnostics and expertise, on the basis of autopsies, clinical examinations, and laboratory diagnostics, for the requirements of courts, health care facilities, faculties of medicine, and other persons.

The forensic medicine institute covers as a minimum forensic and chemical and toxicological activities, verification of success of operational and other procedures and means of treatment, as well as verification of diagnoses made.

The forensic medicine institute may also administer other affairs in the area of forensic medicine.

The forensic medicine institute may be founded only in the seat of a university which includes a medical faculty.

The founder may organize the forensic medicine institute as an institute – center of excellence if the requirements laid down by Article 116 of this Law are met.

Virology, Vaccines, and Serums Institute

Article 126

The virology, vaccines, and serums institute shall be founded by the Republic.

The virology, vaccines, and serums institute is a health care facility that monitors and studies, tests, establishes and introduces, and/or implements professional and scientific methods of prevention and diagnostics of communicable diseases, produces serums, vaccines, and other immunobiological and diagnostic preparations and media, which are supplied to the health care facilities in the territory of the Republic.

The virology, vaccines, and serums institute shall participate in establishing and implementation of doctrinaire instructions in the area of prevention and diagnostics of communicable diseases.

The virology, vaccines, and serums institute may be set up only in the seat of a university that has within its complement a medical faculty.

The virology, vaccines, and serums institute as an institute – center of excellence if the requirements laid down by Article 116 of this Law are met.

Rabies Prophylaxis Institute

Article 127

The rabies prophylaxis institute shall be founded by autonomous province.

The rabies prophylaxis institute shall be engaged in the health care activity in the area of prevention and laboratory diagnostics of rabies and other communicable diseases, and/or monitor and study spreading of rabies and propose the measures for its control.

The rabies prophylaxis institute shall test and implement new methods of prevention and immunoprophylaxis of rabies, and/or establish professional and medical and doctrinaire positions in rabies prophylaxis and provide professional and methodological assistance in their implementation.

The rabies prophylaxis institute may also administer other affairs of health care.

Psychophysiological Disorders and Speech Pathology Institute

Article 128

The state owned psychophysiological disorders and speech pathology institute shall be founded by the Republic.

The psychophysiological disorders and speech pathology institute shall be engaged in outpatient and inpatient health care activity in the area of psychophysiological and speech disorders, monitor and study the status of developmental disorders, hearing impairment among children and young adults and speech disorders of persons of all ages, as well as blind and partially sighted preschool age children.

The psychophysiological disorders and speech pathology institute shall investigate and discover causes and phenomena of disorders and the method and measures for their early detection, efficient and quality treatment, rehabilitation, and prevention of disability.

The psychophysiological disorders and speech pathology institute shall monitor and implement professionally and scientifically established methods of diagnostics, treatment, and rehabilitation, and/or establish professional and methodological and doctrinaire criteria and coordinate the work of all health care practitioners and medical associates engaged in this health care activity in the territory of the Republic.

The psychophysiological disorders and speech pathology institute may also administer other affairs of health care.

Biocides and Medical Ecology Institute

Article 129

A stated owned biocides and medical ecology institute shall be founded by a city.

The biocides and medical ecology institute shall engage in the health care activity in the area of preventive health protection of the population from communicable diseases.

The biocides and medical ecology institute shall implement the measures of disinfection, pest control, and pest extermination in prevention and control of communicable diseases in the health care and other facilities, in compliance with the law.

The biocides and medical ecology institute shall establish and monitor implementation of uniform doctrine in the implementation of biocides in prevention and control of communicable diseases and implement programs of medical ecology through assessment of risks in the implementation of biocides.

The biocides and medical ecology institute may also administer other affairs, in compliance with the law.

Article 129

(1) Administration for Screening Programs shall be established for conducting the public administration activities in the field for improvement, organizing and conduct of screening programs, which shall:

1) Propose the adoption of specific health care screening programs, or their amendments;

2) Propose the adoption of standards for conducting the screening programs;

3) Propose the adoption of professional-methodological instructions for conducting the screening programs;

4) Organize and monitor the execution of the screening programs;

5) Propose to the Minister the measures for the improvement of organization and operation of health care institutions, or private practice, or other legal entities dealing with health care pursuant to law, for conducting the screening programs;

6) Provide professional help to health care institutions, or private practice, or other legal entities dealing with health care pursuant to law, for conducting the screening programs;

7) Establish and conduct the program for continual education for the realization of screening programs;

8) Assess the efficiency of the realization of the screening programs and propose measures for the improvement of public health care in areas where the screening programs are conducted;

9) Participate in the organization and realization of screening program promotion campaigns;

10) Carry out applied research in the domain of screening programs;

11) Performs other activities pursuant to law.

(2) The programs set out in paragraph 1, item 1) of this Article shall be adopted by the Government and acts in paragraph 1, items 2) and 3) shall be adopted by the Minister.

Article 129b

(1) The Administration for Screening Programs shall be managed by the Director.

(2) The Director is appointed by the Government, based on the proposal by the Minister, for the period of five years, in compliance with the law regulating positions of public officers.

(3) The Director reports to the Minister.

(4) The Director makes administrative decisions within the scope of

the Administration for Screening Programs and decides on employee rights and obligations.

Article 129c

(1) The Director of the Administration for Screening Programs has several assistants for specified types of screening programs implemented in the Republic of Serbia.

(2) Assistant Directors report to the Director and to the Minister.

(3) An Assistant Director is appointed by the Government, based on the proposal by the Minister, for the period of five years, in compliance with the law regulating positions of public officers.

C. BODIES OF A HEALTH CARE FACILITY AND PROFESSIONAL BODIES OF A HEALTH CARE FACILITY

1. Bodies of a Health Care Facility

Article 130

The bodies of a health care facility shall be: the director, the management board, and the supervisory board.

A health care facility may also have a deputy director, who will be appointed and relieved under the conditions, in the manner, and according to the procedure, which is specified for appointment and relieving of the director of the health care facility.

The director, deputy director, the members of the management board, and the supervisory board of a health care facility shall be appointed and relieved by the founder.

The director, deputy director, the members of the management board, and the supervisory board of an institute, clinic, institute, and clinical center, or the Health Care of Employees Institute of the Ministry of Interior Affairs, the founder of which is the Republic, shall be appointed and relieved by the Government.

The director, deputy director, the members of the management board, and the supervisory board of health care facilities the founder of which is the Republic, except for the facilities referred to in paragraph 4 of this Article, shall be appointed and relieved by the minister.

The persons referred to in paragraph 3 of this Article in the state owned health care facilities, as well as their kins by blood in lineal line of descent irrespective of the degree of kinship, kins by blood in collateral line of descent including the second degree of kinship, spouses and in-laws including the first degree of kinship, must not, either directly or through a third natural or legal person, have a share as the owners of a share, be shareholders, in legal person who is engaged in a health care activity, or type of practice within the health care activity, and/or must not engage in this activity as entrepreneurs, about which they shall sign a statement for the purpose of prevention of the conflict of public and private interest.

(7) After the expiration of term, the bodies of a health care facility continue to work pursuant to law and articles of association of the facility until the appointment of new, or temporary bodies.

Director

Article 131

The director shall organize the work and manage the process of work, represent and act as proxy of the health care facility and shall be responsible for the legality of work of health care facility.

If the director does not have medical university qualifications, the deputy, or assistant director shall be responsible for the professional and medical work of the health care facility.

In the health care facility that is engaged in educational and scientific and research activities, the director shall appoint the assistant for the educational and scientific and research activities.

The director shall submit to the management board a written quarterly, and/or six-monthly report about the business operations of health care facility.

The director shall attend the meetings and participate in the work of the management board, without the right to vote.

Article 132

A person may be appointed as the director of a health care facility:

1) If he/she has a medical university qualifications or university qualifications of other profession has completed education in the area of health care management;

2) If he/she has minimum five years of service in the area of health care;

3) If he/she also meets other requirements specified by the articles of association of the health care facility.

If the person appointed as the director of health care facility does not have medical university qualifications, but university qualifications of another profession, the deputy or assistant director for the health care activity must be a person who has a medical university qualifications.

The director of a health care facility will be appointed on the basis of vacancy publicly announced by the management board of the health care facility.

The publicly announced vacancy referred to in paragraph 3 of this Article shall be announced 60 days prior to expiry of the term of office of the director.

The management board of a health care facility shall within 30 days from the date of completion vacancy announcement make selection of the candidate and to submit the proposal to the founder.

On the basis of the proposal of the management board, the founder shall appoint the director, within 15 days from the date of submitting of the proposal.

Article 133

The director of a health care facility shall be appointed for a period of four years, maximum two times successively.

The tenure of the director of a health care facility shall be reckoned from the date of assuming the duty.

Article 134

Should the management board of a health care facility fail to elect the candidate for the director of the health care facility, or should the founder of a health care facility fail to appoint the director of the health care facility, in accordance with the provisions of this Law, the founder shall appoint the acting director for a period of six months.

The conditions for election, rights, obligations, and responsibilities of the director of a health care facility shall also apply to the acting director of the health care facility.

Article 135

The duty of the director of a health care facility shall terminate with the expiry of the term of office and when relieved.

The founder of a health care facility shall relieve the director prior to the expiry of the term of office:

- 1) At personal request;
- 2) If he/she performs the function contrary to the provisions of the law;
- 3) If by unskilled, improper, and negligent work, he/she causes major damage to the health care facility or neglects or unconscientiously performs his duties in such a way that major disruptions in the operation of the health care facility have occurred or may occur;
- 4) If the competent association brings one of the disciplinary actions laid down by the law against him/her;
- 5) If by the finding of the health inspectorate, breach of regulations and bylaws of the health care facility or irregularity in work of the director has been established;
- 6) If the circumstances referred to in Article 130, paragraph 6 of this Law, occur;
- 7) If criminal proceedings have been instituted against him/her for the act that makes him/her discreditable to perform that function, or if sentenced for the criminal offence, which makes his/her discreditable to perform the function of the director of the health care facility by judgment absolute;

8) If he/she misappropriates, or if he/she allows misappropriation of funds of the health insurance organization, or if he/she uses the funds contrary to the agreement concluded with the health insurance organization;

9) If the health care facility acquires funds contrary to this Law or by charging health services to insured persons contrary to the law regulating health insurance;

10) For other reasons specified by the law or the articles of association of the health care facility.

Management Board

Article 136

The management board of a health care facility shall:

1) Adopt the articles of association of the health care facility with the approval by the founder;

2) Adopt other bylaws of the facility in compliance with the law;

3) Decide on the business operations of the health care facility;

4) Adopt the program of work and development;

5) Adopt financial plan and annual statement of account of the health care facility in compliance with the law;

6) Adopt annual report on the work and business operations of the health care facility;

7) Decide on the use of the resources of the health care facility, in compliance with the law;

8) Announce vacancy and implement the procedure of election of the candidates for performing of the function of the director;

9) Administer other affairs specified by the law and the articles of association.

The documents referred to in paragraph 1, Item 5) of this Article concerning the portion of the funds that health care facilities acquire from the budget and from the funds of the organization in charge of compulsory health insurance shall be passed in the manner and according to the procedure by which the budgetary system of the Republic is regulated.

The management board shall bring decisions when more than a half of the members of the management board are present and shall hand down decisions by the majority vote out of the total number of the members.

Article 137

The management board in a outpatient department, pharmacy, institute, and the public health institute shall have five members of whom two members will be from the health care facility, and three members will be the representatives of the founder.

The management board in a hospital, clinic, institute, clinical hospital, and clinical center shall have seven members of whom three members will be from the health care facility, and four members will be the representatives of the founder.

At least one member from the ranks of the employees in the management board must be a health care practitioner with university qualifications.

Members of the management board of a health care facility shall be appointed for a period of four years.

Supervisory Board

Article 138

The supervisory board of health care facility shall exercise supervision over the work and business operations of a health care facility.

The supervisory board shall bring decisions if more than a half of the members of the supervisory board are present and shall pass decisions by the majority vote out of the total number of members.

Article 139

The supervisory board in a outpatient department, pharmacy, institute, and public health institute shall have three members out of whom one member shall be from the health care facility, and two members shall be the representatives of the founder.

The supervisory board in a hospital, clinic, institute, clinical hospital and clinical center shall have five members out of whom two members shall be from the health care facility, and three members shall be the representatives of the founder.

The members of the supervisory board of a health care facility shall be appointed for a period of four years.

Article 140

In the management board and supervisory board of the state owned health care facility, which is engaged in the activity for the territory of several municipalities, the respective municipalities must be proportionally represented.

The founder shall appoint the members of the management and supervisory board from the health care facility at the proposal of the professional board of the health care facility.

Articles of Association of a Health Care Facility

Article 141

A health care facility shall have the articles of association regulating: the activity, internal organization, management, business operations, requirements for appointment and relieve of the director, deputy director, or assistant director for

educational and scientific and research work, as well as other issues of importance for the work of the facility.

The founder shall approve the articles of association of a health care facility, which are adopted by the management board.

The opinion of the Ministry shall previously be obtained concerning the provisions of the articles of association of a state owned health care facility, in the part regulating the area of health care, or specialties in which it practices health care activity, internal organization and the requirements for appointment and relieve of the director.

The Government shall approve the articles of association of a clinic, institute, and clinical center, as well as of the Health Care of Employees Institute of the Ministry of Interior Affairs, the founder of which is the Republic.

The Ministry shall approve the articles of association of an institute, public health institute, general and specialized hospital, and the hospital the founder of which is the Republic.

Internal Organization of a Health Care Facility

Article 142

A health care facility shall form organizational units subject to the kind of activity, number of employees, and other statutory requirements.

An organizational unit, which is a part of health care facility, may bear the name that is by this Law envisaged for the type of the health care facility referred to in Article 46, paragraph 3, Items 2), 6), and 7) of this Law, if such organizational unit meets the requirements specified by this Law concerning that type of health care facility.

The Minister shall specify the conditions and the method of internal organization of health care facilities.

The state owned health care facility shall establish the system of internal auditing for all transactions in the account of revenues and expenditures, the account of the financial funds and liabilities and the financing account, as well as for the management of state-owned property, by organizing a special service of internal auditors.

The purpose of the system of internal auditing referred to in paragraph 4 of this Article is to ensure enforcement of the laws, regulations, rules and procedures; successful business operations; economic, efficient, and earmarked use of resources; safeguarding of resources and investments from losses, including from frauds, irregularities or corruption; integrity and reliability of information, accounts, and data.

Internal auditors shall be directly accountable to the director of the health care facility, and shall submit the report on administering of the affairs of internal audit to the management board of health care facility at least twice a year.

Internal organization of internal audit and the number of internal auditors in a health care facility shall be regulated in detail by the articles of association of the health care facility.

The provisions of the law regulating the budgetary system, as well as the regulations adopted for enforcement of that law shall apply to the procedure and method of carrying out internal auditing in state owned health care facilities.

2. Professional Bodies in a Health Care Facility

Article 143

Professional bodies of a health care facility shall be:

- 1) Professional council;
- 2) Professional collegiate body;
- 3) Ethics board;
- 4) Commission for Improvement of the Quality of Work.

Professional Council

Article 144

The professional council shall be the advisory body of the director and the management board.

The members of the professional council shall be health care practitioners with university qualifications who shall, at the proposal of the organizational unit of the health care facility be appointed by the director.

The head nurse of the health care facility shall also participate in the work of the professional council.

The director of the health care facility may not be a member of the professional council.

The professional council shall convene minimum once in 30 days.

Article 145

The professional council shall:

- 1) Review and decide on issues of professional work of the health care facility;
- 2) Propose the program of professional work as well as professional development of the health care facility;
- 3) Propose the plan of professional advancement of health care practitioners and medical associates;
- 4) Propose the plan for improvement of the quality of professional work in the health care facility;

5) Monitor and organize implementation of internal quality assessment of professional work in the health care facility;

6) Administer other affairs specified by the articles of association.

The tasks and the method of work of the professional council shall be regulated by the articles of association of the health care facility.

Professional Collegiate Body

Article 146

The professional collegiate body is a professional body, which for the purpose of reviewing and adoption of professional and doctrinaire positions is formed in health care facilities, which within its complement have clinics and institutes as their organizational units, or in health care facilities, which within their complement have a larger number of organizational units.

The composition and work of the professional collegiate body shall be regulated by the articles of association of the health care facility.

Ethics Board

Article 147

The Ethics Board is a professional body that monitors providing and implementation of health care on the principles of professional ethics.

The director of health care facility shall nominate the ethics board at the proposal of the professional council.

The members of the ethics board shall be appointed from the ranks of the employed health care practitioners in the health care facility and citizens graduates of the faculty of law who live or work in the territory for which the health care facility has been founded.

The number of members of the ethics board shall be regulated by the articles of association of the health care facility.

Article 148

The tasks of the ethics board of a health care facility shall be to:

1) Monitor and analyze implementation of the principles of professional ethics in engaging in a health care activity;

2) Give approval for implementation of scientific research works, medical experiments, as well as clinical tests of drugs and Medical devices in the health care facility, and/or monitor their implementation;

3) Hand down decisions and review professional issues related to taking parts of human body for medical and scientific and training purposes, in compliance with the law;

4) Hand down decisions and review professional issues related to the implementation of measures for treatment of infertility applying the procedures of biomedically assisted fertilization, in compliance with the law;

5) Monitor and analyze ethic attitude in the relationships between health care practitioners and patients, particularly in the area of giving consents by the patients to the proposed medical measure;

6) Monitor, analyze, and hand down opinions on the implementation of the principles of professional ethics in prevention, diagnostics, treatment, rehabilitation, research as well as about introduction of new health care technologies;

7) Contribute to establishing habits of respecting and implementing of the principles of professional ethics in engaging in a health care activity;

8) Perform continuous advisory function concerning all issues in the implementation of health care;

9) Review other ethical issues in engaging in the activity of health care facility.

Article 148

(1) The Ethics Committee of a health care facility in which clinical trials of medicines and medical devices in stock are conducted shall, in addition to other members set out in Article 147, have at least three medical specialists with PhD degree in the branch of medicine specific of the facility.

(2) The medical doctors in paragraph 1 of this Article shall be experienced in the scientific and medical assessment of the results obtained in clinical trials of medicines and medical devices, as well as in ethical principles of clinical trials.

(3) All members set out in paragraph 1 of this Article shall be present at the Ethics Committee meeting where a decision is made on clinical trials of medicines or medical devices.

(4) In the course of deciding on clinical trials of medicines or medical devices, only the Ethics Committee members who are not investigators in clinical trials being discussed and who are not dependent on clinical trial sponsors and who signed a statement on the absence of conflict of interest with a clinical trial sponsor can vote, or provide opinions on issues associated with clinical trials of medicines or medical devices.

(5) The list of members who participated in the adoption of the decision is an integral part of the decision on clinical trials of medicines or medical devices.

(6) In the course of deciding on clinical trials of medicines or medical devices, the Ethics Committee can request professional opinion of prominent experts, who are not members of the Ethics Committee, in specific fields necessary for making a decision on clinical trial.

(7) For the purpose of a multicentric clinical trial of medicines or medical devices conducted according to the regulations governing the area of medicines and medical devices in several health care facilities in the territory of the Republic of Serbia, the Ethics Committee of each facility in which a trial is conducted shall make a decision on conducting such clinical trial in the given health care facility.

(8) The Ethics Committee in paragraph 1 of this Article shall, in the course of work, or making decisions on clinical trials of medicines or medical devices, act pursuant to the regulations governing the area of medicines and medical devices, and implement the guidelines of Good Clinical Practice in such clinical trials.

(9) The health care facility in which a clinical trial of medicines or medical devices is carried out shall keep the documentation on conducted clinical trials during the period of at least five years after clinical trials of medicines or medical devices ended.

Commission for Improvement of the Quality of Work

Article 149

The Commission for Improvement of the Quality of Work is a professional body that looks after continuous improvement of the quality of health care that is provided in a health care facility.

The Commission for Improvement of the Quality of Work shall adopt the annual program of the quality assurance of professional work in a health care facility.

The number of members, composition, and the method of work of the Commission for Improvement of the Quality of Work shall be regulated by the Articles of Association of the health care facility.

D. PROFESSIONAL BODIES ON THE REPUBLIC LEVEL

1. Health Council of Serbia

Article 150

The Health Council of Serbia (hereinafter referred to as: the Health Council) shall be formed, as a professional and advisory body, which shall look after the development and the quality of the health care system, organization of health service and the health insurance system.

Composition of the Health Council

Article 151

The Health Council shall have 15 members elected by the National Parliament, at the proposal of the Government, as follows:

1) Two prominent experts from the ranks of full professors of the faculties of medicine in the Republic, who are superior scientific workers with internationally recognized papers or with proven contribution to the improvement and development of the health care system;

2) One prominent expert from the ranks of full professors of the faculty of dental medicine in the Republic, who is superior scientific worker with internationally recognized papers or with proven contribution to the improvement and development of the system of dental health care;

- 3) One prominent expert from the ranks of full professors of the pharmaceutical faculty in the Republic, who is superior scientific worker with internationally recognized papers or with proven contribution to the improvement and development of the pharmaceutical health care;
- 4) One representative of the Serbian Academy of Sciences and Arts;
- 5) One each representative from the ranks of the members of associations of health care practitioners;
- 6) One representative of the Serbian Medical Society;
- 7) One representative of the association of health care facilities;
- 8) Two representatives from the ranks of prominent experts in the area of health insurance and financing of health care;
- 9) One prominent expert who is superior scientific worker with internationally recognized papers or with proven contribution to the improvement and development of the area of public health.

Article 152

The tenure of the members of the Health Council shall be five years.

A member of the Health Council may not be a person elected, appointed or nominated for the function in a government authority, an authority of the territorial autonomy or local self-government, a person nominated the bodies of the organizations that administer the affairs of health insurance, or the bodies of health care facilities, institutes of advanced education, associations of health care practitioners, the Serbian Medical Society, or association of health care facilities.

The Health Council shall elect the chairperson from the ranks of its members.

Article 153

The National Parliament may relieve a member of the Health Council prior to the expiry of the term of office, as follows:

- 1) At personal request;
- 2) If he/she does not fulfill this/her duty as a member of the Health Council or by his/her actions compromises the reputation of the duty he/she performs, at the proposal of the Government;
- 3) If he/she assumes the function referred to in Article 152, paragraph 2 of this Law.

Sphere of Competence of the Health Council

Article 154

The competence of the Health Council shall be to:

- 1) Monitor the development of the systems of health care and health insurance in the Republic and their harmonization with the European and international standards;

- 2) Propose measures for preservation and improvement of the state of health and strengthening of the health potential of the population;
- 3) Propose measures for uniform exercising of health care for all citizens in the Republic, as well as the measures for improvement of the health care of the vulnerable populations;
- 4) Propose measures for functioning of the health care system based on the principles of sustainability and efficiency;
- 5) Propose measures for functioning of the compulsory health insurance on the principles of sustainability, business economics, and efficiency, as well as the measures for establishing and development of other forms of health insurance;
- 6) Implement the procedure of quality assessment of professional work of the program of continuous education of health care practitioners and medical associates (hereinafter referred to as: accreditation of programs of continuous education), in accordance with Article 187, paragraph 3 of this Law;
- 7) Hand down opinion on the proposal of the plan of development of staff in the health care system;
- 8) Hand down opinion about enrolment policy at the medical faculties and schools and cooperate with the competent government authorities and other professional bodies in proposing measures of rational enrolment policy at medical faculties and schools;
- 9) Give initiative and propose measures for the purpose of implementation of the reform in the areas of health care and health insurance;
- 10) Review other issues from the area of health care and health insurance and provide professional assistance to government authorities, organizations, and institutes in the implementation of tasks related to the social care for health;
- 11) Administer other affairs, in compliance with the law.

Work of the Health Council

Article 155

The work of the Health Council shall be public.

The Health Council may form separate working bodies.

The Health Council shall adopt its rules of procedure.

The funds for the work of the Health Council shall be provided in the budget of the Republic.

Professional and administrative and technical affairs for the requirements of the Health Council shall be administered by the Ministry.

The Health Council shall submit its reports on its work to the National Parliament minimum once a year.

2. Ethics Board of Serbia

Article 156

The Ethics Board of Serbia shall be a professional body, which shall look after the provision and implementation of health care on the Republic level, on the principles of professional ethics.

The Government shall nominate and relieve the chairperson and the members of the Ethics Board of Serbia, at the proposal of the minister.

The tenure of the members of the Ethics Board of Serbia shall be five years.

The Ethics Board of Serbia shall have nine members who shall be elected from the ranks of prominent experts who have major results in the work, as well as contribution in the areas of health care, professional ethics of health care practitioners and of humanistic sciences.

The members of the Ethics Board of Serbia may not be the persons referred to in Article 152, paragraph 2 of this Law.

The Ethics Board of Serbia shall adopt its rules of procedure.

The funds for the work of the Ethics Board of Serbia shall be provided in the budget of the Republic.

Sphere of Competence of the Ethics Board of Serbia

Article 157

The competence of the Ethics Board of Serbia shall be to:

- 1) Propose the basic principles of professional ethics of health care practitioners;
- 2) Monitor implementation of the principles of professional ethics of health care practitioners in engaging in a health care activity in the territory of the Republic;
- 3) Coordinate the work of the ethics boards in the health care facilities;
- 4) Monitor the implementation of scientific research works and clinical tests of drugs and Medical devices in health care facilities in the territory of the Republic;
- 5) Decide and hand down opinions concerning disputable issues that are of importance for the implementation of scientific research works, medical experiments, as well as for clinical tests of drugs and Medical devices in health care facilities in the Republic;
- 6) Monitor implementation of decisions and review professional issues related to the procedure of taking of parts of human body for medical and scientific and educational purposes in the health care facilities in the territory of the Republic, in compliance with the law;

7) Monitor implementation of decisions and review professional issues related to the implementation of measures for treatment of infertility by applying biomedically assisted fertilization, in the health care facilities in the territory of the Republic, in compliance with the law;

8) Submit annual report to the Ministry about the implementation of scientific research and clinical research of drugs and Medical devices in the health care facilities in the territory of the Republic, as well as about identified problems, deficiencies and remarks on the work of the ethics boards in the health care facilities;

9) Review other issues of professional ethics in the implementation of health care.

The Agency for Drugs and Medicines of Serbia shall inform the Ethics Board of Serbia about the conducting of clinical tests of drugs and Medical devices for which the approval for conducting the clinical tests has been handed down, in compliance with the law governing the area of drugs and Medical devices.

The Agency for Drugs and Medicines of Serbia may, prior to issuing the permit for conducting of clinical tests of drugs and Medical devices, seek opinion from the Ethics Board of Serbia about the submitted application for conducting of clinical tests of drugs and Medical devices, and/or about all disputable issues that may emerge in the course of conducting of clinical tests of drugs and Medical devices.

3. Professional Republic Commissions

Article 158

A professional Republic commission shall be formed for individual areas of health care activity for the purpose of harmonization of professional proposals and positions of the referential health care facilities, professional associations and chambers, institutes of higher education, and prominent experts in the field of health care.

A professional Republic commission shall establish professional doctrines concerning the preservation and improvement of health, prevention and detection of diseases, treatment and health care, rehabilitation of the diseased and injured persons, as well as the improvement and development of the organization of health service.

The members of a professional Republic commission shall be prominent scientific and other health care practitioners who have made major contribution to the work and development of a certain areas of medicine, dentistry, or pharmacy.

A professional Republic commission shall be formed by the minister.

The document on formation of the professional Republic commission shall regulate the tasks, composition, and method of work of the professional Republic commission.

The tenure of the members of a professional Republic commission shall be five years.

A professional Republic commission shall adopt its rules of procedure.

The funds for the work of the professional Republic commission shall be provided in the budget of the Republic.

(9) The Public Health Institute, founded for the territory of the republic of Serbia, provides for carrying out professional, administrative and technical activities for the work of Republic professional commissions.

E. ACQUIRING OF FUNDS FOR WORK OF HEALTH CARE FACILITIES AND PRIVATE PRACTICE

Article 159

(1) For extending public services, the health care facility in the Network Plan, as a public resources user, obtains its operating assets from public revenue as follows:

1) Mandatory health insurance tax by concluding a contract with the mandatory health insurance organization;

2) Republic, i.e. founder's budget;

3) Revenue on grounds of the use of public resources for services not included in contract with the mandatory health insurance organization (renting free capacities, or state-, autonomous province- or local self government-owned property and movables, revenue obtained by the sale of public resources user services contracted with physical persons or legal entities on the basis of their free will, scientific and research activity or education purposes etc.).

(2) The health care facility in the Network Plan can also acquire operating resources from gifts, donations, legacies and heritage, as well as from other sources pursuant to law.

(3) The health care facility in the Network Plan can do the payments only in the amount not exceeding expenditures and costs specified in the financial plan of the health care facility, that are equivalent to the appropriation from the financial plan for that purpose for the budget year.

(4) The obligations undertaken by the health care facility in the Network Plan according to the established appropriations, which were not performed during the year, are transferred and have the status of undertaken obligations that are to be performed in the next year on account of the approved appropriations for the current budget year, in compliance with the requirements set out in the law regulating the budget system.

(5) The obligations undertaken by the health care facility in the Network Plan amounting to more than the sum of resources provided by the financial plan or those occurring as opposed to the law, bylaws or in contrast with the contract concluded with the mandatory health insurance organization, cannot be performed on account of the mandatory health insurance resources, or on account of other health care facility's resources envisaged by the financial plan.

(6) The appropriations specified in the financial plan of the health care facility in the Network Plan intended for funding salaries cannot be made on account of forced collection.

(7) In case that there was no legal ground for a payment made to the health care facility in the Network Plan, such health care facility shall immediately refund the mandatory health insurance organization, or the budget.

(8) In cases set out in paragraphs 5 and 7 of this Article, the Managing Board of a health care facility shall, within eight days of the learning, notify the founder of the health care facility in the Network Plan of the fact indicative of the health care facility action against the law.

(9) The health care facility in the Network Plan shall submit the balance sheet to the mandatory health insurance organization in order to generate the consolidated report of the organization, and other reports specified by regulations governing the budgetary system.

(10) The financial resources acquisition and disposition required for Network Plan health care facility functioning are specified by the regulations governing mandatory health insurance, and regulations governing the budgetary system.

(11) Health care facilities founded by privately owned or otherwise owned funds, as well as private practice, acquire and use funds as specified by law.

A health care facility or private practice may acquire the funds for work from:

- 1) Health insurance organization;
- 2) Budget;
- 3) Sales of services and products that are directly related to the health care activity of the health care facility;
- 4) Engaging in scientific and research and educational activities;
- 5) Renting out of free capacities;
- 6) Legates;
- 7) Gifts;
- 8) Bequests.

Article 160

A health care facility or private practice shall acquire funds for work from the health insurance organization by concluding agreements for providing health care, in compliance with the law regulating health insurance.

A health care facility shall acquire the funds referred to in Article 18, paragraph 2 of this Law for the implementation of health care of general interest, by concluding the agreement with the Ministry.

A health care facility shall acquire the funds referred to in Article 13, paragraphs 3 and 4 of this Law for implementation of health care of interest to autonomous province, municipality, or city, by concluding the agreement with the competent authority of the autonomous province, municipality, or city.

Article 161

The health services provided by a health care facility or private practice at the request of an employer at the cost of the employer shall be charged at the prices fixed by the management board of the health care facility or by the founder of private practice.

The health services provided by a health care facility or private practice to the citizens at their request, as well as the health services that are not covered by health insurance, shall be charged to the citizens, at the prices fixed by the management board of the health care facility or the founder of private practice.

Article 162

The fee for the provided emergency medical care shall be paid by the Republic, autonomous province, municipality, or city – the founder of the health care facility, if the health care facility has not charged the health insurance organization for this service within 90 days from the date of issuing of the invoice.

The fee referred to in paragraph 1 of this Article for the provided emergency medical care by private practice shall be paid by the Republic if the founder of private practice has not charged the health insurance organization for this service within 90 days from the date of issuing of the invoice.

By paying up the fee referred to in paragraphs 1 and 2 of this Article, the Republic, autonomous province, municipality, or city shall be entitled to request reimbursement of the paid amount from the health insurance organization.

Article 163

Health care facilities and private practice, for the purpose of improvement of work, business economics, and implementation of other tasks and goals of common interest, may set up the association of health care facilities or private practice association.

The articles of association of the association referred to in paragraph 1 of this Article shall regulate the internal organization, composition, election, and the method of decision-making of the bodies, financing, and other issues of importance for the work of the association.

Renting out Free Capacities in a Health Care Facility

Article 164

For the purpose of rational use of the capacities in a health care activity and creating conditions for more comprehensive and higher-quality health care of citizens, health care facilities with the resources in state ownership, which have been founded for exercising of the statutory rights of the citizens in the area of health care, in case they have free capacities (premises and equipment), they may rent out such capacities, in compliance with the law.

If several persons who are engaged in the health care activity are interested in the free capacities referred to in paragraph 1 of this Article, the

capacities will be rented out to the person for whose work there is the bigger demand and who offers the most favorable terms and conditions.

F. HEALTH CARE PRACTITIONERS AND MEDICAL ASSOCIATES

1. Common Provisions

Article 165

Health care practitioners are the persons who have graduate from the faculty of medicine, dental medicine, or pharmacy, as well as the persons who are the graduates from other medical school, and who are directly engaged in a health care activity as a profession in a health care facilities or private practice, under the conditions laid down by this Law.

A medical associate is a person having secondary school, two-year post-secondary school, or university qualifications, who is engaged in certain types of practice of health care in a health care facility or private practice.

In order to engage in a health care activity, health care practitioners, or medical associates must, for certain types of practice, also have relevant specialization, or super-specialization, in accordance with the provisions of this Law.

Article 166

A health care practitioner, depending on the professional qualifications, shall be:

- 1) A doctor of medicine, doctor of dental medicine, a graduate pharmacist and a graduate pharmacist medical biochemist - graduate of the relevant medical faculty;
- 2) Other health care practitioner – graduate of the relevant faculty, two-year post-secondary, or a secondary medical school.

Article 167

Membership in the association shall be mandatory for the health care practitioners referred to in Article 166 of this Law, who are engaged in a health care activity as their profession.

A separate law shall govern setting up of associations, the activities of an association, organization, and the work of an association as well as other issues of importance for the work of an association.

Article 168

A health care practitioner may autonomously provide health care (hereinafter referred to as: independent practice) in a health care facility, private practice or with another employer who may, in the sense of this Law, engage in certain types of practice within the health care activity, if he/she has:

- 1) Has served internship and passed intern's exit exam;

- 2) Has registered in the directory of the association;
- 3) Been issued, or renewed the license for independent practice.

The independent practice, in the sense of this Law, shall imply autonomous providing of health care without direct supervision by another health care practitioner.

A foreign citizen who is engaged in a health care activity in the Republic, must, apart from the requirements laid down in paragraph 1 of this Article, speak the Serbian language as well as other language that is in official use, in accordance with the regulations on the official use of the language in the Republic, and/or must also meet other requirements in accordance with the regulations governing the area of employment of foreign citizens in the Republic.

Article 168

(1) A health care practitioner who is a foreign citizen can, exceptionally, perform health care activities at a health care facility, or private practice, or with other legal entity dealing with health care activity pursuant to this Law provided that he/she obtained a temporary license in the Republic of Serbia in compliance with this Law.

(2) Such temporary license set out in paragraph 1 of this Article can be issued to a health care practitioner who is a foreign citizen if, in addition to the requirements specified by law regulating the area of employment of foreign citizens in the Republic of Serbia, meets the following requirements:

1) That he/she received a written invitation from the health care facility, or private practice, or other legal entity dealing with health care activity pursuant to this Law for temporary, or intermittent engagement to perform certain health care activities;

2) That he/she has work permit, or other relevant document issued by the competent authority of the country of residence or abode;

3) That he/she implements health care technologies used in the Republic of Serbia, or that he/she implements health care technologies not used in the Republic of Serbia but for which, as new health care technologies, the implementation permit was issued pursuant to this Law, or implements the treatment methods and procedures, as well as that he/she uses medicines and medical devices in compliance with the regulations related to health care.

(3) The temporary license set out in paragraph 1 of this Article is issued by the competent medical association.

(4) The temporary license set out in paragraph 1 of this Article can be issued by the competent medical association for the period not longer than 180 days during a calendar year.

(5) The competent medical association shall issue a decision within not longer than 15 days from the submission of application for temporary license.

(6) The method and procedure for temporary license issuing are subject to the provisions of this Law, or the law regulating the operation of medical associations related to the method and procedure for issuing licenses to health care practitioners, unless otherwise specified by this Law.

(7) Detailed conditions, method of issuance, form and contents of the temporary license, and other issues regulating in more detail the procedure for temporary license issuance are regulated by the common act of Article 190, paragraph 8 of this Law.

(8) Engagement of health care professionals, foreign citizens, by a health care facility, or private practice, or other legal entity dealing with health care activity pursuant to this Law is prohibited contrary to this Law.

(9) A health care professional who obtained a temporary license in compliance with this Article is entitled to insurance from medical malpractice pursuant to law.

Article 169

Health care practitioners shall engage in a health care activity in accordance with the prevailing health care doctrine and in accordance with the code of professional ethics.

For their work, health care practitioners shall assume professional, ethical, penal and material responsibility.

Health care practitioners with university qualifications referred to in Article 166, Item 1) of this Law shall, when receiving the university diploma, sign a statement - oath that they will in practicing their profession adhere to the principles established in Hippocratic oath, as well as to the principles of professional ethics.

Health care practitioners referred to in Article 166, Item 2) of this Law, or medical associates shall, when signing employment contract, sign a statement - oath that they will in practicing their profession adhere to the principles established in the Hippocratic oath, as well as to the principles of professional ethics.

Article 170

Health care practitioners and medical associates as well as other persons employed in a health care facility, or private practice may not leave workplace until their replacement is provided even if their working hours have expired, if thereby engaging in a health care activity would be disrupted and the health of a patient threatened.

Article 171

A health care practitioner may refuse to provide health care if the health service that should be provided is not in agreement with his/her conscious, or with the international rules of medical ethics (hereinafter referred to as: conscientious objection).

A health care practitioner shall inform the director of health care facility, or immediate superior, as well as the founder of private practice about his/her conscientious objection.

A health care facility or private practice shall respect the expressed conscientious objection of the health care practitioner, as well as ensure providing of health care to the patient by another health care practitioner.

A health care practitioner may not refuse to provide emergency medical care by expressing the conscientious objection.

Article 172

The rights, duties, and responsibilities of the employees in a health care facility or private practice shall be exercised in accordance with the labor regulations, unless otherwise specified by this Law.

Article 173

Engaging in a health care activity by the persons who, in the sense of this Law, are not considered to be health care practitioners and medical associates shall be prohibited.

(2) Provision of health care by a medical doctor, doctor of dental medicine, graduated pharmacist, graduated pharmacist – medical biochemist through which he/she gains profit or any other property or non-property benefit outside the health care facility or private practice operating pursuant to this Law, except in case of the provision of emergency aid pursuant to law, is prohibited.

(3) If a health care professional acts contrary to paragraph 2 of this Article, the competent medical association can withdraw the license for independent work from such health care professional, pursuant to law.

Article 173

(1) The human resources plan for health care facilities in the Network Plan for the territory of the Republic (hereinafter: the human resources plans) consisting of the total number of employees included in individual human resources plans of health care facilities on the Network Plan (hereinafter: facility human resources plan) is adopted by the Minister.

(2) The procedure for the adoption of the human resources plan in paragraph 1 of this Article for the health care facilities in the territory of an autonomous province shall provide for the participation of the autonomous province representatives in a relevant task force of the Ministry.

(3) The human resources plan in paragraph 1 of this Article means the maximum number of employees in health care facilities in the Network Plan, or in any individual health care facility in the relevant budgetary, adopted by the Minister in compliance of the data set out in paragraph 16 of this Article.

(4) The human resources plan in paragraph 1 of this Article contains the data on the total number of employees, or employees in a health care facility, whose salaries are provided by the mandatory health insurance organization, as well as the number of employees whose salaries are provided by other sources pursuant to law, or the data on the number of employees with permanent or fixed-term contract, or those with full- or part-time contract or those employees working short hours or on leave, and other human resources data of the health care facility.

(5) The human resources plan in paragraph 1 of this Article is adopted by the Minister for each budgetary year not later than December 31 of the current calendar year for the next budgetary year.

(6) If, for reasons specified by law or for any other justified reasons, the human resources plan is not adopted in the term specified in paragraph 5 of this Article, the current human resources plan shall be used until the adoption of the Republic or facility human resources plan.

(7) The human resources plan in paragraph 1 of this Article, and its amendments, shall be in line with the financial resources of the mandatory health insurance organization, health care facility, or the founder's budget for the budgetary year for which the plan or its amendments are adopted the evidence of which is submitted to the Ministry.

(8) The total number of employees in the human resources plan in paragraph 1 of this Article during one budgetary year can be changed by the Minister on the basis of authorization based on the data specified in paragraph 16 of this Article or on request by the Director of a health care facility by reconciliation of the number of employees against the standards or norms prescribed by this Law and bylaws intended for the enforcement of the Law; or by the reconciliation of the number of employees in order to provide for the rights of mandatory health insurance pursuant to law.

(9) The health care facility can submit to the Ministry the application for a change or addition of the human resources plan of a health care facility accompanied with the necessary documentation specified in paragraph 8 of this Article not more frequently than twice during a calendar year: in the period April 1 to April 30 and October 1 to October 30 of the current year for the next budgetary year.

(10) The Minister shall either adopt such change of or addition to the human resources plan not later than by June 15 of the current calendar year or adopt a human resources plan for the next budgetary year by December 31 of the current calendar year.

(11) The submissions made before after the term specified in paragraph 9 of this Article, as well as incomplete submissions, shall not be considered.

(12) The Ministry shall submit the human resources plans in paragraph 1 of this Article, and their amendments to the mandatory health insurance organization, health care facility, and the Ministry of Finance within eight days of adoption.

(13) The Ministry shall publicize the human resources plans in paragraph 1 of this Article, and their amendments on the official web presentation of the Ministry within five days from the date of their submission to the mandatory health insurance organization or health care facility.

(14) The number of employees in a health care facility shall not be greater than that established by the human resources plan.

(15) Engagement with the health care facility in the Network Plan of the number of employees exceeding that established by the human resources plan in paragraph 1 of this Article is prohibited.

(16) In order to generate the human resources plan in paragraph 1 of this Article, The Public Health Institute established for the territory of the Republic, shall keep and generate the database on the total staffing of the health care facilities in the Network Plan, including the structure and number of employees per health care facility, certain organizational units, per method of funding their salaries, fixed

and permanent contracts, part-time and full-time employees, those working short ours, make amendments to those databases, staffing analysis and propose measures for improving the staffing of health care facilities.

(17) The Public Health Institute established for an autonomous province territory shall keep and generate a database set out in paragraph 16 of this Article for health care facilities in the territory of the autonomous province, which shall form an integral part of the common database.

2. Internship and Intern's Exit Exam of Health care practitioners and Medical Associates

Article 174

On the day of commencement of serving internship, a health care practitioner shall be registered in the directory of the association in which separate records are kept on the members of the association who are interns.

Article 175

Health care practitioners and medical associates may not practice independent practice until they complete serving internship and pass intern's exit exam, in compliance with this Law.

Internship for health care practitioners and medical associates having university qualifications shall last 12 months, unless otherwise specified by this Law.

Internship for doctors of medicine whose basic studies at the faculty of medicine, on the basis of the program of the competent authority of the faculty, are established to last six years – shall last for six months.

Internship for health care practitioners and medical associates, who have two-year post-secondary school, or secondary school qualifications, shall last for six months.

Article 176

Internship shall be served according to the established program.

Internship is practical work under the supervision of a licensed health care practitioner, or medical associate - mentor, by which a health care practitioner and medical associate are trained for independent practice.

Internship is served in a health care facilities and private practice under direct supervision of the health care practitioner, or medical associate who has minimum five years of service after having passed intern's exit exam.

(4) The part of internship related to quality control of medicines and medical devices can be served with the Medicines and Medical Devices Agency of Serbia.

A health care facility, or private practice, shall keep records, exercise supervision, and shall be responsible for consistent implementation of program of internship of health care practitioners and medical associates.

In the course of internship, the intern who has sign employment contract with a health care facility, or private practice, shall be entitled to income earnings and all other rights emanating from employment, in compliance with the law regulating labor, and/or in compliance with the employment contract.

Article 177

The plan and program of internship, detailed requirements that must be satisfied by the health care facilities and private practice in which internship may be served, the form of the intern's record book, the method of keeping intern's record book, as well as other issues of importance for serving of internship, shall be specified by the minister.

The minister shall establish the number of interns, which the health care facility specified by the Plan of the Network shall receive to serve internship, on annual level.

Voluntary Internship

Article 178

Internship may also be served in the form of voluntary work, as work outside employment.

A health care facility or private practice may provide remuneration/compensation for work and other rights in compliance with the law and other bylaws to the person with whom it concludes the contract on voluntary work.

The person with whom the contract on voluntary work has been concluded in compliance with this Law shall have the rights emanating from compulsory social insurance, in compliance with the law.

Intern's Exit Exam

Article 179

Upon expiry of internship, health care practitioners and medical associates shall pass intern's exit exam within 12 months from the date of completion of the program of internship, before the examination board formed by the minister.

The minister shall specify the program, contents, method, and procedure taking the intern's exit exam, as well as the form of the certificate of certification exam referred to in paragraph 1 of this Article.

(3) The resources obtained by payments for exit exams to be taken by health care practitioners and medical associates form the income of the Republic and are intended for funding the costs related to such exit exams.

Article 180

To the health care practitioners and medical associates who have served their internship or a part of internship abroad, the Ministry may, at their request, recognize the internship or a part of internship, under the condition that the

program of served internship corresponds to the program of internship in compliance with this Law.

3. Professional advancement of Health care practitioners and Medical Associates

Article 181

Professional advancement, in the sense of this Law, implies acquiring knowledge and skills by health care practitioners and medical associates, which includes:

- 1) Specialization and super-specialization;
- 2) Continuous education.

The costs of professional advancement of health care practitioners and medical associates shall be borne by the employer.

Article 182

Health care practitioners and medical associates shall have the right and duty to, in the course of their work, continuously follow the development of medical, dental medical, pharmaceutical sciences, as well as of other relevant sciences, and to professionally improve for the purpose of maintaining and improvement of the quality of their work.

Professional advancement of health care practitioners shall be a precondition for their being issued, or for renewing of their license.

A health care facility or private practice shall provide paid leave for continuous education for the purpose of renewal of the license for independent practice to an employed health care practitioner and medical associate, in compliance with the law.

Plan of Professional advancement

Article 183

A health care facility or private practice shall provide professional advancement to a health care practitioner and medical associate, in compliance with this Law, and according to the plan of professional advancement of health care practitioners and medical associates in the health care facility or private practice.

The plan of professional advancement referred to in paragraph 1 of this Article shall be adopted by the health care facility on the basis of the plan of development of staff in the health care system, which shall be handed down by the Minister.

The plan of development of staff in the health care system referred to in paragraph 2 of this Article shall contain:

- 1) The program of professional advancement of health care practitioners and medical associates;

2) Number of specializations and super-specializations that are approved on the annual level;

3) Criteria and detailed requirements for approval of specializations and super-specializations;

4) Other issues of importance for professional advancement of health care practitioners and medical associates, in compliance with the law.

Specializations and Super-specializations

Article 184

A health care practitioner and medical associate having university qualifications may undergo specialization if he/she has served internship and passed intern's exit exam and two years of practice in health care activity upon passing the intern's exit exam.

(2) Notwithstanding paragraph 1 of this Article, a health care practitioner can, after the internship term and passed exit exam, be referred to specialization courses in scarce branches of medicine, dental medicine or pharmacy.

(3) The Minister shall, for each calendar year, pass the decision on scarce fields of medicine, dental medicine or pharmacy in the Republic of Serbia not later than by December 31 of the current year on the basis of the opinion of the Public Health Institute founded for the territory of the Republic, pursuant to law.

(4) A higher education health care practitioner can go for advancement after a finished specialization and take a sub specialization as a specialist in a certain branch of medicine, dental medicine or pharmacy for the period of at least two years provided that he/she performed health care activities pursuant to this Law.

A health care practitioner and medical associate may practice health care in the area in which he/she undergoes specialization only under the supervision by a licensed health care practitioner, or medical associate - mentor.

A health care practitioner with university qualifications may, after completed specialization, further specialize by undergoing super-specialization.

Specializations and super-specializations shall be approved by health care facilities or private practice, in accordance with the plan of professional advancement referred to in Article 183, paragraph 1 of this Law.

The decision on approval of specialization and super-specialization, in accordance with paragraph 4 of this Article, shall be handed down by the director of health care facility, or the founder of private practice.

The Minister shall, by own decision, give approval of the decision referred to in paragraph 5 of this Article.

The decision of the minister referred to in paragraph 6 of this Article shall be final in the administrative procedure and an administrative suit may be instituted against it.

(9) A health care practitioner or associate shall conclude a contract with a health care facility or private practice on rights, obligations and responsibilities during professional advancement in the course of specialization or sub specialization.

(10) A health care practitioner or associate shall be employed with a health care facility in the Network Plan for the period twice as that of specialization or sub specialization.

(11) A health care practitioner or associate can provide health care in the field of specialization under the supervision of an authorized health care professional or medical associate – mentor.

(12) A health care facility or private practice can approve specialization or subspecialisation to a health care practitioner or associate provided he/she performed the activity in compliance with this Law during at least two years before the submission of the application for the approval of such specialization or subspecialisation.

Article 185

The minister, by own decision, may approve specialization, or super-specialization for the requirements of work with the specified employers to a person who has graduated from a medical faculty, and who is engaged a health care activity as a profession in a health care facility or private practice and who is employed in a government authority, an authority of the territorial autonomy, or local self-government, at a medical faculty, or school, a scientific and research facility, legal person engaged in production, trade in, and control of drugs and Medical devices, the agency in charge of the area of drugs and Medical devices, the organization administering health insurance, institution of social protection, penitentiary instruction, as well as with an employer who has set up an outpatient unit of occupational medicine in compliance with this Law –, in compliance with this Law and the regulations adopted for enforcement thereof.

The minister, by own decision, may approve specialization, or super-specialization to a foreign citizen who has graduated from a medical faculty, and who is not engaged in a health care activity as a profession in the Republic, in compliance with the law.

Article 186

The kinds, duration, and contents of specializations and super-specializations, the programs of specialization, or super-specialization, the method of serving registrarship and taking the certification exam, composition and work of examination boards, the requirements that health care facility and private practice must fulfill to serve registrarship, conditions and the method of recognizing of the time spent working as a part of registrarship, as well as the forms of the matriculation book and the diploma on the certification exam, or on the exam passed upon super-specialization, shall be specified by the minister.

The Ministry shall, by own decision, establish whether the requirements for implementation of the programs of specializations, or super-specializations in health care facilities and private practice have been fulfilled.

Continuous Education

Article 187

Continuous education shall imply:

- 1) Participation at professional and scientific gatherings;
- 2) Participation in seminars, training courses, and other programs of continuous education.

The kind, programs, method, procedure, and the duration of continuous education referred to in paragraph 1 of this Article, institutes and associations that may implement the procedure of continuous education, the criteria on basis of which the programs of continuous education are accredited, as well as other issues of importance for the implementation of continuous education, shall be specified by the minister.

Accreditation of the programs of continuous education referred to in paragraph 2 of this Article shall be done by the Health Council.

(4) Continual education can be provided under the conditions specified by this Law also in the Medicines and Medical Devices Agency of Serbia, Agency for Licensing Health care facilities in Serbia, Administration for Biomedicine, and in other public agencies, bodies and organizations supervised by the Ministry.

Recognition of a Foreign School Document (Validation of Diploma)

Article 188

A health care practitioner, or medical associate who has finished relevant school, faculty and specialization abroad, as well as a health care practitioner, or medical associate who is a foreign citizen, may engage in a health care activity as a profession, if their foreign school document is recognized (validation of diploma).

Recognition of a foreign school document referred to in paragraph 1 of this Article shall be done in compliance with the law.

Awarding the Title of Head Doctor

Article 189

Doctors of medicine, doctors of dental medicine, and graduate pharmacist who have minimum 12 years of practice in a health care activity, who have passed the certification exam, professional and scientific papers, may submit the application, or be proposed to receive the title of head doctor, as a professional recognition for a long-term successful health care, educational, and professional work.

The proposal for awarding of the title of head doctor may be submitted by the relevant section or branch of the Serbian Medical Society, or Pharmaceutical Society of Serbia, as well as by the competent association.

Detailed requirements, method, and procedure for awarding of the title of head doctor shall be specified by the minister.

For the health care practitioners referred to in paragraph 1 of this Article from the territory of autonomous province, when deciding on the awarding of the title of head doctor, the opinion from the competent authority of the autonomous province shall be previously obtained.

(3) Detailed requirements, method, procedure and costs of acquiring the title of Head Doctor, the reviewer cost, and other issues related to the procedure for acquiring the title of Head Doctor shall be specified by the Minister.

(4) The resources obtained from the payment of compensation for acquiring the title of Head Doctor are the revenue of the budget of the Republic and intended for funding all costs related to the procedure of acquiring the title of Head Doctor.

(5) For health care practitioners in paragraph 1 of this Article from the territory of an autonomous province, the opinion of the competent authority of the autonomous province shall be obtained before deciding on the title of Head Doctor.

The title of head doctor shall be awarded by the minister.

4. Issuing, Renewing, and Revoking the License for Independent practice

Article 190

Issuing, renewing, and revoking of the license for independent practice (hereinafter referred to as: the license) to health care practitioners is the procedure, which is implemented by the competent association for the purpose of establishing professional qualifications of health care practitioners for independent practice.

The association shall issue, renew or revoke the license of a health care practitioner.

The manager of the competent association shall hand down the decision on the issued, renewed or revoked license of a health care practitioner.

The decision referred to in paragraph 3 of this Article shall be final in the administrative procedure and an administrative suit may be instituted against it.

The license shall be a public document.

The costs of issuing and renewing the license shall be established by the competent body of the association, under the conditions laid down by the law.

The costs referred to in paragraph 6 of this Article shall be borne by the applicant requesting issuing or renewing the license.

Detailed requirements for issuing, renewing or revoking of the license, the procedure, and the method of issuing, renewing or revoking of the license, the form and the contents of the issued, renewed or revoked license, the program of continuous education, which is implemented for the purpose of gaining professional

qualifications of health care practitioner for independent practice, as well as other requirements for issuing, renewing or revoking of the license, shall be specified by the minister.

Article 191

A health care practitioner who has not been issued, or who has not renewed the license, under the conditions laid down by this Law and the regulations adopted for enforcement of this Law, may not practice independent practice in a health care facility or private practice.

Until the issuing, or renewal of the license, the health care practitioner referred to in paragraph 1 of this Article shall provide health care in a health care facility or private practice under the supervision of the health care practitioner who has been issued or who has renewed the license with the competent association, who will be designated by the director of the health care facility or the founder of private practice.

Article 192

The health care practitioner to whom the competent association has not renewed the license, or whose license has been revoked, under the conditions laid down by this Law, shall, within eight days from the date of receipt of the decision, submit to the competent association the formerly issued license.

Article 193

The competent association shall ex officio keep the directory of issued, renewed, or revoked licenses, in compliance with the law.

Issuing the License

Article 194

The association shall issue the license to the health care practitioner who has passed intern's exit exam.

The health care practitioner shall submit the application for issuing of the license to the competent association.

The manager of the competent association shall hand down the decision about the application for issuing the license and shall issue the license.

The association shall issue the license for a period of seven years.

Article 195

The association shall issue the license to a health care practitioner under the condition that he/she:

- 1) Meets the requirements referred to in Article 166 of this Law with respect to the medical qualifications;
- 2) Has served internship and passed intern's exit exam;

- 3) Has registered in the directory of the association;
- 4) Has not been sentenced for the criminal act, by judgment absolute, which would make him/her discreditable to engage in a health care activity, or has not been sentenced to a jail term due to a serious criminal offence against the health of people by judgment absolute.

Renewal of the License

Article 196

For the purpose of renewing the license, a health care practitioner shall submit the application to the competent association, 60 days prior to the expiry of the period for which the license was issued.

Together with the application for renewal of the license, the health care practitioner shall also submit the evidence on the implemented procedure of continuous education in compliance with this Law and the regulations adopted for enforcement of this Law, as well as the evidence of professional qualifications for continuation of work in his/her profession.

Renewal of the license shall take place every seven years.

Revoking the License

Article 197

The association shall temporarily revoke the license of a health care practitioner:

- 1) Should the health care practitioner fail to renew the license, under the conditions laid down by this Law;
- 2) If a health care practitioner is engaged in an activity for which he has not been issued the license;
- 3) If a health care practitioner in engaging in a health care activity makes a professional misconduct due to which the state of health of a patient is ruined or aggravated;
- 4) If one of the actions of temporary ban on independent practice has been brought against a health care practitioner by the competent body of the association, due to a major breach of professional duty and prejudice to reputation of a member of the association, in compliance with the law and the articles of association of the association;
- 5) If a health care practitioner has been sentenced by judgment absolute for the criminal offence, which makes him/her discreditable to practice the profession of a health care practitioner;
- 6) If, in engaging in a health care activity, he/she misappropriates the funds of the health insurance;
- 7) In other cases laid down by the law.

Temporary revoking of the license for the reasons specified in paragraph 1, Item 1) of this Article may last until the renewal of the license, under the conditions laid down by this Law.

Temporary revoking of the license for the reasons specified in paragraph 1, Items 2) to 7) of this Article may last from six months to five years from the date of receipt of the decision on temporary revoking of the license.

The professional misconduct, in the sense of this Law, shall imply unconscientious treatment, and/or negligence of professional duties in providing health care, and/or noncompliance with or ignorance of the established rules and professional skills in providing health care, which give rise to ruining, aggravation, injury, loss or damage of the health or of parts of the body of a patient.

The professional misconduct referred to in paragraph 4 of this Article shall be established in the disciplinary proceeding before the competent body of the association, or in the process of regular and extraordinary external quality assurance of the professional work of health care practitioners.

Article 198

An association shall permanently revoke the license of a health care practitioner if the health care practitioner has been, by judgment absolute, sentenced to jail term due to a serious criminal offence against the health of people.

The health care practitioner whose license has been permanently revoked, may engage in certain types of practice within the health care activity under the supervision of the health care practitioner whose license has been issued, or renewed, who will be designated by the director of the health care facility, or the founder of private practice in which the health care practitioner is engaged in certain types of practice within the health care activity.

Article 198

(1) For carrying out the activities of a medical associate in a health care facility, private practice or other legal entity dealing with certain health care activity pursuant to this Law, the Minister shall, by decision, issue, renew or withdraw the license for independent work (hereinafter: health care associate license).

(2) The Minister shall issue the license to a medical associate based on the application submitted by the medical associate to the Ministry, provided such medical associate finished their internship and passed the exit exam pursuant to this Law.

(3) The decision in paragraph 1 of this Article is final in the enforcement procedure and an administrative suit may be instituted against it.

(4) The records on issued, renewed or withdrawn licenses of medical associates shall be kept by the Ministry.

(5) The medical associate license is issued for the period of seven years.

(6) The medical associate license is a public document.

(7) The costs of medical associate license issuance or renewal shall be established by the Minister.

(8) The resources obtained from the payment of compensation for issuing or renewal of medical associate license are the revenue of the budget of the

Republic and intended for funding all costs related to issuing or renewal of medical associate licenses.

(9) The costs in paragraph 7 of this Article are borne by the license issuing or renewal applicant.

Article 198b

(1) A medical associate who failed to obtain or renew the license under the conditions specified by this Law and regulations adopted for the enforcement of this Law cannot work independently in a health care facility or private practice or with other legal entity dealing with certain health care activity pursuant to this Law.

(2) A medical associate shall submit the application to the Ministry for license approval 60 days before the expiry of the license term.

(3) Medical associate's license shall be renewed at 7-year intervals.

(4) Medical associate's license is withdrawn by the Minister if:

1) the medical associate fails to renew the license pursuant to this Law and bylaws adopted for the enforcement of this Law or fails to submit evidence on acquired continual education, as well as evidence on the expertise for continuing professional work;

2) the medical associate performs the activity without being issued the medical associate license;

3) the medical associate was convicted, by a valid court decision, for a criminal act making them unworthy of the medical associate profession;

4) in other cases set out by law.

(5) Detailed conditions for, renewal or withdrawal of the medical associate license, method of issuance, renewal or withdrawal of license, form and contents of the issued, renewed and withdrawn license, continual education program conducted for gaining professional skills and capabilities of a medical associate for independent work or license renewal, and other issues regulating in more detail the procedure for temporary license issuance, renewal and withdrawal are specified by the Minister.

5. Sideline Work of Health care practitioners

Article 199

A health care practitioner employed in a health care facility and private practice, who works full hours, may engage in certain types of practice within the health care activity in their profession with his/her employer, or with another employer, outside the regular working hours, by concluding the sideline contract with the director of the health care facility, or the founder of private practice.

A sideline contract may be concluded:

1) For providing of health services that are not covered by compulsory health insurance with respect to the contents, coverage and standards, or for the health services that are not provided in accordance with the method and procedure for exercising of the rights emanating from compulsory health insurance;

2) For providing of health services that the health care facility provides for the requirements of the compulsory health insurance organization, for which it cannot otherwise provide adequate health care practitioners;

3) For providing of health services that the health care facility provides for the requirements of the persons who do not have the capacity of insured person in compliance with the law regulating health insurance.

The health care practitioner referred to in paragraph 1 of this Article, after previously providing the approval from the professional council and the director of health care facility or from the founder of private practice in which he/she is employed, may conclude only one sideline contract with another employer.

The professional council and the director of health care facility may hand down the previous approval referred to in paragraph 3 of this Article only under the condition that the work of a health care practitioner outside the regular working hours for which the sideline contract is concluded, does not affect the organization of work of individual parts of the health care facility or of the health care facility as a whole.

The health care practitioner who is engaged in practice on the ground of the sideline contract with another employer contrary to the provisions of paragraph 3 of this Article shall represent the breach of professional duty.

The method, procedure, and the conditions, as well as other issues of importance for organization and engaging in sideline work of health care practitioners in a health care facility or private practice shall be specified by the Minister.

Article 200

Sideline work contract can be concluded for:

1) the provision of health care services not included in the scope of mandatory health insurance in terms of contents, range and standards or health services which are not provided by the method and procedure specified for performing the rights in mandatory health insurance;

2) the provision of health care services which a health care facility is unable to provide for the mandatory health care insurance organization and for which it is otherwise unable to provide the staff;

3) the provision of health care services which a health care facility extends to persons who are not in the status of an insured pursuant to law regulating health insurance. The employed health care practitioner who is engaged in practice on the ground of the contract referred to in Article 199 of this Law may engage in that practice to the total time that may not exceed one third of the full working hours, for certain number of patients, or health care services or medical procedures.

By the document referred to in Article 199, paragraph 6 of this Law, the Minister shall specify, which number of patients, or health care services or medical procedures a health care practitioner may administer on the ground of the contract referred to in Article 199 of this Law.

Article 201

The contract referred to in Article 199 of this Law shall be concluded in writing and shall contain: the kind, method, duration of the work, the amount and the method of establishing of the compensation for work, the party liable to pay the established compensation for the provided health service, in compliance with the law and bylaws.

The patient, to whom a health service has been provided by a health care practitioner in compliance with Article 199 of this Law, shall pay the specified fee for the provided health service to the health care facility, for which payment the health care facility shall issue to the patient the bill on the specified form.

A state owned health care facility shall pay to a health care practitioner the contracted compensation referred to in paragraph 1 of this Article, out of the fee, which has been paid by the patient to health care facility.

A state owned health care facility shall pay to a health care practitioner the amount of the established fee from the funds of health insurance when such practice is provided in the health care facility for the requirements of insured persons, on the basis of the agreement on providing of health care concluded between the health care facility and the health insurance organization, in the sense of Article 199, paragraph 2, Item 2) of this Law.

A health care facility or private practice, shall keep records of the contract referred to in Article 199 of this Law that it has concluded.

In its financial plan, a health care facility shall separately presented and kept the funds that are acquired on the ground of providing health services in compliance with Article 199 of this Law.

A health care facility shall provide to the patient full information about the method and procedure of providing health services within the sideline work of health care practitioners, as well as put up on prominent places in the health care facility the information on the options and the method of providing health care to the patients outside regular working hours of health care practitioners.

A patient who is dissatisfied with the provided health service, in compliance with Article 199 of this Law, may file a complaint to the advocate of patients' rights in the health care facility, health inspectorate, as well as to the management board of the health care facility.

Article 202

The health care practitioner who engages in practice on the ground of the contract referred to in Article 199 of this Law shall be entitled to compulsory social insurance, in compliance with the law.

G. QUALITY OF HEALTH CARE, QUALITY ASSURANCE OF PROFESSIONAL WORK, AND ACCREDITATION

1. Quality of Health Care

Article 203

The quality of health care, in the sense of this Law, implies the measures and activities by which, in line with the modern achievements of medical, dental medical, and pharmaceutical sciences and practices, as well as with the modern achievements of science and practice that contribute to a higher level of the quality of health care services provided by health care practitioners, the chances for a favorable outcome will be increased and the risk of onset of undesired consequences for the health and the state of health of an individual and the community as a whole will be diminished.

The quality of health care referred to in paragraph 1 of this Article shall be assessed on the basis of relevant indicators that are related to the coverage of the population by health care practitioners, the capacities of health care facilities, equipment, i.e. that are related to the indicators of the process and results of work and the outcome for the health of the population, as well as on the basis of other indicators based on which the quality of health care is assessed.

The indicators of the quality of health care referred to in paragraph 2 of this Article shall be laid down by the Minister.

The quality of health care shall be assessed in the process of the quality assurance of professional work, in compliance with this Law.

2. Quality Assurance of Professional Work

Article 204

The quality assurance of professional work, in the sense of this Law, implies the procedure of the quality assurance of professional work of the health care facilities, private practice, health care practitioners, and medical associates.

Article 205

The quality assurance of professional work shall be carried out as:

- 1) Internal quality assurance of professional work;
- 2) External quality assurance of professional work.

Internal Quality Assurance of Professional Work

Article 206

Internal quality assurance of professional work shall be implemented in every health care facility and private practice, as well as concerning the work of health care practitioners and medical associates.

Internal quality assurance of professional work in a health care facility shall be implemented on the basis of the annual program of quality assurance of professional work, which shall be instituted by the commission for improvement of the quality of professional work of the health care facility.

Internal quality assurance of professional work of a private practice shall be implemented on the basis of the annual program of quality assurance of professional work, which shall be instituted by the founder of private practice.

Article 207

Health care practitioners and medical associates shall be accountable for the quality of professional work to the head professional of the organizational unit, or service.

The head professional of the organizational unit, or service referred to in paragraph 1 of this Article shall be accountable to the director of the health care facility, or the founder of private practice for the quality of his/her work as well as for the quality of professional work of the organizational unit, or the service he/she heads.

External Quality Assurance of Professional Work

Article 208

External quality assurance of professional work may be regular and extraordinary.

Regular external quality assurance of professional work shall be organized and implemented by the Ministry, on the basis of the annual plan of quality assurance of professional work, which shall be adopted by the Minister.

Extraordinary external quality assurance of professional work shall be undertaken by the Ministry at the request of a citizen, a company, facility, health insurance organization, and a government authority.

The request referred to in paragraph 3 of this Article shall be submitted to the Ministry, which will review the request and notify the party who submitted the request about the established facts.

A health care facility, or private practice, as well as a health care practitioner, or medical associate shall cooperate with the professional supervisors, as well as submit to them all the required data and other documentation required for the implementation of the regular and extraordinary external quality assurance of professional work.

Article 209

Regular and extraordinary external quality assurance of professional work shall be implemented by the professional supervisors from the list of supervisors, which will be made by the Minister.

The association in charge shall propose to the Minister a list of supervisors from the ranks of distinguished experts in certain areas of health care.

For the implementation of regular and extraordinary quality assurance of professional work a professional supervisor shall be designated with as a minimum the same professional qualifications, or scientific degree that holds the head professional of the relevant organizational unit or service that is to be supervised, or that holds the health care practitioner whose quality of professional work is to be assessed.

The supervisors from the list of supervisors shall carry out regular and extraordinary external quality assurance of professional work conscientiously and professionally, and in accordance with the modern scientific achievements and the code of professional ethics.

The supervisors from the list of supervisors may not refuse to participate in the implementation of the procedure of the regular and extraordinary external quality assurance of professional work.

Article 210

Regular and extraordinary external quality assurance of professional work may be carried out by one or more supervisors depending on the type and complexity, or on the plan for implementation of the external quality assurance of professional work.

Supervisors shall make reports on the quality assessment of professional work, which will include the identified deficiencies and failures in professional work, as well as professional opinion about possible consequences for the health of the citizens, which they will, within 15 days from the date of completion of regular and extraordinary external quality assurance of professional work, submit to the Minister and to the health care facility, or to the private practice, as well as to the association in charge if a health care practitioner was the subject of the quality assurance of professional work.

Supervisors shall, in the course of carrying out regular and extraordinary external quality assurance of professional work, give professional advice and proposals for elimination of failures in the work of a health care facility, private practice, health care practitioner, or medical associate.

Supervisors, on the basis of the reports referred to in paragraph 2 of this Article, shall propose to the Minister the measures that are necessary to be undertaken for the purpose of elimination of identified deficiencies in the professional work of health care facilities, private practice, health care practitioner, or medical associate.

The health care facility, private practice, health care practitioner, or medical associate may file a complaint to the Minister against the report of the supervisor referred to in paragraph 2 of this Article within three days from the date of receipt of the report.

Article 211

Upon review of the reports submitted and the measures proposed by supervisors, as well as of the filed complaint referred to in Article 210 of this Law, the Minister shall hand down the decision by which he/she may:

- 1) Temporarily ban, fully or partially, administering of certain affairs by the health care facility, or private practice;
- 2) Temporarily ban, fully or partially, the work of an organizational part of a health care facility, or private practice;
- 3) Temporarily ban the work of a health care facility, or private practice;
- 4) Propose to the association in charge to revoke the license of the health care practitioner, under the conditions laid down by this Law.

Temporary ban of work referred to in paragraph 1, Items 1) to 3) of this Article shall last until the reasons that gave rise to the imposition of the ban are eliminated.

On the basis of the reports submitted and the measures proposed by supervisors referred to in Article 210 of this Law, as well as on the basis of the proposal of the Minister referred to in paragraph 1, Item 4) of this Article, if a failure in the professional work of a health care practitioner or compromising of the principles of professional ethics is established, the association in charge may revoke the license for private practice of a health care practitioner, or pronounce one of the disciplinary actions laid down by the law governing the work associations of health care practitioners.

Article 212

The conditions, method, the procedure, deadlines, and organization of the implementation of internal and external quality assurance of professional work, the measures that may be undertaken for elimination of identified deficiencies and other issues of importance for implementation of the quality assurance of professional work of health care facilities and private practice, health care practitioners, and medical associates – are laid down by the Minister.

3. Accreditation

Article 213

Accreditation, in the sense of this Law, is the procedure of assessment of the quality of work of a health care facility, on the basis of implementation of the optimal level of the established standards of work of a health care facility in a certain area of health care, or branch of medicine , dental medicine or pharmacy.

Agency for Accreditation of Health Care Facilities of Serbia

Article 214

The accreditation referred to in Article 213 of this Law shall be administered by the Agency for Accreditation of Health Care Facilities of Serbia (hereinafter referred to as: the Agency), as the organization administering professional, regulatory, and developmental affairs, which will be founded by the Government in the name of the Republic, in compliance with the law regulating public agencies.

The Agency shall have the capacity of a legal person, which it will get by its registration in the court register.

The Agency shall be independent in its work.

Article 215

The Agency shall be entrusted the following affairs of government administration as its public authorities:

- 1) Establishing of standards for accreditation of health care facilities;
- 2) Assessment of the quality of the health care provided to the population;
- 3) Determination of the administrative matters concerning the accreditation of health care facilities;
- 4) Issuing of official accreditation documents (hereinafter referred to as: the certificate) and keeping records on the issued certificates.

The Government shall give its consent on the act referred to in paragraph 1, Item 1) of this Article.

Accreditation Procedure

Article 216

Accreditation is voluntary and it shall be carried out at the request of a health care facility.

A health care facility shall submit the application for accreditation to the Agency.

Accreditation will be acquired by a health care facility for which the Agency establishes that it meets the established standards for a certain area of health care, or branch of medicine.

The Agency shall issue the certificate of accreditation to a health care facility, in the administrative procedure.

The decision on issued certificate referred to in paragraph 4 of this Article shall be final in the administrative procedure and an administrative suit may be instituted against it.

The method, the procedure, and the requirements for accreditation of health care facilities shall be laid down by the Minister.

Article 217

The Certificate referred to in Article 216, paragraph 4 of this Law may be related to:

- 1) Individual area of health care or the branch of medicine the health care facility is engaged in;

2) The entire activity of a health care facility.

The Certificate shall be issued for a certain period, maximum for a period of seven years.

Upon expiry of the time period referred to in paragraph 2 of this Article, the accreditation procedure may be repeated at the request of the health care facility.

The Certificate of Accreditation of a health care facility shall be published in the *Official Gazette of the Republic of Serbia*.

Article 218

The health care facility that has been accredited shall report to the Agency every change related to the accreditation.

The Certificate of Accreditation obtained in compliance with this Law or a certificate recognized by the European agency in charge of accreditation of health care facilities evidences that the health care facility meets the national or internationally recognized standards in providing health care.

The Agency shall be financed from its own revenues.

The charges for accreditation shall be borne by the health care facility that has submitted the application for accreditation.

The amount of the charges referred to in paragraph 4 of this Article, which represent the revenue of the Agency, shall be regulated by the Agency.

The Government shall give its consent on the act referred to in paragraph 5 of this Article.

Procedure for Withdrawal of Accreditation

Article 218

(1) The Agency can, by virtue of duty, withdraw the accreditation certificate provided that a health care facility failed, after the certificate had been issued, to meet the established standards related to a specific area of health care or branch of medicine, dental medicine or pharmaceutical health activity based on which the accreditation certificate had been issued.

(2) The accreditation certificate withdrawal is the subject of the decision issued by the Agency, which is final in the enforcement procedure and an administrative suit may be instituted against it.

(3) The decision in paragraph 2 of this Article is published in the "Official Journal of the Republic of Serbia".

(4) Detailed conditions and method for accreditation certificate withdrawal are specified by the Minister.

IX. ESTABLISHING THE TIME AND CAUSE OF DEATH AND AUTOPSY OF DECEASED PERSONS

Article 219

For each deceased person, the time and cause of death is established on the basis of direct examination of the deceased person.

Establishing of the time and cause of death may be done only by a doctor of medicine.

For the persons who have died in a health care facility, the time and cause of death is established in the health care facility, and the competent authority of the municipality, or city is notified thereon.

The competent authority of a municipality, or of city, shall designate the doctor of medicine for professional establishing of the time and cause of death of those who have died outside a health care facility and issuing of the death certificate.

The doctor of medicine referred to in paragraph 4 of this Article shall, within 12 hours from the received call, perform direct examination of the deceased and establish the time and cause of death.

The funds for examination of the deceased persons and professional establishing of the time and cause of death for the persons who have died outside a health care facility shall be provided in the budget of the municipality or city.

Article 220

The doctor of medicine who conducts direct examination of a deceased person for the purpose of establishing of the cause and time of death, irrespective of whether the death occurred in a health care facility, private practice or elsewhere, shall, without delay, notify the competent organizational unit of the ministry in charge of interior affairs about the death case if:

- 1) He/she is unable to establish the identity of the deceased person;
- 2) By examining the deceased person he/she establishes injuries or otherwise suspects a violent death;
- 3) It is not possible to establish the cause of death on the basis of available medical indications.

In the cases referred to in paragraph 1 of this Article, the doctor of medicine who conducts direct examination of the deceased person shall not issue the death certificate until the competent court hands down the decision related to the autopsy.

Article 221

A health care facility shall inform an adult member of the family about the cause and time of death of the deceased person, within the shortest possible time, as well as enable that person to have direct access to the body of the deceased person in the presence of the doctor of medicine who has, by direct examination, established the time and cause of death.

The member of the family referred to in paragraph 1 of this Article may refuse to have direct access to the body of the deceased person, on which an annotation shall be made, which shall be signed by a member of the family of the deceased person.

Article 222

Autopsy shall be performed as a special measure of establishing of the time and cause of death of deceased persons.

Autopsy shall be obligatorily performed:

- 1) On the person who has died in a health care facility if the cause of death has not been established;
- 2) On the person who has died prior to expiry of 24 hours from the beginning of treatment in an inpatient health care facility;
- 3) On the newborn baby who has died in a health care facility immediately after being born or in the course of treatment;
- 4) At the request of the doctor of medicine who treated the deceased person;
- 5) At the request of the doctor of medicine designated to establish the cause of death by the competent authority of the municipality or city;
- 6) When that is of a particular importance for the protection of health of the citizens or when that is required due to the epidemiological or sanitary reasons;
- 7) At the request of the competent court;
- 8) At the request of a member of the immediate family of the deceased person;
- 9) If the death occurs in the course of a diagnostic or therapeutical procedure.

A deceased person shall be buried after the death has been established, as a rule, within 24 to 48 hours from occurrence of death, in compliance with the law.

Exceptionally from paragraph 4 of this Article, on the basis of a special request from the sanitary inspection, burial may be carried out even prior to the expiry of the period of 24 hours, or after expiry of the period of 48 hours.

While doing an autopsy, the doctor of medicine who performs the autopsy may retain organs, parts of organs, and other samples of biological origin, in accordance with the rules of the profession, when that is necessary for the purpose of establishing of the cause of death or it is of special importance for protection of health of the citizens.

In case of autopsy on the person referred to in paragraph 2, Item 3), it shall be obligatory to take and permanently keep the samples of biological origin, in accordance with the rules of the profession.

The method and procedure for establishing the time and cause of death of deceased persons and for the autopsy of a corpse, as well as for disposal of

the parts of human body that are surgically or otherwise eliminated, shall be specified by the minister.

Article 223

The costs of autopsy of a deceased person shall be borne by the party liable to pay the costs of treatment of the deceased person, unless otherwise specified by this Law.

The costs of autopsy of a deceased person referred to in Article 222, paragraph 2, Item 5) of this Law shall be borne by the municipality, or city.

The costs of autopsy of a deceased person referred to in Article 222, paragraph 2, Items 7) and 8) of this Law shall be borne by the applicant.

X. TAKING, TRANSPLANTATION OF ORGANS AND PARTS OF HUMAN BODY

Article 224

Organs, tissues, and cells, as parts of human body, may be taken and transplanted only if that is medically justified, or if that is the most favorable method of treatment of persons and if the requirements laid down by the law are met.

The method, procedure, and the conditions for taking and transplantation of organs, tissues, and cells, as parts of human body, and/or the method, procedure, and conditions for treatment of infertility by applying biomedically assisted fertilization, shall be specified by a separate law.

XI. TAKING OVER OF BODIES OF DECEASED PERSONS FOR THE PURPOSE PROVIDING PRACTICAL TRAINING

Article 225

The medical faculties (hereinafter referred to as: the Faculty) may take over bodies, organs, and tissues of the deceased and identified persons for the purpose of giving practical training:

- 1) If the deceased person has expressly, in writing, bequeathed his/her body for the purpose of practical laboratory training;
- 2) If it is a person who has died without a family and he/she personally, while he/she was alive, was not expressly opposing it, in writing;
- 3) With the consent of the family, if the deceased person, while he/she was alive, was not expressly opposing it, in writing.

The bequest, in the sense of paragraph 1, Item 1) of this Article, shall be the declaration on bequeathing the body, which is certified in a court and in which the administrator of the bequest is stated.

Article 226

The family in the sense of Article 225 of this Law shall imply: spouses and common-law partners, children born in wedlock and out of wedlock, adopters and adoptees, guardians and wards, foster parents and foster children, parents and other kins by blood in lineal line of descent irrespective of the degree of kinship, as well as kins by blood in collateral line of descent inclusive of the third degree of kinship.

Article 227

A health care facility, penitentiary institution, institution of social protection, the competent court, the authority in charge of interior affairs, as well as other institutes and organizations, or citizens who have learnt about the death of the person who fulfills the requirements laid down by this Law concerning the providing of practical training at faculties, shall within 12 hours from the death of that person inform the authority of the local self-government in charge of keeping the register of records of deceased persons, as well as the faculty, about the death of that person, for the purpose of taking over of the body of the deceased by the faculty.

The decision on taking over of the body by the faculty shall be handed down by the ethics board of the faculty.

A faculty may take over the body of a deceased person for the purpose of providing practical training in anatomy only if there is a report on death that has been signed by a specialist in forensic medicine – medical examiner, and under the condition that there are no statutory reasons for performing of obligatory autopsy.

Article 228

A faculty may not use the body of a deceased person who has no family in practical training within six month from the date of takeover.

A faculty shall not take over the body of a person who has died of a communicable disease, or the body on which marked postmortem changes, which prevent fixation (embalming) have occurred.

A faculty shall treat the body of a deceased person with dignity, it shall use it exclusively for the purpose of providing practical training, and shall bury it after completion the training at its own cost.

A faculty shall, within the limits of its abilities, honor special wishes of the testator related to burial, cremation, religious ceremony, and other clearly expressed wishes of the testator related to the treatment of his/her body for the purpose of providing practical training in anatomy.

A faculty shall honor the wish of the testator that, after the process of practical training, his/her body be used for assembly of the osteological set (skeleton), which will be used in practical training in anatomy.

Article 229

A faculty may directly take over the body of a deceased and identified person referred to in Article 225, paragraph 1, Items 1) and 3) of this Law.

A faculty shall take over the body referred to in Article 225, paragraph 1, Item 2) of this Law upon having obtained the approval from the competent authority of the local self-government.

The competent authority of the local self-government shall promptly notify the faculty about the deceased and identified person whose body may be used to provide practical training at medical faculties, under the conditions laid down by this Law.

Article 230

Should a member of the family of the deceased person, who was not known at the moment of death, within six months from the date of taking over of the body by the faculty, submit a written request to the faculty for returning of the body of the deceased person, the faculty shall return the body of the deceased person to the members of the family.

Article 231

A faculty shall keep as a professional secret all the data related to the person whose organs or parts of the body have been taken in the sense of this Law, as well other necessary documentation about the deceased person whose body has been taken over for the purpose of providing practical training.

The data referred to in paragraph 1 of this Article shall include: family name and name of the deceased, date of birth, place and date of death, cause of death, the number from the medical documentation, which must coincide with the number of the tag - marker next to the body of the deceased person, place and date of burial.

The documentation referred to in paragraph 1 of this Article shall include: the report of the medical examiner, death certificate, ID card, health insurance card, and the declaration on bequeathal of the body.

A faculty shall keep the data and the documentation referred to in this Article as permanent documentation, which must be made available to the competent services of the faculty, the Ministry, the ministry in charge of the affairs of education, the ministry in charge of interior affairs, as well as to the competent authority of the local self-government.

Article 232

Exclusively the students of undergraduate, postgraduate, and specialization studies at a faculty shall be trained in the practical training in anatomy on the body of the deceased person, under the supervision of the lecturers and associates of the faculty.

Article 233

After completion of the process of practical training in anatomy, the body of the deceased person shall be buried.

The funeral shall be announced in the form of an announcement and a paid advertisement in mass media, and the ceremony of internment shall imply lined up guard of honor by the lecturers and students of the faculty, as well as the appropriate religious ceremony if the deceased person requested it when he/she was alive.

Article 234

The ethics board of a faculty shall supervise the implementation of the procedure of taking over of parts of the bodies of deceased persons referred to in Articles 225 to 233 of this Law.

XII. TRADITIONAL MEDICINE

Article 235

The traditional medicine, in the sense of this Law, shall include those verified professionally undisputable traditional, complementary, and alternative methods and procedures of diagnostics, treatment, and rehabilitation (hereinafter referred to as: the traditional medicine), which have a therapeutical effect or which could have a therapeutical effect on human health or his/her state of health and which, in accordance with prevailing medical doctrine, are not covered by the health services.

The method and procedures of the traditional medicine referred to in paragraph 1 of this Article may be introduced in a health care facility or private practice only with the approval of the Ministry.

Article 236

Only those methods and procedures of the traditional medicine shall be permitted that:

- 1) Are not detrimental to health;
- 2) Do not discourage the user/patient from the use of health services that are beneficial for him;
- 3) Are practiced in accordance with the recognized standards of the traditional medicine.

The methods and procedures of the traditional medicine may be practiced by the health care practitioners who have a permit for implementation of the methods and procedures of traditional medicine, which shall be issued by the Ministry.

Detailed conditions, method, and procedure of implementing the methods and procedures of traditional medicine in a health care facility or private practice shall be specified by the minister.

The Ministry shall exercise supervision over the implementation of the methods and procedures of traditional medicine in health care facilities or private practice, in compliance with this Law.

The provisions of this Law issuing, renewal, and revoking of the license, as well as the provisions of the law regulating the associations of health care practitioners shall apply to the health care practitioners who implement the methods and procedures of the traditional medicine.

Article 237

The health care practitioners who implement the methods and procedures of the traditional medicine shall undertake professional, ethical, penal, and material responsibility for their work.

XIII. HEALTH CARE OF FOREIGNERS

Article 238

Foreign citizens, stateless persons, and the persons status of a refugee has been recognized or who have been granted asylum in compliance with the international and domestic legislation in Serbia and Montenegro (hereinafter referred to as: the foreigners), who have permanent or temporary residence in the Republic, or who are in transit through the territory of the Republic, shall have the right to health care, in compliance with this Law, unless otherwise specified by international agreement.

The persons, who have the status of refugees from the territories of the Republics of the former Socialist Federal Republic of Yugoslavia, shall exercise the right to health care in compliance with the regulations governing the area of refugees.

The funds for exercising of the right to health care referred to in paragraph 2 of this Article shall be provided in the budget of the Republic.

The foreigners who meet the requirements for eligibility for insurance in compliance with the law governing the area of compulsory health insurance shall be provided health care in compliance with those regulations.

Article 239

Health care of foreigners shall be provided in the way in which health care is provided to the citizens of the Republic.

Article 240

A health care facility and private practice, as well as health care practitioners, shall provide emergency medical care to a foreigner.

Foreigners shall personally bear the expenses for the provided emergency medical care, as well as for other kinds of health care services provided

to foreigners at their request, unless otherwise specified by this Law or by international agreements.

For the use of health care services referred to in paragraph 2 of this Article, a foreigner shall pay a fee according to the pricelist of the health care facility or according to the pricelist of private practice.

Article 241

The fee shall be paid to the health care facilities from the budget of the Republic according to the pricelist of the health services, which has been adopted by the compulsory health insurance organization for the health care services that are covered by compulsory health insurance, for the following health services provided:

1) To the foreigners to whom health care is provided free of charge on the basis of an international agreement – social insurance, unless otherwise specified by that agreement;

2) To the foreigners who stay in the Republic against the invitation by the government authorities – in the course of their stay, in accordance with the principles of reciprocity, and who do not fulfill the requirements for eligibility to become a compulsory insured person in compliance with the law governing the area of compulsory health insurance;

3) To the foreigners who have been granted asylum in Serbia and Montenegro, if they are materially unprovided;

4) To the foreigners who have contracted variola, plague, cholera, viral hemorrhagic fever (except for the hemorrhagic fever with kidney syndrome), malaria or yellow fever, as well as other communicable diseases due to which such person shall be put under medical supervision in compliance with the regulations governing the area of protection of the population from communicable diseases;

5) To the foreigners – members of crews of foreign ships or vessels, who have contracted a venereal disease;

6) To the foreigners who are victims of people trafficking.

Article 242

The fee shall be paid from the budget of the Republic to the health care facilities and private practice for the emergency medical care provided to a foreigner if the health care facility or private practice could not collect such fee from the foreigner, because he/she does not have the necessary money.

The fee referred to in paragraph 1 of this Article shall be paid on the basis of the request of a health care facility or private practice and of the evidence that a health care service has been provided.

A health care facility or private practice shall submit to the Ministry the request for payment of the fee referred to in paragraph 1 of this Article, together with the medical documentation about the health care services provided to a foreigner.

In the procedure of deciding on the request referred to in paragraph 3 of this Article, the Ministry may have insight in the medical and other documentation about the treatment of foreigners, as well as to seek professional opinion from the referential health care facility.

Upon effected payment of the fee to health care facility or private practice, the Ministry shall undertake measures, through the competent authorities, to collect such expenses from the foreigner in favor of the Republic budget.

XIV. SUPERVISION OVER THE WORK OF HEALTH CARE FACILITIES AND PRIVATE PRACTICE

Article 243

Supervision over the work of health care facilities and private practice, in the sense of this Law, shall be exercised as supervision over the legality of work of health care facilities and private practice and inspection supervision.

The Republic shall provide administering of the affairs of health inspection.

The supervision referred to in paragraph 1 of this Article shall be exercised by the Ministry through health inspectors and inspectors in charge of the area of drugs and Medical devices (hereinafter referred to as: the pharmaceutical inspector).

(4) The inspector referred to in paragraph 3 of this Article shall perform the supervisory duty dressed in suit which appearance is specified by the Minister.

Health Inspectorate

Article 244

A health inspector shall be independent in the work within the limits of the authorities specified by this Law and the regulations adopted for enforcement of this Law and shall be personally responsible for his/her work.

A health inspector shall act conscientiously and impartially in administering the affairs of supervision, and/or keep as official secret the data he/she obtains in the course of exercising the supervision, and in particular the data related to the medical documentation of patients.

The provisions of the law regulating general administrative procedure, as well as of the law regulating the work of the government administration shall apply to the exercising of supervision by a health inspector, unless otherwise regulated by this Law.

Article 245

The affairs of a health inspector may be administered by a person who has graduated from the faculty of medicine, dental medicine, pharmacy or law, who has passed intern's exit exam in compliance with this Law and the certification exam for work in the authorities of government administration and minimum three years of service in the profession.

A health inspector shall have the official identity document by which he/she will identify himself/herself and which he/she shall present at the request of

the person in charge or other interested person on the occasion of exercising of supervision.

The form and contents of the identity document referred to in paragraph 3 of this Article shall be specified by the Minister.

Article 246

Health care facilities and private practice shall enable the health inspector to administer the affairs of supervision without hindrance, in compliance with this Law, and/or to enable him/her unhindered inspection of the premises, equipment, enactments and other data required for exercising the supervision.

A health inspector, in administering the affairs of supervision over a health care facility and private practice, for the purpose of obviation of possible suppression of evidence, shall have the right to temporarily sequester items and original documentation of a health care facility and private practice, with the mandatory issuing of the receipt for the temporarily sequestered items, and/or documentation.

Article 247

In exercising supervision, a health inspector shall be authorized to:

- 1) Review bylaws and individual enactments of a health care facility and private practice, and/or have insight in the medical and other documentation, which is of importance for handing down the decision in exercising the supervision;
- 2) Examine and take the statements from the person in charge, and/or health care practitioner and medical associate, as well as from other interested persons;
- 3) Inspect the premises and equipment, and/or examine the conditions for setting up, commencement of work, and engaging in a health care activity, laid down by this Law;
- 4) Have insight in the documentation of a health care facility and private practice, on the basis of which health care of citizens is provided, and/or have direct insight in providing of health care and the rights of patients in the health care facility, or private practice;
- 5) Have direct insight in the implementation of the measures handed down in compliance with this Law in the procedure of quality assurance of professional work in the health care facility, or private practice;
- 6) Review the submissions of legal and natural persons related to the work of health care facility and private practice, and/or to the provision of health care;
- 7) Administer other affairs of supervision, in compliance with the law.

Article 248

The health inspector shall make the minutes on the completed inspection in the procedure of supervision, containing the findings of the facts established in a health care facility, or private practice.

The minutes referred to in paragraph 1 of this Article, shall be submitted by the health inspector to the health care facility, or private practice, over which supervision has been exercised.

The health inspector, on the basis of the minutes referred to in paragraph 2 of this Article, shall hand down the decision ordering the measures, actions, as well as deadlines for implementation of the measures ordered to health care facility, or private practice.

Against the decision referred to in paragraph 3 of this Article a complaint may be filed to the minister.

The decision of the minister referred to in paragraph 4 of this Article shall be final in the administrative procedure and an administrative suit may be instituted against it.

Should a health inspector assess that by acting or failing to act a health care facility, or private practice over which supervision has been exercised, a criminal act, economic offence or an offence has been committed, he/she shall without delay inform the competent authority against the committed criminal act, economic offence, or the claim for initiation of minor offence proceedings.

Article 249

In exercising supervision, a health inspector shall have the authority to:

1) Establish whether the requirements have been fulfilled for the commencement of work and engaging in a health care activity of health care facility or private practice, with respect to the premises, equipment, staff, and drugs laid down by this Law and by the regulations adopted for enforcement of this Law;

2) Order elimination of the established irregularities and deficiencies in the work of a health care facility or private practice, within the time period that may not be shorter than 15 days or longer than six months from the date of receipt of the document by which such measure was ordered and, in emergency cases, order elimination of the established irregularities and deficiencies forthwith;

3) Order implementation of the specified measure to health care facility or private practice, within the time period that may not be shorter than 15 days or longer than three months from the date of receipt of the document by which that measure was ordered and, in emergency cases, order implementation of the specified measures forthwith;

4) Temporarily ban engaging in the activity of a health care facility or private practice, and/or engaging in certain types of practice within a health care facility and private practice, if practiced contrary to the provisions of this Law and the regulations adopted for enforcement of this Law, within the time period that may not be shorter than 60 days or longer than six months from the date of receipt of the document by which that action was brought;

5) Temporarily ban engaging in the health care activity, or engaging in certain types of practice within the health care activity, by a health care practitioner or medical associate who is engaged in a health care activity contrary to the provisions of this Law and the regulations adopted for enforcement of this Law, within the time period that may not be shorter than 30 days or longer than six months from the date of receipt of the documents by which that action was brought;

6) Temporarily ban independent practice of a health care practitioner against whom the competent association has brought one of the disciplinary actions of temporary ban on independent practice, in compliance with the law regulating the work of the associations of health care practitioners;

7) Temporarily ban the work of a health care facility or private practice if, within the specified time period established in Items 2) and 3) of this Article, it has not harmonized its engaging in the health care activity with this Law and the regulations adopted for enforcement of this Law, or if it has not eliminated the established irregularities and deficiencies in its work, and/or it has not implemented the specified measures handed down by the health inspector;

8) Temporarily ban the work of a health care facility or private practice, in cases laid down in Articles 53 and 65 of this Law;

9) Ban the independent practice of a health care practitioner who has not been issued, or renewed the license for independent practice, or whose license for independent practice has been revoked, under the conditions laid down by this Law;

10) Propose to the competent association revoking of the license of a health care practitioner for the reasons laid down by Article 197 of this Law;

11) Refer a health care practitioner, or medical associate, to examination for the purpose of assessment physical fitness in case of doubt in physical fitness to engage in a health care activity, or in certain type of practice within the health care activity;

12) Ban engaging in a health care activity and undertake other actions, in compliance with the law, against legal and natural persons who are engaged in a health care activity without the decision of the Ministry establishing fulfillment of the requirements for engaging in a health care activity;

13) Ban engaging in a health care activity and undertake other actions, in compliance with the law, against natural persons who engage in a health care activity, who, in the sense of this Law, are not considered to be health care practitioners;

14) Undertake other measures laid down by the law.

Article 250

The costs of health inspection incurred in the procedure at the request of a client shall be borne by the applicant.

The minister shall specify the amount of expenses referred to in paragraph 1 of this Article.

(3) The resources obtained in the procedure at the client's request are the revenue of the budget of the Republic and intended for funding all costs related to the enforcement of that procedure.

Article 251

Supervision over pharmaceutical health care activity in a pharmacy or any other organizational unit of the facility dealing with pharmaceutical health care activity, in a hospital pharmacy, and in a pharmacy established as private practice pursuant to this Law shall be conducted by medical and pharmaceutical inspectors,

pursuant to law. A health inspector and a pharmaceutical inspector shall jointly participate in the supervision over the pharmaceutical health care activity in a pharmacy or other organizational part of a health care facility that is engaged in a type of practice of the pharmaceutical health care activity, or hospital pharmacy, as well as in a pharmacy founded as a private practice, in compliance with this Law.

In exercising of the supervision referred to in paragraph 1 of this Article, the health inspector shall hand down the measures laid down in Article 249, Items 1) to 5), 7), 8), 12), and 13) of this Law, on the basis of the opinion of the pharmaceutical inspector, whereas the other measures laid down in Article 249 of this Law will be handed down by the health inspector individually.

Pharmaceutical Inspectorate

Article 252

For starting to engage in a pharmaceutical health care activity in a pharmacy as an independent health care facility, which within its complement has a galenic laboratory, as well as in a hospital pharmacy making galenic remedies, the decision on fulfillment of the requirements for making of galenic remedies shall be handed down by the pharmaceutical inspector, in compliance with the law governing the area of drugs and Medical devices, and for engaging in the activity of a pharmacy laid down in Article 100 of this Law, the decision on fulfillment of the requirements for engaging in the pharmaceutical health care activity shall be handed down by health inspector.

A pharmaceutical inspector shall have the authority to exercise inspection supervision on his/her own, and/or to undertake and order specified measures against the pharmacy, or against the hospital pharmacy, which make galenic remedies, in compliance with the law governing the area of drugs and Medical devices.

Article 253

A pharmaceutical inspector shall have the authority to independently exercise supervision over the retail trade in drugs, and/or over making of magistral preparations in a pharmacy as an independent health care facility or other organizational part of the health care facility that is engaged in the practice of the pharmaceutical health care activity, in a hospital pharmacy, or in a pharmacy set up as a private practice.

In exercising the inspection supervision referred to in paragraph 1 of this Article, the pharmaceutical inspector shall have the authority to:

- 1) Examine bylaws and individual enactments, records and other documentation that is related to the making of magistral preparations, retail trade in drugs and Medical devices, testing of the quality of drugs, as well as the documentation that is related to the implementation of the guidelines for the Best Laboratory Practice, the Best Distribution Practice, as well as of standard and operational procedures for the area of drugs;

- 2) Inspect the premises and equipment, and/or examine other conditions for the retail trade in drugs, and/or making of magistral preparations;

3) Have direct insight in the implementation of the guidelines for the Best Laboratory Practice and the Best Distribution Practice, under the conditions laid down by the law;

4) Have direct insight in the implementation of the Best Pharmaceutical Practice;

5) Take samples of galenic remedies, magistral preparations, and/or officinal drugs, as well as of certain types of Medical devices that are in retail trade without compensation and in the quantities that are necessary, for the purpose of quality control;

6) Undertake other measures and actions related to the retail trade in drugs, and/or making of magistral preparations, in compliance with the law.

The costs of laboratory control of the taken samples of drugs and certain types of Medical devices referred to in paragraph 2, Item 5) of this Article shall be covered by the health care facility, or private practice in which the sample of a drug and certain types of Medical devices has been taken for the purpose of quality control.

Article 254

In exercising the supervision, the inspector in charge of the area of drugs and Medical devices shall be authorized to:

1) Ban making, and/or issuing of magistral preparations if they are not made in compliance with the law;

2) Ban retail trade in galenic remedies, and/or officinal drugs, if they do not meet the requirements for putting into circulation laid down by the law;

3) Ban retail trade in galenic remedies, and/or officinal drugs, which do not meet the requirements with respect to the quality laid down by the law;

4) Order recall from retail trade in magistral preparation, galenic remedy, and/or officinal medicine, or a series thereof, in the cases specified by the law;

5) Order destroying of a faulty drug found in retail trade;

6) Undertake other measures, in compliance with the law.

Article 255

In the process/procedure of exercising supervision over the pharmaceutical health care activity, in the sense of this Law, the provisions of Articles 244 - 248 and Article 250 of this Law shall apply accordingly.

XV. PENAL PROVISIONS

Misdemeanors

Article 256

A health care facility shall be fined from 200,000 to 1,000,000 Dinars for misdemeanor if it:

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7) In case of break out of epidemics and other major disasters and accidents, fails to timely and truthfully submit the data to the competent authority of the municipality, city, autonomous province, and the Republic (Article 41, paragraph 3);

8) Within 48 hours from the date of admittance of the patient for inpatient treatment, concerning whom the doctor in charge assesses that the nature of mental illness of the patient is such that it may threaten the life of the patient or the life of other persons or property, fails to notify the competent court (Article 44, paragraph 2);

9) Engages in a health care activity and does not fulfill the requirements referred to in Article 49 of this Law;

10) Starts engaging in a health care activity prior to receiving the decision of the Ministry by which it has been established that the requirements for engaging in the health care activity have been fulfilled or if it is engaged in a health care activity contrary to the above decision (Article 51);

11) Applies new health care technologies without the permit of the Ministry for use of new health care technologies (Article 70, paragraph 1);

12) Advertises, and/or publicizes health services, professional medical procedures and methods of health care, including the health care services, methods, and procedures of the traditional medicine (Article 71, paragraph 1);

13) Puts up the name of the health care facility, which does not contain the data on the activity, which is specified by the decision of the Ministry, working hours, the founder and the seat of the health care facility, or if it puts up the name of the health care facility that has a trait to which the character of advertising, and/or publicizing can be attributed (Article 72, paragraphs 1 and 2);

14) Does not keep the medical documentation and records, and/or if within the specified timeframes, it fails to submit individual, summary, and periodic reports to the competent authority, or if it in any way violates the confidentiality of the data from the medical documentation of a patient, and/or if it fails to protect the medical documentation from unauthorized access, copying, and abuse (Article 73, paragraphs 1 and 3);

15) Fails to notify the municipality, or the city in the territory of which the health care facility in private ownership has its seat, about the weekly work schedule, opening and closing hours (Article 75, paragraph 3);

16) Fails to ensure minimum work process during a strike, and/or if a strike is organized in the health care facility that provides emergency medical care (Article 75, paragraphs 5 and 6);

17) Fails to submit the data on cases of poisoning to the poison control center, in compliance with this Law (Article 92, paragraph 5);

18) Organizational units, which are an integral part of the health care facility, bear the name of pharmacy, clinic, or institute, and do not fulfill the requirements specified by this Law concerning their formation (Article 142, paragraph 2);

19) Fails to organize professional bodies in the health care facility (Article 143);

20) Acquires the funds for work contrary to the provisions of Articles 159 and 160 of this Law;

21) Does not respect the conscientious objection expressed by a health care practitioner, and/or if it fails to ensure providing of health care to a patient by another health care practitioner in case of an expressed conscientious objection (Article 171, paragraph 3);

22) Fails to create conditions and fails to organize serving of internship (Article 176, paragraph 3);

23) Does not provide to an employed health care practitioner and medical associate a paid leave for continuous education for the purpose of renewal of the license for independent practice (Article 182, paragraph 3);

24) Fails to provide professional advancement and fail to adopt the plan of professional advancement of health care practitioners and medical associates (Article 183, paragraphs 1 and 2.);

25) Engages a health care practitioner employed in that or in another health care facility, or private practice for the work outside regular working hours, contrary to the provisions of this Law, which regulate conclusion of sideline contracts (Articles 199 - 201);

26) Fails to implement internal quality assurance of professional work, and/or if it fails to adopt the annual program of quality assurance of professional work in the health care facility, in compliance with this Law (Article 206);

27) Fails to cooperate in the implementation of regular and extraordinary external quality assurance of professional work by professional supervisors, as well as if it fails to submit to them all the required data and other documentation (Article 208, paragraph 5);

28) Does not act upon the decision of the minister by which temporary ban on work has been handed down in the procedure of implementation of regular and extraordinary quality assurance of professional work (Article 211, paragraph 1);

29) Practices the traditional medicine by applying methods and procedures for which it has not been granted the approval of the Ministry (Articles 235 - 237);

30) Fails to provide health care to a foreigner in compliance with this Law or fails to provide emergency medical care to a foreigner (Articles 238, 239, and Article 240, paragraph 1).

The person in charge in a health care facility shall also be fined from 30,000 to 50,000 Dinars for the misdemeanor referred to in paragraph 1 of this Article.

A health care practitioner entrepreneur shall be fined from 100,000 to 500,000 Dinars for the misdemeanor referred to in paragraph 1, Items 2) to 15), Items 17), 18) and Items 20) to 30) of this Article.

Article 257

A health care facility shall be fined from 500,000 to 1,000,000 Dinars for misdemeanor if it:

1) Enables independent practice to a health care practitioner who does not meet the requirements referred to in Article 168, paragraph 1 of this Law;

1) Engages a health care practitioner who is a foreign citizen contrary to the provisions of Article 168 , paragraph 7 of this Law;

1) Engages a medical associate who was not issued or failed to renew the license for independent work, contrary to Article 198 , paragraph 1 of this Law;

2) Fails to establish time and cause of death of the person who has died in the health care facility and fails to notify the competent authority of the municipality, or city thereon (Article 219, paragraph 3);

3) Fails to inform an adult member of the family of the deceased person about the cause and time of his/her death or if it does not enable him/her direct access to the body of the deceased person (Article 221, paragraph 1);

4) Fails to perform autopsy in compliance with Article 222 of this Law;

5) Does not act upon the decision of the health, or pharmaceutical inspector (Articles 249 and 254).

The person in charge in a health care facility shall be fined from 30,000 to 50,000 Dinars for the misdemeanor referred to in paragraph 1 of this Article.

A health care practitioner entrepreneur shall be fined from 300,000 to 500,000 Dinars for the misdemeanor referred to in paragraph 1, Items 1) and 5) of this Article.

Article 258

A health care practitioner entrepreneur shall be fined from 100,000 to 500,000 Dinars for misdemeanor if he/she:

1) Sets up more than one form of private practice (Article 56, paragraph 5);

2) Practices a health care activity and does not meet the requirements laid down by Article 58 of this Law;

3) Starts engaging in certain types of practice within the health care activity prior to the receipt of the decision of the Ministry by which it is established that the requirements for engaging in certain types of practice within the health care

activity have been fulfilled or if he/she is engaged in a health care activity contrary to above decision (Articles 59 and 60);

4) Fails to notify the Ministry, the competent authority in the territory of which the seat of private practice is situated, as well as the competent association about the restarting to engage in a health care activity (Article 61, paragraph 4);

5) Fails to carry out the duties referred to in Article 62 of this Law;

6) Fails to provide constantly available ambulance transport (Article 63, paragraph 1);

7) Fails to provide emergency medical care to a foreigner (Article 240, paragraph 1).

Article 259

A health care practitioner shall be fined from 30,000 to 50,000 Dinars for misdemeanor if he/she:

1) Fails to provide information to a patient, which is needed for the patient to be able to take the decision on whether to give or not to give the consent to the proposed medical measure or if he/she fails to enable insight in the costs of treatment to a patient (Article 28);

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7) In engaging in the pharmaceutical health care activity, acts contrary to Articles 86 and 87 of this Law;

8) Fails to join the associations of health care practitioners in compliance with the law (Article 167, paragraph 1);

9) Leaves the workplace after expiry of working hours, without having been provided replacement, whereby engaging in the health care activity has been disrupted or health of a patient has been threatened (Article 170);

10) Fails to provide emergency medical care by expressing conscientious objection (Article 171, paragraph 4);

11) Works autonomously in a health care facility, or private practice without having been issued, or without having renewed the license, or if his/her license has been revoked (Article 191);

12) Within eight days from the date of receipt of the decision on revoking the license, fails to submit the same to the competent association (Article 192);

13) Engages in sideline work contrary to Articles 199 to 201 of this Law;

14) Fails to cooperate with the professional supervisors in the implementation of regular or extraordinary external quality assurance of professional work or if he/she fails to provide all the required data and to submit the necessary documentation for the implementation of regular and extraordinary external quality assurance of professional work (Article 208, paragraph 5);

15) Refuses to participate in the implementation of the procedure of regular and extraordinary external quality assurance of professional work as a supervisor from the list of supervisors (Article 209, paragraph 5);

16) Fails to perform direct examination of a deceased person and to establish the time and cause of death within 12 hours from the received call (Article 219, paragraph 5);

17) Fails to notify, without delay, the competent organizational unit of the ministry in charge of interior affairs about a death case under the conditions laid down in Article 220, paragraph 1 of this Law;

18) Practices traditional medicine by applying the methods and procedures for which he/she has not obtained the permit of the Ministry (Articles 235 - 237).

A medical associate shall also be fined from 30,000 to 50,000 Dinars for the misdemeanor referred to in paragraph 1, Items 10), 14), and 15) of this Article.

(3) A medical associate or other employee shall be fined from RSD 30,000 to 50,000 for the violation referred to in paragraph 1, Item 13.

Article 259

A person referred to in Article 173, paragraph 2 of this Law shall be fined in the amount of RSD 30.000 to 50.000 for violation related to the provision of health care outside a health care facility or private practice functioning according to this Law in order to gain property or non-property benefits, except in case of the provision of emergency aid pursuant to law.

Article 260

The employer, who is a legal person, shall be fined from 200,000 to 800,000 Dinars for misdemeanor if he/she fails to organize and provide health care of employees from his/her own funds (Article 14).

The employer who is an entrepreneur shall be fined from 100,000 to 500,000 Dinars for the misdemeanor referred to in paragraph 1 of this Article.

Article 261

The Agency for Drugs and Medicines of Serbia shall be fined from 200,000 to 800,000 Dinars for misdemeanor if it fails to notify the Ethics Board of Serbia about conducting of clinical tests of drugs and Medical devices for which the approval for conducting of clinical tests has been handed down (Article 157, paragraph 2).

Article 262

The medical faculties shall be fined from 300,000 to 800,000 Dinars for misdemeanor if, when taking over the bodies of deceased persons for the purpose of providing practical training, they act contrary to Articles 225 to 234 of this Law.

Article 263

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XVI. TRANSITIONAL AND FINAL PROVISIONS

Article 264

A municipality, city, or autonomous province shall assume the foundation rights to the health care facilities it is the founder of up to January 1, 2007.

The decision on assuming of the foundation rights referred to in paragraph 1 of this Article shall be handed down by the competent authority of the municipality, city, or autonomous province and, after registration in the register with the competent authority, it shall notify the Ministry thereon within 15 days from the date of registration.

By the time of assuming of the foundation rights referred to in paragraph 1 of this Article, the foundation rights to those health care facilities shall be exercised by the authorities in charge according to the regulations prevailing up to the date of coming into force of this Law.

From the date of assuming of the foundation rights to the health care facilities, the municipality, city, or the autonomous province shall nominate the bodies of the health care facility in compliance with this Law, and the obligations of the founder with respect to the financing of the health care facility shall be fulfilled by the Republic up to January 1, 2007.

The provisions of this Law shall apply to the nomination of the bodies health care facilities referred to in paragraphs 1 and 2 of this Article.

Article 265

Outpatient departments, general hospitals, and pharmacies that are, in compliance with this Law, founded as independent health care facilities, which have been within the complement of a health center and pharmaceutical institute up to the date of coming into force of this Law, may organize joint medical services for laboratory, x-ray, and other diagnostics, as well as joint non-medical services for legal, economic and financial, technical, and other similar affairs.

Article 266

A health center as a kind of health care facility, which has a outpatient department within its complement, concerning which the local self-government cannot secure sufficient funds for assuming of the foundation rights in the budget of

the local self-government, may exceptionally, on the basis of the decision of the Government, continue to work for five years as of the date of coming into force of this Law.

The competent authority of the local self-government referred to in paragraph 1 of this Article shall submit the application for continuation of work of the health center as a kind of health care facility – to the Ministry, within six months from the date of coming into force of this Law.

Up to the date of assuming of the foundation rights to the outpatient department, which is within the complement of a health center referred to in paragraphs 1 and 2 of this Article by the local self-government, the foundation rights to the health center shall be exercised by the Republic, or autonomous province, in compliance with the regulations prevailing up to the date of coming into force of this Law.

Up to the time of assuming of the foundation rights to the outpatient department and general hospital that are within the complement of the health center referred to in paragraph 1 of this Article, in compliance with this Law, the funds for exercising of foundation rights to the health center shall be provided in the budget of the Republic, or autonomous province.

Article 267

Institutes for specialized rehabilitation that may engage in the health care activity as a specialty hospital, under the conditions laid down by this Law and the regulations adopted for enforcement of this Law, shall harmonize their organization, bylaws and other enactments with the provisions of this Law within 12 months from the date of coming into force of this Law.

Article 268

Health care facilities and private practice shall harmonize their bylaws, organization, and work with the provisions of this Law that are related to types of health care facilities, or types of private practice, requirements for setting up and commencement of work, as well as to the organization of work with the provisions of this Law within six months from the date of coming into force of this Law.

Up to the passing of the bylaws referred to in paragraph 1 of this Article, health care facilities and private practice shall apply the bylaws that are not contrary to the provisions of this Law.

Article 269

Institutes for laboratory and other diagnostics, as a type of health care facilities, that have been founded in accordance with the regulations governing health care, prevailing up to the date of coming into force of this Law, shall continue to work in accordance with the decision on fulfillment of the requirements for engaging in a health care activity, handed down by the ministry in charge of the affairs health.

Article 270

The Government shall adopt the Plan of the Network within 12 months from the date of coming into force of this Law.

Article 271

The Minister shall adopt the regulations for enforcement of this Law within 12 months from the date of coming into force of this Law.

Up to the adoption of the regulations referred to in paragraph 1 of this Article, the regulations prevailing up to the date of coming into force of this Law shall apply, which are not contrary to the provisions of this Law.

Article 272

Other legal persons, except for the legal persons that, within their complement have organized an outpatient unit for occupational medicine, and which have set up organizational units for engaging in the health care activity for their own employees, as well as other forms of engaging in health care activity shall, within six months from the date of coming of this Law into force, harmonized their work with the provisions of this Law.

Article 273

The Agency for Accreditation of Health Care Facilities of Serbia shall start working within three years from the date of coming into force of this Law.

Until the commencement of the work of the Agency for Accreditation of Health Care Facilities of Serbia, the affairs from the competence of the Agency laid down by this Law and the regulations passed for enforcement of this Law shall be discharged by the Ministry.

The Ministry shall start administering the affairs referred to in paragraph 2 of this Article within 12 months from the date of coming into force of this Law.

Until the commencement of the work of the Agency for Accreditation of Health Care Facilities of Serbia, the charges for accreditation shall be regulated by the Minister.

Article 274

Within six months from the date of commencement of the work of the association, the competent association shall start issuing, renewing, or revoking the licenses of health care practitioners, in accordance with the provisions of this Law.

Article 275

The Minister shall nominate the Ethics Board of Serbia within six months from the date of coming of this Law into force.

The Minister shall nominate the Republic professional commissions within 90 days from the date of coming of this Law into force.

Article 276

The National Parliament shall elect the members of the Health Council of Serbia within nine months from the date of coming into force of this Law.

The National Parliament shall adopt the Plan of Development of Health Care within six months from the date of election of the members of the Health Council of Serbia.

Article 277

Deleted ("Official Journal of the RS", No. 88/10)

Article 278

Until the termination of functioning of the interim legal system established further to the Resolution 1244 of the UN Security Council in the territory of the Autonomous Province of Kosovo and Metohija, the Government shall have all the rights and obligations of the founder to the health care facilities the founder of which is the Republic, in compliance with the law.

Article 279

On the date of coming into force of this Law, the Law on Health Care (the *Official Gazette of the Republic of Serbia*, Nos. 17/92, 26/92, 50/92, 52/93, 53/93, 67/93, 48/94, 25/96, and 18/02) shall cease to be effective, except for Articles 77 to 77 and Articles 78 to 85.

On the date of coming into force of this Law, the Law on Health Care of Foreigners in the Federal Republic of Yugoslavia (the *Official Gazette of the Federal Republic of Yugoslavia*, Nos. 59/98 and 37/02) shall cease to be effective.

Article 280

This Law shall come into force on the eighth day from the date of its publishing in the *Official Gazette of the Republic of Serbia*.

PROVISIONS NOT INCLUDED IN THE REVISED TEXT

Law on Amendments to the Health Care Law ("Official Journal of the RS", No. 88/10)

Article 8.

(1) The bylaw for the enforcement of this Law shall be adopted within 90 days from the effective date of this Law.

(2) The bylaw provisions that were in force until the enforcement of the new Law, which were not in contrast to it, shall be in force until the adoption of the bylaw based on this law.

Law on Amendments to the Health Care Law ("Official Journal of the RS", No. 57/11)

Article 46.

The bylaw for the enforcement of this Law shall be adopted within 12 months from the effective date of this Law.

Article 47.

(1) The Administration for Screening Programs shall start with operation on January 1, 2013.

THE HEALTH CARE LAW

(Official Journal of the RS, Nos. 107/05 , 72/09 – Other law, 88/10 , 99/10 , 57/11 , 119/12 , 45/13 – Other law)

The revised text including the amendments referred to in the Official Journal of the RS No. 45/13 that are in force from 05/30/2013 (amendments to Articles: 26 , 27 , 28 , 29 , 30 , 31 , 32 , 33 , 34 , 35 , 36 , 37 , 38 , 40 , 40 , 42 , 43 , 256 , 259 , 263).

I. GENERAL

Article 1.

This Law governs the health care system, organization of the health service, social care for the health of the population, general interest in health care, the rights and obligations of patients, health care of foreigners, setting up of the Agency for Accreditation of Health care Facilities of Serbia, supervision over the enforcement of this Law, as well as other issues of importance for the organization and implementation of health care.

Health Care

Article 2

(1) Health care, in the sense of this Law, is the organized and comprehensive activity of the society with the underlying goal to achieve the highest possible level of preservation of the health of citizens and families.

(2) Health care, in the sense of this Law, includes implementation of

measures for the preservation and improvement of health of citizens, prevention, control, and early detection of diseases, injuries, and other health disorders and timely and efficient treatment and rehabilitation

The Right to Health Care

Article 3

A citizen of the Republic of Serbia (hereinafter referred to as: the Republic), as well as any other person who has permanent or temporary residence or abode in the Republic, has the right to health care, in accordance with the law, and duty to preserve and improve his/her health and the health of other citizens, as well as the conditions of living and working environment

Participants in Health Care

Article 4

Citizens, family, employers, educational and other facilities, humanitarian, religious, sports and other organizations, associations, health service, the health insurance organization, as well as municipalities, cities, autonomous provinces, and the Republic shall be involved in the provision and implementation of health care in the Republic

Health Care Activity

Article 5

(1) Health care activity is the activity by which health care of the citizens is provided, which includes implementation of health care measures and activities, which are, in accordance with the health care doctrine and using health care technologies, used for the preservation and improvement of the health of people, and which is provided by the health service.

(2) The measures and activities of health care must be based on scientific evidence, i.e. they must be safe, reliable and efficient and in compliance with the principles of professional ethics.

Health Service

Article 6

The health service in the Republic is comprised of the health care facilities and other forms of health service (hereinafter referred to as: private practice), which are established for the purpose of implementation and provision of health care, as well as of health care practitioners, and/or medical associates, who are engaged in health care activity, pursuant to this Law

Financing of Health Care

Article 7

The resources for the implementation of health care, as well as for the work and development of health service, shall be provided pursuant to the law.

II. SOCIAL CARE FOR THE HEALTH OF THE POPULATION

Article 8

(1) Social care for the health of the population is achieved on the level of the Republic, autonomous province, municipality, or city, employer, and individual.

(2) Within the social care for health referred to in paragraph 1 of this Article health care is provided, which includes:

1) Preservation and improvement of health, detection, and control of risk factors influencing the occurrence of diseases, acquiring knowledge and habits concerning healthy lifestyle;

2) Prevention, control, and early detection of diseases;

3) Early diagnosis, timely treatment and rehabilitation of the diseased and injured;

4) Information needed by the population or individual for responsible actions and for exercising the right to health.

Social Care for Health on the Republic Level

Article 9

Social care for health on the Republic level consists of the measures for economic and social policies by which conditions are created for implementation of health care for the purpose of preservation and improvement of health of people, as well as the measures for harmonizing the activity and development of the health care system.

Article 10

(1) Social care for health on the Republic level, in the sense of Article 9 of this Law, includes:

1) Establishing priorities, planning, adoption of special programs for implementation of health care, as well as the adoption of regulations in this area;

2) Implementation of measures of fiscal and economic policies stimulating the development of healthy lifestyle habits;

3) Provision of the conditions for education concerning the health of the population;

4) Provision of the conditions for development of an integrated health care information system in the Republic;

5) Development of scientific research activity in the field of health care;

6) Provision of the conditions for professional advancement of medical workers and medical associates.

(2) Social care for health on the Republic level also includes adoption of the Republic Program in the area of protection of health from polluted environment, which is caused by noxious and hazardous matters in air, water and soil deposited by waste disposal, hazardous chemicals, sources of ionizing and non-ionizing radiation, noise and vibrations, as well as systematic testing of food stuffs, consumer products,

mineral drinking waters, drinking water and other waters used for the production and processing of foodstuffs and for sanitary and hygienic and recreational requirements for the purpose of establishing their sanitary and hygienic condition and the specified quality (monitoring).

(3) The Program referred to in paragraph 2 of this Article shall be jointly adopted by the Minister of health (hereinafter referred to as: the Minister) and the Minister of environmental protection.

(4) The resources for the implementation of the social care for health on the Republic level shall be provided in accordance with the law.

Article 11

(1) Social care for health, under equal conditions, shall be exercised in the territory of the Republic by providing health care to the groups of population that are exposed to increased risk of contracting diseases, health care of persons related to prevention, control, early detection, and treatment of diseases of major social and medical importance, as well as by health care of the socially vulnerable population.

(2) Health care referred to in paragraph 1 of this Article includes:

1) Children of 18 years of age, conclusive, school children and students until the end of statutory schooling, and not later than up to 26 years of age, pursuant to the law;

2) Women related to family planning, as well as during pregnancy, childbirth and maternity up to 12 months after childbirth;

3) Persons over 65 years of age;

4) Persons with a disability and mentally insufficiently developed persons;

5) Persons suffering from HIV infection or other communicable diseases that are specified by a separate law governing the area of protection of the population from communicable diseases, malignant diseases, hemophilia, diabetes mellitus, psychosis, epilepsy, multiple sclerosis, persons in the terminal stage of chronic kidney insufficiency, cystic fibrosis, systemic autoimmune disease, rheumatic fever, addiction diseases, diseased and/or injured persons related to providing emergency medical care, as well as health care related to donation and receiving of tissues and organs;

6) Monks and nuns;

7) Materially unprovided persons who receive relief according to the regulations on social welfare and protection of veterans, military and civilian invalids of war, as well as members of their families if they are not health insured;

8) Beneficiaries of permanent pecuniary aid according to the regulations on social welfare as well as of benefit for placement in social care facilities or in foster families;

9) Unemployed persons and other categories of socially vulnerable persons whose monthly income earnings are below income earnings established in compliance with the law governing health insurance;

10) Beneficiaries of cash benefit for the family members whose breadwinner is doing his military service;

11) Persons of the Roma nationality who, due to their traditional lifestyle do not have permanent or temporary residence in the Republic.

12) Domestic violence victims;

13) People trafficking victims;

14) Persons to whom mandatory immunization is provided pursuant to the provisions regulating public health protection from infectious diseases;

15) Persons to whom targeted preventive examinations, or screening, are provided pursuant to the relevant government programs;

16) Single parents of children up to seven years of age, with monthly income below that established by law regulating health insurance

(3) The Government of the Republic of Serbia (hereinafter referred to as: the Government) shall regulate the contents and scope, the method and procedure, as well as the conditions for exercising of health care of the persons referred to in paragraph 2 of this Article, unless otherwise laid down by the legislation.

Article 12

(1) Health care for the persons referred to in Article 11 of this Law who are covered by compulsory health insurance shall be provided from the funds of compulsory health insurance in compliance with the law governing the area of compulsory health insurance.

(2) Unless otherwise laid down by the legislation, the funds for exercising of health care referred to in Article 11, paragraph 3 of this Law for the persons who are not covered by compulsory health insurance shall be provided in the budget of the Republic and shall be transferred to the organization in charge of compulsory health insurance.

Social Care for Health on the Level of the Autonomous Province, Municipality, or City

Article 13

(1) Social care for health on the level of an autonomous province, municipality, or city, includes the measures for providing and implementation of health care of interest for the citizens in the territory of autonomous province, municipality, or city, as follows:

1) Monitoring of the state of health of the population and the operation of the health service in their respective territories, as well as looking after the implementation of the established priorities in health care;

2) Creating the conditions for accessibility and equal use of the primary health care in their respective territories;

3) Coordination, encouraging, organization, and targeting of the implementation of health care, which is exercised by the activity of the authorities of the local self-government units, citizens, enterprises, social, educational, and other facilities and other organizations;

4) Planning and implementation of own program for preservation and protection of health from polluted environment, which is caused by noxious and hazardous matters in air, water, and soil, waste disposal, hazardous chemicals, sources of ionizing and non-ionizing radiation, noise and vibrations in their respective territories, as well as by systematic testing of foodstuffs, consumer products, mineral drinking waters, drinking water, and other waters used for production and processing of foodstuffs, and sanitary and hygienic and recreational requirements, for the purpose of establishing their sanitary and hygienic condition and the specified quality;

5) Providing of the funds for the execution of the foundation rights in the health care facilities which founder acts in compliance with the law and with the Network Plan of health care facilities, and which includes construction, maintenance, and equipping of health care facilities, and/or capital investment, capital-current maintenance of premises, medical and non-medical equipment and means of transport, equipment in the area of integrated health care information system, as well as for other liabilities specified by the law and by the articles of association;

6) Cooperation with humanitarian and professional organizations, unions and associations, in the affairs of health care development.

7) Provision of conditions for better staffing of its health care institution along with norms, or standards established pursuant to this Law and bylaws adopted for the enforcement of this Law, for which, due to lack of resources of the mandatory health insurance, the required resources cannot be provided based on the contract concluded with the mandatory health insurance organization, or due to lack of resources of the health care institution, until the conditions are provided for funding the staffing by mandatory health insurance, or from the income of the health care institution itself;

8) Provision of resources for emergency medical aid pursuant to Article 162. paragraphs 1 and 2 of this Law

(2) A municipality or city shall ensure the operation of coroner's service in their respective territories.

(3) An autonomous province, municipality, or city shall provide the funds for realization of social care for health referred to in paragraph 1 of this Article in the of the autonomous province, municipality, or city, in accordance with the law.

(4) An autonomous province, municipality, or city may adopt special health care programs for certain categories of the population, and/or kinds of diseases that are specific for the autonomous province, municipality, or city, for which no special health care program has been adopted on the Republic level, in accordance with their respective capabilities, and shall set prices of such individual services, or programs.

Article 13

(1) Social care for health at the level of autonomous province, municipality, or city can also include measures for the provision of health care of interest to the citizens in the territory of such autonomous province, municipality or city, which provide the conditions for better accessibility to the use of health care in their territories in health care institutions founded it and which are of higher priority than the norms, or standards set out by this Law and bylaws adopted for the enforcement of this Law in terms of space, equipment, staff, medicines and medical devices that are not provided pursuant to the provisions of the law governing mandatory health insurance, including other necessary costs of operation of the said health care institution

contributing to higher standards in the provision of health care.

(2) The provision of staff set out in Article 13, paragraph 1, item 7) of this Law, and paragraph 1 of this Law involves the provision of resources for employee salaries, bonuses and other compensations according to law, or the collective agreement, and the mandatory health care fees.

(3) An autonomous province, municipality or city can provide the resources also for the execution of founder's rights over a health care institution in order to perform the obligations of the health care institutions, for obligations not funded from the mandatory health insurance or in any other way pursuant to law for which a health care institution cannot provide the resources in the financial plan.

(4) An autonomous province, municipality or city can provide the resources also for security of the facilities and equipment of the health care institution of which it is founder, pursuant to law.

(5) An autonomous province, municipality or city shall provide the resources for providing social care of health set out in paragraphs 1-4 of this Article in the budget of such autonomous province, municipality or city pursuant to law

Social Care for Health on the Employer Level

Article 14

(1) Employer shall organize and provide, from his/her own funds, health care of the employees for the purpose of creating conditions for health-responsible behavior and protection of health at the workplace of the employee, which includes as a minimum:

1) Physical examinations for the purpose of establishing the capacity for work against the order of the employer;

2) Implementation of measures for prevention and early detection of occupational diseases, diseases related to work, and prevention of accidents at work;

3) Preventive physical examinations of the employees (preliminary, periodic, control and targeted examinations) depending on the sex, age, and working conditions, as well as incidence of occupational diseases, accidents at work, and chronic diseases;

4) Compulsory physical examinations of employees for the protection of the living and working environment, and of the employees from communicable diseases in accordance with the regulations governing the area of protection of the population from communicable diseases, protection of consumers, or users and other compulsory physical examinations, in compliance with the law;

5) Familiarization of employees with the health care measures of safety at work and their education related to the specific conditions, as well as to the use of personal and collective protective devices;

6) Provision of sanitary, technical, and hygienic conditions (sanitary conditions) in the facilities under sanitary supervision and in other facilities in which an activity of public interest takes place in compliance with the law governing the area of sanitary supervision, as well as the provision and implementation of general measures for protection of the population from communicable diseases in compliance with the law governing the area of protection of the population from communicable diseases;

7) Other preventive measures (non-mandatory vaccinations, non-mandatory periodic medical periodic checkups), in accordance with the general act of the employer;

8) Monitoring of the working conditions and safety at work, as well as assessments of occupational hazards for the purpose of improvement of the working conditions and ergonomic measures, by adjustment of work to the psycho-physiological abilities of the employees;

9) Monitoring of incidences of diseases, injuries, sick-leaves, and mortality rate, particularly from occupational diseases, diseases related to work, accidents at work, and other health damages that affect temporary or permanent change of capacity for work;

10) Participation in the organization of the work and vacation schedules of employees, as well as in the assessment of new equipment and new technologies from the health and ergonomic aspects;

11) Implementation of measures for improvement of health of the workers exposed to health risks during the process of work, including assessment and referral of the workers working on particularly difficult and risky jobs to health care and preventive activities and vacation;

12) Administering of first aid in case of injury at workplace and providing of conditions for emergency medical interventions.

(2) Social care for health on the employer level, in the sense of paragraph 1 of this Article, includes both preliminary and periodic physical examinations of the workers working at workplaces with increased hazard, in the manner and according to the procedure established by the regulations governing the area of safety and health at work.

(3) In providing social care for health on the employer level, the employer shall also provide to the employees other measures of safety and health at work, in accordance with the regulations governing the area of safety and health at work.

Social Care for Health on Individual Level

Article 15

(1) An individual shall, within the limits of his/her knowledge and abilities join in the social care for health, as well as administer first aid to an injured or diseased person in an emergency case and enable him/her access to the emergency medical service.

(2) An individual shall look after his/her own health, the health of other people, as well as the living and working environment.

(3) An individual shall be subjected to compulsory vaccination in international circulation against certain communicable diseases specified by the law governing the area of protection of the population from communicable diseases, as well as bear the expenses of vaccination incurred in the procedure of implementation of that measure.

Health Care Development Plan

Article 16

(1) For the purpose of providing and implementation of the social care for health on the Republic level, the National Parliament of the Republic of Serbia shall adopt the Health Care Development Plan (hereinafter referred to as: the Development Plan).

(2) For the purpose of implementation of the Development Plan, the Government shall adopt health care programs.

Article 17

(1) The Development Plan is based on the analysis of the state of health of the population, needs of the population for health care, available staff, financial and other capabilities.

(2) The Development Plan shall contain:

- 1) The priorities in the development of health care;
- 2) Goals, measures, and health care activities;
- 3) Health needs of the groups of the population that are exposed to particular risk of contracting diseases of the interest for the Republic;
- 4) Specific needs of the population for health care and possibility of their meeting in certain areas;
- 5) Indicators for monitoring of achievements in the achievement of goals;
- 6) Agents of measures and activities and timeframes for attaining the objective of health care;
- 7) Criteria for setting up of the network of health care facilities in the Republic the founder of which is the Republic, autonomous province, municipality, or city, as well as the bases for the development of health service on the primary, secondary, and tertiary levels;
- 8) Elements for planning, education, and improvement of the employees within the health care system, as well as the elements for planning of construction of new and restructuring of the existing capacities with respect to the premises and equipment;
- 9) Sources for financing of health care and development of the health insurance system;
- 10) Other data of importance for the development of the health care system.

III. ACCOMPLISHING OF GENERAL INTEREST IN HEALTH CARE

Article 18

(1) The Republic shall provide the following issues of general interest for health care:

- 1) Monitoring and studying living and working conditions and health condition of the population, and/or individual groups of the population, causes of onset, spreading, and methods of prevention and control of diseases and injuries of major social and medical importance;
- 2) Health promotion in compliance with the health care programs and provision of the conditions for implementation of special programs for preservation and improvement of health;
- 3) Implementation of epidemiological supervision and organizing and implementation of special measures for the protection of the population from communicable diseases, implementation of emergency measures established in compliance with the law governing the area of protection of the population from communicable diseases, as well as implementation of the programs for prevention, control, elimination, and eradication of communicable diseases, in compliance with the law;
- 4) Prevention, control, and eradication of epidemics of communicable diseases;
- 5) Monitoring and prevention of chronic mass non-communicable diseases and addictions;
- 6) Systematic epidemiological and systematic hygienic monitoring, as well as systematic monitoring and testing of the effects of environment pollution on the health of people, as well as systematic testing of sanitary quality of foodstuffs, items of general use, and drinking water;
- 7) Emergency medical care to persons of unknown residence as well to other persons who are not otherwise entitled to emergency medical aid pursuant to law;
- 8) Health care of persons serving a prison sentence, which is provided to them outside the penitentiary institution, implementation of security measures of compulsory psychiatric treatment and placement in a health care facility, compulsory psychiatric outpatient treatment, compulsory treatment of alcoholics and drug addicts;
- 9) Prevention and elimination of consequences to health caused by natural and other disasters and emergency situations;
- 10) Organization and development of an integrated health care information system by acquisition, processing, and analysis of health and statistical and other data and information on health condition and health needs of the population, as well as monitoring of the data on the functioning of the health service with respect to the provided premises, staff, equipment and medicines, as well as monitoring of the performance indicators;
- 11) Monitoring and continuous improvement of health care quality and implementation and quality control of health care;
- 12) Organization and implementation quality test of professional work;
- 13) Extraordinary control of the quality of medicines, as well as control of random medicines samples that are used in medicine, according to the program of the Ministry of health (hereinafter referred to as: the Ministry);
- 14) Encouraging the activities to improve rational pharmacotherapy in the treatment of the diseased and injured;

15) Encouraging the activities on popularization of voluntary blood donation and implementation of programs of blood collection, as well as of organ and tissue donation for transplantation;

16) Provision of conditions for the work of the Republic expert commissions, as well as of the commission for evaluation of health care technologies;

17) Encouraging the activities of the humanitarian and professional organizations, unions and associations on issues that are, as a priority, envisaged by the Development Plan, and/or by special health care programs;

18) Participation in the provision of funds for equalization of the conditions for the provision of health care in the entire territory of the Republic, and in particular on the primary health care level in the municipalities having unfavorable demographic characteristics and in underdeveloped municipalities, in accordance with the priorities;

19) Provision of funds for construction and equipping of state owned health care facilities the founder of which is the Republic, which includes: capital investment, capital - current maintenance of premises, medical and non-medical equipment and means of transport, equipping in the area of integrated health care information system, as well as providing of funds for other liabilities specified by the law and by the foundation act;

20) Financing of applied research works in the area of health care;

21) Implementation of the Government measures in natural and other major disasters and emergency situations pursuant to the law governing emergency situation activities.

(22) Provision of funds for conducting the activities referred to in Article 124, paragraph 2, items 1) to 7) of this Law, and the procedure for the assessment of the level of ionizing and non-ionizing radiation in the health care domain by the Occupational Medicine Institute established for the territory of the Republic of Serbia.

(2) The funds for the achievement of the general interest in health care referred to in paragraph 1 of this Article shall be provided from/in the budget of the Republic.

(3) The Commission which shall propose the priorities for purposes referred to in paragraph 1, item 19) of this Article shall be formed by the Minister.

IV. PRINCIPLES OF HEALTH CARE

The Principle of Accessibility to Health Care

Article 19

The principle of accessibility to health care shall be realized by providing adequate physically, geographically, and economically, and/or culturally acceptable health care to the citizens of the Republic, and in particular health care on the primary level.

The Principle of Equity of Health Care

Article 20

The principle of equity of health care shall be realized by the ban of discrimination while providing health care on the grounds of race, sex, age, national affiliation, social origin, religious beliefs, political or other affiliations, income scale, culture, language, kind of disease, mental or physical disability.

The Principle of Comprehensiveness of Health Care

Article 21

The principle of comprehensiveness of health care shall be realized by inclusion of all citizens of the Republic in the health care system, with the implementation of uniform measures and procedures of health care, including health promotion, prevention of diseases at all levels, early diagnosis, treatment, and rehabilitation.

The Principle of Continuity of Health Care

Article 22

The principle of continuity of health care shall be realized by the overall organization of the health care system, which must be functionally interconnected and harmonized by levels, from the primary through the secondary to the tertiary level of health care and which shall provide continuous health care to the citizens of the Republic at any age of life.

The Principle of Continuous Improvement of the Quality of Health Care

Article 23

The principle of continuous improvement of health care quality shall be realized by the measures and activities by which, in line with the modern achievements of the medical science and practice, the possibilities of favorable outcome are increased and the risks and other unwanted consequences for the health and the state of health of individuals and the community as a whole are reduced.

The Principle of Efficiency of Health Care

Article 24

The principle of health care efficiency shall be realized by achieving the best possible results compared to the available financial resources, and/or by achieving the highest level of health care at the lowest expenditure of funds.

V. HUMAN RIGHTS AND VALUES IN HEALTH CARE AND PATIENT RIGHTS

1. Human Rights and Values in Health Care

Article 25

(1) Every citizen has the right to be provided health care while respecting the highest possible standard of human rights and values, i.e. he/she has the right to physical and mental integrity and to the security of his/her personality, as well as to the respect of his/her moral, cultural, religious, and philosophical affiliations.

(2) Every child up to 18 years of age conclusive shall have the right to the highest possible standard of health and health care.

2. Patient Rights

The Right to Availability of Health Care

Article 26

Deleted (Official Journal of the RS No. 45/13)

The Right to Information

Article 27

Deleted (Official Journal of the RS No. 45/13)

The Right to Be Informed

Article 28

Deleted (Official Journal of the RS No. 45/13)

The Right to Free Choice

Article 29

Deleted (Official Journal of the RS No. 45/13)

The Right to Privacy and Confidentiality of Information

Article 30

Deleted (Official Journal of the RS No. 45/13)

The Right to Independent Decision and Consent

Article 31

Deleted (Official Journal of the RS No. 45/13)

Article 32

Deleted (Official Journal of the RS No. 45/13)

Article 33

Deleted (Official Journal of the RS No. 45/13)

Article 34

Deleted (Official Journal of the RS No. 45/13)

Article 35

Deleted (Official Journal of the RS No. 45/13)

The Right to Insight in Medical Documentation

Article 36

Deleted (Official Journal of the RS No. 45/13)

The Right to Confidentiality of Data

Article 37

Deleted (Official Journal of the RS No. 45/13)

The Right of Patient on Whom Medical Experiment is Conducted

Article 38

Deleted (Official Journal of the RS No. 45/13)

The Right to Complaint

Article 39^{l*ñ}

(1) The patient who has been denied the right to health care, and/or a patient who is not satisfied with the provided health service, or with the act of a health or other worker in a health care facility, may file a complaint to the health care practitioner who manages the work process or to a person employed in the health care facility who administers the affairs of protection of patient rights (hereinafter referred to as: the advocate of patient rights).

(2) health care facility shall organize the work of the advocate of patient rights.

- (3) The director of a health care facility shall nominate the advocate of patient rights.
- (4) The complaint shall be filed orally when the minutes are made or in writing.
- (5) Further to the complaint referred to in paragraph 4 of this Article, the advocate of patient rights, promptly and not later than within five days from the date of filing of the complaint, shall establish all the important circumstances and facts related to the allegations presented in the contest.
- (6) Promptly and not later than within three days, the advocate of patient rights shall inform the manager of the organizational unit, the director of the health care facility, as well as the party filing the complaint about his/her findings.
- (7) The patient who is dissatisfied with the finding further to the complaint may, in compliance with the law, apply to the health inspectorate, or to the competent authority of the health insurance organization with which the patient is health insured.
- (8) The advocate of patient rights shall submit a monthly report on the filed complaints to the director of the health care facility, and a bi-annual and annual report to the management board of the health care facility and to the Ministry.
- (9) The advocate of patient rights shall be independent in his/her work and the director of the health care facility, or any other health care practitioner may not influence his/her work and decision making.

The Right to Indemnity

Article 40

Deleted (Official Journal of the RS No. 45/13)

The Right to Respect for Patients Time

Article 40

Deleted (Official Journal of the RS No. 45/13)

3. Informing the Public

Article 41

- (1) The citizens of the Republic have the right to information that is needed for preservation of health and acquiring of healthy lifestyle habits, as well as to information on the harmful factors of the living and working environment, which may have negative consequences to health.
- (2) The citizens of the Republic have the right to be informed about the protection of their respective health in case of break out of epidemics and other major disasters and accidents (threat from ionizing radiation, poisoning, etc.).
- (3) The competent health care facility and private practice shall timely and truthfully submit the data about break out of epidemics and disasters referred to in paragraph 2 of this Article to the competent authorities of the municipality, city, autonomous province, and the Republic, responsible for public information.

VI. DUTIES OF PATIENTS

Article 42

Deleted (Official Journal of the RS No. 45/13).

Article 43

Deleted (Official Journal of the RS No. 45/13).

VII. MANDATORY REFERRAL TO A PSYCHIATRIC INSTITUTION

Article 44

(1) Should a doctor of medicine, or a specialist psychiatrist, or a specialist neuropsychiatrist assess that the nature of mental illness of a patient is such that it may threaten the life of the patient or the life of other persons or property, he/she may refer him/her to hospital treatment, and the relevant doctor of medicine of the relevant inpatient health care facility in charge admit him/her for hospital treatment without the personal consent of the patient in compliance with the law, provided that the day following the admittance, the collegiate body of the inpatient health care facility should decide whether the patient will be withheld for hospital treatment.

(2) The inpatient health care facility shall, within 48 hours from the date of admittance of the patient, notify the competent court about the admittance of the patient referred to in paragraph 1 of this Article.

(3) The method and procedure, as well as organization and the conditions of treatment of mentally ill persons, and/or placement of such persons in an inpatient health care facility, shall be regulated by a separate law.

VIII. HEALTH SERVICE

Article 45

(1) Health service is comprised of:

- 1) Health care facilities and private practice;
- 2) Health care practitioners and medical associates who engage in a health care activity in health care facilities and in private practice.

(2) health care facility is engaged in a health care activity, and private practice – in certain types of practice within the health care activity.

. HEALTH CARE FACILITIES AND PRIVATE PRACTICE

1. Types, Establishment and Termination Requirements for Health Care Facilities

Article 46

(1) health care facility may be founded by the Republic, autonomous province, local self-government, legal or natural person, under the conditions laid down by this Law.

(2) Health care facilities may be founded with the funds in state ownership or private ownership, unless otherwise regulated by this Law.

(3) health care facility may be founded as:

- 1) Outpatient department;
- 2) Pharmacy;
- 3) Hospital (general and specific);
- 4) Institute;
- 5) Public health institute;
- 6) Clinic;
- 7) Institute – center of excellence;
- 8) Clinical hospital;
- 9) Clinical center.

Article 47

(1) Health care facilities that are founded with the funds in state ownership (hereinafter referred to as: state owned health care facility) are founded in accordance with the Plan of the network of health care facilities (hereinafter referred to as: Plan of the network), which shall be adopted by the Government.

(2) The Plan of the network for the territory of autonomous province shall be established at the proposal of the autonomous province.

(3) The Plan of the network shall be generated based on:

- 1) Development Plan;
- 2) Health condition of the population;
- 3) Number and age structure of the population;
- 4) The existing number, capacities, and distribution of the health care facilities;
- 5) The degree of urbanization, development, and communications of certain areas;
- 6) Equal access to health care;
- 7) Required scope of certain levels of health care activity;

8) Economic capabilities of the Republic.

(4) The Plan of the Network specifies: the number, structure, capacities, and spatial distribution of health care facilities and their organizational units by levels of health care, organization of the service of emergency medical care, as well as other issues of importance for the organization of health service in the Republic.

Article 48

(1) State owned health care facilities referred to in Article 46 of this Law, depending on their type, are founded by the Republic, autonomous province, municipality, or city, in compliance with this Law and the Plan of the network.

(2) Health care facilities referred to in paragraph 1 of this Article shall be founded as follows:

1) Outpatient department and pharmacy – shall be founded by the municipality, or city;

2) Institute on the primary level of engaging in a health care activity and clinical hospital – shall be founded by a city;

3) A general hospital, specific hospital, clinic, institute and clinical center – shall be founded by the Republic, and in the territory of the autonomous province – by the autonomous province;

4) Health care facilities engaged in the activity on several levels of health care, as follows: public health institute, blood transfusion institute, occupational medicine institute, forensic medicine institute, virology, vaccines, and serums institute, rabies prophylaxis institute, psycho-physiological disorders and speech pathology institute, and disinfection, pest control and pest extermination institute – shall be founded in compliance with this Law.

(3) Health care facilities that provide emergency medical care, supply of blood and blood derivative products, taking, keeping, and transplantation of organs and parts of human body, production of serums and vaccines and pathoanatomical and autopsy activity, as well as the health care activity in the area of public health, shall be founded exclusively in state ownership^[**].

Article 49

(1) A health care facility may engage in a health care activity if it meets the requirements laid down by this Law, provided that:

1) it has certain profile and number of health care practitioners of adequate professional qualifications, who have passed intern's exit exam, and for engaging in certain practices with the relevant specialization, or scientific, and/or academic title;

2) it has diagnostic, therapeutic and other equipment for safe and modern providing of health care in the activity for which it has been founded;

3) it has adequate premises for admitting patients, or healthy persons, for carrying out diagnostic and therapeutic procedures and accommodation of patients, as well as for keeping medicines and medical devices.

4) it has sufficient quantity of the required types of medicines and medical devices that are required for engaging in certain health care activities for which the health care facility is founded.

(2) Two or more health care facilities may organize joint medical services for laboratory, radiographic and other diagnostics, as well as joint non-medical services for legal, economic and financial, technical and other affairs.

(3) Detailed requirements for staff, equipment, premises, and medicines for establishing and engaging in a health care activity by health care facilities referred to in paragraph 1 of this Article shall be specified by the Minister.

(4) A health care facility using the sources of ionizing radiation must, apart from the requirements referred to in paragraphs 1 and 3 of this Article, also meet other requirements laid down by the law regulating protection from ionizing radiation.

Article 50

(1) The founder of a health care facility shall adopt the foundation act, which shall contain:

- 1) Name and seat, or name and address of the founder;
- 2) Name and seat of the health care facility;
- 3) Activity of the health care facility;
- 4) The amount of funds required for establishment and commencement of work of the health care facility and the method of providing the funds;
- 5) The rights and obligations of the founder with respect to engaging in the activity for which the health care facility is founded;
- 6) Mutual rights and obligations of the health care facility and the founder;
- 7) Management bodies of the health care facility that is being founded and their authorizations;
- 8) The person who will, up to the appointment of the director of the health care facility, administer the affairs and exercise the authorities of the director;
- 9) The deadline for adoption of the articles of association, appointment of the director and management bodies.

(2) The foundation act of the health care facility, engaged in the health care activity on the primary level of health care, and founded for the territory of several municipalities, shall regulate mutual rights and obligations of the founder of the health care facility and of other municipalities in the territory for which that health care facility has been founded.

Article 51

(1) A health care facility may engage in a health care activity should the Ministry by its decision establish that the requirements laid down by the law for engaging in health care activities have been met.

(2) A health care facility may only engage in the health care activity that is specified by the decision of the Ministry concerning fulfillment of the requirements for engaging in a health care activity.

(3) The decision referred to in paragraph 1 of this Article shall be handed down by health inspector, in compliance with this Law and the law regulating general administrative procedure.

(4) Against the decision referred to in paragraph 3 of this Article a complaint may be filed to the minister, within 15 days from the date of receipt of the decision of the health inspector.

(5) The decision of the Minister referred to in paragraph 4 of this Article shall be final in the administrative procedure and an administrative suit may be instituted against it.

(6) On the basis of the decision concerning fulfillment of the requirements for engaging in a health care activity, the health care facility shall be registered in the register with the competent court, in compliance with the law.

(7) A health care facility shall start working on the date of registration in the register referred to in paragraph 6 of this Article.

Article 52

(1) A health care facility may be closed down, merged with another health care facility or divided into several health care facilities, in compliance with the law.

(2) Such closing down, merger and division of state owned health care facilities shall be decided by the Government, in accordance with the Plan of the Network, upon the consultation with the founder.

(3) The founder shall decide about closing down, merger and division of the private-owned health care facilities.

Article 53

(1) The Ministry shall hand down the decision on temporary ban of operation, or on temporary ban of conduct of certain types of health care activities if:

1) a health care facility fails to meet the requirements laid down by the law with respect to the staff, equipment, premises, and medicines;

2) a health care facility engages in a health care activity that is not specified by the decision on commencement of engaging in a health care activity;

3) one of the measures specified by this Law is handed down in the as a result of quality assessment of professional work, or supervision over the work of the health care facility;

4) a health care facility puts up the name, or marks the health care facility contrary to the decision on commencement of engaging in a health care activity;

5) a health care facility advertises its practice of professional medical procedures and methods of health care, as well as other health services that are provided in the health care facility, contrary to the provisions of Article 71 of this Law;

6) for other reasons specified by the law.

(2) A health inspector, upon establishing the facts referred to in paragraph 1 of this Article shall issue the decision on the temporary ban of work, or conduct of a health care activity or in certain types of practice within the health care activity.

(3) A complaint against the decision referred to in paragraph 2 of this Article, which is handed down by health inspector, may be filed to the minister, within 15 days from the date of receipt of the decision.

(4) The decision of the Minister referred to in paragraph 3 of this Article shall be final in the administrative procedure and an administrative suit may be instituted against it.

(5) A health care facility may, on the basis of the decision of the Ministry, resume its work if it, within the time period laid down by the law, or by the decision of the Ministry, eliminates the reasons that gave rise to the temporary ban on work of health care facility or the temporary ban on engaging in certain types of practice within the health care activity.

Article 54

(1) The medical faculties may engage in health care activities through their organizational units should the Ministry conclude that those organizational units meet the requirements laid down by this Law concerning certain type of a health care facility.

(2) Institutions of social protection, penitentiary institutions, as well as other legal entities which are, by a separate law, designated to engage in certain types of practice within the health care activity, may engage in a health care activity should the Ministry conclude that they meet the requirements concerning certain type of health care facility, or the requirements concerning certain type of private practice.

2. Types, Establishment and Termination Requirements Related to Private Practice

Article 55

A private practice may be founded by:

- 1) An unemployed health care practitioner who has passed intern's exit exam;
- 2) A health care practitioner beneficiary of old age pension, with the approval of the medical association.

Article 56

(1) A private practice may be founded as:

- 1) Physician's or dentist's office (general-practice and specific);
- 2) Polyclinic;
- 3) Laboratory (for medical, and/or clinical biochemistry, microbiology, pathohystology);
- 4) Pharmacy;

5) Outpatient department (for health care and recovery);

6) Dental laboratory.

(2) The private practice referred to in paragraph 1, Items 5) and 6) of this Article may be founded by a health care practitioner having adequate medical two-year post-secondary school qualifications, or secondary school qualifications, in compliance with this Law and bylaws adopted for enforcement of this Law.

(3) Private practice referred to in paragraph 1, Item 2) of this Article may be founded by several health care practitioners having medical university qualifications, in compliance with this Law and bylaws adopted for enforcement of this Law.

(4) The founder of private practice referred to in paragraph 1 of this Article shall independently engage in the activity in the capacity of an entrepreneur.

(5) A health care practitioner may set up only one form of private practice referred to in paragraph 1 of this Article.

(6) The private practice may not perform a health care activity in the area of emergency medical care, supply of blood and blood derivative products, taking, keeping and transplantation of organs and parts of human body, production of sera and vaccines, pathoanatomical – autopsy activity, or a health care activity in the area of public health.

Article 57

The health care practitioner referred to in Article 55 of this Law may set up private practice under the condition that he/she:

- 1) Is generally physically fit;
- 2) Has graduated from a university, or relevant medical school and passed intern's exit exam, and for specialists, the relevant certification exam;
- 3) Has been registered in the directory of the competent association;
- 4) Has been issued, or renewed the license for independent practice, in compliance with the law;
- 5) Meets the requirements laid down by this Law concerning the setting up and commencement of work of private practice with respect to the staff, equipment, premises, and drugs;
- 6) By judgment absolute, he/she has not been handed down a criminal sanction – security measure banning engagement in the health care activity, or by a decision of the competent body of the association, he/she has not been handed down one of the disciplinary actions banning independent practice, in compliance with the law regulating the work of the associations of health care practitioners;
- 7) Meets other requirements laid down by the law.

Article 58

(1) Private practice may engage in certain types of practice within the health care activity if it meets the requirements laid down by this Law, as follows:

1) If it has certain number of health care practitioners of adequate professional qualifications, who have passed intern's exist exam, or of the relevant specialty for practicing in a certain branch;

2) If it has diagnostic, therapeutic, and other equipment for safe and modern provision of health care for the activity for which it has been set up;

3) If it has adequate premises for practicing medicine, or certain types of medical practice for which it has been set up;

4) If it has adequate kinds and quantities of medicines and medical devices required for engaging in certain types of practice with the health care activity for which the private practice is set up.

(2) Detailed requirements with respect to the staff, equipment, premises, and medicines for setting up and engaging in certain types of practice within the health care activity of private practice referred to in paragraph 1 of this Article shall be specified by the Minister.

(3) Private practice using the sources of ionizing radiation must, apart from the requirements referred to in paragraphs 1 and 2 of this Article, also meet other requirements laid down by the law regulating the protection from ionizing radiation.

Article 59

(1) Private practice may engage in certain types of practice within the health care activity should the Ministry by its decision establish that the requirements laid down by the law concerning engaging in certain types of practice within the health care activity have been met.

(2) The decision referred to in paragraph 1 of this Article shall be issued by the health inspector, in compliance with this Law and the law regulating general administrative procedure.

(3) A complaint may be filed to the minister against the decision referred to in paragraph 2 of this Article, within 15 days from the date receipt of the decision of the health inspector.

(4) The decision of the Minister referred to in paragraph 3 of this Article shall be final in the administrative procedure and an administrative suit may be instituted against it.

(5) On the basis of the decision concerning fulfillment of the requirements for engaging in certain types of practice within the health care activity, private practice shall be registered in the registry of the competent authority, in compliance with the law.

(6) Private practice shall start working on the date of registration in the registry referred to in paragraph 5 of this Article.

Article 60

(1) Private practice may engage only in certain types of practice within the health care activity that are specified by the decision of the Ministry on the fulfillment of the requirements for engaging in certain types of practice within the health care activity.

(2) The decision of the Ministry referred to in paragraph 1 of this Article shall also specify the work of private practice in one or in two shifts.

Article 61

(1) Private practice may temporarily terminate certain types of medical practice after the notification of the Ministry on the reasons for temporary termination of engagement in such practice.

(2) The Ministry shall issue the decision on temporary termination of engagement in certain types of practice within the health care activity of the private practice referred to in paragraph 1 of this Article.

(3) The temporary termination may last for not longer than 12 months.

(4) The private practice referred to in paragraph 2 of this Article shall notify the Ministry, municipal, or city administration in the territory of seat, as well as the competent association on its resumption in certain types of practice within the health care activity.

Article 62

Private practice shall:

- 1) Provide emergency medical care to all the citizens;
- 2) Participate, upon the invitation from the competent government authority, in the prevention and control of communicable diseases, as well as in protection and rescue of the population in case of natural and other major disasters and emergency situations;
- 3) Carry out continuous quality assurance of its professional work in compliance with law;
- 4) Put up the information on work schedule and adhere to that schedule;
- 5) Put up the pricelist of health services and issue the bill for the provided health services;
- 6) Submit, on regular basis, medical and statistical reports and other records related to health care to the competent institute, or public health institute, in compliance with law;
- 7) Organize, and/or provide measures for disposal and/or destruction of medical waste, in compliance with law.

Article 63

(1) Private practice referred to in Article 56, paragraph 1, Items 1) and 2) of this Law, apart from the requirements laid down by the law and the regulations adopted for enforcements of this Law, in accordance with activity it is engaged in, must also provide constantly available ambulance transport, by concluding the agreement with the closest health care facility that can secure such ambulance transport.

(2) Private practice referred to in paragraph 1 of this Article may provide the laboratory and other additional diagnostics that is required to make the diagnosis for

its own patient, exclusively in the areas of medicine, or dentistry, which represent the basic activity of the private practice specified in the decision of the Ministry concerning fulfillment of the requirements for engagement in certain types of practice within the health care activity of private practice, by concluding the agreement with the closest health care facility or private practice.

(3) A health care facility, or private practice, with which the founder of private practice has concluded the agreement referred to in paragraphs 1 and 2 of this Article, shall admit the patient with the referral by a private practice, or that issued by a health care practitioner employed with that private practice.

(4) The costs of the provision of health care referred to in paragraphs 1 and 2 of this Article shall be borne by the patient.

(5) The funds for the expenses incurred by providing emergency medical care by a private practice shall be provided in compliance with the law.

Article 64

A private practice shall be deleted from the registry in case of:

- 1) Notice of withdrawal;
- 2) Death of the founder of private practice;
- 3) Permanent loss of work capacity of the founder of private practice related to health care activity, by the decision of the competent authority;
- 4) Complete or partial loss of business capacity of the founder of private practice, by the decision of the competent court;
- 5) The founder of private practice concludes an employment contract, or starts any other independent activity as the main occupation, or in case he/she is elected, nominated or appointed to a certain function in a government authority, or an authority of the territorial autonomy or a local self-government unit, for which he/she receives salary;
- 6) The founder fails to start engaging in certain types of practice within the health care activity within 12 months from the date of registration in the registry with the competent authority, in compliance with the law;
- 7) He/she sets up more than one forms of private practice;
- 8) He/she engages in the activity at the time of temporary termination of practice upon the decision of the competent authority;
- 9) He/she is sentenced, more than three times, for engaging in the activity for which he/she fails to fulfill the statutory requirements;
- 10) The measure of the ban on engaging in an activity is brought against him/her because of failing to fulfill the requirement for engaging in that activity, and within the time period specified in the measure handed down, fails to fulfill those requirements, or fails to harmonize the activity;
- 11) For other reasons laid down by the law.

Article 65

(1) The Ministry shall hand down the decision on temporary ban on the work of private practice, if:

1) Private practice fails to meet the statutory requirements with respect to the staff, equipment, premises, and drugs;

2) Practices a health care activity contrary to the decision of the Ministry by which it has been established that the requirements for engaging in certain types of practice within the health care activity have been met;

3) In the procedure of quality assessment of professional work, or exercising supervision over the work of private practice, one of the measures/actions specified by this Law is handed down;

4) It fails to renew the license for independent practice, or if the license for its independent work is revoked, in compliance with this Law;

5) By the decision of the competent body of the association, one of the disciplinary actions concerning the ban on independent practice is brought against the founder of private practice;

6) Puts up the business name, or marks private practice contrary to the decision of the Ministry concerning the fulfillment of the requirements for engaging in certain types of practice within the health care activity;

7) Advertises professional practicing of medical procedures and methods of health care, as well as other health services that are provided in private practice, contrary to the provisions of Article 71 of this Law;

8) For other reasons laid down by the law.

(2) The health inspector shall, upon establishing the facts referred to in paragraph 1 of this Article, hand down the decision on the temporary ban on work of private practice.

(3) A complaint may be filed with the Minister against the decision referred to in paragraph 2 of this Article, within 15 days from the date of receipt of the decision.

(4) The decision of the minister referred to in paragraph 3 of this Article shall be final in the administrative procedure and an administrative suit may be instituted against it.

(5) Private practice may, on the basis of the decision of the Ministry, resume engaging in certain types of practice within the health care activity if it, within the time period laid down by the law, or specified by the decision of the Ministry, eliminates the causes that gave rise to temporary ban on work of private practice.

Article 66

The regulations governing the area of private entrepreneurship shall apply to the work of private practice, unless otherwise regulated by this Law.

3. Evaluation of Health care Technologies

Article 67

(1) In the provision of health care, a health care facility and private practice shall apply scientifically verified, tested, and safe health care technologies for the prevention, diagnosis, treatment, and rehabilitation.

(2) The health care technologies, in the sense of this Law, imply all health care methods and procedures that can be used for the purpose of improvement of the health of people, in prevention, diagnostics, and treatment of diseases, injuries, and in rehabilitation, which include safe, quality, and efficient medicines and medical devices, medical procedures, as well as the conditions for health care provision.

(3) The health care technologies referred to in paragraph 2 of this Article shall be evaluated by the Ministry based on the analyses of medical, ethical, social, and economic consequences and effects of development, spreading or use of health care technologies for health care provision.

(4) For the purpose of assessment of health care technologies, the Minister shall form the Commission for Assessment of health care technologies, as a professional body.

(5) The members of the Commission for Evaluation of health care technologies shall be prominent healthcare professionals who have made a considerable contribution to the development of certain areas of medicine, dentistry, or pharmacy; application and development of health care technologies, and/or in engaging in a health care activity.

(6) The mandate of the members of the Commission for Evaluation of health care technologies shall be five years.

(7) The Commission for Health Care Technologies Evaluation shall adopt its rules of procedure.

(8) Detailed requirements, the method for health care technologies assessment and provision of opinion pursuant to this Law, and other issues regulating in more detail the operation and work of the Commission for Health Care Technologies Evaluation, shall be specified by the Minister.

Article 68

(1) The Commission for Health Care Technologies Evaluation shall:

1) Monitor and coordinate the development of health care technologies in the Republic;

2) Harmonize the development of health care technologies with the goals specified in the Development Plan;

3) Harmonize the development of health care technologies in the Republic with the international standards and experiences;

4) Make assessment of the existing and establish the requirements for introducing new health care technologies required for the provision of health care that is based on the evidence of the quality, safety, and efficiency of the methods and procedures of health care;

5) Participate in the elaboration of national guidelines of best practice for certain areas of health care;

6) Deleted (Official Journal of the RS, No. 57/11)

7) Take care of other affairs in compliance with the foundation act of this Commission.

(2) The Commission for Health Care Technologies Evaluation shall, in the process of evaluation of health care technologies that are based on application of medical equipment containing the sources of ionizing radiation, seek opinion of the Ministry responsible for environmental protection.

(3) In order to assess and offer opinion on issues in Commission jurisdiction pursuant to this Law, the Commission for Health Care Technologies Evaluation can request a professional position of a competent professional commission of the Republic, competent health care institutions, relevant university departments, scientific and research institutions, Government agencies and other authorities or organizations, as well as of recognized experts.

(4) The funds for the work of the Commission for Health Care Technologies Evaluation shall be provided in the budget of the Republic.

Article 69

(1) A health care facility or private practice shall submit the application to the Ministry for issuing of the permit to use new health care technologies.

(2) The new health care technologies, in the sense of this Law, imply the health care technologies that are for the first time introduced for use in the health care facilities in the Republic, or at certain levels of health care, as well as health care technologies that are for the first time used by a certain health care facility or private practice.

(3) The Commission for Health Care Technologies Evaluation shall provide the opinion based on new technologies from the area of medicine that are applied in other highly developed countries, the scientific acceptability of which has been confirmed in medical practice of those countries, and they can be applied in the implementation of health care with us.

(4) On the basis of the opinion of the Commission for Health Care Technologies Evaluation, the Ministry by its decision issues the permit for use of new health care technologies in a health care facility or in private practice.

(5) The decision referred to in paragraph 4 of this Article shall be final in the administrative procedure and an administrative suit may be instituted against it.

(6) The decision referred to in paragraph 4 of this Article shall be submitted to the Accreditation Agency for health care facilities of Serbia, Public Health Institute founded for the territory of the Republic, and the Public Health Institute founded for the territory of the Autonomous Territory Vojvodina for health care facilities founded for the Autonomous Territory Vojvodina.

Article 70

(1) A health care facility or private practice may not use new health care technologies without the permit for use of new health care technologies issued by the Ministry in compliance with this Law.

(2) should a health care facility or private practice use new health care technologies without the permit to use new health care technologies, the Ministry shall issue the decision on the ban on the use of such new health care technologies.

(3) The decision referred to in paragraph 2 of this Article shall be final in the administrative procedure and an administrative suit may be instituted against it.

4. Prohibition of Advertising

Article 71

(1) It is prohibited to advertise, and/or publicize health care services, professional medical procedures and methods of health care, including health services, methods and procedures of the traditional medicine (alternative, homeopathic, and other complementary medicine), practiced in a health care facility, private practice or with other legal entity engaged in health care activity, in the media and on other carriers of advertising messages that are regulated by the law governing the area of advertising (publicizing).

(2) It shall be permitted to advertise the name of a health care facility, or the business name of private practice, seat, activity that is specified by the decision concerning compliance with the requirements for engaging in a health care activity, and to place a notification of working hours.

(3) The results of the implementation of professional medical methods and procedures of health care may be presented only at professional and scientific gatherings and published in professional and scientific journals and publications.

5. Indication of Health Care Facility and Private Practice

Article 72

(1) A health care facility and private practice shall put up the name, or the business name with the data on the activity that is specified by the decision concerning fulfillment of the requirements for engaging in a health care activity, working hours, the founder and the seat of a health care facility or private practice, in compliance with the law.

(2) The name of a health care facility or the business name of private practice shall not include the characteristics to which the character of advertising or publicizing could be attributed.

(3) The minister shall specify the method of interior and exterior marking of a health care facility and private practice.

6. Keeping Medical Documentation and Records

Article 73

(2) A health care facility, private practice, institutions of social protection, penitentiary institutions, medical faculties that are engaged in certain type of practice within the health care activity, as well as other legal persons that are engaged in certain types of practice within the health care activity in compliance with the law, shall keep medical documentation and records and in the specified timeframes submit individual, summary, and periodic reports to the competent institute of public health, as well as to other organizations in the manner laid down by a separate law.

(2) Confidentiality shall be guaranteed concerning the data from the medical documentation of patients that is processed and submitted for individual, summary, and periodic reports referred to in paragraph 1 of this Article, and/or that are processed for the medical documentation and records.

(3) A health care facility, private practice, as well as other legal entities referred to in paragraph 1 of this Article shall safeguard the medical documentation of patients from unauthorized access, copying, and abuse, irrespective of the form in which the data from the medical documentation are kept (paper, microfilm, optical and laser disks, magnetic media, etc.), in compliance with the law.

(4) Keeping medical documentation and recording data in the medical documentation shall be exclusively performed by authorized persons, in compliance with the law.

(5) The types and contents of the medical documentation and records, the manner and the procedure for their keeping and recording, the persons authorized to keep medical documentation and record data, the timeframes for submitting and processing of data, the manner of disposing of the data from the medical documentation of patients that is used for data processing, as well as other issues of importance for keeping medical documentation and records, shall be regulated by a separate law.

7. Integrated Health Care Information System

Article 74

(1) The integrated health care information system in the Republic shall be organized and developed for the purpose of planning and efficient management of the health care system, as well as of acquisition and processing of data related to the state of health of the population and functioning of the health service, or acquisition and processing of health care information.

(2) The program for the integrated health care information system operation, development and organization, and the contents of health care information referred to in paragraph 1 of this Article, shall be adopted by the Government.

8. Schedule of Work, Working Hours and Health Care during Strike

Article 75

(1) Weekly work schedules, opening and closing times of a health care facility and private practice, shall be established depending on the type of the health care facility

or private practice, as well as on the type of the health care activity they are engaged in, in accordance with the needs of the citizens and the organization of work of other health care facilities and private practices in a certain territory.

(2) Weekly work schedules, opening and closing times of a health care facility, or private practice, shall be specified by the founder, and in case of the health care facilities founded by the Republic – by the Ministry.

(3) A health care facility, and a private practice, founded in private ownership shall inform the municipality, or the city in the territory of seat, about the weekly work schedule, and opening and closing times.

(4) Weekly work schedules, opening and closing times of a health care facility and private practice at the time of epidemics and elimination of the consequences caused by natural and other major disasters and emergency situations shall be specified by the Minister, and those of the health care facilities and private practices located in the territory of autonomous province shall be specified based on the proposal of the a government authority of the province responsible for health affairs.

(5) During a strike, a health care facility shall, depending on the activity, ensure the minimum work process, which shall include: continuous and unhindered regular vaccination according to the established schedules; implementation of hygienic and epidemiological measures in case of a break out threat, or in the course of an epidemic of a communicable disease; diagnosis and therapy including the transport of patients, emergency and acute diseases, states and injuries; collecting, treatment, processing of and giving blood and blood products; supply with essential medicines and medical devices; health care of and providing meals to hospitalized patients, and other forms of necessary medical care.

(6) Strike organizing in health care facilities providing emergency medical care is prohibited.

(7) The minimum work process during the strike referred to in paragraph 5 of this Article, by types of state owned health care facilities, shall be specified in detail by the Government.

9. Organization of Work of Health Care Facilities and Private Practices

Article 76

(1) A health care facility shall, within the established weekly work schedule and working hours, provide health care by working in one, two or more shifts, in accordance with the activity of the health care facility, on which the decision will be handed down by the director of the health care facility.

(2) Private practice shall, within the established weekly work schedule and working hours, provide health care in one or in two shifts, in accordance with the decision of the Ministry referred to in Article 60, paragraph 2 of this Law.

10. Overtime Work in a Health Care Facility

Duty Hours

Article 77

(1) A health care facility may introduce duty hours as overtime work if it is not in a position to provide health care by organizing work in shifts referred to in Article 76 of this Law or by rescheduling working hours.

(2) During the duty hours, a health care practitioner must be present in the health care facility.

(3) The duty hours referred to in paragraph 1 of this Article may be introduced during night, national holidays, and on Sundays.

(4) The duty hours that are introduced during night shall start after the second shift and end at the beginning of the work of the first shift.

(5) The decision on the introduction and number of duty hours on the level of a health care facility, as well as per health care practitioner, shall be made by the director of the health care facility.

(6) Duty hours of a health care practitioner may not last longer than ten hours per week.

(7) Exceptionally from paragraph 6 of this Article, the director of the health care facility may specify longer duty hours, up to 20 hours a week, for a specific health care professional depending on the activity of the health care facility, available staff, and the organization of the health service in the territory covered by the health care facility.

(8) The Ministry shall approve the decision referred to in paragraph 7 of this Article, with the previously obtained opinion from the competent public health institute.

(9) The health care practitioner for whom duty hours have been introduced by the decision of the director of the health care facility shall be entitled to increased income earnings for duty hours as overtime work, in compliance with the law and labor regulations.

Standby Hours and On-Call Hours in a Health Care Facility

Article 78

(1) Duty hours, in the sense of this Law, shall also imply both standby hours and on-call hours.

(2) A health care facility may introduce both standby hours and on-call hours.

(3) Standby hours is a special form of overtime work whereby a health care practitioner does not have to be present in the health care facility, but must be constantly available for the purpose of providing emergency medical care in the health care facility.

(4) On-call hours is a special form of overtime work whereby a health care practitioner does not have to be present in the health care facility, but must respond to the call for the purpose of providing health care.

(5) The decision on the introduction and the scope of standby hours and on-call hours shall be made by the director of the health care facility.

(6) Health care practitioners who are engaged in the types of practice referred to in paragraphs 3 and 4 of this Article shall be entitled to increased income earnings in compliance with the law and labor regulations.

B. ACTIVITY AND ORGANIZATION OF HEALTH CARE FACILITIES

1. Common Provisions

Article 79

Health care activity shall be provided on the primary, secondary, and tertiary levels.

Article 80

A health care facility shall:

1) Monitor the state of health of the population in the territory for which it has been founded and undertake and propose measures for its improvement;

2) Monitor and implement methods and procedures of evidence-based prevention, diagnosis, treatment, and rehabilitation, and in particular the established professional, methodological, and doctrinaire protocols;

3) Organize the provision of health care extended by nurses, medical technicians or midwives

4) Provide conditions for continuous professional advancement of its employees;

5) Implement the health care programs;

6) Implement measures for the purpose of prevention of undesired complications and outcomes while providing health care, as well as the public safety measures during the stay of the citizens in health care facilities, and ensure continuous control of such measures;

7) Organize and implement the measures of continuous improvement of the quality of professional work;

8) Organize and implement the measures in case of natural and other major disasters and emergency situations;

9) Organize, and/or provide measures for collection and/or disposal of medical waste, in compliance with the law;

10) Administer other affairs, in compliance with the law.

Article 81

(1) An institute, public health institute, clinic, institute, clinical hospital, and clinical center, shall, in addition to the practices referred to in Article 80 of this Law:

1) Investigate and detect root causes, onset and spreading of diseases, and/or injuries, and methods and measures for their prevention, control, early detection and efficient and timely treatment and rehabilitation;

2) Test and propose introduction of new methods of prevention, diagnosis, treatment, and rehabilitation;

3) Participate in establishing professional medical and doctrinaire positions and provide professional and methodological assistance in their implementation;

4) Organize and implement practical training in the course of education and professional advancement of health care practitioners and medical associates;

5) Participate in the implementation of external quality assurance of professional work in other health care facilities and private practice;

6) Organize and implement other measures, in compliance with the law.

(2) A clinic, which is an organizational part of a clinical hospital or clinical center, and an institute, which is an organizational part of the clinical center, shall engage in the practices referred to in paragraph 1 of this Article and shall meet the requirements laid down by this Law concerning a clinic, or an institute.

Referential Health Care Facilities

Article 82

(1) For the purpose of engaging in health care practices, implementation, monitoring, and improvement of a common doctrine and methodology for the prevention, diagnosis, treatment, and rehabilitation of diseases in certain areas of health care, the Minister shall, by decision, designate the referential health care facilities for certain areas of the health care activity that meet the requirements laid down by this Law.

(2) The referential health care facilities, apart from the requirements referred to in Article 49 of this Law, shall also meet the following requirements:

1) Possess an organized service, and/or adequate staff to monitor and propose new health care technologies, study and evaluate health care and health service in the territory for which they have been founded;

2) Apply the latest achievements of medical science and practice;

3) Have recognized results in fundamental and applied scientific and research work;

4) Have recognized results in the area of professional advancement, postgraduate improvement, specialization and subspecialization in the area of health care activity for which they the referential ones.

Pharmaceutical Health care Activity

Article 83

(1) Health care facilities engaged in the health care activity on the primary, secondary, and tertiary level shall also engage in the practices of the pharmaceutical health care activity, under the conditions laid down by this Law.

(2) The pharmaceutical health care activity, in the sense of this Law, shall imply responsible supply with drugs and certain types of medical devices to the population, health care facilities and private practices, by providing rational pharmacotherapy for the purpose of treatment, improvement, and maintaining the quality of life of the patients by graduate pharmacists, or graduate specialist pharmacists in cooperation with other health care practitioners, as well as a continuous process of improvement of the use of medicines and certain types of medical devices, and/or monitoring undesired reactions to medicines and medical devices.

(3) The pharmaceutical health care activity shall be conducted as set out by this Law, the Law regulating the filed of pharmaceuticals and medical devices, the Law governing health insurance, and in compliance with the Good Pharmacy Practice.

(4) The Good Pharmacy Practice set out in paragraph 3 of this Article shall comply with this Law, and the Law regulating the filed of pharmaceuticals and medical devices, the Law governing health insurance, and in compliance with current developments of the pharmaceutical profession.

(5) The Good Pharmacy Practice shall be generated by the Pharmaceutical Chamber of Serbia which activity shall be approved by the Minister.

(6) Detailed requirements with respect to the staff, equipment, premises, and drugs, as well as the method of engaging in the pharmaceutical health care activity shall be specified by the Minister.

Article 84

(1) The pharmaceutical health care activity shall include:

1) Implementation of preventive measures for health preservation and care of the population, and/or health promotion;

2) Improvement of pharmacotherapeutic measures and procedures for rational use of medicines and certain types of medical devices;

3) Rationalization of expenses incurred due to the implementation of established therapeutic protocols;

4) Monitoring of undesired reactions to medicines and medical devices, as well as avoidance or reduction of such reactions;

5) Avoidance of interactions of therapeutic duplication in administering medicines;

6) Other affairs of the pharmaceutical health care activity, in compliance with the law.

Article 85

(1) The pharmaceutical health care activity shall be practiced in a pharmacy as an independent health care facility, in a dedicated organizational unit of an inpatient health care facility (hereinafter referred to as: the hospital pharmacy), or in another organizational unit of the health care facility supplying medicines and certain types of medical devices.

(2) Specified practices of the pharmaceutical health care activity shall also be implemented in a pharmacy set up as a private practice, under the conditions laid down by this Law and bylaws adopted for enforcement of this Law.

(3) The pharmaceutical health care activity shall be practiced by a graduate pharmacist, or a graduate specialist pharmacist (hereinafter referred to as: the pharmacist) or by a pharmaceutical technician who has graduated from the relevant secondary medical school.

Article 86

(1) In performing the pharmaceutical health care activity, the pharmacist shall not:

1) Engage in retail trade of unauthorized medicines and medical devices, in compliance with the law;

2) Issue, or sell a prescription medicine without submitted doctor's prescription and/or other medical documentation specified by law;

3) Engage in retail trade of medicines and medical devices produced by a legal entity which does not have the production license, and/or medicine production at a licensed pharmacy, as well as those procured from a legal entity having no wholesale permit for medicines and medical devices;

4) Engage in retail trade in medicines and medical devices that are not labeled in compliance with the law;

5) Engage in retail trade in medicines and medical devices that do not have relevant documentation on their quality;

6) Engage in retail trade in medicines and medical devices past the expiry date indicated on the packaging, or those for which deficiency in quality has been established;

7) Engage in retail trade in medicines and medical devices on the Internet.

(2) Retail trade in medicines and medical devices, in the sense of this Law, includes ordering, storage, issuing on prescription/order or without prescription, as well as sale of medicines and medical devices, and/or manufacture of galenic and magistral preparations.

Article 87

In the pharmaceutical health care activity, a pharmaceutical technician shall not:

1) Engage in the pharmaceutical health care activity without the presence of a pharmacist;

2) Issue, and/or sell prescription medicines as well as those containing narcotics, or specified medical devices;

3) Manufacture galenic, and/or magistral preparations on his/her own.

Primary, Secondary, and Tertiary Health Care Activity

Article 88

(1) The health care activity on the primary level shall include:

1) Protection and improvement of health, prevention and early detection of diseases, treatment, rehabilitation of the diseased and injured;

2) Preventive health care of population groups exposed to increased risk of contracting diseases and other citizens, in accordance with the specific preventive health care program;

3) Health education and counseling for health preservation and improvement;

4) Prevention, early detection, and control of malignant diseases;

5) Prevention, detection, and treatment of diseases of the oral cavity and teeth;

6) Home care, treatment, and rehabilitation in patient's home;

7) Prevention and early detection of diseases, health care and rehabilitation of persons placed in institutions of social protection;

8) Emergency medical care and ambulance transport;

9) Pharmaceutical health care;

10) Rehabilitation of children and young adults with physical and mental disorders;

11) Protection of mental health;

12) Palliative care;

13) Other issues specified by law.

(2) In engaging in the health care activity on the primary level, health care facilities cooperate with other health care, social welfare, educational, and other facilities and organizations in preparing and implementing programs for health preservation and improvement.

Article 89

(1) Any specialist and consulting activity may be practiced at the outpatient department and other health care facility on the primary level.

(2) Such specialist and consulting activity performed at the primary level must have in place, for its own purposes, adequate laboratory and other diagnostic procedures.

(3) An outpatient department, and other primary level health care facilities, shall be interconnected, professionally and organizationally, in their engagement in the specialist and consulting activity with the relevant secondary level health care facility.

Article 90

(1) Secondary level health care activities include specialist, consulting and hospital health care activities.

(2) Secondary level specialist and consulting activities include, compared to primary level health care activities, more complex measures and procedures for detecting diseases and injuries and treatment and rehabilitation of the diseased and injured.

(3) Hospital health care activity shall include diagnosis, treatment, and rehabilitation, inpatient health care, as well as the pharmaceutical health care activity in the hospital pharmacy.

Article 91

(1) The tertiary level health care activities include the provision of the most complex forms of health care, specialist-consulting and hospital health care as well as scientific-research and educational activities, in compliance with the law governing the scientific-research and/or educational activity.

(2) The tertiary level health care activities also include engaging in the pharmaceutical health care activity in the hospital pharmacy.

Article 92

(1) By decision, the Minister shall designate the tertiary level health care facility specialized for the activities of the Republic poison control center.

(2) The Poison Control Center referred to in paragraph 1. of this Article shall: collect and process the data on the effect of toxic chemicals and natural poisons; keep the register of incidents of poisoning; participate in the formation and supervision over the central stocks of antidotes in the Republic; provide information and advice related to acute poisonings to the health care facilities, private practices, health care practitioners, as well as to other legal and natural persons; perform testing and apply new methods of prevention of poisoning; establish professional medical and doctrinaire positions related to the protection from poisoning, as well as providing medical assistance and elimination of the consequences of poisoning.

(3) The Poison Control Center must include an information center for collecting and processing data within its scope of activity.

(4) The Poison Control Center shall also have a toxicological laboratory and the inpatient health care service.

(5) A health care facility and private practice shall submit the data on cases of poisoning to the Poison Control Center, in compliance with the law.

(6) The Poison Control Center shall, by March 31 of the current year, submit the acquired data on poisoning with chemicals for the previous year to the Ministry, as well as to the ministry in charge of the affairs of chemicals management.

(7) The method of acquisition, processing, and storage of data on poisoning and effects of toxins/poisons, as well as the scope and contents of the data submitted to the competent ministries referred to in paragraph 6 of this Article, shall be jointly

specified by the Minister and the minister in charge of the affairs of chemicals management.

Article 92

(1) The tertiary health care institutions operating as centers for specific types of rare diseases (hereinafter: Center for Rare Diseases) shall be appointed by the ministerial decision.

(2) The Center for Rare Diseases shall involve the diagnostic procedures for patients with rare diseases, prenatal, and neonatal screening, genetic consulting, management of patients with rare diseases, keeping the registry of patients suffering from rare diseases in the territory of the Republic of Serbia pursuant to law, professional relationship with international reference centers for diagnosing and treatment of rare diseases, and with the network of European and global organizations for rare diseases, continual education in rare diseases, and other activities for improving diagnosis and treatment of patients suffering from rare diseases.

(3) Based on the Decision of the Minister, The Center for Rare Diseases can conduct other activities in order to improve diagnosis and treatment of patients suffering from rare diseases..

(4) The in-house organization, activities and other issues of importance for the operation of the Center for rare Diseases are specified in more details by the articles of association of health care institutions set out in paragraph 1 of this Article.

(5) Health care facilities, or private practice, or other legal entities dealing with health care set out by this Law shall, pursuant to law, submit to the Center for Rare Diseases the data on number, type, diagnosed, or treated patients suffering from rare diseases, and other data necessary for keeping the register of patients with rare diseases set out in paragraph 2 of this Article.

Article 93

(1) Apart from the health care facilities that are engaged in the health care activity on the tertiary level, educational activity may also be practiced in the facilities of the primary and secondary levels of health care.

(2) A health care facility may engage in educational activity should it conclude an agreement with the relevant school, or faculty.

(3) The requirements that a health care facility must meet in order to provide practical training of medical pupils and students shall be jointly specified by the minister and the minister in charge of the affairs of education.

2. Primary Level Health Care Activity

Outpatient Department

Article 94

(1) An outpatient department is a health care facility that is engaged in a health care activity on the primary level.

(2) A state owned outpatient department shall be founded for the territory of one or several municipalities, or a city, in compliance with the Plan of the Network.

(3) A state owned outpatient department shall be founded by a municipality or city.

(4) The founder of a state owned outpatient department that has been founded for the territory of several municipalities shall be the municipality of the seat of the outpatient department.

Article 95

(1) An outpatient department is a health care facility that provides minimum preventive health care to all categories of the population, emergency medical care, general medicine, health care of women and children, home care service, as well as laboratory and other diagnostics.

(2) An outpatient department shall also provide prevention and treatment in the area dental health care, health care of the working population, or occupational medicine and physical medicine and rehabilitation, unless such health care has not been organized in another health care facility in the territory for which the outpatient department has been founded.

(3) An outpatient department shall also provide ambulance transport if such service is not available in a hospital or any other health care facility in the territory for which the outpatient department has been founded.

(4) An outpatient department shall also engage in the pharmaceutical health care activity, in compliance with this Law.

(5) If a municipality has an outpatient department and a general hospital that are state owned, the laboratory, radiological, and other diagnostics may be established in one of them.

Article 96

(1) Depending on the number of citizens in a municipality as well as on their health needs, distance to the nearest general hospital, and/or existence of other health care facilities in the municipality, an outpatient department may also provide other specialist and consulting services unrelated to hospital care, in accordance with the Plan of the Network.

(2) Exceptionally, maternity hospital and inpatient clinic for diagnosis and treatment of acute and chronic diseases can be included within an outpatient department in areas with specific health care needs and where transport and geographic conditions are such to justify that, and in accordance with the Plan of the Network.

Article 97

(1) For the purpose of availability of health care outpatient, health care units and offices can be included in an outpatient department, in accordance with the Plan of the Network.

(2) As a minimum, a health care office provides emergency medical care, general medicine services, and pediatric health care.

(3) As a minimum, a health care unit provides general medicine services.

Article 98

(1) The primary health care shall be provided to the citizens in an outpatient department by the chosen physician.

(2) The chosen physician shall be:

1) A medical doctor or a specialist physician (general medicine) a specialist in occupational medicine;

2) A medical doctor specialist in pediatrics;

3) A medical doctor specialist in gynecology;

4) A doctor of dental medicine or a dental medicine doctor specialist in pediatric dentistry.

(3) The chosen physician shall provide health care together with a health technician of adequate medical qualifications.

(4) Exceptionally from paragraph 2 of this Article, the chosen physician may also be a medical doctor of some other specialty, under the conditions specified by the Minister.

Article 99

(1) The chosen physician shall:

1) Organize and implement measures for health preservation and improvement of individuals and families;

2) Work on detection and control of risk factors for onset of diseases and/or the screening programs as specified by specific programs adopted pursuant to this Law;

3) Administer diagnosis and timely treatment of patients;

4) Provide emergency medical care;

5) Refer patients to a relevant health care facility or to a specialist doctor based on medical indications and harmonize the opinions and proposals for the continuation of treatment of the patient;

6) Provide home care and palliative management, as well as treatment of patients who do not require hospital treatment;

7) Prescribe drugs and medical devices;

8) Provide health care in the area of mental health;

9) Carry out other assignments in compliance with the law.

(2) In the process of exercising health care, the chosen physician shall refer the patient to the secondary and tertiary levels.

(3) Based on the opinion of a medical specialist in the relevant branch of medicine, the chosen physician shall refer the patient to the tertiary level.

(4) The chosen physician shall keep full medical documentation on the patient's health conditions.

(5) The health care provision by the chosen physician is regulated by the law governing health insurance.

Pharmacy

Article 100

(1) A pharmacy is a health care facility providing primary level pharmaceutical health care.

(2) A state owned pharmacy shall be founded for the territory of one or several municipalities, or a city, in accordance with the Plan of the Network.

(3) A state owned pharmacy shall be founded by a municipality or a city.

(4) The founder of a state owned pharmacy founded for the territory of several municipalities, shall be the municipality of the seat of the pharmacy.

(5) A pharmacy provides pharmaceutical health care including:

1) Health promotion, and/or health education and counseling on health preservation and improvement by proper use of medicines and certain types of medical devices;

2) Retail of medicines and certain types of medical devices, on the basis of plans for procurement of medicines and medical devices for regular and emergency supply;

3) Monitoring of advanced professional and scientific developments in the area of pharmacotherapy and providing to the citizens, health care practitioners, other health care facilities and private practice, as well as to other interested subjects, information on medicines and types of medical devices;

4) Offering advice to patients concerning proper use of medicines and certain types of medical devices, and/or instructions for their proper use;

5) Manufacture of magistral preparations;

6) Other affairs, in compliance with the law.

Article 101

(1) The pharmacy referred to in Article 100 of this Law may have within its complement a galenic laboratory for the preparation of galenic products (hereinafter referred to as: the licensed pharmacy), in accordance with the regulations governing the area of medicines and medical devices.

(2) A galenic preparation prepared in a licensed pharmacy may be sold in retail in such pharmacy, or another pharmacy unequipped with a galenic laboratory within its complement, and with which the licensed pharmacy has concluded the agreement on retail trade in galenic preparations.

(3) A pharmacy may organize branches of pharmacy units for dispensing the officinal medicines.

(4) A pharmacy shall put out on a prominent place the name of the licensed pharmacist, who shall be responsible for the entire handling of drugs, and/or making of galenic remedies and magistral preparations, in compliance with the law governing the area of medicines and medical devices.

(5) In addition to retail trade in medicines and medical devices, a pharmacy may also supply citizens with baby food, dietary products, certain kinds of toiletries and other items for health care, in accordance with the enactment adopted by the competent association.

Institute

Article 102

(1) An institute is a health care facility that is engaged in the health care activity on the primary level and provides health care to certain groups of the population, or health care activity in certain areas of health care.

(2) An institute can be founded as:

- 1) Students' Health-Care Institute;
- 2) Employees' Health-Care Institute;
- 3) Emergency Medical Care Institute;
- 4) Gerontology and palliative care institute;
- 5) Dentistry Institute;
- 6) Lung Diseases and Tuberculosis Institute;
- 7) Skin And Venereal Diseases Institute.

(3) The institute referred to in paragraph 2 of this Article may also engage in the specialist and consulting activity.

(4) The state owned institute referred to in paragraph 2 of this Article may be founded only in the territory of seat of a university having, within its complement, a medical faculty, in accordance with the Plan of the Network.

(5) The institute referred to in paragraph 4 of this Article shall be founded by a city, except for the Health Care of Employees Institute of the Ministry of Interior, which shall be founded by the Republic.

Article 103

(1) The students' health care institute is a health care facility that provides health care to students organizing preventive and curative health care in the area of general medicine, dentistry, gynecology, laboratory and other diagnostics and therapy for this category of population.

(2) The students' health care institute may also engage in specialist and consulting activity, as well as inpatient health care activity.

(3) Health care of students may also be provided in a outpatient department, in compliance with the law.

Article 104

(1) The employees health care institute is a health care facility that provides health care and preservation of health of employees in a safe and healthy working environment, by engaging in the activity of occupational medicine.

(2) The employees health care institute may also engage in preventive and curative health care activities in the areas of general medicine, dentistry, gynecology, as well as in specialist and consulting activity.

(3) An employer may set up an outpatient unit for occupational medicine for his/her employees' needs, which shall provide preventive health care services in the area of occupational medicine.

(4) The requirements for setting up, commissioning and provision of services of an outpatient unit for occupational medicine referred to in paragraph 3 of this Article shall be specified by the Minister.

Article 105

The emergency medical care institute is a health care facility that provides emergency medical care and ambulance transport of the acutely ill and injured to other relevant health care facilities, transport of patients on dialysis, as well as supply with medicines needed in emergency cases.

Article 106

The gerontology and palliative care institute is a health care facility that provides health care to elderly persons and implements measures for preservation and improvement of health and prevention of diseases among this group of population, and/or home treatment and care, palliative care and rehabilitation of elderly persons.

Article 107

(1) The dentistry institute is a health care facility dealing with health care in the area of dental medicine, including preventive, diagnostic, therapeutic, and rehabilitation health services.

(2) The dentistry institute may also engage in specialist and consulting activity in the area of dentistry.

Article 108

(1) The lung diseases and tuberculosis institute is a health care facility that is engaged in specialist and consulting activity providing preventive, diagnostic, therapeutic, and rehabilitation health services in the area of health care of patients who have contracted tuberculosis and other lung diseases that may be treated in outpatient units.

(2) Within its preventive health care domain, the lung diseases and tuberculosis institute shall organize and implement the measures for the prevention, control, early detection, and monitoring of tuberculosis and other lung diseases.

Article 109

(1) The skin and venereal diseases institute is a health care facility that is engaged in specialist and consulting activity providing preventive, diagnostic, therapeutic, and rehabilitation health services in the area of dermatovenerology and microbiology including parasitology.

(2) Within its preventive health care domain the skin and venereal diseases institute shall provide preventive health care activity, organize and implement the measures for prevention, control, early detection, and monitoring of sexually transmitted infections.

3. Secondary Level Health Care

Hospital (General and Specific)

Article 110

(1) A hospital is a health care facility that is engaged in health care activity on the secondary level.

(2) As a rule, a hospital is engaged in health care activity as a continuation of diagnostics, treatment and rehabilitation in an outpatient department, i.e. when, due to complexity and seriousness of a disease, special conditions are required with respect to the staff, equipment, accommodation, and medicines.

(3) A hospital shall cooperate with an outpatient department and provide it with professional assistance in the implementation of measures of the primary health care.

(4) The inpatient and specialist and consulting activity of the hospital shall make single functional and organizational unity.

(5) A hospital shall organize its work in such a way that the majority of patients is tested and treated within a polyclinic, and provide inpatient treatment to the diseased and injured persons only when necessary.

(6) A hospital may have, or establish special organizational units for extended hospital care (geriatrics), palliative management of the diseased in the terminal stage of illness, as well as day treatment of the diseased (day hospital).

(7) A hospital may be general and specialty hospital.

Article 111

(1) A general hospital shall provide health care to the persons of all ages suffering from different types of diseases.

(2) A state owned general hospital shall be founded for the territory of one or more municipalities.

(3) As a minimum, a general hospital must have organized services for:

- 1) Admittance and management of emergency states;

2) Engaging in the specialist and consulting and inpatient health care activity in internal medicine, pediatrics, gynecology and obstetrics, and general surgery;

3) Laboratory, radiographic, and other diagnostics in accordance with its activity;

4) Anesthesiology with resuscitation;

5) Rehabilitation unit;

6) Pharmaceutical health care provided by hospital pharmacies.

(4) A general hospital must also provide either on its own or through another health care facility:

1) Ambulance transport for patients' referral to a secondary or tertiary level facility;

2) Supply with blood and blood products;

3) Pathological anatomy department.

(5) A general hospital may also engage in specialist and consulting activities of other branches of medicine.

(6) A general hospital founded for the needs of several municipalities, as well as a regional hospital, can, in addition to the services specified in paragraph 3 of this Article, also engage in the hospital health care activity of other branches of medicine.

Article 112

(1) A specialty hospital shall provide health care to the persons of certain age groups, or to those suffering from certain diseases.

(2) A specialty hospital shall engage in the specialist, consulting, and inpatient health care activity in the field for which it has been founded, laboratory and other diagnostics, as well as the pharmaceutical health care activity through the hospital pharmacy.

(3) A specialty hospital, in accordance with the activity it is engaged in, must also provide either on its own or through another health care facility:

1) Ambulance transport for patients' referral to a secondary or tertiary level facility;

2) Supply of blood and blood products;

3) Pathological anatomy department.

Article 113

(1) A specialty hospital that, in the provision of health care, uses a natural factor of treatment (gas, mineral water, peloid, etc.) shall, in the course of use of the natural factor, monitor its therapeutic properties and, at least once in three years, repeat testing of its therapeutic qualities in a relevant health care facility.

(2) The specialty hospital referred to in paragraph 1 of this Article may also provide the services in tourism, in accordance with the regulations governing the area of tourism.

Article 114

A hospital founded by the Republic or an autonomous province shall be connected and cooperate with primary level facilities in the territory for which it has been founded, with the aim to establish and maintain appropriate referral of patients to secondary level health care facilities and exchange professional knowledge and experience.

4. Tertiary Level Health Care

Clinic

Article 115

(1) A clinic is a health care facility engaged in highly specialized specialist and consulting and inpatient health care activity in a specific branch of medicine, or dentistry.

(2) A clinic shall also engage in educational and scientific and research activity, in compliance with the law.

(3) A clinic, in accordance with the activity it is engaged in, shall also meet the requirements referred to in Article 111, paragraphs 3 and 4 of this Law.

(4) A clinic may be founded only at the seat of a university with a medical school as one of its parts.

(5) A state owned clinic can also engage in the relevant activity of a general hospital for the territory for which it has been founded if there is no general hospital in the territory.

Institute – Center of Excellence

Article 116

(1) An institute – center of excellence is a health care facility that is engaged in a highly specialized specialist and consulting and inpatient health care activities, or only a highly specialized specialist and consulting health care activity in one of several branches of medicine or dentistry.

(2) An institute – center of excellence is engaged in educational and scientific and research activity, in compliance with the law.

(3) In addition to the requirements laid down by this Law concerning engaging in health care activity, an institute – center of excellence shall also meet the requirements that are laid down by the law governing the area of scientific and research activity.

(4) An institute – center of excellence, in accordance with the activity it is engaged in, shall also meet the requirements referred to in Article 111, paragraphs 3 and 4 of this Law.

(5) An institute – center of excellence may be founded only in the seat of a university with a medical school as one of its parts.

(6) A state owned institute – center of excellence can also engage in the relevant activity of a general hospital for the territory if there is no general hospital in the territory.

Clinical Hospital

Article 117

(1) A clinical hospital is a health care facility that is engaged in a highly specialized specialist and consulting and inpatient tertiary level health care activity in one or several branches of medicine.

(2) In addition to the requirements specified by this Law concerning general hospital, a clinical hospital shall also meet the requirements for a clinic pursuant to this Law.

(3) A clinical hospital may only be founded in the seat of a university with a medical school as one of its parts.

(4) A state owned clinical hospital can also engage in the relevant activity of a general hospital for the territory if there is no general hospital in the territory.

Clinical Center

Article 118

(1) A clinical center is a health care facility that combines the activities of three or more clinics, in such a way that it makes a functional unit organized and capable for efficient performance of tasks and duties:

1) Engaging in a highly specialized specialist and consulting and inpatient health care activity;

2) Educational and teaching activities;

3) Scientific and research activity.

(2) A clinical center is engaged in a specialized polyclinic and hospital health care activities in several branches of medicine, and/or areas of health care.

(3) A clinical center may be founded only in the seat of the university with a medical school as one of its parts.

(4) A state owned clinical center can also engage in the relevant activity of a general hospital for the territory if there is no general hospital in the territory.

5. Combined-Level Health Care

Public Health Institute

Article 119

(1) A public health institute shall be founded by the Republic and an autonomous province for their respective territories.

(2) The public health institute is a health care facility that is founded for the territory of several municipalities, or a city, as well as for the territory of the Republic, in accordance with the Plan of the Network.

(3) Public health, in the sense of this Law, implies the achievement of public interest by creating the conditions for protecting physical and mental health of the population and/or the environment, and prevention the occurrence of risk factors for the onset of diseases and injuries, which is achieved by the implementation of health care technologies and measures intended to promote health, prevent diseases, and improve the quality of life.

Article 120

The public health institute shall:

- 1) Monitor, assess, and analyze the state of health of the population and report to the competent authorities and the public;
- 2) Monitor and study health problems and risks for the health of the population;
- 3) Propose elements of health care policy, plans, and programs with measures and activities intended to preserve and improve the health of the population;
- 4) Disseminate information, provide education, and training of the population for looking after their own health;
- 5) Make assessment of efficiency, accessibility to and quality of health care;
- 6) Plan the development of professional advancement of health care practitioners and medical associates;
- 7) Encourage development of integrated health care information system;
- 8) Carry out applied research in the area of public health;
- 9) Cooperate and develop partnerships in the community for identifying and dealing with health problems of the population;
- 10) Perform other activities, in compliance with the law.

Article 121

(1) The public health institute is a health care facility that is engaged in social-medical, hygienic and ecological, epidemiological, and microbiological health care activities.

(2) The public health institute carries out bacteriological, serological, virological, chemical, and toxicological evaluations and tests related to the production of and trade in foodstuffs, water, air, consumer goods, and the diagnosis of communicable and non-communicable diseases.

(3) The public health institute shall coordinate, harmonize, and professionally correlate the work of health care facilities from the Plan of the Network, for the territory for which it has been founded.

(4) The public health institute shall cooperate with other health care facilities in the territory for which it has been founded, as well as with the competent authorities of the local self-government units and other institutes and organizations of importance for the improvement of public health.

(5) The founder can organize the public health institute as a center of excellence provided that the requirements laid down by Article 116 of this Law have been met.

(6) The public health institute can engage in the practice of disinfection, pest control, and pest extermination if there is no other health care facility engaged in such types of practice in the territory for which it has been founded.

Article 122

(1) In addition to the practices referred to in Articles 120 and 121 of this Law, the public health institute founded for the territory of the Republic, shall also engage in the following types of practices:

1) Coordinate and monitor professional work of the public health institute and other health care facilities engaged in hygienic and epidemiological and social and medical activities in the Republic;

2) Study and in cooperation with other health care facilities, propose long-term health care strategy with priorities, and methodologically manages its implementation, in cooperation with the medical faculties;

3) Establish the necessary measures in natural and other major disasters and emergencies and implement them in cooperation with other institutions.

(2) The method and procedure, as well as the requirements for organization and implementation of public health shall be regulated by a separate law.

Blood Transfusion Institute

Article 123

(1) A blood transfusion institute is founded by the Republic and an autonomous province for their respective territories.

(2) A blood transfusion institute is a health care facility engaged in blood and blood plasma collection for processing, performing blood tests, in meeting the demand for blood derivative products and medicines produced from blood, distribution of blood derivative products, diagnostic tests, therapeutic procedures, control and supervision of the transfusiological treatment, collection of stem cells, typification of tissues, consultations in clinical medicine, as well as promotion and organization of voluntary blood donation.

(3) A blood transfusion institute may be founded only in the seat of the university with a medical school as one of its parts.

(4) A blood transfusion institute shall establish a uniform doctrine, ensure its implementation and professional liaison with the blood transfusion services in inpatient health care facilities.

(5) Supply of blood and blood derivative products shall be provided by blood transfusion institutes and blood transfusion services in inpatient health care facilities.

(6) The blood transfusion institute, in cooperation with the Red Cross of Serbia, shall stimulate and organize activities of popularization of voluntary blood donation, implementation of programs of collection of blood, and those of planning the demand for blood-derived medication.

(7) In addition to the duties referred to in paragraph 2, 4, 5, and 6 of this Article, the blood transfusion institute founded for the territory of the Republic shall also perform other activities pursuant to the law governing the area of blood transfusion.

(8) The founder may organize a blood transfusion institute as a center of excellence provided the requirements laid down by Article 116 of this Law are met.

(9) The method and procedure, as well as the conditions and organization of transfusiological activities, shall be regulated by a separate law.

Occupational Medicine Institute

Article 124

(1) The occupational medicine institute for the territory of the Republic shall be founded by the Republic.

(2) The occupational medicine institute referred to in paragraph 1 of this Article is a health care facility engaged in the activities of occupational medicine, and/or protection of health at work, as follows:

1) Monitors and studies working conditions, organization and implementation of the information system for data collection and monitoring epidemiological situation in the territory of the Republic in the field of occupational diseases, work-related diseases, and accidents at work and proposes measures for their prevention and containment;

2) Plans, organizes, implements, and evaluates measures, activities, and procedures in the area of protection of health at work, establishes professional and medical and doctrinaire positions in the area of occupational medicine, promotion of health at work, and provides professional and methodological assistance in their implementation;

3) Improves organization and work of health care facilities in the area of protection of health at work and coordinates their work;

4) Adopts common methodology and procedures for scheduling, planning, and implementation of measures of preventive care of workers;

5) Introduces and tests new health care technologies and implements new methods of prevention, diagnosis, treatment, and rehabilitation in the area of occupational medicine;

6) Being in track of new achievements in the area of organization of occupational medicine and proposes health care improvement and development standards;

7) Studies all the factors of occupational hazards and their identification, qualification, and assessment;

8) Conducts physical and other examinations and measurements related to ionizing and non-ionizing radiation in health care, and/or provides radiological health care;

9) Implements professional medical procedures and activities related to job specifications, high risk jobs and/or jobs for which contribution period is calculated with increased duration;

10) Proposes and implements preventive checkups of workers working at workplaces with increased hazard;

11) Proposes and implements criteria for the assessment of fitness for driving motor vehicles;

12) Assesses the capacity for work of those suffering from occupational diseases, work-related diseases, consequences of accidents at work and outside work, assesses the capacity for work and overall vitality, assesses physical disability and performs other expert evaluations related to capacity for work of employees;

12) Provides the diagnosis and treatment of occupational diseases, subacute and chronic poisoning, work-associated diseases, and consequences of injuries at work.

13) Performs other duties in the domain of health protection at work, in compliance with the law.

(3) The occupational medicine institute shall also engage in educational activity in the area of protection of health at work.

(4) The founder may organize the occupational medicine institute as a center of excellence provided that the requirements laid down by Article 116 of this Law have been met.

Forensic Medicine Institute

Article 125

(1) A state owned forensic medicine institute shall be founded by the Republic.

(2) The forensic medicine institute is a health care facility engaged in the activities in the area of forensic medicine, i.e. autopsy-based forensic diagnosis and expertise, clinical examinations, and laboratory diagnostics, for the requirements of courts, health care facilities, faculties of medicine, and other persons.

(3) The forensic medicine institute covers as a minimum forensic and chemical and toxicological activities, verification of success of operational and other procedures and means of treatment, as well as verification of diagnoses made.

(4) The forensic medicine institute can also carry out other tasks in the area of forensic medicine.

(5) The forensic medicine institute may be founded only in the seat of a university which includes a medical faculty.

(6) The founder may organize the forensic medicine institute as a center of excellence provided that the requirements laid down by Article 116 of this Law are met.

Virology, Vaccines, and Serums Institute

Article 126

(1) The virology, vaccines, and serums institute shall be founded by the Republic.

(2) The virology, vaccines, and serums institute is a health care facility that monitors and studies, tests, establishes and introduces, and/or implements professional and scientific methods of prevention and diagnosis of communicable diseases, produces serums, vaccines, and other immunobiological and diagnostic preparations and media, which are supplied to the health care facilities in the territory of the Republic.

(3) The virology, vaccines, and serums institute shall participate in establishing and implementation of doctrinaire instructions in the area of prevention and diagnosis of communicable diseases.

(4) The virology, vaccines, and serums institute may be set up only in the seat of a university with a medical faculty as one of its parts.

(5) The virology, vaccines, and serums institute can be founded as a center of excellence provided that the requirements laid down by Article 116 of this Law are met.

Institute for Anti-Rabies Protection

Article 127

(1) The institute for anti-rabies protection shall be founded by autonomous province.

(2) The institute for anti-rabies protection shall be engaged in the health care activity in the area of prevention and laboratory diagnosis of rabies and other communicable diseases, and/or monitor and study the spreading of rabies and propose actions for its control.

(3) The institute for anti-rabies protection shall test and implement new methods of prevention and immunoprophylaxis of rabies, and/or establish professional and medical and doctrinary positions in anti-rabies protection and provide professional and methodological assistance in their implementation.

(4) The institute for anti-rabies protection may also carry out other health care activities.

Institute for Psychophysiological Disorders and Speech Pathology

Article 128

(1) The state owned institute for psychophysiological disorders and speech pathology

shall be founded by the Republic.

(2) The institute for psychophysiological disorders and speech pathology shall be engaged in outpatient and inpatient health care activities in the area of psychophysiological and speech disorders, monitor and study the status of developmental disorders, hearing impairment among children and young adults and speech disorders of persons of all ages, as well as blind and partially sighted preschool age children.

(3) The institute for psychophysiological disorders and speech pathology shall investigate and discover causes and types of disorders and the method and measures for their early detection, efficient and quality treatment, rehabilitation, and prevention of disability.

(4) The institute for psychophysiological disorders and speech pathology shall keep track with and implement professionally and scientifically established methods of diagnosis, treatment, and rehabilitation, and/or establish professional and methodological and doctrinary criteria and coordinate the work of all health care practitioners and medical associates engaged in this health care activity in the territory of the Republic.

(5) The institute for psychophysiological disorders and speech pathology can also carry out other health care activities.

Institute for Biocides and Medical Ecology

Article 129

(1) A stated owned institute for biocides and medical ecology shall be founded by a city.

(2) The institute for biocides and medical ecology shall engage in health care activity related to preventive health care of the population from communicable diseases.

(3) The institute for biocides and medical ecology shall implement the measures of disinfection, pest control, and pest extermination in order to prevent and control communicable diseases in health care and other facilities, in compliance with the law.

(4) The institute for biocides and medical ecology shall establish and monitor the implementation of the common doctrine of the implementation of biocides for the prevention and control of communicable diseases and implement programs of medical ecology by risk assessment in the implementation of biocides.

(5) The institute for biocides and medical ecology can also carry out other activities, in compliance with the law.

Article 129

(1) The Screening Program Administration shall be established for conducting the public administration activities in the field of improvement, organizing and conduct of screening programs, which shall:

1) Propose the adoption of specific health care screening programs, or their amendments;

2) Propose the adoption of standards for conducting the screening programs;

3) Propose the adoption of professional-methodological instructions for conducting the screening programs;

4) Organize and monitor the implementation of the screening programs;

5) Propose to the Minister the measures for improving the organization and operation of health care institutions, or private practices, or other legal entities dealing with health care pursuant to law for conducting the screening programs;

6) Provide professional help to health care institutions, or private practices, or other legal entities dealing with health care pursuant to law, for conducting the screening programs;

7) Establish and conduct the program for continual education for the realization of screening programs;

8) Assess the efficiency of the realization of the screening programs and propose measures for the improvement of public health care in areas where the screening programs are conducted;

9) Participate in the organization and realization of screening program promotion campaigns;

10) Carry out applied research in the domain of screening programs;

11) Performs other activities pursuant to law.

(2) The programs set out in paragraph 1, item 1) of this Article shall be adopted by the Government and acts in paragraph 1, items 2) and 3) shall be adopted by the Minister.

Article 129b

(1) The Screening Program Administration shall be managed by the Director.

(2) The Director is appointed by the Government, based on the proposal by the Minister, for the period of five years, in compliance with the law regulating positions of public officers.

(3) The Director reports to the Minister.

(4) The Director makes administrative decisions within the scope of activity of the Screening Program Administration and decides on employee rights and obligations.

Article 129c

(1) The Director of the Screening Program Administration has several assistants for specified types of screening programs implemented in the Republic of Serbia.

(2) Assistant Directors report to the Director and to the Minister.

(3) Assistant Directors are appointed by the Government, based on the proposal by the Minister, for the period of five years, in compliance with the law regulating positions of public officers.

C. HEALTH CARE FACILITY MANGERIAL AND PROFESSIONAL BODIES

1. Health Care Facility Managerial Bodies

Article 130

(1) The managerial bodies of a health care facility are: director, management board, and supervisory board.

(2) A health care facility can also have a deputy director who will be appointed and relieved under the conditions, in the manner, and according to the procedure specified for the appointment and relieving of a health care facility director.

(3) The director, deputy director, members of the management board, and the supervisory board of a health care facility shall be appointed and relieved by the founder.

(4) The director, deputy director, members of the management board, and the supervisory board of an institute, a clinic, center of excellence, and clinical center, or the Institute for health care of the Ministry of Interior employees, the founder of which is the Republic, shall be appointed and relieved by the Government.

(5) The director, deputy director, members of the management board, and the supervisory board of health care facilities founded by the Republic, except for the facilities referred to in paragraph 4 of this Article, shall be appointed and relieved by the Minister.

(6) The persons referred to in paragraph 3 of this Article in the state owned health care facilities, as well as their kinds by blood in lineal line of descent irrespective of the degree of kinship, kinds by blood in collateral line of descent including the second degree of kinship, spouses and in-laws including the first degree of kinship, shall not, either directly or through a third natural or legal person, have a share as the owners of a share, be shareholders, in legal person who is engaged in a health care activity, or type of practice within the health care activity, and/or must not engage in this activity as entrepreneurs, about which they shall sign a statement for the purpose of prevention of the conflict of public and private interest.

(7) After the expiration of term, the health care facility managerial bodies continue to work pursuant to law and articles of association of the facility until the appointment of new, or temporary bodies.

Director

Article 131

(1) The director shall organize the work and manage the work process, represent and act as proxy of the health care facility and shall be responsible for the legality of work of health care facility.

(2) If the director does not have medical university qualifications, the deputy, or assistant director shall be responsible for the professional and medical work of the health care facility.

(3) The director of a health care facility engaged in educational and scientific and research activities shall appoint his/her assistant for the educational and scientific and research activities.

(4) The director shall submit to the management board a written quarterly, and/or six-monthly report about the business operations of health care facility.

(5) The director shall attend the meetings and participate in the work of the management board, without the right to vote.

Article 132

(1) A director of a health care facility can be a person who:

- 1) has a medical university qualifications or university qualifications of other profession and training in the area of health care management;
- 2) has minimum five years of service in the area of health care;
- 3) meets other requirements specified by the articles of association of the health care facility.

(2) If the person appointed for the director of a health care facility does not have medical but university qualifications of another profession, the deputy or assistant director for the health care activity must be a person who has medical university qualifications.

(3) The director of a health care facility will be appointed on the basis of vacancy publicly announced by the management board of the health care facility.

(4) The publicly announced vacancy referred to in paragraph 3 of this Article shall be announced 60 days prior to expiry of the term of office of the director.

(5) The management board of a health care facility shall choose the candidate within 30 days from the closing date for vacancy announcement and submit the proposal to the founder.

(6) The founder shall appoint the director based on the proposal of the management board within 15 days from the date of proposal.

Article 133

(1) The director of a health care facility shall be appointed for a period of four years, maximum two times in succession.

(2) The mandate of the director of a health care facility shall start from the date of assuming the duty.

Article 134

(1) Should the management board of a health care facility fail to elect the candidate for the director of the health care facility, or should the founder of a health care facility fail to appoint the director of the health care facility, in accordance with the provisions of this Law, the founder shall appoint the acting director for a period of six months.

(2) The conditions for election, rights, obligations, and responsibilities of the director of a health care facility shall also apply to the acting director of the health care facility.

Article 135

(1) The duty of the director of a health care facility shall terminate with the expiry of the term of office and when relieved.

(2) The founder of a health care facility shall relieve the director prior to the expiry of the term of office:

- 1) At personal request;
- 2) If the director acts contrary to the provisions of the law;
- 3) If the director causes major damage to the health care facility due to lack of skill, improper or negligent work, or neglects or unconscientiously performs his duties in such a way that major disruptions in the operation of the health care facility have occurred or may occur;
- 4) If the competent association brings one of the disciplinary actions laid down by the law against him/her;
- 5) If breach of regulations and common acts of the health care facility or irregularity of work of the director has been established by the finding of health inspectorate;
- 6) If the circumstances referred to in Article 130, paragraph 6 of this Law, occur;
- 7) If criminal proceedings have been instituted against him/her for the act implying that he/she is discreditable to perform that function, or if sentenced by court for the criminal offence, which makes him/her discreditable to perform the function of the director of the health care facility;
- 8) If he/she misappropriates, or allows misappropriation of funds of the health insurance organization, or if he/she uses the funds contrary to the agreement concluded with the health insurance organization;
- 9) If the health care facility acquires funds contrary to this Law or by charging health services to insured persons contrary to the law regulating health insurance;
- 10) For other reasons specified by law or the articles of association of the health care facility.

Management Board

Article 136

(1) The management board of a health care facility shall:

- 1) Adopt the articles of association of the health care facility with the approval by the founder;
- 2) Adopt other common acts of the facility in compliance with the law;
- 3) Decide on the business operations of the health care facility;
- 4) Adopt operating and development programs;

5) Adopt financial plan and annual statement of the health care facility in compliance with the law;

6) Adopt annual operating and financial report of the health care facility;

7) Decide on the use of resources of the health care facility, in compliance with the law;

8) Announce vacancy and implement the procedure of election of the candidates for performing of the function of the director;

9) Carry out other activities specified by law and articles of association.

(2) The documents referred to in paragraph 1, Item 5) of this Article concerning the funds obtained from the budget and mandatory health insurance organization shall be adopted in the manner and according to the procedure by which the budgetary system of the Republic is regulated.

(3) The management board shall make decisions when more than a half of the members of the management board are present and shall hand down decisions by the majority vote out of the total number of the members.

Article 137

(1) The management board of an outpatient department, pharmacy, institute, and the public health institute each has five members of whom two members are from the health care facility, and three members are the representatives of the founder.

(2) The management board of a hospital, clinic, institute, clinical hospital, and clinical center each has seven members of whom three members are from the health care facility, and four members are the representatives of the founder.

(3) At least one member representing the employees in the management board shall be a university graduate health care professional.

(4) Members of the management board of a health care facility are appointed for a period of four years.

Supervisory Board

Article 138

(1) The supervisory board of health care facility shall supervise the work and business operations of a health care facility.

(2) The supervisory board shall make decisions if more than a half of the members of the supervisory board are present by the majority vote out of the total number of members.

Article 139

(1) The supervisory board of a outpatient department, pharmacy, institute, and public health institute each has three members, one from the health care facility and two members are the representatives of the founder.

(2) The supervisory board of a hospital, clinic, institute, clinical hospital and clinical center each has five members, two from the health care facility and three members shall be the representatives of the founder.

(3) The members of the supervisory board of a health care facility shall be appointed for a period of four years.

Article 140

(1) Municipalities shall be proportionally represented in the management board and supervisory board of the state owned health care facility operating in the territory of several municipalities.

(2) The founder shall appoint the members of the management and supervisory board from the health care facility at the proposal of the professional council of the health care facility.

Articles of Association of a Health Care Facility

Article 141

(1) A health care facility shall have the articles of association regulating: the activity, internal organization, management, business operations, requirements for the appointment and relieve of the director, deputy or assistant director for educational and scientific and research work, as well as other issues of importance for the work of the facility.

(2) The articles of association of a health care facility, which are adopted by the management board, shall be approved by the founder.

(3) The opinion of the Ministry shall previously be obtained concerning the provisions of the articles of association of a state owned health care facility, in the part regulating the area of health care, or specialties in which it practices health care activity, internal organization and the requirements for appointment and relieve of the director.

(4) The articles of association of a clinic, institute, and clinical center, as well as of the Health Care Institute of the Ministry of Interior Employees, the founder of which is the Republic shall be approved by the Government.

(5) The articles of association of a Republic-founded institute, public health institute, general and specialized hospital, and the hospital shall be approved by the Ministry.

Internal Organization of a Health Care Facility

Article 142

(1) A health care facility shall form organizational units by type of activity, number of employees, and other statutory requirements.

(2) An organizational unit that forms part of a health care facility, can use the name set out by this Law for the type of the health care facility referred to in Article 46, paragraph 3, Items 2), 6), and 7) of this Law, if such an organizational unit meets the requirements specified by this Law for the given type of health care facility.

(3) The Minister shall specify the conditions and method of internal organization of health care facilities.

(4) Health care facility internal auditing shall be in place in compliance with the regulations governing the budgetary system.

2. Professional Bodies in a Health Care Facility

Article 143

Professional bodies of a health care facility are:

- 1) Board of Experts;
- 2) Expert Team;
- 3) Ethics Committee;
- 4) Quality of Work Commission.

Board of Experts

Article 144

(1) The board of experts is the advisory body of the director and the management board.

(2) The members of the board of experts are university-graduate health professionals who are appointed by the director at the proposal of the organizational unit of the health care facility.

(3) The head nurse of the health care facility shall also participate in the work of the board of experts.

(4) The director of the health care facility may not be a member of the board of experts.

(5) The board of experts shall meet at least once in 30 days.

Article 145

(1) The board of experts shall:

- 1) Review and decide on issues practice of the health care facility;
- 2) Propose the operating and development program of the health care facility;
- 3) Propose the plan of professional advancement of health care practitioners and medical associates;
- 4) Propose the plan for the improvement of quality of practice of the health care facility;
- 5) Monitor and organize the implementation of internal quality audit of practice in the health care facility;
- 6) Carry out other duties specified by the articles of association.

(2) The duties and method of work of the board of experts shall be regulated by the articles of association of the health care facility.

Expert Team

Article 146

(1) The expert team is a professional body established, for the purpose of reviewing and adoption of professional and doctrinary positions, within health care facilities consisting of clinics and institutes as their organizational units, or in health care facilities consisting of a number of organizational units.

(2) The membership and work of the expert team shall be regulated by the articles of association of the health care facility.

Ethics Committee

Article 147

(1) The Ethics Committee is a professional body that monitors the provision and implementation of health care based on professional ethics principles.

(2) The director of a health care facility shall nominate the ethics committee at the proposal of the board of experts.

(3) The members of the ethics committee are appointed from health care practitioners of the health care facility and law school graduate citizens who live or work in the territory for which the health care facility was founded.

(4) The number of members of the ethics committee is regulated by the articles of association of the health care facility.

Article 148

The tasks of the ethics committee of a health care facility are:

1) Monitoring and analysis of the implementation of the principles of professional ethics in the provision of health care services;

2) Approval for conducting scientific research, medical experiments, as well as clinical studies of medicine and medical devices in the health care facility, and/or monitor their implementation;

3) Making decisions and reviewing professional issues related to taking parts of human body for medical and scientific and training purposes, in compliance with law;

4) Making decisions and reviewing professional issues related to the implementation of measures for the treatment of infertility applying the procedures of biomedically-assisted fertilization, in compliance with law;

5) Monitoring and analysis of the ethical attitude in the relationships between health care practitioners and patients, particularly in the area of giving consents by the patients to the proposed medical measure;

6) Monitoring, analysis and provision of opinion on the implementation of the principles of professional ethics in the prevention, diagnosis,

treatment, rehabilitation, research as well as on the introduction of new health care technologies;

7) Contributing to the development of habits to follow and implement of the principles of professional ethics in the provision of health care services;

8) Performing continual advisory function concerning all issues in the implementation of health care;

9) Reviewing other ethical issues in the provision of health care services within the facility.

Article 148

(1) The Ethics Committee of a health care facility in which clinical trials of medicines and medical devices in stock are conducted shall, in addition to other members set out in Article 147, have at least three medical specialists with PhD degree in the branch of medicine specific of the facility.

(2) The medical doctors in paragraph 1 of this Article shall be experienced in the scientific and medical assessment of the results obtained in clinical trials of medicines and medical devices, as well as in ethical principles of clinical trials.

(3) All members set out in paragraph 1 of this Article shall be present at the Ethics Committee meeting where a decision is made on clinical trials of medicines or medical devices.

(4) In the course of deciding on clinical trials of medicines or medical devices, only the Ethics Committee members who are not investigators in clinical trials being discussed and who are not dependent on clinical trial sponsors and who signed a statement on the absence of conflict of interest with a clinical trial sponsor can vote, or provide opinions on issues associated with clinical trials of medicines or medical devices.

(5) The list of members who participated in the adoption of the decision is an integral part of the decision on clinical trials of medicines or medical devices.

(6) In the course of deciding on clinical trials of medicines or medical devices, the Ethics Committee can request professional opinion of prominent experts, who are not members of the Ethics Committee, in specific fields necessary for making a decision on clinical trial.

(7) For the purpose of a multicentric clinical trial of medicines or medical devices conducted according to the regulations governing the area of medicines and medical devices in several health care facilities in the territory of the Republic of Serbia, the Ethics Committee of each facility in which a trial is conducted shall make a decision on conducting such clinical trial in the given health care facility.

(8) The Ethics Committee in paragraph 1 of this Article shall, in the course of work, or making decisions on clinical trials of medicines or medical devices, act pursuant to the regulations governing the area of medicines and medical devices, and implement the guidelines of Good Clinical Practice in such clinical trials.

(9) The health care facility in which a clinical trial of medicines or medical devices is carried out shall keep the documentation on conducted clinical trials during the period of at least five years after clinical trials of medicines or medical devices ended.

Commission for the Improvement of Quality of Work

Article 149

(1) The Commission for Improvement of the Quality of Work is a professional body that looks after continuous improvement of the quality of health care that is provided in a health care facility.

(2) The Commission for Improvement of the Quality of Work shall adopt the annual program of the quality assurance of professional work in a health care facility.

(3) The number of members, composition, and the method of work of the Commission for Improvement of the Quality of Work shall be regulated by the Articles of Association of the health care facility.

D. PROFESSIONAL BODIES ON THE REPUBLIC LEVEL

1. Health Council of Serbia

Article 150

The Health Council of Serbia (hereinafter referred to as: the Health Council) shall be formed, as a professional and advisory body, which shall look after the development and the quality of the health care system, organization of health service and the health insurance system.

Membership of the Health Council

Article 151

The Health Council shall have 15 members elected by the National Parliament, at the proposal of the Government, as follows:

1) Two prominent experts from the ranks of full professors of the faculties of medicine in the Republic, who are superior scientific workers with internationally recognized papers or with proven contribution to the improvement and development of the health care system;

2) One prominent expert from the ranks of full professors of the faculty of dental medicine in the Republic, who is superior scientific worker with internationally recognized papers or with proven contribution to the improvement and development of the system of dental health care;

3) One prominent expert from the ranks of full professors of the pharmaceutical faculty in the Republic, who is superior scientific worker with internationally recognized papers or with proven contribution to the improvement and development of the pharmaceutical health care;

4) One representative of the Serbian Academy of Sciences and Arts;

5) One representative from each of associations of health care practitioners;

6) One representative of the Serbian Medical Society;

7) One representative of the association of health care facilities;

8) Two representatives from the ranks of prominent experts in the area of health insurance and financing of health care;

9) One prominent expert who is superior scientific worker with internationally recognized publications or with proven contribution to the improvement and development of the area of public health.

Article 152

(1) The mandate of the members of the Health Council shall be five years.

(2) A member of the Health Council may not be a person elected, appointed or nominated for the function with a government authority, an authority of the territorial autonomy or local self-government, a person nominated by the bodies of the organizations dealing with health insurance, or the bodies of health care facilities, institutes of advanced education, associations of health care practitioners, the Serbian Medical Society, or association of health care facilities.

(3) The Health Council shall elect the chairperson from the ranks of its members.

Article 153

The National Parliament may relieve a member of the Health Council prior to the expiry of the term of office, as follows:

1) At personal request;

2) If he/she fails to fulfill this/her duty as a member of the Health Council or compromises, by his/her actions, the reputation of the duty he/she performs, at the proposal of the Government;

3) If he/she assumes the function referred to in Article 152, paragraph 2 of this Law.

Competences of the Health Council

Article 154

The competence of the Health Council shall be to:

1) Monitor the development of health care systems and health insurance in the Republic and their harmonization with the European and international standards;

2) Propose measures for the protection and improvement of health and strengthening health potential of the population;

3) Propose measures for uniform provision of health care to all citizens in the Republic, as well as the measures for improving health care of the vulnerable populations;

4) Propose measures for the functioning of the health care system based on the principles of sustainability and efficiency;

5) Propose measures for functioning of the mandatory health insurance on the principles of sustainability, cost-effectiveness, and efficiency, as well as the measures for establishing and development other forms of health insurance;

6) Implement the procedure of quality assessment of the continuous education program of health practitioners and medical associates (hereinafter referred to as: accreditation of programs of continuous education), in accordance with Article 187, paragraph 3 of this Law;

7) Provide opinion on the proposal of the plan of development of staff in the health care system;

8) Provide opinion about the policy of enrolment to the medical faculties and schools and cooperate with the competent government authorities and other professional bodies in proposing measures of rational enrolment policy to medical faculties and schools;

9) Give initiative and propose measures for the purpose of implementation of the reform in the areas of health care and health insurance;

10) Review other issues from the area of health care and health insurance and provide professional assistance to government authorities, organizations, and institutes in the implementation of tasks related to the social care for health;

11) Carry out other activities, in compliance with the law.

Work of the Health Council

Article 155

(1) The work of the Health Council shall be public.

(2) The Health Council may form separate working bodies.

(3) The Health Council shall adopt its rules of procedure.

(4) The funds for the work of the Health Council shall be provided in the budget of the Republic.

(5) Professional and administrative and technical affairs for the requirements of the Health Council shall be administered by the Ministry.

(6) The Health Council shall submit its reports on its work to the National Parliament minimum once a year.

2. Ethics Committee of Serbia

Article 156

(1) The Ethics Committee of Serbia shall be a professional body, which shall look after the provision and implementation of health care on the Republic level, based on the principles of professional ethics.

(2) The Government shall nominate and relieve the chairperson and the members of the Ethics Committee of Serbia, at the proposal by the Minister.

(3) The mandate of the members of the Ethics Committee of Serbia shall be five years.

(4) The Ethics Committee of Serbia shall have nine members who shall be elected from the ranks of prominent experts who have major results in the work, as well as contribution in the areas of health care, professional ethics of health care practitioners and of humanistic sciences.

(5) The members of the Ethics Committee of Serbia may not be the persons referred to in Article 152, paragraph 2 of this Law.

(6) The Ethics Committee of Serbia shall adopt its rules of procedure.

(7) The funds for the work of the Ethics Committee of Serbia shall be provided in the budget of the Republic.

Competences of the Ethics Committee of Serbia

Article 157

(1) The competence of the Ethics Committee of Serbia shall be to:

1) Propose the basic principles of professional ethics of health care practitioners;

2) Monitor implementation of the principles of professional ethics of health care practitioners in engaging in a health care activity in the territory of the Republic;

3) Coordinate the work of the ethics committees of the health care facilities;

4) Monitor the implementation of scientific research works and clinical tests of medicines and medical devices in health care facilities in the territory of the Republic;

5) Decide and provide opinions concerning disputable issues that are of importance for the implementation of scientific research works, medical experiments, as well as for clinical tests of medicines and medical devices in health care facilities in the Republic;

6) Monitor the implementation of decisions and review professional issues related to the procedure of taking of parts of human body for medical and scientific and educational purposes in the health care facilities in the territory of the Republic, in compliance with the law;

7) Monitor the implementation of decisions and review professional issues related to the implementation of measures for treatment of infertility by applying biomedically assisted fertilization, in the health care facilities in the territory of the Republic, in compliance with the law;

8) Submit annual reports to the Ministry about the implementation of the scientific research and clinical studies of medicines and medical devices in the health care facilities in the territory of the Republic, as well as about identified problems, deficiencies and remarks on the work of the ethics committees of health care facilities;

9) Review other issues of professional ethics in the implementation of health care.

(2) The Medicines and Medical Devices Agency of Serbia shall inform the Ethics Committee of Serbia about the conduct of clinical studies of medicines and Medical

devices for which the approval for conducting such clinical studies has been handed down, in compliance with the law governing the area of medicines and medical devices.

(3) The Medicines and Medical Devices Agency of Serbia may, prior to issuing the permit for conducting clinical studies of medicines and medical devices, seek opinion from the Ethics Committee of Serbia about the submitted application for conducting such clinical studies of medicines and medical devices, and/or about all disputable issues that may emerge in the course of conducting of clinical studies of medicines and medical devices.

3. Professional Commissions of the Republic

Article 158

(1) A professional Republic commission shall be formed for individual areas of health care activity for the purpose of harmonization of professional proposals and positions of the referential health care facilities, professional associations and chambers, institutes of higher education, and prominent experts in the field of health care.

(2) A professional Republic commission shall establish professional doctrines concerning the preservation and improvement of health, prevention and detection of diseases, treatment and health care, rehabilitation of the diseased and injured persons, as well as the improvement and development of the organization of health service.

(3) The members of a professional Republic commission shall be prominent scientific and other health care practitioners who have made major contribution to the work and development of a certain areas of medicine, dentistry, or pharmacy.

(4) A professional Republic commission shall be formed by the Minister.

(5) The document on formation of the professional Republic commission shall regulate the tasks, composition, and method of work of the professional Republic commission.

(6) The mandate of the members of a professional Republic commission shall be five years.

(7) A professional Republic commission shall adopt its rules of procedure.

(8) The funds for the work of the professional Republic commission shall be provided in the budget of the Republic.

(9) The Public Health Institute, founded for the territory of the republic of Serbia, provides for carrying out professional, administrative and technical activities for the work of Republic professional commissions.

E. ACQUIRING OF FUNDS FOR WORK OF HEALTH CARE FACILITIES AND PRIVATE PRACTICES

Article 159

(1) For extending public services, the health care facility in the Network Plan, as a public resources user, obtains its operating assets from public revenue as follows:

1) Mandatory health insurance tax by concluding a contract with the mandatory health insurance organization;

2) Republic, i.e. founder's budget;

3) Revenue on grounds of the use of public resources for services not included in contract with the mandatory health insurance organization (renting free capacities, or state-, autonomous province- or local self government-owned property and movables, revenue obtained by the sale of public resources user services contracted with physical persons or legal entities on the basis of their free will, scientific and research activity or education purposes etc.).

(2) The health care facility in the Network Plan can also acquire operating resources from gifts, donations, legacies and heritage, as well as from other sources pursuant to law.

(3) The health care facility in the Network Plan can do the payments only in the amount not exceeding expenditures and costs specified in the financial plan of the health care facility, that are equivalent to the appropriation from the financial plan for that purpose for the budget year.

(4) The obligations undertaken by the health care facility in the Network Plan according to the established appropriations, which were not performed during the year, are transferred and have the status of undertaken obligations that are to be performed in the next year on account of the approved appropriations for the current budget year, in compliance with the requirements set out in the law regulating the budget system.

(5) The obligations undertaken by the health care facility in the Network Plan amounting to more than the sum of resources provided by the financial plan or those occurring as opposed to the law, bylaws or in contrast with the contract concluded with the mandatory health insurance organization, cannot be performed on account of the mandatory health insurance resources, or on account of other health care facility's resources envisaged by the financial plan.

(6) The appropriations specified in the financial plan of the health care facility in the Network Plan intended for funding salaries cannot be made on account of forced collection.

(7) In case that there was no legal ground for a payment made to the health care facility in the Network Plan, such health care facility shall immediately refund the mandatory health insurance organization, or the budget.

(8) In cases set out in paragraphs 5 and 7 of this Article, the Managing Board of a health care facility shall, within eight days of the learning, notify the founder of the health care facility in the Network Plan of the fact indicative of the health care facility action against the law.

(9) The health care facility in the Network Plan shall submit the balance sheet to the mandatory health insurance organization in order to generate the consolidated report of the organization, and other reports specified by regulations governing the budgetary system.

(10) The financial resources acquisition and disposition required for Network Plan health care facility functioning are specified by the regulations governing mandatory health insurance, and regulations governing the budgetary system.

(11) Health care facilities founded by privately owned or otherwise owned funds, as well as private practice, acquire and use funds as specified by law.

Article 160

(1) A health care facility or private practice shall acquire funds for work from the health insurance organization by concluding agreements for providing health care, in compliance with the law regulating health insurance.

(2) A health care facility shall acquire the funds referred to in Article 18, paragraph 2 of this Law for the implementation of health care of general interest, by concluding the agreement with the Ministry.

(3) A health care facility shall acquire the funds referred to in Article 13, paragraphs 3 and 4 of this Law for implementation of health care of interest to autonomous province, municipality, or city, by concluding the agreement with the competent authority of the autonomous province, municipality, or city.

Article 161

(1) The health services provided by a health care facility or private practice at the request of an employer at the cost of the employer shall be charged at the prices fixed by the management board of the health care facility or by the founder of private practice.

(2) The health services provided by a health care facility or private practice to the citizens at their request, as well as the health services that are not covered by health insurance, shall be charged to the citizens, at the prices fixed by the management board of the health care facility or the founder of private practice.

Article 162

(1) The fee for the provided emergency medical care shall be paid by the Republic, autonomous province, municipality, or city – the founder of the health care facility, if the health care facility has not charged the health insurance organization for this service within 90 days from the date of issuing of the invoice.

(2) The fee referred to in paragraph 1 of this Article for the provided emergency medical care by private practice shall be paid by the Republic if the founder of private practice has not charged the health insurance organization for this service within 90 days from the date of issuing of the invoice.

(3) By paying up the fee referred to in paragraphs 1 and 2 of this Article, the Republic, autonomous province, municipality, or city shall be entitled to request reimbursement of the paid amount from the health insurance organization.

Article 163

(1) Health care facilities and private practice, for the purpose of improvement of work, business economics, and implementation of other tasks and goals of common interest, may set up the association of health care facilities or private practice association.

(2) The articles of association of the association referred to in paragraph 1 of this Article shall regulate the internal organization, composition, election, and the method of decision-making of the bodies, financing, and other issues of importance for the work of the association.

Renting out Free Capacities of a Health Care Facility

Article 164

(1) For the purpose of rational use of the capacities in a health care activity and creating conditions for more comprehensive and higher-quality health care of citizens, health care facilities with the resources in state ownership, which have been founded for exercising of the statutory rights of the citizens in the area of health care, in case they have free capacities (premises and equipment), they may rent out such capacities, in compliance with the law.

(2) If several persons who are engaged in the health care activity are interested in the free capacities referred to in paragraph 1 of this Article, the capacities will be rented out to the person for whose work there is the bigger demand and who offers the most favorable terms and conditions.

F. HEALTH CARE PRACTITIONERS AND MEDICAL ASSOCIATES

1. Common Provisions

Article 165

(1) Health care practitioners are the persons who have graduate from the faculty of medicine, dental medicine, or pharmacy, as well as the persons who are the graduates from other medical school, and who are directly engaged in a health care activity as a profession in a health care facilities or private practice, under the conditions laid down by this Law.

(2) A medical associate is a person having secondary school, two-year post-secondary school, or university qualifications, who is engaged in certain types of practice of health care in a health care facility or private practice.

(3) In order to engage in a health care activity, health care practitioners, or medical associates must, for certain types of practice, also have relevant specialization, or super-specialization, in accordance with the provisions of this Law.

Article 166

A health care practitioner, depending on the professional qualifications, shall be:

- 1) A doctor of medicine, doctor of dental medicine, a graduate pharmacist and a graduate pharmacist medical biochemist - graduate of the relevant medical faculty;
- 2) Other health care practitioner – graduate of the relevant faculty, two-year post-secondary, or a secondary medical school.

Article 167

(1) Membership in the association shall be mandatory for the health care practitioners referred to in Article 166 of this Law, who are engaged in a health care activity as their profession.

(2) A separate law shall govern setting up of associations, the activities of an association, organization, and the work of an association as well as other issues of importance for the work of an association.

Article 168

(1) A health care practitioner can provide health care independently (hereinafter referred to as: independent work) in a health care facility, private practice or with another employer who may, in the sense of this Law, engage in certain types of practice within the health care activity, if he/she:

- 1) Has served internship and passed intern's exit exam;
- 2) Has been registered in the directory of the association;
- 3) Been issued, or renewed the license for independent practice.

(2) Independent practice, in the sense of this Law, shall imply the independent provision of health care without direct supervision by another health care practitioner.

(3) A foreign citizen who is engaged in a health care activity in the Republic, must, apart from the requirements laid down in paragraph 1 of this Article, speak the Serbian language as well as any other language in official use, in accordance with the regulations governing the area of employment of foreign citizens in the Republic.

Article 168

(1) A health care practitioner who is a foreign citizen can, exceptionally, perform health care activities at a health care facility, or private practice, or with other legal entity dealing with health care activity pursuant to this Law provided that he/she obtained a temporary license in the Republic of Serbia in compliance with this Law.

(2) Such temporary license set out in paragraph 1 of this Article can be issued to a health care practitioner who is a foreign citizen if, in addition to the requirements specified by law regulating the area of employment of foreign citizens in the Republic of Serbia, meets the following requirements:

1) That he/she received a written invitation from the health care facility, or private practice, or other legal entity dealing with health care activity pursuant to this Law for temporary, or intermittent engagement to perform certain health care activities;

2) That he/she has work permit, or other relevant document issued by the competent authority of the country of residence or abode;

3) That he/she implements health care technologies used in the Republic of Serbia, or that he/she implements health care technologies not used in the Republic of Serbia but for which, as new health care technologies, the implementation permit was issued pursuant to this Law, or implements the treatment methods and procedures, as well as that he/she uses medicines and medical devices in compliance with the regulations related to health care.

(3) The temporary license set out in paragraph 1 of this Article is issued by the competent medical association.

(4) The temporary license set out in paragraph 1 of this Article can be issued by the competent medical association for the period not longer than 180 days during a calendar year.

(5) The competent medical association shall issue a decision within not longer than 15 days from the submission of application for temporary license.

(6) The method and procedure for temporary license issuing are subject to the provisions of this Law, or the law regulating the operation of medical associations related to the method and procedure for issuing licenses to health care practitioners, unless otherwise specified by this Law.

(7) Detailed conditions, method of issuance, form and contents of the temporary license, and other issues regulating in more detail the procedure for temporary license issuance are regulated by the common act of Article 190, paragraph 8 of this Law.

(8) Engagement of health care professionals, foreign citizens, by a health care facility, or private practice, or other legal entity dealing with health care activity pursuant to this Law is prohibited contrary to this Law.

(9) A health care professional who obtained a temporary license in compliance with this Article is entitled to insurance from medical malpractice pursuant to law.

Article 169

(1) Health care practitioners shall engage in a health care activity in accordance with the prevailing health care doctrine and in accordance with the code of professional ethics.

(2) For their work, health care practitioners shall assume professional, ethical, penal and material responsibility.

(3) Health care practitioners with university qualifications referred to in Article 166, Item 1) of this Law shall, when receiving the university diploma, sign a statement - oath that they will in practicing their profession adhere to the principles established in Hippocratic oath, as well as to the principles of professional ethics.

(4) Health care practitioners referred to in Article 166, Item 2) of this Law, or medical associates shall, when signing employment contract, sign a statement - oath that they will in practicing their profession adhere to the principles established in the Hippocratic oath, as well as to the principles of professional ethics.

Article 170

Health care practitioners and medical associates as well as other persons employed in a health care facility, or private practice may not leave workplace until their replacement is provided even if their working hours have expired, if thereby engaging in a health care activity would be disrupted and the health of a patient compromised.

Article 171

(1) A health care practitioner may refuse to provide health care if the health service that should be provided is not in agreement with his/her conscience, or with the international rules of medical ethics (hereinafter referred to as: conscientious objection).

(2) A health care practitioner shall inform the director of health care facility, or immediate superior, as well as the founder of private practice about his/her conscientious objection.

(3) A health care facility or private practice shall respect the expressed conscientious objection of the health care practitioner, as well as ensure providing of health care to the patient by another health care practitioner.

(4) A health care practitioner may not refuse to provide emergency medical care by expressing the conscientious objection.

Article 172

The rights, duties, and responsibilities of the employees in a health care facility or private practice shall be exercised in accordance with the labor regulations, unless otherwise specified by this Law.

Article 173

(1) Engaging in a health care activity by the persons who, in the sense of this Law, are not considered to be health care practitioners and medical associates shall be prohibited.

(2) Provision of health care by a medical doctor, doctor of dental medicine, graduated pharmacist, graduated pharmacist – medical biochemist through which he/she gains profit or any other property or non-property benefit outside the health care facility or private practice operating pursuant to this Law, except in case of the provision of emergency aid pursuant to law, is prohibited.

(3) If a health care professional acts contrary to paragraph 2 of this Article, the competent medical association can withdraw the license for independent work from such health care professional, pursuant to law.

Article 173

(1) The human resources plan for health care facilities in the Network Plan for the territory of the Republic (hereinafter: the human resources plans) consisting of the total number of employees included in individual human resources plans of health care facilities on the Network Plan (hereinafter: facility human resources plan) is adopted by the Minister.

(2) The procedure for the adoption of the human resources plan in paragraph 1 of this Article for the health care facilities in the territory of an autonomous province shall provide for the participation of the autonomous province representatives in a relevant task force of the Ministry.

(3) The human resources plan in paragraph 1 of this Article means the maximum number of employees in health care facilities in the Network Plan, or in any individual health care facility in the relevant budgetary, adopted by the Minister in compliance of the data set out in paragraph 16 of this Article.

(4) The human resources plan in paragraph 1 of this Article contains the data on the total number of employees, or employees in a health care facility, whose salaries are provided by the mandatory health insurance organization, as well as the number of employees whose salaries are provided by other sources pursuant to law, or the data on the number of employees with permanent or fixed-term contract, or those with full- or part-time contract or those employees working short hours or on leave, and other human resources data of the health care facility.

(5) The human resources plan in paragraph 1 of this Article is adopted by the Minister for each budgetary year not later than December 31 of the current calendar year for the next budgetary year.

(6) If, for reasons specified by law or for any other justified reasons, the human resources plan is not adopted in the term specified in paragraph 5 of this Article, the current human resources plan shall be used until the adoption of the Republic or facility human resources plan.

(7) The human resources plan in paragraph 1 of this Article, and its amendments, shall be in line with the financial resources of the mandatory health insurance organization, health care facility, or the founder's budget for the budgetary year for which the plan or its amendments are adopted the evidence of which is submitted to the Ministry.

(8) The total number of employees in the human resources plan in paragraph 1 of this Article during one budgetary year can be changed by the Minister on the basis of authorization based on the data specified in paragraph 16 of this Article or on request by the Director of a health care facility by reconciliation of the number of employees against the standards or norms prescribed by this Law and bylaws intended for the enforcement of the Law; or by the reconciliation of the number of employees in order to provide for the rights of mandatory health insurance pursuant to law.

(9) The health care facility can submit to the Ministry the application for a change or addition of the human resources plan of a health care facility accompanied with the necessary documentation specified in paragraph 8 of this Article not more frequently than twice during a calendar year: in the period April 1 to April 30 and October 1 to October 30 of the current year for the next budgetary year.

(10) The Minister shall either adopt such change of or addition to the human resources plan not later than by June 15 of the current calendar year or adopt a human resources plan for the next budgetary year by December 31 of the current calendar year.

(11) The submissions made before after the term specified in paragraph 9 of this Article, as well as incomplete submissions, shall not be considered.

(12) The Ministry shall submit the human resources plans in paragraph 1 of this Article, and their amendments to the mandatory health insurance organization, health

care facility, and the Ministry of Finance within eight days of adoption.

(13) The Ministry shall publicize the human resources plans in paragraph 1 of this Article, and their amendments on the official web presentation of the Ministry within five days from the date of their submission to the mandatory health insurance organization or health care facility.

(14) The number of employees in a health care facility shall not be greater than that established by the human resources plan.

(15) Engagement with the health care facility in the Network Plan of the number of employees exceeding that established by the human resources plan in paragraph 1 of this Article is prohibited.

(16) In order to generate the human resources plan in paragraph 1 of this Article, The Public Health Institute established for the territory of the Republic, shall keep and generate the database on the total staffing of the health care facilities in the Network Plan, including the structure and number of employees per health care facility, certain organizational units, per method of funding their salaries, fixed and permanent contracts, part-time and full-time employees, those working short ours, make amendments to those databases, staffing analysis and propose measures for improving the staffing of health care facilities.

(17) The Public Health Institute established for an autonomous province territory shall keep and generate a database set out in paragraph 16 of this Article for health care facilities in the territory of the autonomous province, which shall form an integral part of the common database.

2. Internship and Intern's Exit Exam of Health Care Practitioners and Medical Associates

Article 174

On the day of commencement of serving internship, a health care practitioner shall be registered in the directory of the association in which separate records are kept on the members of the association who are interns.

Article 175

(1) Health care practitioners and medical associates may not practice independent practice until they complete serving internship and pass intern's exit exam, in compliance with this Law.

(2) Internship for health care practitioners and medical associates having university qualifications shall last 12 months, unless otherwise specified by this Law.

(3) Internship for doctors of medicine whose basic studies at the faculty of medicine, on the basis of the program of the competent authority of the faculty, are established to last six years – shall last for six months.

(4) Internship for health care practitioners and medical associates, who have two-year post-secondary school, or secondary school qualifications, shall last for six months.

Article 176

- (1) Internship shall be served according to the established program.
- (2) Internship is practical work under the supervision of a licensed health care practitioner, or medical associate - mentor, by which a health care practitioner and medical associate are trained for independent practice.
- (3) Internship is served in a health care facilities and private practice under direct supervision of the health care practitioner, or medical associate who has minimum five years of service after having passed intern's exit exam.
- (4) The part of internship related to quality control of medicines and medical devices can be served with the Medicines and Medical Devices Agency of Serbia.
- (5) A health care facility, or private practice, shall keep records, exercise supervision, and shall be responsible for consistent implementation of program of internship of health care practitioners and medical associates.
- (6) In the course of internship, the intern who has sign employment contract with a health care facility, or private practice, shall be entitled to income earnings and all other rights emanating from employment, in compliance with the law regulating labor, and/or in compliance with the employment contract.

Article 177

- (1) The plan and program of internship, detailed requirements that must be satisfied by the health care facilities and private practice in which internship may be served, the form of the intern's record book, the method of keeping intern's record book, as well as other issues of importance for serving of internship, shall be specified by the Minister.
- (2) The Minister shall establish the number of interns, which the health care facility specified by the Plan of the Network shall receive to serve internship, on annual level.

Voluntary Internship

Article 178

- (1) Internship may also be served in the form of voluntary work, as work outside employment.
- (2) A health care facility or private practice may provide remuneration/compensation for work and other rights in compliance with the law and other bylaws to the person with whom it concludes the contract on voluntary work.
- (3) The person with whom the contract on voluntary work has been concluded in compliance with this Law shall have the rights emanating from compulsory social insurance, in compliance with the law.

Intern's Exit Exam

Article 179

(1) Upon expiry of internship, health care practitioners and medical associates shall pass intern's exit exam within 12 months from the date of completion of the program of internship, before the examination board formed by the Minister.

(2) The Minister shall specify the program, contents, method, and procedure taking the intern's exit exam, as well as the form of the certificate of certification exam referred to in paragraph 1 of this Article.

(3) The resources obtained by payments for exit exams to be taken by health care practitioners and medical associates form the income of the Republic and are intended for funding the costs related to such exit exams.

Article 180

To the health care practitioners and medical associates who have served their internship or a part of internship abroad, the Ministry may, at their request, recognize the internship or a part of internship, under the condition that the program of served internship corresponds to the program of internship in compliance with this Law.

3. Professional Advancement of Health Care Practitioners and Medical Associates

Article 181

(1) Professional advancement, in the sense of this Law, implies acquiring knowledge and skills by health care practitioners and medical associates, which includes:

- 1) Specialization and sub-specialization;
- 2) Continuous education.

(2) The costs of professional advancement of health care practitioners and medical associates shall be borne by the employer.

Article 182

(1) Health care practitioners and medical associates shall have the right and duty to, in the course of their work, continuously follow the development of medical, dental medical, pharmaceutical sciences, as well as of other relevant sciences, and to professionally improve for the purpose of maintaining and improvement of the quality of their work.

(2) Professional advancement of health care practitioners shall be a precondition for their being issued, or for renewing of their license.

(3) A health care facility or private practice shall provide paid leave for continuous education for the purpose of renewal of the license for independent practice to an employed health care practitioner and medical associate, in compliance with the law.

Professional Advancement Plan

Article 183

(1) A health care facility or private practice shall provide professional advancement to a health care practitioner and medical associate, in compliance with this Law, and according to the plan of professional advancement of health care practitioners and medical associates in the health care facility or private practice.

(2) The plan of professional advancement referred to in paragraph 1 of this Article shall be adopted by the health care facility on the basis of the plan of development of staff in the health care system, which shall be handed down by the Minister.

(3) The plan of development of staff in the health care system referred to in paragraph 2 of this Article shall include:

1) The program of professional advancement of health care practitioners and medical associates;

2) Number of specializations and sub-specializations that are approved on the annual level;

3) Criteria and detailed requirements for approval of specializations and sub-specializations.

4) Other important issues for the professional advancement of health care practitioners and medical associates, pursuant to law.

Specializations and Sub-Specializations

Article 184

(1) A health care practitioner and medical associate having university qualifications may undergo specialization if he/she has served internship and passed intern's exit exam and two years of practice in health care activity upon passing the intern's exit exam, unless set out differently by this Law.

(2) Notwithstanding paragraph 1 of this Article, a health care practitioner can, after the internship term and passed exit exam, be referred to specialization courses in scarce branches of medicine, dental medicine or pharmacy.

(3) The Minister shall, for each calendar year, pass the decision on scarce fields of medicine, dental medicine or pharmacy in the Republic of Serbia not later than by December 31 of the current year on the basis of the opinion of the Public Health Institute founded for the territory of the Republic, pursuant to law.

(4) A higher education health care practitioner can go for advancement after a finished specialization and take a sub-specialization as a specialist in a certain branch of medicine, dental medicine or pharmacy for the period of at least two years provided that he/she performed health care activities pursuant to this Law.

(5) Specializations and subspecializations are approved by health care facilities or private practices, pursuant to the professional advancement plan set out in Article 183, paragraph 1 of this Law.

(6) The decision on the approval of a specialization and subspecialization is made by the Director of the health care facility or by a private practice founder pursuant to paragraph 5 of this Article.

(7) By Decision, the Minister shall approve of the decision referred to in paragraph 5 of this Article.

(8) The Decision of the Minister referred to in paragraph 7 of this Article shall be final in the administrative procedure and an administrative suit may be instituted against it.

(9) A health care practitioner or associate shall conclude a contract with a health care facility or private practice on rights, obligations and responsibilities during professional advancement in the course of specialization or sub specialization.

(10) A health care practitioner or associate shall be employed with a health care facility in the Network Plan for the period twice as that of specialization or sub specialization.

(11) A health care practitioner or associate can provide health care in the field of specialization under the supervision of an authorized health care professional or medical associate – mentor.

(12) A health care facility or private practice can approve specialization or subspecialization to a health care practitioner or associate provided he/she performed the activity in compliance with this Law during at least two years before the submission of the application for the approval of such specialization or subspecialization.

Article 185

(1) By decision, the Minister can approve specialization or subspecialization, based on the articulated need of the employer, to a graduate from a medical faculty who is engaged in a health care activity as a profession in a health care facility or private practice and who is employed with a government authority, an authority of the territorial autonomy, or local self-government, at a medical faculty, or school, a scientific and research facility, legal person engaged in production, trade in, and control of drugs and Medical devices, the agency in charge of the area of drugs and Medical devices, the organization administering health insurance, institution of social protection, penitentiary instruction, as well as with an employer who has set up an outpatient unit of occupational medicine in compliance with this Law –, in compliance with this Law and the regulations adopted for enforcement thereof.

(2) By decision, the Minister can approve specialization, or subspecialization to a foreign citizen who has graduated from a medical faculty, and who is not engaged in a health care activity as a profession in the Republic, in compliance with the law.

Article 186

(2) The type, duration, and contents of specializations and subspecializations, the specialization or subspecialization curricula, residency or fellowship period and the certification exam, membership and functions of examination boards, the requirements that health care facility, a private practice or the Medicines and Medical Devices Agency must fulfill to be eligible for the provision of residency or fellowship conditions and the method of recognizing the time spent at work as a part of

fellowship, as well as the forms of the matriculation book and the diploma on the residency or fellowship certification exam, shall be specified by the Minister.

(2) The Ministry shall, by the decision, assess if the requirements for the implementation of specialization or subspecialization programs in health care facilities and private practices have been met.

Continual Education

Article 187

(1) Continual education shall imply:

- 1) Participation in professional and scientific gatherings;
- 2) Participation in seminars, training courses, and other continual education programs.

(2) The continual education types, programs, methods, procedures, and duration, referred to in paragraph 1 of this Article, institutions and associations eligible for the provision of continual education, the accreditation criteria for such continual education programs, as well as other issues of importance for the provision of continual education, shall be specified by the Minister.

(3) The continual education programs referred to in paragraph 2 of this Article shall be accredited by the Health Council.

(4) Continual education can be provided under the conditions specified by this Law also in the Medicines and Medical Devices Agency of Serbia, Agency for Licensing Health care facilities in Serbia, Administration for Biomedicine, and in other public agencies, bodies and organizations supervised by the Ministry.

Recognition of a Foreign School Document (Validation of Diploma)

Article 188

(1) A health care practitioner, or medical associate who has graduated from a relevant school, faculty and specialization abroad, as well as a health care practitioner, or medical associate who is a foreign citizen, may engage in a health care activity as a profession, if their foreign school documents are recognized (validation of diploma).

(2) Recognition of a foreign school document referred to in paragraph 1 of this Article shall be done in compliance with the law.

Awarding the Title of Head Doctor

Article 189

(1) Medical, dental medicine doctors, and graduate pharmacists who have minimum 12 years of practice of a health care activity, who have passed the certification exam and published professional and scientific papers, may submit the application, or be proposed to receive the title of head doctor, as a professional recognition for a long-term successful health care, educational, and professional work.

(2) The proposal for the head doctor title award can be submitted by the relevant section or branch of the Serbian Medical Society, or Pharmaceutical Society of Serbia, as well as by the competent association.

3) The d

detailed requirements, method, and procedure for the head doctor title award shall be specified by the Minister.

(3) Detailed requirements, method, procedure and costs of acquiring the title of Head Doctor, the reviewer cost, and other issues related to the procedure for acquiring the title of Head Doctor shall be specified by the Minister.

(4) The resources obtained from the payment of compensation for acquiring the title of Head Doctor are the revenue of the budget of the Republic and intended for funding all costs related to the procedure of acquiring the title of Head Doctor.

(5) For health care practitioners in paragraph 1 of this Article from the territory of an autonomous province, the opinion of the competent authority of the autonomous province shall be obtained before deciding on the title of Head Doctor.

(6) The title of head doctor shall be awarded by the minister

4. Issuing, Renewing, and Withdrawal of the License for Independent practice

Article 190

(1) Issuing, renewal, and withdrawal of the license for independent practice (hereinafter referred to as: the license) of health care practitioners is the procedure, conducted by the competent association for the purpose of establishing professional qualifications of health care practitioners for independent practice.

(2) The association shall issue, renew or withdraw the license of a health care practitioner.

(3) The decision on the issued, renewed or withdrawn license of a health care practitioner shall be made by the head person of a competent association.

(4) The decision referred to in paragraph 3 of this Article shall be final in the administrative procedure and an administrative suit may be instituted against it.

(5) The license is a public document.

(6) The costs of issuing and renewing the license shall be assessed by the competent body of the association, under the conditions laid down by the law.

(7) The costs referred to in paragraph 6 of this Article shall be borne by the applicant requesting license issuance or renewal.

(8) Detailed requirements for license issuing, renewal or withdrawal, the procedure, and the method of license issuing, renewal or withdrawal, the form and the contents of the issued, renewed or withdrawn license, the program of continual education conducted for the purpose of gaining professional qualifications of health care

practitioner for independent practice, as well as other requirements for license issuing, renewal or withdrawal shall be specified by the minister.

Article 191

(1) A health care practitioner who fails to obtain or renew the license, under the conditions laid down by this Law and the regulations adopted for enforcement of this Law, may not practice independently with a health care facility or a private practice.

(2) By the time of license issuing or renewal, the health care practitioner referred to in paragraph 1 of this Article shall provide health care in a health care facility or private practice under the supervision of a health care practitioner who had his/her license issued or renewed with the competent association, who will be designated for that task by the director of the health care facility or the founder of a private practice.

Article 192

The health care practitioner to whom the competent association denied to renew the license, or whose license was withdrawn under the conditions laid down by this Law, shall, within eight days from the date of receipt of the decision, submit the formerly issued license to the competent association.

Article 193

The competent association shall, by duty, keep the directory of issued, renewed, or withdrawn licenses, in compliance with the law.

License Issuance

Article 194

(1) The association shall issue the license to a health care practitioner who has passed intern's exit exam.

(2) The health care practitioner shall submit the application for license issuance to the competent association.

(3) The chairperson of the competent association shall make the decision on the license application and issue the license.

(4) The association shall issue the license for a period of seven years.

Article 195

The association shall issue the license to a health care practitioner under the condition that he/she:

- 1) Meets the requirements referred to in Article 166 of this Law with respect to the medical qualifications;
- 2) Has served internship and passed intern's exit exam;
- 3) Has been registered in the directory of the association;

4) Has not been sentenced for a criminal act, by judgment absolute, which would make him/her discreditable to engage in a health care activity, or has not been sentenced to a jail term due to a serious criminal offence against the health of people by judgment absolute.

License Renewal

Article 196

(1) For the purpose of renewing the license, a health care practitioner shall submit the application to the competent association, 60 days prior to the expiry of the period for which the license was issued.

(2) Together with the application for license renewal, the health care practitioner shall also submit the evidence of the implemented procedure of continuous education in compliance with this Law and the regulations adopted for enforcement of this Law, as well as the evidence of professional qualifications for continuing his/her practice.

(3) License shall be renewed every seven years.

License Withdrawal

Article 197

(1) The association shall temporarily withdraw the license from a health care practitioner if the practitioner:

1) Fails to renew the license, under the conditions laid down by this Law;

2) Is engaged in an activity for which he has not been issued the license;

3) Makes a professional mistake while performing his/her practice conduct due to which the state of patient's health is compromised or aggravated;

4) Was temporarily banned from independent practice by the competent body of the association, due to a major breach of professional duty and prejudice to reputation of a member of the association, in compliance with the law and the articles of association of the association;

5) Has been sentenced by judgment absolute for the criminal offence, which makes him/her discreditable to practice the profession of a health care practitioner;

6) When engaging in a health care activity misappropriates the funds of the health insurance;

7) In other cases laid down by the law.

(2) Temporary withdrawal of the license for the reasons specified in paragraph 1, Item 1) of this Article may last until the renewal of the license, under the conditions laid down by this Law.

(3) Temporary withdrawal of the license for the reasons specified in paragraph 1, Items 2) to 7) of this Article may last from six months to five years from the date of receipt of the decision on temporary withdrawal of the license.

(4) Malpractice, in the sense of this Law, implies unconscientious treatment, and/or negligence of professional duties in providing health care, and/or noncompliance with or ignorance of the established rules and professional skills in the provision of health care leading to compromising, aggravation, injury, loss or damage of the health or of parts of the body of a patient.

(5) The malpractice referred to in paragraph 4 of this Article shall be established in the disciplinary proceeding before the competent body of the association, or in the process of regular and unscheduled external quality assurance of the professional work of health care practitioners.

Article 198

(1) An association shall permanently withdraw the license from a health care practitioner if the health care practitioner has been, by judgment absolute, sentenced to jail term due to a serious criminal offence against the health of people.

(2) The health care practitioner whose license has been permanently withdrawn can engage in certain types of practice within the health care activity under the supervision of a health care practitioner whose license has been issued, or renewed, who will be designated by the director of the health care facility, or the founder of private practice in which the health care practitioner is engaged in certain types of practice within the health care activity.

Article 198

(1) For carrying out the activities of a medical associate in a health care facility, private practice or other legal entity dealing with certain health care activity pursuant to this Law, the Minister shall, by decision, issue, renew or withdraw the license for independent work (hereinafter: health care associate license).

(2) The Minister shall issue the license to a medical associate based on the application submitted by the medical associate to the Ministry, provided such medical associate finished their internship and passed the exit exam pursuant to this Law.

(3) The decision in paragraph 1 of this Article is final in the enforcement procedure and an administrative suit may be instituted against it.

(4) The records on issued, renewed or withdrawn licenses of medical associates shall be kept by the Ministry.

(5) The medical associate license is issued for the period of seven years.

(6) The medical associate license is a public document.

(7) The costs of medical associate license issuance or renewal shall be established by the Minister.

(8) The resources obtained from the payment of compensation for issuing or renewal of medical associate license are the revenue of the budget of the Republic and intended for funding all costs related to issuing or renewal of medical associate licenses.

(9) The costs in paragraph 7 of this Article are borne by the license issuing or renewal applicant.

Article 198b

(1) A medical associate who failed to obtain or renew the license under the conditions specified by this Law and regulations adopted for the enforcement of this Law cannot work independently in a health care facility or private practice or with other legal entity dealing with certain health care activity pursuant to this Law.

(2) A medical associate shall submit the application to the Ministry for license approval 60 days before the expiry of the license term.

(3) Medical associate's license shall be renewed at 7-year intervals.

(4) Medical associate's license is withdrawn by the Minister if:

1) the medical associate fails to renew the license pursuant to this Law and bylaws adopted for the enforcement of this Law or fails to submit evidence on acquired continual education, as well as evidence on the expertise for continuing professional work;

2) the medical associate performs the activity without being issued the medical associate license;

3) the medical associate was convicted, by a valid court decision, for a criminal act making them unworthy of the medical associate profession;

4) in other cases set out by law.

(5) Detailed conditions for, renewal or withdrawal of the medical associate license, method of issuance, renewal or withdrawal of license, form and contents of the issued, renewed and withdrawn license, continual education program conducted for gaining professional skills and capabilities of a medical associate for independent work or license renewal, and other issues regulating in more detail the procedure for temporary license issuance, renewal and withdrawal are specified by the Minister.

5. Sideline Work of Health Care Practitioners

Article 199

(1) A health care practitioner, a medical associate or other person employed with a health care facility or private practice, working in a team with a health care practitioner in the provision of health care pursuant to this Law (hereinafter: other employee), may engage in sideline practice within the health care facility or private practice, outside the regular working hours, pursuant to this Law.

(2) Such sideline practice in paragraph 1 of this Article can be conducted with the employer with whom the health care practitioner, medical associate or another employee has concluded a contract on full time employment, or with another employer, provided that the practice of such health care practitioner, medical associate or other employee outside the regular working hours for which a sideline practice contract is concluded, does not interfere with the work organization of certain parts of the overall health care facility.

(3) For conducting sideline practice referred to in paragraphs 1 and 2 of this Article, a health care practitioner, medical associate or another employee concludes the sideline practice contract with the employer for whom such practice is conducted.

(4) A health care practitioner, medical associate or another employee can conclude a sideline practice contract for not more than one third of the full time practice.

(5) The method, procedure and requirements, and other issues relevant to sideline practice of health care practitioners, medical associates or other employees shall be specified by the Minister.

Article 200

A sideline practice contract can be concluded:

1) For the provision of health services that are not covered by mandatory health insurance with respect to the contents, coverage and standards, or for the health services that are not provided in accordance with the method and procedure for exercising the rights from the mandatory health insurance;

2) For the provision of health services that the health care facility provides for the requirements of the mandatory health insurance organization, for which it cannot otherwise provide adequate health care practitioners;

3) For the provision of health services that the health care facility provides for the requirements of the persons who do not have the capacity of insured person in compliance with the law regulating health insurance.

Article 201

(1) The sideline practice contract shall be concluded in writing and shall contain: the type, method, duration of the work, the amount and the method of the assessment of earning, the party liable to pay the established compensation for the provided health service, in compliance with law common acts of the employer.

(2) The patient, to whom a health service has been provided by a health care practitioner in compliance with Article 200, item 1) and 3) of this Law, or a health insurance company, pursuant to the regulations governing voluntary health insurance, or a mandatory health insurance organization, in case of Article 200, item 2) of this Law, shall pay the assessed compensation to the health care facility for provided services.

(3) A health care facility or a private practice shall either issue a bill to the patient for provided health care services on a specified form, or an invoice to the mandatory health insurance company or an insurance company, pursuant to the regulations governing health insurance.

(4) A health care facility or a private practice shall pay the contractual fee in paragraph 1 of this Article to a health care practitioner, medical associate or other employee with the first next salary but not later than 30 days from the date of service provision, or the date of transfer of funds from the mandatory health insurance company or other insurance company.

(5) A health care facility or a private practice shall keep records of the contract concluded for sideline practice.

(6) In its financial plan, a health care facility shall separately present and keep the records on funds incurred on the ground of sideline work in compliance with this Law.

(7) Employers which organize such sideline practice pursuant to this Law shall provide the patient, and persons hired on grounds of sideline work contract, with necessary information about the method and procedure of the provision of health services within the sideline work of health care practitioners, as well as put up on prominent places in the health care facility the information on the availability of sideline practice.

Article 202

(1) The health care practitioner or any other employee who engages in the practice on the ground of the sideline practice contract pursuant to this Law shall have the rights in the mandatory compulsory social insurance, in compliance with law.

G. QUALITY OF HEALTH CARE, QUALITY ASSURANCE OF PROFESSIONAL PRACTICE AND ACCREDITATION

1. Quality of Health Care

Article 203

(1) Quality of health care, in the sense of this Law, implies the measures and activities by which, in line with the modern achievements of medical, dental medical, and pharmaceutical sciences and practices, as well as with the modern achievements of science and practice that contribute to a higher level of the quality of health care services provided by health care practitioners, the chances for a favorable outcome will be increased and the risk of onset of undesired consequences for the health and the state of health of an individual and the community as a whole will be diminished.

(2) The quality of health care referred to in paragraph 1 of this Article shall be assessed on the basis of relevant indicators that are related to the coverage of the population by health care practitioners, the capacities of health care facilities, equipment, i.e. that are related to the indicators of the process and results of work and the outcome for the health of the population, as well as on the basis of other indicators based on which the quality of health care is assessed.

(3) The indicators of the quality of health care referred to in paragraph 2 of this Article shall be laid down by the Minister.

(4) The quality of health care shall be assessed in the process of the quality assurance of professional work, in compliance with this Law.

2. Quality Assurance of Professional Practice

Article 204

The quality assurance of professional practice, in the sense of this Law, implies the procedure of the quality assurance of professional practice of the health care facilities, private practices, health care practitioners, and medical associates.

Article 205

The quality assurance of professional practice shall be carried out as:

- 1) Internal quality assurance of professional practice;
- 2) External quality assurance of professional practice.

Internal Quality Assurance of Professional Practice

Article 206

(1) The internal quality assurance of professional practice shall be conducted in every health care facility and private practice, as well as of health care practitioners and medical associates.

(2) Internal quality assurance of professional practice in a health care facility shall be conducted on the basis of the annual quality assurance program of professional practice, which shall be instituted by the commission for the improvement of the quality of professional practice of the health care facility.

(3) Internal quality assurance of professional practice of a private practice shall be conducted on the basis of the annual quality assurance program of professional practice, which shall be instituted by the founder of private practice.

Article 207

(1) Health care practitioners and medical associates shall report to the head practitioner of the organizational unit, or service for the quality of their professional practice.

(2) The head practitioner of the organizational unit or service referred to in paragraph 1 of this Article shall report to the director of the health care facility, or to the founder of a private practice for the quality of his/her work as well as for the quality of professional practice of the organizational unit or the service he/she manages.

External Quality Assurance of Professional Practice

Article 208

(1) External quality assurance of professional practice can be regular and unscheduled.

(2) Regular external quality assurance of professional practice shall be organized and implemented by the Ministry, on the basis of the annual plan of quality assurance of professional practice, which shall be adopted by the Minister.

(3) Unscheduled external quality assurance of professional practice shall be undertaken by the Ministry at the request of a citizen, a company, facility, health insurance organization, and a Government authority.

(4) The application referred to in paragraph 3 of this Article shall be submitted to the Ministry which will review it and notify the applicant on the conclusions.

(5) A health care facility, or private practice, as well as a health care practitioner, or medical associate shall cooperate with the professional supervisors and submit to them all the required data and other documentation required for conducting a regular or unscheduled external quality assurance of professional practice.

Article 209

(1) Both regular and unscheduled external quality assurance audits of professional practice are conducted by the professional inspectors listed in the inspector list composed by the Minister.

(2) The competent association shall propose to the Minister a list of inspectors from the ranks of distinguished experts in certain areas of health care.

(3) Regular and unscheduled quality assurance audits of professional practice shall be conducted by a professional inspector having at least identical professional qualifications, or scientific degree as that of the head practitioner of the relevant organizational unit or service that is to be audited, or as that of the health care practitioner whose quality of professional practice is to be assessed.

(4) The inspectors in the inspector list shall carry out regular and unscheduled external quality assurance audit of professional practice conscientiously and professionally, and in accordance with the modern scientific achievements and the code of professional ethics.

(5) The inspectors in the inspector list cannot refuse to participate in the conducting regular and unscheduled external quality assurance of professional practice.

Article 210

(1) Regular and unscheduled external quality assurance of professional practice can be carried out by one or more inspectors depending on the type and complexity, or on the plan for conducting external quality assurance of professional practice.

(2) Inspectors shall make reports on the quality assessment of professional practice, which will include the identified deficiencies and failures in professional practice, as well as professional opinion about possible consequences for the health of the citizens, which they will, within 15 days from the date of completion of regular and unscheduled external quality assurance of professional practice submit to the Minister and to the health care facility or to the private practice, as well as to the competent association if a health care practitioner is the subject of the quality assurance of professional practice.

(3) Inspectors shall, in the course of carrying out regular and unscheduled external quality assurance of professional practice, give professional advice and proposals for eliminating failures in the work of a health care facility, private practice, health care practitioner, or medical associate.

(4) Inspectors shall, on the basis of the reports referred to in paragraph 2 of this Article, propose to the Minister the actions necessary to be undertaken for the purpose of elimination of identified deficiencies in the professional practice of health care facilities, private practices, health care practitioners, or medical associates.

(5) The health care facility, private practice, health care practitioner, or medical associate can file a complaint to the Minister against the report of the inspector referred to in paragraph 2 of this Article within three days from the date of receipt of the report.

Article 211

(1) Upon review of the reports submitted and the actions proposed by the inspectors, as well as of any filed complaints referred to in Article 210 of this Law, the Minister shall issue the decision by which he/she may:

1) Temporarily ban, fully or partially, the conduct of specified practices by the health care facility, or private practice;

2) Temporarily ban, fully or partially, the operation of an organizational unit of a health care facility, or private practice;

3) Temporarily ban the operation of a health care facility, or private practice;

4) Propose to the competent association to withdraw the license from the health care practitioner, under the conditions laid down by this Law.

(2) The temporary prohibition of operation referred to in paragraph 1, Items 1) to 3) of this Article shall be effective until the causes of such prohibition are eliminated.

(3) On the basis of the reports submitted and the actions proposed by inspectors referred to in Article 210 of this Law, as well as on the basis of the proposal by the Minister referred to in paragraph 1, Item 4) of this Article, if a failure in the professional practice of a health care practitioner or compromising of the principles of professional ethics are established, the competent association can withdraw the license for independent practice of a health care practitioner, or pronounce one of the disciplinary actions laid down by the law governing the work of health care practitioners associations .

Article 212

The conditions, method, the procedure, deadlines, and organization of the implementation of internal and external quality assurance audits of professional practice, the actions that may be undertaken for eliminating the identified deficiencies and other relevant issues for conducting a quality assurance audit of professional practice of health care facilities and private practices, health care practitioners, and medical associates – are laid down by the Minister.

3. Accreditation

Article 213

Accreditation, in the sense of this Law, is the procedure of assessing the quality of work of a health care facility, on the basis of the implementation of the optimal level of established standards of work of a health care facility in a certain area of health care, or branch of medicine, dental medicine or pharmaceutical health care activity.

Agency for Accreditation of Health Care Facilities of Serbia

Article 214

(1) The accreditation referred to in Article 213 of this Law shall be administered by the Agency for Accreditation of Health Care Facilities of Serbia (hereinafter referred to as: the Agency), as the organization administering professional, regulatory, and developmental affairs, which will be founded by the Government in the name of the Republic, in compliance with the law regulating public agencies.

(2) The Agency shall have the capacity of a legal person obtained by its registration in the court register.

(3) The Agency shall be independent in its work.

Article 215

(1) The Agency shall be entrusted with the following affairs of government administration as its public authorities:

- 1) Establishing of standards for accreditation of health care facilities;
- 2) Assessment of the quality of the health care provided to the population;
- 3) Settling the administrative matters concerning the accreditation of health care facilities;
- 4) Issuing and withdrawal of official accreditation documents (hereinafter referred to as: the certificate) and keeping records on the issued certificates.

(2) The Government shall give its consent on the act referred to in paragraph 1, Item 1) of this Article.

Accreditation Procedure

Article 216

(1) Accreditation is voluntary and it shall be carried out at the request of a health care facility.

(2) The application for accreditation shall be submitted to the Agency by a health care facility.

(3) Accreditation will be acquired by a health care facility for which the Agency establishes to have met the established standards for a certain area of health care, or branch of medicine, dental medicine or pharmaceutical health care activity.

(4) The Agency shall issue the certificate of accreditation to a health care facility, in the administrative procedure.

(5) The decision on issued certificate referred to in paragraph 4 of this Article shall be final in the administrative procedure and an administrative suit may be instituted against it.

(6) The method, procedure, and the requirements for accreditation of health care facilities shall be laid down by the Minister.

Article 217

(1) The Certificate referred to in Article 216, paragraph 4 of this Law may be related to:

- 1) Individual area of health care or the branch of medicine, dental medicine or pharmaceutical health care activity the health care facility is engaged in;
- 2) The entire activity of a health care facility.

(2) The Certificate shall be issued for a certain period, maximum for a period of seven years.

(3) Upon expiry of the time period referred to in paragraph 2 of this Article, the accreditation procedure may be repeated at the request of the health care facility.

(4) The Certificate of Accreditation of a health care facility shall be published in the Official Journal of the Republic of Serbia.

Article 218

(1) The health care facility that has been accredited shall report to the Agency every change related to the accreditation.

(2) The Certificate of Accreditation obtained in compliance with this Law or a certificate recognized by the European agency in charge of accreditation of health care facilities evidences that the health care facility meets the national or internationally recognized standards in providing health care.

(3) The Agency shall be financed from its own revenues.

(4) The accreditation cost shall be borne by the health care facility that has submitted the application for accreditation.

(5) The amount of the fees referred to in paragraph 4 of this Article, which represent the revenue of the Agency, shall be regulated by the Agency.

(6) The act referred to in paragraph 5 of this Article is approved by the Government.

Procedure for Withdrawal of Accreditation

Article 218

(1) The Agency can, by virtue of duty, withdraw the accreditation certificate provided that a health care facility failed, after the certificate had been issued, to meet the established standards related to a specific area of health care or branch of medicine, dental medicine or pharmaceutical health activity based on which the accreditation certificate had been issued.

(2) The accreditation certificate withdrawal is the subject of the decision issued by the Agency, which is final in the enforcement procedure and an administrative suit may be instituted against it.

(3) The decision in paragraph 2 of this Article is published in the "Official Journal of the Republic of Serbia".

(4) Detailed conditions and method for accreditation certificate withdrawal are specified by the Minister.

IX. ESTABLISHING THE TIME AND CAUSE OF DEATH AND AUTOPSY OF DECEASED PERSONS

Article 219

(1) For each deceased person, the time and cause of death are established on the basis of direct examination of the deceased person.

(2) Establishing the time and cause of death may be done only by a medical doctor.

(3) For persons died in a health care facility, the time and cause of death are established in the health care facility that notifies the competent authority of the municipality, or city of the circumstances.

(4) The competent authority of a municipality or a city shall designate the medical doctor to determine the time and cause of death of and issue death certificate for those died outside a health care facility.

(5) The medical doctor referred to in paragraph 4 of this Article shall, within 12 hours from the received call, perform a physical examination of the deceased and establish the time and cause of death.

(6) The funds for examination of the deceased persons and professional establishing of the time and cause of death for the persons who have died outside a health care facility shall be provided in the budget of the municipality or city.

Article 220

(1) The medical doctor who conducts direct examination of a deceased person for the purpose of establishing the cause and time of death, irrespective of whether the death occurred in a health care facility, private practice or elsewhere, shall, without delay, notify the competent organizational unit of the ministry in charge of interior affairs about the death case if:

- 1) He/she is unable to establish the identity of the deceased person;
- 2) By examining the deceased person he/she detects injuries or otherwise suspects a violent death;
- 3) It is not possible to establish the cause of death on the basis of available medical indications.

(2) In the cases referred to in paragraph 1 of this Article, the medical doctor who conducts direct examination of the deceased person shall not issue the death certificate until the competent court hands down the decision related to the autopsy.

Article 221

(1) A health care facility shall inform an adult member of the family about the cause and time of death of the deceased person, within the shortest possible time, as well as enable that person to have direct access to the body of the deceased person in the presence of the medical doctor who has, by direct examination, established the time and cause of death.

(2) The member of the family referred to in paragraph 1 of this Article may refuse to have direct access to the body of the deceased person, on which an annotation shall be made, which shall be signed by a member of the family of the deceased person.

Article 222

(1) Autopsy shall be performed as a special measure of establishing the time and cause of death of deceased persons.

(2) Autopsy shall be obligatorily performed:

1) On the person died in a health care facility if the cause of death has not been established;

2) On the person died prior to the expiry of 24 hours from the beginning of treatment in an inpatient health care facility;

3) On the newborn baby that died in a health care facility immediately after birth or in the course of treatment;

4) At the request of the medical doctor who treated the deceased person;

5) At the request of the medical doctor designated to establish the cause of death by the competent authority of the municipality or city;

6) When that is of a particular importance for the protection of health of the citizens or when that is required due to the epidemiological or sanitary reasons;

7) At the request of the competent court;

8) At the request of a member of the immediate family of the deceased person;

9) If the death occurs in the course of a diagnostic or therapeutic procedure.

(3) A deceased person is buried after the death has been established, as a rule, within 24 to 48 hours from the occurrence of death, in compliance with the law.

(4) Exceptionally from paragraph 4 of this Article, on the basis of a special request from the sanitary inspection, burial may be carried out even prior to the expiry of the period of 24 hours, or after expiry of the period of 48 hours.

(5) While doing an autopsy, the medical doctor who performs the autopsy may retain organs, parts of organs, and other samples of biological origin, in accordance with the rules of the profession, when that is necessary for the purpose of establishing the cause of death or it is of special importance for protection of health of the citizens.

(6) In case of the autopsy of the person referred to in paragraph 2, Item 3), it shall be obligatory to take and permanently keep biological samples, in accordance with the rules of the profession.

(7) The method and procedure for establishing the time and cause of death of deceased persons and for the autopsy of a corpse, as well as for disposal of the parts of human body that are surgically or otherwise eliminated, shall be specified by the minister.

Article 223

(1) The costs of autopsy of a deceased person shall be borne by the party liable to pay the costs of treatment of the deceased person, unless otherwise specified by this Law.

(2) The costs of autopsy of a deceased person referred to in Article 222, paragraph 2, Item 5) of this Law shall be borne by the municipality, or city.

(3) The costs of autopsy of a deceased person referred to in Article 222, paragraph 2, Items 7) and 8) of this Law shall be borne by the applicant.

X. TAKING AND TRANSPLANTATION OF ORGANS AND PARTS OF HUMAN BODY

Article 224

(1) Organs, tissues, and cells, as parts of human body, can be taken and transplanted only if that is medically justified, or if that is the most favorable method of treatment and if the requirements laid down by the law are met.

(2) The method, procedure, and the conditions for taking and transplantation of organs, tissues, and cells, as parts of human body, and/or the method, procedure, and conditions for treatment of infertility by applying biomedically assisted fertilization, shall be specified by a separate law.

XI. TAKING OVER OF BODIES OF DECEASED PERSONS FOR THE PURPOSE PROVIDING PRACTICAL TRAINING

Article 225

(1) Medical faculties (hereinafter referred to as: the Faculty) can take over bodies, organs, and tissues of the deceased and identified persons for the purpose of practical training:

1) If the deceased person has expressly, in writing, bequeathed his/her body for the purpose of practical laboratory training;

2) If it is a person who died without a family and he/she personally, while still alive, did not expressly oppose to it in writing;

3) With the consent of the family, if the deceased person, while he/she was alive, did not expressly oppose to it in writing.

(2) The bequest, in the sense of paragraph 1, Item 1) of this Article, is the declaration of bequeathing the body, certified in court and containing the statement pertaining to the administrator of the bequest.

Article 226

The family in the sense of Article 225 of this Law shall imply: spouses and common-law partners, children born in wedlock and out of wedlock, adopters and adoptees, guardians and wards, foster parents and foster children, parents and other kins by blood in lineal line of descent irrespective of the degree of kinship, as well as kins by blood in collateral line of descent inclusive of the third degree of kinship.

Article 227

(1) A health care facility, penitentiary institution, institution of social protection, the competent court, the authority in charge of interior affairs, as well as other institutes and organizations, or citizens who have learnt about the death of the person who fulfills the requirements laid down by this Law concerning the providing of practical training at faculties, shall within 12 hours from the death of that person inform the authority of the local self-government in charge of keeping the register of records of deceased persons, as well as the faculty, about the death of that person, for the purpose of taking over of the body of the deceased by the faculty.

(2) The decision on taking over of the body by the faculty shall be handed down by the ethics committee of the faculty.

(3) A faculty may take over the body of a deceased person for the purpose of providing practical training in anatomy only if there is a report on death that has been signed by a specialist in forensic medicine – medical examiner, and under the condition that there are no statutory reasons for performing of obligatory autopsy.

Article 228

(1) A faculty may not use the body of a deceased person who has no family in practical training within six month from the date of takeover.

(2) A faculty shall not take over the body of a person who has died of a communicable disease, or the body on which marked postmortem changes, which prevent fixation (embalming) have occurred.

(3) A faculty shall treat the body of a deceased person with dignity, it shall use it exclusively for the purpose of providing practical training, and shall bury it after completion the training at its own cost.

(4) A faculty shall, within the limits of its abilities, honor special wishes of the testator related to burial, cremation, religious ceremony, and other clearly expressed wishes of the testator related to the treatment of his/her body for the purpose of providing practical training in anatomy.

(5) A faculty shall honor the wish of the testator that, after the process of practical training, his/her body be used for assembly of the osteological set (skeleton), which will be used in practical training in anatomy.

Article 229

(1) A faculty may directly take over the body of a deceased and identified person referred to in Article 225, paragraph 1, Items 1) and 3) of this Law.

(2) A faculty can take over the body referred to in Article 225, paragraph 1, Item 2) of this Law upon having obtained the approval from the competent authority of the local self-government.

(3) The competent authority of the local self-government shall promptly notify the faculty about the deceased and identified person whose body may be used to provide practical training at medical faculties, under the conditions laid down by this Law.

Article 230

Should a member of the family of the deceased person, who was not known at the moment of death, submit, within six months from the date of taking over of the body by the faculty, a written request to the faculty for returning the body of the deceased person, the faculty shall return the body of the deceased person to the members of the family.

Article 231

(1) A faculty shall keep as a professional secret all the data related to the person whose organs or parts of the body have been taken in the sense of this Law, as well other necessary documentation about the deceased person whose body has been taken over for the purpose of providing practical training.

(2) The data referred to in paragraph 1 of this Article shall include: family name and name of the deceased, date of birth, place and date of death, cause of death, the number from the medical documentation, which must coincide with the number of the tag - marker next to the body of the deceased person, place and date of burial.

(3) The documentation referred to in paragraph 1 of this Article shall include: the report of the medical examiner, death certificate, ID card, health insurance card, and the declaration on bequeathal of the body.

(4) A faculty shall keep the data and the documentation referred to in this Article as permanent documentation, which must be made available to the competent services of the faculty, to the Ministry, Ministry of Education, Ministry of Interior, and to the competent authority of the local self-government.

Article 232

Only the students of undergraduate, postgraduate, and specialization studies on the Faculty shall be trained in the practical training in anatomy on the body of the deceased person, under the supervision of the lecturers and associates of the faculty.

Article 233

(1) After the completion of the process of practical training in anatomy, the body of the deceased person shall be buried.

(2) The funeral shall be announced in the form of an announcement and a paid advertisement in mass media, and the funeral ceremony shall imply lined up guard of honor by the lecturers and students of the faculty, as well as the appropriate religious ceremony if the deceased person requested it when he/she was alive.

Article 234

The ethics committee of a faculty shall supervise the procedure of taking over of parts of the bodies of deceased persons referred to in Articles 225 to 233 of this Law.

XII. TRADITIONAL MEDICINE

Article 235

(1) The traditional medicine, in the sense of this Law, shall include those verified professionally undisputable traditional, complementary, and alternative methods and procedures of diagnosis, treatment, and rehabilitation (hereinafter referred to as: the traditional medicine), which have or could have a therapeutic effect on human health or their health condition and which, in accordance with prevailing medical doctrine, are not covered by the health services.

(2) The method and procedures of the traditional medicine referred to in paragraph 1 of this Article may be introduced in a health care facility or private practice only upon the approval of the Ministry.

Article 236

(1) Only those methods and procedures of the traditional medicine shall be permitted that:

- 1) Are not detrimental to health;
- 2) Do not discourage the user/patient from the use of beneficial health services;
- 3) Are practiced in accordance with the recognized standards of the traditional medicine.

(2) The methods and procedures of the traditional medicine can be practiced by the health care practitioners who have permits for applying the methods and procedures of traditional medicine, which shall be issued by the Ministry.

(3) Detailed conditions, method, and procedure of implementing the methods and procedures of traditional medicine in a health care facility or private practice shall be specified by the Minister.

(4) The Ministry shall supervise the implementation of the methods and procedures of traditional medicine in health care facilities or private practices, in compliance with this Law.

(5) The provisions of this Law related to issuing, renewal, and withdrawal of the license, as well as the provisions of the law regulating the associations of health care

practitioners shall apply to the health care practitioners who implement the methods and procedures of the traditional medicine.

Article 237

The health care practitioners who implement the methods and procedures of the traditional medicine shall undertake professional, ethical, penal, and material responsibility for their work.

XIII. HEALTH CARE OF FOREIGNERS

Article 238

(1) Foreign citizens, stateless persons, and the persons whose refugee status has been recognized or who have been granted asylum in compliance with the international and domestic legislation in Serbia and Montenegro (hereinafter referred to as: the foreigners), who have permanent or temporary residence in the Republic, or who are in transit through the territory of the Republic, shall have the right to health care, in compliance with this Law, unless otherwise specified by international agreement.

(2) The persons, who have the status of refugees from the territories of the former Socialist Federal Republic of Yugoslavia states, shall have the right to health care in compliance with the regulations governing the area of refugees.

(3) The funds for exercising of the right to health care referred to in paragraph 2 of this Article shall be provided in the budget of the Republic.

(4) The foreigners who meet the requirements for eligibility for insurance in compliance with the law governing the area of mandatory health insurance shall be provided with health care in compliance with those regulations.

Article 239

Health care of foreigners shall be provided in the way in which health care is provided to the citizens of the Republic.

Article 240

(1) A health care facility and private practice, as well as health care practitioners, shall provide emergency medical care to a foreigner.

(2) Foreigners shall personally bear the expenses for the provided emergency medical care, as well as for other types of health care services provided to them at their request, unless otherwise specified by this Law or by international agreements.

(3) For the use of health care services referred to in paragraph 2 of this Article, a foreigner shall pay a fee according to the pricelist of the health care facility or according to the pricelist of private practice.

Article 241

The fees shall be paid to the health care facilities from the budget of the Republic according to the pricelist of the health services which has been adopted by the mandatory health insurance organization for the health care services covered by mandatory health insurance, for the following extended health services:

1) To the foreigners to whom health care is provided free of charge on the basis of an international agreement social insurance, unless otherwise specified by that agreement;

2) To the foreigners who stay in the Republic against the invitation by the government authorities – in the course of their stay, in accordance with the principles of reciprocity, and who do not fulfill the requirements for eligibility to become a compulsory insured person in compliance with the law governing the area of compulsory health insurance;

3) To the foreigners who have been granted asylum in Serbia and Montenegro, if they are materially unprovided;

4) To the foreigners who have contracted small pocks, plague, cholera, viral hemorrhagic fever (except for the hemorrhagic fever with kidney syndrome), malaria or yellow fever, as well as other communicable diseases due to which such person shall be put under medical supervision in compliance with the regulations governing the area of protection of the population from communicable diseases;

5) To the foreigners – members of crews of foreign ships or vessels, who have contracted venereal diseases;

6) To the foreigners who are victims of people trafficking.

Article 242

(1) The fee shall be paid from the budget of the Republic to the health care facilities and private practices for the emergency medical care provided to foreigners if the health care facility or private practice could not collect such fee from the foreigner, because he/she does not have the necessary money.

(2) The fee referred to in paragraph 1 of this Article shall be paid on the basis of the request of a health care facility or private practice and of the evidence that a health care service has been provided.

(3) A health care facility or private practice shall submit to the Ministry the request for payment of the fee referred to in paragraph 1 of this Article, together with the medical documentation about the health care services provided to a foreigner.

(4) In the procedure of deciding on the request referred to in paragraph 3 of this Article, the Ministry may have insight into the medical and other documentation on the treatment of foreigners, as well as to seek professional opinion from the referential health care facility.

(5) Upon effected payment of the fee to health care facility or private practice, the Ministry shall undertake measures, through the competent authorities, to collect such expenses from the foreigner in favor of the Republic budget.

XIV. SUPERVISION OVER THE WORK OF HEALTH CARE FACILITIES AND PRIVATE PRACTICES

Article 243

(1) Supervision and inspection supervision over the work of health care facilities and private practices, in the sense of this Law, shall be exercised as supervision over the legality of work of health care facilities and private practices.

(2) The Republic shall provide for the administration of health inspection issues.

(3) The supervision referred to in paragraph 1 of this Article shall be conducted by the Ministry through health inspectors and inspectors in charge of the area of medicines and medical devices (hereinafter referred to as: the pharmaceutical inspector).

(4) The inspector referred to in paragraph 3 of this Article shall perform the supervisory duty dressed in suit which appearance is specified by the Minister.

Health Inspection

Article 244

(1) A health inspector shall be independent in the work within the limits of the authorities specified by this Law and the regulations adopted for enforcement of this Law and shall be personally responsible for his/her work.

(2) A health inspector shall act conscientiously and impartially in administering the affairs of supervision, and/or keep as official secret the data he/she obtains in the course of exercising the supervision, and in particular the data related to the medical documentation of patients.

(3) The provisions of the law regulating general administrative procedure, as well as of the law regulating the work of the government administration shall apply to the exercising of supervision by a health inspector, unless otherwise regulated by this Law.

Article 245

(1) The affairs of a health inspector may be administered by a person who has graduated from the faculty of medicine, dental medicine, pharmacy or law, who has passed intern's exit exam in compliance with this Law and the certification exam for work in the authorities of government administration and minimum three years of service in the profession.

(2) A health inspector shall have the official identity document by which he/she will identify himself/herself and which he/she shall present at the request of the person in charge or other interested person on the occasion of exercising of supervision.

(3) The form and contents of the identity document referred to in paragraph 3 of this Article shall be specified by the Minister.

Article 246

(1) Health care facilities and private practices shall enable the health inspector to administer the affairs of supervision without hindrance, in compliance with this Law, and/or to enable him/her unhindered inspection of the premises, equipment, enactments and other data required for exercising the supervision.

(2) A health inspector, in administering the affairs of supervision over a health care facility and private practice, for the purpose of obviation of possible suppression of evidence, shall have the right to temporarily sequester items and original documentation of a health care facility and private practice, with the mandatory issuing of the receipt for the temporarily sequestered items, and/or documentation.

Article 247

In exercising supervision, a health inspector shall be authorized to:

1) Review bylaws and individual enactments of a health care facility and private practice, and/or have insight in the medical and other documentation, which is of importance for handing down the decision in exercising the supervision;

2) Examine and take the statements from the person in charge, and/or health care practitioner and medical associate, as well as from other interested persons;

3) Inspect the premises and equipment, and/or examine the conditions for setting up, commencement of work, and engaging in a health care activity, laid down by this Law;

4) Have insight in the documentation of a health care facility and private practice, on the basis of which health care of citizens is provided, and/or have direct insight in providing of health care and the rights of patients in the health care facility, or private practice;

5) Have direct insight in the implementation of the measures handed down in compliance with this Law in the procedure of quality assurance of professional work in the health care facility, or private practice;

6) Review the submissions of legal and natural persons related to the work of health care facility and private practice, and/or to the provision of health care;

7) Administer other affairs of supervision, in compliance with the law.

Article 248

(1) The health inspector shall make the minutes on the completed inspection in the procedure of supervision, containing the findings of the facts established in a health care facility, or private practice.

(2) The minutes referred to in paragraph 1 of this Article, shall be submitted by the health inspector to the health care facility, or private practice, over which supervision has been exercised.

(3) The health inspector, on the basis of the minutes referred to in paragraph 2 of this Article, shall hand down the decision ordering the measures, actions, as well as deadlines for implementation of the measures ordered to health care facility, or private practice.

(4) Against the decision referred to in paragraph 3 of this Article a complaint may be filed to the minister.

(5) The decision of the Minister referred to in paragraph 4 of this Article shall be final in the administrative procedure and an administrative suit may be instituted against it.

(6) Should a health inspector assess that by acting or failing to act a health care facility, or private practice over which supervision has been exercised, a criminal act, economic offence or an offence has been committed, he/she shall without delay inform the competent authority against the committed criminal act, economic offence, or the claim for initiation of minor offence proceedings.

Article 249

In exercising supervision, a health inspector shall have the authority to:

1) Establish whether the requirements have been met for the commencement of work and engaging in a health care activity of health care facility or private practice, with respect to the premises, equipment, staff, and drugs laid down by this Law and by the regulations adopted for enforcement of this Law;

2) Order elimination of the established irregularities and deficiencies in the work of a health care facility or private practice, within the time period that may not be shorter than 15 days or longer than six months from the date of receipt of the document by which such measure was ordered and, in emergency cases, order elimination of the established irregularities and deficiencies forthwith;

3) Order implementation of the specified measure to health care facility or private practice, within the time period that may not be shorter than 15 days or longer than three months from the date of receipt of the document by which that measure was ordered and, in emergency cases, order implementation of the specified measures forthwith;

4) Temporarily ban engaging in the activity of a health care facility or private practice, and/or engaging in certain types of practice within a health care facility and private practice, if practiced contrary to the provisions of this Law and the regulations adopted for enforcement of this Law, within the time period that may not be shorter than 60 days or longer than six months from the date of receipt of the document by which that action was brought;

5) Temporarily ban engaging in the health care activity, or engaging in certain types of practice within the health care activity, by a health care practitioner or medical associate who is engaged in a health care activity contrary to the provisions of this Law and the regulations adopted for enforcement of this Law, within the time period that may not be shorter than 30 days or longer than six months from the date of receipt of the documents by which that action was brought;

6) Temporarily ban independent practice of a health care practitioner against whom the competent association has brought one of the disciplinary actions of temporary ban on independent practice, in compliance with the law regulating the work of the associations of health care practitioners;

7) Temporarily ban the work of a health care facility or private practice if, within the specified time period established in Items 2) and 3) of this Article, it has not harmonized its engaging in the health care activity with this Law and the regulations adopted for enforcement of this Law, or if it has not eliminated the established irregularities and deficiencies in its work, and/or it has not implemented the specified measures handed down by the health inspector;

8) Temporarily ban the work of a health care facility or private practice, in cases laid down in Articles 53 and 65 of this Law;

9) Ban the independent practice of a health care practitioner who has not been issued, or renewed the license for independent practice, or whose license for independent practice has been revoked, under the conditions laid down by this Law;

10) Propose to the competent association revoking of the license of a health care practitioner for the reasons laid down by Article 197 of this Law;

11) Refer a health care practitioner, or medical associate, to examination for the purpose of assessment physical fitness in case of doubt in physical fitness to engage in a health care activity, or in certain type of practice within the health care activity;

12) Ban engaging in a health care activity and undertake other actions, in compliance with the law, against legal and natural persons who are engaged in a health care activity without the decision of the Ministry establishing fulfillment of the requirements for engaging in a health care activity;

13) Ban engaging in a health care activity and undertake other actions, in compliance with the law, against natural persons who engage in a health care activity, who, in the sense of this Law, are not considered to be health care practitioners;

14) Undertake other measures laid down by the law.

Article 250

(1) The costs of health inspection incurred in the procedure at the request of a client shall be borne by the applicant.

(2) The Minister shall specify the amount of expenses referred to in paragraph 1 of this Article.

(3) The resources obtained in the procedure at the client's request are the revenue of the budget of the Republic and intended for funding all costs related to the enforcement of that procedure.

Article 251

A health inspector and a pharmaceutical inspector shall jointly participate in the supervision over the pharmaceutical health care activity in a pharmacy or other organizational part of a health care facility that is engaged in a type of practice of the pharmaceutical health care activity, or hospital pharmacy, as well as in a pharmacy founded as a private practice, in compliance with this Law.

Pharmaceutical Inspection

Article 252

(1) For starting to engage in a pharmaceutical health care activity in a pharmacy as an independent health care facility, which within its complement has a galenic laboratory, as well as in a hospital pharmacy making galenic remedies, the decision on fulfillment of the requirements for making of galenic remedies shall be handed down by the pharmaceutical inspector, in compliance with the law governing the area

of medicines and medical devices, and for engaging in the activity of a pharmacy laid down in Article 100 of this Law, the decision on fulfillment of the requirements for engaging in the pharmaceutical health care activity shall be handed down by health inspector.

(2) A pharmaceutical inspector shall have the authority to exercise inspection supervision on his/her own, and/or to undertake and order specified measures against the pharmacy, or against the hospital pharmacy, which make galenic remedies, in compliance with the law governing the area of medicines and medical devices.

Article 253

(1) A pharmaceutical inspector shall have the authority to independently exercise supervision over the retail trade in drugs, and/or over making of magistral preparations in a pharmacy as an independent health care facility or other organizational part of the health care facility that is engaged in the practice of the pharmaceutical health care activity, in a hospital pharmacy, or in a pharmacy set up as a private practice.

(2) In exercising the inspection supervision referred to in paragraph 1 of this Article, the pharmaceutical inspector shall have the authority to:

1) Review bylaws and individual enactments, records and other documentation that is related to the making of magistral preparations, retail trade in medicines and medical devices, testing of the quality of drugs, as well as the documentation that is related to the implementation of the guidelines for the Best Laboratory Practice, the Best Distribution Practice, as well as of standard and operational procedures for the area of medicines;

2) Inspect the premises and equipment, and/or examine other conditions for the retail trade in drugs, and/or making of magistral preparations;

3) Have direct insight in the implementation of the guidelines for the Good Laboratory Practice and the Good Distribution Practice, under the conditions laid down by the law;

4) Have direct insight in the implementation of the Good Pharmaceutical Practice;

5) Take samples of galenic remedies, magistral preparations, and/or officinal drugs, as well as of certain types of medical devices that are in retail trade without compensation and in the quantities that are necessary, for the purpose of quality control;

6) Undertake other measures and actions related to the retail trade in medicines, and/or making of magistral preparations, in compliance with the law.

(3) The costs of laboratory control of the taken samples of medicines and certain types of medical devices referred to in paragraph 2, Item 5) of this Article shall be covered by the health care facility, or private practice in which the sample of a medicine and certain types of medical devices has been taken for the purpose of quality control.

Article 254

In exercising the supervision, the inspector in charge of the area of medicines and medical devices shall be authorized to:

- 1) prohibit manufacture and/or issuing of magistral preparations if they are not made in compliance with the law;
- 2) prohibit retail trade in galenic remedies, and/or officinal medicines, if they do not meet the requirements for putting into circulation laid down by the law;
- 3) prohibit retail trade in galenic remedies, and/or officinal medicines, which do not meet the requirements with respect to the quality laid down by the law;
- 4) Order recall from retail trade in magistral preparation, galenic remedy, and/or officinal medicine, or a series thereof, in the cases specified by the law;
- 5) Order destroying of a faulty medicine found in retail trade;
- 6) Undertake other measures, in compliance with the law.

Article 255

In the process/procedure of exercising supervision over the pharmaceutical health care activity, in the sense of this Law, the provisions of Articles 244 - 248 and Article 250 of this Law shall apply accordingly.

XV. PENAL PROVISIONS

Violation

Article 256

A health care facility or other legal entity dealing with health care activities shall be fined from RSD 300,000 to 1,000,000 for misdemeanor if it:

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- 4) **Deleted (Official Journal of the RS No. 45/13)**
- 4a) **Deleted (Official Journal of the RS No. 45/13)**
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- 5) **Deleted (Official Journal of the RS No. 45/13)**
- 6) **Deleted (Official Journal of the RS No. 45/13)**
- 7) In case of break out of epidemics and other major disasters and accidents, fails to timely and truthfully submit the data to the competent authority of the municipality, city, autonomous province, and the Republic (Article 41, paragraph 3);
- 8) Fails, within 48 hours from the date of admittance of the patient for inpatient treatment, whom the doctor in charge assesses that the nature of mental

illness of the patient is such that it may threaten the life of the patient or the life of other persons or property, to notify the competent court (Article 44, paragraph 2);

9) Engages in a health care activity and does not fulfill the requirements referred to in Article 49 of this Law;

10) Starts engaging in a health care activity prior to receiving the decision of the Ministry by which it has been established that the requirements for engaging in the health care activity have been fulfilled or if it is engaged in a health care activity contrary to the above decision (Article 51);

11) Applies new health care technologies without the permit by the Ministry for use of new health care technologies (Article 70, paragraph 1);

12) Advertises, and/or publicizes health services, professional medical procedures and methods of health care, including the health care services, methods, and procedures of the traditional medicine (Article 71, paragraph 1);

13) Puts up the name of the health care facility, which does not contain the data on the activity, which is specified by the decision of the Ministry, working hours, the founder and the seat of the health care facility, or if it puts up the name of the health care facility that has a trait to which the character of advertising, and/or publicizing can be attributed (Article 72, paragraphs 1 and 2);

14) Does not keep the medical documentation and records, and/or if within the specified timeframes, it fails to submit individual, summary, and periodic reports to the competent authority, or if it in any way violates the confidentiality of the data from the medical documentation of a patient, and/or if it fails to protect the medical documentation from unauthorized access, copying, and abuse (Article 73, paragraphs 1 and 3);

15) Fails to notify the municipality, or the city in the territory of which the health care facility in private ownership has its seat, about the weekly work schedule, opening and closing hours (Article 75, paragraph 3);

16) Fails to ensure minimum work process during a strike, and/or if a strike is organized in the health care facility that provides emergency medical care (Article 75, paragraphs 5 and 6);

17) Fails to submit the data on cases of poisoning to the poison control center, in compliance with this Law (Article 92, paragraph 5);

18) Organizational units, which are an integral part of the health care facility, bear the name of pharmacy, clinic, or institute, and do not fulfill the requirements specified by this Law concerning their formation (Article 142, paragraph 2);

19) Fails to organize professional bodies in the health care facility (Article 143);

20) Acquires the funds for work contrary to the provisions of Articles 159 and 160 of this Law;

21) Does not respect the conscientious objection expressed by a health care practitioner, and/or if it fails to ensure the provision of health care to a patient by another health care practitioner in case of an expressed conscientious objection (Article 171, paragraph 3);

22) Fails to create conditions and fails to organize serving of internship (Article 176, paragraph 3);

23) Does not provide to an employed health care practitioner and medical associate a paid leave for continuous education for the purpose of renewal of the license for independent practice (Article 182, paragraph 3);

24) Fails to provide professional advancement and fail to adopt the plan of professional advancement of health care practitioners and medical associates (Article 183, paragraphs 1 and 2.);

25) Engages a health care practitioner, a medical associate or any other employee for the work outside regular working hours, contrary to the provisions of this Law (Articles 199 - 201);

26) Fails to implement internal quality assurance of professional practice, and/or if it fails to adopt the annual program of quality assurance of professional practice in the health care facility, in compliance with this Law (Article 206);

27) Fails to cooperate in the implementation of regular and extraordinary external quality assurance of professional work by professional supervisors, as well as if it fails to submit to them all the required data and other documentation (Article 208, paragraph 5);

28) Fails to act upon the decision of the Minister by which temporary ban on work has been handed down in the procedure of implementation of regular and extraordinary quality assurance of professional practice (Article 211, paragraph 1);

29) Practices traditional medicine by applying methods and procedures not granted by the approval of the Ministry (Articles 235 - 237);

30) Fails to provide health care to a foreigner in compliance with this Law or fails to provide emergency medical care to a foreigner (Articles 238, 239, and Article 240, paragraph 1).

(2) The responsible person of a health care facility shall also be fined from RSD 30,000 to 50,000 for violation referred to in paragraph 1 of this Article.

(3) A health care practitioner - entrepreneur shall be fined from RSD 100,000 to 500,000 for violation referred to in paragraph 1, Items 2) to 15), Items 17), 18) and Items 20) to 30) of this Article.

Article 257

(1) A health care facility or any other legal entity dealing with health care activities pursuant to this Law shall be fined from RSD 500,000 to 1,000,000 for violation if it:

1) Enables independent practice to a health care practitioner who fails to meet the requirements referred to in Article 168, paragraph 1 of this Law;

1) Engages a health care practitioner who is a foreign citizen contrary to the provisions of Article 168 , paragraph 7 of this Law;

1) Engages a medical associate who was not issued or failed to renew the license for independent work, contrary to Article 198 , paragraph 1 of this Law;

2) Fails to establish time and cause of death of the person who has died in the health care facility and fails to notify the competent authority of the municipality, or city thereon (Article 219, paragraph 3);

3) Fails to inform an adult member of the family of the deceased person about the cause and time of his/her death or if it does not enable him/her direct access to the body of the deceased person (Article 221, paragraph 1);

4) Fails to perform autopsy in compliance with Article 222 of this Law;

5) Does not act upon the decision of the health, or pharmaceutical inspector (Articles 249 and 254).

(2) The responsible person of a health care facility shall be fined from RSD 30,000 to 50,000 for violation referred to in paragraph 1 of this Article.

(3) A health care practitioner - entrepreneur shall be fined from RSD 300,000 to 500,000 for violation referred to in paragraph 1, Items 1) and 5) of this Article.

Article 258

A health care practitioner - entrepreneur shall be fined from RSD 100,000 to 500,000 for violation if he/she:

1) Sets up more than one form of private practice (Article 56, paragraph 5);

2) Practices a health care activity and does not meet the requirements laid down by Article 58 of this Law;

3) Starts engaging in certain types of practice within the health care activity prior to the receipt of the decision of the Ministry by which it is established that the requirements for engaging in certain types of practice within the health care activity have been fulfilled or if he/she is engaged in a health care activity contrary to above decision (Articles 59 and 60);

4) Fails to notify the Ministry, the competent authority in the territory of which the seat of private practice is situated, as well as the competent association about the restarting to engage in a health care activity (Article 61, paragraph 4);

5) Fails to carry out the duties referred to in Article 62 of this Law;

6) Fails to provide constantly available ambulance transport (Article 63, paragraph 1);

7) Fails to provide emergency medical care to a foreigner (Article 240, paragraph 1).

Article 259

(1) A health care practitioner shall be fined from RSD 30,000 to 50,000 for violation if he/she:

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7) In engaging in the pharmaceutical health care activity, acts contrary to Articles 86 and 87 of this Law;

8) Fails to join the associations of health care practitioners in compliance with the law (Article 167, paragraph 1);

9) Leaves the workplace after expiry of working hours, without having been provided replacement, whereby engaging in the health care activity has been disrupted or health of a patient has been threatened (Article 170);

10) Fails to provide emergency medical care by expressing conscientious objection (Article 171, paragraph 4);

11) Works independently in a health care facility, or private practice without having been issued, or without having renewed the license, or if his/her license has been withdrawn (Article 191);

12) Within eight days from the date of receipt of the decision on revoking the license, fails to submit the same to the competent association (Article 192);

13) Engages in sideline work contrary to Articles 199 to 201 of this Law;

14) Fails to cooperate with the professional supervisors in the implementation of regular or extraordinary external quality assurance of professional practice or if he/she fails to provide all the required data and to submit the necessary documentation for the implementation of regular and extraordinary external quality assurance of professional practice (Article 208, paragraph 5);

15) Refuses to participate in the implementation of the procedure of regular and unscheduled external quality assurance of professional practice as a supervisor from the list of supervisors (Article 209, paragraph 5);

16) Fails to perform direct examination of a deceased person and to establish the time and cause of death within 12 hours from the received call (Article 219, paragraph 5);

17) Fails to notify, without delay, the competent organizational unit of the ministry in charge of interior affairs about a death case under the conditions laid down in Article 220, paragraph 1 of this Law;

18) Practices traditional medicine by applying the methods and procedures for which he/she has not obtained the permit of the Ministry (Articles 235 - 237).

(2) A medical associate shall also be fined from RSD 30,000 to 50,000 for violation referred to in paragraph 1, Items 10), 14), and 15) of this Article.

(3) A medical associate or any other employee shall be fined from RSD 30,000 to 50,000 for violation referred to in paragraph 1, Items 13) of this Article.

Article 259

A person referred to in Article 173, paragraph 2 of this Law shall be fined in the amount of RSD 30.000 to 50.000 for violation related to the provision of health care outside a health care facility or private practice functioning according to this Law in order to gain property or non-property benefits, except in case of the provision of emergency aid pursuant to law

Article 260

(1) The employer, who is a legal person, shall be fined from RSD 200,000 to 800,000 for violation if he/she fails to organize and provide health care of employees from his/her own funds (Article 14).

(2) The employer who is an entrepreneur shall be fined from RSD 100,000 to 500,000 for the violation referred to in paragraph 1 of this Article.

Article 261

The Medicines and Medical Devices Agency of Serbia shall be fined from RSD 200,000 to 800,000 for violation if it fails to notify the Ethics Committee of Serbia on conducting clinical studies of medicines and medical devices for which the approval for conducting such clinical studies has been handed down (Article 157, paragraph 2).

Article 262

The medical faculties shall be fined from RSD 300,000 to 800,000 for violation for act contrary to Articles 225 to 234 of this Law when taking over the bodies of deceased persons for the purpose of providing practical training.

Article 263

Deleted (Official Journal of the RS. No. 45/13)

XVI. TRANSITIONAL AND FINAL PROVISIONS

Article 264

(1) A municipality, city, or autonomous province shall assume the foundation rights to the health care facilities it is the founder of up to January 1, 2007.

(2) The decision on assuming of the foundation rights referred to in paragraph 1 of this Article shall be handed down by the competent authority of the municipality, city, or autonomous province and, after registration in the register with the competent authority, it shall notify the Ministry thereon within 15 days from the date of registration.

(3) By the time of assuming of the foundation rights referred to in paragraph 1 of this Article, the foundation rights to those health care facilities shall be exercised by the authorities in charge according to the regulations prevailing up to the date of coming into force of this Law.

(4) From the date of assuming of the foundation rights to the health care facilities, the municipality, city, or the autonomous province shall nominate the bodies of the health care facility in compliance with this Law, and the obligations of the founder with respect to the financing of the health care facility shall be fulfilled by the Republic up to January 1, 2007.

(5) The provisions of this Law shall apply to the nomination of the bodies health care facilities referred to in paragraphs 1 and 2 of this Article.

Article 265

Outpatient departments, general hospitals, and pharmacies that are, in compliance with this Law, founded as independent health care facilities, which have been within the complement of a health center and pharmaceutical institute up to the date of coming into force of this Law, may organize joint medical services for laboratory, x-ray, and other diagnostics, as well as joint non-medical services for legal, economic and financial, technical, and other similar affairs.

Article 266

(1) health center as a type of health care facility, which has an outpatient department within its complement, concerning which the local self-government cannot secure sufficient funds for assuming of the foundation rights in the budget of the local self-government, may exceptionally, on the basis of the decision of the Government, continue to work for five years as of the date of coming into force of this Law.

(2) The competent authority of the local self-government referred to in paragraph 1 of this Article shall submit the application for continuation of work of the health center as a kind of health care facility – to the Ministry, within six months from the date of coming into force of this Law.

(3) By the date of assuming of the foundation rights to the outpatient department, which is within the complement of a health center referred to in paragraphs 1 and 2 of this Article by the local self-government, the foundation rights to the health center shall be exercised by the Republic, or autonomous province, in compliance with the regulations prevailing up to the date of coming into force of this Law.

(4) By the time of assuming of the foundation rights to the outpatient department and general hospital that are within the complement of the health center referred to in paragraph 1 of this Article, in compliance with this Law, the funds for exercising of foundation rights to the health center shall be provided in the budget of the Republic, or autonomous province.

Article 267

Institutes for specialized rehabilitation that may engage in the health care activity as a specialty hospital, under the conditions laid down by this Law and the regulations adopted for enforcement of this Law, shall harmonize their organization, bylaws and other enactments with the provisions of this Law within 12 months from the date of coming into force of this Law.

Article 268

(1) Health care facilities and private practices shall harmonize their bylaws, organization, and work with the provisions of this Law that are related to types of health care facilities, or types of private practice, requirements for setting up and

commencement of work, as well as to the organization of work with the provisions of this Law within six months from the date of coming into force of this Law.

(2) Until the bylaws referred to in paragraph 1 of this Article are adopted, health care facilities and private practices shall apply the bylaws that are not contrary to the provisions of this Law.

Article 269

Institutes for laboratory and other diagnostics, as a type of health care facilities, that have been founded in accordance with the regulations governing health care, prevailing up to the date of coming into force of this Law, shall continue to work in accordance with the decision on fulfillment of the requirements for engaging in a health care activity, handed down by the Ministry of Health.

Article 270

The Government shall adopt the Plan of the Network within 12 months from the date of coming into force of this Law.

Article 271

(1) The Minister shall adopt the regulations for the enforcement of this Law within 12 months from the date of coming into force of this Law.

(2) Until the regulations referred to in paragraph 1 of this Article are adopted, the regulations prevailing up to the date of coming into force of this Law shall apply, which are not contrary to the provisions of this Law.

Article 272

Other legal entities, except for the legal entities that, within their complement have organized an outpatient unit for occupational medicine, and which have set up organizational units for engaging in the health care activity for their own employees, as well as other forms of engaging in health care activity shall, within six months from the date of coming of this Law into force, harmonized their work with the provisions of this Law.

Article 273

(1) The Agency for Accreditation of Health Care Facilities of Serbia shall start working within three years from the date of coming into force of this Law.

(2) Until the commencement of the work of the Agency for Accreditation of Health Care Facilities of Serbia, the affairs from the competence of the Agency laid down by this Law and the regulations passed for the enforcement of this Law shall be conducted by the Ministry.

(3) The Ministry shall start administering the affairs referred to in paragraph 2 of this Article within 12 months from the date of coming into force of this Law.

(4) Until the commencement of the work of the Agency for Accreditation of Health Care Facilities of Serbia, the accreditation fees shall be assessed by the Minister.

Article 274

Within six months from the date of commencement of its work, the competent association shall start issuing, renewing, or withdrawing the licenses of health care practitioners, in accordance with the provisions of this Law.

Article 275

(1) The Minister shall nominate the Ethics Committee of Serbia within six months from the date of coming of this Law into force.

(2) The Minister shall nominate the Republic professional commissions within 90 days from the date of coming of this Law into force.

Article 276

(1) The National Parliament shall elect the members of the Health Council of Serbia within nine months from the date of coming into force of this Law.

(2) The National Parliament shall adopt the Plan of Development of Health Care within six months from the date of election of the members of the Health Council of Serbia.

Article 277

Deleted (Official Journal of the RS, No. 88/10)

Article 278

Until the termination of functioning of the interim legal system established pursuant to the Resolution 1244 of the UN Security Council in the territory of the Autonomous Province of Kosovo and Metohija, the Government shall have all the rights and obligations of the founder to the health care facilities the founder of which is the Republic, in compliance with the law.

Article 279

(1) On the date of coming into force of this Law, the Law on Health Care (the Official Journal of the *RS*, Nos. 17/92, 26/92, 50/92, 52/93, 53/93, 67/93, 48/94, 25/96, and 18/02) shall cease to be effective, except for Articles 77 to 77 and Articles 78 to 85.

(2) On the date of coming into force of this Law, the Law on Health Care of Foreigners in the Federal Republic of Yugoslavia (the Official Journal of the Federal Republic of Yugoslavia, Nos. 59/98 and 37/02) shall cease to be effective.

Article 280

This Law shall come into force on the eighth day from the date of its publishing in the Official Journal of the Republic of Serbia.

PROVISIONS NOT INCLUDED IN THE REVISED TEXT

**Law on Amendments to the Health Care Law
("Official Journal of the RS", No. 88/10)**

Article 8.

(1) The bylaw for the enforcement of this Law shall be adopted within 90 days from the effective date of this Law.

(2) The bylaw provisions that were in force until the enforcement of the new Law, which were not in contrast to it, shall be in force until the adoption of the bylaw based on this law.

**Law on Amendments to the Health Care Law
("Official Journal of the RS", No. 57/11)**

Article 46.

The bylaw for the enforcement of this Law shall be adopted within 12 months from the effective date of this Law.

Article 47.

(1) The Administration for Screening Programs shall start with operation on January 1, 2013.